FINAL AGENDA

Barnett International and Cambridge Healthtech Institute's Inaugural

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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Barnett International and 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.

THURSDAY, JUNE 24, 2010

7:00 am **Registration and Morning Coffee**

8:00 **Welcome & Chairperson's Opening Remarks**

MONITORING IN 2010

8:15 **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 main function of a clinical research associate is to monitor clinical trials to ensure subject protection, protocol and ICH compliance, and data integrity. This main function remains the priority, but it is also clear that expanding the role to incorporate a management skill set to assess, explore, and develop sites, relationships, and expectations is necessary to meet the needs of the business behind the science. Cost, speed, and quality drive business, and current trends in monitoring models integrate skill sets to support this demanding environment. This presentation will focus on identification of an updated skill set required to excel in today's clinical trial monitoring environment. The speakers will share an overview of Pfizer's monitoring group trends.

8:55 **The Risk-Based Monitoring Plan**

John Creech, CCRP, Clinical Research Associate, Clinical Operations, Abbott Vascular

There is often a tendency to over-emphasize routine monitoring processes rather than identifying the most appropriate means of addressing the underlying concerns. A risk-based monitoring program focuses a sponsor's resources on areas of highest potential risk that contribute to the success of the study, mainly protection of subjects' safety and rights and integrity of study data. A pre-enrollment risk analysis results in a monitoring plan that includes an ongoing quality assurance program. To remain competitive, sponsors need to adopt risk-based monitoring plans to better allocate resources, better prepare themselves for audits, and increase their chances for successful clinical trials. In this presentation, we will review the creation, implementation, and results of a successful risk-based monitoring plan.

KEY REGULATORY PERSPECTIVE

9:35 **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

This session will provide a key regulatory point of view. This presentation will focus on what to expect during an FDA inspection, and will include a discussion of federal regulations covering clinical research, clinical investigator obligations, specific problems seen during inspections, and various methods used to ensure compliance. Identification of problems to avoid and various methods to ensure compliance with regulations and study protocol will also be addressed.

10:15 **Networking Coffee Break and Exhibit Viewing**

FDA AUDITS: PREPARATION AND FOLLOW-UP

10:45 **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

This presentation will include a review of trends in recent FDA Warning Letters, both from a process perspective and from an individual responsibility perspective. The clearest guidance provided by the FDA is contained in the FDA Warning Letters. A review of these letters will provide an overview of compliance hot spots as well as emerging areas of interest. The audience will gain a blueprint for building and maintaining a compliant, effective clinical monitoring system, including process and personnel.

11:25 **Monitoring in an Era of Change**

Barbara E. Tardiff, M.D., MBA, Corporate Vice President, Clinical Research Services, PAREXEL International

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership of the FDA's Office of Critical Path Programs and Duke University, established in November 2007. Stakeholders include over 50 organizations including government agencies, industry representatives, patient and consumer representatives, professional societies, investigator groups, academic institutions, and other interested parties. The mission of CTTI is, "To identify practices that through broad adoption will increase the quality and efficiency of clinical trials." One of CTTI's projects is an assessment of monitoring activities. The objectives are to review current monitoring practices and rationale, define quality objectives, and provide qualitative assessment of monitoring techniques. Dr. Barbara Tardiff, a thought leader in the conduct of clinical research and a member of the CTTI Steering Committee, will present: current thinking on the intent and goals of monitoring; practices that are currently employed to meet; monitoring objectives; an assessment of how well current methods enable us to achieve objectives; and changes in monitoring methods being considered to improve our ability to meet intent and goals.

12:05 pm **Sponsored Luncheon** *(Opportunity Available, Contact Arnie Wolfson: 781-972-5431, awolfson@healthtech.com)* **or Lunch on Your Own**

1:20 **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

This session will provide a first-hand account from an academic site that experienced an FDA audit. The presentation will be all-inclusive, ranging from the initial call from the FDA requesting the audit, to the follow-up communications post-audit, to the issuance of FDA Form 483. This session will provide helpful tools which can only be gained from the real-life experience of an FDA audit. The audience will receive tips on how to prepare for an FDA audit, what to do during the process, how to delegate tasks, and how to ensure proper follow-up with the FDA and other key participants, including the IRB.

BEST PRACTICES FOR SITE MONITORING AND MANAGEMENT

2:00 Monitoring "Worst Practices": The Impact of Bad Habits and Corner Cutting

Christine Sahagian, M.S., Associate Director, Clinical Compliance, Biogen Idec

A monitor's work is never done... or so it seems. Between source data verification, query resolution, investigational product management, regulatory document review, trip reports, follow-up letters, and other important site management activities, it is sometimes tempting to take shortcuts or skip a few of the details. This presentation will review, through presentation of actual examples and case studies, the possible consequences and impact of these "bad habits."

2:40 Working with Clinical Sites to Implement Corrective Action Plans that Work!

BJ Guthrie, Manager, Clinical Operations, Clinical Research, Abbott Vascular

This is a session focused on how monitors can work effectively with clinical sites to develop and implement appropriate corrective action plans in order to address non-compliance. This discussion will also include how and when to evaluate the effectiveness of the corrective action plan. Our organization has effectively implemented the use of the site Corrective Action Plan (CAP) in order to maintain compliance at our clinical research sites. The audience will gain an understanding of when sites need to develop a CAP; how to work with sites to implement a CAP; and how to evaluate the effectiveness of their corrective measures.

3:20 Networking Refreshment Break and Exhibit Viewing

3:40 A Discussion of Best Practices in Site Budget and Contract Negotiations for 2010: Getting to Win-Win

Felicia Favorito, RN, MS, Senior Manager, Clinical Operations, Millennium: The Takeda Oncology Company

There are a variety of issues that may come up in the budgeting and contracting process that may cause obstacles and delay the Site Initiation Visit. This session will concentrate on identification of common pitfalls to avoid and best practices to implement to optimize efficiencies. The focus will be on Site/Sponsor or Site/CRO relationships that are critical to success. In addition, the speaker will touch on factors to consider in building an acceptable budget, including start-up fees, standard of care, insurance reimbursement, and other hot topics.

4:20 The Monitor's Guide to Effective Site Training

Millie Shultz, Senior Manager, Clinical Operations, Millennium: The Takeda Oncology Company

This talk will provide a background on sponsor and investigator responsibilities as they pertain to investigator selection and clinical trial training. A brief introduction to current training programs for institutions and investigators will be reviewed. The most common deficiencies noted during audits and how to mitigate these with effective training will be discussed. The speaker will discuss how to effectively train an investigative site team to ensure understanding of the protocol across all team members. The value of emphasizing the science behind the molecule and protocol as a means of increasing patient safety will be reviewed. Implementing ongoing training during the course of a study will also be addressed.

5:00 It's Not About the M&M's: Measuring Quality in Clinical Research Activities

Maggie Ayers, B.Sc., Director, Clinical Studies, Astellas Pharma Global Development, Inc.

Investigators, study coordinators, and monitors are essential in the conduct of a successful quality-driven study. After the database is locked and sites closed, Study Managers provide a statement in the clinical study report summarizing study quality activities which support study outcomes, including overall data integrity and GCP compliance. If a Clinical Quality Plan is developed in conjunction with the Study Monitoring Plan, pre-defined quality targets, criteria, and standards can be used to manage and assess overall study quality. The focus of the Quality Plan is on source data verification and GCP compliance requirements, with proactive definition of measures for investigator site management and clean, consistent data. This session will incorporate a didactic presentation with facilitated group discussion and an interactive case study simulation to identify the advantages of defining quality targets in clinical research activities. In addition, the challenges of interpreting measured outcomes will be reviewed, with open discussion relative to formulating strategies to meet the challenges of how best to incorporate quality into daily clinical research activities.

5:45-6:45 Reception and Exhibit Viewing *(Opportunities Available, Contact Arnie Wolfson: 781-972-5431, awolfson@healthtech.com)*

FRIDAY, JUNE 25, 2010

7:15 am Sponsored Breakfast *(Opportunity Available, Contact Arnie Wolfson: 781-972-5431, awolfson@healthtech.com)* **or Breakfast on Your Own**

GLOBAL VIEW ON MONITORING

8:00 Creating a Collaborative Environment at Monitoring Visits: A Global Perspective

Carol Opalek, Clinical Research Associate, Abbott Vascular

In 2008, a survey was developed comparing and contrasting CRA and CRC perceptions of qualities of an interim monitoring visit. In a follow-up to that survey, the same instrument was administered to a primarily South African population of coordinators and monitors in 2009. Respondents to this follow-up survey were from Kenya, India, and Australia. This session will explore both the remarkable similarities and the differences in the responses, and the possible cultural implications of the answers given. Discussions will focus on the subjective responses given, and the importance of professionalism, visit preparation, and follow-up after a monitoring visit. Key take away messages include the importance of communication and time management skills. The roles of CRCs and CRAs are truly global in nature. Just like Good Clinical Practice principles, the harmonization of roles and expectations at visits must be practiced no matter where the visits take place. This survey is a small step in understanding perceptions from both sites and sponsors point of view and working collaboratively in this endeavor.

8:40 Global Monitoring: Strategies for Managing Sites in both Developed and Developing Regions

Rodrigo Crispim, Site Monitoring Manager, Brazil Regional Clinical Operations, Bristol-Myers Squibb

Globalization is a reality for conducting clinical trials, and with that comes the need to understand how the regulatory climate and the overall level of clinical trial experience of each country effects the monitoring responsibilities required. Additionally, the understanding of the relationships and expectations that the medical community has of the pharmaceutical industry can be different for developed versus developing regions. Given that clinical trials around the globe can bring opportunities, like more efficient subject recruitment as well as potential financial savings, how to ensure patient safety and consistent data quality throughout all regions is a key monitoring deliverable.

9:20 Monitoring Informed Consent in India: Addressing Ethical, Regulatory, Sponsor, Protocol, and IRB Requirements

Rao Teki, M.D., Vice President, Clinical Operations, MakroCare

As India is becoming a global hub for clinical research and services, there is a current need for good understanding of local regulations and ethics. This presentation covers the required information, including how to work with India and its service providers with local guidelines; GCP and Drug Controller General of India (DCGI); and local regulatory agency's guidelines on ICF. Clinical research activities are shared among multiple players like sponsor, investigator, IRB, and monitor. Each player needs to be aware of their specific responsibilities, and most importantly, how the socioeconomic, cultural, and literacy of study subject plays a role in executing ICF.

10:00 Networking Refreshment Break and Exhibit Viewing

MONITORING IN THE OUTSOURCED ENVIRONMENT

10:20 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

Research has shown based on the current economic situation, pharmaceutical companies are going to continue to downsize, restructure, and increase their outsourcing of clinical trials to CROs. This increased outsourcing will result in a need for monitors who understand the CRO model, the preconceived opinions of a CRO monitor, site conceptions of a CRO monitor, and the job expectations of a CRO monitor. The success of a CRO truly lies within the monitoring team. This presentation will focus on providing guidance, practical tips, and demonstrate through case studies how one can truly be a GREAT CRO monitor and, in turn, be a part of a great CRO. In her roles at large pharmaceutical companies, small biotechnology companies, and both large and small CROs, this session's speaker has extensive experience improving site and monitor relationships. Sponsors, CROs, and monitors alike will gain insight into becoming and appreciating the GREAT CRO monitor.

11:00 Whose Job Is It Anyway? 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

Sponsors face unique challenges when clinical trial monitoring is outsourced to a third party. This session will explore the importance of sponsor oversight of outsourced monitoring activities. We will look at Otsuka's successful "Accompanied Visit Program," a program which provides oversight of clinical trials globally when the monitoring function is outsourced. Your speaker will share the details of the program, as well as real-world applications of lessons learned from this initiative. Monitors will gain a deeper understanding of the rationale for sponsor oversight and how this responsibility can further develop the CRO-Site-Sponsor relationship.

11:40 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

Best practices for the CRO monitor are required throughout the entire clinical research area. In the global environment, there are many hidden practices that can help us manage the quality, cost, and timeliness of research and decision-making. Complete management of clinical trial process involves patient management, clinical data management, and clinical trial staff management. Given the complexities that exist in clinical trials, it has been difficult to measure the efficiency and effectiveness of the trial process quantitatively. The best practice by sponsors assures that clinical investigators abide by their obligations for the proper conduct of clinical trials. This session will present different scenarios and variations of results in multi-centric trials. The audience will learn the benefits of employing best practices of clinical research findings in operational and decisional research, the key factor in research success and failure.

12:05 pm Sponsored Luncheon *(Opportunity Available, Contact Arnie Wolfson: 781-972-5431, awolfson@healthtech.com)* **or Lunch on Your Own**

SITE RELATIONSHIP MANAGEMENT: BUILDING PARTNERSHIPS

1:35 Sponsor and Site Communication: Principles for Developing an Effective and Rewarding Site-Sponsor Partnership

Deborah Lasher, RN, MPH, CCRC, CCRA, Senior Clinical Research Specialist, Diabetes Clinical Research, Medtronic, Inc.

Site management of clinical trials is both an art and a science. The regulations and processes of the clinical research enterprise are more concrete and overt than the subtle nuances of effective communication between the site and sponsor as partners in a clinical trial. Individuals have varying degrees of inherent communication skills. Most monitoring professionals are hungry for new perspectives on what makes communication effective and how we can influence others by the messages we send. Effective, positive, and productive communication skills are a critical component of a "Master" Clinical Trial Monitor. In fact, in the U.S., it has been noted that "communication skills" have recently surpassed "technical skills" as the most important quality when hiring professionals. This presentation will provide communication principles for any clinical research professional with specific examples tailored for monitors in preparing for site visits and when communicating critical information with study partners.

2:15 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, Inc.

This presentation will include ideas and information for monitors on how to improve their reputation with their sites, as well as how to remove the authoritarian stigma that sites often perceive. The speaker will focus on ways to approach sites in a more collaborative manner to create a better working team environment for the sites and the sponsor. Currently, in RCHSPP/SAIC-Frederick, Inc., we begin collaborating with our sites very early in the clinical research process; hence we establish a positive working relationship that ensures data quality and encourages mutual respect. Our foundation, as a program, has been to promote team work with our sites, work with them to overcome challenges, and provide a support system for them when needed.

2:55 Monitors are from Mars, Sites are from Venus: Establishing Successful and Collaborative Site Relations

Harry Barnett, J.D., Managing Partner, Clinical Assistance Programs

There is a marked disconnect when it comes to clinical monitors effectively communicating and working with investigative sites for clinical studies. Although a monitor's success depends upon his/her ability to establish a productive and positive relationship with the site investigator and study coordinator, the regulatory focus of traditional CRA training is insufficient to serve as a basis for effective site relations. This presentation will emphasize the importance of indication and endpoint-specific knowledge as a precursor to developing a better working relationship with key site personnel.

3:35 Networking Refreshment Break and Exhibit Viewing

MONITORING IN THE ELECTRONIC ENVIRONMENT

3:55 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

Effective EDC training is crucial for an EDC trial to be successful. A monitor's role within EDC encompasses not only onsite and in-house review of data, but also acting as a site's resource for EDC data entry/query resolution. A clinical trial is only as successful as the quality of data entered. It is crucial for CRAs to understand both study team and site activities within EDC to increase data quality, and cut down on the time from last patient in (LPI) to database lock.

4:35 Electronic Medical Records: Overcoming the Obstacles in Monitoring the EMR

Dana Haudek, Manager, Clinical Operations, Research/Vascular, Abbott Vascular

This is a discussion about how a monitor can overcome the many obstacles of monitoring the electronic medical record. Beginning with managing the sponsor's expectations and responsibilities in site selection, this session will cover how to manage time with the site's research coordinator, communicate difficulties with the site to the sponsor, gain access to the EMR, and ultimately verify copies of the medical record. The speaker will share her monitoring group's experience with difficult processes at sites in getting access to the EMR. Best practices will be shared, including questions to be asked during site assessment, and statements that may be added to a site selection standard operating procedure for accessing and monitoring the EMR.

5:55 Close of Conference

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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.

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MASTERING CLINICAL TRIAL MONITORING

Royal Sonesta Hotel, Cambridge, MA | June 24th & 25th, 2010

HOW TO REGISTER:

Online: www.healthtech.com/crm

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❑ **Yes! Please register me for the Mastering Clinical Trial Monitoring**

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	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

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GROUP DISCOUNTS AVAILABLE! Special rates are available for multiple attendees from the same organization. For more information on group discounts contact **David Cunningham at 781-972-5472**

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❑ Please send information on exhibiting and opportunitites to present workshops.

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- 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

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Program and speakers are subject to change.

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