Cambridge Healthtech Institute’s

SCOPE

Summit for Clinical Ops Executives

March 8-11, 2010 | Crowne Plaza Philadelphia Downtown | Philadelphia, PA

Final Agenda

Register by January 29 and SAVE up to $200

Overcoming Key Challenges in

Site Selection, Recruitment, and Data Collection

March 8-9, 2010

Short Courses

• Designing and Implementing a Clinical Enrollment Plan
• Utilization of Electronic Health Record (EHR) Data in Clinical Research
• Country and Site Feasibility and Selection for Global Clinical Trials

Interactive Panels and Breakout Discussion Groups

March 10-11, 2010

Effective Planning and Implementing Clinical Research and Trials

Register by January 29 and SAVE up to $200

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March 10, 2010

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We invite you to attend CHI’s Summit for Clinical Ops Executives (SCOPE) taking place March 8-11, 2010 in Philadelphia, PA. The program brings together four annual conferences and short courses. By bringing these four events and three short courses together under the SCOPE umbrella, an opportunity for idea sharing and cross pollination amongst clinical operations professionals from different groups has been created. Despite a shared exhibit floor where the community can share ideas, each conference remains autonomous and goes deeply into its own set of issues with its expert faculty. Each conference will feature best practice case studies and interactive discussions relevant to clinical operations experts as well as those new to the field.

**CONFERENCE-AT-A-GLANCE**

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CHI’s Third Annual Patient Recruitment in Clinical Trials: Successfully Planning and Managing Recruitment and Retention will be held March 8-9, 2010 at the Crowne Plaza Philadelphia City Center in Philadelphia, PA. This year this gathering will be co-located with the Summit for Clinical Ops Executives (SCOPE), a four-day cluster of events taking place March 8-11, 2010. CHI’s Patient Recruitment will open with a pre-conference short course on ‘Designing and Implementing a Clinical Enrollment Plan’ and will be followed immediately by a short course on ‘Country and Site Feasibility and Selection for Global Clinical Trials’ and the Second Annual Drug Development Latin America conference.

Patient recruitment and retention are critical to drug development programs. Patient recruitment, if not adequately planned for, can extend your development timeline by a number of years. Retention of patients throughout the life of a clinical trial is essential in order have complete data sets for your analysis and subsequent filings. In order to optimize both you have to have a plan. This conference is intended to cover the topics one should consider when drafting and strategically implementing a patient recruitment and retention plan for a clinical development program.

### Monday, March 8, 2010

**7:30 AM**  Morning Coffee & Conference and Short Course Registration

**8:30**  Organizer’s Welcome & Chairperson’s Opening Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

**Sponsored by**

**MORNING SHORT COURSE: DESIGNING AND IMPLEMENTING A CLINICAL ENROLLMENT PLAN**

**8:40**  Part 1: Clinical Recruitment Planning Strategies: When is the Right Time to Plan, Implement, and Spend?

Manley Finch, MS, MPH, Vice President, Clinical Research, SleepMed, Inc

It is well documented in the literature that eighty percent of clinical programs fail to meet their predetermined recruitment objectives. Either the study does not recruit the entire cohort projected or fails to do so on time. The need for comprehensive recruitment strategies to obtain enrollment objectives is acknowledged by most clinical research professionals including those at sponsors and academia. What is not intuitively understood is the right time to plan, implement, and spend to obtain the recruitment goals dictated by corporate executives or funding agencies. With research budgets shrinking and demands for decreased time to market increasing, knowing the answers to these questions are of critical importance to the success of any clinical development program or research project. This discussion will highlight and define the key indicators that will guide stakeholders and decision makers to strategically determine when, and when not to, begin planning, implementing and spending on comprehensive recruitment programs.

**9:10**  Part 2: Patient Retention and Compliance Strategies

Helen West, Vice President, Strategic Development, MMG

Patient retention and compliance strategies for global clinical trials will be presented by one of MMG’s senior strategists. This presentation will arm attendees with:

- Key drivers in designing retention programs
- Evolving trends in patient retention methodologies
- Best practices for the implementation of retention programs
- Adapting retention tactics for global implementation


Abbe Steel, Executive Director, United BioSource Corporation

This session will identify steps necessary to develop the nuts and bolts of a detailed patient recruitment plan. Each study is different, regardless of patient enrollment expectations, it is essential to define goals, plans, and strategies at the onset of every study. Key Drivers of a Patient recruitment plan include:

- Critical Dates and Scope
- Protocol Evaluation
- Medical Condition and Subject Profile
- Site Profile

Critical elements of a recruitment plan will include:

- Site based support
- Advertising
- Public Relations and Outreach
- Contingencies
- Milestones
- Triggers
- Retention

### 10:15  End of Short Course, Networking Coffee Break

**Patient Recruitment in Clinical Trials: Session A**

### 10:50  Chairperson’s Opening Remarks

**Sponsored by**

**11:00  Opening Panel: The Study Volunteers - Hearing it from Their Perspective; That is What Really Counts!**

Moderator: Christine Pierre, President & Chief Executive Officer, Clinical Research, RxTrials

Panelists: Clinical Trial Volunteers

The study volunteer is the person we are all chasing after in this industry, however we seldom stop and ask their opinion with regard to much of what we do. This session will shed light on their opinions, beliefs, and actions which will in turn provide the audience with the gift of true knowledge in how to better recruit and retain study volunteers. During this interactive panel discussion with “real” study volunteers we will discuss with them and gain a deeper understanding of:

- Their motivation to participate in a clinical study
- What are the most effective methods to reach them
- What they want and need to hear to make decisions
- The role of the study staff and so much more!
and manage information. This technology can be readily applied to users asynchronously, and provide a central forum to deliver metrics.

Web-based applications help to quickly and easily reach numerous budgets.

• Planning your next trial: this session we’ll give you the following tools to begin proactively focusing efforts on proactively planning clinical trial.

Jaclyn Larsen, Marketing Strategy Manager, Praxis

• Site Selection and ROI Metrics for Local Recruitment Budgets

Lisa LaLuna, Senior Vice President of Corporate Development, ePharmaSolutions

Web-based applications help to quickly and easily reach numerous users asynchronously, and provide a central forum to deliver metrics and manage information. This technology can be readily applied to optimize two main components of clinical trials: Site Selection and Management of Local Recruitment Budgets. Site Selection has been hindered by an inability to aggregate information for sound business decision-making while millions of dollars are spent to support local recruitment efforts without ROI metrics. Attendees will be introduced to ClinicalCollaborator™, an online application that optimizes site selection and provides never before seen metrics for local recruitment.

Lance Nickens, President, The Patient Recruiting Agency™

Sink your teeth into the metrics and costs of recruiting patients through Facebook advertising.

• Appetizers includes an assortment of real response metrics carved from indications all over the United States

• For the main course we will compare metrics from centralized campaigns including results from Facebook to Television, Radio and/or Print advertising

• For Desert you will learn about the savoy costs from every indication on the menu

3:00 Networking Refreshment Break and Exhibit Viewing

3:45 Interactive Panel: Using Social Networks and Emerging Technologies to Accelerate Clinical Trial Recruitment

Ros Cheetham, Vice President, Neurosciences MDC, Medicine Development Leader, GlaxoSmithKline
Brian Loew, Chief Executive Officer, Inspire
David Williams, Chief Marketing Officer, PatientsLikeMe
Kirstin Woody-Scott, Program Manager, Vanderbilt Institute for Clinical and Translational Research, ResearchMatch.org

• Utilizing Web 2.0 and Health 2.0; social networking for clinical research and recruitment

• Leveraging database searches, pharmacy records, electronic medical records

• Ensuring regulatory compliance and patient privacy/HIPAA

BREAK-OUT DISCUSSION GROUPS

4:15 Interactive Break-Out Discussion Groups

Concurrent break-out discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the more poignant questions facing the industry. Delegates will join a table of interest to them and become an active part of the discussion at hand. It is an informal yet informative format, that allows attendees to learn from each other and make some new contacts. To get the most out of this interactive format please come prepared to: share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

Topics Include:

• Can Sponsor/CRO Collaboration Yield an Effective Recruitment Strategy?

• When Do You Need to Hire a Patient Recruitment Service Provider?

• Informed Country Selection for Multinational Clinical Studies

• Can we Improve Site and Patient Recruitment Forecasting?

• Challenges and Opportunities for Optimizing Patient Recruitment in Emerging Regions

• Using Social Networks to Accelerate Clinical Trial Recruitment

• Development of Effective Strategies for Recruitment of Minority Populations into Clinical Trials

• Do You Have an Implementable Protocol?

5:30 Closing Comments and Welcome to Reception

5:45-6:45 Networking Cocktail Reception and Exhibit Viewing

Tuesday, March 9, 2010
8:00 Can Electronic Healthcare Data be applied to Trial Design, Site Selection & Patient Recruitment?
Malcolm Bohm, President, Trialytics
Effective clinical development teams see the process of enrollment as starting at trial design, continuing through site selection and ending with the completion of recruitment. The emergence of effective tools that bring the evidence base of medical standard of care to clinical operations is empowering all clinical operations teams to adopt this paradigm shift. This presentation is designed to provide all attendees an opportunity to understand how healthcare data can contribute to more cost effective and accelerated clinical development programs.

Patient Recruitment in Clinical Trials: Session C

8:40 KEYNOTE PRESENTATION
Case Study: Recruiting Competitively - Internet Marketing or Traditional Media?
Ros Cheetham, Vice President, Neurosciences MDC, Medicine Development Leader, GlaxoSmithKline
Patient recruitment requires targeted and cost effective approaches to meet timelines and stay within budget. The value of internet marketing methods (Search Engine Optimization), traditional media (TV and radio) and low tech options such newspaper coupons, will be explored through two case studies. The response to these media and the costs will be evaluated. The balance between speed of patient recruitment and cost is critical for all clinical trials, especially in areas of clinical research where recruitment is highly competitive. With the advent of internet marketing methods it is important to understand what options are available and how they compare to “traditional” media methods. Through the use of two case studies, one of which used “traditional” media for patient recruitment and one of which used internet marketing, the audience will gain an understanding of the potential effectiveness, costs, and pitfalls of these approaches.

9:15 Comprehensive Patient Recruitment Programs: The Role of Community Organization and Social Marketing
Manley Finch, MS, MPH, Vice President, Clinical Research, SleepMed, Inc
This presentation will review the need for the assessment of feasibility, design, and implementation of comprehensive programs at the program design level versus “band-aiding” as a rescue strategy. A review of the ROI for proper planning versus rescue mode will be provided. A review of the basics of recruitment programs will be offered with a latter concentration on discussion of using the principles of community organization and social marketing to drive trial awareness and recruitment enhancement. A case study will be offered as a cap-stone to summarize the information reviewed.
• Rationale for comprehensive programs - Understanding of feasibility assessments
• ROI for these programs versus band-aiding
• Overall design of comprehensive program; menu items
• Feasibility determination
• Focus on the concepts of social behavioral modification, community organization, and social marketing to promote trial awareness and increase screening

9:45 Focus on Electronic Patient Recruiting
David Hadlick, Co-Founder and CEO, KDH Systems, Inc.
• Hospital-based, real-time automated patient screening for CT recruiting
• Subject identification and decision support enhances staff productivity
• Face-to-face meetings with candidates and physicians allows CT be to included in treatment decisions
• Collaborative, personal touch enhances enrollment while patient is on-site
• Benefits of clinical trials extended to complete population cross-section

10:00 Networking Coffee Break and Exhibit Viewing
10:45 Regulatory Challenges and Expectations in Latin America and Asia Pacific to Effective Clinical Trial Development
Jerry Stewart, Associate Director, Global Regulatory Affairs, Asia & Latin America, Wyeth Research
Today, more than ever, clinical research is experiencing a geographical shift in country selection, and clinical trials are truly becoming more and more “global.” One of the industry’s goals is to execute simultaneous global development. That is, to use global data to develop a single dossier (e.g., Clinical Trial Application) that supports the next critical phase of development, enabling simultaneous submissions to and approvals from health authorities and ethics committees globally. There are a number of barriers that significantly restrict simultaneous development, ultimately delaying the availability of innovative drug therapy to emerging markets and limiting patient access to new and preventative treatments.
Presentation topics:
• Regulatory barriers in the AP and LA regions to simultaneous clinical development
• Industry’s expectations of a health authority’s regulatory framework
• Clinical elements to the ideal clinical trial infrastructure

11:15 Retention Begins with the First Screening Call
Mrs. Jeffree Itrich, Senior Communications Recruitment Specialist, ADCS Administration, University of California, San Diego
Too often clinical trials focus solely on recruitment, never giving any dedicated thought to retaining study participants once they sign on the dotted line. Retention is equally if not more important than recruitment because without a good retention strategy in place sites cannot maintain the participants they worked so hard to attract. My presentation will focus on retention techniques that have worked well for the over ADCS study sites over the last 18 years.

12:00 PM Luncheon Presentation (Sponsorship Available. Contact Arnie Wolfson: 781.972.5431, awolfson@healthtech.com) or Lunch on Your Own

Patient Recruitment in Clinical Trials: Session D

1:25 Chairperson’s Remarks

1:30 When Senior Management Says “Prove It!”...Can You Articulate Patient Recruitment ROI?
Richard Malcolm, Ph.D., Chief Executive Officer, Acurian
The session helps trial managers, patient recruitment specialists, and outsourcing personnel evaluate and budget patient recruitment fees, and illustrates how this can be a very cost effective spend (investment) through offsetting savings in personnel and trial costs, and can enable large financial returns through speeding time to market.

2:00 PARTNERS Initiative: sanofi-aventis’ approach to Enhancing Patient Recruitment
Richard Robinson, Assistant Director, Internal Medicine, Metabolism and Diabetes, US-CRU, sanofi-aventis
The PARTNERS initiative is the sanofi-aventis’ “site management” program designed to improve site relationships and recruitment performance. This program began in 2006 with the goal of becoming “sponsor of choice” but over the years has morphed into a much more broad approach to site relationships. The program is designed around a customer focused approach and building of long term partnerships.

2:30 Sponsorship Available. Contact Arnie Wolfson: 781.972.5431, awolfson@healthtech.com

2:45 Networking Refreshment Break and Exhibit Viewing

3:30 An Update on Innovative Recruitment at Washington University: A Site Perspective
Charles Rathmann, Director, Recruitment Enhancement Core, Center for Applied Research Sciences, Washington University School of Medicine
The presentation will be addressing the unique, proactive, marketing based approach to recruitment at an Academic Medical Center. The discussion will focus on implemented planning and results, as well as challenges and opportunities associated with both. Case studies of successful recruitment for specific clinical trials and the strategies executed will also be shared.
4:00  Co-Presentation: Lessons Learned in Planning and Managing Adaptive Trials
Brendan O’Neill, Associate Director, Global Trial Optimization, Merck & Co., Inc.
Kelly White, Patient Recruitment Specialist, Merck & Co., Inc.

4:30  One Size Doesn’t Fit All: Site Level Case Studies from $0 to Centralized National Campaigns
Mark Metzner, Director, Marketing & Recruiting Department, Community Research

Patient recruitment is always challenging. Pharma and CROs are constantly looking at delivery models, historical data and PROs to try and forecast or deliver patient populations. This is an end-user perspective from the site level on what works and what may not be as effective as it appears on paper. Learn how you’re helping and perhaps harming your study by the choices you make. As an active General Medical, CNS and Oral Care site with a prototypical marketing and recruiting department, we have amassed a wealth of metrics. Far from an indictment of any one choice, this presentation focuses on the strengths and weaknesses of study media funding from the end-user or site level. This unique perspective offers all connected with the industry a chance to see what really happens when they make one choice compared to another.

5:00  Close of Patient Recruitment Conference
CHI's Second Annual Electronic Data in Clinical Trials: Collecting and Leveraging Data to Optimize Clinical Trials will be held March 8-9, 2010 at the Crowne Plaza Philadelphia City Center in Philadelphia, PA. This year this gathering will be co-located with the Summit for Clinical Ops Executives (SCOPE), a four-day cluster of events taking place March 8-11, 2010. CHI's Electronic Data in Clinical Trials will open with an inclusive short course on ‘Utilization of Electronic Health Record (EHR) Data in Clinical Research’ and will be followed immediately by a one-day seminar eCTD 2010 co-hosted with Bio-IT World and eCliniqusa.

New technology is available and being created everyday to make the collection, correction, and assessment of data from clinical trials more efficient. The goal is to better integrate systems and data across departments and regions in order to optimize the speed and cost of trials and drug development. This conference is intended to cover the challenges related to which technologies and systems to use, measuring the ROI of technology investment, and how best to overcome the common problems with implementation.

### Monday, March 8, 2010

**8:40** Part 1: Connecting eHealth to Clinical Research

Susan K. Howard, Therapeutic Program Manager, Oncology Data Management, GlaxoSmithKline

Achieving effective integration between Healthcare Records and Clinical Research environments is highly desirable for many parties, yet a number of legal, technical and ethical barriers mean that today this connectivity remains largely a vision. This presentation introduces a project undertaken as a joint effort between PhRMA and the eClinical Forum which has bought together interested parties from across the worlds of eHealth and eResearch to establish an EHRCR Profile outlining suitable criteria to certify EHR systems as suitable for use in Clinical Research environment.

**Learning Objectives:**
1. To become familiar with EHR systems and current certification process.
2. To learn about the creation and adoption of a common profile.
3. To better understand the value of an EHRCR profile to inform the development of a harmonized view of all data from all sources.

**Applications:**
- Enhances connectivity between eHealth and eResearch systems.
- Helps establish a common language and standards.
- Maximizes productivity in highly skilled knowledge workers.

**9:40** Part 3: Experiences Leveraging Electronic Health Records (EHR) in Direct Support of Drug Development

Jane Myles, Global Patient and Site Recruitment Specialist, Genentech

Within Roche Pharma Development and Genentech, we are conducting 3 pilot projects focused on leveraging Electronic Health Records (EHR) in direct support of specific drug development programs/clinical trials: (1) Concept Development (mining clinical data to better understand targeted patient populations), (2) Protocol Design (fusing current real-world clinical data to determine the impact of specific criteria on the feasibility of a protocol), and (3) Patient Identification (having study sites identify potentially eligible patients directly from their EHR for proactive patient recruitment). Herein we present our experiences in conducting these 3 pilot projects.

**10:15** End of Short Course, Networking Coffee Break

### MORNING SHORT COURSE: UTILIZATION OF ELECTRONIC HEALTH RECORD (EHR) DATA IN CLINICAL RESEARCH

**8:40** Part 1: Connecting eHealth to Clinical Research

Susan K. Howard, Therapeutic Program Manager, Oncology Data Management, GlaxoSmithKline

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**10:15** End of Short Course, Networking Coffee Break

**10:50** Chairperson's Opening Remarks

**11:00** Innovative Integration of Mobile and Web-based Technologies to Enable a New Model for Clinical Research – Patient-Centered Clinical Trials

Craig Lipset, Director, Global Clinical Technology, Pfizer, Inc.

The sustainable development of new medicines is challenged by clinical trial cost and complexity. The central node for trials is the brick-and-mortar investigator site, which limits the available pool of participants to those within geographic proximity. Trials are increasingly burdensome to participating patients, further contributing to delays secondary to patient recruitment. An innovative integration of mobile and internet-based technologies, along with principles of telemedicine and tools of health information technology, brings the potential for a disruptive new model, a patient-centered clinical trial. Such a model enables the patient to participate in a trial entirely from their home, removes barriers to access while opening trials to patients from traditionally underserved populations, simplifies recruitment by expanding geographic reach, and simplifies clinical trial participation. An ongoing pilot is identifying solutions to meet regulatory obligations and ensure the safety and protection of participating patients, while collecting quality data on the efficacy and safety of an investigational medicine.

**11:30** Connectivity: A Critical Component for eClinical Success

Ingrid Akerblom, Executive Director, Development IT, Merck & Co., Inc.

Connecting Merck to clinical sites to drive scientific engagement as well as site productivity is central to the success of the eClinical experience. Clinical portals are being used to support this goal where success relies on well-integrated information and document management systems. The presentation will discuss the progress as well as the challenges in achieving connectivity of information as well as Connectivity with our clinical sites and CRO partners.
Electronic Data in Clinical Trials: Session B

1:25 Chairperson’s Remarks

1:30 Leveraging Technology to Mitigate Financial Risk when Partnering with an EDC Vendor

Rachel Shah, MPH, CCDM, Senior Clinical Data Associate, Gilead Sciences

It is increasingly challenging to select an ideal EDC vendor. Many factors have to be taken into consideration. The key factors are financial stability of the vendor, operational performance and cost efficiency. It is often difficult to achieve all three of them equally well. This presentation illustrates a strategy that has successfully maximized our return on investment by implementing a technology solution to minimize the dependency on the vendor while achieving optimal cost efficiency and high operational performance.

2:10 eClinical Solutions – Playing Well with Others

Anne Zielinski, Vice President, Alliances - Medidata Solutions

Today’s biopharmaceutical companies pressed to increase clinical development efficiency are increasingly using technologies in their quest. They are carefully evaluating and choosing applications to address the requirements of specific aspects of clinical trials - investigator gathered data, eDiary data, adverse event reporting, text message reminders for subjects, and more. Using clinical data standards, these systems can now share data, eliminating duplicate entry of data, minimizing data reconciliation, and taking advantage of systems’ ability to enforce data requirements. This presentation will detail the evolution of eClinical toward this vision of integrated data from disparate systems, looking at the benefits from various users’ perspectives. It will also peer into the future of integrated systems, and the value-add they can offer sponsors.

2:30 Safeguarding the Security and Reliability of Electronic Clinical Trials (ECT)

Presented by Medidata and Akamai Technologies

Jeff Livingstone, Contractor Industry Marketing, Akamai Technologies
Jim Attardi, Vice President Information Technology, Medidata Solutions

Clinical trials, which are becoming increasingly global in nature, are demanding a greater number of sites. Many of the sites selected for these trials – particularly in Asia Pacific and Latin American regions – are dispersed throughout a wide geographic area. This sparseness creates an urgent need for digitized delivery of clinical applications that can be distributed securely and reliably over the public Internet. Unfortunately, public networks linking hospitals, clinics, and doctor’s offices are often not optimal for business use, suffering from large latencies and little to no real security. In this session you will learn how Akamai has helped customers like Medidata overcome these limitations to attain the highest levels of security, reliability, and speed for Global ECT systems. These enhancements that today are providing medical practitioners with a more secure and reliable ECT experience, are decreasing the risk of drug development failure worldwide.

3:00 Networking Refreshment Break and Exhibit Viewing

3:45 Information Security and EDC: Areas of Concern

Rich Rauscher, Director of Information Technology, Pennsylvania State University

The promise of technology to speed and optimize clinical trials and research is accepted. However, when collecting and utilizing data something that must not be overlooked and offers great risk (legal, regulatory, public perception) is information security. This talk offers a realistic assessment and best practices as they relate to:

- Site-to-site authentication
- The differences between electronic and digital signatures
- Public key and private key encryption
- Public Key Infrastructure and the challenges of managing certificates
- Trust relationships

4:15 Interactive Break-Out Discussion Groups

Concurrent break-out discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the more poignant questions facing the industry. Delegates will join a table of interest to them and become an active part of the discussion at hand. It is an informal yet informative format that allows attendees to learn from each other and make some new contacts. To get the most out of this interactive format, please come prepared to: share examples from your work, set some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

Topics Include:

- Differences in Approaching Data Integration for BioTech, Small/ Midsize Pharma and Big Pharma
- Lessons Learned from Practical Implementation of Clinical Data Acquisition Standards Harmonization (CDASH)
- Training (sponsor staff, site, CROs) Methods and Logistics
- Overcoming Challenges in Integrating Systems (EDC, IVRS, CTMS) and Clinical Operations Data
- Establishing Governance and a Community of Best Practice for Electronic Data Capture
- Achieving Document Management/Control and Inter-departmental Collaboration
- Utilization of Electronic Medical Records (EHR/EMR) for Clinical Research
- Integrating Safety Reporting Data Into Your EDC System

5:30 Closing Comments and Welcome to Reception

5:45-6:45 Networking Cocktail Reception and Exhibit Viewing

Tuesday, March 9, 2010

7:45 AM Morning Coffee or Sponsored Breakfast Presentation (Sponsorship Opportunity Available)

Electronic Data in Clinical Trials: Session C

8:40 Chairperson’s Remarks

8:45 Incorporating and Integrating the eClinical Systems and Practices of Two Organizations

Ed Kellar, EDC Implementation Leader, Wyeth

Sponsors and vendors alike are in a period of rapid consolidation, which is expected to continue. The benefits to consumers and shareholders are widely discussed, but how are other stakeholders affected? In this session we will discuss the impact of eClinical excellence, including: the integration of technologies, likely strategies to assimilate best practices and processes, and the effect on the people and the culture of the combined companies.

9:15 Independent Electronic Adjudication of Patient Eligibility and Clinical Endpoints in Local and Global Clinical Trials

Drew Kilpatrick, M.D., Director, Global Safety and Pharmacovigilance, Kendle

Traditionally, adjudication of clinical endpoints has involved a paper based approach. Replacement of paper by electronic adjudication offers several process/cost advantages to sponsors of clinical trials. When the electronic adjudication system is linked to IVR/WVR systems/ eCRF, it is possible to independently adjudicate that a patient should be randomized into a study and b) identify when a patient has reported a potential clinical endpoint. Furthermore, the electronic approach allows adjudicators to access the system from anywhere in the world, review the corresponding endpoint documentation and complete the electronic adjudication form, confirming (or not) that the event reported by the patient is an endpoint as defined in the protocol.

9:45 Increasing Clinical Trial Efficiency through Operational Data Management

Bob Webber, President and Chief Executive Officer, TranSenda International, LLC

Sponsored by TranSenda
Clinical trial professionals are faced with managing studies that involve a myriad of disconnected software applications, each with a unique database and user interface. Even after costly point-to-point integration, users need to deal with a number of different systems to extract information. The future of clinical trial management is a portal environment that translates data from multiple clinical systems into targeted user information based upon role and access permissions, leveraging the latest software technologies like Microsoft Office SharePoint Server. This session will include real-world examples.

10:00 Networking Coffee Break and Exhibit Viewing

10:40 Chairperson’s Remarks

10:45 Integrating SAE and AE Best Practice
Darlene Kalinovski, Associate Director, EDC Operations, Bristol-Myers Squibb Co.
The topic of SAE integration is a current topic that benefits all companies and an issue whose challenges need to be met. This presentation will summarize considerations for moving SAE data into an EDC system.
- How do we start? Where do we go? And how do we get there?
- Collated experiences from several companies and discussion of the SAE to EDC Checklist that was developed will be presented.

11:15 Interactive Panel: Overcoming the Challenge of Integrating Safety Reporting Data into your EDC System
This panel will discuss collection of Drug Safety serious adverse event data through an EDC system and the subsequent transfer of these data to the Drug Safety database.
- What are the major issues companies encounter when tackling integration of drug safety data collection into company-wide EDC systems?
- What are the pitfalls and lessons learned when addressing different perspectives of clinical trial data collection vs. safety reporting from a technical and organizational perspective?
- How have different companies accomplished this? What was the impact on or between the drug safety and clinical research departments? What organizational best practices can be learned?
Moderator: Steven Olsen, M.S., Principal, SJO Consulting, LLC
Rachel Shah, MPH, CCDM, Senior Clinical Data Associate, Gilead Sciences
Michael Goedde, Director, Clinical Data Management, HGS (Human Genome Sciences)
Darlene Kalinovski, Associate Director, eDC Operations, Bristol-Myers Squibb Co.
Jonathan S. Helfgott, Consumer Safety Officer, CDRH, Office of Compliance, Division of Bioresearch Monitoring, FDA

11:45 Post-Panel Q&A with FDA: Discuss Compliance Issues on the Use of Computerized Systems in Clinical Investigations
Jonathan S. Helfgott, Consumer Safety Officer, CDRH, Office of Compliance, Division of Bioresearch Monitoring, FDA

12:00 PM Luncheon Presentation (Sponsorship Available, Contact Arnie Wolfson: 781.972.5431, awolfson@healthtech.com) or Lunch on Your Own

Electronic Data in Clinical Trials: Session D

1:25 Chairperson’s Remarks

1:30 Clinical Observations Interoperability: Leveraging Semantics for Effective and Accurate Sharing of Clinical Data
Vipul Kashyap, Director, Applied Informatics, CIGNA
The imperative to control rising healthcare costs and yet achieve optimum outcomes suggests the need for holistic services to deliver optimum therapy and care for patients. Those services embrace biomedical research, clinical research and practice. Re-use of clinical data is also beneficial to healthcare providers, e.g., evaluating clinical care quality; payors, e.g., monitoring patient risk profile, and pharma, e.g., determining patient eligibility for clinical trials, monitoring adverse events during and after trials. We propose an extensible framework and architecture for sharing and exchange of clinical data. This is illustrated via a demonstration utilizing eligibility specifications from several clinical research protocols (using the CDISC-based standards) and (structural patient data from a real world EHR (using HL7-based standards) to screen the EHR data for potential candidates.

2:00 The Highway to Successful Data Integration in Clinical Trials, Without Taking the Wrong Exits
Michael Goedde, Director, Clinical Data Management, HGS (Human Genome Sciences)
Starting with some basic background information and definitions on data integration, this presentation will deal with the question, if technical hurdles are truly the biggest challenge in the effort of companies to integrate clinical data or if there are other aspects that could result in bigger roadblocks. It will also look into different approaches for successful data integration for BioTech, small pharma and big pharma. After sharing experiences of different integration models this presentation will also try to raise questions around ROI of integrating data.

2:30 Integration in eClinical Trials - World - A Critical Path Perspective
Ram Kamath, CEO, Vsoft Infoware, Inc.
Clinical trials are becoming increasingly complex and data collection a significant challenge with global trials. In a landscape of over 150 vendors/applications and over 100 IT staff, simplification through integration has become inevitable. Critical path initiatives are the driving force behind improvement in the success rate of trial.
- Features of silo-based solutions with glue-on approach
- Adaptive/Seamless-phase trials and its advantages
- How to make clinical trials more worry-free
- Transition from paper to eClinical world and from partial integration to full integration
- Move to Infoware with single information repository based transactional and reporting system

2:45 Networking Refreshment Break and Exhibit Viewing

3:00 Development and Implementation of a Standard Methodology for the Assessment of Sites that have EMR/EHR Systems for Support of Drug Development
Aaron Kamauu, M.D., Healthcare Data Strategy, Biometrics, Roche
We have developed a standard methodology for assessing sites with EMR/EHR systems for the direct support of drug development programs/clinical trials. This includes assessment of their content/quality, technical capabilities, biomedical informatics capabilities and past experience using EMR/EHR data in support of clinical research and/or drug development. Herein we present this methodology and its application to specific drug projects.

4:00 EDC and Data Quality
Reza Rostami, MBA, CCDM, RAC, Assistant Director, Quality Assurance & Regulatory Compliance, Duke Clinical Research Institute, Duke University Medical Center
Transitioning from paper-based data collection to electronic data capture (EDC) systems has resulted in much measurable efficiency such as quick data availability and fast database lock. However, the level of data quality is more perceived than empirically measured. To date, data that demonstrate high levels of quality of electronically collected data are very limited and inconclusive. The main source of error in paper-based trials was data extracted from the patient chart and transcribed to the CRF. This activity stays the same with EDC: data is extracted from patient charts and entered into the system. To use an EDC system with confidence, data managers, programmers, and managers must understand how this new technology and processes affect data quality. This presentation will address techniques for measuring data quality, provide examples of published evidence of data quality in EDC, and recommend steps to assure a higher data quality.

4:30 Standards in Your Future: How SAFE-BioPharma, IHE and CDISC are Collaborating to Improve Safety Reporting
Rich Furr, Head, Global Regulatory Affairs and Chief Compliance Officer, Headquarters, SAFE-BioPharma Association
Reliance on paper forms is a major obstacle preventing the clinical investigation process from becoming fully electronic. Signing, handling, archiving and storing paper is expensive, error-prone and time-consuming. This presentation will explain a collaboration by three industry standards groups to achieve faster safety trend analysis, data mining and data migration from electronic health records 1) to archived and digitally signed electronic case report forms and 2) to individual case safety report forms.

5:00 Close of Electronic Data in Clinical Trials Conference
CHI's Inaugural eCTD 2010: Achieving Efficiency and Compliance in Electronic Submissions will be held March 10, 2010 at the Crowne Plaza Philadelphia City Center in Philadelphia, PA. This conference will be co-located with the Summit for Clinical Ops Executives (SCOPE), a four-day cluster of events taking place March 8-11, 2010. eCTD 2010 is co-hosted by CHI, Bio-IT World, and eCliniqua and is preceded by its partner events, CHI's Second Annual Electronic Data in Clinical Trials, Third Annual Patient Recruitment in Clinical Trials and a short course on ‘Utilization of Electronic Health Record (EHR) Data in Clinical Research.’

Filing new submissions is time consuming and costly to both regulators and drug development organizations. Global regulatory agencies are committed to improving the approval process and the electronic Common Technical Document (eCTD) is seen as a practical solution. It has been mandated in some countries and, to date, over 30,000 eCTD sequences have been submitted to the FDA alone. Despite the promise of eCTD to move your data through the approval process more efficiently, there are challenges to adoption and implementation. This conference is intended to cover how to achieve efficiency and compliance in electronic submissions.

### Wednesday, March 10, 2010

<table>
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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>7:30 AM</td>
<td>Conference Registration and Morning Coffee or Sponsorded Breakfast Presentation (Sponsorship Opportunity Available)</td>
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<tr>
<td>8:30</td>
<td>Organizer’s Welcome &amp; Chairperson’s Opening Remarks</td>
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<tr>
<td>8:45</td>
<td>How to Prepare Your Product Dossier for Global Simultaneous eCTD/CTD Submissions – A Look at Tools, Tips and Taking the Mystery Out of Submission Planning and Publishing</td>
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<tr>
<td>9:30</td>
<td>Case Study: Global Submission Management from Concept to Realization</td>
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<td>Networking Coffee Break and Exhibit Viewing</td>
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<td>11:00</td>
<td>Taking eCTDs off the Critical Path to Drug Development</td>
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<td>11:45</td>
<td>Interactive Panel: Looking Forward at Global Submission Management Across New Regions</td>
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<tr>
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<td>Luncheon Presentation (Sponsorships available. Contact Arnie Wolfson: 781.972.5431, <a href="mailto:awolfson@healthtech.com">awolfson@healthtech.com</a>) or Lunch on Your Own</td>
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<td>1:25</td>
<td>Chairperson’s Remarks</td>
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**Applications of eCTD**

- **Case Study: Global Submission Management from Concept to Realization**
  - Dominique Lagrave, Senior Director, Regulatory Operations and Innovations, Novo Nordisk
  
  The presentation will provide an in-depth view of the journey that Novo Nordisk is taking from the company's first simultaneous global eCTD submission two years ago and the current achievements in globalization activities. We will review the processes and technologies leveraged to support our long-term vision and lessons learned during this project.

**Interactive Panel: Looking Forward at Global Submission Management Across New Regions**

- **Interactive Panel: Looking Forward at Global Submission Management Across New Regions**
  - Moderator: Dominique Lagrave, Senior Director, Regulatory Operations and Innovations, Novo Nordisk
  
  Concerns have surfaced over the time taken to prepare eCTDs, and the effect this might have on the time to submit applications. Management may ask that submission times be reduced. We will take a journey through how one company answered this request with metrics and look at some future opportunities to reduce cycle times for preparing eCTDs.
1:30 Working with an eCTD Vendor: Best Practices and Lessons Learned
Thomas Noto, Vice President, Regulatory Affairs, Covance’s Periapproval Services
Writing, assembling, and submitting eCTDs is a very complex process. Working with outside vendors has the potential to add both time and complexity, potentially delaying filing. This presentation focuses on lessons-learned and best practices gained from over 15 years of electronic publishing experience. Recent experience includes the filing of a large eCTD containing over 250 study reports.

2:00 Electronic Signatures and Regulatory Processes, What the Agencies are Saying
Richard Furr, Head, Global Regulatory Affairs and Compliance, SAFE-BioPharma Association
This presentation provides an overview of the current positions of global regulatory agencies related to the acceptance of electronic signatures on documents which are components of e-submissions. The presentation also discusses the status of the eCTD in the EU in terms of the National Competent Authorities. The presentation provides a comparison between the different classes of electronic signatures with the emphasis on the type of signatures the Agencies are requiring and how sponsor companies can effectively meet those requirements.

2:30 Achieving Efficiency through Rounding Out Submission Standards: Format, Data, and Content Standards
Donald Palmer, Associate Director, Regulatory Systems, Regulatory Affairs, MedImmune, Inc.
This presentation will look at how the CTD format standard and the CDISC data standards have improved global operations and registrations. It will then consider rounding out these submission standards with document and ultimately content standards. This rounding-out will be considered as a trend toward electronic submission efficiencies.

3:00 Networking Refreshment Break and Exhibit Viewing

3:45 Interactive Break-Out Discussion Groups
Concurrent break-out discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the more poignant questions facing the industry. Delegates will join a table of interest to them and become an active part of the discussion at hand. It is an informal yet informative format that allows attendees to learn from each other and make some new contacts.

To get the most out of this interactive format, please come prepared to: share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.
Topics Include:
- Managing eCTD Lifecycle: Tracking and reporting, variations and amendments, controlling an ever-changing dossier
- Is Your Organization Moving toward Collaborative Authoring and Content Management?
- Are you Leveraging your EDC System for Support for Electronic Regulatory Submissions?
- Preparing for Future FDA and EU Initiatives for eCTD: What is ahead and what does it mean to you?
- Best Practices and Practical Approaches to Working Effectively with eCTD Vendors
- Preparing compliant eCTD Submissions: What could go wrong and why?
- Maximizing the Reusability of Data Across Submissions: The challenges and the benefits
- Current Challenges and Implications of eCTD Implementation

4:55 Closing Comments and Welcome to Reception

5:00-6:00 Networking Cocktail Reception and Exhibit Viewing

Stay on for Drug Development Latin America Day Two
CHI’s and the BioPharma Strategy Series’ Second Annual Drug Development Latin America: Effectively Planning and Implementing Clinical Research and Trials will be held March 10-11, 2010 at the Crowne Plaza Philadelphia City Center in Philadelphia, PA. This year this gathering will be co-located with the Summit for Clinical Ops Executives (SCOPE), a four-day cluster of events taking place March 8-11, 2010. CHI’s Drug Development Latin America will open with an inclusive short course on ‘Country and Site Feasibility and Selection for Global Clinical Trials’ and will be preceded immediately by its sister conference, the Third Annual Patient Recruitment in Clinical Trials conference.

The globalization of R&D into emerging regions continues. Growing R&D spending in Asia, Latin America and CIS countries has been driven by many factors including the attractiveness of commercial markets there, more favorable economics including lower relative costs for greater speed, access to highly skilled professional labor and a large pool of patients, particularly treatment-naïve ones. Pharmaceutical and biotechnology companies are seeing rapid growth in the volume of their clinical research, development, and clinical trials activity in Latin America. At the same time, this region presents unique challenges that must be anticipated and managed. This conference is intended to cover the key issues, opportunities, and challenges of clinical research, development, and clinical trials in Latin America.

### Wednesday, March 10, 2010

**7:30 AM** Morning Coffee or Sponsored Breakfast Presentation (Sponsorship Opportunity Available) and Short Course Registration

**MORNING SHORT COURSE: COUNTRY AND SITE FEASIBILITY AND SELECTION FOR GLOBAL CLINICAL TRIALS**

**8:30** Organizer’s Welcome & Chairperson’s Opening Remarks  
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

**8:45** Part 1: Understanding Regional and Country-Specific Challenges and Opportunities for Country and Site Selection  
Julio Camps, M.D., Director, Regional Head Latin America, Amgen Development Operations  
- How to position Latin America when competing with other Regions in the allocation of global sites  
- Understanding the best approach when selecting the Region to participate in a Global Clinical Trial  
- Once the Region is selected, which countries should be explored?  
- The Regulatory Factor: Is there a preferred Therapeutic Area expertise in certain countries?  
- Site selection: Experienced big sites vs. small new sites. Academic sites vs. private clinics. Sites located in big cities vs. sites located in peripheral cities

**9:15** Part 2: Using Qualitative and Quantitative Data to Drive Global Country and Site Selection from the Sponsor Perspective  
Charles Schweizer, Ph.D., Senior Director, Clinical Operations, Morphotek, Inc.  
Selection of optimal countries and sites is pivotal to the success of clinical programs. Factors to be considered include a balance of long-term strategic objectives versus short-term study goals and requirements. This session will review these strategic and tactical considerations, and then review the methods used to collect and analyze primary and secondary data that can be used to facilitate decision-making. This methodology should be comprehensive and identify both risks and opportunities to the sponsor. Reviews both traditional and newer methods to comprehensive country/site selection, including a shift toward a more comprehensive analysis rather than the more traditional focus primarily on patient accrual.

Understanding of the importance of a comprehensive analysis for country and site selection, and what methods should be considered for the overall analysis. Focus is on the application of health service/epidemiological methods to country/site selection, with the session aimed toward additional risks sponsors should be cognizant of during the analysis process.

**9:45** Overcoming Common Challenges in Global Site Selection from the Site Perspective  
Gaynor Anders, Vice President, Global Operations, MMG  
Considerations and strategies for accelerating patient recruitment in Latin American countries will be presented by a pair of global patient recruitment experts. Case studies illustrating specific enrollment barriers and the tactics used to overcome them will be shared. Attendees will apply session learnings to sample scenarios in work groups.

- Learn how variable regional and country conditions impact patient recruitment  
- Deepen understanding of how to maximize the effectiveness of patient recruitment programs in Latin America  
- Discuss specific challenges with patient recruitment in Latin America

**10:15** End of Short Course  
Main Conference Registration and Networking Coffee Break and Exhibit Viewing

**Drug Development Latin America: Session A**

**10:55** Chairperson’s Opening Remarks

**11:00** Latin America vs. Other Emerging and Non-Emerging Markets in Clinical Research: Regulations, Investigators, and Ethics Committees  
Ana Maria Valderrama, M.D., Area Head, Clinical Operations, Canada/Latin America/Africa/Middle East Region, Pfizer, Inc.  
Latin American countries operate increasingly in accordance with international standards and guidelines. Even though they are considered to have many similarities, it is important to keep in mind that in reality these are different countries, with different cultures, regulatory requirements, pathologies, incidence rates, standards of care, etc. For this reason it is very important to have local knowledge to accommodate diversity while leveraging shared characteristics. Also, of great importance is the increasing competition from other countries to attract clinical research. This session will provide a quick overview of LA’s current clinical research environment, summarize its challenges and opportunities, will share the successful stories of other countries out of LA, and will close with a discussion on lessons learned.
Use of Customer Capital Management to Identify and Develop Study Sites in Brazil
Carlos Sanmarco, Clinical Operations Manager, Clinical Development Organization, Eli Lilly do Brasil Ltda.
This presentation will demonstrate a new and excellent way to understand how to manage the customer capital in a pharmaceutical company or CRO and how to transform this knowledge not used or mapped in the main competitive weapon of the area. The audience will be able to identify and map the main processes and factors that must be considered in Customer Capital Management, and also will have an example tool that may be used to manage this information.

12:00 PM Luncheon Presentation (Sponsorship Available.
Contact Arnie Wolfson: 781.972.5431, awolfson@healthtech.com) or Lunch on Your Own

Drug Development Latin America: Session B

1:40 Chairperson’s Remarks
1:45 Implementing Trials in Brazil, Mexico, Argentina and Other Countries in Latin America
Oscar Enrique García Gálvez, M.D., Clinical Research Director, sanofi aventis Mexico
Latin America is more and more attractive for Clinical Trials, however the implementation is not as easy as could be expected. There are several differences among the Latin American countries that do not allow managing the region easily, so when trying to involve Latin America we should take differences into account to succeed. Main issues in Latin America are the timelines for getting the protocols approved and in some countries the increasing concern about the use of a placebo. Knowledge of the region and some flexibility to adapt to local needs are key to succeed.

2:15 Contracts and Budget Negotiation in Latin America
Luis Augusto Russo, M.D., Medical Director and Chief Executive Officer, CCBR Brasil; Director, Brazilian Society of Investigators and Research Centers (APCB)
This presentation will discuss the key issues and trends for contract and budget negotiation in Latin America. Attendees will better understand timelines, turnaround in private and public centers, average reimbursement, comparison with U.S. and Europe, complex issues to be solved and currency to be used in the future. Lastly, advantages of good negotiation for all sides (sites, sponsors, and for health public and private systems) will be summarized.

2:45 Optimizing Patient Recruitment in Argentina by Streamlining Approval Process
Ing. Andrea Pascual, Head, Clinical Operations Latin America, GRS Worldwide
Enrolling subjects in Argentina can greatly benefit a global clinical trial program. However, lack of knowledge of the approval process in Argentina can halt a study in its tracks and prevent timely subject enrollment. This session will instruct attendees on how to work effectively with investigational sites, IRB’s/EC’s and the government regulatory agency in Argentina to streamline approval timelines and avoid costly delays in study start up and time to first patient in.

3:00 Networking Refreshment Break and Exhibit Viewing

BREAK-OUT DISCUSSION GROUPS
3:45 Interactive Break-Out Discussion Groups
Concurrent break-out discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the more poignant questions facing the industry. Delegates will join a table of interest to them and become an active part of the discussion at hand. It is an informal yet informative format that allows attendees to learn from each other and make some new contacts. To get the most out of this interactive format, please come prepared to: share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.
Topics Include:
• Designing and Planning Clinical Trials in Brazil: What has changed and what needs to be considered from now on
  Carlos Sanmarco, Clinical Operations Manager, Clinical Development Organization, Eli Lilly do Brasil Ltda.
• The Importance of Site Support in Enhancing Enrollment and Compliance for Oncology Clinical Programs
  Michael Choukas, Chief Executive Officer and President, Oncopartners
  Helio Pinczowski, M.D., Executive Director of the Centro de Pesquisa en Hematologia e Oncologia da Faculdade de Medicina do ABC
• Experimental Medicine, Exploratory Pharmacogenomics Research, and Phase I Studies in Latin America
• How to set up a Private Research Center in Brazil and Latin America
  Gustavo Kesselring, M.D., President, Brazilian Society for Pharmaceutical Medicine; Director, Clinical Operations, Clinical Research Center, Oswaldo Cruz Hospital, São Paulo Brazil
• Choosing Contract Partners to Assist in Implementing Clinical Programs
• Access to the Drug Test After the Trial
  Luis Augusto Russo, M.D., Medical Director and Chief Executive Officer, CCBR Brasil; Director, Brazilian Society of Investigators and Research Centers (APCB)
• Latin America, a Growing Target for Clinical Research: Are we exhausting the region’s capacity?
  Oscar Enrique García Gálvez, M.D., Clinical Research Director, sanofi aventis Mexico
• Overcoming Misconceptions in Public Affairs and Addressing Ethical Issues in Multinational Clinical Trials

4:55 Closing Comments and Welcome to Reception

5:00-6:00 Networking Cocktail Reception and Exhibit Viewing

Thursday, March 11, 2010

7:45 AM Morning Coffee or Sponsored Breakfast Presentation (Sponsorship Opportunity Available)

Drug Development Latin America: Session C

8:40 Chairperson’s Remarks
8:45 Early Phase Development in Latin America: Challenges and Opportunities
Jorge Rodriguez-Larrain, M.D., FACC, Director, Regional Operations, Latin America, Merck & Co., Inc.
9:15 Emerging Jurisdictions in Latin America
Maureen Bennett, Partner, Global Life Sciences Practice Group Leader, Squire Sanders
• Ethical issues in informed consent
• Continuing access to investigational medicines
• Investigator and institution payment issues
• Recent Costa Rican suspension of clinical trials
9:45 Networking Coffee Break and Exhibit Viewing
10:45 Enhancing Accessibility to Innovative Medicines in Latin America
Integration of the Latin American countries in the modern clinical drug development brings these countries in direct contact with the highest scientific standards in methodology and procedures used in clinical trials and requires significant resources and trained personnel. Integration also fosters the development of expertise and experience among all involved parties (regulators, academic institutions, investigators, and industry) and helps to create a new source of high-technology employment. However, one of the main bottlenecks in the region is to have a workforce of trained personnel and implementation of regional and/or national training programs in clinical research become more important as the entire Latin American region evolve as part of a globalized world with scientific and technical ambitions of becoming an effective partner in the drug development arena.

• Attendees will learn about the development of IAFCR (Inter American Foundation of Clinical Research) and its program to foster education, training, and development of clinical research to improve health care throughout the Americas.

• Attendees will learn about an innovative initiative from the Brazilian Government to foster the clinical research capabilities in Brazil through a Brazilian Research Network of Academic Hospitals and supporting a National Clinical Research Course for this network.

• Attendees will learn about an innovative funding program for clinical research activities developed by the Brazilian Health Ministry.

Promoting Education and Training on Clinical Research in Latin America
Honório Silva, M.D., President of IAFCR (Inter American Foundation for Clinical Research)

Brazilian Government Program for Clinical Research (academic hospitals network and national clinical research course)
Gustavo Kesselring, M.D., President, Brazilian Society for Pharmaceutical Medicine; Director, Clinical Operations, Clinical Research Center, Oswaldo Cruz Hospital, São Paulo Brazil

12:00 PM Luncheon Presentation (Sponsorship Available. Contact Arnie Wolfson: 781.972.5431, awolfson@healthtech.com) or Lunch on Your Own

Drug Development Latin America: Session D

1:25 Chairperson’s Remarks

1:30 Leveraging Site Networks to Enhance Performance in Global Oncology Programs: Update on the IBPC Network of Public Oncology Hospitals in Brazil
Helio Pinczowski, M.D., Executive Director of the Centro de Pesquisa em Hematologia e Oncologia da Faculdade de Medicina do ABC
Denise de la Reza, M.D., Director of Clinical Operations, Oncopartners Instituto Brasileiro de Pesquisa em Cancer (IBPC) is the largest non-profit network of public oncology hospitals in Brazil. In collaboration with Oncopartners, a U.S. and Brazil-based SMO/CRO, IBPC has established a unique model to create a tradeable and operational support to member public hospitals that enable them to more effectively interact with regulatory agencies, promote themselves internationally, negotiate agreements with pharma and biotech companies, screen patients for oncology programs, monitor key study metrics and receive regular GCP and study-specific training. This presentation highlights the challenges and the lessons learned from the network’s participation in a recently completed international oncology protocol. Contributing over 50% of the patients, the IBPC team developed novel approaches to regulatory, patient identification and site support challenges which we now apply to new programs. Of particular interest to the audience, IBPC has developed a strategy to expand opportunities to include referral sites that do not routinely participate in clinical research.

2:00 Identifying and Developing Appropriate Investigators and Research Centers in Latin America
Celsa Arabetti, Ph.D., Director, Unidad de Investigacion Clinica, Hospital University Austral
This presentation will discuss the efforts to develop high performance Research Centers focused in quality and efficiency and how this strategy impacts in the Clinical Research Process. The CRU at the Austral University Hospital actually is in charge of 100 different protocols and developed management tools to deliver quality and efficiency.

2:30 Networking Refreshment Break and Exhibit Viewing

3:00 Case Study: Advancing International Collaboration and Partnerships in Scientific and Clinical Cancer Research, Training, and Infrastructure Development in Latin America
Jorge Gomez, M.D., Ph.D., Director, OLACPD (Office of Latin American Program Development), NCI, NIH
This presentation will discuss recent efforts and outcomes to date of the OLACPD (Office of Latin American Program Development). OLACPD represents an exciting new partnership between NCI (National Cancer Institute) and FIC (Fogarty International Center) of NIH (National Institutes of Health). OLACPD was founded in 2008 by Dr. Gomez with the goal of supporting and advancing international collaboration and partnerships in scientific and clinical cancer research, training, and infrastructure development in Latin America.

3:30 Biotechnology Product Development in Cuba, From Me-too’s to Original Drugs: The Heberprot P Case
Pedro A. López-Saura, Ph.D., Head of Department, Clinical Trials, Center for Biological Research, Cuba
Cuba’s Biotechnology program, launched in the early 80’s, first developed me-too products such as interferon, streptokinase and hepatitis B vaccine to satisfy national needs and self-sustainable development. In recent years original, patent-protected drugs have emerged. These required full clinical program design and performance. Heberprot P, a parenteral formulation containing epidermal growth factor, is a good example. Starting from preclinical data the project passed through proof of concept and phase I to III trials, following GXP and has already impact on advanced diabetic foot ulcer management and outcome.

4:00 Brazil is Becoming a Pharma Innovator, But…..
Michael P Ryan, Ph.D., Director, Creative and Innovative Economy Center, George Washington University Law School
In this presentation research findings regarding pharmaceutical R&D in Brazil will be discussed as will Brazilian public research and university roles, private sector business strategies, and policy and regulatory environment issues. Key points to be covered:

• Strengths of Brazil pharma R&D system
• Role of biodiversity in Brazilian pharma R&D
• Capacity weaknesses
• Policy and regulatory challenges

4:30 Close of Drug Development Latin America Conference

End of SCOPE
NEW! Medical Device Development: Regulation and Law
This practical reference provides the most comprehensive and updated analysis of US medical device and diagnostics development and approval requirements anywhere.

PAREXEL’s Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010
Considered ‘a must-have resource’ for the drug development industry. This statistical sourcebook is filled with pharma/biotech R&D trends, data, market intelligence, articles, and graphs providing fresh insights into the developments reshaping pharma R&D and the drug development industry. Also available in electronic format.

A one-of-a-kind compendium filled with hundreds of key trends and metrics used by professionals to gain industry insights, new benchmarks, and analysis to help plan their own R&D projects, improve company performance, and assess various drug approval options and strategies.

New Drug Development: A Regulatory Overview 2008
Addresses the most cutting-edge developments redefining how new drugs are developed and regulated today. The book is considered the “go-to” resource for regulatory, clinical, project management, training, and other drug development disciplines navigating the FDA’s drug development approval processes.

Expediting Drug and Biologics Development: A Strategic Approach
Using a unique “reverse-engineering” approach, dozens of leading experts with extensive experience in all disciplines of drug and biologic development show how careful planning and a sharp focus on the end-goals can be used to expedite the most complex product development program.

Biologics Development: A Regulatory Overview
The only textbook on biologics development and regulation in the post-CBER/CDER Consolidation Era! Offering an expansive examination of the FDA’s regulation of biologic products, from preclinical testing to post-marketing regulatory requirements, and from user fees to electronic submissions.

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**Gain a Competitive Advantage!**  
Your company has a unique opportunity to influence a major gathering of key biopharma executives and academic leaders who will come together at SCOPE – Summit for Clinical Ops Executives.

Brand your company as a thought leader in site selection, recruitment or data collection by participating as an active Sponsor. Presenting your solutions or services directly to our top-tier delegates can significantly impact their purchasing and collaboration decisions and help you achieve your sales and business development objectives.

These Sponsorship opportunities include Agenda, Breakfast and Luncheon Presentations, Invitation-only functions, Networking Receptions and an exhibiting program.

CHI will support your Sponsorship and brand your company with strong marketing programs before, during and after the event. The earlier you secure your Sponsorship, the more opportunity for exposure.

For details, please contact:  
Arnie Wolfson  
Manager, Business Development  
Phone: 781-972-5431  
Mobile: 857-636-8354  
Fax: 781-972-5470  
Email: awolfson@healthtech.com

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**HOTEL & TRAVEL INFORMATION**

**Conference Hotel:**  
Crowne Plaza Philadelphia Downtown  
1800 Market Street  
Philadelphia, PA 19103  
Phone: 215-561-7500  
Fax: 215-561-4484

**Discounted Room Rate:** $128 s/d  
**Discounted Room Rate Cut-off Date:** February 12th, 2010

Please visit our website to make your reservations online or 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 (authorization code 3130AG).
- Go online at www.aa.com (enter 3130AG in promotion discount box)
- 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 call AVIS directly at 800-331-1600 and reference our Avis Worldwide Discount (AWD) Number J868190.

Network with your peers and receive conference updates!  
Join the SCOPE Group on Linked In!  
http://www.linkedin.com/groups?home=&gid=2160330&trk=anet_ug_hm

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Online: ClinicalOps.com  
Email: reg@healthtech.com  
Fax: 781-972-5425
Yes! Please register me for the Summit for Clinical Ops Executives

REGISTRATION INFORMATION

- Name ____________________________  - Job Title ____________________________  - Div/Dept. ____________________________
- Company ____________________________  - Address ______________________________________
- City/State/Postal Code ________________  - Country ______________________________________________________________________________________________________________
- Telephone ____________________________  - Fax ____________________________  - Email: ____________________________

How would you prefer to receive notices from CHI?  o Yes  o No  Fax:  o Yes  o No  Email*: ____________________________________
*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.

Conference Package Pricing

4 DAY PREMIUM PACKAGE (BEST VALUE)  (Includes access to four conference short courses, all conference sessions, exhibit hall functions and conference proceedings)

- Early Registration by Dec. 11, 2009  - Advance Registration by Jan. 29, 2010  - Registration after Jan. 29, 2010
- Commercial  - Academic, Gov't, Hospital
- 2-day conferences
  - March 8-9 (please select one)
    - 3rd Annual Patient Recruitment in Clinical Trials (March 8-9)
    - 2nd Annual Drug Development Latin America (March 10-11)

Please select which 2-day conference and short courses you will most likely attend.

2-day conferences
- March 8-9 (please select one)
  - Designing and Implementing a Clinical Enrollment Plan (Morning-March 8)
  - Country & Site Feasibility and Selection for Global Clinical Trials (Morning-March 10)
  - Utilization of Electronic Health Record Data in Clinical Research (Morning-March 8)
  - eCTD 2010 (Full Day-March 10)

3 DAY STANDARD PACKAGE  (Includes access to one 2-day conference, eCTD 2010, plus one additional conference short course, and exhibit hall functions and conference proceedings)

- Early Registration by Dec. 11, 2009  - Advance Registration by Jan. 29, 2010  - Registration after Jan. 29, 2010
- Commercial  - Academic, Gov't, Hospital
- 2-day conferences
  - March 8-9 (please select one)
    - 3rd Annual Patient Recruitment in Clinical Trials (March 8-9)
    - 2nd Annual Drug Development Latin America (March 10-11)

Please select which 2-day conference and short course in addition to eCTD 2010 you will most likely attend.

2-day conferences
- March 8-9 (please select one)
  - Designing and Implementing a Clinical Enrollment Plan (Morning-March 8)
  - Utilization of Electronic Health Record Data in Clinical Research (Morning-March 8)
  - eCTD 2010 (Full Day-March 10)

2 DAY STANDARD PACKAGE  (Includes access to one 2-day conference, plus one additional conference short course, and exhibit hall functions and conference proceedings)

- Early Registration by Dec. 11, 2009  - Advance Registration by Jan. 29, 2010  - Registration after Jan. 29, 2010
- Commercial  - Academic, Gov't, Hospital
- 2-day conferences
  - March 8-9 (please select one)
    - 3rd Annual Patient Recruitment in Clinical Trials (March 8-9)
    - 2nd Annual Drug Development Latin America (March 10-11)

Please select which 2-day conference and short course you will most likely attend.

2-day conferences
- March 8-9 (please select one)
  - Designing and Implementing a Clinical Enrollment Plan (Morning-March 8)
  - Utilization of Electronic Health Record Data in Clinical Research (Morning-March 8)
  - eCTD 2010 (Full Day-March 10)

1 DAY REGISTRATION PACKAGE  eCTD 2010 Short Course Only

- Early Registration by Dec. 11, 2009  - Advance Registration by Jan. 29, 2010  - Registration after Jan. 29, 2010
- Commercial  - Academic, Gov't, Hospital-affiliated
- 1-day conference
  - March 8, 2010

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.

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 ($750) 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.

PAYMENT INFORMATION

- o Check enclosed
- o AMEX (15 digits)  o Visa (13-16 digits)  o MasterCard (16 digits)
- Card #: ____________________________  - Exp. ____________________________
- Cardholder: ____________________________  - Signature ____________________________
- Cardholder’s Address (if different from above) ______________________________________
- City/State/Postal Code ____________________________  - Country ____________________________
- Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.
- I cannot attend but would like to purchase the Summit for Clinical Ops Executives conference CD for $750 (plus shipping). Massachusetts delivery will include sales tax.
- Please send information on exhibiting and opportunities to present workshops.

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

How would you like to pay?  o 781-972-5400  o 781-972-5425  o Fax: 781-972-5425

Mail Registration to:
Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
T: 781.972.5400  Toll-free in the U.S. 888.999.6288
F: 781.972.5425  www.healthtech.com

Key Code 1035F