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Cambridge Healthtech Institute's *Fourth Annual*

Patient Recruitment in Clinical Trials

Overcoming Key Challenges in Recruitment and Retention

February 8 - 9, 2011 Westin Colonnade Coral Gables ■ Miami, FL

Understanding the Changing Landscape of Sites and Strategies to Adapt in Today's Trial and Recruitment World

Gretchen Goller, Patient Recruitment and Compliance Strategist, Operations, sanofi-aventis

Emerging Trends in Sponsor-Investigator Partnerships in Global Studies

Bonnie Brescia, Founding Principal, BBK Worldwide

Community Engagement as a More Sustainable, Efficient and Cost-Effective Model for Recruitment

Nariman Nasser, Director, Participant Recruitment Service Clinical and Translational Science Institute University of California, San Francisco

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

Karen Brooks, Director, Clinical Projects, Clinical Operations, sanofi-aventis

Part of Cambridge Healthtech Institute's *Second Annual*

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

Forecasting, Site Selection, Recruitment, Data Collection, & Project Management

Interactive Panels and Breakout Discussion Groups

Sunday Afternoon Pre-Conference Short Course with *CenterWatch*:

Optimize the Process of Site Selection, Study Activation and Patient Recruitment

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Cambridge Healthtech Institute's *Second Annual*

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

February 7 - 9, 2011 ■ Westin Colonnade Coral Gables ■ Miami, FL

We invite you to attend Cambridge Healthtech Institute's *Summit for Clinical Ops Executives (SCOPE)* taking place on February 7-9, 2011 in Miami, FL. The program brings together five conferences under the SCOPE umbrella, which creates an opportunity for idea sharing and cross pollination amongst clinical operations professionals from different groups. 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

February 6 Sunday PM	Pre-Conference Short Course Hosted by *CenterWatch:* **Optimize the Process of Site Selection, Study Activation and Patient Recruitment***		
February 7 Monday AM	**Electronic Data in Clinical Trials**	**Global Site Selection, Feasibility Assessment, Operations and Site Management**	**Drug Development Latin America**
Monday PM	**Electronic Data in Clinical Trials**	**Global Site Selection, Feasibility Assessment, Operations and Site Management**	**Drug Development Latin America**
February 8 Tuesday AM	**Electronic Data in Clinical Trials**	**Global Site Selection, Feasibility Assessment, Operations and Site Management**	**Drug Development Latin America**
Tuesday PM	**Patient Recruitment in Clinical Trials**	**Clinical Trial Forecasting, Budgeting, and Project Management**	
February 9 Wednesday AM	**Patient Recruitment in Clinical Trials**	**Clinical Trial Forecasting, Budgeting, and Project Management**	
Wednesday PM	**Patient Recruitment in Clinical Trials**	**Clinical Trial Forecasting, Budgeting, and Project Management**	

**Separate registration required*

Sunday PM Pre-Conference Short Course* with *CenterWatch:*

1:00 - 2:00 PM Short Course Registration

2:00 – 5:30 PM Optimize the Process of Site Selection, Study Activation and Patient Recruitment

This workshop focuses on the strategies, tools and technologies for site identification and selection, study and budget planning, and explores a variety of new initiatives that sponsors, CROs and investigative sites are implementing to improve patient recruitment and retention effectiveness. Specifically, the workshop focuses on the following critical areas:

- Site Identification, Assessment and Selection: Strategies and metrics employed by Sponsors and CROs in this process
- Study and Budget Planning: Positioning your site for success in the study and budget planning process
- Patient Recruitment: Exploring a variety of new approaches to improve patient recruitment and retention

Workshop Leader: Joan Chambers, COO, CenterWatch

Panelists:

Nye Pelton, CPC (Clinical Portfolio Consultant-Enrollment), US Medical Division - Oncology, Eli Lilly

Michael Jay, Vice President, RxTrials

**Separate registration required*

Bonnie Brescia, Founding Principal, BBK Worldwide

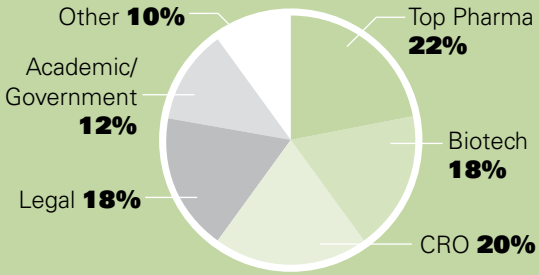
Arrive early (February 7) and attend one of the following events prior to Patient Recruitment in Clinical Trials:

- **Inaugural Global Site Selection, Feasibility, Assessment, Operations and Site Management**
- **Third Annual Electronic Data in Clinical Trials**
- **Third Annual Drug Development Latin America conference**

Who Attended

SCOPE 2010 was attended by more than 350 participants from 15 different countries representing more than 220 organizations.

Profile by Company Type



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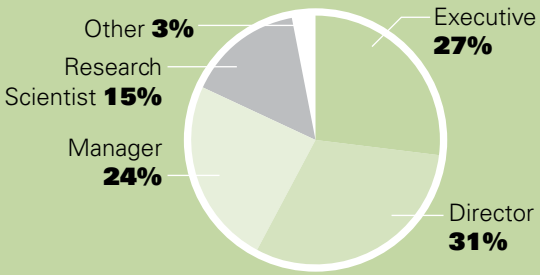

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Online: scopesummit.com **Email:** reg@healthtech.com **Fax:** 781-972-5425

Faculty:

- **Diana Anderson,** *CEO and President, D. Anderson & Company*
- **Celso Arabetti, M.D.,** *Director, Unidad de Investigacion, Clinica Hospital Unversitario Austral, Facutad de Ciencias Biomedicas*
- **Marcelo Belgrano,** *Clinical Study Manager, Novartis Argentina S.A.*
- **Rhonda Benotti,** *Business Manager, Contracts and Outsourcing, Genentech*
- **David Borbas,** *Director, Clinical Data Management, Jazz Pharmaceuticals, Inc.*
- **Bonnie Brescia,** *Founding Principal, BBK Worldwide*
- **Karen Brooks,** *Director, Clinical Projects, Clinical Operations, sanofi-aventis*
- **Kathleen Castro,** *Nurse Consultant, Division of Cancer Control and Prevention, Outcomes Research Branch, National Cancer Institute*
- **Joan Chambers,** *COO, CenterWatch*
- **Suzanne Collins,** *Director, Operations, Trifecta Multimedical*
- **Scott Connor,** *Vice President, Marketing, Acurian, Inc.*
- **Jonathan Curry,** *Associate Director, Analysis and Planning Lead , GCTM Business Operations, Pfizer*
- **Cecilia D'Antuono, Ph.D.,** *Manager, Site Management, Regional Clinical Operations, Bristol-Myers Squibb Argentina*
- **Peter DiBiaso,** *Senior Director, Clinical Planning & Performance, Clinical Development Operations, Vertex Pharma*
- **Thamer Draper,** *Senior Director, Product Strategy, OmniComm Systems Inc.*
- **Erica Elefant,** *Senior Clinical Scientist, Discovery Medicine Clinical Pharmacology, Bristol-Myers Squibb*
- **Chet Elias,** *Director, Global Regulatory Affairs and Safety, Emerging Markets, Amgen*
- **Carolina Errobidart,** *Clinical Data Coordinator, Global Data Management and Standards, Schering-Plough Argentina*
- **Francisco Estevez-Carrizo, Ph.D.,** *Professor, Clinical Pharmacology, University of Montevideo*
- **Manley Finch,** *Head, Neuroscience Clinical Trials, Clinical Operations, SleepMed*
- **Gretchen Goller,** *Patient Recruitment and Compliance Strategist, Operations, sanofi-aventis*
- **Pablo Graiver,** *Co-Founder & CEO, Management, TrialReach, Inc.*
- **David Haddick,** *Co-Founder and CEO, KDH Systems, Inc.*
- **Jonathan Helfgott,** *Consumer Safety Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA*
- **Dale Jackson,** *President, Virtual Clinical Solutions*
- **Michael Jay,** *Vice President, RxTrials*
- **Ze Jiang,** *Project Leader, Senior Strategist, iQuartic*
- **Michael Jones,** *Senior Director, Regional Clinical Operations, Eli Lilly and Company*
- **Darlene Kalinowski,** *Associate Director, EDC Operations, Bristol-Myers Squibb Co.*
- **Aaron Kamauu,** *Director, Healthcare Data Strategy, Pharma Development Biometrics, Genentech*
- **Vipul Kashyap,** *Director, Clinical Decision Support and Knowledge Management, CIGNA*
- **Matt Kibby,** *Market Intelligence, BBK Worldwide*
- **Matt Kiernan,** *Partner, PHARMICA Consulting*
- **Steven Kludt,** *Senior Vice President, Cambridge Semantics, Inc.*
- **Leif Kuse,** *Managing Director, Cilique UG*
- **Lisa LaLuna,** *Senior Vice President, Corporate Development & Implementation, ePharmaSolutions*
- **Zorba Lieberman,** *Co-Founder, Citeline, Inc.*
- **Marlene Llopiz-Aviles,** *Regional Director for Latin America, Venn Life Sciences, Mexico; Vice President, AMEIFAC*
- **Susan Lubin,** *Outsourcing Manager, Phase I, Bristol-Myers Squibb*
- **Daniela Luzi,** *Researcher, Institute for Research on Population and Social Policies, National Research Council*
- **Richard Mayewski,** *Patient Recruitment Specialist, Merck & Co.*
- **Michael Marcarelli,** *Pharm.D., Director, CDRH, Division of Bioresearch Monitoring, US Food and Drug Administration*
- **Florencia Masciottra,** *Clinical Trials Reviewer, ANMAT (Argentina)*
- **Bobbi McDonough,** *Director, Resource Management & Communications, Bristol-Myers Squibb*
- **Debra Mimo,** *Nurse Researcher/Research Coordinator, College of Nursing, University of South Florida*
- **Janet Mulheron,** *Director, Project Planning & Management, Bristol-Myers Squibb*
- **Nariman Nasser,** *Director, Participant Recruitment Service, Clinical and Translational Science, Institute University of California, San Francisco*
- **Michelle Noe,** *Senior Regulatory Operations Officer, Office of Regulatory Affairs, US Food and Drug Administration*
- **Miguel Orri, M.D.,** *Senior Director, Primary Care Business Unit, Pfizer, Inc.*
- **John Parkinson, Ph.D.,** *B.Sc., Director, GPRD, MHRA*
- **Nye Pelton,** *CPC (Clinical Portfolio Consultant-Enrollment), US Medical Division - Oncology, Eli Lilly*
- **Richard Penson, M.D.,** *M.R.C.P., Clinical Director, Medical Gynecologic Oncology, Massachusetts General Hospital; Chairman of Dana Farber/Harvard Cancer Center IRB Panels*
- **Marlene Peters-Lawrence,** *Clinical Manager, National Heart, Lung, and Blood Institute, NIH*
- **Christine Pierre,** *President, RxTrials*
- **Gabriele Pohlig, Ph.D.,** *Project Leader, Clinical Research Scientist, QA Manager, Medicines Research, Swiss Tropical and Public Health Institute*
- **Geri Pumper, RN,** *Program Manager, Mayo Clinic*
- **Massimo Raineri, Ph.D.,** *Head of Systems Development, Biometry, Actelion*
- **Aaron Rasch,** *Vice President, Asian Operations, Summit Analytical, LLC*
- **Brenda Reese,** *Executive Director, West Coast Operations, DSP Clinical Research*
- **Renato Ribeiro, Ph.D.,** *Clinical Research Manager, Global Clinical Trials Operations, Merck & Co., Inc.*
- **Mark Ridge,** *MBA, Senior Director, Global Business Operations, Pfizer*
- **Richard Robinson,** *Assistant Director, Internal Medicine, Metabolism, and Diabetes Group, US-CRU, Clinical Development, sanofi-aventis*
- **Nan Rothrock, Ph.D.,** *Research Assistant Professor, Medical Social Sciences, Northwestern University*
- **Adam Ruskin, Ph.D.,** *D.V.M., M.P.H., Director, Clinical Operations, Emergent Biosolutions*
- **Luis Russo, M.D.,** *CEO, Research Clinic, CCBR Brazil*
- **Jorge Taveira Samaha,** *Head for Clinical Trials, ANVISA*
- **Mary Jane Schoepfer,** *Associate Director, Program Study Manager, Oncology-Axitinib, Global Clinical Trial Management, Pfizer*
- **Edward S. Seguine,** *President, Clinical Ink*
- **Elizabeth Shewell,** *Director, Outsourcing, Incyte*
- **Marjorie Speers, Ph.D.,** *President and CEO, Association for the Accreditation of Human Research Protection Programs (AAHRPP)*
- **Jerry Stewart,** *Regulatory Policy Head, Emerging Markets, Pfizer*
- **Martin Stricker,** *Head Data Management, Data Management, bioskin GmbH*
- **Sameer Tandon,** *Group Head, Outsourcing, Outsourcing and Resource Management, Novartis Pharmaceuticals Corporation*
- **Fabio Thiers, M.D.,** *M.Sc., Ph.D., CEO, VIS Research Institute; Co-Director, Global Clinical Trials Research Program, MIT/NBER*
- **Helen West,** *Vice President, Strategic Development, MMG*
- **Kelly Willenberg,** *President, Sole Member, Synergism, LLC*
- **David Williams,** *CMO, PatientsLikeMe*
- **Dave Young,** *CEO, Trifecta Multimedical*
- **Jeffrey Zucker,** *Senior Director and Global Head, Patient Recruitment, Kendle*

Attention Pharma!

25 for 25 Special Offer

If you are an employee of the following TOP 25 Pharmaceutical companies as cited by *Pharmaceutical Executive,* you may attend this meeting at a **25% discount** off the current rate.

Group registrations are encouraged and we suggest calling **Elizabeth Andrews at 781-972-5418, eandrews@healthtech.com** to get your team to Miami at special company rates.

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14. **Boehringer-Ingelheim**
15. **Takeda**
16. **Astellas**
17. **Schering-Plough**
18. **Bayer**
19. **Schering AG**
20. **Genentech**
21. **Novo Nordisk**
22. **Eisai**
23. **Teva**
24. **Merck KGaA**
25. **Sankyo**

Patient Recruitment in Clinical Trials

Overcoming Key Challenges in Recruitment and Retention

TUESDAY, FEBRUARY 8, 2011

11:00 am - 12:00 pm Conference Registration

12:00 Luncheon Presentation (Sponsorship Opportunity Available) **or Lunch on your Own**

RECRUITMENT PLANNING AND STRATEGY

1:25 Chairperson's Remarks

Sponsored by McKESSON Empowering Healthcare

Suzanne Obst, M.B.A., Vice President, Corporate Strategy, McKesson Corporation

1:30 Understanding the Changing Landscape of Sites and Strategies to Adapt in Today's Trial and Recruitment World

Gretchen Goller, Patient Recruitment and Compliance Strategist, Operations, sanofi-aventis

With today's ongoing enrollment challenges, it is imperative that sponsors and CROs be open-minded with regard to planning their enrollment. Specifically what research sites are the best fit for any given protocol. Academic medical centers, SMOs, and other non-traditional research sites should be considered as well as viable options.

1:55 Patient Databases and Advertising Are not the only Tools to Power Recruitment: A Review of Clinical Trial Recruitment Strategic Planning

Manley Finch, Vice President, Clinical Research, Clinical Research Solutions, SleepMed, Inc.

Published literature documents a wide variance in the recruitment source of clinical trial subjects within and across disease indications. Variance outside of disease prevalence can be accounted for by many factors; trial design, seasonal, competing trials, recruitment planning, trial management competency, and others. Regardless, the commonly accepted recruitment mainstays are investigative site patient databases and advertising. Industry averages reveal that over 80% of clinical trials are delayed due to poor enrollment; clearly the mainstay recruitment practices require augmentation. This review will focus on powerful adjunctive and supporting initiatives that will accelerate enrollment velocity. A brief case study follows.

2:20 Beyond Posters and Brochures: Using Data, Expertise, and Common Sense to Drive Toward Patient Recruitment Success

Sponsored by Kendle Real people. Real results.

Jeffrey Zucker, Senior Director and Global Head, Patient Recruitment, Kendle

With the increased complexity of clinical trial design and the trend toward more targeted patient populations, using the same old methods of determining feasibility and developing patient recruitment plans will only lead to failure and timeline extensions. Employing historical data as it relates to enrollment feasibility, identification of countries and sites, and development of a specific and targeted patient recruitment plan is essential to enrollment success. This session covers how key data is gathered and used in protocol development and implementation, and how to avoid failure through proactive and contingency-based planning.

2:45 Afternoon Refreshment Break in Exhibit Hall

3:15 Anticipating IRB Requirements: Fast Track Tips

Richard Penson, M.D., M.R.C.P., Clinical Director of Medical Gynecologic Oncology, Massachusetts General Hospital; Chairman of Dana Farber/Harvard Cancer Center IRB panels C,E, and F

What strategies are optimal for avoiding the anticipated delays navigating IRB approval and study activation? How can protocols be simple, efficient and effective while still protecting participant safety? The NCI has approved a 6 month trial activation deadline that has focused concerns about delays, and is improving the culture invested in streamlining SRC, and IRB review. This session will review data, and suggest strategies aimed at stripping out redundancy and confusion and getting the job done.

3:40 Emerging Trends in Sponsor-Investigator Partnerships in Global Studies

Sponsored by BBK WORLDWIDE

Bonnie Brescia, Founding Principal, BBK Worldwide

This presentation will offer new ideas to consider regarding the nexus of the short- and long-term needs for these critical members of the clinical study community – and the impact of operational and/or business decisions on study recruitment. Key issues to be discussed include: Conflicting financial pressures and their impact on study enrollment; Who owns the relationships with investigators? Sponsor or CRO?; How can we integrate recognition and consequences with regard to patient enrollment?; What can we do to align long-term interests for faster study start-up and improved enrollment?

4:05 A New Approach to Pharmacy-Based Recruitment: The McKesson StudyLink Program

Sponsored by McKESSON Empowering Healthcare

Suzanne Obst, MBA, Vice President, Corporate Strategy, McKesson Corporation

J. Daniel Jones, Senior Global Program Manager, Cardiovascular, Metabolic, Critical Care Division, PPD, Inc.

Combining robust patient data with strong pharmacist-patient relationships is proven to more efficiently identify, qualify and engage the right patients for clinical studies. Hear sponsor/CRO viewpoints and learn from case studies demonstrating increased recruitment rates and the potential for reduced study timelines. In addition, gain a better understanding of the critical role that pharmacists play as a trusted healthcare provider for many patients, and their particular ability to reach diverse patient populations.

4:30 Informal 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.

5:30 pm - 6:30pm Networking Cocktail Reception

WEDNESDAY, FEBRUARY 9, 2011

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) **or Morning Coffee**

OPTIMIZING RECRUITMENT AND RETENTION

8:25 Chairperson's Opening Remarks

Sponsored by D. Anderson & Company

Diana Anderson, CEO and President, D. Anderson & Company

8:30 Community Engagement as a More Sustainable, Efficient and Cost-Effective Model for Recruitment

Nariman Nasser, Director, Participant Recruitment Service Clinical and Translational Science Institute University of California, San Francisco

Expansive numbers of sites in multiple countries has proven more cumbersome and less effective than expected as a broad solution to recruiting in today's competitive market. Key partnerships between industry, academic research/medical institutions, practice-based networks and community leaders can lead to long-term benefits for both sponsors and participants. This session will explore how local communities view clinical research, how to increase general interest in clinical research participation given the current healthcare climate, and why this is the best approach for the future.

8:55 Sponsor and CRO Co-Presentation: Referral Programs Can Work for Clinical Research Studies

Tess Drahzal, United Biosource Corp.

Kate Boneck, Global Trial Optimization - Specialist, Merck & Co., Inc.

Marketing experts say that it takes the average person 8 times to see and/or hear a message before taking action. Then why do we think that one "Dear Colleague" letter is going to do the trick? Some research docs have perfected the referral network by concentrating on a few simple techniques. While this can be time consuming, it can lead to a steady stream of referrals at a much lower cost than a TV spot. Successful referral networks will utilize direct mailings, phone calls, e-mails, lunch 'n learns and research information that may be of interest to them. This session will give an overview of available tactics and discuss one case study that successfully used a referral network program.

SOCIAL MEDIA, WEB 2.0 AND NEW TECHNOLOGY

9:20 Leveraging eRecruitment for Clinical Trial Enrollment

Sponsored by Acurian Predictable Patient Recruitment

Scott Connor, Vice President, Marketing, Acurian, Inc.

With Web 2.0 and social media continuing to gain mindshare with consumers and marketers alike, the focus surrounding its effectiveness in recruiting patients for clinical trials has increased dramatically in recent months. Acurian provides insight into the pitfalls and possibilities of eRecruitment as a patient enrollment strategy, including performance metrics from recent trials.

9:45 Sponsored Presentation (Opportunity Available)

10:00 Networking Coffee Break in Exhibit Hall

10:40 Chairperson's Remarks

Sponsored by PRAXIS

David Fox, President & CEO, Praxis

10:45 Navigating the PRO Labyrinth: Selecting a Patient Recruitment Organization to Ensure Enrollment Optimization

Sponsored by PRAXIS

Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

Choosing the right Patient Recruitment Organization (PRO) to design and deploy an effective recruitment campaign that will enhance enrollment for your research sites.

11:00 Imagine Unity: EMR Search and Network for Clinical Care and Research

Ze Jiang, Project Leader, Senior Strategist, iQuartic

Our group of Health IT engineers is leveraging Electronic Medical Record (EMR) infrastructures to facilitate clinical trial patient identification and accrual. Our economic model is intended to create synergy between clinical care and research, while optimizing the return to both parties from the transition to EMR systems. Our approach can theoretically cut clinical trial patient recruitment cost and time by more than 50%.

11:15 Case Report: Pilot Study Results Presented for PatientLocate™ — Multi-Site Electronic Patient Recruitment Technology

Sponsored by KDH Systems

David Haddick, Co-Founder and CEO, KDH Systems, Inc.

Usefulness of a new technology for managing the process of candidate identification for clinical trials was evaluated using PatientLocate™ at point-of-care. PatientLocate™ is a proprietary system that matches patients' medical conditions to trial criteria in real time, and provides CRA's with real-time feedback on patient identification and enrollment at trial sites. Data will be presented on the relative accrual rates of the sites in a trial that employed the technology vs. the sites that did not.

11:30 INTERACTIVE PANEL

Using Social Networks and Emerging Technologies to Accelerate Clinical Trial Recruitment

Moderator: Suzanne Collins, Director, Operations, Trifecta Multimedical

David Williams, Chief Marketing Officer, PatientsLikeMe

Gretchen Goller, Patient Recruitment and Compliance Strategist, Operations, sanofi-aventis

- 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

12:00 pm Lunch on your Own

1:25 Chairperson's Remarks

Sponsored by Kendle Real people. Real results.

Jeffrey Zucker, Senior Director and Global Head, Patient Recruitment, Kendle

1:30 Exceeding Recruitment Milestones-A Physician Perspective

Sponsored by Vince & Associates Clinical Research

Bradley Vince, D.O., President and Medical Director, Vince and Associates Clinical Research

Recent industry trends incorporating traditional clinical pharmacology safety, tolerability and pharmacokinetics parameters in early patient studies will be evaluated from the "real-world" research physician's perspective for feasibility and challenges. Specifically, recruitment, retention and medical management of special populations in Proof of Concept (POC) studies will be discussed and the competing needs of adequate dosing to

demonstrate efficacy vs. safety in special populations will be evaluated.

1:55 Development of Effective Strategies for Recruitment of Minority Populations into Clinical Trials

Karen Brooks, Director, Clinical Projects, Clinical Operations, sanofi-aventis

This session will provide insightful information to understand the various demographics of the minority patient. Awareness of these behavioral aspects will assist in the development of strategies to recruit minority patients within today's media network. In addition, for study trial completion, this discussion will provide focused techniques to retain patients under a transforming environment.

2:20 Patient Recruitment Begins with Site Selection *Sponsored by* PAREXEL Right where you need us™

Jill Guary, Director, Global Patient Recruitment and Retention Strategy Group, PAREXEL International

Patient recruitment is about a thoughtful way of identifying effective investigators that can contribute patients to a study. It is about selecting and qualifying the right sites based on data-driven decisions. It is about being prepared to deliver and knowing your patient database. It is not a step to consider after sites have been selected.

2:45 Afternoon Refreshment Break in Exhibit Hall

IMPROVING SITE AND PATIENT RECRUITMENT FORECASTING

(Shared Session with Clinical Trial Forecasting, Budgeting, and Project Management)

3:10 Chairperson's Remarks *Sponsored by* Virtual Clinical SOLUTIONS

Dale Jackson, President, Virtual Clinical Solutions

3:15 Closing the Gap between Perception and Reality: A Model for Improved Study Planning, Forecasting and Start Up

Mary Jane Schoepfer, Associate Director, Program Study Manager, Oncology-Axitinib, Global Clinical Trial Management, Pfizer

Jonathan Curry, Associate Director, Analysis and Planning Lead, GCTM Business Operations, Pfizer

The operational aspects of a protocol are often far more complex and "mine laden" than clinical teams recognize. Acknowledging the potential stumbling blocks up-front may lead to better decision making which could lead to a faster start-up and recruitment. This model attempts to highlight the reality of executing the study by focusing on country selection and providing options for success.

3:40 Centralized Patient Recruitment as a Site Support Initiative: Leveraging Coordinator Buy-In for Integrated Strategies *Sponsored by* ICTS Connect.

Gregg Sweet, MBA, Vice President of Strategy and Development, ICTS Patient Recruitment (Integrated Clinical Trial Services, LLC)

Study coordinators are the gatekeepers of all patient recruitment plans. Their buy-in is essential for the success of any centralized recruitment effort. This session will explore proven tactics that assure the highest level of coordinator buy-in resulting in optimized cost, time and quality of the entire patient accrual strategy. Balancing the requirements of the protocol with the investigator sites' threshold in processing referrals is key to successful integration of patient enrollment activities. Metrics from recent studies will be used to illustrate the cooperation between sponsor, sites and the centralized patient recruitment provider. Examples will be shown of study branded strategies that incorporate high levels of creativity with message retention and a good deal of fun for the recruitment teams and the prospective patients.

3:55 Utilizing Video Ad Network Aggregators as a Tactic in your Patient Recruitment Campaigns *Sponsored by* SiteAvail

Daniel D. Weddle, President & Founder, SiteAvail, Inc.

The application of Video Ad Networks (VAN) for placement of patient recruitment video is an innovative tactic within an overall campaign strategy. In this showcase, SiteAvail will present the "what, when, where, why, who, how" of working with VANs. Metrics associated with the first waves of using this VAN medium through its SiteCloud VAN Aggregator service will be provided. Challenges to adoption, target disease applications and future plans of the medium will also be addressed.

4:10 Clinical Trial Modeling and Simulation: Utilizing Real-Time Data from the Site Level Up through Regions and Countries

Manley Finch, Vice President, Clinical Research, Clinical Research Solutions, SleepMed, Inc.

Clinical development programs are continually shrinking "time-to-market" goals with earlier go/no-go decisions. Unsteady economic climate and the impact of tighter managed care reimbursement are the drivers. Cutting time to study start, last patient in (LPI), and database lock can save a Pharma millions in resources and preserve investor confidence. By strategically utilizing real time reporting of study metrics, competent program and project managers can reach these tighter utilization goals. Although commercial software can provide this needed technology, experienced clinical project managers, in collaboration with IT can easily craft tools providing the needed clinical trial forecasting and modeling.

4:35 Closing Remarks

4:45 End of Patient Recruitment in Clinical Trials

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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.

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To explore ways for your company to participate, please contact:

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Manager, Business Development
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E: jvacca@healthtech.com

Regarding this meeting, please contact:

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For media and association partnerships, please contact:

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For registration and group discounts, please contact: Elizabeth Andrews at (+1) 781.972.5418, eandrews@healthtech.com

CHI's INTRONET Networking at its Best

Maximize your experience on-site at SCOPE 2011!

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people you want to meet. This online system was designed with your privacy in mind and is available only to registered session attendees of this event.

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HOTEL & TRAVEL INFORMATION

Conference Hotel:

The Westin Colonnade Coral Gables
180 Aragon Avenue
Coral Gables, FL 33134
Phone: 305-441-2600 Fax: 305-445-3929
Discounted Room Rate: $199 s/d
Discounted Cut-off Date: January 7, 2011

Please visit our conference website to make your reservation online or you may call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted 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.

Car Rental Discounts:

Special discount rentals have been established with Hertz for this conference. Please use one of the following methods:

- Call HERTZ, 800-654-3131 use our Hertz Convention Number (CV): 04KL0002
- Go online www.hertz.com use our Hertz Convention Number (CV): 04KL0002

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February 8 - 9, 2011
Westin Colonnade Coral Gables ■ Miami, FL

HOW TO REGISTER:

Online: SCOPEsummit.com
Email: reg@healthtech.com **Phone:** 781-972-5400 Option 1 **Fax:** 781-972-5425

❑ **Yes! Please register me for SCOPE Summit**

Key Code RCTF

REGISTRATION INFORMATION

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City/State/Postal Code _____
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How would you prefer to receive notices from CHI? Email: ❑Yes ❑No Fax: ❑Yes ❑No
Email* _____ Fax _____

*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 PRICING

"Best Value" Access to full event for 3 days (February 7-9)	Commercial	Academic, Government, Hospital-affiliated
Early Registration by November 5, 2010	❑ $1845	❑ $875
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Please select the *two* conferences you are *most likely* to attend

February 7-8
- ❑ Global Site Selection, Feasibility Assessment, Operations and Site Management
- ❑ Electronic Data in Clinical Trials
- ❑ Drug Development Latin America

February 8-9
- ❑ Clinical Trial Forecasting, Budgeting, and Project Management
- ❑ Patient Recruitment in Clinical Trials

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Please select the *one* conference you are going to attend

February 7-8
- ❑ Global Site Selection, Feasibility Assessment, Operations and Site Management
- ❑ Electronic Data in Clinical Trials
- ❑ Drug Development Latin America

February 8-9
- ❑ Clinical Trial Forecasting, Budgeting, and Project Management
- ❑ Patient Recruitment in Clinical Trials

CONFERENCE SHORT COURSE (Sunday, February 6)

Optimize the Process of Site Selection, Study Activation and Patient Recruitment	❑ $695	❑ $395

☛ **REGISTER 3 - 4th IS FREE**
Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply. Please reproduce this registration form as needed.

❑ I cannot attend but would like to purchase the Summit for Clinical Ops Executives conference CD for $750 (plus shipping). Massachusetts delivery will include 6.25% sales tax.
❑ Please send information on exhibiting and opportunities to present workshops.

PAYMENT INFORMATION

❑ Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.
❑ Invoice me, but reserve my space with credit card information listed below.
Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.

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

Card # _____ Exp. Date _____
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Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
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CHI Insight Pharma Reports
A series of diverse reports designed to keep life science professionals informed of the salient trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets. For a detailed list of reports, visit **InsightPharmaReports.com**, or contact Rose LaRaia, rlaraia@healthtech.com, 781-972-5444.

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

Group Discounts
Special rates are available for multiple attendees from the same organization. **Contact Elizabeth Andrews at 781-972-5418** to discuss your options and take advantage of the savings.

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