Clinical Trial Optimization: Strategy, Planning + Recruitment

Patient Centricity in Developing Strategies for Trial Execution

Evidence-Based, Data-Driven Patient Recruitment and Retention

Don’t miss:
• Short Course: Key Technical, Scientific and Operational Considerations in Conducting a Patient-Centric Study
• Co-Located with Executive Decision Making 2013: Strategic Resource Management, Portfolio Management & Evidence-Based Reimbursement Summit
• Network with your peers at the Interactive Breakout Discussions

Corporate Sponsors

FEATURING PRESENTATIONS FROM...

Bristol-Myers Squibb
Cystic Fibrosis Foundation
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OptumInsight
Patients Know Best
Reg4ALL / Genetic Alliance
RxTrials
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Tufts University School of Medicine
United BioSource Corporation
Vanderbilt University Medical Center

healthtech.com/Clinical-Trial-Optimization
Key Technical, Scientific and Operational Considerations in Conducting a Patient-Centric Study

Technology continues to grow at an exponential rate and is allowing us to incorporate new and innovative concepts into clinical trials. By leveraging these technologies and newer communication channels, studies can be designed so part or all of a study can be executed without the need for investigative sites. Patient-centric studies are more in demand than ever before, however, new concepts and procedures bring an entirely new set of considerations that must be carefully thought through before starting any clinical trial.

Attendees will learn the most important technological, scientific and operational considerations when designing and executing a patient-centric study:

- How to collect and share data with patients using the latest technologies and tools: EDC systems, smartphones, social media, wireless medical devices and more
- Scientific design considerations such as targeting the right patient population, selecting study endpoints, including a control group, etc.
- Operational study enhancements, such as utilizing centralized clinics, pharmacies and home health nurses
- During the workshop, attendees will divide into teams to work through a sample study design

Instructors:
Nancy Mulligan, Senior Director, Operations, Patient and Physician Services, United BioSource
Krista Payne, Executive Director of Value Demonstration within Peri- and Post-Approval Services, and Senior Research Scientist, United BioSource Corporation
Halleluya Dunn, Clinical Recruitment Manager, Patient & Physician Services, United BioSource Corporation

* Separate registration required
Sponsorship, Exhibit, and Lead Generation Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre- and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on early will allow you to maximize exposure to qualified decision-makers.

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

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

**Invitation-Only VIP Dinner/Hospitality Suite**
Sponsor will select invitees from the conference pre-registration list for an evening of networking at the hotel or a top local venue. CHI will extend invitations, conduct follow-up and monitor responses. Reminder cards will be placed in the badges of delegates who will be attending.

*Inquire about exhibit space, branding and more!*

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**Looking for additional ways to drive leads to your sales team?**

We offer clients numerous options for custom lead generation programs to address their marketing and sales needs, including:

- Web Symposia
- White Papers
- Market Surveys
- Podcasts
- And More!

**Benefits of working with CHI for your lead generation needs:**

- Your campaign will receive targeted promotion to Cambridge Healthtech Institute’s unparalleled database of over 800,000 individuals, representing all sectors of the life sciences – lists can be segmented based on geography, research area, title and industry.
- All custom lead generation programs are promoted through our experienced marketing team that will develop and drive targeted campaigns to drive awareness and leads to your lead generation program.
- For our web symposia, we offer assistance in procuring speakers for your symposium through our extensive roster of industry recognized speakers across multiple disciplines within life sciences, as well as provide an experienced moderator and dedicated operations team to coordinate all efforts.
- If choosing a white paper program, we can offer editorial experience and provide an industry recognized author to write your whitepaper.

**To customize your participation at this event, please contact:**

Ilana Quigley | Business Development Manager  
T: (+1) 781.972.5457 | E: iquigley@healthtech.com

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**HOTEL & TRAVEL INFORMATION**

**Conference Venue & Hotel:**
Hyatt Regency Bethesda  
One Bethesda Metro Center  
Bethesda, MD 20814  
T: 301-657-1234

**Discounted Room Rate:** $249 s/d  
**Discounted Room Rate Cutoff Date:** September 23, 2013

Please visit our conference 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:**

- Take advantage of the $249 group rate!  
- DC Metro is located under the hotel

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**Special discounts have been established with American Airlines.**
Please use one of the following methods:

- Call 1-800-433-1790 (authorization code 32H3AC).  
- Go online at www.aa.com/group (enter 32H3AC in promotion discount box).  
- Contact our dedicated travel agent, Rona Meizler at 1-617-559-3735 or rona.meizler@protravelinc.com  

**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) 04KL0003  
- Go online www.hertz.com use our Hertz Convention Number (CV) 04KL0003

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**Top Reasons to Stay at the Hyatt Regency Bethesda**

- Complimentary wireless internet in all guest rooms  
- Restaurants and Shops are just minutes from the Hotel
2:30 Co-Presentation: Establishing a Culture of Clinical Research in a Chronic Disease Patient Population
Jill VanDelfsen, Director of Operations, Therapeutics Development Network Coordinating Center (TDNCC)
Cindy George, Director, Clinical Research Resources, Cystic Fibrosis Foundation
Christopher Dowd, Clinical Research Program Manager, Cystic Fibrosis Foundation
The purpose of this presentation will be to discuss the origins and growth of a culture of research within the Cystic Fibrosis Foundation and community. The audience will learn about the transformation of the CF Foundation, the tools and methodologies that have been developed to increase patient engagement, the current challenges we face and the involvement of the foundation and the patient registry in the Phase 4, post-marketing arena.

3:15 Refreshment Break with Exhibit Viewing

4:00 Benchmarking Patient Recruitment and Retention Practices
Mary Jo Lambert, Ph.D., Senior Project Manager, Tufts CSDD, Tufts University
Tufts CSDD initiated a working group of 12 biopharmaceutical companies and CROs to gather critical patient recruitment and retention benchmark metrics. Tufts CSDD collected and analyzed global trial data from 151 studies completed between 2008 and 2010. Phase II-II study data was collected and analyzed across five therapeutic areas. Researchers examined a variety of variables including enrollment rates and timelines, activation rates and drop out and completion rates by region and therapeutic area. Analyses of activation rates and enrolment achievement rates revealed differences by region and by therapeutic area. Centralized recruitment and retention tactics across studies were also examined by region and therapeutic area. Despite numerous tactics available, participating companies indicated using a small number of patient recruitment and retention tactics. The relationship between recruit tactics and enrollment was also explored.

4:30 Leveraging Technology to Expedite the Creation, Distribution and Collection of Study Feasibility Questionnaires
Kevin McNulty, Director, Product Marketing, Life Sciences, Intralinks
Developing the feasibility questionnaire, distributing it to potential sites and managing the collection and analysis of the surveys is typically a manual and time-intensive process. Pharmaceutical companies and CROs are now turning to technology to streamline and automate study feasibility and site recruitment in a secure manner. This session provides a practical look at how technology can simplify and speed the process.

5:00 Using Predictive Indicators to Measure Recruitment Vendor Performance
Elizabeth Mascherino, Associate Director, Clinical Operations, Shire Pharmaceuticals
Preventative screenings are an important part of managing our health. Screenings identify potential health problems before they develop or worsen and when they are easier to treat. Why not apply the same principles to the management of central recruitment campaigns? Predictive indicators can result in early detection of recruitment campaign results and allow for course correction before your campaign needs “resuscitation.”

5:30 Networking Cocktail Reception with Exhibit Viewing

6:15 Close of Day

TUESDAY, OCTOBER 22, 2013

Data-Driven Site Selection

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

8:25 Chairperson’s Remarks
Tania Bojanowski, Director, Development Operations & Strategic Planning, sanofi oncology
8:30 Using a Data-Driven Approach with Sites during the Feasibility Process to Help Ensure a More Accurate and Successful Trial Outcome
Nicole Burgeson, Site Director, RxTrials
Many Sponsors/CROs do not effectively challenge sites to think through their enrollment estimates during feasibility and site selection. Therefore, sponsors and CROs must design feasibility methods that force sites to take a data-driven approach to their estimates by asking for specific numbers that come directly from EMR or chart reviews.

9:00 Mapping Chronic Disease for Efficient Identification of Clinical Trial Outpost Development
Les Lebson, Director, University of Florida - Pathology, University of Florida Academic Health Center
With the implementation of the internet and growth of factors such as population, and analytical resources, and the need for comprehensive clinical trial populations, identifying best practices for establishing clinical trial outposts is paramount. Establishing clinical trial outposts in countries around the world has numerous benefits and drawbacks, including but not limited to ethical, legal and cultural implications. This presentation discusses novel strategies for preemptively researching and identifying regions in which to establish clinical trial outposts.

9:30 Why Patients Leave Clinical Trials and How to Better Engage Them
Ed Watson, Senior Director, Acurian
Early termination from clinical trials is a serious problem. First we need to understand the exact reasons why people enter trials and, in particular, why they drop out. This session reveals the results of a September 2013 survey of clinical trial participants that provides these patient insights and more. Also included is a recent case study exploring patient engagement for a large, cardiovascular outcomes study and the surprising data that resulted, along with a quantification of the cost savings attributed to strategic retention support.

10:00 Coffee Break with Exhibit Viewing

10:45 Advancing Patient Recruitment and Retention through Patient-Controlled Medical Records
David Beyer, Vice President, Patients Know Best
The real potential for successful patient recruitment and retention lies in a patient-centric online personal health record shared with the patient’s clinical and personal community simultaneously. We have evidence that working in this fashion helps clinical trials to advance beyond the one-dimensional view offered by patient profiles, the low retention and engagement generated by the current EMRs and the shortage of clinically verifiable information when online communities are used to target populations.

11:15 Optimizing Social Media in Clinical Research
Stella Stergiospolous, Project Manager, Tufts Center for the Study of Drug Development, Tufts University School of Medicine
The emergence of interactive web-based communities has introduced a host of opportunities and major challenges with respect to program planning, patient recruitment and pharmacovigilance. Although these communities play a growing role in clinical research, no standard policies and practices have been established to guide clinical research professionals. Tufts CSDD, with the help of a working group of pharmaceutical executives, has gathered primary and secondary data and will glean proposed principles and standard practices involving social media.

11:45 Pilot Project to Utilize a Social Media Platform for Sponsors and Investigator Site Personnel
Speaker to be Announced

Special Luncheon Presentation

12:15 pm Luncheon Presentation: Using Insurance Claims and Electronic Health Records to Ensure a Patient-Centric Trial
Bill Gwinn, MBA, Vice President, Clinical Informatics Solutions, OptumInsight
Year after year, about half of trials run late, but it will not stay that way. There is an explosion in quantitative data that can result in better planning and execution, for faster trials. The presentation will start with planning feasibility with insurance claims and electronic health records, including statistical projections of disease prevalence. For recruitment, the session will teach how to "fish where the fish are" to find patients. Techniques include ranking areas and investigators based on patient count. A new application will show how to improve media placements to reach the actual patients and improve response rates.
AdditionAl registrAtion detAils

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

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

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

If you are unable to attend but would like to purchase the Clinical Trial Optimization CD for $350 (plus shipping), please visit healthtech.com/Clinical-Trial-Optimization. Massachusetts delivery will include sales tax.