February 24-25

Global Site Selection, Feasibility Assessment, Operations and Site Management

Improving Timelines and Outcomes with Strategy, Relationships, Data and Execution

CONFERENCE HIGHLIGHTS

- Protocol Design, Feasibility and Country Selection Strategies
- Feasibility and Site Selection from the Sponsor, Investigator and Site Perspectives
- Improving Operational Efficiencies in Site, CRO, and Sponsor Interactions

February 25-26

Improving Site-Study Activation and Performance

Strategically Implementing a Process for Rapid Study Start-Up

CONFERENCE HIGHLIGHTS

- Optimizing Clinical Study Planning, Protocol Development, Feasibility, and Site Selection
- Overcoming Common Challenges in Feasibility, Site Selection, Budgeting and Contracting
- Transforming Site Management to Improve Outcomes

FEATURING PRESENTATIONS BY:


Kathy Vandebelt, Senior Director, Clinical Development Innovation, Eli Lilly and Company


Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Merck & Co., Inc.


Gregory Opiteck, Ph.D., Senior Principal Scientist, Clinical Pharmacogenetics, Merck & Co., Inc


John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer


Debbie Profit, Ph.D., Director, Corporate Projects, Otsuka Pharmaceuticals Development and Commercialization


Jackie Kent, Sr. Director, Clinical Development Information & Optimization (CDIO), Eli Lilly & Co.; TransCelerate Shared Investigator Platform Leader


Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer


Cindy Levy-Petelinkar, Director, Clinical Platforms Transformation, GlaxoSmithKline


Christine Pierre, President, The Society for Clinical Research Sites (SCRS)


Michelle Everill-Flinders, Director, Feasibility Center Of Excellence, Development Operations, Pfizer


Susie Campos, Associate Director, Clinical Trial Intelligence, Novartis


Carol Seider, Senior Director, Global Clinical Operations, Clinical Country Management, Biogen Idec

PLENARY KEYNOTES AND PANEL:

- The Investigator's Voice and Patient-Centered Trials
- Embracing Open Innovation and Collaboration
- Appling Innovative Technology to Enable Clinical Research

Part of

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

February 24 - 26, 2015

Hyatt Regency Orlando

Orlando, FL

SCOPEsummit.com

PREMIER SPONSORS

BBK WORLDWIDE · BIOCLINICA · Clinical ink · DrugDev do more trials · EXOSTAR · imshealth

Mapi Insight for solutions · medidata · OPTUM · ORACLE HEALTH SCIENCES · PRAHEALTHSCIENCES · QUINTILES

Conference-at-a-Glance

	SITE ACTIVATION	RECRUITMENT	PROJECT MANAGEMENT	MONITORING	DATA	PERI-APPROVAL
Tuesday, February 24, 2015						
AM & PM	CONFERENCE 1A **Global Site Selection, Feasibility Assessment, Operations and Site Management**	CONFERENCE 2A **Enrollment Planning and Patient Recruitment**	CONFERENCE 3A **Clinical Trial Forecasting and Budgeting**	CONFERENCE 4A **From QbD and Risk Assessment to Risk-Based Monitoring**	CONFERENCE 5A **Electronic Data in Clinical Trials**	CONFERENCE 6A **Managing Late Stage Research, Observational Studies and Registries**
Wednesday, February 25, 2015						
AM	CONFERENCE 1A **Global Site Selection, Feasibility Assessment, Operations and Site Management**	CONFERENCE 2A **Enrollment Planning and Patient Recruitment**	CONFERENCE 3A **Clinical Trial Forecasting and Budgeting**	CONFERENCE 4A **From QbD and Risk Assessment to Risk-Based Monitoring**	CONFERENCE 5A **Electronic Data in Clinical Trials**	CONFERENCE 6A **Managing Late Stage Research, Observational Studies and Registries**
PM	CONFERENCE 1B **Improving Site-Study Activation and Performance**	CONFERENCE 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**	CONFERENCE 3B **Clinical Project Management for Outsourced Clinical Trials**	CONFERENCE 4B **Implementing Risk-Based Monitoring**	CONFERENCE 5B **Integrating and Leveraging Clinical Trial Operations Data**	CONFERENCE 6B **Pharmacovigilance and Adverse Event Reporting**
Thursday, February 26, 2015						
AM & PM	CONFERENCE 1B **Improving Site-Study Activation and Performance**	CONFERENCE 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**	CONFERENCE 3B **Clinical Project Management for Outsourced Clinical Trials**	CONFERENCE 4B **Implementing Risk-Based Monitoring**	CONFERENCE 5B **Integrating and Leveraging Clinical Trial Operations Data**	CONFERENCE 6B **Pharmacovigilance and Adverse Event Reporting**

Premier Sponsors:

BBK Worldwide · Bioclinica · Clinical ink · DrugDev do more trials · Exostar · imshealth · Mapi Insight for solutions · medidata · Optum · Oracle Health Sciences · PRAHEALTHSCIENCES · Quintiles

Corporate Sponsors:

Acurian · Appian · Chiltern · citeline · CPI Global CRO · Cytel · DAC Patient Recruitment Services · ERT · HealthCarePoint · ICON · inc Research · Intra Links Study Space · Intrinsic Clinical Systems · inVentiv Health · MAXISIT · MEDPACE · OmniComm · PerkinElmer · Pharmica Consulting · Praxis · SimuLyve · ta-Scan · Thomson Reuters · UBC · Veeva

Corporate Support Sponsors:

Advanced Clinical · greenphire · INFINATA · Insearch · NCGS · Paragon · PharPoint Research · pwc

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. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

Agenda Presentations

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15 or 25-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

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects. Evening will be customized according to sponsor's objectives i.e.:

- Purely social
- Focus group
- Reception style
- Plated dinner with specific conversation focus

Exhibit

Exhibitors will enjoy facilitated networking opportunities with 700+ qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

Additional opportunities are available for sponsorship, including:

- Game Card
- Mobile App
- Cell Phone Charging Station (SOLD)
- Focus Group
- Hotel Room Key
- User Group Meeting
- Footprint Trails
- Program Guide Advertisement
- Padfolios
- Lanyards (SOLD)
- Totebags (SOLD)

To customize your participation at this event, please contact:

Ilana Quigley
Business Development Manager
Cambridge Healthtech Institute
T: 781-972-5457
E: iquigley@healthtech.com

Lead Generation

Obtain more targeted, qualified leads within life sciences with CHI's Lead Generation programs. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
- Custom Market Research Surveys
- Podcasts

Advertising opportunities such as marketing and promotional emails are also available.

NEW PRODUCT SHOWCASE

New Product Showcase

Exhibitors have the opportunity to showcase their new product. CHI will promote your new product with the following:

- NPS displayed in prime location in the exhibit hall
- NPS logo displayed on the conference website
- Your company logo, booth number, website, and product name included in the Program Guide
- Multiple pre-show marketing campaigns sent to our targeted database (including one overall product update campaign emailed to 100,000+ prospects and pre-registered delegates)
- Product/service description (30 words) in a press release announcing product launches at the event

Current Sponsors and Exhibitors *(as of October 10, 2014)*

Acurian
Advanced Clinical
AMC Health
Aspire IRB
BBK
BioFortis
BioPharm Clinical
Chiltern
Citeline
Clinical Ink
Clinical SCORE
Compliance Insight, Inc.
CORE – Centers for Research Excellence
CPI Global CRO
Cytel
DAC Patient Recruitment Services
DrugDev
Elite Research Network
Exostar
GoBalto, Inc.
Greenphire
IMS Health
INC Research
Insearch and Meridien Research
IntegReview IRB
IntraLinks, Inc.
inVentiv Clinical Trial Recruitment Solutions
Langland
Liaison Healthcare Informatics
MakroCare
Mapi
MDCPartners
Medpace
Meridien Research
MMG
OmniComm Systems, Inc.
Optum
The Patient Recruiting Agency™ (TPRA)
PerkinElmer
Pharmica Consulting
PharPoint Research, Inc.
Phlexglobal
PHT Corporation
Praxis
Quintiles
RxTrials, Inc.
Sidus BioData
Society for Clinical Research Site (SCRS)
ThreeWire, Inc.
TrialDynamics
United Biosource Corporation (UBC)
Vector Psychometric Group, LLC
Veeva Systems
Wake Research Associates

Global Site Selection, Feasibility Assessment, Operations and Site Management

Improving Timelines and Outcomes with Strategy, Data and Execution

February 24-25, 2015

TUESDAY, FEBRUARY 24

About This Conference

Data-driven global site selection, an optimized feasibility assessment process, and effective site management are critical to improving clinical trial timelines and outcomes. Too often companies fail to learn from past mistakes and take the same approach to trial planning and execution. In order to overcome challenges in clinical trial planning, operations and site management leaders should learn from the best practices of their peers, utilize data and technology to support decision making, and improve communication and relationships between Sites, CROs, and Sponsors. Cambridge Healthtech Institute's *Fifth Annual* **"Global Site Selection, Feasibility Assessment, Operations and Site Management"** conference will cover the topics one should consider when planning and implementing a trial.

7:30 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes

PLENARY KEYNOTES AND PANEL: THE INVESTIGATOR'S VOICE AND PATIENT-CENTERED TRIALS

8:25 am Organizer's Welcome

8:30 Plenary Keynote Chairperson's Opening Remarks: Balancing Risk and Opportunity in the Evolving Drug Development World
Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Merck & Co., Inc.

8:40 The Evolution and Implementation of Patient-Centered Trials
Kathy Vandebelt, Senior Director, Clinical Development Innovation, Eli Lilly and Company

9:05 TRIAL INVESTIGATOR PANEL: Improve Protocol Feasibility, Trial Conduct and Operations by Learning from a Key Partner in Research
Moderator: Claire Sears, Ph.D., Director, Investigator Engagement, DrugDev
Panelists: Investigator Panelists

9:45 Grand Opening Coffee Break in the Exhibit Hall

PROTOCOL DESIGN, FEASIBILITY AND COUNTRY SELECTION STRATEGIES

10:45 Chairperson's Remarks
Eric Lake, Partner, Pharmica Consulting

Sponsored by PHARMICA CONSULTING Get Better

10:50 Global Trial Placement Strategies; Linking Early Research with Phase III Execution
John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

Balancing site performance, regulatory strategy, and patient access is a difficult yet achievable goal in clinical research. This presentation will provide an overview of Pfizer's Global Trial Placement Strategies which are designed to select the right countries and right sites that allow for speed in trial conduct and regulatory approvals.

11:15 Protocol Design, Feasibility and Country Selection: Integrating Teams and Processes for Improved Trial Execution
Stephen Yoo, M.D., Chief Medical Officer, ReGenX Biosciences

Drug development has become increasingly difficult and expensive. Exacerbating these challenges is the fact that more companies are trying to solve for unmet medical needs in diseases where the populations are heterogeneous and endpoints are poorly developed. This puts an increasing amount of pressure on ensuring the protocol design targets the intended population, data collection and interpretation are accurate, and that these trials can be delivered on time and on budget. This requires increased attention to the up-front planning, maximal utilization of the available data at hand, and processes that ensure the quality of the data during the conduct of the clinical trial. We will explore some case studies in development and focus on the impact that both newer processes and team integration.

11:40 Case Study: TransCelerate Shared Investigator Platform
Jackie Kent, Sr. Director, Clinical Development Information & Optimization (CDIO), Eli Lilly & Co.; TransCelerate Shared Investigator Platform Leader

This presentation will focus on defining the purpose of the TransCelerate Shared Investigator Platform and the shared industry problems it addresses. Also, it will share the Future Release Roadmap and next steps. During the cross-industry multi-year effort the following points from pharma, site and investigator users were taken into account: Seamless user experience with a single point of access for interaction with multiple study sponsors; Harmonized training content delivery (e.g., GCP) and certification; Critical notifications, alerts, task lists in an integrated view across sponsors, studies; Comprehensive site personnel and facility profile that is leveraged across participating sponsors; Secure document exchange to facilitate communication during study planning and study conduct.

12:05 pm Country, Site, and Investigator Selection Strategies for a Global Epidemic: Case Study in Type 2 Diabetes

Sponsored by citeline an Informa business Robust. Reliable. Relevant.

Anne LiCata, Relationship Manager, Citeline

Type 2 diabetes is on the rise globally, presenting new opportunities and challenges in clinical drug development. Selecting the best sites and investigators is crucial and can be particularly challenging in emerging regions. This case study will provide attendees with deeper insight into data-driven country, site, and investigator selection strategies in this increasingly prevalent disease.

12:35 LUNCHEON CO-PRESENTATION: Mining the Mother Lode: Leveraging Metrics to Identify Top Performing Sites & Activate Them Quickly

Sponsored by imshealth

Elisabeth Otto, Product Manager, SiteOptimizer, Clinical Trial Optimization Solutions, IMS Health

Ying Jiang, Senior Manager, Client Services, Clinical Trial Optimization Solutions, IMS Health

The process of identifying, selecting and activating best performing sites for clinical trials is undergoing a significant transformation as organizations adapt to changes in the industry and start leveraging new sources of data, innovative tools, and technologies. Learn what data is available and how best to mine it to build your investigator list.

1:15 Session Break

FEASIBILITY AND SITE SELECTION FROM THE SPONSOR, INVESTIGATOR AND SITE PERSPECTIVES

1:25 Chairperson's Remarks
Maria Cipicchio, Campaign Operations, BBK Worldwide

1:30 Optimizing Site Selection to Initiate and Maintain a Positive Site Relationship
Christine Pierre, President, The Society for Clinical Research Sites (SCRS)

This presentation will provide a comprehensive look at model site selection from the sites' perspective with consideration for industry's limitations and deliverables. Attendees will gain a competitive advantage by understanding the site's hurdles that ultimately impact the sponsors' timelines. By expanding your knowledge of key elements important to sites and understanding how to provide a personal touch in an impersonal, technology-driven environment, attendees will master the initiation and maintenance of a positive site relationship. This behind-the-screens look will demonstrate a fresh approach to site selection, and will equip you with the tools to secure an effective site relationship.

1:55 CO-PRESENTATION:
Part 1: Sponsors and Sites: Getting on the Same Page With Feasibility
Part 2: Study Feasibility, the Sites' First Hurdle
Deena Bernstein, Director, Clinical Research, Sheridan Clinical Research, Inc.
Chris Hoyle, President, Elite Research Network
Michelle Everill-Flinders, Director, Feasibility Center Of Excellence, Development Operations, Pfizer

This presentation from the Site and the Sponsor perspective will address what all parties are faced with during the initial point of contact until site selection. How can the Sponsors and CROs improve the process and get better results and responses from Sites? What do Sites need to better understand from the Sponsor perspective in order to improve their business process? Three presenters representing different perspectives will share the Site and the Sponsor experiences and make recommendations for efficiencies in feasibility activities.

2:45 Pioneering Feasibility Assessment Using Both Electronic Health Records and Insurance Claims

Sponsored by OPTUM

Bill Gwinn, MBA, Vice President, Clinical Informatics Solutions, Optum

Do the patients you are looking for exist? How can you find them? Explore new ways to locate your trial patients by combining insurance claims data and clinical data from electronic medical records (EMR). A case study will show the impact of innovation, ranging from protocol designers to operational managers.

HALL BREAK AND BREAKOUT DISCUSSION GROUPS

3:00 Refreshment Break in the Exhibit Hall

4:00 Find Your Table and Meet Your Moderator

4:05 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and 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.

5:00 Welcome Reception in the Exhibit Hall

6:15 Close of Day

WEDNESDAY, FEBRUARY 25

7:30 am BREAKFAST PRESENTATION: Evaluating the ROI of Outsourcing Investigator Payments

Sponsored by DrugDev do more trials

Stuart (Stu) Thiede, President, DrugDev Payments

Everyone knows the # 1 complaint of Investigators is slow payments to the sites. Pharmaceutical companies often outsource investigator payments to improve efficiencies, provide costs savings and build better investigator relationships. But how do you quantify whether or not you made the right decision to outsource? Do you go with anecdotal evidence and assume your goals are being realized or can you prove it with real metrics? This program will review a model that enables you to assess the ROI of outsourcing your investigator payments. See how this model measures benefits such as increased operational efficiencies, enhanced investigator relationships, improved budget management and increased compliance to determine whether or not you're accomplishing your business objectives.

8:25 Plenary Keynote Session

PLENARY KEYNOTES AND PANEL: EMBRACING OPEN INNOVATION AND COLLABORATION

8:25 am Organizer's Welcome

8:30 Plenary Keynote Chairperson's Opening Remarks: Open Innovation as a Solution to Clinical Research Bottlenecks

Ibraheem "Ibs" Mahmood, President and CEO, DrugDev

8:40 Alternative and Lean Approaches to Trial Planning and Execution

Dave Gillogly, MBA, Vice President, Head, Global Clinical Operations, Mylan

9:05 PANEL DISCUSSION: Open Innovation/Cross-Industry Collaboration and the Current State of Affairs In Pharma

Moderator: Ibraheem "Ibs" Mahmood, President and CEO, DrugDev

Panelists: Kathy Vandebelt, Senior Director, Clinical Development Innovation, Eli Lilly and Company

Dave Gillogly, MBA, Vice President, Head, Global Clinical Operations, Mylan

Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Merck & Co., Inc.

John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

9:45 Coffee Break in the Exhibit Hall

IMPROVING OPERATIONAL EFFICIENCIES IN SITE, CRO, AND SPONSOR INTERACTIONS

10:45 Chairperson's Remarks

Stephen Yoo, M.D., CMO, ReGenX Biosciences

10:50 Investigator Registries: Collaborating to Benefit Both Investigators and Sponsors in Feasibility, Site Selection, and Start-Up

Susie Campos, Associate Director, Clinical Trial Intelligence, Novartis

In this session we will discuss investigator registries, including a taxonomy of current registries, how they are used, the benefit to pharmaceutical companies/CROs, and value for investigators. Using the Investigator Databank as a case example, we will also discuss: the type of data shared; how this information supports feasibility, site identification, and start-up; and the added value generated through integration of multiple data sources and sharing of information across companies. The Investigator Databank is a global collaboration among Janssen, Lilly, Merck, Novartis and Pfizer whereby the members share investigator information for the benefit of both industry and investigators.

11:15 Adaptive Recruitment: Maintaining Deadline

Sponsored by BBK

Integrity Despite a Changing Landscape

Jaime Cohen, Strategic Consultation, BBK Worldwide

Designed to protect global enrollment integrity, within a changing or threatened landscape, adaptive recruitment helps maximize tight budgets and timeframes by offering the tools and best-practices needed to ensure more informed enrollment decisions – and the ability to seamlessly employ real-time corrections. This session will explore how adaptive recruitment fosters a shared understanding of enrollment data and encourages a reverence for operational efficiencies that make the difference in meeting your deadlines – not moving them.

11:40 PANEL DISCUSSION: Two Heads Are Better Than One: The Necessary Shift of Sponsors and CROs from Adversaries to Partners

Moderator: April Lewis, Director, Global Client Management, Clinical Trial Optimization Solutions, IMS Health

Panelists:

Zahida Aktar, Trial Optimization Lead, Pfizer

Elisabeth Mascherino, Associate Clinical Operations Director, Shire

Allen Gidner, Senior Project Director, Parexel International

The Sponsor / CRO relationship has historically translated into more of an order-fulfillment / client-vendor relationship than anything that could have been called remotely collaborative. An emerging trend, though, is being guided by innovative sponsors looking to change that dance into one that creates more symbiotic partnerships. Several industry sponsors have put a significant focus over the last few years in building out Sponsor / Site level relationships as a key factor to performance improvement and now are realizing the same gains can be achieved with focus on relationships at the Sponsor / CRO level. there is no doubt that the relationship landscape is changing in a way that will only be beneficial to the industry.

Topics to be discussed:

- Best practices for aligning critical performance and operational data between sponsor/CRO
- An overview of realized performance gains through partnership
- Practical examples of alliance building through all stages of the relationship
- The performance impact of a shared decision making platform

12:05 pm Leveraging Big Data for Trial Optimization: Myth or Magic?

Sponsored by ta-Scan

David Cocker, Senior Consultant, ta-Scan, MDC Partners

"Nobody wants 'data.' What we need are answers." Big data is an ill-defined term for a massive phenomenon that has created new expectations in science, government and the pharmaceutical industry. Today we are told of cutting-edge initiatives that disentangle the digital exhaust of thousands of trials, lab tests and healthcare records. While this big data hype sounds compelling, clinical teams now face the challenge to incorporate new knowledge discovery tools within traditional Trial Planning and Site Selection processes. This presentation will shortlist the essential characteristics of actionable data and put in perspective the potential surrounding exploitable public data for decision support.

12:20 Sponsored Presentation *(Opportunity Available)*

12:35 BRIDGING LUNCHEON PRESENTATION:

Sponsored by DrugDev do more trials

Optimizing Protocol Planning, Feasibility, and Site Selection through an Integrated View of Clinical Trial Operations and Other Data Sources

Elisa Cascade, President, Data Solutions, DrugDev

As the amount of available data for the support of clin ops continues to expand, organizations are challenged with the task of integrating these disparate data sources into actionable information. One novel solution to this challenge is DrugDev'sSiteCloud, a platform that offers global users an integrated view of clinical trial operations, clinicaltrials.gov, investigator entered information, and other investigator, site, and protocol level data. In this session, we will discuss available data sources; lessons learned for optimal use of data from CITMS; and a validated technology solution for virtually matching and visualizing this information within and across companies.

1:15 Session Break/Close of Conference

> "Thank you for inviting me to this meeting. I had a great experience with SCOPE and learned a lot from it. I expect to attend more SCOPE meetings in the future."
>
> *Brenda Y., Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer*

Improving Site-Study Activation and Performance

Strategically Implementing a Process for Rapid Study Start-Up

February 25-26, 2015

WEDNESDAY, FEBRUARY 25

About This Conference

Clinical trial site activation and efficient study start up are critical to drug development programs, in terms of time, cost and quality of data. In order to improve start-up times and outcomes, one needs an experienced clinical research investigator, motivated and capable team members and efficient communication by all. Everyone (Sponsor, CRO, Site) must communicate and execute effectively in order to improve: the study feasibility process, contract and budget negotiations, standardization of source documents and other study-related materials, development of patient and staff educational materials, and development of patient recruitment and retention programs. Cambridge Healthtech Institute's *Second Annual* **"Improving Site-Study Activation and Performance"** conference will cover the topics one should consider when strategically implementing a process for rapid study start-up.

OPTIMIZING CLINICAL STUDY PLANNING, PROTOCOL DEVELOPMENT, FEASIBILITY, AND SITE SELECTION

12:35 pm BRIDGING LUNCHEON PRESENTATION: Optimizing Protocol Planning, Feasibility, and Site Selection through an Integrated View of Clinical Trial Operations and Other Data Sources

Sponsored by DrugDev do more trials

Elisa Cascade, President, Data Solutions, DrugDev

As the amount of available data for the support of clinical trial operations continues to expand, organizations are increasingly challenged with the task of integrating these disparate data sources into actionable information. One novel solution to this challenge is DrugDev'sSiteCloud, a platform that offers global users an integrated view of clinical trial operations, clinicaltrials.gov, investigator entered information, and other investigator, site, and protocol level data. In this session, we will discuss available data sources; lessons learned for optimal use of data from Clinical Trial Management Systems (CTMS); and a validated technology solution for virtually matching and visualizing this information within and across companies.

1:25 Chairperson's Remarks

Sponsored by PHARMICA CONSULTING Get Better

Greg Cohee, Partner, Pharmica Consulting

1:30 FEATURED CO-PRESENTATION: Creative Trial Designs – How Technology and Digital Medicine Is Changing it All

Debbie Profit, Ph.D., Director, Corporate Projects, Otsuka Pharmaceuticals Development and Commercialization

Leonard Chuck, M.D., Ph.D., Clinical Investigator, Co-Medical Director, Diablo Clinical Research

Tools and technology are readily available for use in the clinical trial process, from eConsent, to eSource, to digital medicine. How pharma brings these solutions and digital medicine together to improve the clinical trial process and provide data in real time to those who need it, is now at our finger tips. More importantly, what value does this bring to clinical investigators and patients participating in clinical research studies? Diablo Clinical Research and Otsuka have partnered together to revolutionize the clinical trial process by thinking way outside the proverbial pharma R&D box.

2:20 Signal Detection and Evaluation for Drug-Induced Liver Injury during Clinical Phases of Drug Development

Nariman A Nasser, CCRP, Digital Strategist, Patient Recruitment & Retention, Roche

Matt Miller, Associate Director of Marketing, WCCT Global

- Regulatory considerations for AE monitoring/reporting of digital and social networking channels for patient recruitment & retention
- Current state of Sponsor perceptions of social media influence on clinical trial participation
- Patient and site data perspective of social media influence on clinical trial participation
- Effective use of digital and social networking tools of managing content

3:15 Refreshment Break in the Exhibit Hall

OVERCOMING COMMON CHALLENGES IN FEASIBILITY, SITE SELECTION, BUDGETING AND CONTRACTING

4:05 Chairperson's Remarks

Clare Grace, Ph.D., Vice President, Site and Patient Access, INC Research

4:10 TIMI Case Study: Landing a Jumbo Jet: Tools to Help Close Out Large Trials in an Efficient, Orderly and High-Quality Manner

Marc Bonaca, M.D., Cardiologist, Brigham and Women's Hospital; TIMI Study Group

Considering all of the organizations, data points and processes involved, closing out a trial by completing final patient visits and resolving all data queries accurately and on time is a daunting challenge for any study - especially two global cardiovascular megatrials with more than 18,000 and 20,000 subjects respectively. To accomplish this impressive feat, the TIMI Study Group engaged a technology provider to develop a Closeout Tracker application to track and manage an efficient closeout process. Case studies featuring the global megatrials will be presented.

4:35 Using Quality Management Systems to Easily Connect Investigative Sites with Sponsors, CROs, and IRBs

Sponsored by HealthCarePoint Professional Collaborative Networks

Al O. Pacino II, President, HealthCarePoint.com

Collaborative Quality Management Systems enable organizations across the industry to easily be connected and allow credentialing documents, training and verified education records to be shared in real time. This allows Sponsors and CROs to easily qualify investigative sites and streamline site operations and minimize regulatory compliance audit risks.

4:50 CO-PRESENTATION: Will CRO Maturation Create Another Link in the Outsourcing Supply Chain?

Adam Chasse, MHA, COO, RxTrials

Eva Kantanas, Director, R&D Procurement, Janssen (invited)

Increased outsourcing combined with rising pressure on CROs to meet timelines cost-effectively is leading to a "tipping point" that will force CROs to redefine their role in the trial management space, particularly as large pharma gives CROs more autonomy within strategic partnerships. While certain core services will still be firmly within the realm of CROs' internal, CROs will need to consider outsourcing functions that they have not consistently performed well. This creates opportunity for vendors skilled in ancillary areas. It also requires a re-examination of CRO budgets in order to balance lower revenue with increased probability of study success.

5:15 CO-PRESENTATION: SCRS Case Study: Overcoming Hurdles in Study Initiation and Closeout through Collaboration

Christine Pierre, President, The Society for Clinical Research Sites (SCRS)

Dex Bilkic, MBA, Leader, Business Support Group, Boehringer Ingelheim

This presentation will share the commitment and progress The Society for Clinical Research Sites (SCRS) and TransCelerate have made in addressing one of the major areas of study delay – the clinical trials agreement (CTA). You will discover an innovative solution to a major challenge inhibiting study initiation, and learn how the clinical trial landscape is being reshaped by this initiative.

5:40 Reception in the Exhibit Hall

7:00 Close of Day

THURSDAY, FEBRUARY 26

7:30 am BREAKFAST PRESENTATION: What's New in Protocol Feasibility: An Exploration of the Six Key Elements of Data-Driven Feasibility and What Has Changed

Sponsored by QUINTILES

Chris Frega, Senior Director, Head, Global Feasibility & Patient Recruitment, Quintiles

The process for conducting protocol feasibility and developing operational strategies has been evolving along with the need for better and more robust planning for clinical studies. As a result, we must include the latest and most

relevant data and insights in study planning. By using six data elements, trial managers can ensure the right data is utilized: company proprietary, public and commercial, sponsor, investigator perspectives/input, patient perspectives, and country/medical/operational experts.

TRANSFORMING SITE MANAGEMENT TO IMPROVE OUTCOMES

8:15 Chairperson's Remarks

Jackie Kent, Senior Director, Clinical Development Information & Optimization(CDIO) & NGD Trial Execution, Eli Lilly & Co.

8:20 CO-PRESENTATION: Utilization of a Recruitment and Retention Specialist in Multi-Site Clinical Trials: Transforming Site Management to Improve Clinical Trial Success

Susan McMahan, Research Nurse and Lead Coordinator, Office for Clinical and Translational Research, Cincinnati Children's Hospital Medical Center

Stephanie Sullivan, Office for Clinical and Translational Research, Cincinnati Children's Hospital Medical Center

To achieve enrollment success, trial managers must establish a detailed plan to provide long-term, proactive oversight. This includes close monitoring of site performance, protocol adherence, and recruitment and retention progress. This session will provide information about lessons learned in the MILES Trial, CAE Trial and CHAMP Study and how to effectively anticipate, manage and overcome challenges site performance, recruitment and retention of multi-site clinical trials. Areas to be discussed include planning (funding and written site management plans), education, methods, and monitoring.

8:45 Optimizing Site, CRO, and Sponsor Interactions to Improve Outcomes

Carol Seider, Senior Director, Global Clinical Operations, Clinical Country Management, Biogen Idec

When utilizing a CRO, that CRO represents the sponsor company. How do you optimize up-front planning and processes in order to get the best outcome for all interactions with a site concentrating on a customer-focused approach? This talk will share some common pitfalls and success stories for those interactions and how to provide a path directly to the sponsor company when applicable.

Sponsored by Appian

9:10 Data & Process in Clinical Trial Study Start-up: The Importance of Awareness, Knowledge AND Action

Michael Robbins, Global Head & Associate Director, Clinical BPM, Sanofi

The range of approaches to handling the ever changing world of clinical study start up continues to plague organizations. In particular, many solutions focus on a data-centric approach with some process and other focus on process-centric approaches with a little bit of data. At Sanofi, we have found that the both data and process need to be viewed as first class citizens. We have begun to move away from an application view of the world, to a topic centric approach. In this model, we focus on the way people want to work - Awareness, Knowledge and Action.

9:35 POINT-COUNTER POINT PANEL: Preparing CRAs to be Site Recruitment Managers: The Pros, the Cons and The Process

Beth Harper, President, Consultant, CPP, Inc.

Nikki Christison, Clinical Resolutions, Inc.

Gretchen Goller, Senior Director, Therapeutic Expertise, PRA International

CRAs as site recruitment managers? Absolutely say some. CRAs are key site liaisons and in best position to support site recruitment and retention performance. Others claim this should not be the focus of CRAs whose job is to monitor and ensure protocol and GCP compliance. They claim that CRAs neither have the time nor the skill set to finesse recruitment planning and management discussions with the site. This moderated Point-Counter Point panel discussion will highlight the pros and cons of the role of the CRA as site recruitment manager and discuss process and implementation considerations for setting CRAs to be successful Site Recruitment Managers.

- Insights into how the industry views the role of the CRA as a Site Recruitment Manager
- Considerations for preparing CRAs to play this role
- An understanding of the need to invest in some type of site recruitment oversight to ensure successful delivery of enrollment goals

10:00 Coffee Break in the Exhibit Hall

10:40 Closing Plenary Keynote

PLENARY KEYNOTES AND PANEL: APPLYING INNOVATIVE TECHNOLOGY TO ENABLE CLINICAL RESEARCH

10:40 Organizer's Welcome

10:45 Clinical Informatics News Best Practices Awards

11:00 Chairperson's Opening Remarks: Digital Tools Making an Impact on Clinical Research

Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer

11:25 Cross-Pharma Collaboration in Clinical IT

Francis Kendall, GLIDE Future Investigation Team Lead & Global Head, Genentech

11:50 Using Predictive Analytics to Drive Site Health and Quality

John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

12:15 Healthcare Reform, the Connected Patient, Mobile Tech and Innovation: Health Care Reform and What It Means Beyond the Pill

Gregory Opiteck, Ph.D., Senior Principal Scientist, Clinical Pharmacogenetics, Merck & Co., Inc

12:40 PANEL: Mobile Tech, Realworld Data and Innovative Platforms to Enable Trial Operations and Research

Moderator: Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer

Panelists: Francis Kendall, GLIDE Future Investigation Team Lead & Global Head, Genentech

Munther Baara, Senior Director, Development Business Technology, Pfizer

Gregory Opiteck, Ph.D., Senior Principal Scientist, Clinical Pharmacogenetics, Merck & Co., Inc

1:10 Closing Remarks

1:15 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016!)

Hotel & Travel Information

Conference Venue and Hotel:

Hyatt Regency Orlando
9801 International Drive
Orlando, FL 32819
T: 407 284-1234

Reservations: Go to the travel page of **www.scopesummit.com**

Discounted Room Rate: **$239 s/d**
Discounted Cut-off Date: **January 23, 2015**

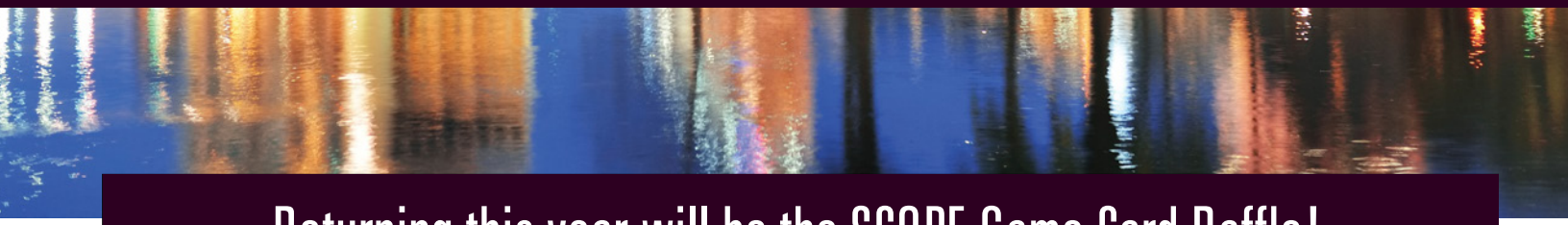
Why Stay at the Hyatt Regency Orlando?

The Hyatt Regency Orlando offers guests the very best of both worlds from business travel to tourism. Located on I-Drive in the Convention District, it is an upscale vacation resort with an unrivaled radius to top attractions for corporate travel or theme park adventures. Top scale, yet family (and pet) friendly, the Hyatt has mixing business with pleasure down to a "T".

After conference sessions, our attendees may enjoy

- Complimentary internet in their guest room
- Three different swimming pools, with waterfalls and a water slide
- 24 hour state of the art fitness center and spa
- First rate onsite restaurants, including upscale, pool dining, family friendly and grab-and-go options.

Go to the travel page of **www.scopesummit.com** for additional info



Returning this year will be the SCOPE Game Card Raffle!

Be sure to play for a chance to win:

iPad® mini

Bose® QC®15 Headphones

Kindle Fire

Thank You to Our Current Sponsors! *(Sponsorship Opportunities Available)*

BIOCLINICA · Clinical ink · CPI GLOBAL CRO · EXOSTAR · OPTUM · ORACLE HEALTH SCIENCES · PRAHEALTHSCIENCES · QUINTILES

** Please note: all prizes are given away on behalf of CHI. Apple®, Amazon, and Bose® are not sponsors of this event or raffle.*

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

February 24 - 26, 2015
Hyatt Regency Orlando
Orlando, FL

Register Early and SAVE!

Pricing and Registration Information

CONFERENCE PACKAGE PRICING

BEST VALUE! - Includes access to the entire 3-day SCOPE program

	Commercial	Academic, Government, Hospital-affiliated	Student
Registration after January 23, 2015, and on-site	$2799	$1199	$599

Tuesday-Wednesday, February 24-25	Wednesday-Thursday, February 25-26
C1A Global Site Selection, Feasibility Assessment, Operations and Site Mgmt	C1B Improving Site-Study Activation and Performance
C2A Enrollment Planning and Patient Recruitment	C2B Patient Engagement, Enrollment and Retention through Communities and Tech
C3A Clinical Trial Forecasting and Budgeting	C3B Clinical Trial Project Management for Outsourced Clinical Trials
C4A From QbD and Risk Assessment to Risk-Based Monitoring	C4B Implementing Risk-Based Monitoring
C5A Electronic Data in Clinical Trials	C5B Integrating and Leveraging Clinical Trial Operations Data
C6A Managing Late Stage Research, Observational Studies and Registries	C6B Pharmacovigilance and Adverse Event Reporting

Standard Registration - Includes access to ONE conference

	Commercial	Academic, Government, Hospital-affiliated	Student
Registration after January 23, 2015, and on-site	$1849	$999	$399

CONFERENCE DISCOUNTS

Alumni Discount - SAVE 20%: CHI appreciates your past participation at Summit for Clinical Ops Executives (SCOPE). As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

Alumni Discount*	20% Off	20% Off
SAFE BioPharma Association membership discount*	10% Off	10% Off

***Register 3 and 4th is Free Discount, Alumni, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined.**
Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact Melissa Dolen at +1-781-972-5418

If you are unable to attend but would like to purchase the SCOPE Summit CD for $750 (plus shipping), please visit SCOPEsummit.com. Massachusetts delivery will include sales tax.

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

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

How to Register: SCOPEsummit.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **SSG** when registering!

Please refer to the Registration Code below:

Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
www.healthtech.com • Fax: 781-972-5425