Sixth Annual  February 24 - 26, 2015  | Hyatt Regency Orlando, Orlando, FL

SUMMIT FOR CLINICAL OPS EXECUTIVES

February 24-25
Global Site Selection, Feasibility Assessment, Operations and Site Management
Enrollment Planning and Patient Recruitment
Clinical Trial Forecasting and Budgeting
From QbD and Risk Assessment to Risk-Based Monitoring NEW
Electronic Data in Clinical Trials
Managing Late Stage Research, Observational Studies and Registries

February 25-26
Improving Site-Study Activation and Performance
Patient Engagement, Enrollment and Retention through Communities and Tech
Clinical Trial Project Management for Outsourced Clinical Trials NEW
Implementing Risk-Based Monitoring NEW
Integrating and Leveraging Clinical Trial Operations Data
Pharmacovigilance and Adverse Event Reporting NEW

Keynotes
Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.
Ibrahim “Ibs” Mahmood, President and CEO, DrugDev
Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer
John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

Event Features
- 12 Conferences
- 3 Plenary Keynote Sessions
- 4 New Conferences
- 700+ Industry Leaders Expected in 2015
- Clinical Informatics News’ Best Practices Awards
- Dedicated Exhibit Hall Hours & Networking Functions
- Interactive Breakout Discussions

Register by December 5 and SAVE up to $400!

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### Conference-at-a-Glance

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### Stay Connected

Join the Clinical Trials Ops Executives group [LinkedIn](https://www.linkedin.com), [Twitter](https://twitter.com), [YouTube](https://www.youtube.com) @SCOPEsummit

### CHI's INTRONET

Networking at its Best

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 that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event.
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**Ilana Quigley**
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**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.:
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- Whitepapers
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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
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- Product/service description (30 words) in a press release announcing product launches at the event

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

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SCOPE Summit for Clinical Ops Executives | 5
Plenary Keynotes & Panel

**TUESDAY, FEBRUARY 24**

**THE INVESTIGATOR’S VOICE AND PATIENT-CENTERED TRIALS**

8:25 am Organizer’s Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

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, Genzyme Corp., a Sanofi Co.

What is the true current “State of the Union” in our industry and in clinical trials today? Have we over-engineered a process into such complexity that it is doomed to failure and inefficiency? Have we leveraged the technologies available to better develop new medicines and manage trials? How do we re-build credibility in our data and our conduct as an industry?

8:40 The Evolution and Implementation of Patient-Centered Trials
Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, Eli Lilly and Company

Applying patient-centered healthcare delivery principles to the clinical trial space leads to better outcomes, both for the patient and for the trial. We need to apply lessons learned on the commercial side in the clinical trial world — starting with patient recruitment, to improve the design, timeline and outcomes of our trials. One of the realities in the clinical trial space is the majority of patients and investigators who participate in a study do so only once. How can we become more patient and investigator friendly in an ever increasingly competitive environment?

9:05 TRIAL INVESTIGATOR PANEL: Improve Protocol Feasibility, Trial Conduct and Operations by Learning from a Key Partner in Research

The sharp rise in ongoing clinical research studies with over 5000 medicines currently in development globally, is driving demand for greater participation in research by physicians as well as by patients. However, global investigator turnover rates are high, with 35-55% of investigators not returning to conduct another clinical trial after their first experience. These turnover rates contribute to high site selection, qualification and start-up costs. Come to hear what doctors have to say about the realities of conducting clinical trials today, and what they see as the potential solutions to the current challenges they face. The global community of clinical trial investigators is a common and highly valued resource upon which the pharmaceutical industry relies. Supporting investigators, and helping to optimize how they partner with industry, is a key part of the story of how we continue to develop new therapies for the patients who need them. In the session, the panel of doctors will address the following questions:

- What makes participating in clinical research difficult for investigators and what can pharma and CROs do to overcome this?
- What are some of the barriers for investigators when working with pharma or CROs and how can relationships be improved?
- What innovations can doctors and pharma/CROs collaborate on to improve clinical trial conduct?
- How can both doctors and industry help support the investigators of tomorrow?
- How can we support the group of ‘1 and done’ investigators who don’t return for a 2nd clinical trial?

Moderator: Claire Sears, Ph.D., Director, Investigator Engagement, DrugDev
Panelists: Investigator Panelists

9:45 - 10:45 Grand Opening Coffee Break in the Exhibit Hall

**WEDNESDAY, FEBRUARY 25**

**EMBRACING OPEN INNOVATION AND COLLABORATION**

8:25 Organizer’s Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:30 Plenary Keynote Chairperson’s Opening Remarks: Open Innovation as a Solution to Clinical Research Bottlenecks
Ibraheem “Ibs” Mahmood, President and CEO, DrugDev

Industry experts have long been proselytizing the need for dramatic change in the drug development process to bring down the cost of development and increase the speed of bringing new drugs to the patients who need them. So why is it taking so long to bring about change in an industry that so desperately needs it? What new developments or technology are there to accomplish the goal of faster and cheaper trials?

8:40 Case Study: Otsuka’s Approach to Trial Planning and Execution
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.

Otsuka Pharma Development is able to conduct a large number of clinical trials while maintaining a relatively small footprint. In order to provide appropriate oversight Otsuka has developed several operational methodologies. These operational practices help ensure outsourced trials maintain high levels of safety, quality, and compliance. This session will cover an overview of these operational methods.

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: Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, Eli Lilly and Company; TransCelerate Operations Committee Member
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.
Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.
John Oidtman, Vice President, Clinical Trial Support and Compliance & IIV Clinical Operations, Pfizer

This panel will be a provocative discussion featuring panelists from leading biopharmaceutical companies, the Investigator Databank and TransCelerate who have been improving efficiency and advancing innovation in research and development through open collaboration. Key discussion points:

- Why is it taking so long to bring about change in an industry that so desperately needs it?
- What new developments or technologies are there to accomplish the goal of faster and cheaper trials?
- What are the opportunities and potential risks of publishing clinical trial reports and increasing access to data?
- How do you foresee the increasing use of EHRs effecting innovative change in the industry?
- What are your thoughts on the best model for cross-industry collaboration? Are there any examples we can learn from where things haven’t worked?

9:45 - 10:40 Coffee Break in the Exhibit Hall

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Plenary Keynotes & Panel

THURSDAY, FEBRUARY 26

APPLYING INNOVATIVE TECHNOLOGY TO ENABLE CLINICAL RESEARCH

10:40 Organizer’s Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

10:45 Clinical Informatics News Best Practices Awards
Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News

11:00 Plenary Keynote Chairperson’s Opening Remarks: Digital Tools Making an Impact on Clinical Research
Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer

Digital tools including mobile, social media, and leveraging diverse data sets are making an impact on clinical research today, from supporting site selection to patient recruitment and retention to more efficient data capture. Looking ahead, the evolution of these tools brings the potential to radically transform clinical development through deep phenotyping of patients and roles for digital tools as diagnostics or co-therapies. What organizations are best positioned to leverage these new opportunities?

11:15 Cross-Pharma Collaboration in Clinical IT
Francis Kendall, GLIDE Future Investigation Team Lead & Global Head, Genentech

This talk will discuss collaboration between several pharma companies with the prime objective of devising solutions to the challenges that we face as an industry. This cross-pharma consortium focused discussions on technology, standards and data with a view to creating a common framework for how we process data especially in the changing data landscape. Key focus areas included: Transition to CDSIC, Data Aggregation (including broad categories of data - Clinical Trial data, Payer databases, Registry data, Electronic Medical Records Genome data, Biomarker data and Legacy data), key technologies related to data warehousing/data reporting, validation of data analysis tools and open source approaches.

11:30 Using Predictive Analytics to Drive Site Health and Quality
John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

In Clinical Research we are often finding errors that have occurred in the past. This “find and fix” mentality has shaped many processes that we rely on to oversee an investigative site. Pfizer has implemented a methodology that provides a more proactive and predictive approach to site quality. This presentation will provide an overview of the implementation of a predictive analytics methodology that drives site health.

11:55 CO-PRESENTATION: Healthcare Reform, the Connected Patient, Mobile Tech and Innovation

Part 1: Health Care Reform and What It Means Beyond the Pill
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

Health care reform in the US brought population health management and value-based payment models to the forefront. How is this shift impacting the life science industry to innovate beyond the pill?

Part 2: Open Data Initiatives and the Convergence of Healthcare and Pharma
Aman Bhandari, Director, Health IT & Data Partnerships, Business Development, and Strategy, Merck & Co.

12:30 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
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

An exciting universe of new tools and platforms are becoming available for the clinical trial professional. From leveraging data both old and new, to cutting edge digital tools, what barriers must we overcome to fully appreciating an impact on our development programs?

- How can organizations position themselves to generate impact and value in using new tools and platforms?
- What is our ideal future state for clinical research, and what barriers must we overcome to get there?
- What new tools can conference attendees begin to leverage immediately?

1:05 Closing Remarks

1:10 SCOPE 2015 Conference Adjourns (See you in Miami for 2016!)

Clinical Informatics News is seeking submissions to its Second Annual Clinical Informatics News Best Practices Awards. This awards program seeks to recognize outstanding examples of applied strategic innovation—partnerships, deployments, and collaborations that manifestly improve the clinical trial process.

Deadline for Entry: December 12, 2014
(If received by November 14, 2014, there is no application fee)

For additional details and to apply online visit: SCOPEsummit.com

We encourage all SCOPE Exhibitors and Sponsors to participate!

Register at the BEST VALUE rate and receive access to the entire SCOPE event and all Keynotes
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

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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

10:50 Global Trial Placement Strategies; Linking Early Research with Phase III Execution
John Oldtman, 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.

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 Presentation to be Announced

12:35 LUNCHEON PRESENTATION
Speaker to be Announced

1:15 Session Break

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

1:25 Chairperson’s Remarks
Bonnie Brescia, Founding Principal, 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-scenes 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
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 Talk Title to be Announced
Bill Gwinn, MBA, Vice President, Clinical Informatics Solutions, Optum

HALL BREAK AND BREAKOUT DISCUSSION GROUPS

3:00 Refreshment Break in the Exhibit Hall

4:00 Find Your Table and Meet Your Moderator
8:25 am B
Y
EDNESDAY, FEBRUARY 25

7:30 am BREAKFAST PRESENTATION: Evaluating the ROI of Outsourcing Investigator Payments
Stuart (Stu) Thiede, President, Global Payment Services, CFS Clinical, Part of DrugDev
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

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John Oldman, 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 Yao, 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 Executing Global Site Selection in an Adaptive Recruitment Environment
Bonnie Brescia, Founding Principal, BBK Worldwide

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: Pfizer, Shire, PPD
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?
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 "big data," but a simple query of the past, "big data?" elicits "why?" While the term "big data" has high visibility and high hype, the value proposition can be less obvious. Effective implementation of big data requires a clear understanding of the goals of the initiative and the value of the data. 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: Optimizing Protocol Planning, Feasibility, and Site Selection through an Integrated View of Clinical Trial Operations and Other Data Sources
Elisa Cascade, President, Hosted Data Solutions, DrugDev.org
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’s SiteCloud, 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
This EHR-driven approach brings a new level of precision to site identification and recruit eligible patients and to identify potential sites for a late stage clinical trial. An example of using an eResearch network enabled by EHR technologies to identify recruitment and simulation of a virtual placebo arm. We will share a successful research. At AstraZeneca, we have been doing a serial of projects to test and extend your development timeline by a number of years. Retention of patients throughout the life of a clinical trial is essential in order have complete data sets for your analysis and subsequent filings. In order to optimize both you have to have a plan. Cambridge Healthtech Institute’s Eighth Annual “Enrollment Planning and Patient Recruitment” conference will cover the topics one should consider when drafting and strategically implementing a patient recruitment plan for a clinical development program.

9:05 The Evolution and Implementation of Patient-Centered Trials
Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, 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

EVALUATING TRADITIONAL AND NEW OUTREACH STRATEGIES TO CHOOSE A PATH FORWARD

10:45 Chairperson’s Remarks
Tim McGarty, Global Director, Clinical Innovative Services, Development Strategic Sourcing, Novartis

11:00 Leveraging Patient Database: How to Improve Recruitment in Oncology Trials
Sarah Quinlan, Director of Clinical Research, Miltenyi Biotec

11:15 A New Era of Clinical Research Enabled by Electronic Health Records
Hui Cao, M.D., Ph.D., Head, Health Informatics, AstraZeneca

The wide adoption of electronic health records has led to a new era of clinical research. At AstraZeneca, we have been doing a serial of projects to test and evaluate the use of EHR in clinical trial feasibility, patient identification, patient recruitment and simulation of a virtual placebo arm. We will share a successful example of using an eResearch network enabled by EHR technologies to identify and recruit eligible patients and to identify potential sites for a late stage clinical trial. This EHR-driven approach brings a new level of precision to site identification and patient recruitment processes.

11:40 Group Recruitment as a Strategy to Improve Enrollment and Retention
Steve Kepes, Administrative Director, Center for Research and Innovation, CoxHealth

This session will introduce the concept of group recruitment as a strategy to improve the integration of clinical research into clinical care, improve the informed consent process, and increase patient awareness and engagement. These benefits make it an advantageous approach over traditional processes, for organizations seeking to improve enrollment and retention rates. At the conclusion of this presentation, attendees will be able to recognize how the group recruitment strategy addresses common challenges impacting patient recruitment and retention, describe the 4 phases of the group recruitment process; feasibility, planning, execution, and assessment; and employ the group recruitment strategy for a given clinical trial.

12:05 pm Presentation to be Announced
Payer data, and payers' ability to analyze it, are uniquely powerful and extensive means to
determine suitability for clinical trials. Combined with a payer's ability to touch its membership
directly, these capabilities make for an unparalleled central recruiting approach. Healthagen/Aetna have refined our approach so that clinical trial collaborations are valuable to the member, the physician, the trial sponsor, and the healthcare field at large. This presentation will offer a greater understanding of the broad value of centralized recruiting efforts and engagement strategies as well as a detailed look at how one payer, Aetna, views this as a service to its patients and providers.

2:45 Presentation to be Announced

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
5:15 Close of Day

WEDNESDAY, FEBRUARY 25

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee
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 Case Study: Otsuka's Approach to Trial Planning and Execution
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.
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: Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, Eli Lilly and Company; TransCelerate Operations Committee Member
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.
Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.
John Otdman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer
9:45 Coffee Break in the Exhibit Hall

10:45 Chairperson's Remarks
Van Crocker, President, Healthagen Outcomes, Healthagen/Aetna
10:50 Practical Lessons in Operationalizing Social Media & Social Listening in Clinical Trials
Therese Johnsen, Manager, Clinical Trial Intelligence, Novartis
The Clinical Trial Intelligence team is using social scraping to gain insights for clinical trials in rare disorders: Analytical Tools can be used to identify influencers, geographic distribution, language and key areas of concern for patients and caregivers as well as trends in the media. These insights can then inform your social media campaign. This presentation will share real life experience using SM analytical tools such as Sysomos and GenPac as well as lessons learned in setting up a social listening initiative and social media campaign.

11:15 Discovering the Potential of Online Advertising for Rare Diseases: A Case Study Revealing the Outcome of an Online Outreach Campaign Across 3 Rare Disease Programs
Elizabeth Mascherino, Associate Director, Patient Recruitment and Engagement, Clinical Programs Support, Shire
Diane Montross, Associate Director, Patient Recruitment and Engagement, Clinical Programs Support, Shire
Patient Recruitment for Rare Diseases is inherently challenging due to the already small pool of patients we seek to recruit. There is much speculation about the potential of "digitally-sourced" patients, but is there merit in this tactic? This case study will present the results of an Online Outreach Campaign for 3 Rare Disease Populations. We'll explore the rationale, methods and how the results stack up against other more traditional means of recruiting rare disease patients.

11:40 How Listening to the Voice of the Patient Can Increase Enrollment
Taisa (Taya) Skubiak, MBA, Associate Director, Global Recruitment & Analytics, Bristol-Myers Squibb
The “design it and patients will enroll” approach to clinical trials rarely works in this age of complex studies that are often conducted niche populations or rare diseases. Much more effort needs to go into learning about the patients you want to recruit in order to understand what motivates them to enter and stay on treatment. Several strategies of how to listen to the patient will be discussed, including partnerships with advocacy groups and a unique concept called the Voice of the Patient event.

12:05 pm Enrollment is Open, But We Have No Drug! Making Lemons into Lemonade
Barry Simms, MBA, Senior Executive Director, Clinical Operations, Chiltern
When a Sponsor announced during the investigator meeting that there was no drug available to begin enrollment as planned the next day, the study could have been completely lost. But by taking advantage of added time, previously unplanned efforts toward motivating site staff and preparing them for enrollment allowed the study team to build significant momentum and excitement. Through active efforts by CRAs, provision of new tools to aid in patient recruitment, pre-screening and pre-scheduling visits, and frequent transparent communication, enrollment was completed in a tenth of the planned time despite a 12 week delay to start. This compelling case study demonstrates how active techniques toward planning recruitment, even in the worst of circumstances, can save a study from catastrophe.

12:35 BRIDGING LUNCHEON PRESENTATION: The Impact of Online Communities and Mobile Communication on Recruitment and Retention
Melynda Geurts, Vice President, Operations, DAC Patient Recruitment Services
Dennis Upah, Executive Vice President, Enterprise Markets, Remedy Health Media
Pharmaceutical companies and their recruitment agencies can successfully recruit and retain highly specialized patient populations via outreach to key patient communities, and retain them via proven multi-media technology. We'll showcase studies showing where the most active patients can be found online, as well as the latest research showing the power of patient-led emotional storytelling in persuading other patients to take action. We'll also discuss a wide variety of ways to engage existing communities.

1:15 Session Break/Close of Conference
Clinical Trial Forecasting and Budgeting
Creating Realistic Budgets and Minimizing Financial Risk

TUESDAY, FEBRUARY 24

About This Conference
With the rise in clinical trial costs and industry pressure towards greater efficiency, the need for accurate trial forecasting and budgeting is vital. Better financial planning, budgeting, and communication can reduce the burden of cost and resource pressures leading to more efficient trials. Cambridge Healthtech Institute’s Fifth Annual “Clinical Trial Forecasting and Budgeting” conference shares best practices and case studies on methods and tools to creating realistic budgets and minimizing financial risks.

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, Genzyme Corp., a Sanofi Co.
8:40 The Evolution and Implementation of Patient-Centered Trials
Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, 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

ENSURING ACCURATE TRIAL BUDGETING AND FORECASTING

10:45 Chairperson’s Remarks
10:50 The Application of Financial Engineering Principles to Improve the Fidelity and Accuracy of Clinical Trial Forecasting and Budgeting
Kailash Swarna, Senior Director, Global Development Operations, Takeda Pharmaceuticals
Even today, Clinical Trial Forecasting and Budgeting remains more an art than a science. Constrained budgets combined with the need to make every dollar count, have made it necessary to improve our capabilities in trial forecasting and budgeting. We describe a novel approach based on the application of financial engineering principles and portfolio theory to significantly improve the fidelity and accuracy of trial forecasting, trial budgeting, cost hedging, and alternative opportunity assessment.

11:15 Financial Accruals: What It Is, Why It’s Essential for Accurate Budgeting, and How to Do It
Chris Chan, Senior Director, R&D Finance, Finance, FibroGen, Inc.
Financial accruals is a challenging task for biopharmaceuticals of all sizes. It is essential for all clinical operations personnel to understand the underlying concepts of what it is, why it’s so important, why the endeavor is so challenging, and how to enhance and simplify the process in their respective companies.

11:40 Simplifying Accruals for Clinical Trials: Bayer Case Study
Piet Theisohn, Director, Resource Management & Business Support, Global Clinical Development, Bayer Healthcare Pharmaceuticals
The clinical trials industry is special compared with other industries. We are ‘assembling’ relatively unique products (i.e. clinical study reports) by working with diverse, globally distributed suppliers (i.e. clinical sites). Global accounting standards require sponsors to report “service rendered” as R&D expenses, when the actual invoices from sites tend to come late and the contracts with service providers (e.g. CROs) are high-volume but with tricky payment milestones and depending on study progress. Bayer is implementing a simplified approach to help the clinical organization to plan and apply financial accruals more efficiently.

12:05 pm Sponsored Presentation (Opportunity Available)
12:35 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own
1:15 Session Break
1:25 Chairperson’s Remarks
Chris Chan, Senior Director, R&D Finance, Finance, FibroGen, Inc.

1:30 Clinical Trial Financial Planning in a Dynamic Portfolio
Daniel Matarazzo, Head of Finance, Clinical Development & Regulatory Affairs, Regeneron Pharmaceuticals
Creating realistic operating budgets is a challenge for all companies; Financial budgets in drug development are particularly complex and need to provide Project teams with clarity as well as mirroring the timelines and complexity in an environment which protects patients while preserving data quality and delivering outcomes. This, coupled with increasingly stringent financial regulations can wreck havoc on financial planning and operational execution. Discussion will focus in experience in a growing biotech as well as aspects of portfolio management and collaboration dynamics.

NOVEL METHODS TO MINIMIZING STUDY COSTS
1:55 Optimize Protocol Design: A Path to Efficient, Lower Cost Trial Execution
Marina Malikova, Ph.D., Executive Director, Surgical Translational Research: Operations and Compliance, Surgery, Boston University Medical Center
This presentation will explore the challenges clinical teams face in developing protocols to ensure that the right patients are enrolled and that the right data are collected to demonstrate a drug is safe and efficacious, while at the same time managing study costs and study complexity. The ability to develop comprehensive budgets and ensure billing compliance for clinical trials is challenging for many clinical sites. Poor financial planning/forecasting and undefined billing compliance practices are associated with increased risk leading to deficits and OIG investigations. Strategies for covering true costs related to protocol design will be discussed.

2:20 Mitigating and Managing Cost Variables in Clinical Trial Budgeting
Speaker to be Announced
2:45 Sponsored Presentation (Opportunity Available)

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, yet 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
the communication can reduce the burden that change orders place on project teams. ARs. The time has come for a closer look at how better planning, budgeting and as well as the budget, can lead to tremendous discord between sponsor and CRO/ regarding the impact of the requested change, to the operation of the project as Change Orders are an inevitability during a clinical trial. Lack of communication

John Hogan, Director, Project Management, Harvard Clinical Research Institute

10:45 Chairperson’s Remarks

10:50 Changing the Change Order Paradigm
John Hogan, Director, Project Management, Harvard Clinical Research Institute

Change Orders are an inevitability during a clinical trial. Lack of communication regarding the impact of the requested change, to the operation of the project as well as the budget, can lead to tremendous discord between sponsor and CRO/ ARO. The time has come for a closer look at how better planning, budgeting and communication can reduce the burden that change orders place on project teams.

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 Case Study: Otsuka’s Approach to Trial Planning and Execution
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.

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: Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, Eli Lilly and Company; TransCelerate Operations Committee Member
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Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.
John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

9:45 Coffee Break in the Exhibit Hall

MANAGING BUDGET ISSUES ACROSS PROJECT TEAMS

11:15 Talk Title to be Announced
Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer

11:40 PANEL DISCUSSION: Mastering Budget Negotiations and Achieving Cost Savings
Moderator to be Announced
Stalled contract negotiation can result in significant delays in the clinical trial process. Mastering negotiations from site to sponsor and site to CRO can lead to cost reduction and more efficient clinical trials.

Topics discussed in this session Include:
- Effective CRO management to achieve substantial cost performance
- Optimizing CRO/outside vendor budget negotiation and cost reduction

12:05 pm Sponsored Presentation (Opportunity Available)

12:35 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:15 Session Break/Close of Conference

Thanks to you and your team for planning a well thought-out program. I appreciate all of your coordination efforts to make sure that the participants left with a better understanding of the various aspects of the Sunshine law. I have attended a number of conferences, and I think that yours is really successful due to the interactive and open nature of the sessions. It was fun participating as both a faculty member and student of the aggregate-spend/Sunshine track, and I look forward to again joining you all next year.

Juliet M., Associate, King & Spalding LLP
Laying the Foundation

From QbD and Risk Assessment to Risk-Based Monitoring

TUESDAY, FEBRUARY 24

About This Conference

Building quality and risk management into the design and planning of clinical trials leads to earlier detection and resolution of issues and higher overall quality of clinical trials. Proactively applying Quality by Design (QbD) principles into clinical trials improves trial efficiency and ensures data quality. Cambridge Healthtech Institute’s "Inaugural From QbD and Risk Assessment to Risk-Based Monitoring" conference provides guidance on how to proactively build quality standards into clinical trial conduct with emphasis on identifying appropriate key risk indicators and critical-to-quality metrics, thereby laying the foundation for successful risk-based monitoring.

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, Genzyme Corp., a Sanofi Co.

8:40 The Evolution and Implementation of Patient-Centered Trials

Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, 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

CASE STUDIES ON PROACTIVE QUALITY RISK MANAGEMENT

10:45 Chairperson’s Remarks

10:50 Quality by Design and Proactive Quality Risk Management: Planning for High-Quality Clinical Trials

David Nickerson, Senior Director, Clinical Quality Management, Pfizer

Historical approaches to quality management in clinical trials have been heavily reliant on review of documentation at sites and retrospective audits/inspections. While these techniques will undoubtedly continue to play an important role in the oversight of quality in clinical trials in the future, it has been recognized that more proactive approaches that target the prevention of quality-related issues before they occur must be a priority. This presentation will outline an approach that Pfizer has implemented with the objective to build quality into clinical trials from the beginning and to prevent issues from occurring during study conduct which may undermine trial quality.

11:15 Risk-Based Quality and Compliance Management in Clinical Trials with Combination Products

Marina Malikova, Ph.D., Executive Director, Surgical Translational Research: Operations and Compliance, Surgery, Boston University Medical Center

A risk-based approach requires not only a strategy but tools to define key indicators to measure specific risks. As reference from the recent FDA and EMA guidelines, Key Risk Indicators (KRI) and Critical to Quality (CTQ) metrics should focus on “what really matters” and safety of research subjects and data integrity should be emphasized. Combination products, due to their specific nature, can increase risks while being tested in clinical trials. These critical metrics should be linked to particular processes within development program for combination products.

11:40 QbD and Risk Management: How One Company Is Designing and Implementing a Solution

Brian Nugent, Associate Director, Clinical Operations & Process, Gilead Sciences

During this presentation we will look at a quality framework and how risk management and QbD fit within the design, specific aspects covered will be: 1. An example of a Quality Framework as well as sub-frameworks that address risk management and quality control 2. How the QbD system was designed including initial build and ongoing maintenance 3. Review of implementation challenges and solutions 4. The role of risk management training as a foundational element of risk management 5. Example of risk tools designed to communicate down acceptable risk tolerances and communicate up residual risk status.

12:05 pm Sponsored Presentation (Opportunity Available)

12:35 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:15 Session Break

BUILDING QUALITY INTO CLINICAL TRIALS & MONITORING

1:25 Chairperson’s Remarks

1:30 QbD Requires Standards and Sharing of Best Practices: The Role and Contribution of ACRES

Beat Widler, Ph.D., Managing Partner, Widler & Schiemann Ltd.

QbD as well as quality risk management and risk-based monitoring require eliminating uncertainties about participants or contributors to a clinical trial. This means, the goal of any sponsor – be this an academic, commercial or even a patient group that is a sponsor – must be to acquire confidence that stakeholders involved have reliable processes and are able to consistently deliver quality, i.e., ensuring patients’ safety, integrity and rights as well as data integrity. ACRES brings the shared platform to the table that is an essential enabler of QbD!

1:55 Quality by Design: A Merck Case Study

MyLe Hoang, Director, Clinical Quality and Process Management, Merck

The audience will hear about Merck’s quality management model. I will be sharing our tools and steps toward implementing quality risk management within our trials and processes.

2:20 PANEL DISCUSSION: Identifying Risk When Doing Risk-Based Monitoring

Moderator: Michael Howley, Ph.D., Associate Clinical Professor, College of Business, Drexel University

Risk is an increasingly important concept for the clinical trials industry, especially as applied to risk-based monitoring. Indeed, all of clinical trial oversight depends on the ability to locating the risks within a clinical trial. In this session, I will show managers how they can identify risks with clinical trials using performance measures and apply these techniques to improve their oversight of clinical trials.

2:45 Sponsored Presentation (Opportunity Available)

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, yet 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
The objective of this session is to provide participants with the key people, process, and technology considerations when implementing Risk-Based Monitoring within their organization. Key learnings and real experiences will be shared to highlight challenges and successes with a focus on the critical role organizational culture plays in successful implementation.

12:05 pm Sponsored Presentation  (Opportunity Available)
7:30 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes

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

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Moderator: Claire Sears, Ph.D., Director, Investigator Engagement, DrugDev Panelists: Investigator Panelists

9:45 Grand Opening Coffee Break in the Exhibit Hall

NEW MEDICAL DATA LANDSCAPE AND CLINICAL RESEARCH

10:45 Chairperson’s Remarks

Kuno van der Post, Senior Vice President, Business Development, OmniComm Systems, Inc.

10:50 Roche Biometrics and the Evolving New Medical Data Landscape: The Plan, Opportunities & Challenges

Francis Kendall, Global Head, Statistical Programming and Analysis, GLIDE Future Investigation Team Lead, Genentech

This talk will look at the challenges and opportunities the new Medical Data Landscape for Pharma brings, and how Roche are setting the foundation with implement a new systems. Roche has explored what was the best approach and systems to implement and is now at the start of it implementation phase. The talk will explain how we got here and what is next...

11:15 What RBM Needs: Breaking Down the System and Functional Silos

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

RBM requires a holistic approach from the whole clinical team from the initial assessment through to risk reporting at the end of the trial. The systems that we use are not conducive to such cross-functional approaches. This presentation describes an integrated approach centred around a web-based tool, that allows the integration of onsite and central monitoring, and also facilitates a directed onsite monitoring strategy based on the regular risk assessment centrally and from the onsite monitor.

11:40 Integrating Big Data in Clinical Databases

Speaker to be Announced, Merck

With all of the large amounts of different electronic data now available, our industry is changing so fast. The challenge is converging all of that data, aggregating it and trying to find meaningful insight into the information, to speed up clinical development and improve patient care.

12:05 pm Designing Innovation: Using eSource to Streamline Clinical Trials

Ed Seguiné, CEO, Clinical Ink

The rising cost and complexity of clinical trials requires a willingness to do new things – often with the help of novel technology. This presentation will explore how data capture has evolved to enable more innovative approaches like risk-based monitoring and adaptive design. We will use case studies to demonstrate how forward-thinking companies are streamlining and innovating clinical development via electronic source (eSource) data capture.

12:35 LUNCHEON PRESENTATION: Practical Considerations for eSource

Keith Howells, Senior Vice President, Product Development, OmniComm Systems, Inc.

The recent FDA guidance on eSource in clinical investigations lays out the expected processes and controls when clinical data is populated directly from electronic instruments rather than being transcribed from paper records. This session will cover some of the practical considerations in implementing eSource, such as how to communicate from an instrument to a web-based EDC system, manage the audit trail when the source instrument and the eCRF may have different timestamps, and facilitate monitoring and regulatory inspections for eSource data.

1:15 Session Break

E-CLINICAL INNOVATION

1:25 Chairperson’s Remarks

1:30 Implementing Innovative Clinical IT Technologies: The Bayer Approach

Kirstin Holzapfel, Head, Clinical Data Process Technology, Global Clinical Data Center, Bayer / Global Clinical Operations

It seems to be the right time for a change in the way how Bayer processes clinical study data. Contrary to the phrase: “never change a running system” it became necessary to streamline processes and renew the underlying IT infrastructure. Focused on study setup, conduct and analysis Bayer strives for managing the split between flexible data structures supporting data cleaning and review on the one hand and CDISC requirements on the other hand. Innovative technologies are seen as the key for success.

1:55 The Diffusion of Mobile and Data Sensors into Clinical Trials

Munther Baara, Senior Director, Development Business Technology, Pfizer

Will the use of mobile tools and data sensors in clinical trials reshape the landscape and modernize the current trial execution model? The diffusion of mobile solutions and sensors will unleashes an unprecedented amount of data and create the opportunity to make clinical trials cheaper and easier to execute, while also improving data accuracy.

Can we leverage the power of mobile and data sensors to:

• Improve clinical trial operations while reducing costs
• Generate data-driven insights to inform drug efficacy
• Drive innovation in patient outcomes
• Transform the clinical trial experience for key stakeholders

2:20 Whispering: Iteratively Specifying, Refining, and Exercising Your Data Model Prior to Deploying Your Study to the Production Platform(s)

John Perkins, Application Architect, MAVERIC Boston CSP Coordinating Center, Department of Veterans Affairs

Although collection mechanisms vary from study to study due to logistical constraints, the data modeling needs of studies, including collection, storage, reporting, monitoring, and analysis, are inherently tool and platform independent. Learn how Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) uses a process we call Whispering combining generation techniques and freely available Veteran Affairs enterprise tools such as SharePoint, InfoPath, SQL Server, Access, Excel, and Word to secure the study team iteratively refines and exercises the data model prior to first patient and independent of production tools and platforms.

2:45 Sponsored Presentation (Opportunity Available)
Seven Annual SCOPE Summit for Clinical Ops Executives
February 24-25, 2015
SCOPesummit.com/Electronic-Data
SCOPE Summit for Clinical Ops Executives | 17

Electronic Data in Clinical Trials
Collecting and Leveraging Data to Optimize Clinical Trials

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
Stuart (Stu) Thiede, President, Global Payment Services, CFS Clinical, Part of DrugDev
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 Case Study: Otsuka’s Approach to Trial Planning and Execution
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.

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: Jeffrey Kasher, Ph.D., Vice President, Clinical Innovation and Implementation, Eli Lilly and Company; TransCelerate Operations Committee Member
Dave Gillogly, MBA, Global Head, Clinical Operations & Strategic Sourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.
Andrew Lee, M.D., Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.
John Oldman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer

9:45 Coffee Break in the Exhibit Hall

KEEPING UP WITH DATA STANDARDS, INTEGRITY AND SECURITY

10:45 Chairperson’s Remarks
Ed Seguin, CEO, Clinical Ink

10:50 SIOP/CMSO – Risk-Based Strategy to Monitor and Mitigate Threats to Clinical Trial Scientific Integrity
Kenneth Mark Mills, Director, Clinical Scientific Data Warehouse, Pfizer
Oversight of scientific integrity in ongoing trials is an important component of clinical/medical review. Monitoring adherence to protocol requirements and ensuring that the assumptions made during trial design are not being grossly violated as the trial unfolds is an important aspect of blinded aggregate data review. Such a proactive data monitoring strategy serves to optimize trial outcomes and ensure that the study yields results that are more likely to answer the primary research question and stand up to scrutiny of regulators and scientific peer review. The presentation will provide insight into processes and tools used to support Pfizer’s strategy for monitoring study scientific integrity.

11:15 Doing More, Faster, Better! How CDISC Data Standards Shorten the Clinical Trial Life Cycle Across the Globe
Vincent Amoruccio, Director, Clinical and Statistical Programming, Alexion Pharmaceuticals
The primary goal of the pharmaceutical industry is to develop, produce, and market life changing and life saving drugs as quickly as possible but with the highest quality and standards possible. CDISC data standards offer significant improvements in clinical trial operations. This presentation will address the regulatory requirements for CDISC in the countries that make up 85% of the market and how CDISC can get medications to the public faster.

11:40 How the Exostar/SAFE-BioPharma Alliance Is Optimizing Drug Development and Clinical Trials
Mollie Shields-Jehling, President and CEO, Corporate Headquarters, SAFE-BioPharma Association
Tom Johnson, Senior Director, Life Science Product Management, Exostar
The centralized research model is moving toward a distributed global model leveraging the cloud to improve communications, information sharing, and collaboration with external partners. This change in paradigm for clinical trials comes with an increase in security risk, data control and greater need for IP protection. Large Pharma companies who recognize the need for joint development must adopt a secure cloud access solution that enables greater access to partner information and applications while maintaining a federated, trusted environment. This presentation will provide use cases from current Pharma customers utilizing federated identity services to enable cloud based research and development.

12:05 pm Simplifying the Investigator Experience by Using a Single ID
Tom Johnson, Senior Director, Life Science Product Management, Exostar
Life science organizations are fundamentally changing the way they conduct and manage clinical trials. More and more, the biopharmaceutical industry is leveraging the resources and expertise of their partners to gain greater efficiency. However, enabling these teams to quickly connect and share information creates new risks to security, data control and the protection of intellectual property proportional to the increased levels of access. This presentation will demonstrate how utilizing a single managed ID can enable secure collaboration in the cloud with critical partners without compromising security.

12:35 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:15 Session Break/Close of Conference
About This Conference
Non-interventional studies are an integral part of clinical development programs and product development plans. Product benefit risk profiles, comparative effectiveness data, and health economic evidence obtained from non-interventional studies are essential for multiple stakeholders, including regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute’s Fourth Annual Managing Late Stage Research, Observational Studies and Registries conference is designed to facilitate knowledge exchange around all aspects of observational research, from design of non-interventional studies and their management, to application of the obtained data, to business and stakeholder decisions.

MANAGING OBSERVATIONAL STUDIES AND REGISTRIES

1:25 Chairperson’s Remarks
1:30 Increasing Late Stage Patient Recruitment through Patient-Centered Technologies
Nariman Nasser, Digital Strategist, Genentech
Making observational studies more accessible to patients is key to increasing recruitment and retention. In this session we will examine opportunities to better align the study experience to the daily lives of our patients.

1:55 Next-Generation Oncology Registry Management, Big Data Considerations and Applications
Jomol Mathew, Ph.D., Director, Clinical and Translational Informatics, IS, Dana-Farber Cancer Institute
Patient data registries that systematically gather longitudinal clinical data that includes family history, exposure/risk factors, health status, diseases, treatments and outcomes along with genomic/molecular profiles are important in conducting correlative studies and establishing diagnostic and prognostic markers of diseases and treatment outcomes. We will be presenting our experiences and perspectives on systems that we have developed for oncology registries at the Dana Farber Cancer Institute.

2:20 Collaborating with a regulator: EMA-commissioned risk-minimization studies
Vera Ehrenstein, MPH, DSc, Associate Professor, Department of Clinical Epidemiology, Institute of Clinical Medicine, Aarhus University
In 2006, the European Medicines Agency (EMA) established the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) to facilitate assessment of drug utilization and safety in Europe. Collaboration with the EMA will be illustrated from the vantage point of an ENCePP center. Topics will include preparing a competitive tender, formulating the research question, finding collaborators, and role of EMA. Guidelines for risk minimization studies will be reviewed, and risk minimization studies of antidiabetic agents will be used as examples.

2:45 Sponsored Presentation (Opportunity Available)

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
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5:00 Welcome Reception in the Exhibit Hall
6:15 Close of Day
Managing Late Stage Research, Observational Studies and Registries

Overcoming Operational Challenges

February 24-25, 2015

WEDNESDAY, FEBRUARY 25

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

8:25 Plenary Keynote Session

PLENARY KEYNOTES AND PANEL: EMBRACING OPEN INNOVATION AND COLLABORATION

8:25 am Organizer’s Welcome

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

9:45 Coffee Break in the Exhibit Hall

ADDRESSING THE NEEDS OF VARIOUS STAKEHOLDERS

10:45 Chairperson’s Remarks

10:50 Using Observational Research and Registries to Support Drug Development across the Lifecycle: Pfizer’s Experience
Rachel Sobel, Dr.Ph., Senior Director, Epidemiology - Team Lead Global Innovative Pharmaceuticals, Pfizer, Inc.
This talk will describe how epidemiologists at Pfizer use observational research and registries to support drug development across the lifecycle, with a focus on how they can be used to better understand the patient populations and safety profiles of drugs to ensure an appropriate benefit-risk balance and enable faster drug approvals and/or maintain medicine licensures. The presentation will cover some of the major regulatory frameworks and provide examples utilized at Pfizer.

11:15 CO-PRESENTATION: Registry Scope and Stakeholders: Matching scope feasibility with stakeholder needs and expectations
Catherine (Koepper) Connelly, Director, Global Registry Operations, Genzyme, a Sanofi Company
Christian Denzel, Director, Registry Programs, Genzyme, a Sanofi Company
Registry research continues to proliferate. Registries offer important research value, and associated stakeholders are often associated with multiple registry stages, such as planning and development, patient enrollment and data collection, and data reporting and publishing. While the stakeholders may be the same across stages, their needs and expectations may evolve. We will investigate how to actively support various stakeholders throughout the lifecycle of a registry, while also actively managing overall expectations and program scope.

11:40 CO-PRESENTATION: Value of the Patient Voice: Role of PROs in Pricing and Reimbursement Strategy
Kelly Hollis, MBA, Global Head, Surveys and Observational Studies, RTI Health Solutions
Carla DeMuro, Head, Patient Reported Outcomes, RTI Health Solutions
Patient-reported outcomes (PROs) are an accepted and often actively solicited source of evidence in evaluating and approving pharmaceutical interventions based on their clinical efficacy. Likewise, real world data including PROs plays an important role in the evaluation of the costs and benefits of new technologies. This presentation will include case studies and provide discussion on leveraging the patient voice to support pricing and reimbursement decision-making.

12:05 pm Presentation to be Announced

12:35 BRIDGING LUNCHEON PRESENTATION: Speaker to be Announced

1:15 Session Break/Close of Conference
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
Elisa Cascade, President, Hosted Data Solutions, DrugDev.org
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’s SiteCloud, 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
Greg Cohee, Partner, Pharmacis 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
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 Site Selection Optimization: Using Technology to Harness External and Internal Data to Reduce the Percentage of Non- or Low-Performing Sites
Cindy Levy-Petelinkar, Director, Clinical Platforms Transformation, GlaxoSmithKline
Partnering with Big Data tech companies, GSK is transforming clin ops through enhanced identification of high-performing sites and remediation of inefficiencies such as wastage of investigational product. Data integration from public and GSK-proprietary data sources incorporated into a new platform will address these business processes and include information on disease prevalence, investigators, recruiting, medical facilities, site performance, site data queries, regulatory audits, drug clinical supply manufacturing, shipping and dispensing.

2:45 The Changing Landscape of Site Start-Up Technology
Todd Esporlas, Vice President, Study Start-Up and Regulatory, INC Research
The landscape of clinical trial site activation is complex and ever-changing. Focusing on internal process efficiency is not enough to meet the needs of complex, global clinical trials. In such a dynamic environment there is a greater need for visibility for all parties involved – on process, on status and on delivery. Innovation in work flow transparency allows us to set and manage expectations, while creating efficiencies for the multiple stakeholders that are reliant on the information contained within. This innovation must be engineered prior to any study and must be flexible enough to change as the site activation environment continues to evolve.

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

4:05 Chairperson’s Remarks
Carol Aliyar, Senior Vice President, Global Head Study Start-Up, 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 megatrails 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 megatrails will be presented.

4:35 Presentation to be Announced

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 Bilic, 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
### Improving Site-Study Activation and Performance

Strategically Implementing a Process for Rapid Study Start-Up

**THURSDAY, FEBRUARY 26**

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| 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  
  *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  
  • Country / medical / operational experts |

**TRANSFORMING SITE MANAGEMENT TO IMPROVE OUTCOMES**

8:15 Chairperson’s Remarks  
Jackie Kent, Senior Director, Clinical Development Information & Optimization(CDIO) & NGLD 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.

9:10 Sponsored Presentation (Opportunity Available)

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

11:15 Cross-Pharma Collaboration in Clinical IT  
*Francis Kendall, GLIDE Future Investigation Team Lead & Global Head, Genentech*

11:30 Using Predictive Analytics to Drive Site Health and Quality  
*John Oidtman, Vice President, Clinical Trial Support and Compliance & WW Clinical Operations, Pfizer*

11:55 CO-PRESENTATION: Healthcare Reform, the Connected Patient, Mobile Tech and Innovation  
*Part 1: Health Care Reform and What It Means Beyond the Pill  
  Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.*  
*Part 2: Open Data Initiatives and the Convergence of Healthcare and Pharma  
  Arman Bhandari, Director, Health IT & Data Partnerships, Business Development, and Strategy, Merck & Co.*

12:30 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  
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

1:05 Closing Remarks

1:10 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016!)
ENGAGING PATIENT GROUPS FOR IMPROVED RESEARCH AND SUCCESSFUL CLINICAL TRIALS

12:35 pm BRIDGING LUNCHEON PRESENTATION: The Impact of Online Communities and Mobile Communication on Recruitment and Retention
Melynda Geurts, Vice President, Operations, DAC Patient Recruitment Services
Dennis Upah, Executive Vice President, Enterprise Markets, Remedy Health Media
Pharmaceutical companies and their recruitment agencies can successfully recruit and retain highly specialized patient populations via outreach to key patient communities, and retain them via proven multi-media technology. We’ll showcase studies showing where the most active patients can be found online, as well as the latest research showing the power of patient-led emotional storytelling in persuading other patients to take action. We’ll also discuss a wide variety of ways to engage existing communities.

1:25 Chairperson’s Remarks
Kelly McKee, Associate Director, Global Trial Optimization, Clinical Development Execution Organization, Merck & Co., Inc.

1:30 Early “Dating” is Critical to Clinical Trial Success
Barbara Wuebbels, Vice President, Patient Advocacy and Medical Affairs, Audenst Therapeutics Inc.
Early engagement of the patient community is critical for a successful clinical development program. Patients’ organizations are demanding their voices be heard in the drug development process and by regulatory agencies. Successful relationship development will increase the likelihood of timely trial enrollment, successful market launch, and the resolution of issues. The leading role of the patient advocate in developing the when, how, where and why of how this relationship is fostered and its importance in handling challenging issues will be discussed.

1:55 Patient Cultivation Case Study: Exploring Tactics Used in the “Long-Term Process of Nurturing Patients towards Higher Levels of Understanding And Commitment” and the Results It Yielded
Elizabeth Mascherino, Associate Director, Patient Recruitment and Engagement, Clinical Programs Support, Shire
Diane Montross, Associate Director, Patient Recruitment and Engagement, Clinical Programs Support, Shire
Building relationships with donors is one of the most important things non-profits can do to ensure fundraising success. But can the non-profit strategies of “donor cultivation,” be applied successfully to clinical research participation? This case study will review an ongoing “Patient Cultivation Program” and the impact it has had on patient engagement.

2:20 CO-PRESENTATION: Can You Hear Me Now? Finding the Patient Voice for Improved Clinical Trials
Abbe Steel, CEO, Health2Vibe, LLC
Jery Matczak, Community Manager, Lilly Clinical Open Innovation, Eli Lilly and Company

3:15 Refreshment Break in the Exhibit Hall

INSPIRING TRIAL PARTICIPATION AND RESEARCH THROUGH PATIENT EMPOWERMENT AND TECH

4:05 Chairperson’s Remarks
Jery Matczak, Community Manager, Lilly Clinical Open Innovation, Eli Lilly and Company

4:10 CO-PRESENTATION: Point-of-Care Clinical Trial and the Precision Oncology Programs at the VA: A Patient-Centric Alternative to Traditional Explanatory Trials
Ryan Ferguson, Sc.D., MPH , Associate Director, Scientific and Technical Operations, Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), Veterans Health Administration
Louis Fiore, M.D., MPH, Executive Director, Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), Veterans Health Administration
The high cost of traditional trials, a growing appetite for pragmatic comparative effectiveness data and the emergence of the concept of a ‘learning healthcare system’ collectively account for an increasing interest in embedding research activities into the clinical care ecosystem. Progress in this area requires rethinking of all aspects of clinical research from confidentiality of data to ethical issues of randomization into pragmatic studies without explicit informed consent of subjects. This presentation will define the approach taken at the VA to advance the field of pragmatic learning by presenting two novel programs; the Point-of-Care Clinical Trial and the Precision Oncology Programs.

4:35 Presentation to be Announced

MEASURING THE EFFECTIVENESS AND COSTS OF TRADITIONAL AND NEW MEDIA AND METHODS

4:50 What Your iPhone Can Teach You About Patient Centricity
Jen Burtchell, Founder, PartnersInResearch.org; Patient Advocate Blogger, Gilenya and Me
Like iPhones out of the box, a clinical trial’s IC is identical for everyone. But Apple knows that no two customers are alike, so they let you customize your experience using apps, skins, ringtones and more. Everyone ends up with a phone that was once identical but is now as unique as the person holding it. Take a page from Apple’s playbook: by letting the trial participant select patient-centricity options from an à la carte menu that best suit their own lifestyle, retention will surely follow.

5:15 A PATIENT RECRUITMENT AND RETENTION PANEL: What Works, What Doesn’t, and What Needs to Change, Perspectives from Sponsors, CROs, And Sites
Moderator: Kelly McKee, Associate Director, Global Trial Optimization, Clinical Development Execution Organization, Merck & Co., Inc.
Panelists:
Joe Kim, Senior Advisor, Clinical Development Innovation, Eli Lilly and Company
Brendan O’Neill, Director, Patient Recruitment Strategy Group, PAREXEL
Adam Larrabee, Director, Business Development & Patient Recruitment, Rochester Clinical Research
Mark Sloan, M.D., Hematology & Medical Oncology, Boston Medical Center

With sweeping changes in healthcare, particularly with patient engagement, patients have an opportunity to participate in the healthcare process even BEFORE drugs are developed by providing feedback around patient preferences and clinical trial design. This feedback can be leveraged to support the many operational aspects of the trial as well as shaping the clinical endpoints for the study. This will help sponsors better understand patient perceptions and treatment preferences. We will examine the impact this feedback could have short term to improve delivery of the trial and long term as commercial viability and label for the drug are being considered.
Patient Engagement, Enrollment and Retention through Communities and Technology

Patient-Centric Approaches to Optimize Clinical Trial Participation

February 25-26, 2015

Cameron Snider, Vice President, TrialNetworks

Patient centricity…Disruptive innovation….Digital recruitment….Trial optimization…..Our industry is full of buzz words, but do the latest and greatest tactics actually work and do our sites and patients respond? This collaborative session will focus on the balance that sponsors, CROs, and sites must employ to successfully recruit and retain patients in an increasing competitive landscape.

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

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
- Country / medical / operational experts

9:10 Patient Advocacy Organizations and Their Influence on Clinical Studies

Brandon Kashfian, President & CEO, ALTATHERA Pharmaceuticals

According to Tufts University’s Center for the Study of Drug Development, less than half of Phase II and Phase III clinical studies complete enrollment within their original timelines. This presentation will explore how patient advocacy organizations continue to play a bigger role in partnering with pharmaceutical companies on mutually beneficial goals, particularly to ease the significant recruitment burdens for disorders for which few treatment options exist.

9:35 Sponsored Presentation (Opportunity Available)

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

11:15 Cross-Pharma Collaboration in Clinical IT

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

11:30 Using Predictive Analytics to Drive Site Health and Quality

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

11:55 CO-PRESENTATION: Healthcare Reform, the Connected Patient, Mobile Tech and Innovation

Part 1: Health Care Reform and What It Means Beyond the Pill

Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

Part 2: Open Data Initiatives and the Convergence of Healthcare and Pharma

Aman Bhandari, Director, Health IT & Data Partnerships, Business Development, Pfizer

12:30 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

Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

1:05 Closing Remarks

1:10 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016)
WEDNESDAY, FEBRUARY 25

About This Conference
As the biopharmaceutical industry moves toward more outsourcing of clinical trial activities to contract research organizations (CROs), sponsors must effectively manage their in-house activities in addition to the needs of their CRO partners. Effective management of outsourced clinical trials requires realistic and explicit expectations from each partner in the outsourcing relationship. Cambridge Healthtech Institute’s Inaugural “Clinical Trial Project Management for Outsourced Clinical Trials” conference features case studies and lessons learned from sponsors and CROs on how to optimize the outsourcing partnership to achieve more efficient clinical trials.

OPTIMIZING OUTSOURCING RELATIONSHIPS

1:25 pm Chairperson’s Remarks
Joan Chambers, COO, CenterWatch

1:30 Leveraging Project Management to Build Strong Partnerships
Thomas Lawler III, MBA, PMP, Senior Director, Global Project Management, AstraZeneca
Building valuable partnerships is reliant on building strong relationships as well as fit-for-purpose infrastructure to support inevitable breakdowns that occur during project delivery. Use of sound project management practices greatly increase the chance for success in relatively simple and pragmatic ways. The presentation covers: 1. Project Planning and its critical role in setting expectations 2. Risk and opportunity management versus being experts at resolving issues 3. Tracking to plan in place of traditional metrics approach 4. Scope management as an alternative to managing change orders.

1:55 Optimizing Outsourcing Relationship Models
Mary Jo Lambert, Ph.D., Senior Research Fellow, Tufts CSDD, Tufts University
Tufts CSDD has conducted a study among top 10 biopharmaceutical companies to capture specific use of outsourcing models (e.g., niche, full-service, FSP, integrated alliances). In this study, Tufts CSDD analyzed specific collaboration and risk-sharing models being utilized, their impact on performance and efficiency to date. The study also explores ways in which organizations have adapted their collaboration models to achieve greater efficiencies and best practices. The study benchmarked the incidence and impact of various organizational approaches through gathering company study data.

2:20 Determining the Right Outsourcing Strategy
Speaker to be Announced

2:45 Sponsored Presentation (Opportunity Available)

3:15 Refreshment Break in the Exhibit Hall

EFFECTIVE PROJECT OVERSIGHT OF OUTSOURCED CLINICAL TRIALS

4:05 Chairperson’s Remarks

4:10 Avoiding Duplicative Efforts between Sponsor and CRO
Mick Ribeiro, Head, Clinical Trial Management, Novartis Vaccines and Diagnostics
This presentation would cover: 1. How to work effectively and efficiently with a CRO partner on a clinical trial. 2. Methods to making the best use of time between CROs and sponsors and to ensure minimal overlap on activities. 3. How to set up the relationship early on to ensure a successful collaboration.

4:35 Sponsored Presentation (Opportunity Available)
THURSDAY, FEBRUARY 26

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

MEETING THE NEEDS OF EVERY PARTNER IN AN OUTSOURCED TRIAL

8:15 Chairperson’s Remarks

8:20 CO-PRESENTATION: Improving Outsourcing Partnerships
Anca Copaescu, Senior Director, Clinical Outsourcing and Analytics, BioMarin
Susan Seroskie, Executive Vice President, Advanced Clinical
Strong service provider oversight and healthy relationship management make the difference between success and failure in clinical trial execution. This session balances the sponsor’s and the service provider’s views on: 1. Designing and implementing service provider-sponsor relationship management, 2. Building operational oversight infrastructure within the sponsor organization, 3. Empowering functional teams to resolve operational issues vs. prematurely escalating to functional and senior management, 4. Highlighting the importance of having clear communication pathways and building trust.

8:45 PANEL DISCUSSION: Managing Clinical Trials Together: Setting Realistic Expectations for Outsourced Deliverables between Sponsors and CROs
Moderator: Thomas Lawler III, MBA, PMP, Senior Director, Global Project Management, AstraZeneca
One of the biggest impediments to successful clinical trial execution is setting realistic and explicit expectations for deliverables between sponsors and CROs. Clear accountability and communication are key to successful outsourcing partnerships.
Topics discussed include:
- Setting realistic and explicit expectations for the quality and scope of outsourced deliverables
- Establishing clear assignments on accountabilities and responsibilities
- Frameworks issue escalation and resolution
- Setting and defining communication pathways and expectations

9:35 Sponsored Presentation (Opportunity Available)

10:00 Coffee Break in the Exhibit Hall

10:40 Closing Plenary Keynote

MORNING 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
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Aman Bhandari, Director, Health IT & Data Partnerships, Business Development and Strategy, Merck & Co.

12:30 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
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

1:05 Closing Remarks

1:10 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016)
Implementing Risk-Based Monitoring
Ensuring Efficient Monitoring and Data Quality

WEDNESDAY, FEBRUARY 25

About This Conference
In response to the rising complexity and cost of clinical trials, pharma is shifting towards adoption of risk-based monitoring (RBM) approaches. RBM holds the promise to improve clinical trial efficiency while ensuring data quality. However, one of the major challenges to implementing risk-based monitoring is determining the best approach and ensuring the necessary change management to support RBM. Cambridge Healthtech Institute’s Inaugural “Implementing Risk-Based Monitoring” conference offers case studies and practical solutions from across pharma and TransCelerate member organizations covering topics such as identification of critical data and processes necessary for RBM and aligning the organizational culture to support RBM.

12:35 BRIDGING LUNCHEON PRESENTATION:
Implementing a Risk-Based Monitoring Approach: A CRO Perspective
Alexander Artymenko, Ph.D., M.D., Global Director, Late Phase, Medpace
Realizing the potential of Risk-Based Monitoring (RBM) requires coordination and collaboration across functions within both the Sponsor and CRO organizations. Working on RBM implementation with various sponsors presents puts a partner CRO into the unique perspective. The attendees will learn about the main challenges and solutions when taking a holistic approach to build a customized adaptive monitoring program, while working with the medical, operational and technology teams.

RISK-BASED MONITORING CASE STUDIES

1:30 Update on TransCelerate’s Risk-Based Monitoring
David Knepper, Head, Continuous Improvement, Forest Laboratories
In May 2013, TransCelerate BioPharma Inc. (TCB) published a Position Paper describing a Risk Based Monitoring Methodology. Since that time, TCB has continued to develop several core concepts including protocol risk assessment, SDV vs. SDR, risk indicators and mitigation, and RBM success metrics. Moreover, the FDA has provided feedback on six pilot study submissions, providing valuable insight into the Agency’s view of the TCB methodology. This presentation will give an overview of the TCB methodology, dive into several key features, and discuss key lessons learned from member pilots and FDA review.

1:55 Case Study: Implementing a Cost-Effective RBM Approach
David Knepper, Head, Continuous Improvement, Forest Laboratories
The goal is maximally efficient studies that consistently produce reliable data and protect research participants. Efficiency and effectiveness are not competing objectives when implementing RBM, but instead are correlated when produced from a single underlying quality strategy. This case study explores practical applications learned from one company’s efforts to implement RBM within an overarching QRM approach on a limited budget. This presentation will discuss the value of an integrated RBM approach to reduce operational complexity and drive both quality and efficiency.

2:20 Adaptive Monitoring in Action: 3 Years and Counting
Grant Simmons, Director, Global Clinical Operations Systems, Clinical Operations, Novartis Pharma
Implementation of adaptive monitoring won’t happen overnight, so where do you start? What are the challenges and obstacles of implementation, what are the critical steps, and how do you manage change in your organization? Hear about best practices and lessons learned from one company’s implementation so that your company can get started. Novartis started with a risk assessment tool in 2011, and implemented analytics functions, central remote monitoring functions, and operational monitoring plans in 2012 with up to 100 studies in action in 2014.

2:45 Remote: The Other ‘R’ in Risk-Based Monitoring
Andrew Mitchell, Director, Strategy and Product Marketing (Life Sciences), Intralinks Ltd.
Remote access to all appropriate investigator-held documents is a key enabler for any holistic risk-based monitoring strategy. This requires moving sites away from paper without imposing additional burden on overstretched sites while equipping them with life-time control over their content such that sponsors never gain “uncontrolled access” to investigator site files and shared documents are protected appropriately.

3:15 Refreshment Break in the Exhibit Hall

ADDRESSING TECH & DATA CHALLENGES TO RISK-BASED MONITORING IMPLEMENTATION

4:05 Chairperson’s Remarks

4:10 Merits of the TransCelerate RBM Technology Recommendations
Shelly Barnes, Senior Project Manager, Global Clinical Solution Center – Strategy and Innovation, Sanofi

4:35 Utilizing the Power of Data Analytics to Maximize the Efficiency of Clinical Trials and Provide Real-Time, Actionable Insights
Gregory Moody, Senior Manager, Clinical and Translational, PerkinElmer Informatics

4:50 Sponsored Presentation (Opportunity Available)

5:15 Challenges Encountered by Implementing Risk-Based Monitoring
Rachel Edwards, Ph.D., Director and Regional Head, Global Clinical Site Management, Amgen
Successful implementation of risk based monitoring requires a fundamental change in managing data flow as continuous data cleaning is essential to ensure data integrity and patient safety. Changes in data cleaning and review requires an alternative approach to study planning and development by the sponsor. Working closely with the site to manage this change is essential for success. The impact of reduced SDV and the changes of a flexible monitoring model will impact the site needs to be clearly communicated and any new approaches introduced with full rationale and guidance. The success of risk based monitoring depends on the site and the sponsor working together by ensuring continuous communication and support during the transition to a new working model.

5:40 Reception in the Exhibit Hall
7:00 Close of Day
Implementing Risk-Based Monitoring
Ensuring Efficient Monitoring and Data Quality

THURSDAY, FEBRUARY 26

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

8:15 Chairperson’s Remarks
Lori Convy, Associate Director, Monitoring Subject Matter Expert, Sanofi

8:20 FEATURED CO-PRESENTATION: Implementing RBM at Boehringer Ingelheim – The Holistic Approach to Monitoring
Andy Lavron, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.
Mary Mills, President, CRA Consultant, Mary Mills, LLC

The RBM world of monitoring is no longer limited to the onsite monitor, but consists of a holistic team approach. The onsite and offsite monitoring activities conducted by the onsite monitor are integrated with the central monitoring and summarized in the quality report.

9:10 Effective Change Management Strategies for Implementation of Risk-Based Monitoring
Lori Convy, Associate Director, Monitoring Subject Matter Expert, Sanofi

Risk-Based Monitoring presents many implementation challenges. Organizations should not underestimate the importance of change management, beginning early to carefully plan for a change of this magnitude. This presentation will assist participants to identify strategies, understand how to define the scope of the change and identify the stakeholders while providing a framework to develop a comprehensive implementation toolkit.

9:35 Speaking from Experience: Lessons Learned from Risk-Based Monitoring Implementations
Sponsored by
Teresa Lamantia, Vice President, Strategic Operations, Quintiles

To maximize the ROI on R&D spend, Biopharma needs to transform clinical development. Current views of risk-based monitoring show it can reduce costs, while having a positive impact on quality and patient safety. To achieve these goals, change is required. By discussing numerous examples of RBM implementations, attendees will gain an understanding as to the changes required in roles, processes and procedures, as well as how technology is enabling this transformation.

10:00 Coffee Break in the Exhibit Hall

10:40 Closing Plenary Keynote

1:05 Closing Remarks

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

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10:45 Clinical Informatics News Best Practices Awards

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Aman Bhandari, Director, Health IT & Data Partnerships, Business Development, and Strategy, Merck & Co.

12:30 PANEL: Mobile Tech, Realworld Data and Innovative Platforms to Enable Trial Operations and Research
Moderator: Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer

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Munther Baara, Senior Director, Development Business Technology, Pfizer
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

1:05 Closing Remarks

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.
Integrating and Leveraging Clinical Trial Operations Data

Novel Integrative Systems, Portals, Data Warehouses

February 25-26, 2015

WEDNESDAY, FEBRUARY 25

About This Conference
We are witnessing an unprecedented burst of technology that completely changes the way we run clinical trials. The use of technology in the support of Clinical Trials has continued to increase, including solutions such as Investigator Portal, EDC, IRT, ePRO, etc. Cambridge Healthtech Institute’s Fourth Annual "Integrating and Leveraging Clinical Trial Operations Data" conference will feature an array of topics such as data integration and accessibility, novel data visualization technologies, data sensors and others.

TRANSFORMING CLINICAL DEVELOPMENT THROUGH ANALYTICS AND COLLABORATION

1:25 pm Chairperson’s Remarks
Matt Kiernan, Partner, Pharmica Consulting

1:30 Next-Generation Data Visualization and Collaboration
Ed Kellar, Director, Global Data Management Operational Support, Data Management, Astellas

In an effort to streamline clinical, operational and safety data analysis at Astellas, advanced analytics and event-driven collaboration capabilities were employed worldwide. The key to the system is a novel clinical data review tool built around a virtual on-demand data warehouse that provides dependable decision making based on a single source of truth. The solution equipped end users with the ability to perform self-service data discovery and report building without having to rely on IT or biostatistics for report generation so they could focus on higher value-add tasks.

1:55 Using English Language Queries To Gain Insights Into Clinical Data
Munther Baara, Senior Director, Development Business Technology, Pfizer

Clinical staff have traditionally had to work with programmers in an iterative process to gain insights into clinical data. Using revolutionary technology, users are able to gain insights into the data by asking questions in plain English. At Pfizer, we piloted the use of this technology to augment our Enhanced Quantitative Drug Design process for selected studies related to our product. I will share the outcome of our pilot:

2:20 Visual Analytics: Sailing Big Data in Clinical Research
Charles Romano, Senior Director, Clinical Research, Amniox Medical

Whether designing a hot new study or standing in the remnants of a terminated project, determining whether a program is excelling or sailing is an old science with some new tools. With millions of dollars, new indications and patients’ lives depending on our innovation, what do you watch in the spyglass to see where your program is going? In this session, we will examine some useful measures for study startup, execution and conclusion.

2:45 Talk Title to be Announced
Jennifer Goldsmith, Vice President, Vault R&D, Veeva

3:15 Refreshment Break in the Exhibit Hall

IT TECHNOLOGY TO ADDRESS PARTICULAR CHALLENGES

4:05 Chairperson’s Remarks

4:10 Meeting Recruitment Targets: Improving Your Chances to Randomize That Last Subject on Time
Ozgur Ozkan, Ph.D., Principal Decision Scientist, Biometrics and Information Sciences, AstraZeneca

Accurate estimation of recruitment performance as well as better assessment of alternative strategies could improve the delivery of clinical studies. For this purpose, a model is developed to track activities at country, site and patient level and simulate trial progress given actual and planned performance. The model is used to estimate the probability distribution of time to randomize the last patient and calculate confidence in completing recruitment by planned timeline. The approach is tested with ongoing trials and alternative strategies are evaluated.

4:35 Presentation to be Announced

4:50 Technology Framework to Operationalize Precision Medicine
Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer

Biomarkers become an integral part of clinical trials. In order to run a biomarker-driven trial we need to put in place an effective system of sample and biospecimen management and tracking. IT technologies come instrumental in this process. This talk will discuss the use of a specimen management framework to operationalize biomarker-focused clinical research and the precision medicine development.

5:15 A Study of eClinical Technology Usage and Standards Adoption
Mary Jo Lamberti, Ph.D., Senior Research Fellow, Tufts CSDD, Tufts University

Tufts CSDD in collaboration with CDISC conducted a study among biopharmaceutical, CRO companies and vendors in order to examine uptake and usage of eClinical trial technologies and standards adoption. Both overall perceptions and utilization is assessed as well as the challenges and barriers to adoption. Other key areas will be explored included integration of systems, planned implementation of standards, and satisfaction with current processes.

5:40 Reception in the Exhibit Hall

7:00 Close of Day

SCOPE SUMMIT 2015 FEATURES:

- 12 Conferences
- 3 Plenary Keynote Sessions
- 4 New Conference Tracks
- 700+ Industry Leaders Expected in 2015
- Clinical Informatics News’ Best Practices Awards
- Dedicated Exhibit Hall Hours & Networking Functions
- Interactive Breakout Discussions

It was great being at the conference — you have developed a nice group of alumni for SCOPE! We’ve signed up to sponsor again for 2015. “

Suresh K., VP, Products, Clinical Trial Optimization Solutions

SCOPE! We’ve signed up to sponsor again for 2015.

Sponsored by

Veeva
Integrating and Leveraging Clinical Trial Operations Data
Novel Integrative Systems, Portals, Data Warehouses

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
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
- Country / medical / operational experts

CASE STUDIES: NOVEL DATA INTEGRATION TECHNOLOGIES

8:15 Chairperson’s Remarks

8:20 CO-PRESENTATION: Using Clinical Dashboard to Drive Clinical Trial Metrics Improvement
Ron Bourque, R&D IS Senior Manager, Clinical Business Management and Analytics, MedImmune
Graham Irvine, Director, Therapeutic Area & Capacity Management, MedImmune
MedImmune has developed a clinical dashboard to drive clinical trial metrics improvement and operational information compliance. The dashboard utilizes project management and operational data from major clinical systems and provides an easy access and view of trial summary information and key metrics information. It enables R&D executive review and study teams’ review. It provides a single source of truth of critical clinical management information. The dashboard technology also enables view of information from mobile devices such as iPad and iPhone.

8:55 CO-PRESENTATION: Workbench: Improving How We Progress the Portfolio
Eric Grande, Associate Director, Application Architecture, Novartis
David Yee, Ph.D., Translational Sciences Project Leader, IT & Process Improvement, Novartis
Novartis enjoys a rich portfolio with many projects in multiple disease areas managed across many line functions. As such, cross-functional coordination and alignment is challenging. We are designing a simplified environment to enable us to better communicate, collaborate, and manage our work. Our approach is to establish a modern platform based upon a common data model. The benefits of the Workbench include more agile decision making, reduced bureaucracy, and more efficient use of resources.

9:35 Sponsored Presentation (Opportunity Available)

10:00 Coffee Break in the Exhibit Hall

10:40 Closing Plenary Keynote

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

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1:05 Closing Remarks

1:10 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016!)

Group and Company Discounts!

Group Discounts are Available! Special rates are available for multiple attendees from the same organization. For more information on group discounts contact Melissa Dolen at 781-972-5418
About This Conference
Drug adverse events detection and analysis is one of the main goals of any clinical trial, and post-marketing safety surveillance is one of the main functions of late stage research and post-marketing studies and registries. Pharmacovigilance science or drug safety relies heavily on strategic approaches and operational advances that can be applied to any therapeutic areas. Cambridge Healthtech Institute is adding the Inaugural “Pharmacovigilance and Adverse Events Reporting” conference to the SCOPE mix of topics in order to fulfill the need of coverage and information exchange for this important part of clinical research. Some of the specific topics to be discussed are AE aggregate analysis, technology and social media in pharmacovigilance research, risk minimization, and others.

ADVERSE EVENTS DETECTION AND ANALYSIS

1:25 Chairperson’s Remarks
Paul Landesman, Ph.D., Contract Consultant, Drug Safety Risk Management, InterMune, Inc.

1:30 Regulatory Environment and Innovative Pharmacovigilance
Michael Ibara, Head, Business Development Coordination & Innovation, Drug Safety, Pfizer
The underlying problem is that we are using the rules and regulations and concept which were developed when data was hard to find. This presentation will discuss how internet and social media changed this paradigm.

1:55 Aggregated Review of Clinical Trial Safety Data Plays a Critical Role in Clinical Development Risk Management
Sean Zhao, M.D., Head, US Safety Surveillance, AstraZeneca
FDA’s guidance of “Safety Reporting Requirements for INDs and BA/BE Studies” suggests sponsor conduct ongoing periodic aggregate analysis and review of specific safety events occurred in clinical trials that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group. The presentation will focus on (1) establishing risk thresholds of event of special interests in the clinical development program; (2) building standard tools, systems, and process for aggregated safety analysis and review; (3) escalating and managing identified potential risks; and (4) reporting and communicating safety findings from aggregated analysis to FDA and all participating investigators.

2:20 Signal Detection and Evaluation for Drug-Induced Liver Injury during Clinical Phases of Drug Development
Ari Regev, M.D., Head, Safety Advisory Hub, Chairman, Liver and GI Safety Committee, Global Patient Safety, Eli Lilly & Company
Despite increasing efforts to understand and predict idiosyncratic drug induced liver injury (IDILI) it remains largely unpredictable. Currently, the best time to try and identify a drug’s potential to cause IDILI, may be during early clinical development. During this phase, the differentiation between hepatic events which can predict IDILI and those that are not predictive of IDILI is of critical importance. This presentation will review current approaches to identification and monitoring of suspected IDILI during clinical phases of drug development.

4:10 Drug Safety Risk Minimization
Sundos Hamza, M.D., Senior Vice President, Drug Safety Risk Management, InterMune
The goal of risk minimization is to minimize a product’s risks while preserving its benefits. Benefit and risk information emerges continually throughout a product’s lifecycle (i.e., during the investigational and marketing phases) and can reflect the results of both labeled and off-label uses. This presentation will discuss strategies and technologies to minimize drug safety risk.

4:35 Adverse Event Management in Non-Interventional Studies
Miranda Dollen, Vice President, Pharmacovigilance, Optum
Adverse event management for non-interventional post-authorisation safety studies conducted in the European Economic Area must comply with the requirements of Module VI of Good Pharmacovigilance Practices. This session reviews the impact of the September 2014 update to Module VI, looking at practical considerations for study design and protocol development.

5:05 Chairperson’s Remarks
In recent years, rapid progress has been made in developing new tools for monitoring patient safety. These tools range from new biochemical biomarkers and imaging techniques for monitoring drug-induced organ toxicity, to genetic approaches that can help with risk assessment, to new informatics and statistical tools for collecting and analyzing safety data. In this presentation, we will review some of these new tools, and discuss challenges and opportunities for using them for effective monitoring of patients.

8:15 Chairperson’s Remarks
8:20 Implementing New Safety Monitoring Tools: Opportunities and Challenges
Stephen Furlong, Ph.D., Safety Science Lead, Safety Science Section, Patient Safety, AstraZeneca

In recent years, rapid progress has been made in developing new tools for monitoring patient safety. These tools range from new biochemical biomarkers and imaging techniques for monitoring drug-induced organ toxicity, to genetic approaches that can help with risk assessment, to new informatics and statistical tools for collecting and analyzing safety data. In this presentation, we will review some of these new tools, and discuss approaches and challenges for moving these tools from exploratory studies to using them for effective monitoring of patients.

8:45 New Challenges Facing PV and Information Technology Strategies to Meet Them
John Hoskin, Director, AEGIS Operations, Pharmacovigilance and Patient Safety, Abbvie

Pharmacovigilance has moved from the wings to center stage in recent years. Higher scrutiny of product safety and greater focus on benefit/risk have brought more attention to safety and have had major impacts on PV organizations. Even more changes are in the offing, and they are coming at a faster pace than ever before. New regulations, higher case volumes, additional sources of data, and availability of new analytical tools and processes – all will require new approaches to address. This session will explore some of these challenges and suggest technical strategies the industry might adopt.

9:10 Adverse Event Reporting for Social Listening
Melissa Thompson, Patient Recruitment Strategy Associate, Genentech

Social listening can be a powerful tool but there are reservations in collecting insights from patients and caregivers due to the possibility of discovering adverse events. In this session, we will explore the use of social listening to aid in patient recruitment and retention, with a focus on prevalence of reportable AEs on social media platforms and the methodology/timing of reporting findings.

9:35 Sponsored Presentation (Opportunity Available)

10:00 Coffee Break in the Exhibit Hall
10:40 Closing Plenary Keynote

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Panelists: Francis Kendall, GLIDE Future Investigation Team Lead & Global Head, Genentech
Munther Baara, Senior Director, Development Business Technology, Pfizer
Thomas Tsang, M.D., CMO, Healthcare Services and Solutions, Merck & Co.

1:05 Closing Remarks

1:10 pm SCOPE 2015 Conference Adjourns (see you in Miami for 2016)
# Pricing and Registration Information

## Conference Package Pricing

**Best Value!** - Includes access to the entire 3-day SCOPE program

<table>
<thead>
<tr>
<th></th>
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### Standard Registration - Includes access to ONE conference

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## 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.

- **SAFÉ BioPharma Association membership discount**
  - 20% 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](http://www.scopecomm.com). Massachusetts delivery will include sales tax.

## How to Register: [SCOPEsummit.com](http://www.scopecomm.com)

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

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**Please refer to the Registration Code below:**

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**Please use keycode SCOPE F when registering!**

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**Register Early and SAVE!**

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**Pricing and Registration Information**

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**February 24 - 26, 2015**

**Hyatt Regency Orlando**

**Orlando, FL**

**Conference Package Pricing**

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**Tuesday-Wednesday, February 24-25**

<table>
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<th>Activity</th>
<th>Description</th>
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<tr>
<td>C1A Global Site Selection, Feasibility Assessment, Operations and Site Mgmt</td>
<td>C1B Improving Site-Study Activation and Performance</td>
</tr>
<tr>
<td>C2A Enrollment Planning and Patient Recruitment</td>
<td>C2B Patient Engagement, Enrollment and Retention through Communities and Tech</td>
</tr>
<tr>
<td>C3A Clinical Trial Forecasting and Budgeting</td>
<td>C3B Clinical Trial Project Management for Outsourced Clinical Trials</td>
</tr>
<tr>
<td>C4A From QbD and Risk Assessment to Risk-Based Monitoring</td>
<td>C4B Implementing Risk-Based Monitoring</td>
</tr>
<tr>
<td>C5A Electronic Data in Clinical Trials</td>
<td>C5B Integrating and Leveraging Clinical Trial Operations Data</td>
</tr>
<tr>
<td>OSA Managing Late Stage Research, Observational Studies and Registries</td>
<td>OSB Pharmacovigilance and Adverse Event Reporting</td>
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