7th Annual **February 23 - 25, 2016** | Hyatt Regency Miami, Miami, FL

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

Back in Miami!

February 23-24

- Global Site Selection, Feasibility Assessment, Operations and Site Management
- Enrollment Planning and Patient Recruitment
- Clinical Trial Forecasting and Budgeting
- Implementing Risk-Based Monitoring (Part 1)
- Clinical IT Strategy and Governance
- Managing Late Stage Research, Observational Studies and Registries

February 24-25

- Improving Site-Study Activation and Performance
- Patient Engagement, Enrollment and Retention through Communities and Tech
- Managing Outsourced Clinical Trials
- Implementing Risk-Based Monitoring (Part 2)
- Clinical Data Technology and Integration
- Leveraging Existing Data for Clinical and Observational Research

Symposia - February 23-24

Managing Biomarker-Driven Clinical Trials NEW

Clinical Research Statistics for Non-Statisticians NEW

Event Features

- 12 Conferences
- 2 Plenary Keynote Sessions
- 3 Short Courses
- 2 New Symposia
- 1,000+ Industry Leaders Expected in 2016
- Clinical Informatics News Best Practices Awards
- Dedicated Exhibit Hall Hours & Networking Functions
- Interactive Breakout Discussions

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Event-at-a-Glance

Monday, February 22, 2016

Pre-Conference Short Courses (Optional, Separate Registration Required)

1. **Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment**
3. **Views and Conversations on Risk-Based Monitoring**
4. **Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract**

Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

	SITE ACTIVATION	RECRUITMENT	PROJECT MANAGEMENT	MONITORING	DATA	REAL WORLD EVIDENCE	BIOMARKER TRIALS	STATISTICS
Tuesday, February 23, 2016								
AM & PM	CONFERENCE 1A **Global Site Selection, Feasibility Assessment, and Site Management**	CONFERENCE 2A **Enrollment Planning and Patient Recruitment**	CONFERENCE 3A **Clinical Trial Forecasting and Budgeting**	CONFERENCE 4A **Implementing Risk-Based Monitoring (Part 1)**	CONFERENCE 5A **Clinical IT Strategy and Governance**	CONFERENCE 6A **Managing Late Stage Research and Observational Studies**	SYMPOSIUM 7A *NEW* **Managing Biomarker-Driven Clinical Trials**	SYMPOSIUM 8A *NEW* **Clinical Research Statistics for Non-Statisticians**
Wednesday, February 24, 2016								
AM	CONFERENCE 1A **Global Site Selection, Feasibility Assessment, and Site Management**	CONFERENCE 2A **Enrollment Planning and Patient Recruitment**	CONFERENCE 3A **Clinical Trial Forecasting and Budgeting**	CONFERENCE 4A **Implementing Risk-Based Monitoring (Part 1)**	CONFERENCE 5A **Clinical IT Strategy and Governance**	CONFERENCE 6A **Managing Late Stage Research and Observational Studies**	SYMPOSIUM 7A *NEW* **Managing Biomarker-Driven Clinical Trials**	SYMPOSIUM 8A *NEW* **Clinical Research Statistics for Non-Statisticians**
PM	CONFERENCE 1B **Improving Site-Study Activation and Performance**	CONFERENCE 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**	CONFERENCE 3B **Managing Outsourced Clinical Trials**	CONFERENCE 4B **Implementing Risk-Based Monitoring (Part 2)**	CONFERENCE 5B **Clinical Data Technology and Integration**	CONFERENCE 6B *NEW* **Leveraging Existing Data for Clinical and Observational Research**	SYMPOSIUM 7A *NEW* **Managing Biomarker-Driven Clinical Trials**	SYMPOSIUM 8A *NEW* **Clinical Research Statistics for Non-Statisticians**
Thursday, February 25, 2016								
AM & PM	CONFERENCE 1B **Improving Site-Study Activation and Performance**	CONFERENCE 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**	CONFERENCE 3B **Managing Outsourced Clinical Trials**	CONFERENCE 4B **Implementing Risk-Based Monitoring (Part 2)**	CONFERENCE 5B **Clinical Data Technology and Integration**	CONFERENCE 6B *NEW* **Leveraging Existing Data for Clinical and Observational Research**	*SYMPOSIA* JOIN **Main Sessions…**	*SYMPOSIA* JOIN **Main Sessions…**

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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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CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre- and post-show delegate lists. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

Agenda Presentations

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15 or 25-minute podium presentation within the scientific agenda, exhibit space, on-site branding and access to cooperative marketing efforts by CHI.

Breakfast & Luncheon Presentations

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

Invitation-Only VIP Dinner/Hospitality Suite

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

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

Exhibit

Exhibitors will enjoy facilitated networking opportunities with 900+ qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

Lead Generation

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

- Whitepapers
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- Custom Market Research Surveys
- Podcasts

Additional opportunities are available for sponsorship, including:

- Game Card
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- Focus Group
- Hotel Room Key
- User Group Meeting
- Footprint Trails
- Program Guide Advertisement
- Padfolios
- Lanyards
- Totebags (SOLD)

To customize your participation at this event, please contact:

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

NEW PRODUCT SHOWCASE

New Product Showcase

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

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

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Pre-Conference Short Courses*

Monday, February 22, 2016 | 2:00-5:30 pm

Join your colleagues for more in-depth, focused learning at an informational and interactive Short Course. Choose one of the Short Courses below for three hours of instruction and discussion in a small group setting. Get your questions answered, network with colleagues, and share ideas.

SC1: Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment

Matt Miller, Vice President, Global Patient Recruitment & Feasibility, StudyKIK
Nariman Nasser, Digital Strategist, Genentech
Jerome Chiaro, Vice President, Clinical Operations, StudyKIK

With the constant evolution of technology and strategies developed within the marketing sector, properly applying these strategies and tools to the clinical trial patient recruitment industry is of the highest importance. Research has proven that the use of mobile technology and advanced analytics applied to clinical trial patient recruitment has propelled study timelines and decreased resources allocated to drug development. In this workshop we will take a detailed look at different age groups and demographics in correlation with disease states and where these patients in today's society are researching, findings, and consenting for clinical trials. We will explore some of today's most efficient forms of patient recruitment and demonstrate step by step processes to implement first hand to improve enrollment timelines.

Key Learning Objectives:

- Gain practical insights and solutions to the challenge of selecting a clinical trial patient recruitment strategy
- Understand the diverse assortment of other new strategies and tactics to assist in identifying and enrolling patients
- Is social media the answer to the challenge?: Identify which approach is the best solution for your study
- Learn hands-on how to navigate and use various tools and platforms…attendees, bring your smartphones, tablets and laptops!

SC3: Views and Conversations on Risk-Based Monitoring

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.
Mireille Zerola, Clinical Data Management Expert, Boehringer Ingelheim Ltd.
Mary Mills, President, CRA Consultant, Mary Mills, LLC
Ellen Kelso, Executive Director, Chesapeake IRB

This session gives insights into not only the processes surrounding RBM, but also the individual and group responses of those involved. Whether you are considering implementing RBM or if you are an experienced practitioner, this session will have something for everyone.

Key Learning Objectives:

- Review of the processes involved in and process changes with RBM
- Survey results for site staff and onsite monitors on using RBM
- "Conversations" with various groups – auditors, central monitors, etc.
- What are the boundaries of RBM?

SC4: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract

Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer
Charlotte French, Senior Director, Global Head, Contracting & Outsourcing, EMD Serono

In this workshop we will examine various strategies for implementing RFP processes at your company that are appropriate to your type and volume of work. Different companies have different needs, and there is no one size fits all. This workshop will help participants understand industry trends and how people currently conduct RFPs and then convert the selected proposals into start-up work orders and ultimately, final contracts. We will discuss various formats for RFPs, from the minimalist in specifications approach, down to the highly detailed approach. We will also discuss various approaches to putting start-up work orders in place as not to impede the progress of project start-up. Last, but not least, we will dissect various approaches to finalizing the full work order during the start-up phase of the project.

Key Learning Objectives:

- Developing your customized RFP process and strategy
- Determining your needs (time & materials, unit cost, fixed cost)
- Developing your contract and work order templates with ease of implementation in mind
- Developing start-up work orders
- Finalizing your end product, the Full Work Order

** Separate registration is required.*

After the Pre-Conference Short Courses

Welcome and Networking Happy Hour on the Patio hosted by CHI, DrugDev and Praxis

Monday, February 22, 2016 • 7:00 pm - 9:00 pm
Hyatt Regency Miami's Riverwalk Terrace • Miami, FL

Kick off SCOPE at our welcome happy hour Monday, February 22, 2016, 7:00 – 9:00 pm at the Hyatt Regency Miami co-hosted by CHI, DrugDev and Praxis. Each year the majority of delegates arrive at SCOPE on Monday with roller bags and exhibit booths in tow so why not stop by for cocktails and hors d'ouerves. Connect with old friends or make some new ones in this casual setting on the Riverwalk Terrace of Hyatt Regency. CISCRP will be on-hand to share stories and opportunities to educate the public and patients about clinical trials. Come early to attend the pre-conference short courses from 2:00 to 5:30 pm.

Running shoes, jeans, Aloha shirts are all appropriate for Happy Hour. See you in Miami!

Support CISCRP

https://www.ciscrp.org/support

The Center for Information and Study on Clinical Research Participation (CISCRP) is a first-of-its-kind nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. CHI, SCOPE, DrugDev and Praxis are all proud sponsors of CISCRP and support their work.

Plenary Keynotes & Panel

Tuesday, February 23, 2016 | 8:25 – 9:45 am

TUESDAY, FEBRUARY 23, 2016

OPENING PLENARY KEYNOTES

PATIENT-SITE-SPONSOR-COMMUNITY VOICES: ENGAGING THE CUSTOMER, BUILDING TRUST AND FURTHERING RESEARCH

7:30 am Registration and Morning Coffee

8:25 Organizer's Welcome

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

8:30 Plenary Keynote Chairperson's Opening Remarks: Exploring the Need to Improve Clinical Trial Awareness

Kelly McKee, Associate Director, Global Trial Optimization, Clinical Development Execution Organization, Merck & Co., Inc.

The challenge of improving R&D productivity to increase the number of new therapies that advance to market tests the clinical research community every day. To ensure success in this environment, we must produce cost-effective and tangible health improvements and continue to innovate using available technologies. Despite advances in this area, we are failing to move beyond our microcosm of those who operate in our space. A fundamental shift to include the wider ecosystem is needed to better understand the myriad of voices in clinical research to effectively develop new scientific innovations, improve business and clinical operations processes, invest in new technologies, and "get the word out".

8:35 ROI Expectations and Objectives for Optimized Patient Awareness and Engagement

Kenneth Getz, MBA, Director, Sponsored Research Programs, Tufts CSDD; Chairman, CISCRP

There is a need with pharma and now with the ACA requirements in healthcare to actually do a better job of taking our customers' experience into account and into our planning. Moving beyond the concept of patient centricity, which means different things to different people depending on your role in clinical research, how do we actually do this? This presentation will focus on: (1) Setting realistic expectations for patient centric initiatives, (2) Establishing and measuring reasonable ROI (return-on-investment), and (3) Engaging and coordinating enterprise-wide support.

9:00 AN INTERACTIVE MULTI-STAKEHOLDER ADVISORY PANEL: Increasing Clinical Trial Awareness: Who, What, Where, HOW?

One of the major challenges facing clinical trial teams, sites, and patients is the lack of clinical trial awareness in the general community. This interactive panel will take a multi-dimensional approach to bring the "voices of clinical research" into a constructive and open dialogue to explore solutions from multiple perspectives: sponsor, site, patient, and provider. Audience participation is not only encouraged, but mandatory! Be prepared for a lively discussion as we explore this important challenge together.

- How do we increase awareness of clinical research and build trust across the continuum, from the public to the PI to the patient and to our industry partners?
- Can we move beyond the buzzword of patient centricity and figure out how to better listen to the patients/customers to inform clinical trial solutions, whether it be improved protocol design or better understanding the trial volunteer?
- What is the ROI of patient engagement and how are CROs, Sponsors, Sites and Patients contributing or impeding real exchange?
- Why are patients in need of experimental therapies and trial sponsors in need of trial volunteers not more easily connected? How can we reach and enroll patients for the right trial?
- How do we design solutions that are easy for sites and patients to adopt?

Co-Moderators:

Kelly McKee, Associate Director, Global Trial Optimization, Clinical Development Execution Organization, Merck & Co., Inc.

Kenneth Getz, MBA, Director, Sponsored Research Programs, Tufts CSDD; Chairman, CISCRP

Panelists:

Joe Kim, Senior Advisor, Clinical Development Innovation, Eli Lilly and Company

Mark Sloan, M.D., Hematology & Medical Oncology, Boston Medical Center

Carly Medosch, MBA, Chronic Illness Advocate

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

9:45 Grand Opening Coffee Break in the Exhibit Hall

10:45 Join Your Conference

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

Does not include access to short courses

Hotel & Travel Information

Conference Venue and Hotel:

Hyatt Regency Miami
400 South East Second Ave
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T: 305-358-1234

Reservations:
Visit the travel page of **www.scopesummit.com**

Discount Room Rate: **$239 s/d**
Discount Cut-off Date: **January 19, 2016**

Why Stay at the Hyatt Regency Miami?

Located on the Miami River in the heart of downtown, the Hyatt Regency Miami provides luxurious amenities and accommodations in a vibrant setting. Explore the Riverwalk and shops at Bayside Marketplace, or walk to world class restaurants, just steps away. The hotel is 8 miles from Miami International Airport, 20 minutes from South Beach, and is adjacent to Miami's free Metromover transportation system. In addition, enjoy complimentary wifi in your guest room!

We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

Visit the travel page of **SCOPEsummit.com** for additional information

Plenary Keynotes & Panel

Wednesday, February 24, 2016 | 1:30 – 3:00 pm

WEDNESDAY, FEBRUARY 24, 2016

AFTERNOON PLENARY KEYNOTES

ADVANCING CLINICAL RESEARCH WITH TECHNOLOGY AND INNOVATION

1:30 Organizer's Welcome

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

1:35 Plenary Keynote Chairperson's Opening Remarks & Clinical Informatics News Best Practices Awards

Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News

Clinical Informatics News is proud to present its Third 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.

1:50 Innovation, Technology and the Hype Cycle for Clinical Trials: From Emerging to Impact

Craig Lipset, Head, Clinical Innovation, Pfizer

EMRs, big data, remote trials, sensors/wearables, social media, 3D printing… there is no shortage of opportunities and ideas that generate enthusiasm for some and trepidation for others. Whether passed down from management or incubated upward from the internal entrepreneur, some fear getting too involved in hype while others worry about missing opportunities for true impact. How do we separate the emerging areas to watch, the opportunities for which we need to prepare, and the areas of meaningful impact where we may be slipping behind? Applying the hype cycle to clinical development innovation can help ground us today and prepare for tomorrow.

2:25 Adoption of Technology Solutions in Clinical Trials: Are We Ready?

Margaretta Nyilas, M.D., Senior Vice President, Clinical & Business Operations, OTSUKA Pharmaceutical Development & Commercialization, Inc.

Tools and technology are readily available for use in the clinical trial process, from eConsent, to eSource, to digital medicine; hence the ways in which data may be generated, collected, and processed has changed dramatically. However, the emergence and adoption of technology solutions to enhance data collection and reporting to improve overall outcomes and garner operational efficiencies, has been incredibly slow in the last two decades compared to other industries. How do R&D leaders harness resources, transcend existing skill sets and truly maximize the science; a new era is upon industry - are we ready for it? … Our patients certainly are.

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

4:00 Join Your Conference

Clinical Informatics News is seeking submissions to its Third 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 11, 2015

(If received by November 13, 2015, there is no application fee)

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

We encourage all SCOPE Exhibitors and Sponsors to participate!

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Does not include access to short courses

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**All prizes are given away on behalf of CHI. Apple®, Bose® and Fitbit are not sponsors or participants of this program.*

Global Site Selection, Feasibility Assessment, and Site Management

Improving Outcomes through Strategy, Relationships, Data and Execution

February 23-24, 2016

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 protocol development, trial planning and program 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 Sixth Annual "Global Site Selection, Feasibility Assessment, Operations and Site Management" conference will cover the topics one should consider when planning and implementing a trial.

MONDAY, FEBRUARY 22

Recommended Short Course*

2:00 – 5:30 pm

SC1: Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment*

** Separate registration required; please see page 5 for details.*

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes (see page 3 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

IMPROVING TRIAL PLANNING: PRODUCT STRATEGY, NEW RESEARCH ECOSYSTEM & IMPROVED FEASIBILITY

10:45 Chairperson's Remarks

Jackie Kent, Senior Director, Clinical Development Information & Optimization, Eli Lilly and Company

10:50 Tying Product Strategy to Trials: Looking More Strategically at Why and How We Go to Certain Places for Trials

Mark Travers, Ph.D., MBA, Global Head, Monitoring Excellence & Interim Head of NA Region Global Clinical Trial Operations, Merck

Global trials require us to think broadly while also executing as quickly as possible. We look at countries and patient populations, we select sites and launch trials, we build relationships with our partners, CROs, site, PIs and ideally with the patients themselves. We have all of this process broken down by cost, time and key milestones. However, we sometimes skip some of the earlier strategic considerations that can help both our trial run smoothly and improve the likelihood of commercial success for the product.

11:15 CO-PRESENTATION: Designing a New Clinical Research Ecosystem around the Most Important Human – The Patient

Katherine Vandebelt, Senior Director, Clinical Innovation, Eli Lilly and Company

Jackie Kent, Senior Director, Clinical Development Information & Optimization, Eli Lilly and Company

You need to have a physician to care for the patient and then you must add the necessary integrated infrastructure for these two humans to make the trial experience feasible, responsive and considerate. Doing this will enable us to get clinical answers faster. We are currently experimenting with changing the time and place of clinical research to increase the feasibility of conducting research. We need to prove that data quality is maintained and burden for the doctor is reduced such that they can maintain oversight and perform their investigator duties.

11:40 Operational and Strategic Approaches in Conducting Clinical Trial Feasibility

Susie Campos, Associate Director, Clinical Trial Intelligence, Global Clinical Trial Leadership, Novartis Pharmaceuticals

In this session, current approaches in conducting trial feasibility will be discussed with emphasis on the strategic approach needed to successfully operationalize the process. With a variety of study types and needs, approaches for feasibility need to be flexible yet still yield robust results. With the increase in number of trials conducted, improved feasibility methodology is needed to ensure the process is efficient and data obtained is high quality. The Learning Objectives are: 1) define types of trial feasibility 2) outline feasibility methodology currently used 3) benefits of operational and strategic approaches 4) future possibilities.

Sponsored by BBK WORLDWIDE

12:05 pm Are Your Investigators Championing Your Study within the Medical Community? A Strategic Look at Maximizing Referring Physician Contributions

Bonnie Brescia, Founding Principal, BBK Worldwide

As the clinical trial landscape becomes more competitive, those studies that have strategic communication plans to engage and motivate referring physicians will have a distinct edge. Learn about BBK's research initiative, including responses from specialists in over 30 countries, revealing the group's attitudes and practice regarding matching their patients with clinical trial options – along with practical information about what clinical teams can do to maximize the likelihood that they will refer patients to your studies.

Sponsored by QUINTILES

12:35 Luncheon Presentation: Building a Strategic Site Network to Optimize Your Clinical Trial

Kimberly Ray, Vice President, Site & Patient Networks, Quintiles

Understand the value of forming a strategic site network in clinical research to optimize clinical trials from site advocacy to sharing critical information, including setting and measuring metrics to assess the ROI to build peak network performance and leveraging these relationships for innovation. Hear methods to build the relationship using transparency and innovative communication methods.

1:20 Coffee and Dessert in the Exhibit Hall

DATA-DRIVEN COUNTRY FEASIBILITY AND SITE PERFORMANCE PREDICTION

2:00 Chairperson's Remarks

Susie Campos, Associate Director, Clinical Trial Intelligence, Global Clinical Trial Leadership, Novartis Pharmaceuticals

2:05 Country Feasibility: Data-Driven Methodologies

Michelle Everill-Flinders, Director, Feasibility Center of Excellence, Pfizer

Country selection tends to go through methodological changes every couple of years. Country-level data can be a challenge to collate and address. What approaches are being taken across CROs and Pharma to increase local intelligence and application to clinical trials? Trends in emerging markets are showing that added investment is required for trial success. Pfizer has a premier site relationship program to further develop sites in emerging markets and have shown quality, enrollment, and start up success. This talk will share an overview of key items to consider in country feasibility, regional differences, and risk mitigation planning.

Sponsored by imshealth

2:30 CO-PRESENTATION: Predicting Success of an Unknown Site: The Science of Quantifying Performance Opportunity of New Sites

April Lewis, Head, Clinical Trial Optimization Solutions, IMS Health

Bettyna Jones, Senior Process Excellence Leader; Business Process Owner Close Out; Business Lead Site Productivity, Roche

Lucas Glass, Data Sciences, Clinical Trial Optimization Solutions, IMS Health

For those sites with whom a Sponsor or CRO has experience, past performance can be a critical predictor of future performance. But how is site performance potential evaluated on new sites where this information does not exist? This presentation will provide details on a comprehensive analysis performed utilizing site level recruitment patterns, detailed site demographics, and site level claims data to determine the factors that predict site performance in the absence of history or experience.

2:55 INTERACTIVE PANEL: Generating Success of an Unknown Site: The Art of Supporting New Sites in Achievement of Performance Greatness

Richard Mayewski, Associate Director, Clinical Trial Intelligence, Novartis

April Lewis, Head, Clinical Trial Optimization Solutions, IMS Health

E.B. McLindon, Vice President SMO Affairs, Clinical Research Service, ICON

Panelists will hold an open discussion on the trends their organizations are experiencing in the use of new sites, and how both process and relationship management is modified to ensure successful outcomes for both Sponsor and Site. The panel organizations do utilize new sites as a standard practice – but are the outcomes from these sites worth the investment?

Sponsored by MDCPartners

3:20 Advanced Feasibility Modelling

David Cocker, CSO, ta-Scan, MDCPartners

Feasibility is the leading contributing factor for missed timelines

and budget overruns. Feasibility basically is a confidence prediction of your downstream research network. Patient recruitment simulation software is plugging many information gaps in the feasibility departments. This presentation highlights new data sources, algorithms and visualizations to shore up your feasibility assessments.

3:35 Partners in the Study Enterprise: Sponsor, CRO and Large Site Networks

Sponsored by Frenova Renal Research

Brigid Flanagan, Senior Director, Clinical Development, Frenova Renal Research

Vicki Duvall, RN, BSN, Director, Global Site Management and Clinical Monitoring, Clinical Operations, Trevi Therapeutics, Inc.

Selecting the right partners at the beginning of a study has proven to be a success for this specialty CRO and sponsor. At the outset, the sponsor invited the CRO and the respective site networks to the kick off meeting; a novel approach. Both representative teams provided input on challenges with this study population. Having key stake holders at study start improves study success by increasing high quality data, on time deliverables, and staying within study budgets.

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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. See website for details.

5:00 Welcome Reception in the Exhibit Hall 6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries

Sponsored by QUINTILES

Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles

Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

THE ART AND SCIENCE OF SELECTING AND SUPPORTING SITES

8:25 Chairperson's Remarks

Maria Cipicchio, Strategic Consultation, BBK Worldwide

8:30 Trial & Error vs. Evidence-Based Site Selection

Jorge Guerra, M.D., Executive Director, J.G. Guerra ClinOps Management; former Senior Vice President Global Clinical Operations, Biogen Idec

The selection of high quality investigative sites is a key success factor in the execution of clinical trials. According to the Tufts CSDD, 11% of sites fail to enroll a single patient and 37% underenroll. Similar to any other major investment project, Sponsors / CROs should apply systematic due diligence to site selection. The speaker will review the most critical aspects of this process and provide practical examples, with emphasis on the availability of the study population.

8:55 CASE STUDY: Selecting Sites for a Large US Abbott Nutrition Study Recruiting from Hospitals

Sonja Acosta, Project Lead / Senior CRA, Scientific & Medical Affairs, Abbott Nutrition

This presentation will focus on lessons learned from a 3 year nutritional study involving over 100 sites selected from the US. Originally this study was intended to involve 40 sites. However, through many site and recruitment challenges, nearly 120 sites were initiated for this large nutritional study in order to meet enrollment. This presentation will focus on aspects to consider when selecting sites who are recruiting from a hospital setting. Sponsors will learn how to find the appropriate sites for studies. Sites will learn the foundation they need internally to be a successful site recruiting from an in-patient hospital setting.

9:20 CO-PRESENTATION: Innovative Approaches to Decreasing Burdens Placed on Investigator Sites

Jackie Kent, Senior Director, Clinical Development Information & Optimization, Eli Lilly

Jennifer Burgess, Senior Director, Communications & Engagement, TransCelerate

This session will provide an overview of some of the key challenges investigators face in working with sponsors, and what solutions TransCelerate has undertaken to affect change. The session will focus on efforts to reduce administrative burdens with Site Qualification & Training, and the Shared Investigator Platform. A discussion of key lessons and strategies for trial leaders from the sponsor, investigator, site and CRO communites will follow.

9:45 Integrating Multiple Data Sources to Optimize Site Selection

Sponsored by informa

Karen Currie, Executive Director, Citeline/Informa

Susan Hamilton, Research Analyst, Clinical Development Information and Optimization, Eli Lilly and Company

This presentation will demonstrate how to leverage multiple sources in order to identify top investigators in locations with large patient pools and minimal ongoing trial activity. Optimizing site selection through these methods will aid the demands of timely patient enrollment in clinical trials.

10:10 Coffee Break in the Exhibit Hall

GENERATING TRIAL INTELLIGENCE TO ACCELERATE FEASIBILITY AND INCREASE TRIAL PARTICIPATION

11:10 Chairperson's Remarks

11:15 Maximizing Use of Claims and EHR Information During Clinical Development to Improve Diversity in Trials, from Protocol to Enrollment

Devin Trejo, MBA, Director, Oncology Feasibility Lead, Development Operations, Feasibility Center of Excellence, Pfizer

There's a gap in communicating to patients the value-availability of trials. The goal to improve recruitment-retention from diverse demographic, cultural and socio-economic backgrounds benefits patients as well as improves meaningful scientific endpoints. Identifying patients, barriers to participation inclusive of orphan/rare disease, diverse ethnic populations, age, gender and integrating the patient perspective will help better address current clin ops challenges. To address these challenges we have taken a holistic approach from protocol development through patient engagement in order to improve enrollment across diverse patient populations.

11:40 CO-PRESENTATION: Generate Trial Intelligence Insight through Internal and External Trial Information to Accelerate Trial Feasibility

Jill Loftiss, Senior Director, Oncology, Clinical Ops Head, AZ/MedImmune

Jane Fang, M.D., Director, R&D IS Lead, Clinical Business Management & Analytics, AstraZeneca/MedImmune

Conducting evidence-based trial feasibility through advanced analytics is an essential investment to ensure robust clinical program and study planning in today's highly competitive environment of drug development. This talk is to present a use case of building trial feasibility informatics capability for immune-oncology programs to conduct integrated analysis to generate insight by leveraging key trial information sources and an intelligence portal to visualize competition landscape of internal and external trials and usage of countries, sites and PIs across globe.

12:10 pm Bridging Luncheon Presentation: Real World Data in Clinical Trial Planning: Game Changer?

Sponsored by imshealth

Bernadette Collins, Senior Manager, Data Services, Clinical Trial Optimization Solutions, IMS Health

April Lewis, Head, Clinical Trial Optimization Solutions, IMS Health

IMS Health is the world's largest purveyor of healthcare data. Over the past few years, we have developed a team of experts dedicated to evaluating the most influential assets to support trial feasibility and increased success in site selection and trial planning. In this session our experts will review what type of global assets are obtainable, how these assets can validate and substantiate trial planning decisions. Practical examples will be shared and case studies will be reviewed.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

> Stay on and attend ***Part 2: Improving Site-Study Activation and Performance.*** See page 24 for details.

Enrollment Planning and Patient Recruitment:

Successful Recruitment Planning, Forecasting, and Central Campaign Management

February 23-24, 2016

Patient recruitment and up-front enrollment planning are critical to drug development programs. Patient recruitment, if not adequately planned for, can extend your development timeline by a number of years. Retention of patients throughout the life of a clinical trial is essential in order to 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 Ninth 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.

MONDAY, FEBRUARY 22

Recommended Short Course*

2:00 – 5:30 pm

SC1: Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment*

** Separate registration required; please see page 5 for details.*

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes (see page 3 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

PREDICTIVE MODELS FOR PATIENT IDENTIFICATION AND DATA-DRIVEN RECRUITMENT

10:45 Chairperson's Remarks

Stewart Rosen, M.D., Vice President, Medical Affairs, Health Management Solutions, Quintiles

10:50 Leveraging EHR Data for Patient Recruitment: Don't Ask, Tell! (An Updated Case Study)

Tim McGarty, Global Director, Clinical Innovative Services, Novartis

The days of asking Investigators how many patients they have in an indication may soon be over. By leveraging EHR data, one can identify qualified patients that match a majority of your protocol's I/E criteria. The list of patients derived from the data interrogation can now be placed in the hands of the Investigator, who in turn may invite their patients in for consideration in a study. This session will give an update on an ongoing pilot where patients are identified through data mining and recruited, provide preliminary metrics, and to convey what is going well, and where there are opportunities for improvement.

11:15 Innovative Predictive Model for Subject Recruitment Risk in Clinical Trials

Mohanish Anand, Ph.D., Senior Director and Head, Feasibility Center of Excellence, Development Operations, Pfizer

One of the most significant challenges to clinical trial success is the early identification of subject recruitment risk. While progress against agreed to recruitment milestones is the traditional measure of subject recruitment success there is a need for measure to surface future recruitment risk. We have developed a comprehensive methodology incorporating a study's current state of recruitment performance with predictive algorithms to evaluate future outcomes. The predictive algorithms add elements of potential site exhaustion and subsequent subject recruitment slow down to traditional measures to provide insights to future outcomes.

11:40 CO-PRESENTATION: Enabling Strategic and Data Driven Management of Early Development Studies

Timothy Hagerty, Ph.D., Senior Clinical Program Leader, Genentech Research and Early Development Clinical Operations, Genentech

Jennifer Bell, Analytics Lead, Clinical Operations, Genentech

Recently we've shifted to a more data driven focus for study planning and management. Foundationally, this was dependent on defining the architecture and quality assessment of an integrated data warehouse. The EMMA (Enrollment Management and Measurement Application) tool was built on this platform to help teams have leading and lagging indicators on the status of the study in a visually compelling manner. This tool covers the diversity of early development studies down to a patient level view and expands to focus on the drivers at a site and country level perspective aligned to our company's deliverables. This has allowed a level of accuracy and transparency across many functional groups within clinical development, allowing us to be more agile in our decisions and more strategic in our focus

12:05 pm Platform and Processes that Drive Effective Global Patient Enrollment

Sponsored by Acurian

Todd Albin, Senior Director, Site Enrollment Optimization, Acurian

Choosing effective global patient enrollment solutions is more important than ever. An effective global patient enrollment specialist must have core competencies in marketing, localization, regulatory expertise, data handling, tracking and innovative technology, and site relationship management. During this presentation, we explore:

- A framework for pursuing success in each of these areas
- Tips for an effective global recruitment process that enhances site productivity

12: 35 Luncheon Presentation: Understanding Patients Through Social Listening: How Discoverable Data Can Lead to Effective and Efficient Patient Recruitment and Retention Campaigns

Sponsored by PRAXIS

Tricia Barrett, Vice President, Operations, Praxis Communications

As the world becomes more and more digital, it is important to consider tapping into the endless amounts of data living and being shared on the Internet. In this presentation, we'll explore how to use the data collected to determine what is useful and relevant, and then glean insights and understanding for patient-centric recruiting.

1:20 Coffee and Dessert in the Exhibit Hall

IMPLEMENTING THE NEW REALITY OF DIVERSITY IN TRIALS

2:00 Chairperson's Remarks

Bonnie Feldman, M.D., "All Things Autoimmune" Entrepreneur, DrBonnie 360

2:05 Multiculturalism and Your Trials: 3 Reasons to Care and 3 Ways to Rethink Implementation

Lisa Valtierra, Associate Director, Patient Advocacy Relations & Cross Cultural Marketing, Boehringer Ingelheim

Clinical trials have historically and consistently had abysmally low recruitment and retention rates of minorities. Why does it matter? What's culture got to do with it? How can we change this? In this presentation, we will discuss approaches to engaging, enrolling and retaining trial participants. The audience will better understand how demographic shifts in the US population reveal a disproportionate prevalence of certain diseases affecting minorities and how understanding cultural differences among communities regarding health and health behavior can- and should- change the way sponsoring companies choose investigators, trial sites, and methods of recruitment.

2:30 Understanding and Implementing the New Reality of Diversity in Clinical Trials

Karen Machelle Brooks, Senior Director, Clinical Operations Therapeutic Area Group Lead, Oncology, Development Operations, Pfizer

Understand regulatory changes from FDA and updated requirements for ethnicity/race inclusion in trial populations. How do you formalize into a clinical development plan at a company level to make it part of corporate culture by educating and training teams so that they can embrace the ethnicity value? How do you then implement at project team level and operationalize the activities to support diversity in clinical trials?

2:55 CASE STUDY: Operationalizing Diversity Initiatives in Clinical Research

Marisa Rackley, Director, Clinical Research, Global Trial Optimization, Merck

The industry understands that diversity in clinical trial participation is important. Translating those values into operational plans for particular trials has been a challenge. Building a framework for teams is critical in order to realize installation of these corporate initiatives. Real world examples and case studies will provide background for the talk.

3:20 Proactive Patient Recruitment: It's No Longer Novel-It's a Necessity

Sponsored by DAC PATIENT RECRUITMENT SERVICES an Imperial Company

Melynda Geurts, Vice President, Operations, DAC Patient Recruitment Services

Proactive Recruitment is No Longer "Novel" – It's a "Necessity" for Trial Success. I'll explore the rapidly changing landscape of patient recruitment and retention and how it's importance has shifted focus. You'll learn what your "audience" has shared with us about their behaviors in making healthcare decisions, including clinical trials. We'll also examine the importance and cost savings of proactive versus rescue recruitment planning.

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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. See website for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries

Sponsored by QUINTILES

Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles

Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

VALIDATE RECRUITMENT PLANNING AND OPS BY LISTENING TO MANAGEMENT, THE SITE-SPONSOR-VENDOR, PATIENTS, SOCIAL MEDIA

8:25 Chairperson's Remarks

Mark Summers, President & CEO, ThreeWire, Inc.

8:30 A Year in Review CASE STUDY: Evolving and Validating a Patient Recruitment Department

Diane Montross, Director, Patient Recruitment & Engagement, Shire Pharmaceuticals

Is a patient recruitment department a valuable entity for a mid-sized pharma company and how do you demonstrate value to broader clin ops enterprise? Diane will talk candidly about her first year leading the Patient Recruitment & Engagement team at Shire. She'll share her experience in growing the department to support the full development pipeline. Case study examples will include: changing the clinical teams' mindset around recruitment, incorporating recruitment into study start-up process, working with and leveraging internal depts/resources and external vendor partners to effectively expedite enrollment timelines, and proving the value of patient recruitment support for clinical studies to management.

8:55 The Power of Social Media and Content Marketing

Joseph Kim, MBA, Senior Advisor, Clinical Innovation, Eli Lilly and Company

Making use of social media isn't just about engaging in two way dialogue. It's also about creating content that's worth sharing. Come learn about Lilly's foray into a world of using stories to educate and inspire action in clinical research, through the industry's first bona fide documentary on clinical research participants.

9:20 Partnering for Success: Elements of a Healthy Sponsor/Vendor Relationship in Patient Recruitment

Katherine (Katie) Norton, Associate Director, PRE Lead, Patient Recruitment and Engagement, Shire Pharmaceuticals

Most of us spend a significant amount of time either managing patient recruitment vendors or providing patient recruitment vendor services to sponsors…but do we do it well? This presentation looks at the elements of a successful sponsor/vendor collaboration from both the sponsor and vendor perspectives. We'll examine best practices for the RFP and contracting process, start-up and in-study communication, conflict resolution, and project closeout. We'll identify common pain points in sponsor/vendor partnerships and provide recommendations for alleviating these issues for optimal outcomes.

9:45 CASE STUDY: Supporting Sites is the Key to Patient Recruitment Success

Sponsored by

Gretchen Goller, Senior Director, Patient Access and Retention Services (PARS), PRA International

The session will review the different models of site support that being utilized in clinical trials today and define the importance in which these type of supports are crucial to maximize productivity with study sites. It will also provide a case study where various elements of site support was implemented and the outcome of those efforts.

10:10 Coffee Break in the Exhibit Hall

ENROLLMENT PLANNING OPTIMIZATION FOR TARGETED POPULATIONS AND POC TRIALS

11:10 Chairperson's Remarks

Aaron Fleishman, Technology and Product Innovation, BBK Worldwide

11:15 Narrowing Enrollment in Trial Planning

Michelle Everill-Flinders, Director, Feasibility Center of Excellence, Pfizer

Narrowed and more targeted patient populations are creating increased need for innovative trial planning methodology. Data mining can drive directional decision making, but how can we ensure these patients have access to trials that are directed at their specific condition? The Novartis Signature trial and NCI MATCH program are two ways in which we, as sponsors, CROs, sites, site networks, and IRBs, have brought trials to patients.

11:40 CASE STUDY: Remote Trials to Drive Patient Centricity

Hassan Kadhim, Business Consultant, IS BP R&DM, Boehringer Ingelheim

Remote patient centric trials are gaining more ground and exposure in the past years and the industry is moving towards slowly implementing more components of them. We are trying to make a culture shift at BI with promoting clinical innovation and this talk will share insights on how to drive innovation forward in a risk-averse organization as well as insights on our remote trial model.

12:10 pm Bridging Luncheon Presentation: Harnessing Real-Time Data to Optimize Site and Patient Recruitment

Sponsored by UBC AN EXPRESS SCRIPTS COMPANY

Meghan Winegrad, Managing Director, New Solutions, UBC: An Express Scripts Company, The Lab - Express Scripts Technology and Innovation Center

When it comes to use of data for clinical trial optimization, are all data sets created equal? This presentation will illustrate how data-driven insights from more than 130 million patients can fuel smarter, more efficient solutions for patient and site recruitment. Using case studies, the presentation will demonstrate how pharmacy and prescription data can be utilized to inform protocol design, identify study sites with strong enrollment potential, and directly reach qualified patients for a given study.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

> *Stay on and attend **Part 2: Patient Engagement, Enrollment and Retention through Communities and Tech.** See page 26 for details.*

Clinical Trial Forecasting and Budgeting

Innovative Budgeting and Contracting for Cost-Efficient Trials

February 23-24, 2016

As clinical trial costs climb ever higher and industry pressure towards greater efficiency increases, the need for accurate trial forecasting, budgeting and vendor selection 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 Sixth Annual "Clinical Trial Forecasting and Budgeting" conference shares best practices and case studies on building more effective budgets and contracts as well as innovative strategies in communicating and negotiating costs with vendors and CROs.

MONDAY, FEBRUARY 22

Recommended Short Course*

2:00 – 5:30 pm SC4: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract

** Separate registration required; please see page 5 for details.*

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes (see page 6 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

FINANCIAL RISK AND CLINICAL TRIALS

10:45 Chairperson's Remarks

Jamie Cash, Manager, Clinical Planning & Resource Management, Clinical Development, R&D, Abbott Nutrition

10:50 Strategies to Mitigate Fiscal Risks in Clinical Trials: Coverage Analysis, Budgeting and Billing Compliance

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

This session is focused on processes and approaches to increase fiscal return and mitigate fiscal compliance risk for clinical trials. The ability to develop robust budgets, ensure billing compliance and adherence to CMS regulations for clinical trials remains a challenge for many clinical sites, sponsors and contract research organizations (CROs). Lack of fiscal forecasting and unspecified billing compliance practices associated with clinical trials increases the risks of fiscal audits. A risk-based approach requires not only a strategy but tools to define key indicators to measure specific risks. This session is focused on strategies for covering true costs related to clinical research and distinguishing them from routine care charges, and providing methodologies to avoid false claims and/or wrongful billing.

INNOVATIVE BUDGETING STRATEGIES

11:15 Clinical Planning and Budgeting: A Different Perspective

Jamie Cash, Manager, Clinical Planning & Resource Management, Clinical Development, R&D, Abbott Nutrition

A new approach on how to budget for a clinical study and how to accrue. There are also some differences between nutrition and pharma. I would like to explain how a nutrition company budgets and forecasts a clinical study. I would like the show the process from initial conception/idea for a clinical study all the way to approval and study start-up, and how my department (Clinical Planning and Resource Management) plays a key role. For nutrition research, we use a complex accrual payment spreadsheet. It takes into consideration the rate at which sites get up and going, and also enrollment rate.

11:40 Budget Negotiations among Clinical Trial Stakeholders

Fatima Kozar, MBA, Director, Alliance Management, Asahi Kasei Pharma America Corp.

Budget negotiations which take place during the start of a trial or as a result of a change in scope each demand a different approach in communication, process and oversight. While the most efficient budget negotiations come from managing expectations of all stakeholders, this alone is not enough to construct a budget and contract that will allow flexibility for the life of the trial. As a Sponsor, cost control is important to balance without limiting clinical trial progress (due to contract or change order delays). The talk will present alternate strategies to managing clinical trial budgets to retain transparency and drive efficiencies while ensuring Clinical Trial Stakeholder buy-in.

12:05 pm Sponsored Presentation *(Opportunity Available)*

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

1:20 Coffee and Dessert in the Exhibit Hall

WORKING WITH SITES ON CLINICAL TRIAL COSTS, BUDGETING AND CONTRACTING

2:00 Chairperson's Remarks

Lauren Goldsmith, Associate Director, Site Contracts, Portfolio Sourcing and Relationship Management, Celgene

2:05 Clinical Trial Cost Assessment – An Academic Site's Process

Serpil Tutan, Operations Manager, Pediatrics, Baylor College of Medicine

This will be a review of the internal cost assessment/estimation and budget development process. Will review the CTMS financial module, project tracking system which helps in effort estimations and identification of hidden costs for studies.

2:30 Innovative Strategies to Work with Sites on Contract Negotiations and Costs for Successful Partnering

Lauren Goldsmith, Associate Director, Site Contracts, Portfolio Sourcing and Relationship Management, Celgene

Topics to include strategies to expedite study start-up, including use of MSAs, Master Budget Agreements and Partner Site Relationships.

2:55 The Challenges of Budgeting for Clinical Trials at the Site

Michael Jay, Vice President of Contracts, Administration, RxTrials, Inc.

Clinical Trial Sites are faced with shrinking trial budgets, more procedures per protocol, more restrictive inclusion criteria, and lower enrollment goals. In addition, sites are required to take on more uncompensated work. This presentation will use case studies to illustrate the economic struggle of the modern research site and suggest solutions to common problems.

CONTRACTING AND NEGOTIATING WITH SPONSORS, CROS AND VENDORS

3:20 Optimizing CRO Relationships to Standardize Costs and Maximize Efficiencies

Lisa Sergas, Sr. Manager, Clinical Outsourcing, Medivation

This presentation will cover: 1. Considerations and Challenges for a Small Organization, 2. Possible Solutions and Outsourcing Models, 3. Expanding on Existing CRO Relationships to Standardize Costs and Increase Efficiencies, 4. Impact and Value to Sponsor Organization, 5. Tools and Templates, and 6. Key Success Factors

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries

Sponsored by QUINTILES

Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles

Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

CONTRACTING AND NEGOTIATING WITH SPONSORS, CROS AND VENDORS

8:25 Chairperson's Remarks

Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer

8:30 Keys for Successfully Negotiating Budgets and Contracts

JoAnn Pfeiffer, Ph.D., Associate Director, Clinical Research Management, Arizona State University

This session will highlight typical issues sites face when negotiating budgets and contracts with industry sponsors. We will look at key components of budgets and contracts. We will review strategies to negotiate a fair and balanced agreement and an appropriate budget.

CONTRACTING AND NEGOTIATING WITH CROs AND VENDORS

8:55 Balancing Cost Savings with Quality and Speed in the Selection of and Negotiation with CROs/Vendors

Réne Stephens, Executive Director, Global Head, Global Contracts & Outsourcing Management (GCOM), Astellas Global Development

This presentation will identify areas where the link between cost savings and quality and speed in selecting a CRO/vendor is critical for both appropriately planning the spend of a clinical trial and executing within timelines and budgets for product goals.

9:20 Revisiting the Fixed Cost Contracting Model in Order to Minimize Changes in Scope

Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer

Revisiting the process of building a fixed cost contract with a CRO: This can be a difficult process, especially when poor planning occurs, either on part of the CRO or the Sponsor. I will discuss a stepwise process for building a fixed cost contract, with involvement and agreement by all parties involved. The intent of building a fixed cost agreement is to minimize changes in scope and hold the CRO accountable for performance metrics to which they have agreed. Key elements discussed and emphasized will be country/site/patient feasibility and project specifications/key cost drivers with the end result being a fixed cost contract with a small list of parameters that would justify a change in scope.

9:45 Streamlining the Clinical Study Outsourcing Process on a Modernized Platform: Leveraging Improved Data Quality and Data Aggregation for Greater Vendor Analysis and Insight

Sponsored by HighPoint SOLUTIONS

Lior Keet, Vice President, R&D Life Sciences, HighPoint Solutions

Bill Ringbloom, Senior Life Science Solutions Delivery Lead, R&D Information, AstraZeneca

Life Sciences organizations can realize significant savings or losses when on-boarding vendor partners. Sponsors must be able to effectively and efficiently manage and analyze a vast amounts of information as part of the bid review process in order to identify the appropriate vendor/s to support the given clinical study program. However, the traditional vendor proposal process generates heterogeneous data that negatively impacts the Sponsor's ability to conduct a true vendor comparative analysis.This presentation will describe how leveraging the flexibility, agility, and usability of the Salesforce.com platform can provide a modernized solution to procurement teams, allowing them to reduce administrative oversight, improve decision making, realize true cost reductions, and better analyze historical data for improved vendor management.

> "Great topics...Great speakers...Great networking...makes for a great experience!"
>
> *Barbara W., Vice President of Patient Advocacy, Audentes Therapeutics Inc.*

10:10 Coffee Break in the Exhibit Hall

CONTRACTING AND NEGOTIATING WITH CROs AND VENDORS (CONT'D)

11:10 Chairperson's Remarks

Lisa Sergas, Sr. Manager, Clinical Outsourcing, Medivation

11:15 Reducing Impact and Occurrence of Change Orders

Charlotte French, Senior Director, Global Head, Contracting & Outsourcing, EMD Serono

In today's economic and competitive climate there are ever increasing constraints on pharma companies to reduce the cost of their clinical research activities. As a result, one area that continues to be highly scrutinized is the cost of outsourcing of clinical research activities to service providers (CROs). This often results in the need for CROs to commit to much tighter budgets, which unfortunately also translates in so many instances to an increased number of change orders. This presentation will focus on the challenges faced by both the pharma companies and CROs and how transparency in the initial stages of budgeting and contracting can help to mitigate the negative impact of change orders to both stakeholders.

11:40 Explore the Cross between Key Performance Indicators and Financial Modeling

Brenda B. Medina, Associate Director & Head of Analytics, Clinical Outsourcing and Analytics, BioMarin

This presentation will explore the cross between key performance indicators and financial modeling in order to better manage the financial health of a clinical study.

12:10 pm Bridging Luncheon - Sneak Preview: Speed Site Activation Using Collaborative Technology for Contracting and Essential Site Docs

Sponsored by DrugDev do more trials

Liss Easy, Founder, President of Site Identification and Activation, DrugDev

Finding the right sites for your trial is challenging enough. Once identified, you need to get them activated quickly so that they can start enrolling patients. Thanks to new technology including an innovative site activation module on the DrugDev platform (introduced today at SCOPE!), the days of relying on e-mail, manual spreadsheets, and hundreds of man hours to manage site activation are long behind us. Join us at lunch for an exclusive sneak preview of an exciting technology solution - built on years of proven best practices - that will enable you to automate your site activation process, and provide your global sites with an efficient, reliable, and standardized activation experience. Plus, free sandwiches with Liss!

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference.

> Stay on and attend ***Part 2: Managing Outsourced Clinical Trials.*** See page 28 for details.

2nd Annual

Implementing Risk-Based Monitoring - Part 1:

Integrating Quality into Clinical Trials

February 23-24, 2016

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. Cambridge Healthtech Institute's "Implementing Risk-Based Monitoring – Part 1: Integrating Quality into Clinical Trials" conference provides guidance on how to proactively build quality standards into clinical trials with emphasis on the latest quality standards established by TransCelerate and CTTI, thereby laying the foundation for successful risk-based monitoring.

MONDAY, FEBRUARY 22

Recommended Short Course*

2:00 – 5:30 pm SC3: Views and Conversations on Risk-Based Monitoring

** Separate registration required; please see page 5 for details.*

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes (see page 6 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

BUILDING QUALITY INTO CLINICAL TRIALS

10:45 Chairperson's Remarks

David Nickerson, Senior Director, Portfolio & Vendor Quality, Pfizer

10:50 A TransCelerate Issue Management Conceptual Framework – From Challenges to Opportunities (Taming from Within)

Susan Callery-D'Amico, Vice President, R&D Quality Assurance, AbbVie

This session will: 1. summarize the challenges within our industry today by complexities in development, 2. explain how a type of triage mechanism can tame and sort the plethora of issues to focus on issues that impact from the clinical development space, and 3. refresh the use of methodologies that should bring about a decrease in issues that have an impact and consideration that effective management of issues can be the key driver for ensuring a state of control, continuous improvement, and confidence is data.

11:15 A Proactive Application to Clinical Quality

Janis Little, Vice President, Global R&D Quality, Allergan

This session will focus on the benefits of a quality system that engages and supports all aspects of clinical development through ensuring that "quality" is owned by the entire organization, not solely the Quality unit. Moving from proactively reacting to proactively assessing and preventing quality issues that can significantly impact a trial, program or business can be a challenge. While many organizations believe they proactively manage risk, in reality most employ a robust ("proactively reactive") process for addressing quality issues as they arise. A quality system that is well-built, fit for purpose and continually assessed and monitored for suitability and effectiveness should result in proactively anticipating and preventing quality issues before they occur.

11:40 Evaluating the Benefits of a Systematic Approach to Proactive Quality Risk Management in Clinical Trials

David Nickerson, Senior Director, Portfolio & Vendor Quality, Pfizer

The logic and benefits of Quality by Design and proactive analysis and mitigation of risks to GCP quality are broadly recognized. There is, however, relatively little information available demonstrating the impact of such efforts on quality outcomes in clinical trials. This presentation will outline Pfizer's systematic process for proactive quality risk management in clinical trials and describe analytical methods to evaluate the impact of this approach on quality.

12:05 pm Integrating Mobile Application Generated Patient Data into your Risk Based Monitoring Strategy

Sponsored by BIOCLINICA

Ron Burns, Vice President, Product Management, Bioclinica

From the newest biosensors to complete digital health records, innovative patient-centered mobile applications are connecting patients with physicians and other health providers. Integrating this data into your clinical applications, such as the patient diary in your EDC system or as alerts in your Risk Based Monitoring application, now offers new horizons in patient safety and trial quality.

12:35 Luncheon Presentation: Raising the Bar for Central Medical Review

Sponsored by COVANCE SOLUTIONS MADE REAL

Victor Lobanov, Executive Director, Data Sciences, Covance

Periodic review of clinical data is critical for patient safety and data quality. Covance's Medical Review is aligned with the FDA guidance for a greater role of central monitoring and provides timely, integrated views of all relevant clinical data along with the unique, interactive capabilities to detect outliers and trends, create and analyze cohorts, execute review workflows, annotate clinical data, and communicate observations.

1:20 Coffee and Dessert in the Exhibit Hall

CASE STUDIES ON IMPLEMENTING QUALITY BY DESIGN

2:00 Chairperson's Remarks

David Nickerson, Senior Director, Portfolio & Vendor Quality, Pfizer

2:05 Quality by Design Case Study: Can You Really Create a Bulletproof Quality Protocol?

Sheri Kuss, Associate Director, Clinical Process Development, Teva Pharmaceuticals

This session will provide a case study implementing QbD principles which tested three published consortium protocol assessment tools during the development process. The case study incorporates risk management principles while 'challenging' the protocol through its development. The presentation will include a discussion of the development of Quality Risk Indicators, the input from the many roles within Clinical Operations, as well as the challenges and downstream benefits of producing a Quality Protocol.

2:30 CO-PRESENTATION: How to Implement a Risk-Based Quality Management Program (RBQM): From Development to Implementation and Everything in Between

Brian Nugent, Associate Director, PALM, Clinical Operations, Gilead Sciences

Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences

Over the past several years much attention has been directed towards introducing and defining the concepts and day-to-day tools required to carry out Quality by Design (QbD) and Quality Risk Management (QRM) activities, however, many companies have not established a unified risk-based quality management (RBQM) framework based on a holistic approach within Clinical Operations. Gilead began development of this program and framework in 2014 and has now implemented planned components. Successful implementation of such a program cannot occur without proper training and a change management plan. This presentation will address the following topics: 1. RBQM framework and its components, 2. Its impact to Clinical Operations, 3. Change Management: Training and adoption strategies, and 4. How to implement an RBQM program for your organization.

3:20 Pragmatic Approaches to Risk-Based Monitoring

Sponsored by PerkinElmer For the Better

Masha Hoffey, Ph.D., Senior Project Manager, Clinical Informatics, PerkinElmer

In this presentation we will explore successful approaches to implementing Risk-Based Monitoring. Case studies from large, midsize and smaller companies will be discussed.

3:35 A Mid-Size CRO's Roadmap to Successfully Implementing Risk-Based Monitoring

Sponsored by Advanced Clinical

Cheryle Evans, Vice President, Clinical Operations, Clinical Operations, Advanced Clinical

This presentation will describe the strategy and tactics utilized to launch a RBM offering to a mid-size CRO's client base. The implementation included a two-part approach. First, the establishment of the process inclusive of RBM-tool development and a comprehensive RBM Plan, and second, the selection of an analytical tool to organize data from disparate sources and develop a dashboard of key risk indicators (KRIs).

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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. See website for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries

Sponsored by QUINTILES

Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles

Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

TRANSLATING QUALITY FOR RISK-BASED MONITORING

8:25 Chairperson's Remarks

Crona O'Conallain, Director, Global Data and Safety Monitoring, Quintiles

8:30 Integrating Quality to Expedite Innovation

Ann Meeker-O'Connell, MS, Head, Risk Management and External Engagement, Bioresearch Quality & Compliance, Janssen Pharmaceuticals, Inc.

The session will: 1. Provide an update on key quality initiatives at the trial (CTTI clinical quality by design) and enterprise levels (TransCelerate clinical QMS conceptual framework). 2. Describe the relationship between clinical QMS, clinical QbD, and risk-based monitoring and how in combination, these activities can enhance the quality and efficiency of clinical development and drive innovation in clinical development.

8:55 ICH E.6 Addendum – What Changes is Your Organization Facing

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

ICH GCP (E.6) is currently under revision with an addendum that is due for release in November 2016. ICH GCP forms the basis for companies to undertake clinical trials and so it is essential that preparations are made to build the changes from the addendum into our processes. The main changes and the focus of this presentation are in the area of risk based monitoring. RBM was first addressed by regulatory bodies in 2011 for clinical trials. We will cover the changes and preparations to be made.

9:45 Virtual Site Workspaces Re-Inventing Remote Monitoring: Eliminate Patient De-Identification in Source Documents Needed for Verification and/or Review

Sponsored by INTRA LINKS

Andrew Mitchell, Life Sciences Practice Lead, Intralinks

Dan Sfera, CEO, The Clinical Trials Guru

10:10 Coffee Break in the Exhibit Hall

TRANSLATING QUALITY FOR RISK-BASED MONITORING

11:10 Chairperson's Remarks

Crona O'Conallain, Director, Global Data and Safety Monitoring, Quintiles

11:15 Separating Risk Assessment from Risk-Based Monitoring

Jacqueline Gough, Advisor, Clinical Risk Management, Eli Lilly and Company

A discussion of why Risk Assessment should not be tied to risk-based monitoring and the benefits of having separate roles, processes, and procedures for this activity. Included will be a discussion of some of the benefits and challenges of separating these tasks.

11:40 INDUSTRY SURVEY: An Examination of Current Organizational Approaches Driving Risk-Based Monitoring Programs (2013 to 2015)

Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC

This presentation will examine the results of an industry survey about risk-based monitoring practices covering such topics as: 1. Risk assessment and mitigation approaches, 2. Types of RBM approaches, 3. Evolving roles and responsibilities, 4. E-Data sources being used, and 5. Types of data analytic approaches being used in central monitoring programs.

12:10 pm Bridging Luncheon Presentation : How One ClinOps Team Returned 100% of Studies to Within Risk Threshold: A Next Gen Monitoring Case Study

Sponsored by comprehend

Rick Morrison, CEO, Comprehend

Bruno Gagnon, Executive, Clinical Operations, Xenon Consulting

A recent survey of 255 Life Sciences ClinOps executives: of the 34% that have an RBM initiative in place, 68% still use latent, manual spreadsheets. Only 11% have successfully automated their RBM program. Our case study details how a successful ClinOps team automated their next generation risk and centralized monitoring program. After only 10 weeks, they were continuously and efficiently optimizing enrollment, compliance, site productivity to lower risk and increase speed to a quality result.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

*> Stay on and attend **Part 2: Implementing Risk-Based Monitoring**. See page 30 for details.*

E-clinical technology is getting more sophisticated every year; and every year it faces new challenges induced by the changing landscape of the clinical research industry and healthcare IT in general. Digitalization of healthcare data, mobile data capture technologies, and cloud storage of data, are a few of the main technological advances that influence clinical research informatics. Cambridge Healthtech Institute's 8th Annual "Clinical IT Strategy and Governance" conference is designed to bring together clinical research informatics experts to discuss the challenges and find solutions necessary to navigate and thrive in this rapidly changing environment.

MONDAY, FEBRUARY 22

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes **(see page 6 for details)**

9:45 Grand Opening Coffee Break in the Exhibit Hall

DATA ANALYSIS TO ENABLE CLINICAL RESEARCH DECISION MAKING

10:45 Chairperson's Remarks
Jaydev Thakkar, IS Director, R&D Informatics, Amgen

10:50 Building a Trial Design Library to Optimize Protocol Development and Clinical Program Strategic and Operational Positioning In Immune-Oncology TA
Joint Presentation: Jill Loftiss, Senior Director, Oncology Clinical Ops Head, AZ/MedImmune
Jane Fang, M.D., Director, R&D IS Lead, Clinical Business Management & Analytics, AstraZeneca/MedImmune
As industry competition in the Immuno-oncology field becomes fierce, trial protocols become much more complex to validate potential new medicines against right patient population. This presentation is about accelerating better protocol development by building a Trial Design Library to extract, compare and analyze the key study design information. Trial Design Library provides a reference of key inclusion and exclusion criteria by disease areas and indications for the study teams. It also provides deep analysis of patient population requirements to optimize trial design and enable strategic planning and execution of clinical programs that could be potentially competing with or complementing each other.

11:15 Data Visualization Enabling Clinical Scientists in Decision Making
Francis Kendall, Global Head, Statistical Programming and Analysis, GLIDE Future Investigation Team Lead, Genentech
This talk will describe how Roche Biometrics is helping promote the use of visiualisation tools to help gain greater insight and quicker decision making on clinical trial data. I will explain how and when we propose each tool should be used and give a few examples on how these approaches are helping the business. Tools that Roche currently use in this area are Spotfire, Tableau, SAS, & R Shiny.

11:40 Streamlining Clinical Trials by Leveraging New Technologies
Jaydev Thakkar, IS Director, R&D Informatics, Amgen
Today's competitive R&D landscape demands effective use of technology to reduce cost and cycle time from Clinical Development phase. This presentation will take you on a journey to implement an integrated Clinical Development platform with a suite of new, integrated technologies that streamline the execution of clinical trials from study design & feasibility through study conduct & analysis. The discussion will also include the exploration of new, innovative digital health solutions for the next generation of clinical trials and patient engagement (e.g. mHealth Apps, Wearables & Sensors).

12:05 pm Putting Patient and Site Engagement at the Center of Your Clinical Trial
Sponsored by Clinical ink
Jonathan Andrus, BA, MS, CQA, CCDM, Chief Data Officer, Clinical Ink
This presentation will focus on exploring recommendations and ideas around ways to use technology to ensure that site staff are engaged in the collection of clinical trial data in a manner that reduces workload, redundancies and the need for transcription of data. We will explore how to enhance the patient experience in clinical trials and methods in which sites can engage patients using technology. These include medication reminders, updates on the study, site staff interactions with patients via messaging, informational videos and interactive media all of which help to increase patient retention and satisfaction.

12:35 Luncheon Presentation: EHR-EDC Integration an eSource Imperative
Sponsored by OmniComm eClinical Solutions for Life™
Keith Howells, Senior Vice President, Product Development, OmniComm Systems, Inc.

1:20 Coffee and Dessert in the Exhibit Hall

ADOPTION AND IMPLEMENTATION OF INNOVATIVE APPROACHES

2:00 Chairperson's Remarks

2:05 How the Advancement of Technology Will Impact the Business Model of Clinical Trial Execution
Munther Baara, Senior Director, Development Business Technology, Pfizer
There is no day passes by where we don't hear about new technology and initiatives helping business bridge the gap and evolve the organization though digital transformation. Will the new digital advancement, Internet Of Things (IoT), mobile, social media, advanced analytics/big data and cloud disrupt savvy companies and transform the way they do business? I will discuss the new paradigm shift, which requires us to move beyond our current thinking and assumptions to find ways to pave the way to transform the way we execute Clinical Trials.

2:30 Adoption of Innovative E-Clinical Technology: Case Studies
Kelly Kirsch, MPH, Consultant-Shared Investigator Platform, Clinical Development Information and Optimization, Eli Lilly and Company
Adopting and implementing new technologies in Clinical Research can pose challenges given the various internal and external stakeholders. In this session, tactics will be shared to describe an Organizational Change Management approach to implementing two technology solutions in a clinical research organization at Eli Lilly and Company. The Presenter will describe lessons learned from implementing the Shared Investigator Platform and an e-Trial Master file.

2:55 PANEL DISCUSSION: Standardizing Clinical Trial Operations Data Across the Industry: A Look Inside the TransCelerate Investigator Registry Data Mode
Panelists: Elisa Cascade, MBA, President, DrugDev Data Solutions,
Kelly Kirsch, MPH, Consultant-Shared Investigator Platform, Clinical Development Information and Optimization, Eli Lilly and Company
Munther Baara, Senior Director, Data Management & Reporting, Pfizer
This session will take a look into the data model that sits behind TransCelerate's Investigator Registry (IR), a service which enhances the Shared Investigator Platform (SIP) and accelerates identification and recruitment of qualified investigators through data standardization and integration. At the heart of the data model is the need to identify a unique person through a front-end identity provider (Exostar) and the ability to link this person with their historical information from other data sources via the DrugDev Golden Number for persons and facilities.

3:20 Simplifying the Clinical Trial Regulatory Submissions Process
Sponsored by DATATRAK from Concept to Cure.
Barbara Norris, Manager, Sales Operations, DATATRAK
The regulatory submission process can be time-consuming, stressful and tedious. A truly unified Clinical Trial Management System (CTMS) can deliver efficiencies through powerful reporting, elimination of redundant tasks and reduction of risk due to human error. We will cover the follow key topics; building a reusable repository, simplifying data collection, streamlining submission tracking and designing for actionable data.

3:35pm Sponsored Presentation *(Opportunity Available)*

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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. See website for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

> "SCOPE helps foster existing relationships and build new ones. The level of sharing and willingness to collaborate among companies and site/PI is a key reason I attend."
>
> *Amanda H., Associate Director, Study Start-up, Alkermes*

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries
Sponsored by QUINTILES
Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles
Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

VALUE ANALYTICS IN CLINICAL DEVELOPMENT

8:25 Chairperson's Remarks
Aman Thukral, Senior Manager, DSS, Abbvie

8:30 Visual Analytics: Sailing Big Data in Clinical Research
Charlie Romano, Senior Director, Clinical Trial Management, Clearside Biomedical
Whether designing a hot new study or standing in the remnants of a terminated project, determining whether a program is excelling or stalling 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.

8:55 eClinical Optimization to Build Operational Excellence through Smart Integration and Performance Driven Dashboard
Ron Bourque, Associate Director, RDI, AZ/MedImmune
eClinical strategy and implementation is a key component to modernize and accelerate clinical trial conduct and delivery. This talk is to present a use case of designing and implementing an eClinical optimization strategy and roadmap to enable meaningful use of trial information to answer important business questions. The use case will share the key elements to achieve a successful implementation of eClinical strategy.

9:20 A Robust Implementation of Risk-Based Monitoring
Dimitris K. Agrafiotis, Ph.D., Vice President and Chief Data Officer, Covance
We present a new risk-based monitoring platform that uses advanced data integration, analytic, and visualization capabilities to provide unprecedented access to all clinical trial data, enable comprehensive asssessment and mitigation of risk at the study, site, and patient level, and allow central monitors to direct CRAs to the right locations with the right frequency to assure patient safety, data quality and protocol compliance with greater insight, speed, and efficiency.

9:45 Leveraging Clinical Architecture to Optimize Your Organization's Business Processes and Technology Effectiveness
Sponsored by PARAGON SOLUTIONS Value Envisioned. Value Delivered.
Chris McSpiritt, Associate Director, Life Sciences R&D, Paragon Solutions, Inc.
Pharma organizations face challenges when selecting and implementing technology; including the emergence of disruptive technologies, complex outsourcing models and industry initiatives that impact the way research is conducted on a global scale. More often companies are implementing new technology without considering the downstream impact on compliance, operational efficiency or long term return on investment. Learn how clinical architecture can help organizations improve the effectiveness of their IT/R&D planning cycles and overall solution life cycle management.

10:10 Coffee Break in the Exhibit Hall

ERA OF NOVEL CLINICAL DATA REPOSITORIES

11:10 Chairperson's Remarks
Aman Thukral, Senior Manager, DSS, Abbvie

11:15 Metadata Repository and Clinical Data Repository - Taking Clinical Development to Next Generation
Joint Presentation: Malcolm Garden, Principal Architect, IS Lead for CDR Project, Amgen
Dylan Rosser, Director, Global Development Organization, Business Process Lead, CDR project, Amgen
Standardized and integrated clinical and operational data is vital to eliminate information silos and streamline clinical trial delivery, reduce cycle time throughout the lifecycle of a clinical program. This presentation will provide an overview of metadata and clinical data repository implementations, lessons learned and strategic benefits that make this journey worthwhile.

11:40 Next Generation eClinical Data Platform for Clinical Data Aggregation to Generate Meaningful Insights
Nareen Katta, Associate Director, Data and Statistical Sciences, Abbvie
Clinical data repositories gather data from multiple sources like EDC, CTMS, IRT, Drug Supply system and in order to standardize data in unified format to generate meaningful insights is a tedious task. This case study discusses the challenges and implementation experience of AbbVie in developing next generation data warehouse.

12:10 pm Bridging Luncheon Presentation: Pairing Analytics: Solutions Designed to Better Navigate Clinical Trial Data
Sponsored by PPD
Thomas J. Gfroerer, Executive Director, Data Analytics, PPD
Tammy Jackson, Director, Preclarus Development, Biostatistics, PPD
Sponsor companies and CROS have distinct data needs throughout the conduct of a clinical trial. Analytic solutions and visualization tools can help with efficient exploration of the data. This talk will show how coupling uniquely designed analytic solutions can help deliver new approaches to risk surveillance, study management and monitoring safety trends for both sponsors and CROs.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

> *Stay on and attend **Part 2: Clinical Data Technology and Integration.** See page 32 for details.*

5th Annual

Managing Late Stage Research and Observational Studies

Strategies and Technologies to Enable Non-Interventional Studies

February 23-24, 2016

Non-interventional studies are an integral part of clinical development programs and product development plans. Product safety profiles, comparative effectiveness data as well as health economic evidence obtained from non-interventional studies, are essential for multiple stakeholders. These stakeholders include but are not limited to the following: regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's Fifth Annual "Managing Late Stage Research and Observational Studies" conference is designed to facilitate knowledge exchange around all aspects of observational research, from the designing and managing of post-approval studies, to applying the data obtained to pivotal business and medical decisions.

MONDAY, FEBRUARY 22

7:00 – 9:00 pm Welcome and Networking Happy Hour on the Riverwalk hosted by CHI, DrugDev and Praxis

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes (see page 6 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

WHY AND HOW OF OBSERVATIONAL RESEARCH

10:45 Chairperson's Remarks

Christopher-Paul Milne, Ph.D., Director, Research, Tufts CSDD, Tufts University School of Medicine

10:50 Building and Leveraging Data Resources and Capabilities: Patients, Partners and Platforms!

Cathy Critchlow, Executive Director, Amgen Center for Observational Research

We have built a platform to meet increasing demand for real world data to support drug development and portfolio prioritization. Insurance claims and electronic medical record databases are put into a 'data lake', converted to a common data model, and powered by an architecture enabling rapid, simultaneous processing of large datasets. Creation of patient cohorts in conjunction with design, analytic and visualization tools enables broad, enterprise-wide access to data resources to proactively address key questions for internal and external stakeholders.

11:15 Demonstrating Effectiveness with Real World Evidence

Boxiong Tang, M.D., Ph.D., Senior Director, Growth Markets/GHEOR, Teva Pharmaceuticals

Real-world studies provide a different perspective on value than randomized clinical trials (RCTs). They reflect real life utility of drugs and for that reason they are increasingly viewed as viable alternative and complement to RCTs by many decision-makers, particularly payers. This presentation will share Teva's best practices and strategies to study effectiveness of therapeutics with real world evidence.

11:40 Impact of Post-Approval Evidence Generation on the Biopharmaceutical Industry

Christopher-Paul Milne, Ph.D., Director, Research, Tufts CSDD, Tufts University School of Medicine

Meeting marketplace demands for proving the value of new products requires more data than the industry has previously had to routinely produce for a variety of post-approval decisions and an array of health care system stakeholders. These data include evidence from comparative effectiveness research (CER), including randomized, controlled trials, pragmatic clinical trials, observational studies, and meta-analyses. We report the findings of an industry working group that examined the burden of growing demands for CER evidence, the acceptability of post-approval study types, payer-specific issues related to CER, communication of data being genegenerated post-approval, and methods used for facilitating post-approval evidence generation.

12:05 pm Physician Participation in Real World Research – A Global Case Study

Sponsored by

Kathleen Mandziuk, Senior Director, Scientific Affairs, PRA Health Sciences, Late Phase Services

One of the most challenging aspects of non-interventional research is gaining and retaining physician interest in participation. This presentation will cover the key aspects of site recruitment for observational studies, and the impact of various factors such as outreach methods/messaging, study design, target indication and country differences. A variety of case studies and examples will be outlined and presented.

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

1:20 Coffee and Dessert in the Exhibit Hall

HARNESSING THE POWER OF EXISTING DATABASES

2:00 Chairperson's Remarks

Jeff Luross, Senior Director, Operations, Late Phase Services, PRA Health Sciences

2:05 Strengths and Limitations of Various Types of Existing Databases

Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca

Fully understanding the strengths and limitations of various types of these existing databases will help pharmaceutical companies and academic researchers to find the best suitable database and reasonable study design to address clinical research questions with high quality. In some cases, it is necessary to combine two or more types of existing databases or databases from multiple countries to address complex research issues. The presentation will discuss considerations in database selection, study design and analytic approaches, study outcome ascertainment, reduction of selection bias and information bias, and observational research activities based on multiple databases.

2:30 Identifying Drug Use in Hospital Settings in Denmark: A Challenge and a Promise.

Uffe Heide-Jørgensen, Ph.D., Biostatistician, Clinical Epidemiology, Aarhus University

The unique constellation of population-based registries, universal health care, and individual-level linkage have placed Denmark and other Nordic countries at the forefront of clinical and observational research. As in most routine databases, identification of drugs dispensed in hospitals remains a challenge in Denmark, as those dispensations do not feed into the traditional outpatient dispensation registries. Harnessing existing routine registration mechanisms, including electronic health records, may help overcome this limitation in the near future.

2:55 PANEL DISCUSSION: Meeting the Evidentiary Needs of Multiple Stakeholders by Better Non-Interventional Studies

Moderator: Christopher-Paul Milne, Ph.D., Director, Research, Tufts CSDD, Tufts University School of Medicine

Topics to be discussed include but are not limited to the following:

- What are key considerations and approaches to balance scientific and commercial values of non-interventional studies
- What are common utilization of non-interventional studies in supporting clinical development program
- How can evidences generated from non-interventional studies be used in discussions with regulatory agencies during product development and post marketing in support of establishing product benefit risk profile, continual safety monitoring, and risk management and mitigation activities, as well as fulfilling regulatory post marketing safety requirement (PMRs and FUMs)

3:20 Observational Studies; an Optimal Cost Effective Operational Approach

Sponsored by

Hady Khoury, Vice President, Research & Alliance Support Services, PA&OR Project Management Commercialisation & Outcomes, ICON

3:35pm Sponsored Presentation *(Opportunity Available)*

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration

7:45 Breakfast Presentation: Operational Excellence in Real-World Research: Observational Studies & Registries
Sponsored by QUINTILES
Radha Puri, Associate Director, Americas, Real-World Evidence Strategy Unit, Real-World Late Phase Research, Quintiles
Obtaining and maintaining operational excellence in real-world research requires connecting insights for better outcomes. Understand the challenges to mitigating risks while maximizing data quality and hear how to achieve and maintain quality standards in observational studies and registries while minimizing site burdens.

STREAMLINING OPERATIONAL ACTIVITIES

8:25 Chairperson's Remarks
Alicia Gilsenan, Ph.D., Senior Director, Epidemiology, RTI Health Solutions

8:30 Similarities and Differences in Operationalizing Observational Studies Versus Clinical Trials
Alicia Gilsenan, Ph.D., Senior Director, Epidemiology, RTI Health Solutions
While many aspects regarding the implementation of clinical trials and observational studies are similar, there are several aspects that require additional consideration. This talk will highlight strategies for the implementation and management of observational studies as compared to clinical trials from start-up activities through data collection and reporting to minimize selection bias, information bias and impact of confounding on the final results.

8:55 Investigator Initiated Trial Management – A Medical Affairs Perspective
Lynn Bass, Director, Medical Affairs and Global Grants Manager, Jazz Pharmaceuticals
Many Investigator Initiated Trial (IIT) programs initiate with a concept which is received from the field by a medical affairs staff member. From here, the concept is facilitated by the research grant manager through a series of reviews and audits from a variety of medical, clinical, and research personnel. This session will focus on a review of the complexities, communications, and best practices from the receipt of an IIR concept through the completion of the study. Session objectives include:

- Review the role of the research grant manager and the field medical role in the IIT process
- Review how the concept is reviewed by a cross-functional set of stakeholders
- Review the differnet role of the investigator in company sponsored research verses IIT

9:20 Better Data Faster - Using Claims Data to Accelerate Observational Research
Donny Chen, MBA, Director, Medical Affairs Research Operations, PPD
As various stakeholders seek to substantiate the effectiveness, safety, quality-of-life, and economic benefits of new treatments, there's growing pressure to find the optimal observational study design to meet this need. This talk will highlight how a robust claims database can be a powerful complement to a prospective observational study by accelerating site/patient identification, minimizing data collection burden, and linking resource utilization and cost data to clinical endpoints.

> "Year after year, SCOPE is the best meeting for finger-on-the-pulse Clinical Operations insight."
>
> *Fran R., Associate Director, Paragon Solutions*

9:45 Patient Centric Post Approval Research – It's Time to Rethink How Post Approval Studies Are Done
Sponsored by BIOCLINICA
Nayan Nanavati, COO, Post Approval Services, Bioclinica
Post approval research is an evolving science. Over the last decade, post approval studies have evolved, in their objectives, complexities and costs. There have been significant changes in regulatory requirements as well. Yet, the approaches and tactics used to conduct post approval studies has remained virtually the same. With an evolving role and complexities of post approval studies, and a shift toward patient centric outcomes, it's time to rethink the cookie cutter approach and implement innovative, technology-driven research to increase efficiencies, maximize outcomes, and address data collection from the patient perspective.

10:10 Coffee Break in the Exhibit Hall

PATIENT-CENTRICITY IN OBSERVATIONAL RESEARCH

11:10 Chairperson's Remarks

11:15 Leveraging the Patient Perspective to Uncover What Matters Most
Megan Leone-Perkins, Ph.D., Chief Scientist, Corporate, HealthiVibe, LLC
The sterile world of research can sometimes leave even the most experienced and educated scientists operating inside of a vacuum. The clinical knowledge of a disease does not always reveal issues that matter most from a patient perspective and collecting standard PRO data during a Phase III study does not always reveal outcomes that are meaningful to patients. Harnessing real-world insights from those who live with a disease or condition can result in unexpected outcomes and newly defined endpoints. Engaging in a real world research effort collecting insights directly from patients can help sponsors better understand patient perceptions.

11:40 Developing Quality Tools for Patient-Reported Prospective Data Collection
Mark A. Price, MA, MEd, Senior Director, Surveys and Observational Studies, RTI Health Solutions
In designing patient-centered prospective observational research, it is critical to take the necessary time to develop solid survey and diary tools. Adequate pre-planning and cognitive testing (including input directly from patients at the design stage) ensures that quality data meeting a study's objectives emerge during implementation.

12:10 pm Bridging Luncheon Presentation: Pharmacoeconomic Assessment through Market Approval and Beyond: Theory and Operations
Sponsored by MEDPACE
Matthew Page, Epidemiologist, Biometrics, Medpace

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

*> Stay on and attend **Part 2: Leveraging Existing Data for Clinical and Observational Research**. See page 34 for details.*

SYMPOSIUM *NEW*

Inaugural

Managing Biomarker-Driven Clinical Trials

Overcoming Scientific and Operational Challenges from Phase 0 through to NDA and Launch

February 23-24, 2016

TUESDAY, FEBRUARY 23

The concept of personalized or precision medicine, with medical decisions, practices, and/or products being tailored to the individual patient, has brought to life several types of clinical trials that involve biomarkers. Effective management of these trials can be complicated and requires specific operational approaches. CHI's Symposium "Managing Biomarker-Driven Clinical Trials" is designed as an educational event to discuss solutions to overcome operational and scientific challenges with various types of studies including trials with biomarker-based stratified trials, trials for biomarker discovery, and trials with biomarkers as end points. Study design specifics and operational challenges in biomarker-involved clinical trials will be discussed by experts from pharmaceutical companies and academic centers of clinical research excellence.

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes **(see page 6 for details)**

9:45 Grand Opening Coffee Break in the Exhibit Hall

STRATEGIZING DESIGN AND OPERATIONS IN BIOMARKER-DRIVEN TRIALS

10:45 Chairperson's Remarks

Rebecca Blanchard, Ph.D., Executive Director, Genetics and Pharmacogenomics, Head, Clinical Pharmacogenomics, Merck & Co., Inc.

» 10:50 KEYNOTE PRESENTATION: OPERATIONAL CHALLENGES AND OPPORTUNITIES IN DESIGN AND IMPLEMENTATION OF BIOMARKER SELECTIVE CLINICAL TRIALS

Bardia Akbari, Pharm.D., Vice President, Product Global Development, Oncology Genentech, Inc.

Advancements in diagnostic technologies and greater understanding of the underlying molecular pathophysiology of diseases has led to propagation of discovery and development of targeted therapies. Despite the potential to clear higher efficacy bar, early and late stage development of target therapies in biomarker selective patient populations introduces unique scientific, operational, regulatory, and commercial challenges. In this talk we will examine some of these challenges.

11:30 Pharmacogenetics as Innovative Clinical Drug Development

Rebecca Blanchard, Ph.D., Executive Director, Genetics and Pharmacogenomics, Head, Clinical Pharmacogenomics, Merck & Co., Inc.

Our understanding of the consequences of human genetic variation, on the practice of interventional therapeutic medicine, is maturing at a rapid pace. Today, many drug development efforts include evaluation of genetic determinants of drug response. Pharmacogenetic (PGx) data are now being used to impact drug development strategy and the clinical use of drugs. This presentation will highlight methods used to leverage PGx in clinical research and thereby generate data that create new scientific and commercial opportunities.

12:10 pm Interactive Discussion: Clinical Operations to Adjust to the Concept of Personalized Medicine

Topics to be discussed include but are not limited to the following:

- Applying the concept of personalized/precision medicine to clinical development
- Unique operational challenges of early and late stage development of therapies in biomarker selective patient population
- Leveraging pharmacogenomics in clinical research
- Operationalizing biomarker-based randomization
- Multi-drug multi-sponsor trials: new paradigm leads to new challenges
- Collaboration and exchange of information regarding molecular profiling and treatment selection
- Regulatory challenges and impact on FDA submission strategies
- Commercial challenges and solutions

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

1:20 Coffee and Dessert in the Exhibit Hall

LOGISTICAL AND CLINICAL INFORMATICS CONSIDERATIONS

2:00 Chairperson's Remarks

Michael Swietek, Principal Scientist, Informatics, Pfizer, Inc.

2:05 Operationalizing Precision Medicine

Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer

This presentation will cover logistics considerations related to sample management and dealing with central laboratories, as well as clinical informatics requirements and adjustments required for clinical trials in the era of precision medicine. Both US and global trials will be discussed.

2:35 Technology Framework for Sample and Biospecimen Management and Tracking

Kris Kokomoor, Specimen Management Product Owner, Clinical Trial Solutions, Operations CoE, Pfizer Worldwide Research and Development

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.

3:05 Clinical Sample Tracking and Compliance to Enable Data-Driven Drug Development

Daniel Joelsson, Director, Global Business Planning & Operations, MedImmune

MedImmune is implementing a solution to track clinical samples across the complex system of labs and other service providers that support our studies. Knowing what samples we have at any time as well as being able to reconcile what samples we should have is a prerequisite to support biomarker-driven clinical trials for precision medicine. This talk will highlight the capabilities of our approach as well as some of the lessons learned during implementation.

3:35 Interactive Discussion: Biospecimen Handling Technology and IT Framework in Biomarker-Driven Trials

Topics to be discussed include, but are not limited to, the following:

- Clinical informatics solutions for additional logistics challenges of biomarker-driven clinical trials
- Managing sample collection to support clinical trials
- Assuring the quality and the sample – test – result flow
- Addressing the issues related to global trials
- Widely available and in-house IT application for sample management

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration and Morning Coffee

PROTOCOL DESIGN AND OPTIMIZATION IN BIOMARKER-DRIVEN TRIALS

8:25 Chairperson's Remarks

Inaugural

Managing Biomarker-Driven Clinical Trials

Overcoming Scientific and Operational Challenges from Phase 0 through to NDA and Launch

February 23-24, 2016

8:30 Statistical Designs of Master Protocols and on the Design of the SWOG Lung Master Protocol (S1400; Lung-Map)

Mary Redman, Ph.D., Lead Statistician, Lung Cancer Committee Southwest Oncology Group, Lead Statistician, Lung Map Trial, Fred Hutchinson Cancer Research Center

The Master Protocol concept has been around for a long time. The idea behind a master protocol is to gain efficiencies by utilizing one protocol that can be updated as new studies or objectives arise. However, the perceived utility of master protocols has been limited until recently. Genomic characterization studies conducted over the last 10 years have revealed a number of therapeutically targetable alterations, many of which have received therapeutic validation. This has led to a transformation of our standard of care approach for these patients that are now routinely molecularly genotyped in an attempt to pair the identified mutation with the appropriate targeted therapy. The rate of potentially drug-able target identification and associated therapies is increasing and general consensus is that now is the time for master protocols to facilitate speed in development of new therapies and to bring new drugs to patients more quickly. Master protocols are often separated into two categories: umbrella protocols which evaluate multiple drugs and targets among patients with the same disease type and basket protocols which evaluate drugs/target pairs among patients defined by their genetic alternation and across disease type (so-called histology agnostic trials). However, the underlying statistical design of such studies can be broadly categorized into confirmatory and discovery-focused design. The specific details of the design are motivated by the objectives of the study and study population. In this talk we will discuss the basic design options and possible design features for master protocols. The SWOG Lung-MAP protocol will be used to motivate the different decision points and trade-offs between different designs.

9:10 Design and Analysis of Biomarker-Driven Clinical Trials

Robert Bigelow, Ph.D., Associate Director, CT Statistics, Duke Clinical Research Institute

Biomarkers can be useful in disease prognosis and prediction of treatment outcome, giving physicians the ability to more precisely tailor the therapeutic approach to individual patients. While a biomarker may have a plausible biological mechanism, demonstration of its prognostic and predictive accuracy poses numerous statistical challenges, including appropriate use of randomization, multiplicity, stratification and statistical interaction and use of surrogate endpoints.

This session presents design strategies in biomarker-driven studies.

9:50 Interactive Discussion: Statistical Concepts for Biomarker-Driven Trials

Topics to be discussed include but are not limited to the following:

- Stratified trials (or master protocols) can be described by a common underlying framework
- Broadly speaking these designs can be classified as either confirmatory or discovery-based
- The overall goal of the trial determines the design
- We will discuss the relative merits and trade offs for different designs

10:10 Coffee Break in the Exhibit Hall

IMPACT OF POC PRE-SCREENING ON CLINICAL TRIAL DYNAMICS

11:10 Chairperson's Remarks

Paul S. Savuto, President & CFO, Blinded Diagnostics

11:15 Novel Application of Point-of-Care Testing (POCT) in a Global Pharmaceutical Clinical Trial

John J. Brennan, Ph.D., Senior Project Director, Global Pharmaceutical Research and Development, Abbvie

To reduce screen failures, a global pharmaceutical company deployed point-of-care testing (POCT) systems to pre-screen subjects for registration in a new drug trial prior to central lab screening. The sponsor will present data and analysis to show how well POCT correlates to Central Lab and the financial impact this application had on the study budget.

11:35 Evolution of POCT Use in Pharmaceutical Clinical Trials and How to Use Effectively

Paul S. Savuto, President & CFO, Blinded Diagnostics

Point-of-care diagnostic testing (POCT) has been utilized in pharmaceutical clinical trials since the late 1990s. Successful application of this technology relies heavily on the selection of the test device, training of investigators, logistics, data collection and support. Published data, POCT technology options, encryption and case studies will be presented along with outcomes.

11:50 Interactive Discussion: Enabling Clinical Research with the Latest Diagnostics Advances

Topics to be discussed include but are not limited to the following

- Are there any members of the audience that have used POCT in a clinical trial? If so, please share your experience.
- What regulatory challenges might the audience expect to face using POCT in a trial?
- What internal challenges might the audience expect to deal with in proposing POCT use?
- When and what type of trial applications would fit into projects you are initiating now?
- What is the difference between wearable biometric devices and POCT diagnostic devices?

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes **(see page 7 for details)**

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

INTEGRATING LABORATORY SERVICES

4:00 Chairperson's Remarks

Richard Scheyer, M.D., Vice President, Medical Affairs, Medpace

4:05 JOINT PRESENTATION: Collaboration of CRO, Laboratory and Sponsor to Support Biomarker-Driven Clinical Trials

Richard Scheyer, M.D., Vice President, Medical Affairs, Medpace
Matthew Kelso, Pharm.D., Ph.D., Associate Director, Medpace Reference Laboratories
Abdel Halim, Pharm.D., Ph.D., Vice President, Translational Medicine, Biomarkers and Diagnostics, Celldex Therapeutics

Incorporating biomarkers into clinical trials requires coordination of study sites, CRO, lab(s) and sponsor(s). This is critical when rapid turn-around is required for patient eligibility or dose-adjustment. Presenters will share examples from the sponsor, CRO, and laboratory perspectives addressing lab and kit selection, turn-around, and mid-trial changes in assay kit. The challenge of multiple protocols and sponsors, such as when the laboratory is providing safety and efficacy testing for the therapeutic and the companion diagnostic, will also be discussed.

5:05: Interactive Discussion: The Art, Science and Logistics of Sponsor-CRO-Lab Collaboration

Topics to be discussed include but are not limited to the following

- Accelerating assay turnaround in global trials
- Ensuring assay quality in face of extended trial and evolving technology
- Balancing interests and priorities of diagnostic and therapeutic sponsors

5:45 Close of Symposium

THURSDAY, FEBRUARY 25

Join Thursday conference sessions at SCOPE:

- Improving Site-Study Activation and Performance
- Patient Engagement, Enrollment and Retention through Communities and Technology
- Managing Outsourced Clinical Trials
- Implementing Risk-Based Monitoring (Part 2)
- Clinical Data Technology and Integration
- Leveraging Existing Data for Clinical and Observational Research

SYMPOSIUM *NEW*

Inaugural

Clinical Research Statistics for Non-Statisticians

Key Statistical Concepts for Clinical Operations Professionals

February 23-24, 2016

Statistics and statistical concepts touch every point of a clinical trial – and can help you market the trial, recruit participants, apply for an FDA application, and understand the trial outcomes – but there tends to be a lack of understanding in the clinical operations field about what these concepts are, how they apply to clinical research and trials, and why it is important to have an understanding of them. The Clinical Research Statistics for Non-Statisticians symposium will discuss these statistical methods and their applications in the context of clinical operations for those that are in operations, business, and marketing, as well as those that work with clinical scientists and want to contribute more to conversations about planning and execution. Both academic instructors and industry experts will guide you through the two-day course, providing both theory and application.

TUESDAY, FEBRUARY 23

7:15 am Registration and Morning Coffee

8:25 Opening Plenary Keynotes **(see page 6 for details)**

9:45 Grand Opening Coffee Break in the Exhibit Hall

BASIC STATISTICAL CONCEPTS

10:45 Chairperson's Remarks

Paula Bernstein, President, Axcent Advance Analytics

10:50 Statistics for Non-Statisticians

Chetachi Akunna Emeremni, Senior Principal Biostatistician, Novartis Oncology

This module provides a brief overview of basic statistical concepts, methods and applications to clinical trial design and data analysis. This module is designed to give the non-statistician a working understanding of statistical concepts with applications and examples from real clinical trials.

11:30 Statistical Programming Demystified

Vincent Amoruccio, Director, Clinical & Statistical Programming, Alexion Pharmaceuticals

Ever wonder what your statistical programmer does? How do they write programs to apply the concepts, methods, and applications identified by the statistician to source data and create the tables, listings, and figures (TLFs) submitted to regulators? This module will demystify statistical programming for not only the non-statistician, but the non-programmer.

CLINICAL TRIAL DESIGN

12:00 pm The How and Why of Clinical Trial Design: By the Numbers

Fang Xie, Ph.D., Head of Global Biostatistics, CSL Behring

The design of a clinical trial is a group effort between the statistician and the operations group, an effort made easier with a deeper understanding of statistical principles that come into play during the design phase. Discover the different types of trial design, when each are used, and how the design drives the statistics used throughout the development and execution of the trial and in the final analysis and reporting of the trial.

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

1:20 Coffee and Dessert in the Exhibit Hall

PROTOCOL WRITING AND HYPOTHESIS TESTING

2:00 Statistical Concepts and Their Impact on Protocol Writing

Kari Kastango, Director of Biostatistics, Real-World & Late Phase Research, Quintiles

A protocol originates from a desire to answer a research question. Answering a research question involves testing a hypothesis. This session will discuss how the research question and the data elements that will be collected during the study get written into the protocol and their interdependence with statistical concepts (such as sample size, effect size, power, and randomization) that are fundamental to hypothesis testing.

2:45 On the Front Line: Site Training and Its Impact on the Statistical Aspects of a Study

Kathleen E. Thrush, MS, RD, Section Manager, Clinical Operations, Abbott Nutrition

Clinical operations professionals such as monitors and clinical research associates (CRA) are the "feet on the ground" of a clinical study. They are typically the only ones who see the true implementation of a clinical trial and have the opportunity to impact its direction. Drop outs, protocol deviations, and poor study conduct all have costly and timely implications on a clinical study. Therefore, we need to educate these individuals about site issues that can impact the statistical aspects of a study. This presentation will discuss how clinical operations professionals can recognize issues at sites and implement strategies such as risk based monitoring and centralized data review to help course correct early on to assure that the study is delivered on time and within budget.

3:20 Interactive Discussion: From the Basics to the Protocol

Kari Kastango, Director of Biostatistics, Real-World & Late Phase Research, Quintiles

Kathleen E. Thrush, MS, RD, Section Manager, Clinical Operations, Abbott Nutrition

Day 1 covered a lot of ground, from basic statistical concepts through hypothesis testing and protocol writing. Ask a statistician and operations professional to:

- Clarify concepts, from sample size to randomization
- Elaborate on process, including where to begin and how to generate numbers
- Frame these concepts more concretely with real-world situations

BREAKOUT DISCUSSION GROUPS

3:55 Find Your Table and Meet Your Moderator

4:00 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

6:30 Close of Day

WEDNESDAY, FEBRUARY 24

7:15 am Registration and Morning Coffee

PROTOCOL DESIGN AND OPTIMIZATION IN BIOMARKER-DRIVEN TRIALS

8:25 Chairperson's Remarks

Robert Bigelow, Ph.D., Associate Director, CT Statistics, Duke Clinical Research Institute

8:30 Statistical Designs of Master Protocols and the Design of the SWOG Lung Master Protocol (S1400; Lung-Map)

Mary Redman, Ph.D., Lead Statistician, Lung Cancer Committee Southwest Oncology Group, Lead Statistician, Lung Map Trial, Fred Hutchinson Cancer Research Center

Master protocols are often separated into two categories: umbrella protocols which evaluate multiple drugs and targets among patients with the same disease type and basket protocols which evaluate drugs/target pairs among patients defined by their genetic alternation and across disease type (so-called histology agnostic trials). However, the underlying statistical design of such studies can be broadly categorized into confirmatory and discovery-focused design. The specific details of the design are motivated by the objectives of the study and study population. In this talk, we will discuss the basic design options and possible design features for master protocols. The SWOG Lung-MAP protocol will be used to motivate the different decision points and trade-offs between different designs.

Inaugural

Clinical Research Statistics for Non-Statisticians

Key Statistical Concepts for Clinical Operations Professionals

February 23-24, 2016

9:10 Design and Analysis of Biomarker-Driven Clinical Trials

Robert Bigelow, Ph.D., Associate Director, CT Statistics, Duke Clinical Research Institute

Biomarkers can be useful in disease prognosis and prediction of treatment outcome, giving physicians the ability to more precisely tailor the therapeutic approach to individual patients. While a biomarker may have a plausible biological mechanism, demonstration of its prognostic and predictive accuracy poses numerous statistical challenges, including: appropriate use of randomization, multiplicity, stratification and statistical interaction, and use of surrogate endpoints – specifically regarding design strategies for biomarker-driven studies.

9:50 Interactive Discussion: Statistical Concepts for Biomarker-Driven Trials

Mary Redman, Ph.D., Lead Statistician, Lung Cancer Committee Southwest Oncology Group, Lead Statistician, Lung Map Trial, Fred Hutchinson Cancer Research Center

Robert Bigelow, Ph.D., Associate Director, CT Statistics, Duke Clinical Research Institute

Biomarker-driven clinical trials come with their own set of statistical challenges. Discuss a variety of topics, including:

Stratified trials (or master protocols) can be described by a common underlying framework

- Broadly speaking these designs can be classified as either confirmatory or discovery-based
- The overall goal of the trial determines the design
- The relative merits and trade-offs for different designs

10:10 Coffee Break in the Exhibit Hall

CLINICAL TRIAL EXECUTION BY THE NUMBERS

11:10 Chairperson's Remarks

Paula Bernstein, President, Axcent Advance Analytics

11:15 Study Execution Issues and Their Impact on Analysis and Interpretation of Results

Kari Kastango, Director Biostatistics, Real-World & Late Phase Research, Quintiles

Execution of a clinical trial may not always go as planned. Protocol amendments, incorrect treatment allocation by the site, protocol violations and missing data due to a variety of reasons are just a few things that can arise during the conduct of the study. This session will discuss the impact these topics have on the analysis of the data and the interpretation of the results and why it is important to communicate with the clinical trial statistician during the course of the clinical trial and not wait until just before database lock.

11:35 Trial Execution by the Numbers: Understanding the Impact of Protocol Amendments, Site Issues, and Other Study Execution Issues on Trial Enrollment and Analysis

Mike Lonetto, Associate Director, Senior Application Architect, Novartis

There are many risks in clinical trial execution, including changes due to protocol amendments as well as uncertainty due to site issues, patient enrollment, and retention and event rates. This session will explore applications of probability and statistics to understanding and dealing with uncertainty in clinical operation parameters. Topics include understanding uncertainty in patient accrual, and retention, and how these can impact analysis plans.

11:55 Interactive Discussion: Statistical Pain Points in Clinical Trial Execution and Analysis

Kari Kastango, Director Biostatistics, Real-World & Late Phase Research, Quintiles

Mike Lonetto, Associate Director, Senior Application Architect, Novartis

Ask your most burning questions of our presenters in this interactive Q&A session. Possible topics include:

- In-depth explanation of how data is analyzed by a statistician
- A closer look at probability and how it is calculated
- Real-world scenarios of how a statistical and operations team successfully worked together – or lessons learned from when it did not

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes **(see page 7 for details)**

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

POST-TRIAL DATA FLOW

4:00 Post-Trial Information Flow: Direct and Indirect Estimation of Relative Effect to Support Reimbursement

Sarah Goring, MSc, Director, Epidemiology, ICON plc.

Health technology assessment agencies recommend using meta-analysis or network meta-analysis to synthesize evidence of efficacy and safety from medicinal products across the therapeutic space. This presentation will provide an overview of this approach and will highlight considerations at the clinical trial design stage that can support a strong and statistically robust analysis and obviate challenges in downstream evidence synthesis.

4:30 Post Lock Data Flow: From CRF to the FDA

Ben Vaughn, MS, RAC, Senior Statistical Scientist, Rho, Inc.

This presentation will cover the various manipulations to patient data to prepare it for analysis, tabulation, and submission to the FDA. Learn what CDASH, SDTM and ADaM mean to a study and how they fit into project timelines. Approaches to legacy data and the impact of the new electronic data submission guidance will be discussed.

5:00 Post-Trial Information Flow: Integrated Summaries of Effectiveness and Safety Data to Support Marketing Authorization

Kenneth Koury, Ph.D., Executive Director, Clinical Biostatistics, Merck Research Laboratories

This presentation will describe the integrated summaries of effectiveness and safety data, which synthesize results across the entire clinical development program using data from individual trials, and their importance in the FDA review process. These comprehensive analyses are used to support statements in the proposed product label, including describing differences across important sub-populations. Consequently, they provide the basis for obtaining the desired product label and ultimately achieving commercial success.

5:25 Interactive Discussion: What Happens Next?

Ben Vaughn, MS, RAC, Senior Statistical Scientist, Rho, Inc.

Kenneth Koury, Ph.D., Executive Director, Clinical Biostatistics, Merck Research Laboratories

Sarah Goring, MSc, Director, Epidemiology, ICON plc.

From an operational standpoint, running a smooth trial with as few delays and errors as possible is the main goal, but what happens after the trial wraps should be part of the initial planning stage. Ask these professionals your most pressing post-trial data questions, on topics such as:

- Elaboration on FDA forms and processes
- Translating data and analyses for the business and marketing professional
- Incorporating trial data into global reimbursement submissions

5:45 Close of Symposium

THURSDAY, FEBRUARY 25

Join Thursday conference sessions at SCOPE:

- Improving Site-Study Activation and Performance
- Patient Engagement, Enrollment and Retention through Communities and Technology
- Managing Outsourced Clinical Trials
- Implementing Risk-Based Monitoring (Part 2)
- Clinical Data Technology and Integration
- Leveraging Existing Data for Clinical and Observational Research

Improving Site-Study Activation and Performance

Strategically Implementing a Process for Rapid Study Start-Up

February 24-25, 2016

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 Third 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.

*Arrive early and attend **Part 1: Global Site Selection, Feasibility Assessment, and Site Management**. See page 8 for details.*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon Presentation: Real World Data in Clinical Trial Planning: Game Changer?

Sponsored by imshealth

Bernadette Collins, Senior Manager, Data Services, Clinical Trial Optimization Solutions, IMS Health

April Lewis, Head, Clinical Trial Optimization Solutions, IMS Health

IMS Health is the world's largest purveyor of healthcare data. Over the past few years, we have developed a team of experts dedicated to evaluating the most influential assets to support trial feasibility and increased success in site selection and trial planning. In this session our experts will review what type of global assets are obtainable, how these assets can validate and substantiate trial planning decisions. Practical examples will be shared and case studies will be reviewed.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

SITE-SPONSOR COLLABORATION AND DEEP TEAM INTEGRATION TO ACHIEVE SUCCESSFUL STUDY LAUNCH

4:00 Chairperson's Remarks

Silvana Giustino, Global Head, Clinical Development Expert Resources, Roche

4:05 CO-PRESENTATION: The Social Experiment: Deep Team Integration with Sites and Providers Results in a Successful Study Launch

Deirdre BeVard, Vice President, Development Operations, Nektar Therapeutics

Eileen Daniel, Executive Director, Clinical Operations, Nektar Therapeutics

They laughed, they cried, they collaborated! Working as an integrated team with sites and providers is real partnering with real benefit, and it takes real effort. Deirdre BeVard and Eileen Daniel will share recent experience launching a Phase 3 program employing unconventional approaches for study team formation and early site interaction, and a deliberately metered start-up. They will share what really happened along the way and how it shaped the operations and team relationships.

4:30 Integrating TMF and Clinical Processes to Improve Study Operations

Sponsored by Veeva

Jason Methia, MS, Director, Vault eTMF Strategy, Veeva Systems

When TMF processes are integrated and aligned with other clinical development processes through an eTMF, it helps enable a real-time and inspection-ready TMF. It also provides a lens to review and optimize study operations. In this session, we will discuss the improvements that can be made when moving from an archive to an active TMF that can manage workflows and processes. Topics will include metrics and reporting, the importance of using a common language (TMF Reference Model), and collaboration with external partners.

4:55 Case Study: C-Diff Recruitment Challenges and How We Put the Brown in Jean Brown Research! Site and Sponsor Collaboration to Achieve Success

Denise Roberts, President, Jean Brown Research

This presentation will share the story of the challenges faced by both sponsor and site to recruit, and manage a global Cdifficile prevention trial. What are the current enrollment tactics and what strategies have been employed to mobilize and renew site motivation and patient interest. What specific issues has the sponsor faced in onboarding sites of excellence? What specific issues has the site faced in finding and keeping subjects in the trial? What impact has nurturing the site/sponsor relationship had on building momentum for success? What processes and assumptions had to be reassessed?

5:20 Mitigating Clinical Trial Risk and Operational Cycle Times through Cloud Based Workflow Technologies

Sponsored by goBalto

Barry Milton, Director, Pre-Sales, goBalto, Inc.

Given society's growing insistence on faster drug development, an improved SSU process, enabled by cloud-based technology, aligns with that goal by significantly impacting cycle times in clinical trials. This leads to faster access for patients resulting in greater cost savings and faster market entry, making valuable therapies available to more patients sooner.

5:45 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

For years pharmaceutical companies and CROs have struggled to collect, clean and collate site data from disparate sources so they can make better decisions about site feasibility and selection. With the DrugDev Golden Number - a universal identifier for Investigators and sites - individual pharma companies and CROs easily match and master data, and share data across collaborations like the Investigator Databank and TransCelerate. While the Golden Number began as a method for data sharing, innovators are using it to drive operational efficiencies, collaboration and integrated reporting as well. We expect it also will give regulators a more detailed view into the global investigator community, which ultimately can improve patient safety. Join this session for a discussion on the Golden Number and how it can help pharma, CROs and sites do more trials.

SIMPLIFYING RESEARCH AND IMPROVING QUALITY: OPTIMIZING THE SITE EXPERIENCE TO BENEFIT PATIENTS, SITES AND SPONSORS

8:35 Chairperson's Remarks

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

8:40 Optimizing the Site Experience in the Era of Patient-Centric Trials

Silvana Giustino, Global Head, Clinical Development Expert Resources, Roche

As companies refine their overall focus to a limited number of therapeutic areas or disease entities and plan for more than one product in those areas, it is critical to partner with clinical research sites who are experts in those fields of study and gain insight from the patients who experience those diseases. Robust working relationships with sites should be established and maintained throughout the clinical research process and sites should not only participate in more than one trial but also be asked for input into operational design and activities.

9:05 CTA Adoption Case Study: Collaboration to Simplify Research and Processes to Benefit Sponsors, Sites and Patients

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

There are many processes in clin research that are redundant, inefficient and needlessly complex. There are also a number of opportunities to be exploited by industry especially in areas where simplification of our processes can speed up research and development of new medicines. To achieve this, all the stakeholders need to work together. This presentation will share progress The Society for Clinical Research Sites (SCRS) and TransCelerate have made in addressing one of the major areas of study delay – the CTA. This initiative presents a solution to a challenge inhibiting study initiation, and showcases that collaboration, courage and trust can reshape the trial landscape.

9:30 CO-PRESENTATION: Creating a Culture of Quality in Your Organization: New Ideas for Compliance Management

Deborah Guattery, Quality Systems, CAPA Manager, Clinical Quality Control and Compliance, CSL Behring

Sheri Kuss, Associate Director, Clinical Process Development, Teva Pharmaceuticals

This presentation will provide information about how we at CSL Behring formed a quality compliance group within clinical operations. The mission of this team is to increase compliance to sponsor protocol, SOPs and regulations by applying risk management and Quality by Design (QbD) principles to the actions of the team and infusing these into the study operational teams. The audience will gain insight into how infusing and creating a quality culture is achievable.

9:55 Advances in Feasibility Study Technology: Accurately Predict Enrollment Rates, Identify Problem Areas Sooner with the EnForeSys® Simulation Software

Sponsored by Cytel

Speaker to be Announced

Will your trial recruit as planned and start on time? How certain are you? Cytel's EnForeSys®software reveals the likely impact of trade-offs and determine the enrollment plan most likely to succeed. You'll learn to: Align study team members on the range of input parameters to yield accurate simulations; Best apply simulation results for improved planning; Move beyond stakeholder's individual beliefs and toward truly objective assessments of an enrollment plan's feasibility.

10:20 Coffee Break

INTEGRATING PATIENT INSIGHTS AND DATA ANALYTICS TO IMPROVE TRIAL PLANNING, CLIN OPS, INVESTIGATOR RETENTION AND PATIENT ENGAGEMENT

Special Shared Session

10:35 Chairperson's Remarks

David Leventhal, Director, Clinical Innovation, Worldwide Research & Development, Pfizer

10:40 The Challenges and Solutions on Achieving True Patient Centricity: The Site's Perspective from a Data Exchange, Study Design, Technology and Personal Perspective

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

As sites we are privileged and responsible for providing the "personal touch" between the clinical trial and the patients. This unique relationship provides invaluable information for industry stakeholders to gain first hand knowledge of the realities of the study experience and it's impact on truly making the clinical trials a patient centric experience. Data and perspective will be shared regarding the impact of lack of data exchange, study design, technology and more will be discussed in a lively session aimed at making patient centricity a reality and not a phrase.

11:05 Rebuilding Site Partnerships to Optimize Study Execution

Sponsored by Worldwide Clinical Trials

Jeffrey Zucker, MS, Vice President, Feasibility and Recruitment Optimization, Worldwide Clinical Trials

A barrier to successfully completing a clinical trial can be patient recruitment. While there may not be one solution to the issue, a key point has been lost over the last 20 years — the relationship between site and sponsor. Although the merits of direct patient access cannot be denied, we need to re-engage our sites. Through these alliances, we will be able to increase efficiency with trial start-up, recruitment, and implementation. This discussion will suggest various methods to establish and maintain these key relationships while defining the impact on successfully conducted trials.

11:30 CO-PRESENTATION: Integrating Data Science into Clinical Trial Planning and Operations

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

Shashank Rohatagi, Ph.D., Senior Director, Translational Medicine & Think Team, Otsuka Pharmaceuticals Development and Commercialization

The use of technology in the support of clinical trials has continued to increase. However, the disciplines and departments remain very distinct and in some cases siloed. In order to gain the most from your data, to make better decisions based on the data, to formulate more effective trial strategy, and to improve trial operations processes, there must be a more fluid interchange between the data scientists and trial planners.

> "The opportunities for networking were abundant!"
>
> *Helen C., Clinical Research Physician, Chiesi*

11:55 Implementing a Patient Centricity Platform to Better Engage Patients and Sites in Informed Consent Process

Robert Allen, Senior Director, Digital Innovation Group (DIG), AstraZeneca

Often we forget the human-side of a clinical trial. With trial design, protocol development, and clinical data as primary concerns, we forget engaging patients and investigators is just as important. Engagement can lead to a greater understanding of the trial with the hopes of making the experiences better for everyone. This talk will focus on striking the balance between creating trial effectiveness and efficiency through technology, while putting humans at the center through a use case of implementing the Patient Centricity platform to engage patients better in informed consent process.

12:20 INTERACTIVE PANEL: Can We Shift Investigators from "1 and Done" to Repeat Performers

Claire Sears, Ph.D., Director, Investigator Engagement, SiteStart, DrugDev

Immo Zadezensky, PharmD, Ph.D., Clinical Pharmacologist, Professional Affairs and Stakeholder Engagement (PASE), Office of the Center Director, CDER, FDA

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

Jeffrey Rosen, M.D., Medical Director, Clinical Research of South Florida; Associate Professor, University of Miami Miller School of Medicine

In this session we will discuss the problem of investigator turnover – in particular, the large '1 and done' population. Tufts will present information from the FDA 1572 database on the trends, characteristics and size of the '1 and done' population. This information will be supplemented by a presentation of findings from the Investigator Databank related to characteristics of approximately 70,000 '1 and done' sites including site level performance amongst other factors (e.g., geography, pediatrics, therapeutic area). It is clear that the high rate of attrition of investigators and the need to initiate new investigators is detrimental to site and overall trial performance, and is costly and time-consuming for sponsors. The session will conclude with a commentary on the data from the Site perspective regarding what can be done (if anything) to decrease the rate of investigator turnover. The learning objectives for this session are:

- Learn detailed characteristics of the global population of investigators who have only participated in one clinical trial
- Identify factors that can be gleaned from these detailed analyses that help identify investigators at risk of only participating in a single clinical trial
- Based on these insights, discuss strategies/actions that can help reduce the likelihood of future site turnover

12:45 Closing Remarks

12:50 pm SCOPE 2016 Conference Adjourns (see you back in Miami in 2017!)

Enrollment planning and patient recruitment are critical to drug development programs and garner a lot of attention by study teams. However, once the hard work of identifying and recruiting a trial subject has been accomplished they must be retained and remain in compliance. Retention of patients throughout the life of a clinical trial is essential in order have complete data sets for your analysis and subsequent filings. There are strategies, tools and techniques such as social media platforms and mobile technology, empowered patient communities, and a more informed patient population that need to be understood and engaged. Cambridge Healthtech Institute's Third Annual "Patient Engagement, Enrollment and Retention through Tech, Disease Communities and Advocacy Groups" conference will cover the topics one should consider when planning and strategically implementing a patient retention plan in the digital age.

*Arrive early and attend **Part 1: Enrollment Planning and Patient Recruitment.** See page 10 for details.*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon Presentation: Harnessing Real-Time Data to Optimize Site and Patient Recruitment

Sponsored by UBC

Meghan Winegrad, Managing Director, New Solutions, UBC: An Express Scripts Company, The Lab - Express Scripts Technology and Innovation Center

When it comes to use of data for clinical trial optimization, are all data sets created equal? This presentation will illustrate how data-driven insights from more than 130 million patients can fuel smarter, more efficient solutions for patient and site recruitment. Using case studies, the presentation will demonstrate how pharmacy and prescription data can be utilized to inform protocol design, identify study sites with strong enrollment potential, and directly reach qualified patients for a given study.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

LEVERAGING INSIGHTS FROM STUDY PARTICIPANTS AND CLINICAL SITE STAFF IN TRIAL DESIGN AND EXECUTION

4:00 Chairperson's Remarks

Jennifer Kelly, Director of Operations, HealthiVibe LLC

4:05 Championing the Voice of the Customer in Research: Leverage Insights from Study Participants and Clinical Site Staff in Trial Design and Execution

Michelle Collins, Ph.D., Director, Clinical Program Development, AbbVie

Clinical trials often struggle with patient recruitment & retention, and maintaining site engagement through the duration of the trial. This presentation will explore opportunities to improve these trial challenges through effective implementation of key customer insights, in particular those of the study participants and clinical site staff. This talk will identify new opportunities to gain impactful insights from study participants;,ways to effectively leverage those insights in the trial design and execution, and explore examples of successful implementation.

4:30 What's Inn- and Out-ovative in Patient Recruitment

Sponsored by BBK Worldwide

Aaron Fleishman, Technology and Product Innovation, BBK Worldwide

It may be hard to believe but Facebook is already over ten years old! In fact, you could argue that Facebook is no longer considered "cool." When it comes to clinical trial awareness and engagement, what's the new cool? How does it work in sync with the old? In this presentation we will travel back in time to the birth of social media, the rise of digital media, and a look at what's coming next.

4:55 "Patient Centricity"... Now What? Real-World Examples of Patient Centric Strategies to Optimize Enrollment

Taisa Skubiak, Associate Director, Enrollment Optimization, Clinical Trial Planning & Operations, Bristol-Myers Squibb

Patient centricity has been a popular topic in clinical trials, though we don't hear much about how this has been practically applied. As sponsors navigate this space, some strategies are emerging that may help to communicate with and find patients for studies. This talk will share real-world examples of how a biopharma is applying patient centric concepts to patient recruitment.

5:20 INTERACTIVE PANEL: Faces in the Crowd: Why We Do What We Do

Jeffrey Kasher, Ph.D., President, Patients Can't Wait

Brett Kleger, Chief Commercial Officer, DrugDev

Al O. Pacino II, President, HealthCarePoint

Jennifer Kelly, Director of Operations, HealthiVibe LLC

The concept of the "Abstract Patient" has become too common in our industry, especially at conferences where we gather to discuss ideas and debate the best ways to support them. While we hold the patient in high regard, we fail to realize as a collective that patients are not an abstract third-party, but rather our parents, spouses, friends, children and selves. As an industry we are not yet patient centric in our planning and operations. Why not and how can we get there? The goal of this session is to pull out the familiar faces from the crowd and learn the stories that drive them to do what they do.

5:45 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

For years pharmaceutical companies and CROs have struggled to collect, clean and collate site data from disparate sources so they can make better decisions about site feasibility and selection. With the DrugDev Golden Number - a universal identifier for Investigators and sites - individual pharma companies and CROs easily match and master data, and share data across collaborations like the Investigator Databank and TransCelerate. While the Golden Number began as a method for data sharing, innovators are using it to drive operational efficiencies, collaboration and integrated reporting as well. We expect it also will give regulators a more detailed view into the global investigator community, which ultimately can improve patient safety. Join this session for a discussion on the Golden Number and how it can help pharma, CROs and sites do more trials.

DESIGNING AND IMPLEMENTING A PATIENT-CENTRIC TRIAL: SOCIAL LISTENING, ACCESS, INNOVATION

8:35 Chairperson's Remarks

Eric Peacock, CEO, myHealthTeams

8:40 CO-PRESENTATION: Social Media in Clinical Trials – If We Listen, What Will We Hear?

Jerry Matczak, Community Manager, Clinical Open Innovation, Eli Lilly and Company

Paul Ivsin, Director, Offerings Development, Clinical Trial Optimization Solutions, IMS Health

Patient engagement is high on many priority lists, but few clinical development teams have actively worked through the challenges, and even fewer best practices exist. This talk will share lessons learned during our launch into Social Listening in Clinical Trials. There are a lot of challenges and insecurities in choosing to use social media listening in the clinical trial space and this session will review how Lilly overcame internal challenges to drive innovative use of social media in the clinical realm, the lessons that were learned and the things we would do better next time.

9:05 Leveraging the Patient's Voice through Stakeholder Engagement

Immo Zadezensky, PharmD, Ph.D., Clinical Pharmacologist, Professional Affairs and Stakeholder Engagement (PASE), Office of the Center Director, CDER, FDA

The current paradigm of patient involvement in protocol and drug development is shifting towards more systematic inclusion of patient preferences and patient centric endpoints at all stages. How can we leverage this valuable information on risk-benefit assessment in a complex, multi stakeholder drug development environment? This presentation will explore past and current stakeholder engagement efforts, as well as evaluate ideas to enhance and broaden meaningful inclusion of patients' voice in risk-benefit discussions.

9:30 CO-PRESENTATION: Operational Approaches to Speed Progress on Patient-Centered Clinical Trials

Craig Lipset, Head, Clinical Innovation, Pfizer

Jennifer Burgess, Senior Director, Communications & Engagement, TransCelerate BioPharma, Inc.

The industry is headed more and more towards a patient-centered model. Patient centric clinical trials are no exception. This session will focus on key things that can be done to create a better informed patient and better run clinical trials, ultimately with the hope to increase a patient's engagement and satisfaction participating in a clinical trial. This talk will offer an understanding of key challenges with patient centricity in trials, and an overview of what this unique collaboration of 20+ sponsors is doing to address with initiatives in eConsent, patients and trials and other efforts underway to create a better informed patient.

9:55 Engaging Patient Communities for Clinical Research

Sponsored by SYNEXUS
The patient's choice for clinical research

Janet Jones, Ph.D., Vice President, Strategic Patient Engagement, Synexus Clinical Research Limited

There are many ways to build patient communities and get patients engaged to join a study. These range from conventional community interactions with patients or their healthcare providers through to online engagement with social media. To be fully engaged and chose to join a clinical trial, the patient must be at the heart of our thinking. This session will use case studies to explore the impact of using targeted approaches to engage with different patient communities and the pathway from engagement to randomisation.

10:20 Coffee Break

INTEGRATING PATIENT INSIGHTS AND DATA ANALYTICS TO IMPROVE TRIAL PLANNING, CLIN OPS, INVESTIGATOR RETENTION AND PATIENT ENGAGEMENT

Special Shared Session

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11:05 Rebuilding Site Partnerships to Optimize Study Execution

Sponsored by WORLDWIDE CLINICAL TRIALS
SCIENTIFICALLY MINDED • MEDICALLY DRIVEN

Jeffrey Zucker, MS, Vice President, Feasibility and Recruitment Optimization, Worldwide Clinical Trials

A barrier to successfully completing a clinical trial can be patient recruitment. While there may not be one solution to the issue, a key point has been lost over the last 20 years —the relationship between site and sponsor. Although the merits of direct patient access cannot be denied, we need to re-engage our sites. Through these alliances, we will be able to increase efficiency with trial start-up, recruitment, and implementation. This discussion will suggest various methods to establish and maintain these key relationships while defining the impact on successfully conducted trials.

11:30 CO-PRESENTATION: Integrating Data Science into Clinical Trial Planning and Operations

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

> "The best networking conference I have ever attended!!"
>
> *Virginia W., Senior Manager & Global Lead, Covance Clinical Development of LabCorp.*

Shashank Rohatagi, Ph.D., Senior Director, Translational Medicine and Think Team, Otsuka Pharmaceuticals Development and Commercialization

The use of technology in the support of clinical trials has continued to increase. However, the disciplines and departments remain very distinct and in some cases siloed. In order to gain the most from your data, to make better decisions based on the data, to formulate more effective trial strategy, and to improve trial operations processes, there must be a more fluid interchange between the data scientists and trial planners.

11:55 Implementing a Patient Centricity Platform to Better Engage Patients and Sites in Informed Consent Process

Robert Allen, Senior Director, Digital Innovation Group (DIG), AstraZeneca

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12:20 INTERACTIVE PANEL: Can We Shift Investigators from "1 and Done" to Repeat Performers

Claire Sears, Ph.D., Director, Investigator Engagement, SiteStart, DrugDev

Immo Zadezensky, PharmD, Ph.D., Clinical Pharmacologist, Professional Affairs and Stakeholder Engagement (PASE), Office of the Center Director, CDER, FDA

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- Based on these insights, discuss strategies/actions that can help reduce the likelihood of future site turnover

12:45 Closing Remarks

12:50 pm SCOPE 2016 Conference Adjourns (see you back in Miami in 2017!)

2nd Annual

Managing Outsourced Clinical Trials

Forming Quality Partnerships

February 24-25, 2016

As more clinical trial activities are outsourced to contract research organizations (CROs), sponsors must learn to 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 "Managing 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.

*Arrive early and attend **Part 1: Clinical Trial Forecasting and Budgeting**. See page 12 for details.*

> "If you had to choose one conference to attend each year, SCOPE is the place to be."
>
> *Matt K., Partner, PHARMICA Consulting*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon - Sneak Preview: Speed Site Activation Using Collaborative Technology for Contracting and Essential Site Docs

Sponsored by DrugDev do more trials

Liss Easy, Founder, President of Site Identification and Activation, DrugDev

Finding the right sites for your trial is challenging enough. Once identified, you need to get them activated quickly so that they can start enrolling patients. Thanks to new technology including an innovative site activation module on the DrugDev platform (introduced today at SCOPE!), the days of relying on e-mail, manual spreadsheets, and hundreds of man hours to manage site activation are long behind us. Join us at lunch for an exclusive sneak preview of an exciting technology solution - built on years of proven best practices - that will enable you to automate your site activation process, and provide your global sites with an efficient, reliable, and standardized activation experience. Plus, free sandwiches with Liss!

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

UNDERSTANDING AND APPLYING THE RIGHT OUTSOURCING STRATEGIES TO ACHIEVE MORE EFFICIENT CLINICAL TRIALS

4:00 Chairperson's Remarks

Bruno Gagnon, BPharm, MSc, Senior Lead, Clinical Operations, Raptor Pharmaceuticals Inc.

4:05 Working with Your CRO to Improve Activation Performance

Jessica Ibbitson, Director, Clinical Site Services, Vertex Pharmaceuticals

Understanding the challenges, resources and outsourcing strategy needed is essential to improving activation performance. Achieving efficient site activation is the goal for all companies and there is keen interest in how to work optimally with your CRO, sites, networks and internal stakeholders to achieve success.

4:30 Establishing the Framework and Corporate Culture to Effectively Manage Clinical Vendors

Anca Copaescu, Senior Director, Clinical Outsourcing and Analytics, BioMarin

In this presentation, I will discuss: 1. Lessons learned at BioMarin: establishing Strategic Vendor Management function, 2. Defining optimal governance and escalation structures by vendor type and tier, 3. Creating the tools, processes and framework to create an culture of proactive oversight, 4. Utilizing relationship, financial, contractual and operational metrics to empower the oversight teams, and 5. Leveraging technology to optimize vendor performance monitoring.

4:55 CO-PRESENTATION: Outsourcing Strategies & Partnership Models with CROs: Determining the Right Outsourcing Strategy for Small & Large Sponsors

Sponsored by INC Research

Maria Makarovskaya, Director, Strategic Sourcing, Infinity Pharmaceuticals, Inc.

David Burnham, Vice President, Strategic Alliance Management, INC Research

This presentation will provde a case study of a company's sourcing strategy, what factors contributed to the change in strategy and the analysis of the impact. We will focus on industry trends, sourcing models and structure that worked for our companies, and then provide highlights of "lessons learned".

5:45 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

For years pharmaceutical companies and CROs have struggled to collect, clean and collate site data from disparate sources so they can make better decisions about site feasibility and selection. With the DrugDev Golden Number - a universal identifier for Investigators and sites - individual pharma companies and CROs easily match and master data, and share data across collaborations like the Investigator Databank and TransCelerate. While the Golden Number began as a method for data sharing, innovators are using it to drive operational efficiencies, collaboration and integrated reporting as well. We expect it also will give regulators a more detailed view into the global investigator community, which ultimately can improve patient safety. Join this session for a discussion on the Golden Number and how it can help pharma, CROs and sites do more trials.

CASE STUDIES ON OUTSOURCING

8:35 Chairperson's Remarks

Bruno Gagnon, BPharm, MSc, Senior Lead, Clinical Operations, Raptor Pharmaceuticals Inc.

8:40 VIEW FROM THE RAREFIED AIR: Case Studies of Effective Outsourcing Partnerships in the Rare and Ultra-Rare Space

Mark J. Milberg, Director, Clinical Procurement and Outsourcing, Ultragenyx Pharmaceutical Inc.

The basis of effective partnerships is unique in the rare and ultra-rare disease treatment space. Complexity, small subject populations, and the extra "touch" needed all lead to differentiated processes, systems, and skillsets to be successful. In this presentation, you will hear about two outsourcing engagements that are successful due to proper planning, engagement, and attention to detail to meet the needs of the clinical research team, the vendor partners, and most importantly, the human lives we touch.

9:05 CASE STUDY: FibroGen Perspective on Outsourcing in China

Thomas Guntly, Director, Clinical Development, FibroGen, Inc.

Over the past decade, the number of global clinical trials conducted in China has exploded. Regulatory pathways come in the form of domestic new drug applications and imported drug registration, both which offer challenges and opportunities for multinational pharmaceutical companies in this space. Operational activities in both pathways can be favorably navigated with 'boots on the ground' and a sound outsourcing partner. This presentation will discuss these considerations and anecdotal experience.

NEW WAYS OF THINKING ABOUT PARTNERING

9:30 Novel Ideas in Strategic Partnerships - the Embedded Partner Liaison and the Oversight Playbook

Ian Wyglendowski, Director, Strategic Partnering, UCB Biosciences, Inc.

Discuss the operational and relationship value an embedded partner liaison can bring to a strategic partnership including the implementation of an oversight playbook.

9:55 Cloud Technology for Efficiency and Visibility in Outsourced Studies: A Model for Site Payments

Sponsored by medidata

Marcus Thornton, Global Lead, Medidata Solutions

in Outsourced Studies10:20 Coffee Break

NEW WAYS OF THINKING ABOUT PARTNERING (CONT'D)

10:35 Chairperson's Remarks

Thomas P. Lawler III, MBA, PMP, Project & Alliance Management, Ardea Biosciences, A member of the AstraZeneca Group

10:40 Too Much to Ask for?

Thomas P. Lawler III, MBA, PMP, Project & Alliance Management, Ardea Biosciences, A member of the AstraZeneca Group

This interactive presentation will explore why we settle for less than we want in a CRO or sponsor partner, and discuss why we should not settle, and what other approaches we might take.

11:05 CO-PRESENTATION: Infiltrating the Partnership Mentality

Heather Zigmund, PharmD, Senior Director and Head of Alliance Management, MedImmune

Michael Williamson, Associate Director, Outsourcing and Contracts Management, UCB Biosciences

Formal partnership governance models have an important role to play in improving partnership effectiveness and efficiency. However, getting the most out of a partnership is not just about standardising and streamlining through formal governance programs and unit-wide partnership initiatives. It's about everyone associated with the partnership embracing the Partnership Mentality, breaking down silos and feeling accountable for mutual success. Providing opportunities for all team members to participate in the design, set up and management of the partnership invests the team, allows for developmental opportunities and ensures investment in the partnership. This presentation will discuss options for infiltrating the Partnership Mentality within your organization and the cost avoidance and savings capture for teams who are more and less successful in their approach.

11:55 PANEL: Breaking Down Boundaries on How Sponsors and CROs Think about Partnering and Outsourcing

Moderator: Thomas P. Lawler III, MBA, PMP, Project & Alliance Management, Ardea Biosciences, A member of the AstraZeneca Group

Panelists:

Patti O'Malley, Manager, Contracts and Budget, Incyte

Mark J. Milberg, Director, Clinical Procurement & Outsourcing, Ultragenyx Pharmaceutical Inc.

Bruno Gagnon, BPharm, MSc, Senior Lead, Clinical Operations, Raptor Pharmaceuticals Inc.

Julie Ross, Executive Vice President, CRO, Advanced Clinical

Michelle Betz, Director, Alliance Management, Covance

This panel discussion with audience participation will focus on what could be possible in a perfect world, and explore how some of the perceived barriers may not be as difficult to overcome as they seem.

12:45 Closing Remarks

12:50 pm SCOPE 2016 Conference Adjourns (see you in Miami for 2017!)

Implementing Risk-Based Monitoring - Part 2:

Ensuring Effective and Efficient Monitoring and Data Quality

February 24-25, 2016

Risk-based monitoring (RBM) approaches promise to improve clinical trial efficiency while ensuring data quality. As industry adoption of RBM increases it is clear that successful risk-based monitoring implementation requires developing new roles, analytics and processes among the stakeholders in RBM. Cambridge Healthtech Institute's "Implementing Risk-Based Monitoring – Part 2: Ensuring Effective and Efficient Monitoring and Data Quality" conference offers case studies and practical solutions from across pharma and TransCelerate member organizations on effectively working with various stakeholders in RBM as well as leveraging technology to benefit RBM.

*Arrive early and attend **Part 1: Implementing Risk-Based Monitoring**. See page 14 for details.*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon Presentation : How One ClinOps Team Returned 100% of Studies to Within Risk Threshold: A Next Gen Monitoring Case Study

Sponsored by comprehend

Rick Morrison, CEO, Comprehend

Bruno Gagnon, Executive, Clinical Operations, Xenon Consulting

A recent survey of 255 Life Sciences ClinOps executives: of the 34% that have an RBM initiative in place, 68% still use latent, manual spreadsheets. Only 11% have successfully automated their RBM program. Our case study details how a successful ClinOps team automated their next generation risk and centralized monitoring program. After only 10 weeks, they were continuously and efficiently optimizing enrollment, compliance, site productivity to lower risk and increase speed to a quality result.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

NEW DYNAMICS IN WORKING WITH STAKEHOLDERS IN RISK-BASED MONITORING

4:00 Chairperson's Remarks

Gareth Adams, Founder and Strategic Innovations Consultant, Syniad Consulting

4:05 CO-PRESENTATION: IRBs: A Stakeholder in Clinical Trial Quality

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

Ellen Kelso, Executive Director, Chesapeake IRB

This presentation will discuss: 1. The role and responsibility of an IRB; 2. The overlap areas with Risk-Based Approach to Clinical Trials; and 3. Improvement areas and areas of cooperation.

4:55 CO-PRESENTATION: The Evolution of Clinical Operations and Data Management - The Biggest "Risk" in Risk-Based Monitoring?

Sponsored by CHILTERN

Gareth Adams, Founder and Strategic Innovations Consultant, Syniad Consulting

Melissa Nezos, Executive Director, Clinical Monitoring Operations, Chiltern

The presentation will share the experiences and lessons learnt from two Senior Operational leaders in developing new roles, analytics and processes in order to implement a variety of RBM strategies with a "no one size fits all" strategy. Explore the new dynamics between two of the major operational teams responsible for data quality, and how this defines implementation considerations, tools, analytics, and technology for risk based monitoring. This session will help your organization avoid common mistakes in moving to a risk based quality management process.

5:45 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

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LEVERAGING TECHNOLOGY FOR RBM

8:35 Chairperson's Remarks

Steve Young, Senior Director, Transformation Services, OmniComm Systems, Inc.

8:40 How to Select and Leverage Technology, Tools and Techniques for Risk-Based Monitoring (RBM)

Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, Maurer Consulting, LLC

Risk-Based Monitoring (RBM) is changing the way companies are conducting clinical trials. Adopting RBM requires changes to a company's processes and tools for monitoring. Implementing technology will be critical in strategies to increase efficiency and deliver accurate analyses of clinical study site performance and data quality. This presentation will address how to evaluate what RBM technology, tools and techniques to consider for implementation based on your company size, budget, and resources. This includes: 1. Identifying the "must have" and the "nice to have" elements of technology for RBM. 2. Case studies are discussed with examples

9:05 Using Predictive and Advanced Analytics to Enhance Risk-Based Monitoring (RBM)

Sponsored by QUINTILES

Rajneesh Patil, Director, Clinical Development, Quintiles

Execute RBM studies with lower risk while improving patient safety and site performance with new capabilities of advanced statistical monitoring and Predictive Analytics that enable the preemptive identification of patient safety issues and actionable insight into clinical trial performance.

- Learn of new capabilities being used in risk-based monitoring study execution
- Understand how you can improve site performance with advanced statistical monitoring
- Optimize site performance and improve patient safety using Advanced and Predictive Analytics

9:30 Technology Considerations for RBM

Nareen Katta, Associate Director, Data Sciences, AbbVie

RBM implementation is probably one of the most complex problems the industry is trying to tackle since the EDC problem of the 90's. There are several cross-roads companies would run into as they embark on the RBM Journey. In this talk you would hear perspectives on items like "Buy vs. Built", "On-Premise vs. Cloud", "Process vs. Technology", "Flexible vs. Standard", "Agile vs. Waterfall" etc.

9:55 Understanding the Proper Role of Source Data Verification (SDV)

Sponsored by OmniComm eClinical Solutions for Life™

Steve Young, Senior Director, Transformation Services, OmniComm Systems, Inc.

Risk-based monitoring (RBM) has become a clear imperative for the life sciences industry because of its compelling value proposition. The major regulatory authorities have provided strong endorsements for RBM, and industry groups including TransCelerate have provided additional guidance and support. Most organizations in the US and Europe are now moving forward with active RBM planning and implementation, though many are still struggling with some key concepts. One of these in particular is understanding the appropriate role of source data verification (SDV) and source data review (SDR). A number of different approaches are being recommended and employed, and it can be confusing to understand how best to proceed. Many organizations also remain concerned about reducing the amount of SDV too aggressively, fearing a detrimental impact on data quality.

10:20 Coffee Break

CASE STUDIES FOR RBM

10:35 Chairperson's Remarks

Grant Simmons, Director, ClinOps Insights & Innovation (CII), Global Operations Services, IDFR, Novartis Pharma

10:40 Adaptive Monitoring 2016: The Continuing Evolution of RBM at Novartis

Grant Simmons, Director, ClinOps Insights & Innovation (CII), Global Operations Services, IDFR, Novartis Pharma

Risk-based monitoring has been all the buzz at many conferences and webinars over the last 2 years or so. There is still some trepidation around even the terminology "risk-based", let alone actually diving into real implementation. Novartis kicked off its RBM program in 2013 under the name "Adaptive Monitoring" told the story of its evolution last year at SCOPE. Our main focus is on improving site quality and relationships, and collaterally reaping the benefits of greater efficiency and possibly reducing the number of on-site monitoring visits as compared to our legacy process. The approach is based on the three pillars of People, Process and Technology. At SCOPE 2016, we will continue the Novartis story: improvements we have made over the past year in the tools and statistical model, and a review of the metrics that we have been able to gather on the Adaptive monitoring trials related to risk management and onsite monitoring.

11:05 Use of ICH Q9 QRM Methods with an Innovative, Risk-Based Knowledge "System" to Improve the Quality of Clinical Studies and Reduce the Operational Risks

Sponsored by inVentiv Health

Stephen Sun, M.D., MPH, Vice President, Medical Affairs; Head, Quality Risk Management Group, inVentiv Health

Recent draft updates to the ICH E6 GCP Guidance will require sponsor companies to incorporate sound quality risk management (QRM) approaches into every clinical study. This presentation is a discussion of how companies can optimize their resources to meet the new standard of clinical studies by harvesting the knowledge-rich systems inherent in the people, processes, and technology of a CRO (and any company) through dedicated, low-investment, and organized approaches. De-constructing clinical studies using systems engineering approaches from ICH Q9, e.g. FMEA, HACCP, etc. to identify and manage fixed and dynamic risks will serve as the foundation for discussion. Collaborations between Sponsor and CROs and within an organization are likely to concentrate patterns of best practices and identified risk controls if knowledge can be smartly harvested, processed, and re-purposed in a continuous improvement cycle as part of a preliminary risk evaluation and a systematic risk assessment.

> "SCOPE is known for the freshness of it's topics, and maybe more importantly, the freshness of its attendees!"
>
> *Joseph K., Sr. Advisor, Eli Lilly*

11:30 Case Study: Learnings from RBM 'Early Adopter' Studies at Roche

Andrew Taylor, Global Head, Clinical Programming, Biometrics, Roche/Genetech

The first RBM 'early adopter' studies at Roche were set-up during 2015. Experiences gained from these clinical studies, ranging from Phase 1 through to Phase 4, are being used to fine tune tools and processes for full deployment of RBM across many parts of the organization from January 2016. This presentation will summarize learnings from the early adopter studies so far, as well as giving insights into the very early days of full deployment, along with future plans.

11:55 PANEL DISCUSSION: Lessons Learned in Deploying RBM

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

Panelists:

Andrew Taylor, Global Head, Clinical Programming, Biometrics, Roche/Genetech

Jacqueline Gough, Advisor, Clinical Risk Management, Eli Lilly and Company

Dan Sfera, CEO, The Clinical Trials Guru, LLC

As risk-based monitoring adoption increases, leverage insights and lessons learned from early adopters across pharma and biotech to successfully deploy RBM at your organization. Topics discussed include setting realistic expectations and timelines for RBM implementation, key principles for setting up RBM in a small or large organization, and other lessons learned.

12:45 Closing Remarks

12:50 pm SCOPE 2016 Conference Adjourns (see you in Miami for 2017!)

Lead Sponsoring Publications:

Drug Discovery Today · GEN Genetic Engineering & Biotechnology News · Applied Clinical Trials · Journal of Clinical Studies · PharmaVOICE · Science AAAS · The Scientist Exploring Life, Inspiring Innovation

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Clinical Data Technology and Integration

Novel Data Collection Modalities, Integrative Systems and Visual Analytics

February 24-25, 2016

Novel data collection modalities, integrative systems, and visual analytics are becoming game-changing features of modern clinical trials. However, the emergence and adoption of technology solutions to enhance data collection and reporting to improve overall outcomes and garner operational efficiencies, has been slower than we would like them to be. Cambridge Healthtech Institute's Fifth Annual "Clinical Data Technology and Integration" conference will feature a broad array of topics such as data integration and accessibility, novel data visualization technologies, wearable devices, cloud storage, data security and others. We are looking forward to hosting a practical and productive knowledge and experience exchange.

*Arrive early and attend **Part 1: Clinical IT Strategy and Governance**. See page 16 for details.*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon Presentation: Pairing Analytics: Solutions Designed to Better Navigate Clinical Trial Data

Sponsored by PPD

Thomas J. Gfroerer, Executive Director, Data Analytics, PPD

Tammy Jackson, Director, Preclarus Development, Biostatistics, PPD

Sponsor companies and CROS have distinct data needs throughout the conduct of a clinical trial. Analytic solutions and visualization tools can help with efficient exploration of the data. This talk will show how coupling uniquely designed analytic solutions can help deliver new approaches to risk surveillance, study management and monitoring safety trends for both sponsors and CROs.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

DATA INTEGRATION AND SHARING: APPROACHES, INFRASTRUCTURE AND SECURITY

4:00 Chairperson's Remarks

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

4:05 Data Sharing: Providing Access to Data Both for Internal and External Customers at Roche

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

In this talk I will explain how Roche has first created a Patient Level Data Sharing group to meet the EU Regulatory requirement to give access to data and are now due to greater internal demand, developing an Enhanced Data Sharing Ecosystem within Roche.

4:30 Industry Case Studies: Why Clinical Organizations are Going Beyond EDC and Embracing Clinical Data Management

Sponsored by ORACLE HEALTH SCIENCES

James Streeter, Global Vice President, Life Sciences Product Strategy, Oracle Health Sciences

4:55 Integrating In-House and Cloud Based Infrastructure

Pam Duffy, IT Lead , Core Clinical Solutions & Services, Pfizer

Cloud computing bring numerous advances such as speed, agility, flexibility, elasticity and innovation. What does that mean to clinical development and how can we take advantage of it? This presentation will share Pfizer's experience with implementing cloud computing in clinical trials and elaborate on the problems and solutions for integrating in-house and cloud-based infrastructure.

5:20 Blocking the Big Breach: An Overview of Standardized Security Systems and How They Protect Pharmaceutical Data

Moderator: Mollie Shields-Uehling, President & CEO, SAFE BioPharma Association

Panelists: Andrew K. Porter, Director, Enterprise Architecture, IT Planning & Innovation, Applied Technologies, Merck

Greg Koski, Ph.D., M.D., Co-Founder & President / Chief Executive Officer, ACRES

Michael Lavoie, CISSP, PMP, Global Information Security & Identity Services, Pfizer Inc

Mary Emanoil, Lead, Content Management & Authoring, Information Management, Development Operations CoE, Pfizer Worldwide Research and Development

The proposed session is an overview of standardized security systems currently available to the pharmaceutical industry and how they are being used to protect sensitive patient data and intellectual property and to improve clinical trial efficiency. The session also will include presentations about individual company initiatives that allow for the secure free flow of information among collaborating parties within protected and trusted environments.

6:15 Reception Hosted by Exostar

EXOSTAR

7:15 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

For years pharmaceutical companies and CROs have struggled to collect, clean and collate site data from disparate sources so they can make better decisions about site feasibility and selection. With the DrugDev Golden Number - a universal identifier for Investigators and sites - individual pharma companies and CROs easily match and master data, and share data across collaborations like the Investigator Databank and TransCelerate. While the Golden Number began as a method for data sharing, innovators are using it to drive operational efficiencies, collaboration and integrated reporting as well. We expect it also will give regulators a more detailed view into the global investigator community, which ultimately can improve patient safety. Join this session for a discussion on the Golden Number and how it can help pharma, CROs and sites do more trials.

WEARABLES IN CLINICAL TRIALS: DATA CONSIDERATIONS

8:35 Chairperson's Remarks

Steven Nathasingh, Managing Director, Vaxa Inc.

8:40 Remote Digital Biomarker Monitoring - Bringing a Smartphone-Based Diagnostic Test for Parkinson's Disease Progression into an Interventional Trial

Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

In clinical research – and especially in Neuroscience – objective, automated and high-frequency measures of disease progression are hard to come by. Traditional physician-led tests are only done periodically, missing the fluctuations of disease activity that strongly affect patient's quality of life. They also lack the objectivity that is so important when developing medicines. By providing patients with mobile sensors they carry day-in and day-out to conduct tests and capture the data, we are addressing this need.

9:05 CO-PRESENTATION: Collecting, Integrating, and Analyzing Wearable Devices Data in Neurology Studies

Steven Nathasingh, Managing Director, Vaxa Inc.

E. Ray Dorsey, M.D., University of Rochester Medical Center, School of Medicine and Dentistry

Many neurological disorders, like Parkinson's Disease, have external manifestations that make them well suited to assessment by objective wearable or portable sensors. This presentation discusses how data from wearable devices are being collected, integrated, and analyzed in Neurology studies like Parkinson's Disease to help drive new and novel insights and therapies.

9:30 Wearable Sensors' Impact on Trials Design and Execution

Moderator: Steven Nathasingh, Managing Director, Vaxa Inc.

Panelists: E. Ray Dorsey, M.D., University of Rochester Medical Center, School of Medicine and Dentistry

Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research & Early Development

Munther Baara, Senior Director, Development Business Technology, Pfizer

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

Sponsored by ERT

9:55 What Is The Role Of CTMS In A Data-Driven Paradigm?
Brion Regan, Product Manager, eClinical Insights, ERT
With the increased adoption of cloud eTMF/eCTD, investigator payment, patient recruitment modeling, and site feasibility solutions, along with the implementation of risk-based monitoring strategies, the role of the traditional CTMS has come into question. What is its future? Where does it fit? This presentation will explore how these recent process and technology disruptions have created the need for a more connected and data-driven "CTMS"- that can help organizations adapt to the changing dynamics of clinical trials management processes.

10:20 Coffee Break

CUSTOM E-CLINICAL SOLUTIONS

10:35 Chairperson's Remarks
Betsy Fallen, BAFallen Consulting LLC

10:40 CO-PRESENTATION: eISF: The Next Frontier for eTMF
Joanne Malia, Director, Medical Research Process Management, Purdue Pharma
Terry Stubbs, President & CEO, ActivMed Practices & Research, Inc.
Traditionally, the TMF has been considered the sponsor's repository of essential documentation but the site too has its collection of documents. These two repositories are separately maintained and must be manually reconciled throughout the study. The electronic Investigator Site File will revolutionize this process by digitally managing the site documents while reducing duplication and reconciliation with the sponsor eTMF. Sponsor and site representatives will speak on their business cases.
personalized medicine.

Sponsored by medidata

1105 Effective Strategies for Capturing, Leveraging and Visualizing Clinical Data
Diane Carozza, Senior Engagement Consultant, Medidata Solutions
The intersection of clinical research and technology provides opportunities to improve business success by helping to control costs, mitigate risks and improve cycle times. Utilize this technology early in the protocol development lifecycle to:
· Optimize study design
· Reduce downstream quality risks
· Improve operational efficiency using analytics

11:35 CO-PRESENTATION: Integrating Data Science into Clinical Trial Planning and Operations
Debbie Profit, Ph.D., Director, Corporate Projects, Otsuka Pharmaceuticals Development and Commercialization
Shashank Rohatagi, Ph.D., Senior Director, Translational Medicine and Think Team, Otsuka Pharmaceuticals Development and Commercialization
The use of technology in the support of clinical trials has continued to increase. However, the disciplines and departments remain very distinct and in some cases siloed. In order to gain the most from your data, to make better decisions based on the data, to formulate more effective trial strategy, and to improve trial operations processes, there must be a more fluid interchange between the data scientists and trial planners.

12:00 pm Implementing a Patient Centricity Platform to Better Engage Patients and Sites in Informed Consent Process
Robert Allen, Senior Director, Digital Innovation Group (DIG), AstraZeneca
Often we forget the human-side of a clinical trial. With trial design, protocol development, and clinical data as primary concerns, we forget engaging patients and investigators is just as important. Engagement can lead to a greater understanding of the trial with the hopes of making the experiences better for everyone. This talk will focus on striking the balance between creating trial effectiveness and efficiency through technology, while putting humans at the center through a use case of implementing the Patient Centricity platform to engage patients better in informed consent process.

Sponsored by DrugDev do more trials

12:25 pm INTERACTIVE PANEL: Can We Shift Investigators from "1 and Done" to Repeat Performers?
Claire Sears, Ph.D., Director, Investigator Engagement, SiteStart, DrugDev
Immo Zadezensky, PharmD, Ph.D., Clinical Pharmacologist, Professional Affairs and Stakeholder Engagement (PASE), Office of the Center Director, CDER, FDA
Christine Pierre, Founder & President, Society for Clinical Research Sites (SCRS)
Jeffrey Rosen, M.D., Medical Director, Clinical Research of South Florida; Associate Professor, University of Miami Miller School of Medicine
In this session we will discuss the problem of investigator turnover – in particular, the large '1 and done' population. Tufts will present information from the FDA 1572 database on the trends, characteristics and size of the '1 and done' population. This information will be supplemented by a presentation of findings from the Investigator Databank related to characteristics of approximately 70,000 '1 and done' sites including site level performance amongst other factors (e.g., geography, pediatrics, therapeutic area). It is clear that the high rate of attrition of investigators and the need to initiate new investigators is detrimental to site.

12:50 Closing Remarks

12:55 pm SCOPE 2016 Conference Adjourns (see you in Miami for 2017!)

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

Melissa Dolen
Account Manager
Cambridge Healthtech Institute
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Inaugural

Leveraging Existing Data for Clinical and Observational Research

EMRs, Existing Patient Databases and Other Real Word Data Sources

February 24-25, 2016

The abundance of data generated during routine health care is growing in significance and should be re-used for clinical and observational research. Patient electronic records, registries, insurance claims, data from pharmacy and social media, and electronic patient-reported outcomes have been increasingly used as eSources. This process requires strategizing, utilizing novel data technologies, as well as close collaboration between pharmaceutical companies and organizations that possess the data. CHI's Inaugural "Leveraging Existing Data for Clinical and Observational Research" will discuss challenges and solutions with secondary use of existing healthcare data for assessing the effectiveness and safety of medical products.

Arrive early and attend ***Part 1: Managing Late Stage Research and Observational Studies****. See page 18 for details*

WEDNESDAY, FEBRUARY 24

12:10 pm Bridging Luncheon Presentation: Pharmacoeconomic Assessment through Market Approval and Beyond: Theory and Operations

Sponsored by MEDPACE

Matthew Page, Epidemiologist, Biometrics, Medpace

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 7 for details)

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

REAL WORLD DATA SOURCES, ANALYTICS AND APPLICATIONS

4:00 Chairperson's Remarks

Adam Wilcox, Ph.D., Medical Informatics Director, Intermountain Healthcare

» 4:05 KEYNOTE PRESENTATION: INTEGRATED EVIDENCE GENERATION WITH REAL WORLD DATA AND RAPID-CYCLE ANALYTICS

Sebastian Schneeweiss, M.D., Sc.D., Vice Chief, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital; Professor, Medicine, Harvard Medical School; Professor, Epidemiology, Harvard School of Public Health

Electronic healthcare data that are generated during the provision of routine care are increasingly used for assessing the effectiveness of medical products. The lecture describes how such real world data can shape the value profile of drugs, will expedite payer impact, and innovate drug development. The lecture will outline an evidence development model spanning the lifecycle of drugs integrating RWE with RCT evidence.

4:30 Do Patients Defined in My Clinical Trial Protocol Really Exist in Real-World Healthcare Settings?

Sponsored by UBC AN EXPRESS SCRIPTS COMPANY

Irene Cosmatos, M.Sc., Senior Scientific Researcher, Database Analytics Automation, UBC: An Express Scripts Company

An evidence-based approach to understanding clinical and demographic patient profiles early in a trial's design can inform selection criteria before a protocol is finalized. Benefits include improved patient recruitment and a reduced need for costly protocol amendments. Through scenarios using real world healthcare data, attendees will learn how observational data can inform clinical teams of the impact that certain patient selection criteria may have on recruitment, using visualizations that highlight problem criteria.

4:55 Novel Ways to Design and Execute Prospective Observational Studies Using EMR and Linked Data Network

Hui Cao, M.D., Ph.D., Executive Director, Real-world Evidence, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

Technologies such as EHR, mobile health, wearable devices and linked data networks are providing new ways to conduct observational studies. EHR not only enables secondary uses for retrospective studies, but also provides a new platform to observe patients prospectively. We will discuss with the audience the examples of novel prospective studies that leverage EHR and m-Health technologies to maximize the data collection and to follow up patients beyond the study period.

5:20 PANEL DISCUSSION: Blurring the Lines between Primary and Secondary Use of Medical Data

Usman Iqbal M.D., Senior Medical Affairs Leader, Neuroscience, Global Medical Affairs, AstraZeneca

Panelists: Sebastian Schneeweiss, M.D., Sc.D., Vice Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine of the Brigham and Women's Hospital, Professor of Medicine, Harvard Medical School, Professor in Epidemiology, the Harvard School of Public Health

Hui Cao, M.D., Ph.D., Executive Director, Real-world Evidence, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

Adam Wilcox, Ph.D., Medical Informatics Director, Intermountain Healthcare

Khurram Nasir, M.D., Director Center for Healthcare Advancement & Outcomes at Baptist Health South Florida

6:15 Reception Hosted by Exostar EXOSTAR®

7:15 Close of Day

THURSDAY, FEBRUARY 25

7:15 am Registration

7:45 Breakfast Presentation: How One (Golden) Number Can Transform Clinical Trials

Sponsored by DrugDev do more trials

Elisa Cascade, MBA, President, Data Solutions, DrugDev

For years pharmaceutical companies and CROs have struggled to collect, clean and collate site data from disparate sources so they can make better decisions about site feasibility and selection. With the DrugDev Golden Number - a universal identifier for Investigators and sites - individual pharma companies and CROs easily match and master data, and share data across collaborations like the Investigator Databank and TransCelerate. While the Golden Number began as a method for data sharing, innovators are using it to drive operational efficiencies, collaboration and integrated reporting as well. We expect it also will give regulators a more detailed view into the global investigator community, which ultimately can improve patient safety. Join this session for a discussion on the Golden Number and how it can help pharma, CROs and sites do more trials.

PRAGMATIC TRIALS

8:35 Chairperson's Remarks

8:40 Big Clinical Data: Challenges and Approaches in Using Electronic Health Record Data for Research Studies

Adam Wilcox, Ph.D., Medical Informatics Director, Intermountain Healthcare

With the widespread adoption of electronic health records, there is a great opportunity to use the data from these records to advance research studies. However, there are important differences between data from EHRs and data collected for research studies. This presentation discusses these challenges, and outlines approaches and methods to address them, with lessons learned from managing clinical data warehouses and with the Patient Centered Outcomes Research Institute.

9:05 Designing Cardiovascular Pragmatic Clinical Trials: Learning Healthcare System at Work

Khurram Nasir, M.D., Director, Center for Healthcare Advancement & Outcomes at Baptist Health South Florida

Clinical trials have been the main tool used by the health sciences community to test and evaluate interventions. Trials can fall into two broad categories: pragmatic and explanatory. Pragmatic trials are designed to evaluate the effectiveness of interventions in real-life routine practice conditions, whereas explanatory trials aim to test whether an intervention works under optimal situations. Pragmatic trials produce results that can be generalized and applied in routine practice settings.

9:30 Utilizing Pragmatic Clinical Trials in Clinical Development Programs

Usman Iqbal, M.D., Senior Medical Affairs Leader, Neuroscience, Global Medical Affairs, AstraZeneca

The presentation will focus on understanding/using the concept of patient journey through the lens of BIG DATA & secondary databases to identify patient centric unmet needs and gaps in care, and leveraging the related output to design pragmatic trials. A real world case study will be presented in this regard walking the audience through the methodology of patient journey assessment and systematic application of related evidence and knowledge towards pragmatic trial design, patient populations, end point strategy and strategic clinical decision support.

9:55 Leveraging the Electronic Medical Records (EMR) Based Analytics to Optimize Design of a Prospective Observation Study for Asthma and COPD (Chronic Obstructive Pulmonary Disease)

Xia Wang, Ph.D., Principal Health Informatics Scientist, Informatics Lead RIA, AstraZeneca

This talk relates an EMR based analysis to optimize the design of a 3-year, multi-country prospective observational study focusing on chronic obstructive lung disease. This study aims to enroll patients from a non-controlled ("real world") setting and will be the largest coordinated global study of its kind. The analysis of 11 country-specific EMR data sources provides unique insight of clinical practices and patient profiles, promotes optimized design and enables novel data collection workflow.

10:20 Coffee Break

CROSS-LINKING DATA SOURCES

10:35 Chairperson's Remarks

Randy Ramin-Wright, Head, Quality Risk Management, Clinerion

10:40 Improving Transparency, Efficiency, and Quality in Patient Registry-Based Research: AHRQ Strategy and Initiatives

Elise Berliner, Ph.D., Director, The Technology Assessment Program, AHRQ

This presentation will share our work to improve validity of registry studies through three related methods projects to improve the development of registries, a major activity of AHRQ's Effective Health Care Program:

- Framework for record linkage of registry to other data sources.
- Prospectively measuring physicians' treatment allocation decision process to minimize confounding by indication.
- Prospective collection of registry information for deriving instrumental variables.

11:05 Broadening Insight into Cancer Patient Characteristics through Matching Secondary Data Sources

Elizabeth A. MacLean, PharmD, Director, Global Health and Value/Outcomes & Evidence, Pfizer

Use of administrative claims data to address questions related to cancer patient treatment experience may yield limited information. However, match of administrative claims to corresponding medical record data can broaden insight into patients' clinical and disease characteristics. This presentation will describe the experience of conducting a two-part study to examine treatment experience of patients with non-small cell lung cancer.

11:30 Evaluating an Innovative Approach to a Prospective Patient Registry Design using Electronic Medical Record (EMR) Data

Susan Fish, Senior Statistical Programmer Analyst, Genentech

Registries today are more complex and expensive to implement than in past years due to increased regulatory reporting requirements and compliance concerns. This presentation will describe a potential solution for registry data collection using an innovative external partnership model that is both cost effective and collaborative, and present results from a pilot study using EMR based data collection vs traditional CRF data for a lung cancer registry.

11:55 Safety Monitoring for Newly Marketed Products Using a Claims Database

Rui Jiang, M.D., DrPH, Associate Director, Pharmacovigilance & Epidemiology, Gilead Sciences

Prospectively collected electronic healthcare data are more and more used for drug-safety research in complement to passive safety monitoring system such as FDA adverse event reporting system (AERS). The goal of active drug safety monitoring is to detect serious adverse reactions (pre-specified outcomes) as early as possible without too many false alarms. We are applying this method to the study design for analyzing the IMS claims data to monitoring of adverse reactions among patients treated with a newly approved oncology product Zydelig, a treatment for relapsed/refractory chronic lymphocytic leukemia and indolent NHL, from 2014 to 2018.

12:20 INTERACTIVE PANEL: Can We Shift Investigators from "1 and Done" to Repeat Performers

Claire Sears, Ph.D., Director, Investigator Engagement, SiteStart, DrugDev

Immo Zadezensky, PharmD, Ph.D., Clinical Pharmacologist, Professional Affairs and Stakeholder Engagement (PASE), Office of the Center Director, CDER, FDA

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

Jeffrey Rosen, M.D., Medical Director, Clinical Research of South Florida; Associate Professor, University of Miami Miller School of Medicine

In this session we will discuss the problem of investigator turnover – in particular, the large '1 and done' population. Tufts will present information from the FDA 1572 database on the trends, characteristics and size of the '1 and done' population. This information will be supplemented by a presentation of findings from the Investigator Databank related to characteristics of approximately 70,000 '1 and done' sites including site level performance amongst other factors (e.g., geography, pediatrics, therapeutic area). It is clear that the high rate of attrition of investigators and the need to initiate new investigators is detrimental to site and overall trial performance, and is costly and time-consuming for sponsors. The session will conclude with a commentary on the data from the Site perspective regarding what can be done (if anything) to decrease the rate of investigator turnover. The learning objectives for this session are:

- Learn detailed characteristics of the global population of investigators who have only participated in one clinical trial
- Identify factors that can be gleaned from these detailed analyses that help identify investigators at risk of only participating in a single clinical trial
- Based on these insights, discuss strategies/actions that can help reduce the likelihood of future site turnover

12:45 Closing Remarks

12:50 pm SCOPE 2016 Conference Adjourns (see you in Miami for 2017!)

Pricing and Registration Information

CONFERENCE PACKAGE PRICING

BEST VALUE! - Includes access to the entire 3-day SCOPE program (Does not include access to pre-conference short courses)	**Commercial**	**Academic, Government, Hospital-affiliated**
Registration after January 15, 2016, and on-site	$2849	$1349
Basic Registration - Includes access to ONE conference (Does not include access to pre-conference short courses)		
Registration after January 15, 2016, and on-site	$1849	$999

Tuesday-Wednesday, February 23-24	Wednesday-Thursday, February 24-25
C1A: Global Site Selection, Feasibility Assessment and Site Management	C1B: Improving Site-Study Activation and Performance
C2A: Enrollment Planning and Patient Recruitment	C2B: Patient Engagement, Enrollment and Retention through Communities and Tech
C3A: Clinical Trial Forecasting and Budgeting	C3B: Managing Outsourced Clinical Trials
C4A: Implementing Risk-Based Monitoring (Part 1)	C4B: Implementing Risk-Based Monitoring (Part 2)
C5A: Clinical IT Strategy and Governance	C5B: Clinical Data Technology and Integration
C6A: Managing Late Stage Research and Observational Studies	C6B: Leveraging Existing Data for Clinical and Observational Research
S7A: Managing Biomarker-Driven Clinical Trials	
S8A:Clinical Research Statistics for Non-Statisticians	

PRE-CONFERENCE SHORT COURSE PRICING - February 22, 2016 • 2:00 pm - 5:30 pm

Single Short Course	$699	$399

SC1 Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment	SC3 Views and Conversations on Risk-Based Monitoring
~~SC2 Visual Analytics - An Immersive Workshop for Clinical Researchers in Pharma and Device Trials~~	SC4 Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract

CONFERENCE DISCOUNTS

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

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

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

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

ADDITIONAL REGISTRATION DETAILS

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

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

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

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

How to Register: SCOPEsummit.com

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

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

Please refer to the Registration Code below:

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