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FINAL AGENDA

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Fifth Annual

February 4 - 6, 2014 • Hyatt Regency Miami, Miami FL

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

February 4-5

- Electronic Data in Clinical Trials
- Global Site Selection and Management
- Enrollment Planning and Patient Recruitment
- Aggregate Spend and Transparency Reporting in Clinical Trials
- Managing Post-Marketing Studies and Registries
- Sample & Biospecimen Management in Clinical Trials

February 5-6

- Integrating and Leveraging Clinical Trial Operations Data
- Improving Site-Study Activation and Performance
- Subject Retention and Compliance in Studies and Registries
- Clinical Trial Forecasting and Project Management
- Patient-Centered Technologies for Post-Marketing and Real World Data Research

Pre-Conference Short Courses on February 3

PLENARY KEYNOTES

***Jamie Heywood**, Co-Founder and Chairman, PatientsLikeMe*

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

***Jeffrey Kasher**, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member*

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

***Bruno Gagnon**, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.*

***Andrew Lee**, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.*

SCOPEsummit.com

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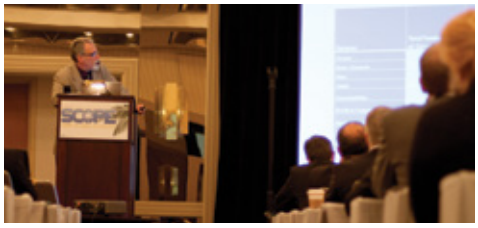
Conference-at-a-Glance

	DATA	SITES	RECRUITMENT	STRATEGY	POST-MARKETING	LOGISTICS
Monday, February 3, 2014						
PM	**Pre-Conference Short Courses***					
Tuesday, February 4, 2014						
AM & PM	Conference 1 Electronic Data in Clinical Trials	Conference 2 Global Site Selection, Feasibility Assessment, Operations and Site Management and Site Management	Conference 3 Enrollment Planning and Patient Recruitment	Conference 4 Aggregate Spend and Transparency Reporting in Clinical Trials	Conference 5 Managing Post-Marketing Studies and Registries	Conference 6 Sample & Biospecimen Management in Clinical Trials
Wednesday, February 5, 2014						
AM	Conference 1 Electronic Data in Clinical Trials	Conference 2 Global Site Selection, Feasibility Assessment, Operations and Site Management	Conference 3 Enrollment Planning and Patient Recruitment	Conference 4 Aggregate Spend and Transparency Reporting in Clinical Trials	Conference 5 Managing Post-Marketing Studies and Registries	Conference 6 Sample & Biospecimen Management in Clinical Trials
PM	Conference 7 Integrating and Leveraging Clinical Trial Operations Data	Conference 8 Improving Site-Study Activation and Performance	Conference 9 Subject Retention and Compliance in Studies and Registries	Conference 10 Clinical Trial Forecasting, Budgeting, and Project Management	Conference 11 Patient-Centered Technologies for Post-Marketing and Real World Data Research	Conference 10 Clinical Trial Forecasting, Budgeting, and Project Management
Thursday, February 6, 2014						
AM & PM	Conference 7 Integrating and Leveraging Clinical Trial Operations Data	Conference 8 Improving Site-Study Activation and Performance	Conference 9 Subject Retention and Compliance in Studies and Registries	Conference 10 Clinical Trial Forecasting, Budgeting, and Project Management	Conference 11 Patient-Centered Technologies for Post-Marketing and Real World Data Research	Conference 10 Clinical Trial Forecasting, Budgeting, and Project Management

**Separate registration required*



Stay Connected:

Join the Clinical Trials Ops Executives group

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CHI's INTRONET
Networking at its Best

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

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SCRS Our Voice.℠ Our Community. Society for Clinical Research Sites

"Well organized program and very pertinent topics. I would highly recommend attendance."

— Carol M., Director, Business Development, Spaulding Clinical Research

"Overall, I find the meeting to be very engaging. The topics and information provided are the common daily issues that are encountered in clinical operations. This conference provides the ideal setting to leverage knowledge across companies."

— Susie C., Clinical Trial Intelligence Manager, Novartis

"The SCOPE conference hit the hot topics with great presentations! Unlike other conferences where the same old (boring) information is covered over and over again."

— Sondra S., Sr. Director, Clinical Operations, Alkermes, Inc.

Sponsorship, Exhibit and Lead Generation Opportunities

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

Agenda Presentations

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

Breakfast & Luncheon Presentations

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

Invitation-Only VIP Dinner/Hospitality Suite

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

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

Exhibit

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

Additional opportunities are available for sponsorship, including:

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

To customize your participation at this event, please contact:

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

Lead Generation

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

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

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

NEW PRODUCT SHOWCASE

New Product Showcase

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

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

Current Sponsors and Exhibitors *(as of September 9, 2013)*

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Trifecta
United BioSource Corporation
Verified Clinical Trials LLC
Wake Research Associates

Pre-Conference Short Courses*

February 3, 2014
Afternoon 2:00-5:30pm | Dinner 6:00-9:00pm

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

Afternoon Short Courses 2:00 pm – 5:30 pm

SC1 Cloud-Based Clinical Data Access and Management: Current Industry Status

- Overview of technical and operational considerations related to clinical data storage and management in cloud
- Data security challenges and solution approaches
- Current vendor landscape

Instructors:
Gary Secrest, CTO and Vice Chairman, SAFE-BioPharma Association
Daniel O' Connor, InnovoCommerce
Munther Baara, Senior Director, Development Business Technology, Pfizer

SC2 Clinical Trial Monitoring and Compliance: The Role of the CRA in Supporting Subject Recruitment and Successful Study Conduct

- Ways to partner with your sites during different phases of clinical trials
- How to have an enrollment discussion with your site; define mutual goals and expectations
- How to ensure ROI on [illegible] activities

CANCELLED

Instructors:
Gretchen Goller, Senior Director, Therapeutic Expertise, Patient Access and Retention Services, PRA International
Nikki Fink, Director, Patient Access and Retention Services, PRA International

SC3 Innovative Approaches to Project Management: Strategic Planning, Forecasting and Quality Improvement

- Project planning: project projections, analyzing risks and challenges
- Effective financial management of clinical trials
- Compliance and performance [illegible] new regulatory landscape

CANCELLED

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

SC4 Building Clinician & Patient Communities for Post-Marketing and Real World Data Research

- Social media analytics driving intelligent, effective outreach to find & attract clinicians and patients
- Common workflow to onboard, manage and engage
- Automated patient referrals to trials and sites

Instructors:
Kate Trainor, Vice President & Global Head, Project Management &Technology, PACE PAREXEL
Nick Darwall-Smith, Vice President, CRS Technology, PAREXEL
Brendan O'Neill, Director, Patient Recruitment Strategy Group, PAREXEL

SC5 Identity Crisis! An Educational Workshop and Guide to Study Branding

- Study names, patient- and physician-facing taglines, logos
- Guidelines for applying corporate identity to study-related materials, as well as strategy and [illegible]
- Tips for site staff on how to play an active role in spreading the word

CANCELLED

Instructors:
Bonnie Brescia, Founding Principal, BBK Worldwide
Additional Instructors to be Announced

SC6 Clinical Trials to Establish Value of Diagnostic Tests: Design and Management

Instructors:
Teresa Raich, Ph.D., Vice President, Nanosphere
Anita Borek, Senior Manager, [illegible] and Specimen Management, Nanosphere, Inc.
Scott Powell, Clinical Marketing Manager, Nanosphere, Inc.

CANCELLED

Dinner Short Course 6:00 pm – 9:00 pm

SC7 Technical and Operational Considerations in Conducting a Patient-Centric Study

- How to collect and share data with patients using the latest technologies: EDC systems, smartphones, and more
- Scientific design considerations such as targeting the right patient population, selecting study endpoints, including a control group, etc.
- Operational study enhancements
- During the workshop, attendees will work through a sample study design

CANCELLED

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

**Separate registration is required*

Hotel and Travel Information

Hyatt Regency Miami
400 SE Second Avenue
Miami, FL 33131
T: 305-358-1234

Discounted Room Rate: $215 s/d
Cut Off Date: December 30, 2013

Please visit the **Hotel and Travel Information** page of our conference website to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute SCOPE conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.

Please visit **SCOPEsummit.com** for hotel booking and flight and car rental discounts.

Plenary Keynotes & Panel

Tuesday, February 4, 2014 | 8:00 – 9:45 am
Thursday, February 6, 2014 | 8:00 – 9:40 am

Tuesday, February 4, 2014 | 8:00 – 9:45 am

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

What Does a Trial Mean in the Era of Real-Time Measurement?

Jamie Heywood, Co-Founder and Chairman, PatientsLikeMe

Our understanding of disease is being rapidly redefined by new genomic and observational insights to the point that the indication we study today may not exist tomorrow. How much longer will the model "one study, one condition, one claim" serve a changing market? Beyond the regulator, is our scientific method providing the patient, the physician, and the payer the personalized and actionable data they need? In the end it's all about getting the right drug to the right patient. We need to master patient-centered, real-time measurement today to serve the needs of the patient and health system of tomorrow.

The Silent Partners and Their Role in Clinical Research: Improving Trial Design and Management by Understanding the Real "Customer"

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

Developing a medical treatment and trying to escort it through a trial and onto the market is a complex production involving many players. Ultimately the stars of this production and complex process are the subject volunteers. However, we are all cast members in this production. We each operate from a set of assumptions on how best to design and run these trials from our own perspective. As the protocols become more complex, as competition for investigators and volunteers becomes more fierce, as regulatory hurdles are raised, as the size of trials both in size and geography grows, and as the burden on the subjects increases, are we actors in the broader research community losing sight of the end game and of each of our key roles in the overall production?

PANEL: Perspective from a Cast of Characters Needed for Any Successful Study Execution

Are we sometimes losing touch with our "customer," the research subjects themselves? It is important to understand how your decisions ultimately impact research volunteers and thereby the reality of study timelines and budgets. Whether you are in protocol writing, drug development, study start-up, feasibility, recruitment, monitoring, compliance, data analysis, or supply chain it is equally as important to take the lessons you'll learn back into the office and ensure that moving forward you and your studies are designed for success among the other players in your production.

Thursday, February 6, 2014 | 8:00 – 9:40 am

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

Accelerating Clinical Research through Collaboration

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

TransCelerate is developing shared-industry research and development solutions to simplify and accelerate the delivery of innovative products to patients. It is a pre-competitive model and its vision is to improve the health of people around the world by accelerating and simplifying the research and development of innovative new medicines. What have we done? Why is it working? Where are we going?

Data across the Clinical Research Continuum: How Data is the Common Denominator

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

The SCOPE Summit features multiple tracks covering a range of issues on clinical trial planning and management. A common thread across these topics is data – how to get it, how to make it available, how to use it to make better decisions. Across much of the clinical research continuum, and we are all in the data business.

PANEL: The Discipline of Innovation in Clinical Research

As an industry and as a community made up of researchers and patients we have a shared goal and interest in improving the development of new medicines. Beyond the current scientific, operational and financial challenges we have to start thinking about improved models and how to build innovation into the clinical research enterprise. Topics to be discussed include:

- Innovation beyond the buzz – moving from ideas to execution
- Supporting innovation in a pragmatic clinical research organization
- Delivering the portfolio today while ensuring a sustainable R&D model for tomorrow
- Can we innovate even if we cannot forecast an ROI

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

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.

Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

8:05 Chairperson's Opening Remarks
Kenneth Getz, Director, Sponsored Programs, Tufts CSDD;Chairman, CISCRP
Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, UBC

8:15 Plenary Keynote Introduction
Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation

» 8:20 PLENARY KEYNOTES AND PANEL

What Does a Trial Mean in the Era of Real-Time Measurement?
Jamie Heywood, Co-Founder and Chairman, PatientsLikeMe

The Silent Partners and Their Role in Clinical Research: Improving Trial Design and Management by Understanding the Real "Customer"
Christine Pierre, President, The Society for Clinical Research Sites (SCRS)

PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

ADDRESSING NEW DATA LANDSCAPE

10:45 Chairperson's Remarks
Kirstin Holzapfel, Deputy Director, Global Clinical Data Center, Bayer / Global Clinical Operations

10:55 KEYNOTE PRESENTATION: Challenges and Opportunities in Building a Foundation System for the New Medical Data Landscape
Francis Kendall, Global Head, Statistical Programming and Analysis, GLIDE Future Investigation Team Lead, Genentech
This talk will look at the challenges and opportunities the new Medical data Landscape for Pharma brings and how Roche are setting the foundation with implement a new systems.

11:20 Development of a Scientific Decision Support Framework across Clinical Development
Paul Konstant, Manager, Translational Informatics, Janssen Pharmaceutical Co.
Scientific decision support presents an ongoing challenge to balance processes with flexibility. This presentation will describe a framework for integrating experimental outcomes being applied at Janssen. Through examples of technology implementations and scientific analyses, this presentation will show how scientific context can be leveraged to meet the diverse needs of clinical development.

11:45 The Use of CRUISE, a Structured Content Management System, to Maximize the Value Realized from Clinical Study Documents
Michael Jasper, Ph.D., Director, Clinical Documentation, Genzyme, a Sanofi Company
The CRUISE (Content Re-Use Information System for e-Health) Program is a topic-based structured content management system being developed at Sanofi. The presentation will focus on the use of Topic Maps, Content Libraries and Metadata to maximize re-use potential and efficiency of clinical document production and improve content standardization within an organization as well as harmonize document structure and content with emerging industry standards.

12:10 pm What Will Clinical Data Applications Look Like in Five Years
Sponsored by OmniComm eClinical Solutions for Life
Keith Howells, Senior Vice President, Development, OmniComm Systems, Inc
The technology landscape is changing quickly, with more data captured electronically at source, an explosion of mobile applications, and an increasing ability for related applications to share data in real time. Similarly there have been surprising new initiatives in regulatory guidance, notably for eSource and risk-based monitoring. This presentation will explore how the market for eClinical applications is likely to evolve to take advantage of these exciting trends.

12:35 LUNCHEON PRESENTATION: Risk-Based Monitoring and eSource – 2 Sides of the Same Coin
Sponsored by Clinical ink
Edward S. Seguine, CEO, Clinical Ink
Risk-Based Monitoring and eSource are complementary and interdependent approaches that, when implemented together, can fundamentally transform existing business practices beyond what is possible if either approach is adopted singly. This presentation will summarize experiences across 40+ studies in a range of study types to identify common issues and specific benefits. **1:15 End of Morning Session**

E-CLINICAL SOLUTIONS

1:25 Chairperson's Remarks
Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, UBC

1:35 Clinical Genomic Data Integration and Clinical Trials
Jomol Mathew, Ph.D, Director, Clinical and Translational Informatics, IS, Dana-Farber Cancer Institute
We present a strategy, systems and tools that we have developed at Dana-Farber Cancer Institute in integrating clinical genomic data for enabling translational research, clinical trial matching and cohort identification.

2:00 Towards Precision Design of Clinical Trial Eligibility Criteria Using Electronic Health Record
Chunhua Weng, Ph.D., Florence Irving Assistant Professor of Biomedical Informatics, Columbia University
I will propose approaches to enable transparent, evidence-based precision design of clinical research eligibility criteria that allow rapid feasibility assessment and testing of research generalizability and clinical effectiveness *in silico*. I envision that the new "precision design" will allow clinical researchers to articulate their rationale for defining clinical trial eligibility criteria (e.g., how was the value of each criterion chosen?).

2:25 Leveraging EHR Infrastructure and Process for Trial Participant Identification, Enrollment and Retention
Les Jebson, Executive Director, Diabetes Center of Excellence, University of Florida Academic Health Center
With broad implementation of comprehensive EHR systems, the ability for brisk data mining and eligible trial participants in an emerging tool for organized research. However, there are key logistical and legal process steps which must be adhered. This presentation walks participants through the essential process steps for efficient and comprehensive participant identification, enrollment and retention through the EHR platform.

2:50 Data Management Re-Mix: The Need for New Tools, Technologies and Terminologies

Sponsored by OPTUM Good for the system.

Subha Krishnan, CCDM Principal Data Manager, Optum

Late phase studies have become a thriving segment of pharmaceutical research, with data management processes evolving to support them. The nature of these studies warrants they be conducted with paper, EDC, or a hybrid approach. This presentation will explore various data capture approaches, while mindful of costs and study needs.

3:05 Refreshment Break in the Exhibit Hall

4:05 Interactive Breakout Discussion Groups

5:15 Welcome Reception in the Exhibit Hall

6:15 End of Day

WEDNESDAY, FEBRUARY 5

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

DATA STANDARDS AS THE KEY TO SUCCESS

8:10 Chairperson's Remarks

Kuno Didier van der Post, MSc, Ph.D., Senior Vice President, Business Development, OmniComm Systems, Inc.

8:20 Why Easy If You Can Make It Comprehensive? A Study about Clinical Data Standards Utilization, Process and System Harmonization and Future Data Warehousing Options Initiated by the Bayer FECD Program

Kirstin Holzapfel, Deputy Director, Global Clinical Data Center, Bayer / Global Clinical Operations

The Future Environment for Clinical Data (FECD) program is supposed to deliver a common framework for various organizations within Global Development. Structured study design, study protocol creation, EDC setup and optimization, clinical data management and programming, statistical analysis and compilation of submission data are built around clinical standards.

8:45 Therapeutic Area Standard Data Elements

Meredith Nahm, Ph.D., Associate Director, Clinical Research Informatics, Biomedical Informatics Core, Duke Translational Medicine Institute

This talk covers the status and landscape of therapeutic area data standards with a focus on 1) relationship to other data standards, 2) opportunities to influence draft standards, and 3) analyzing organizational impact. The talk uses examples from recent work in Schizophrenia and Major Depressive Disorder funded by grants from the FDA.

9:10 QueryMap, the New Way to Clean Your Data

Sponsored by PATIENT PROFILES clinical trial software

Barbara Elashoff, CEO, Patient Profiles, LLC

By integrating data visualization and a clinical review of individual patient data using Patient Profiles' QueryMap, we have developed a more robust and efficient way of evaluating patient data to enhance the monitoring process that preserves the quality of the data and the integrity of the trial.

9:35 Using Patient-Level Electronic Health Records to Identify Clinical Trial Sites and Enhance Patient Recruitment

Sponsored by ANOLINX GO DEEP

Aaron Kamauu, M.D., M.S., M.P.H., CEO, Anolinx LLC

Use of healthcare data as real world evidence has become a forefront for clinical research. This presentation will describe successful approaches to effectively leverage rich sources of electronic healthcare data to support drug development, specifically identification of clinical trial sites by site-specific feasibility analysis, and EHR-based patient recruitment.

9:50 Coffee Break in the Exhibit Hall

DATA-DRIVEN TRIAL MANAGEMENT

Shared Session between *Electronic Data in Clinical Trials* and *Global Site Selection*

10:40 Chairperson's Remarks

Simon Sparkes, Senior Vice President, Clinical, ArisGlobal

10:45 Risk-Based Monitoring Using the Paperless Approach

Mary Flack, M.D., CEO, Elevated Clinical Trials, Former Vice President, Clinical Research, Nanobio

Using a paperless approach to a Phase 3 clinical trial we were able to increase the speed, efficiency and quality of risk-based monitoring. Both site- and study-specific data were entered in real time using three integrated systems, including tablet-based screens with built in audit trails or scanned documents certified as electronic source (such as informed consent documents).

11:10 Reaching Patients Where They Are: Using Medical Claims and Public Data to Geo-Target Sites & Patients

Sponsored by UBC AN EXPRESS SCRIPTS COMPANY

Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation

Through population analytics and advanced targeting, your next project can enroll the right patients faster. This session will show you how to use geographically-rich health datasets to take your enrollment strategies to the next level.

11:35 Getting Real, Validating Data-Driven Feasibility and Country Selection

Michael Jones, Senior Director, Global Site Development, Clinical Operations, Eli Lillly & Co.

Augment use of central process that uses historical performance data with local resources and expertise in target countries. Validate current clinical practice match desired study plan. Minimize futile enrollment projects and decrease cycle time.

12:00 pm Using Insurance Claims and Electronic Health Records to Ensure a Patient-Centric Trial

Sponsored by OPTUM Good for the system.

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

Trials do not have to run late. More quantitative information means better planning. This presentation will cover planning feasibility with insurance claims and electronic health records, including statistical projections of disease prevalence. You'll also learn how to "fish where the fish are" using techniques ranking areas/ investigators based on patient count.

12:15 LUNCHEON PRESENTATION: Integrating Site Survey Management Tools into Your Clinical Trial Workflow

Sponsored by BioPharm Clinical

Ruth McHenry, Managing Director, Infinata, Inc.

The current site survey process is inefficient and outdated. Sponsors desperately need detailed site information (equipment, certifications, capabilities, facility size, etc.) in order to choose the best locations. Attendees will learn how to streamline the process by which pharmaceutical sponsors obtain and manage information about sites and site networks with one integrated, secure, cloud-based solution that allows unprecedented control over all phases of the site evaluation process.

1:00 Close of Conference

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

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PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

NEW STRATEGIES FOR GLOBAL PLANNING

10:45 Chairperson's Remarks
Kevin McNulty, Director, Product Marketing, Life Sciences, Intralinks, Inc.

10:55 Let's Jam: Optimizing Clinical Trial Planning and Design
Jackie Kent, Director, Clinical Development Information & Optimization (CDIO), Eli Lilly & Co.
There is no single solution to solve all the issues with trial planning, feasibility and country allocation. Learn about an innovative approach that covers process, information, people and technology approaches to use to help with this complex area.

11:20 Empowering Patients in Clinical Research: Pfizer's Blue Button Project
Jennifer Wulff, MBA, Director, Clinical Innovation, Pfizer
Pfizer recently launched its Blue Button Project, a first-of-it's-kind initiative enabling patients who have participated in clinical trials the opportunity to download their individual clinical data. Using the Blue Button standard launched by the White House, patients will be empowered to use the data to improve their overall health and wellness, from sharing with healthcare providers to powering clinical risk assessments. In this session Pfizer will share more on why they have launched this initiative, initial learnings, and where the project may go in the future.

11:45 Strategic Approaches to Improve Global Trial Planning and GCP Readiness
Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.
Appropriate planning is key to risk-reduction in global clinical trials. Accurate predictability around site performance and GCP compliance is hard to achieve, especially in rare disease indications or when using new or naïve investigators. In this presentation, we will review some key success factors for protocol optimization, site start-up, monitoring oversight, data clean-up and inspection readiness. Emphasis will be given on how to apply lessons learned from Regulatory Inspection findings early in the project and ensure highest level of team performance while remaining compliant.

12:10 pm Next-Generation Feasibility Analyses
Sponsored by inVentiv Clinical Trial Recruitment Solutions
Irina Ringler, Director, Feasibility & Clinical Informatics, inVentiv Clinical Trial Recruitment Solutions
Effective feasibility analyses demand more sophisticated approaches that can incorporate the many factors that contribute to a successful study. In this session, we will discuss approaches to leveraging data, analytics, internal and external expertise to gather protocol and investigator intelligence prior to engaging sites with a feasibility questionnaire.

12:35 LUNCHEON PRESENTATION: Data-Driven Site Selection Strategies for Orphan Diseases
Sponsored by citeline
Sylvia Marecki, Ph.D., Senior Director, Product Management & Strategy, Citeline
Drug development activity aimed at orphan diseases continues to increase. Identifying and recruiting clinical investigators with relevant expertise and who have a high potential to perform is paramount. This presentation will review a case study providing data-driven strategies for country and site selection in this increasingly competitive space.

1:15 End of Morning Session

SELECTING WINNING SITES AND KEEPING THEM HAPPY

1:25 Chairperson's Remarks
Sylvia Marecki, Ph.D., Senior Director, Product Management & Strategy, Citeline

1:35 Summary Level Clinical Site Data: A Method of Site Selection and Ranking Sites for Audits and Feasibility
Nadia Bracken, Clinical Program Manager, Clinical Operations, Biotie Therapies
Best practices to improve site selection process, developing a lean method to determine adequacy of a site during feasibility for a multicenter trial, and identifying top performers/ weed out underperformers for future trials using retrospective data.

2:00 Site Engagement For The 21st Century
Sponsored by BBK Worldwide
Matthew Stumm, Principal, Creative & Media Strategy, BBK Worldwide
Investigative sites are where the recruitment rubber hits the enrollment road. And today's modern site is "not your father's" site of yesterday. With the technological aptitude, immediacy, and desire to connect over distances as the hallmark characteristics of most professionals today, the sponsors who transform the way they engage sites will take the lead in the race to successful recruitment and also develop long-term partnerships with unsurpassed investigator and site relations. Matthew Stumm, principal, creative and media strategy, BBK Worldwide, will take you through some of the ways you can apply new media to create and sustain an engaging recruitment milieu that focuses site staff efforts, provides motivation, fosters connection, and simplifies common arduous site staff activities.

2:25 Investigator Perspective: How to Avoid the Need for Therapy in a Sponsor-Investigator Relationship (Drugs Are Not Always the Answer!)
Robert Dracker, M.D., Medical Director, Summerwood Pediatrics; Member, Pediatric Advisory Committee, FDA
Sharing the perspective of a P.I. this presentation offers some tangible lessons for study sponsors and trial project leaders on insuring objectives and design of the study are understood and ultimately embraced by the Investigators, site and participants.

2:50 Intelligent Monitoring: Combining Risk, Event and Analytics-Based Monitoring
Sponsored by @ris global.
Simon Sparkes, Senior Vice President, Clinical, ArisGlobal
Early adopters of risk-based monitoring have primarily focused on the analysis of EDC data to drive partial SDV. This session examines how already available technologies can combine operational and study management data to quantify risk, identify trigger events and provide dynamic analytics to promote truly 'intelligent' site monitoring and management.

3:05 Refreshment Break in the Exhibit Hall

4:05 Interactive Breakout Discussion Groups

5:15 Welcome Reception in the Exhibit Hall

6:15 End of Day

WEDNESDAY, FEBRUARY 5

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

IMPROVING FEASIBILITY AND COUNTRY ALLOCATION

8:10 Chairperson's Remarks
Simon Sparkes, Senior Vice President, Clinical, ArisGlobal

8:20 Seamless Feasibility Assessment in Clinical Projects
Silke Ewald, M.D., Head, Trial Feasibility Assessment, Bayer HealthCare AG
Feasibility provides an opportunity to proactively evaluate key parameters to run a clinical project and associated studies, understand the medical environment, ensure suitable countries and sites are approached for participation and validate recruitment and retention strategies.

8:45 Optimizing Up-Front Country Allocation and Early Site Selection: Building a Team, a Process and a Database
Jorge Rodriguez-Larrain, M.D., Head, Global Site Management, Global Clinical Operations, Alcon
Biopharmaceutical companies are facing the same challenges of overly complex protocols, underperforming sites and disappointing enrollment. These problems are all connected. To improve the efficiency of our trials at Alcon we developed a new approach.

9:10 Evolving Clinical Monitoring and Improving Outcomes with a Risk-Based Approach
Sponsored by QUINTILES
Dan White, Vice President, Global Clinical Operations, Quintiles
Rachel Edwards, Director, Clinical Operations, Amgen
Amgen wanted to develop a risk-based approach to clinical monitoring to reduce development costs and more efficiently allocate resources – while maintaining or improving quality. This presentation will demonstrate how Amgen partnered with Quintiles to help create a more efficient monitoring program that included the right mix of on-site and remote monitoring, a centralized and ongoing data review process with reduced SDV based on risk assessments, and key triggers and alerts.

9:35 Leveraging a Single Source of Truth to Improve Site-Sponsor Collaboration from Site Activation to Study Close Out
Sponsored by INTRA LINKS
Kevin McNulty, Director, Product Marketing, Life Sciences, Intralinks, Inc.
Currently available eTMF solutions focus on the Sponsor TMF only and support the interaction with sites by investigator portals. These investigator portals represent a means of communication to receive documents from the site and to publish documents investigators will then incorporate into their ISF. The portals do not replace the ISF and for all solutions the regulatory status of documents that are stored in the portal is unclear. A successful TMF strategy, therefore, needs to include the ISF as a critical component of the full document lifecycle. This presentation will examine the benefits and challenges of implementing such a solution.

9:50 Coffee Break in the Exhibit Hall

DATA-DRIVEN TRIAL MANAGEMENT
Shared Session between *Global Site Selection* and *Electronic Data in Clinical Trials*

10:40 Chairperson's Remarks
Simon Sparkes, Senior Vice President, Clinical, ArisGlobal

10:45 Risk-Based Monitoring Using the Paperless Approach
Mary Flack, M.D., Vice President, Clinical Research, Nanobio
Using a paperless approach to a Phase 3 clinical trial we were able to increase the speed, efficiency and quality of risk-based monitoring. Both site- and study-specific data were entered in real time using three integrated systems, including tablet-based screens with built in audit trails or scanned documents certified as electronic source (such as informed consent document).

11:10 Reaching Patients Where They Are: Using Medical Claims and Public Data to Geo-Target Sites & Patients
Sponsored by UBC AN EXPRESS SCRIPTS COMPANY
Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation
Through population analytics and advanced targeting, your next project can enroll the right patients faster. This session will show you how to use geographically-rich health datasets to take your enrollment strategies to the next level.

11:35 Getting Real, Validating Data-Driven Feasibility and Country Selection
Michael Jones, Senior Director, Global Site Development, Clinical Operations, Eli Lillly & Co.
Augment use of central process that uses historical performance data with local resources and expertise in target countries. Validate current clinical practice match desired study plan. Minimize futile enrollment projects and decrease cycle time.

12:00 pm Using Insurance Claims and Electronic Health Records to Ensure a Patient-Centric Trial
Sponsored by OPTUM Good for the system.
Bill Gwinn, MBA, Vice President, Clinical Informatics Solutions, Optum
Trials do not have to run late. More quantitative information means better planning. This presentation will cover planning feasibility with insurance claims and electronic health records, including statistical projections of disease prevalence. You'll also learn how to "fish where the fish are" using techniques ranking areas/investigators based on patient count.

12:15 LUNCHEON PRESENTATION: Integrating Site Survey Management Tools into Your Clinical Trial Workflow
Sponsored by BioPharm Clinical Complete Clinical Operations Support
Ruth McHenry, Managing Director, Infinata, Inc.
The current site survey process is inefficient and outdated. Sponsors desperately need detailed site information (equipment, certifications, capabilities, facility size, etc.) in order to choose the best locations. Attendees will learn how to streamline the process by which pharmaceutical sponsors obtain and manage information about sites and site networks with one integrated, secure, cloud-based solution that allows unprecedented control over all phases of the site evaluation process.

1:00 Close of Conference

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome

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

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

8:05 Chairperson's Opening Remarks

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

8:15 Plenary Keynote Introduction

Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation

» 8:20 PLENARY KEYNOTES AND PANEL

What Does a Trial Mean in the Era of Real-Time Measurement?
Jamie Heywood, Co-Founder and Chairman, PatientsLikeMe

The Silent Partners and Their Role in Clinical Research: Improving Trial Design and Management by Understanding the Real "Customer"
Christine Pierre, President, The Society for Clinical Research Sites (SCRS)

PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

CASE STUDIES: ENROLLMENT PLANNING AND MANAGING SOCIAL MEDIA

10:45 Chairperson's Remarks

Kelly McKee, Associate Director, Clinical Research, Global Trial Optimization, Merck & Co., Inc.

10:55 A Field of Dreams: Building for the Future

Lisa Vaughan, Head, Global Clinical Site Development, Alcon (a Novartis company)

Recruitment today in clinical trials is challenging and Alcon has developed a unique approach to working with sites and building a foundation for growth. We have blended together best practices to achieve enrollment targets and accelerated project timelines. This organization has established a global pattern which will sustain growth of sites into the future.

11:20 CO-PRESENTATION: Managing Social Media Chatter in Clinical Research – A Joint Venture: "Speak Out, but Speak Smart"

Joe Kim, MBA, Director, Clinical Operations, Shire Pharmaceuticals
Kenneth Getz, Director, Sponsored Programs, Tufts CSDD; Chairman, CISCRP
Jeri Burtchell, Patient Advocate Blogger, Gilenya and Me

There is little evidence that the industry has taken steps to manage the risks that social media presents, until now. Come learn about the inspiration for and materialization of the industry's first educational campaign aimed at helping research participants.

12:10 pm Revealing the True Value of Patient Recruitment

Sponsored by Acurian

Bill Abbott, Vice President, Business Development, Acurian

This session will discuss the steady decline of enrollment rates by evaluating industry trends and determine innovative patient recruitment options for enrollment shortfalls. Included will be information analyzing the costs and value of different patient recruitment strategies.

12:35 LUNCHEON PRESENTATION: A Matter of Perspective: Looking at Enrollment from the Eyes of the Patient and those that Influence Participation

Sponsored by PRAXIS

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

Join us for an interactive lunch as we explore the challenging issues research sites and sponsors face as we review recruitment initiatives used to advance enrollment, how they are often perceived by prospective patients and those that influence their participation.

1:15 End of Morning Session

PARTNERING WITH PATIENT COMMUNITIES

1:25 Chairperson's Remarks

Bonnie Brescia, Founding Principal, BBK Worldwide

1:35 Utilizing Patient Advisory Boards for Clinical Study Strategy and Planning

Kim Mooney, Manager, Patient Advocacy, Clinical Operations, BioMarin Pharmaceutical, Inc.

We have used patient advisory boards throughout the lifecycle of our clinical development programs. We describe the use of these boards with rare disease case study examples, including development of objectives and discussion guides, recruitment, facilitation and outcomes/impacts of the meetings.

2:00 PANEL: Partnerships with Patient Communities to Get from Data to Clinic (Patient Information, Registries, Trials)

Moderator: Jayne Gershkowitz, Vice President, Patient Advocacy & Public Policy, Amicus Therapeutics, Inc.
Brenda Conger, Executive Director, CFC International
Kyle Brown, CEO, PatientCrossroads
Patty Wood, President, NBIA Disorders Association
Neal Weinreb, M.D., Director, Gaucher Disease - Fabry Disease Treatment Center; University Research Foundation for Lysosomal Storage Diseases

Improving lives by developing safe, effective and innovative drugs and devices is our raison d'être. So partnering with the people living with the diseases – and their advocates – seems the best way to learn about their experiences, unmet needs, and the realities of building practical and meaningful clinical programs and supportive information structures. Through case examples and best practices, the panel will explore the importance of building relationships with patient communities.

2:50 Optimising Patient Engagement

Sponsored by SYNEXUS

Janet Jones, Vice President, Access to Patients, Synexus Ltd.

This case study will review the optimization of patient engagement in different European countries and South Africa. We will explore recruitment strategies and tactics used to bring patients into the clinic, the associated recruitment funnels and consider the patient's journey through the recruitment process to deliver high quality patients and maximize recruitment.

3:05 Refreshment Break in the Exhibit Hall

4:05 Interactive Breakout Discussion Groups

5:15 Welcome Reception in the Exhibit Hall

6:15 End of Day

WEDNESDAY, FEBRUARY 5

7:30 am BREAKFAST PRESENTATION: Operations Optimized: How Sponsors Use Novel Technology to Optimize Start-Up, Enrollment, Retention, Site Engagement, Conduct and Closeout

Sponsored by TrialNetworks

Eric Silberstein, Co-founder & CEO, TrialNetworks

Novel technology enables sponsors to collaborate with sites and CROs to optimize clinical trial operations from start-up to closeout - including site activation, patient recruitment and retention, site engagement and conduct. This session will present several case studies featuring evidence-based results achieved by sponsors using optimization systems in global trials.

UTILIZING TECHNOLOGY TO BOOST RECRUITMENT

8:10 Chairperson's Remarks

Ramita Tandon, Senior Vice President & General Manager, Patient Outcomes, inVentiv Health, Inc.

8:20 Boosting Subject Retention with Automated Reimbursement & Messaging Technology

Kelly McKee, Associate Director, Clinical Research, Global Trial Optimization, Merck & Co., Inc.

This discussion focuses on how to leverage technology to automate compensation of subjects and subject messaging. The discussion focuses on challenges inherent in manual compensation systems and how technology systems can be used to increase patient retention in a trial.

8:45 Case Study: Text Message Recruitment

Elizabeth Mascherino, Associate Director, Clinical Operations, Shire Pharmaceuticals

During this case study we will review how patients respond via text, how the system engages patients in an interactive screening and finally, how text messaging stacks up against more traditional methods of response.

9:10 Empower Evidence-Based Feasibility Research and Enrollment Planning through Analytics

Jane Fang, Ph.D., R&D IS Lead, Clinical Business Management & Analytics, MedImmune

Going beyond the traditional trial feasibility and enrollment planning approach, we use internal and external data and informatics tools to enable data-driven trial feasibility evaluation and enrollment projection.

9:35 Enrollment Planning and Patient Recruitment

Sponsored by MRA Miami Research Associates

Howard I Schwartz , M.D., FACP, Medical Director, Founder, Miami Research Associates

Key to a clinical trials success is the recruitment of appropriate volunteers in a timely fashion. Sponsors need to choose the appropriate clinical sites , create a protocol that is representative of the population studied. Clinical sites need to choose projects they will be successful at and have a recruitment plan prior to study start.

9:50 Coffee Break in the Exhibit Hall

CASE STUDIES: OVERCOMING RECRUITMENT CHALLENGES

10:40 Chairperson's Remarks

Ramita Tandon, Senior Vice President & General Manager, Patient Outcomes, inVentiv Health, Inc.

10:45 Factors Affecting Recruitment into Depression Trials: Systematic Review and Meta-Synthesis of Qualitative Evidence

Adwoa Hughes-Morley, NIHR Doctoral Research Fellow, MRC North West Hub for Trials Methodology Research, Centre for Primary Care, Institute of Population, The University of Manchester

This systematic review identifies both barriers and facilitators in recruiting into depression trials. The review will further explore how these findings can be applied pragmatically to develop interventions for effectively recruiting participants into mental health trials.

11:10 CO-PRESENTATION: Using EHR at Multiple Healthcare Sites to Identify Sites and Recruit Patients in a Phase III Clinical Trial: Perspectives from the Vendor and Sponsor

Zhaohui (John) Cai, M.D., Ph.D., Director, Biomedical Informatics, Clinical Medicines Development, AstraZeneca Pharmaceuticals, Inc.

Aaron Kamauu, M.D., President & CEO, Anolinx, LLC

Little has been shown for implementing an EHR-based, data-driven approach at multiple sites from different healthcare institutions using different EHR systems for the same clinical trial. This presentation will share a real example of this approach applied to two phase 3 clinical trials.

THE GREAT RECRUITMENT DEBATE

11:35 PANEL: The Great Debate

Colin Scott, M.D., Senior Director, Respiratory Development, Clinical Development, Forest Research Institute, Inc.

Sarah Luijpers, Director, Global Recruitment Operations, Forest Research Institute, Inc.

This session will be a pro and con debate and interactive discussion with attendees focusing on key topics covering the three main areas of recruitment: where do we get patients, how do we reach more patients, and who do we entrust the trial management to?

12:00 pm Sponsored Presentation (Opportunity Available)

Bridging Luncheon Presentation between *Enrollment Planning* and *Subject Retention*

12:15 LUNCHEON PRESENTATION: Ensuring Site Buy-In and Compliance through Successful Execution of Recruitment and Retention Planning

Sponsored by DAC Patient Recruitment Services

Melynda Geurts, Vice President Operations, DAC Patient Recruitment Services

A successful study consists of a solid protocol, committed research centers and volunteers. This presentation will explore how the right level of recruitment and retention planning during protocol design can enhance site buy-in and study compliance. Learn how to plan, implement, leverage study coordinators, and engage your sites.

1:00 Close of Conference

Inaugural

Aggregate Spend and Transparency Reporting in Clinical Trials:

Sunshine Act Compliance from a Clinical Ops Perspective

New

February 4-5, 2014

SCOPEsummit.com/Aggregate-Spend

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome

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

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

8:05 Chairperson's Opening Remarks

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

8:15 Plenary Keynote Introduction

Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation

» 8:20 PLENARY KEYNOTES AND PANEL

What Does a Trial Mean in the Era of Real-Time Measurement?

Jamie Heywood, Co-Founder and Chairman, PatientsLikeMe

The Silent Partners and Their Role in Clinical Research: Improving Trial Design and Management by Understanding the Real "Customer"

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

PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

IMPACT OF REPORTING REQUIREMENTS ON CLINICAL RESEARCH & INVESTIGATOR RELATIONSHIPS

10:45 Chairperson's Remarks

Kathleen Greenough, Senior Manager, Clinical Systems & Technology, Biogen Idec

10:55 Clinical Trials in Light of Global Transparency Trends

Thomas Sullivan, President, Rockpointe Corporation

During this session we will discuss 1. International Sunshine Laws, 2. Industry and country specific codes of conduct that include payment and clinical trial disclosure, 3. FCPA and UK Bribery Act's impact on clinical trials in emerging markets, 4. Strategies for keeping up with national and international laws, and 5. Tactics to educate your employees on applicable disclosure rules and laws.

11:20 Physician Payment Disclosures: Assessing Requirements and the Impact on Clinical Trials and Physician Interactions

Katherine Cartwright Norris, Director, Compliance & Integrity Programs, Becker & Associates Consulting; former Director, Corporate Compliance, The Spectranetics Corporation

This session includes an overview of the Open Payments reporting requirements with specific focus on clinical trial activities, key operational aspects for implementing and managing an aggregate spend program, improving current processes, payment management for clinical trials, and working with CROs/SMOs to support transparency strategies.

11:45 Shedding Light on Sunshine

Colin Scott, M.D., Senior Director, Respiratory Development, Clinical Development, Forest Research Institute, Inc.

In the scramble for Sunshine Act compliance, scant attention has been paid to mitigation of the negative impact this will have on investigator/sponsor relations. Issues addressed will include: 1.The need for investigator information packs, 2. Methods of reducing the perception of erroneous reporting of transfers of value, 3. The development of processes and procedures to avoid the need for conflict resolution, and 4. Ways to counter negative public opinion.

12:10 pm Aggregate Spend Call Center Support Services: Helping Your Customers Understand and Navigate the Data and Systems

Sponsored by C3i

Jackie S. Hoover, Vice President, Account Management, C3i, Inc.

Pharmaceutical companies have been collecting data and are now submitting it for publication to CMS (Centers for Medicaid & Medicare Services). What does this mean for your customers? What if they have questions? Who do they call? What if patients don't understand? Are you prepared to handle an influx of inquiries and possible disputes about the data you submitted? C3i, Inc. has created specialized call center support services to assist you and your customers with this data and related systems.

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

1:15 End of Morning Session

BUILDING BETTER RELATIONSHIPS TO TACKLE STATE, FEDERAL AND GLOBAL REPORTING REQUIREMENTS

1:25 Chairperson's Remarks

1:35 A Case Study for Managing Clinical Data Collection and Reporting

Andrew Smith, Global Transparency Reporting Associate Consultant, Eli Lilly and Co.

It takes significant effort to both identify an organization's sources of reportable payment data and to work with those sources to ensure complete and accurate reporting of the data. The purpose of this case study is to share learnings from one company's experience, with particular focus on coordinating data collection efforts with clinical research organizations (CROs).

2:00 PANEL: Clinical Operations Building Better Relationships to Tackle State, Federal and Global Reporting Requirements

Moderator: Lisa Ingellis, Global Transparency Reporting Consultant, Eli Lilly and Co.

Kevin Williams, Vice President, Corporate Development & Marketing, CFS Clinical (CFS)

Toby Ann Holetz, Global Head, Global Aggregate Spend Reporting Team, Quintiles

Donna Jarlenski, Vice President, Clinical Development Execution, Global Medicines Development & Affairs, Vertex

Brenda Medina, former Director, Global Head, Clinical Business Operations, Eisai, Inc.

Physician payment disclosures impact all of the stakeholders involved in clinical research, including sponsors, investigators, sites and third parties (CROs, SMOs). Implementing accurate and timely reporting requires the clinical operations executive to strengthen her relationship with each of these players.

Inaugural

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Sunshine Act Compliance from a Clinical Ops Perspective

New

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SCOPEsummit.com/Aggregate-Spend

2:50 Practical Solutions: Ensuring Consistency Across State, Federal and Global Reporting Requirements
Abraham Gitterman, Associate, Arnold & Porter, LLP

3:05 Refreshment Break in the Exhibit Hall

4:05 Interactive Breakout Discussion Groups

5:15 Welcome Reception in the Exhibit Hall

6:15 End of Day

WEDNESDAY, FEBRUARY 5

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

OPERATIONALIZING SUNSHINE ACT COMPLIANCE FROM A CLIN OPS PERSPECTIVE

8:10 Chairperson's Remarks
Jackie S. Hoover, Vice President, Account Management, C3i, Inc.

8:20 Case Study: Sunshine Act/GST Implementation by a Mid-Cap Pharma
Donna Jarlenski, Vice President, Clinical Development Execution, Global Medicines Development & Affairs, Vertex
This presentation will provide a case study of GST compliance at one mid-size, global, pharmaceutical development and sales organization and will share current information on the 1. Internal resourcing logistics and technical delivery team structure; 2. Governance structures; 3. Data collection, review, and aggregation; and 4. Planned future development.

8:45 Collecting Investigator Grant Payments for Sunshine Reporting
Kathleen Greenough, Senior Manager, Clinical Systems & Technology, Biogen Idec
The business driver for keeping tabs on grant payments used to be limited to supporting accruals, but with the Sunshine Act companies are now required to get into the weeds. Biogen Idec has tackled this problem as a whole, addressing why there is such a large gap between payments made and current liabilites. This session will review what makes this process so complex as well as present practical suggestions for building a complete picture of investigator grant payments.

9:10 CO-PRESENTATION: Integration of Operations, Billing Tracking and Reporting Systems for Routine Patient Care and Clinical Research Grants
Marina Malikova, Ph.D., Executive Director, Surgical Translational Research: Operations and Compliance, Surgery, Boston University Medical Center Heidi Gambino, Chief Administrative Director, Surgery, Boston University Medical Center
In order to improve compliance and transparency of reporting we aligned our Financial Disclosure Tracking System with our Grant Payment Management System at BUMC, allowing us to link primary and sub-investigators data directly to payment information, track billing and payments for research grants. Now we can associate grant payment activity with every investigator and research staff involved in our trials, providing a more complete picture of health care practitioner spend activity.

9:35 Understanding & Complying with the Sunshine Act
Sponsored by medidata
Jessica Dolfi, Senior Business Consultant, Medidata Solutions
With the Physician Payments Sunshine Act in full effect and the March 2014 deadline rapidly approaching, sponsors are rapidly preparing for compliance. This presentation will share insights regarding the regulations and what tools sponsors can use to ensure they meet the requirements.

9:50 Coffee Break in the Exhibit Hall

BEYOND REPORTING: NEXT STEPS WITH AGGREGATE SPEND DATA

10:40 Chairperson's Remarks
Abraham Gitterman, Associate, Arnold & Porter, LLP

10:45 Mining Reported Data: Implications for Kickbacks, False Claims, and Violations of Applicable State Laws
Juliet McBride, Associate, King & Spalding
When implementing procedures to comply with Sunshine, it will be critical to evaluate the potential impact of increased transparency under the laws. We will evaluate how Federal and state authorities (e.g., DOJ, OIG, state attorneys) could mine reported data for possible kickbacks, false claims, and violations of applicable state laws.

11:10 Next Steps With Aggregate Spend Data
Brenda Medina, Director, Global Head, Clinical Business Operations, Eisai, Inc.

11:35 Beyond Reporting: Using Aggregate Spend Data for Continuous Improvement
Seth Whitelaw, Director, Health Sciences Compliance, Deloitte & Touche LLP
Now that the first reporting deadline for the Federal Sunshine Act is fast approaching, companies can begin to pause from focusing simply on collecting and reporting transfers of value. With the pause comes the opportunity to examine the data in the broader context of business operations and compliance. This session will explore how companies might use the data for continuous improvement moving forward.

12:00 pm Sponsored Presentation (Opportunity Available)

Bridging Luncheon Presentation between *Aggregate Spend* and *Forecasting*

12:15 LUNCHEON PRESENTATION
Sponsored by CFS CLINICAL Part of DrugDev
Stuart Thiede, Senior Vice-President & General Manager, Global Payment Services, CFS Clinical (CFS)
Investigator grant payments are the single greatest expense in a clinical trial, accounting for 40-60% of the total trial budget, and yet slow payments continue to be the most common complaint and challenge for sites. While the investigator payment process is quite challenging in the U.S. due to the multitude of compliance requirements including the Sunshine Act, the complexity multiplies exponentially in global trials. Challenges in the global environment are many and include but are not limited to working with multiple currencies and CRO's, financial reporting across borders, contracting party issues, VAT taxes, and transparency compliance.

- Review the complexities of global trials
- Reduce administrative work by centralizing systems and improving workflow
- Learn how to improve the bottom line by managing taxes

1:00 Close of Conference

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

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

PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

PARADIGM SHIFT IN POST-MARKETING AND NON-INTERVENTIONAL RESEARCH

10:45 Chairperson's Remarks

10:55 KEYNOTE PRESENTATION: Will Healthcare Settings Become the Major Data Source in Non-Interventional Research?
Charles Barr, M.D., Head, Evidence Science & Innovation, Group Medical Director, US Medical Affairs, Genentech, Inc.

11:20 Using Large Existing Data Systems to Conduct Post-Approval Safety Studies (PASS)
Sean Zhao, M.D., Ph.D., former Pharmaceutical Executive in Global Safety Organization
Strategically planned PASS using one or multiple large existing data systems may be the best approach. The presentation will be focused on strategy, design, common methodology as well as key practical considerations of using large existing data system to conduct PASS.

11:45 Leveraging Existing Patient Databases To Build Out Post-Market Registries
Christian Reich, M.D., Global Head, Discovery Informatics, AstraZeneca

12:10 pm Optimizing Site Selection and Management for Observational Research
Sponsored by PRA
Kathleen Mandziuk, MPH, RN, Senior Scientific Affairs Director, PRA Late Phase Services
Identification, recruitment, activation and long-term management of clinical sites is one of the most challenging aspects of observational research. This presentation will outline a few of the major challenges and multidisciplinary strategies to address each. Several case studies will be presented to depict "real-life" examples, implementation strategies and results.

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

1:15 End of Morning Session

DESIGNING POST-MARKETING STUDIES

1:25 Chairperson's Remarks
Adam Wilcox, Ph.D., Director, Medical Informatics, Intermountain Healthcare

1:35 Development of Post-Marketing Pharmacoepidemiology Study Assessing Long-Term Drug Safety
Fei Xue, M.D., Observational Research Director, Center for Observational Research (CfOR), Amgen, Inc.
The presentation will describe the experience and considerations in developing a prospective, multi-national, multi-year database study to assess the drug safety with input from FDA commensurate to mechanism of action, biological plausability, clinical trial evidence, and/or findings from studies of similar agents.

2:00 Operational Excellence in Phase IV Research
Sponsored by QUINTILES
Barbara Isquith Arone, MS, Senior Director, Service Operation, Real-World Late Phase, Quintiles
In this presentation we will focus on the operational aspects of effective registries. Discussion will include creating and managing effective advisory boards, study design and planning with the end in mind, site recruitment and retention, strategies to reach quality data and successful planning for the analysis of registry data.

2:25 A Step-By-Step Path to Collect Data from Electronic Health Records Systems
Sponsored by Mapi
Lee Walke, Senior Director, Biometrics, Mapi Real World Evidence
Which eCRF elements are best suited for extraction from EHR systems – and which are not? This presentation will describe a system that presents a hybrid approach, in which late phase EDC is used for some elements of the case report form, while an integrated EHR module collects the rest.

2:50 Panel Discussion: Meeting the Evidentiary Needs of Multiple Stakeholders by Better Non-Interventional Studies
Moderator: Sean Zhao, M.D., Ph.D., former Pharmaceutical Executive in Global Safety Organization
Product benefit risk profile, comparative effectiveness data, health economic evidences obtained from non-interventional studies are essential for multiple stakeholders, including regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, health care professionals, as well as patients. The panel discussion will be focused on the following topics and related questions:

- 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) ;
- What are key strategic considerations in planning global non-interventional studies to fulfill regulatory, clinical practice, health economic needs and to meet evidentiary requirements of payers

Panelists: Speakers of the Session

3:05 Refreshment Break in the Exhibit Hall

WEDNESDAY, FEBRUARY 5

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

REGISTRIES: MANAGEMENT AND APPLICATIONS

8:10 Chairperson's Remarks
Derenda Nichols, Vice President, Operations Americas, Mapi

8:20 Utilizing Registries In Post-Marketing and Real-World Data Research – How to Maximize Your Return on Investment
Alicia Gilsenan, Ph.D., Senior Director, Epidemiology, RTI Health Solutions
The presentation will discuss key considerations when planning registries for post-marketing studies including the importance of having clear objectives, stakeholder buy-in and realistic expectations for recruitment, retention and data collection as well as special considerations for rare disease registries.

8:45 Application of Registry Data to Business and Stakeholder Decisions
Cathy Koepper, Director, Global Registry Operations, Genzyme, a Sanofi Company
Registries are increasingly recognized as valuable research programs that support numerous business objectives and stakeholder requirements. As a result, expectations of what registry program can or should do may changes in volume, scope and breadth. This session will focus on how to navigate such expectations and manage the associated changes for the short and long-term viability of a registry.

9:10 Alternative Uses for Patient Registries: A Look into the Utilization of a Chronic Disease Patient Registry in Post-Marketing, FDA-Mandated Studies
Christopher Dowd, Clinical Research Program Manager, Medical, The Cystic Fibrosis Foundation
This presentation will discuss the evolution of the registry from a tool used to track national trends in morbidity and mortality to a robust database that is used in post-marketing research. The audience will learn how the CF Foundation partners with pharmaceutical partners to use this power tool in designing clinical trials and how it has integrated the registry into a Phase IV data collection tool.

9:35 Overcoming the Operational Challenges Inherent in Post-Marketing Studies/Registries
Sponsored by OPTUM Good for the system.™
Denise Hopkins, Pharm.D., Senior Director, Late Phase Research, Optum
Observational studies pose different operational challenges than registration studies. A broader approach to site selection results in working with less research-experienced sites. This presentation will look into the important challenges of global observational studies, from requirements for study start up, site management and patient retention, to data quality management.

9:50 Coffee Break in the Exhibit Hall

EXTERNAL PARTNERING IN NON-INTERVENTIONAL RESEARCH

10:40 Chairperson's Remarks
Derenda Nichols, Vice President, Operations Americas, Mapi

10:45 Issues in Sustaining an Electronic Data Infrastructure for Research Studies and Registries
Adam Wilcox, Ph.D., Director, Medical Informatics, Intermountain Healthcare
Creating a data infrastructure to support clinical trials and registries often involves a substantial investment from multiple stakeholders. I discuss issues in sustaining research data infrastructures through experiences at both academic and clinical institutions with lessons learned about how these structures can be supported over time.

11:10 Outsourcing Post-Marketing Studies: Issues with Study Start-Up
Shailesh Chavan, M.D., Senior Director, Clinical Research, Medical Affairs & Drug Safety, Biotest Pharmaceuticals Corporation
The presentation will discuss some key points such as: to outsource or not in a post-marketing setting, selecting CRO(s) for success, planning and aligning all stakeholders with end in mind, setting the right level of communication with regulatory authorities, implementation challenges and opportunities for small to mid-size companies in terms of outsourcing management and others.

11:35 Optimizing Operations to Deliver Longitudinal Research in the Peri and Post-Approval Space
Sponsored by ICON A Symbol of Excellence
Lee King, Vice President, Operations and Strategic Programs, ICON Commercialisation and Outcomes
Increased regulatory focus on post-approval safety and the need for comparative effectiveness data to support market access are driving more studies into the late phase space. The longitudinal designs and lean budgets for these projects make more efficient/effective operating models and delivery systems necessary. This session will focus on the use of systems and processes that improve study continuity and control in an environment of limited onsite management and extended operational durations.

12:00 Sponsored Presentation *(Opportunity Available)*

12:15 pm Bridging Luncheon Presentation between *Managing Post-Marketing* and *Technologies for Post-Marketing* *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 Close of Conference

Inaugural

Sample & Biospecimen Management in Clinical Trials:

Biospecimen Collection, Transport and Quality from Protocol to Analysis and Banking

New

February 4-5, 2014

SCOPEsummit.com/Clinical-Logistics

TUESDAY, FEBRUARY 4

7:00 am Registration and Morning Coffee

8:00 Organizer's Welcome

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

OPENING PLENARY KEYNOTES AND PANEL: KEEPING THE PATIENT IN MIND

8:05 Chairperson's Opening Remarks

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

8:15 Plenary Keynote Introduction

Nancy Mulligan, Senior Director, Operations, Patient & Physician Services, United BioSource Corporation

» 8:20 PLENARY KEYNOTES AND PANEL

What Does a Trial Mean in the Era of Real-Time Measurement?

Jamie Heywood, Co-Founder and Chairman, PatientsLikeMe

The Silent Partners and Their Role in Clinical Research: Improving Trial Design and Management by Understanding the Real "Customer"

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

PANEL: Perspectives from a Cast of Characters Needed for Any Successful Study Execution

9:45 Grand Opening Coffee Break in the Exhibit Hall

BIOSPECIMEN COLLECTION & MANAGEMENT - IN AN ERA OF PRECISION MEDICINE & BIOMARKER-BASED TRIALS

10:45 Chairperson's Remarks

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

10:55 Operationalizing Precision Medicine through Biospecimen Management Strategy

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

Quality biospecimens are the foundation of precision medicine. This talk will discuss the use of a specimen management framework to operationalize Precision Medicine.

11:20 Mandatory Exploratory Sample Collection in Clinical Trials

Andrea Renninger, Head, BioBank Operations; Senior Manager, Clinical Coordination, Eisai, Inc.

The purpose of this talk is to highlight the current barriers in mandatory sample collection with the intention of banking. Topics will include internal and external resistance, informed consent, sample permissions, and the use and reporting of data.

11:45 Building Future Use Collections

Sponsored by PRECISION BIOSERVICES

Katheryn E. Shea, Vice President, BioServices Operations, Precision Bioservices, Inc

Building high quality collections that will be useful for future research requires the well annotated and standardized processes. This talk will focus on the lifecycle of a biospecimen and the critical elements that must be incorporated into the design of future use collections.

12:10 pm Will Your LIS Handle a Million Tests a Year? From Trials to Launching a Validated, High-Throughput Screening Operation

Sponsored by sample minded

Debi Koltenuk, Vice President, Products and Services, sampleminded

Daniel Steenblik, Vice President, Technology and Operations, sampleminded

Challenges faced transitioning our clinical trial sample tracking system into a simple and sleek LIS that employs tablets, monitoring, workflow metrics, captures quality indicators and maintains traditional LIMS functionality. How supporting the needs of a new lab led us to a new collaborative SAAS model - sampleminded: Service As A Service.

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

1:15 End of Morning Session

BIOSPECIMEN COLLECTION & MANAGEMENT - IN AN ERA OF PRECISION MEDICINE & BIOMARKER-BASED TRIALS (CONTINUED)

1:25 Chairperson's Remarks

Lori Ball, COO, BioStorage Technologies

1:35 Managing the Biospecimen Lifecycle: From Collection to Biomarker Discovery

Nancie Deckard, Biomarker CRA, Clinical Operations, Duke Clinical Research Institute (DCRI)

The DCRI has firsthand experience as an Academic Research Organization (ARO) in sample management for trials varying in size and scope from international, multicenter randomized clinical trials. In addition, we have trial experience across multiple therapeutic areas and with a variety of stakeholders. The Duke Clinical Research Institute (DCRI) created a cross functional group with representation from Informatics, Data Management, Clinical Operations and Statistics to facilitate successful implementation of sample collection in clinical trials.

2:00 Standardizing the Biospecimen Life-Cycle from Procurement to Release via SOPs, Policies, and Processes

Ty Hoover, M.D., J.D., FCLM, FCAP, Director, Biorepository Regulatory Support, University of Texas MD Anderson Cancer Center

This talk will focus on practical tips, lessons learned and the importance of controlling the processes involved the provision of human tissue for clinical trials at a large academic cancer center including pitfalls, SOPs, guidances, and regulatory and administrative obligations.

2:25 Impact of Regulation on Future Biomedical Research in Multinational Clinical Trials?

Amelia Wall Warner, President, Board of Directors, Gentris Corporation; former, Head Clinical Pharmacogenomics and Clinical Specimen Management, Merck

2:50 Megatrends Impacting the Future of Biospecimen Management

Kenneth A. Wilke, Consultant; former Director, Clinical Pharmacogenomics and Clinical Specimen Management, Merck

3:05 Refreshment Break in the Exhibit Hall

4:05 Interactive Breakout Discussion Groups

5:15 Welcome Reception in the Exhibit Hall

6:15 End of Day

Inaugural

Sample & Biospecimen Management in Clinical Trials:

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New

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SCOPEsummit.com/Clinical-Logistics

WEDNESDAY, FEBRUARY 5

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

STANDARDIZATION

8:10 Chairperson's Remarks

Katheryn E. Shea, Vice President, BioServices Operations, Precision Bioservices, Inc

8:20 The Challenges of Developing and Implementing Biospecimen Evidence-Based Practices

Helen Moore, Ph.D., Program Director, Biorepositories & Biospecimen Research Branch

Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute

The U.S. National Cancer Institute has led progress in biobanking with the NCI Best Practices for Biospecimen Resources and the Biospecimen Research Network (BRN). Incorporating new scientific data into best practices is another challenge.

CLINICAL TRIAL SAMPLE MANAGEMENT

8:45 Biospecimen Collection and Management in Clinical Trials

Jerry Chu, M.D., Ph.D., Director of Pathology Core Laboratory, City of Hope National Medical Center

Clinical trial biospecimen repository at City of Hope has served hematopoietic and solid tumor clinical trials for more than 20 years. We collect, store and distribute fresh, frozen and formalin fixed and paraffin embedded (FFPE) tumor tissues or blood samples to PIs followed a well-designed and institute approved SOPs. We also set up special tumor banks for clinical trials.

9:10 Working Effectively with a Central Lab

Terry Robins, Consultant, Former, Global Director, Scientific Affairs, Quest Diagnostics

In the era of whole genome/exome analysis in clinical trials, the role of the central laboratory/CRO has evolved a new capability to be able to manipulate a large amount of molecular information for each patient.

9:35 Sample Inventory Management on a Global Scale: Planning for the Future Use of Research Samples

Sponsored by BioStorage Technologies

Lori Ball, COO, BioStorage Technologies

Global case studies will highlight sample management challenges including collection, logistics, sample storage and data collection and provide solutions for clinical trial operations executives to consider as they are planning studies in order to achieve successful optimization of research samples.

9:50 Coffee Break in the Exhibit Hall

DATA MANAGEMENT IN CLINICAL TRIALS

10:40 Chairperson's Remarks

Katheryn E. Shea, Vice President, BioServices Operations, Precision Bioservices, Inc

10:45 Using Clinical Laboratory Data to Inform Trial Design

Victor Lobanov, Ph.D., Executive Director, Data Sciences, Informatics, Covance

As a market leader in central laboratory and pre-clinical services and top five provider of phase III clinical trial management services, Covance has assembled the most comprehensive investigator knowledge-base in the pharmaceutical industry.

11:10 Seven Habits of Highly Effective Clinical Trial Sample Data Management

Mark. A Collins, Ph.D, Director, Marketing, BioFortis, Inc.

The path to realizing the full potential of samples collected in the course of clinical trials has fast become a data problem. Trials are global, increasingly externalized with multiple stakeholders, generate large amounts of data, and operate in an ever-changing regulatory landscape. Using case studies we will show how emerging best practices in clinical trial sample data management are driving scientific value for trial and future use specimens.

Shared Session between *Sample & Biospecimen Management, Electronic Data in Clinical Trials* and *Global Site Selection*

11:35 Getting Real, Validating Data-Driven Feasibility and Country Selection

Michael Jones, Senior Director, Global Site Development, Clinical Operations, Eli Lilly & Co.

Augment use of central process that uses historical performance data with local resources and expertise in target countries. Validate current clinical practice match desired study plan. Minimize futile enrollment projects and decrease cycle time.

12:00 pm Using Insurance Claims and Electronic Health Records to Ensure a Patient-Centric Trial

Sponsored by OPTUM Good for the system.

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

Year after year, about half of trials run late, but it will not stay that way. There is an explosion in quantitative information that can result in better planning and execution. The presentation will start with planning feasibility with insurance claims and electronic health records, including statistical projections of disease prevalence. For recruitment, the session will teach how to "fish where the fish are" to find patients. Techniques include ranking areas and investigators based on patient count.

12:15 LUNCHEON PRESENTATION: Integrating Site Survey Management Tools into Your Clinical Trial Workflow

Sponsored by BioPharm Clinical Complete Clinical Operations Support

Ruth McHenry, Managing Director, Infinata, Inc.

The current site survey process is inefficient and outdated. Sponsors desperately need detailed site information (equipment, certifications, capabilities, facility size, etc.) in order to choose the best locations. Attendees will learn how to streamline the process by which pharmaceutical sponsors obtain and manage information about sites and site networks with one integrated, secure, cloud-based solution that allows unprecedented control over all phases of the site evaluation process.

1:00 Close of Conference

3rd Annual

Integrating and Leveraging Clinical Trial Operations Data:

Portals, Data Warehouses, Site and Study Execution Metrics

February 5-6, 2014

SCOPEsummit.com/ClinOps-Data-Integration

WEDNESDAY, FEBRUARY 5

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

DATA INTEGRATION AND AGGREGATION

1:20 Chairperson's Opening Remarks
Anna Kravets, Director, Strategy & Planning, Merck & Co., Inc.

1:30 KEYNOTE PRESENTATION: Pfizer's Move to the Cloud – Clinical Aggregation Layer (CAL)
Munther Baara, Senior Director, Development Business Technology at Pfizer

1:55 Clinical Data Challenges in the Alliance Partner Model
Kenneth Mark Mills, Director, Clinical Scientific Data Warehouse, Pfizer
Transitioning from internal management of clinical trials to an external alliance partner model creates unique challenges with respect to clinical data. Ensuring easy access to consistent, high quality deliverables from data collection through reporting requires sound strategy, tools and processes. The presentation will provide insight into some of the key challenges and Pfizer's approach for building a successful platform for clinical data access in the alliance partner model.

2:20 Leveraging Global Clinical Trial Data for Trial Development and Implementation Strategies
Sponsored by THOMSON REUTERS
Larissa Comis-Tis, Director, Clinical Strategy, Thomson Reuters
The proliferation of electronic clinical trials data creates a new opportunity to combine aggregate clinical data with global clinical trials information that includes bio markers, outcomes, endpoints, adverse events, mechanism of action. This will enable the identification of global clinical trial opportunities and white space that leverage the clinical characteristics of your company's aggregate clinical data. This could provide fast insights into portfolio strategy that may have otherwise been undiscovered.

2:45 Technology and Its Impact on Development and the Changing Role of the Data Manager
Ramzi Najm, Vice President, R&D Information and Technology Management, Allergan
The use of technology in the support of Clinical Trials has continued to increase including solutions such as Investigator Portal, EDC, IRT and ePRO. Those tools have increased access to the clinical trial data and generally improved its quality.

3:00 Gaining Operational Intelligence: "Targeted Data" Innovations For Achieving Real-Time Data Insights
Sponsored by CLINICAL INSIGHTS Visionary Clinical Software
Nick Neri, Vice President, Product Development, eClinical Insights
While the adoption of electronic data capture technologies has delivered significant advances in how data are captured and stored, it has also contributed to a critical business challenge the industry faces today: trial data is fragmented across the eClinical continuum, and companies are struggling to put it back together in an automated way. This presentation will explore the difference between top-down Big Data strategies and "Targeted Data" innovations for achieving real-time operational intelligence at the trial level.

3:25 Refreshment Break in the Exhibit Hall

DATA INTEGRATION AND AGGREGATION (CONTINUED)

4:00 Chairperson's Remarks

4:05 CAT – A Next-Generation Platform for Document Authoring and Review at Novartis
John Walker, Director, NIBR IT, Novartis Institutes for BioMedical Research, Inc.
The clinical development process requires the collaborative authoring and reviewing of many documents. Managing the content, format and versioning of these documents is a challenge. CAT is a new web-enabled way to collaboratively author and review the documents associated with a clinical submission, removing the need for complicated document managing systems. CAT provides the authors with significant automation and re-use capabilities through the use of novel graphical user interfaces.

4:30 PANEL: Comparing Various Data Integration Solutions
Panelists: Speakers of the Session

5:20 Networking Reception in the Exhibit Hall

6:20 End of Day

THURSDAY, FEBRUARY 6

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

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

8:00 am Chairperson's Remarks and Keynote Introduction
Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

8:10 Clinical Informatics News Best Practices Awards
Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News

» 8:25 PLENARY KEYNOTES AND PANEL

Accelerating Clinical Research through Collaboration
Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Data across the Clinical Research Continuum: How Data is the Common Denominator
Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer

PANEL: The Discipline of Innovation in Clinical Research
Craig Lipset, Head, Clinical Innovation, Worldwide Research & Development, Pfizer
Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member
Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.
Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

9:40 Coffee Break in the Exhibit Hall

USER-CENTRIC APPROACH TO CLINICAL TRIALS TECHNOLOGY

10:35 Chairperson's Remarks

Ramzi Najm, Vice President, R&D Information and Technology Management, Allergan

10:40 CO-PRESENTATION: Evolving CTMS Data Quality with User Centric Approach

Anna Kravets, Director, User Experience Strategy & Realization, Merck & Co., Inc.
Anita Zubak, Director, Business Systems Integration, Merck & Co, Inc.

A foundation of any Clinical Trial Management System's business value is accurate, timely and accessible data. Data entry staff's effectiveness plays an important role in a number of the critical gate keeping processes that ensure quality of your operational data. Learn Merck's story of taking a user-centric approach to understanding the opportunities for improvement and implementing series of actions for advancing the data entry personnel's experience to gain productivity, quality and retention.

11:30 Merck's EngageZone Portal – Integrating Capabilities to Provide a Central User Experience for Clinical Trial Operations

Andrea Kirby, Director, Enterprise Integration and Customer Collaboration, Merck & Co, Inc.

This talk will present an overview of, EngageZone, Merck's External Collaboration portal and its current capabilities to enable more integrated collaboration and interactions for Merck and its clinical trial partners.

11:55 Predictive Analytics for Improving Clinical Trial Efficiency

Sponsored by ORACLE HEALTH SCIENCES

Laura Bloechl, Senior Product Strategist, Oracle Health Sciences

In today's economy, biopharmaceutical companies are under increased pressure to be more efficient and cost-effective. This session will outline concepts of leveraging clinical study actuals to produce metrics and analytics to predict accurate study plans. Discussion points will include how trial actuals reveal planning variance, historic data analysis best practices, and benefits of using predictive analytics to inform future planning.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:05 End of Morning Session

IMPROVING AND MEASURING SITE AND STUDY QUALITY

Shared Session between *Integrating Clin Ops Data, Site-Study Activation,* and *Forecasting*

1:15 Chairperson's Remarks

Greg Koski, Ph.D., M.D., Co-Founder & President, ACRES; former Director, Office for Human Research Protections, U.S. Department of Health and Human Services

1:20 Optimizing the Informed Consent Process in Global Studies

Rita Viegas, Clinical Operations Lead, Biogen Idec

Taking into account the new transparency requirements and the constant need to minimize the start-up time, Biogen Idec is implementing technology to improve inform consent form development and timeline management. The inclusion of sub-study informed consents, such as future research, and genetic testing permissions are optimized through electronic consent processes and tracking of downstream use and management of samples in biobanks.

1:45 Building Quality by Design (QbD) and Quality Risk Management (QRM) Systems into Clinical Site Operations

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

As risk-based monitoring continues to increase along with the development and expansion of Quality Risk Management, the need for integration of these two concepts becomes apparent. Practical aspects of developing key performance and quality indicators will be discussed.

2:10 Performance Metrics You Can Use and Believe

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

In this presentation, we review and critique current approaches to performance assessment, describe a new approach, and describe the results of the Clinical Trials Outsourcing Performance (C-TOP) study.

2:35 Building Integrated eClinical Ecosystems to Enable Metrics-Driven Clinical Delivery Dashboard

Jane Fang, Ph.D., R&D IS Lead, Clinical Business Management & Analytics, MedImmune

Meaningful clinical trials metrics and performance dashboards are important to an organization to improve clinical delivery. A healthy eClinical ecosystem is necessary to enable an efficient metrics-driven clinical delivery dashboard. Key trial delivery data captured in the eClinical environment can be utilized to measure trial performance and metrics and to support informed decision making.

3:00 Chairperson's Closing Remarks

3:05 Close of Conference

Inaugural

Improving Site-Study Activation and Performance:

Optimizing Site, CRO, and Sponsor Interactions

New

February 5-6, 2014

SCOPEsummit.com/Site-Study-Activation

WEDNESDAY, FEBRUARY 5

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

PREDICTING ENROLLMENT AND BUILDING HIGH-ENROLLING SITES

1:20 Chairperson's Opening Remarks

Adam Chasse, COO, RxTrials

1:30 Case Study: Overcoming Inefficient Study Start-Up Practices

Tina Soares, Senior Director, Trial Coordination Site Management, GCO, Johnson & Johnson

This presentation will reflect on an internal Janssen R&D Initiative that assessed a myriad of study start-up practices, which led to best practice and process changes that resulted in more efficient start-up as well as strengthened relationships with our internal and external stakeholders.

1:55 Mapping Out Global Enrollment

Nye Pelton, Clinical Operations Portfolio Manager, Clinical Research, Eli Lilly & Co.

I will present from a sponsor perspective our Global Operations Roadmap, sharing how we make sure all regions are trained, feasibility is provided, and the right countries and patient allocations are submitted back to the study teams prior to Protocol Approval.

Sponsored by epharmasolutions

2:20 The Reward on Investment - How Integrating Your Study Start-Up Processes Yields True Returns

Lisa La Luna, Senior Vice President, Corporate Development & Implementation, ePharmaSolutions

While many sponsors realize they must face the challenges of streamlining study start-up, few have been able to comprehend the true reward on doing so. This session will describe true quantitative impacts observed in doing so.

2:45 Turning Straw into Gold: Creating Centers of Excellence

Ellie Smith, Global Clinical Site Developer, Alcon (a Novartis company)

Today's pharmaceutical landscape is creating a need to reach a greater number of patients needing treatment. And, in answer to this need, sponsors are tasked not only with development of new clinical sites, but also the cultivation of centers of excellence. The following is an examination of the methods used by one sponsor to affect this change.

3:10 Refreshment Break in the Exhibit Hall

IMPROVE AND MEASURE SPONSOR-CRO-SITE INTERACTIONS

4:00 Chairperson's Remarks

Christopher McSpiritt, Principal Consultant, Clinical and Regulatory Optimization, Paragon Solutions

4:05 Implementing Governance Structures and Processes to Measure and Improve Sponsor-CRO-Site Interactions

Silvana Giustino, Vice President, Operations, Eisai, Inc.

Governance structures are aimed to discuss key projects, performance metrics, and innovative solutions which may not be visible on a day-to-day operational level. This session will share real-world examples of this structure and highlight the key benefits.

4:30 Selection and Efficient Negotiation with Your CRO

Elke Jordan, Ph.D., Manager, Clinical Development, Bavarian-Nordic GmbH

For the success of a project a balanced working relationship between CRO and Sponsor is vital. This includes knowledge transfer from Sponsor to CRO and openness to expertise offered by the CRO in mutual discussions besides negotiating distinct milestones to measure the progress and manage a project.

4:55 PANEL: New Frontiers in Collaboration among Key Industry Stakeholders

Moderator: Adam Chasse, COO, RxTrials

Deborah Manzo, Senior Director, Clinical Business Operations & Transformation, Clinical Operations, AbbVie

Jamie MacDonald, CEO, INC

Sameer Tandon, Global Supplier Performance & Innovation (SP&I) Manager, R&D, Outsourcing, Novartis

The traditional pharma/CRO/site model must be re-examined. All three segments must consider how to more effectively allocate resources so that quality and successful delivery is a collaborative effort that begins much earlier in the planning stage.

5:20 Networking Reception in the Exhibit Hall

6:20 End of Day

THURSDAY, FEBRUARY 6

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

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

8:00 am Chairperson's Remarks and Keynote Introduction

Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

8:10 Clinical Informatics News Best Practices Awards

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

» 8:25 PLENARY KEYNOTES AND PANEL

Accelerating Clinical Research through Collaboration

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Data across the Clinical Research Continuum: How Data is the Common Denominator

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

PANEL: The Discipline of Innovation in Clinical Research

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

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.

Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

9:40 Coffee Break in the Exhibit Hall

Inaugural

Improving Site-Study Activation and Performance:

Optimizing Site, CRO, and Sponsor Interactions

New

February 5-6, 2014

SCOPEsummit.com/Site-Study-Activation

ASSURING A HIGH QUALITY CLINICAL TRIAL ACTIVATION

10:35 Chairperson's Remarks

Bonnie Brescia, Founding Principal, BBK Worldwide

10:40 Improving and Assuring a High Quality Clinical Trial Activation

Bill Hirokawa, Pharm.D., Coordinator, Investigational Drug Section, Pharmaceutical Services, Ronald Reagan UCLA Medical Center

This presentation offers recommendations to streamline processes, ensuring that the individuals representing your organizations are fully trained and knowledgeable about the requirements demanded of the investigational drug entity being studied.

11:05 Clinical Trial or Product Launch? The Importance of Your Company's First Contact with the Customer/Investigator

Charles Love, Vice President, Clinical Affairs, Endologix, Inc.

Strategies to facilitate early cross-functional communication and customer service within the broader goals of the organization are essential to a successful clinical trial and subsequent successful commercial launch of the technology.

11:30 CO-PRESENTATION: Collaboration between Sponsor and Site to Ensure Quality Data and Success: A Case Study of a Seasonal Flu Vaccine Trial in the Elderly

Chris Hoyle, Executive Director, Elite Research Network

Janet Christoff, Clinical Trial Manager, Sanofi Pasteur

This presentation includes site and sponsor perspectives from a large influenza vaccine case study. A site will present processes and resources put in place to ensure quality data and patient safety. A sponsor will present tools, trackers and surveys that were utilized to increase quality.

11:55 eTMF and Site Activation – How Externalization Can Improve Timelines

Sponsored by PARAGON SOLUTIONS *Value Envisioned. Value Delivered.*

Michael Agard, Principal Consultant, Clinical and Regulatory Optimization, Paragon Solutions

This session will explore the benefits of an externalized eTMF in driving the site activation process. Topics discussed will include: how eTMF systems enable the latest version of a document to end needless searching; specific tasks and notices that can be sent out to sites to complete documents and due dates; how collaborative authoring and electronic workflows enable more accurate document completion; using dashboards to view the status of the sites ready to receive drug shipment based on the status of completed documents.

12:20 pm LUNCHEON PRESENTATION: Disruptive Innovation - Breaking Down Silo Challenges by Eliminating Technology Costs – Good for Sites, Sponsors, CROs, Regulators and Industry in General

Sponsored by HealthCarePoint Transnational Collaborative Networks Connecting Healthcare and Clinical Research

Al O. Pacino II, President, HealthCarePoint.com

Site start up can be costly to all stake holders. Constantly Updating information about sites and personnel involved in a clinical trial is inefficient, redundant and can be a regulatory challenge. Based on a proven innovative business model, this presentation will explain how all stakeholders can benefit from a novel networking approach that eliminates technology costs, minimizes redundancies and regulatory risks while saving millions in time and resources at the Sponsor, CRO, and Investigator Sites levels.

1:05 End of Morning Session

IMPROVING AND MEASURING SITE AND STUDY QUALITY

Shared Session between *Site-Study Activation, Integrating Clin Ops Data,* and *Forecasting*

1:15 Chairperson's Remarks

Greg Koski, Ph.D., M.D., Co-Founder & President, ACRES; former Director, Office for Human Research Protections, U.S. Department of Health and Human Services

1:20 Optimizing the Informed Consent Process in Global Studies

Rita Viegas, Clinical Operations Lead, Biogen Idec

Taking into account the new transparency requirements and the constant need to minimize the start-up time, Biogen Idec is implementing technology to improve inform consent form development and timeline management. The inclusion of sub-study informed consents, such as future research, and genetic testing permissions are optimized through electronic consent processes and tracking of downstream use and management of samples in biobanks.

1:45 Building Quality by Design (QbD) and Quality Risk Management (QRM) Systems into Clinical Site Operations

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

As risk-based monitoring continues to increase along with the development and expansion of Quality Risk Management, the need for integration of these two concepts becomes apparent. Practical aspects of developing key performance and quality indicators will be discussed.

2:10 Performance Metrics You Can Use and Believe

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

In this presentation, we review and critique current approaches to performance assessment, describe a new approach, and describe the results of the Clinical Trials Outsourcing Performance (C-TOP) study.

2:35 Building Integrated eClinical Ecosystems to Enable Metrics-Driven Clinical Delivery Dashboard

Jane Fang, Ph.D., R&D IS Lead, Clinical Business Management & Analytics, MedImmune

Meaningful clinical trials metrics and performance dashboards are important to an organization to improve clinical delivery. A healthy eClinical ecosystem is necessary to enable an efficient metrics-driven clinical delivery dashboard. Key trial delivery data captured in the eClinical environment can be utilized to measure trial performance and metrics and to support informed decision making.

3:00 Chairperson's Closing Remarks

3:05 Close of Conference

Inaugural

Subject Retention and Compliance in Studies and Registries:

Engaging and Empowering Patients through Mobile and Social Platforms

New

February 5-6, 2014

SCOPEsummit.com/Subject-Retention

WEDNESDAY, FEBRUARY 5

Bridging Luncheon Presentation between *Subject Retention* and *Enrollment Planning*

Sponsored by DAC PATIENT RECRUITMENT SERVICES an Imperial Company

12:15 pm LUNCHEON PRESENTATION: Ensuring Site Buy-In and Compliance through Successful Execution of Recruitment and Retention Planning

Melynda Geurts, Vice President Operations, DAC Patient Recruitment Services

A successful study consists of a solid protocol, committed research centers and volunteers. This presentation will explore how the right level of recruitment and retention planning during protocol design can enhance site buy-in and study compliance. Learn how to plan, implement, leverage study coordinators, and engage your sites.

ENGAGING AND EMPOWERING PATIENTS FOR RESEARCH

1:20 Chairperson's Opening Remarks

Barbara Wuebbels, Associate Director of Patient Advocacy, BioMarin Pharmaceutical Inc.

1:30 What Does Patient Centricity Mean to Patients?

Jane Perlmutter, Ph.D., MBA, President and Founder, Gemini Group; Steering Committee Member, Clinical Trials Transformation Initiative (CTTI)

"Patient Centricity" means different things to different people. We will explore what patients and advocates mean, how this may differ from what clinical trialists mean, and implications for planning trials that will rapidly accrue patients.

1:55 Understanding Various Types of Patient Advocacy: Partner with and Engage Patient Opinion Leaders (POL) and Patient Advocacy Groups to Further Research

Rose Gerber, Director, Communications and Patient Advocacy, Community Oncology Alliance

For organizations interested in engaging patients as partners/advocates, it is fundamentally important to understand the distinctions between various types of patient advocacy (educational, peer, policy, research based). Opportunities and challenges?

Sponsored by BBK WORLDWIDE

2:20 Six Degrees of Kevin Bacon – Building Lasting Connections with Advocacy Groups

Aaron Fleishman, Social Innovation & Advocacy Engagement, BBK Worldwide

Lasting relationships with patient advocacy and community groups can be an important part of a patient recruitment program. The question is, how do you build those relationships? And once you've built them, how do you maintain them? Aaron Fleishman from BBK Worldwide will discuss several ways you can work with advocacy groups as a patient recruitment tactic.

Sponsored by QUINTILES

2:45 Accelerating Recruitment in Complex Clinical Trials: How Clinical Trial Educators Can Help

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

The CTE solution has been successfully used in trials with a complex patient pathway in therapeutic categories that are also highly competitive (oncology, CNS, and cardiovascular diseases). CTEs have been highly effective in rescuing trials.

3:10 Refreshment Break in the Exhibit Hall

PROACTIVE PATIENT RETENTION PLANNING

4:00 Chairperson's Remarks

Judith Teall, Director, Clinical Excellence, Exco InTouch

4:05 Initiating a Proactive, Multi-Faceted Patient Retention Plan: Challenges, Opportunities and Case Studies

Kelly McKee, Associate Director, Clinical Research, Global Trial Optimization, Merck & Co., Inc.

Patient retention planning and management is just as important as recruitment and requires a study-specific, patient-focused, and success-driven action plan. Proactive retention planning can minimize this risk and set clinical studies up for success.

4:30 CO-PRESENTATION: Patient-Centricity and Marketing the Site to Increase Recruitment and Retention: A Coordinator's Perspective

Jessica Saucier, Clinical Transplant Research Nurse, Baylor Research Institute
Erin Fassett, Clinical Transplant Research Nurse, Baylor Research Institute

By integrating successful recruitment tools into practice, sites can increase screening numbers and reduce time to completion of enrollment. Strategies to market the site can be implemented to ensure rapid identification and utilization by sponsors.

4:55 Harnessing the Momentum of Patient Centricity and Social Media for Patient Recruitment

Liz Moench, President & CEO, MediciGlobal, Inc

The conduct of clinical trials is undergoing rapid change, fueled in part by technological advancements, and an increasingly empowered patient population. While many biopharmaceutical companies currently use a form of direct-to-patient for certain clinical processes, such as online patient recruitment, there are growing opportunities to implement patient centric initiatives across the clinical trial model. From this panel, participants will learn how to: enhance clinical study planning and modeling through patient centric initiatives; optimize social media for added efficiency in clinical trials & utilize direct-to-patient channels for identifying, recruiting and retaining trial participants.

5:20 Networking Reception in the Exhibit Hall

6:20 End of Day

THURSDAY, FEBRUARY 6

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

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

8:00 am Chairperson's Remarks and Keynote Introduction

Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

8:10 Clinical Informatics News Best Practices Awards

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

» 8:25 PLENARY KEYNOTES AND PANEL

Accelerating Clinical Research through Collaboration

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Data across the Clinical Research Continuum: How Data is the Common Denominator

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

PANEL: The Discipline of Innovation in Clinical Research

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9:40 Coffee Break in the Exhibit Hall

Inaugural

Subject Retention and Compliance in Studies and Registries:

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New

February 5-6, 2014

SCOPEsummit.com/Subject-Retention

INCREASE RECRUITMENT, RETENTION AND ADHERENCE OF MINORITY PATIENTS

10:35 Chairperson's Remarks

Gerson Peltz, M.D., Medical Director, Global Pharmacovigilance and Epidemiology, Bristol-Myers Squibb

10:40 CO-PRESENTATION: Challenges and Approaches to Increase Recruitment, Retention and Adherence of Minority Patients in Clinical Trials

Gerson Peltz, M.D., Medical Director, Global Pharmacovigilance and Epidemiology, Bristol-Myers Squibb

Patricia Cornet, Associate Director, Advocacy, Global Recruitment & Analytics, Bristol-Myers Squibb

Addressing diversity in studies is a key factor to understand and improve individual patient outcomes. Therefore, barriers for enrollment of minority patients should be taken into account upfront when planning clinical studies. Sponsors and investigators will need to work collaboratively in developing innovative approaches to improve diversity in outcomes.

11:20 CO-PRESENTATION: Challenges and Importance of Addressing Diversity in Participation to Clinical Trials

Gary Puckrein, Ph.D., President and CEO, National Minority Quality Forum

Alesci Salvatore, M.D., Ph.D., Vice President, Scientific Affairs, PhRMA

12:00 The Role and Methods of Patient Retention in Longitudinal Post-Approval Studies

Sponsored by Mapi

Kristin Tatum, Senior Project Manager, Mapi

Unlike RCTs, post-approval longitudinal studies require a more dynamic retention plan to maintain patient interest over long periods of time while mitigating the long-term burden of participation. This discussion highlights the role of patient retention, common reasons for patient attrition, and methods and tools to retain patients.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* or Lunch on Your Own

1:05 End of Morning Session

> "SCOPE provided access to ideas, information-sharing, and resources in one place. Great forum for sharing best practices and advancing our efforts in clinical research."
>
> *— Sheela G., Director, Health Management Solutions, Quintiles*

ENHANCE PATIENT COMPLIANCE AND RETENTION THROUGH MOBILE TECH

Shared Session between *Subject Retention* and *Technologies for Post-Marketing*

1:15 Chairperson's Remarks

Lynne Nguyen, Director, Population & Community Core, Center for Community-Engaged Translational Research, MD Anderson Cancer Center

1:20 Utilizing Tech to Improve Trial Outcomes, Patient Experience and Retention

Richard Mayewski, Associate Director, Clinical Trial Intelligence, Novartis

The use of technology within clinical trial space will have a tremendous impact for those able to harness its energy. Site/Patient burdens, patient identification, and even increased detail of patient histories can all be attributed to the enhanced presence of technology and what it offers - increased communication. These avenues help maintain direct contact with patients and in turn have the potential to improve patient retention, patient reported outcomes, and ultimately good clean study data.

1:45 Patient-Centered Clinical Research: Engaging Patients in the Design of Clinical Trials

Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

What really matters to a patient when they are deciding whether or not to participate in a given clinical trial? Why do such a small percentage of eligible patients participate in clinical trials? Why is it so hard to say 'thank you'?

2:10 Mobile Patient Engagement to Enhance Cardiovascular Outcomes Studies

Sponsored by exco intouch Healthcare at your fingertips

Judith Teall, Director, Clinical Excellence, Operations, Exco InTouch

Typical outcomes 'mega' trials are a lengthy and costly commitment. Keeping patients engaged and compliant becomes a key issue in order to identify the endpoints and the final vital status. This session will demonstrate how mobile technology can help.

2:35 From Start-Up to Post-Marketing: The Role of The Industry-Wide, Mobile Cyber-Identity in All Phases of the Clinical Trial

Mollie Shields-Uehling, President and CEO, SAFE-BioPharma Association

Use of mobile devices is exploding in all aspects of the clinical trial process. This raises questions about the authenticity of the identities of those submitting important post-marketing drug-risk data, as well as challenging the time and patience of trial personnel submitting the information.

3:00 Chairperson's Closing Remarks

3:05 Close of Conference

WEDNESDAY, FEBRUARY 5

Bridging Luncheon Presentation between *Forecasting* and *Aggregate Spend*

12:15 pm LUNCHEON PRESENTATION: Navigating the Challenges of Global Investigator Site Payments

Sponsored by CFS CLINICAL Part of DrugDev

Stuart Thiede, Senior Vice-President & General Manager, Global Payment Services, CFS Clinical (CFS)

Investigator grant payments are the single greatest expense in a clinical trial, accounting for 40-60% of the total trial budget, and yet slow payments continue to be the most common complaint and challenge for sites. While the investigator payment process is quite challenging in the U.S. due to the multitude of compliance requirements including the Sunshine Act, the complexity multiplies exponentially in global trials. Challenges in the global environment are many and include but are not limited to working with multiple currencies and CRO's, financial reporting across borders, contracting party issues, VAT taxes, and transparency compliance.

- Review the complexities of global trials
- Reduce administrative work by centralizing systems and improving workflow
- Learn how to improve the bottom line by managing taxes

IMPROVING STRATEGIC PLANNING TO IMPROVE OUTCOMES

1:20 Chairperson's Opening Remarks

Chris Chan, Director and Head, R&D Financial Planning and Analysis, Onyx Pharmaceuticals

1:30 Overcoming the Unknown: Managing the Most Common Perils in the Study Planning Phase

Manfred Stapff, M.D., Executive Director, Global Medical Operations, Forest Laboratories

Time pressure, management expectations, or improperly used study startup metrics seduce us to not spending enough energy during the study planning phase on evaluating potential operational hazards. The presentation will provide suggestions on how to convert these perils from surprises into predictables.

1:55 Start with the End: How to Differentiate Your Product in a Changing Healthcare Market through Advanced Planning

Joe Popowicz, Principal Consultant, Emergent Clinical Consulting; former Director, Clinical Operations, Stryker Orthobiologics

More evidence is expected from Sponsors to differentiate their products. Performance and safety remain cornerstones; however, there has been an evolution to look at comparative effectiveness, economics and quality of life measurements over longer patient durations.

2:20 Achieving Faster, Less Costly and More Predictable Trials: a Myth or Reality?

Sponsored by imshealth

Suresh Kannan, Vice President Products, Clinical Trial Optimization Solutions, IMS Health

Clinical and R&D teams are under more pressure than ever to complete their trials on time and within budget. The industry is riddled with information on clinical trial time delays and the impact those delays have on budgets and revenues. While issues always arise that cannot be planned for, a large majority of delays can be reduced by simply creating a balanced and actionable plan before the study starts. More and more the industry is pushing for predictability and foresight in the planning process: at a study level, at an asset level, and across the portfolio. While an abundance of metrics exist – through internal analysis and external tools – what is often lacking is the view of these metrics in a broader context. By rounding out the planning process with standardized data from internal performance benchmarks, external industry benchmarks, predictive analytics and field based insight the industry can make huge strides in their ability to finish trials on time and within budget.

2:45 Talk Title to be Announced

Deborah Manzo, Senior Director, Clinical Business Operations & Transformation, Clinical Operations, AbbVie

3:10 Refreshment Break in the Exhibit Hall

OPTIMIZING CLINICAL PROJECT MANAGEMENT AND PARTNERSHIPS

4:00 Chairperson's Remarks

4:05 Managing Global Project Teams across Cultures and Time Zones

Eric Morfin, Senior Director, Project Management, Allergan

When it comes to clinical excellence and project management, appropriate behavior-based leadership skills coupled with a strong cultural awareness can give you a competitive advantage. The presentation will feature real examples from several clients as well as several mini case studies.

4:30 Importance of Project Controls, Above and Beyond Project Management

Vanessa Kemp, Manager, Project Controls; Master Capital Planning, Engineering, Novartis

Project controls can effectively reduce the variances in projects, increase schedule deliveries, and maintain the budgets set. Effective controls drastically improve stakeholder management and leadership communication.

4:55 CO-PRESENTATION: Strategic Partnership Models with CROs

Rhonda Benotti, Business Manager, Strategic Outsourcing, Genentech, Inc.
Wei Li, Functional Manager, Strategic Outsourcing, Genentech, Inc.

With oversight committees and strategic partnership teams, clinical trials are better managed and executed. These cross-functional teams provide oversight, governance, and a clear communication and escalation path as well as the consistency and commitment required for success.

5:20 Networking Reception in the Exhibit Hall

6:20 End of Day

THURSDAY, FEBRUARY 6

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

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

8:00 am Chairperson's Remarks and Keynote Introduction
Andrew Lee, Senior Vice President & Head, Global Clinical Operations, Genzyme Corp., a Sanofi Co.

8:10 Clinical Informatics News Best Practices Awards
Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News

» 8:25 PLENARY KEYNOTES AND PANEL

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Jeffrey Kasher, Ph.D., Vice President, Global Clinical Trial: Materials, Implementation and Transformation, Eli Lilly & Co.; TransCelerate Operations Committee Member

Data across the Clinical Research Continuum: How Data is the Common Denominator
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9:40 Coffee Break in the Exhibit Hall

TRIAL BUDGETING, FINANCE AND FORECASTING

10:35 Chairperson's Remarks
Suresh Kannan, Vice President Products, Clinical Trial Optimization Solutions, IMS Health

10:40 Top Five "Easy Wins" to Implement Now to Immediately Improve Your Clinical Trials Financial Forecasts
Chris Chan, Director and Head, R&D Financial Planning and Analysis, Onyx Pharmaceuticals
There are steps you can implement to improve forecasting accuracy, including separating "approved to spend" from "likely to spend" amounts; avoid focusing on the "weeds" rather than the forest; training clinical personnel on financial systems and processes; training financial personnel on clinical contract systems and processes; financial accruals training for all.

11:05 Bayer's Approach to Probabilistic Discounts When Planning Clinical Trial External Cost
Piet Theisohn, Director, Resource Management & Business Support, Global Clinical Development, Bayer Healthcare Pharmaceuticals
Planning and execution for phase II and III is influenced by many factors, such as regulatory authorities, competing trials, the reliability of the trial feasibility, etc. Bayer has implemented an approach to apply probabilistic discounts to trial cost to help manage the budget frame for clinical on portfolio level.

11:30 CO-PRESENTATION: Optimizing Site Budgeting and Negotiation to Improve Study Start-Up
Brenda Medina, former Director, Global Head, Clinical Business Operations, Eisai, Inc.
Miriam Cruz, Project Director, Clinical Financial Services; former Director, Clinical Operations, Eisai, Inc.

11:55 Sponsor Perception of Site Standard of Care Practices
Sponsored by RoutineRecovery
Lucas M. Glass, Managing Director, Routine Recovery, LLC
Clinical sites are acutely aware of standard of care (SoC) billing. Most major sponsors, however, are unaware of current SoC practices outside of oncology. This knowledge gap causes sponsors to overpay sites and creates billing compliance issues. A survey of sites suggests that sites are billing insurance providers for SoC far more than sponsors realize. This presentation empirically quantifies how much "Standard of Care" sponsors believe they are paying for along with how often sites are actually billing insurance companies outside of oncology.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:05 End of Morning Session and Refreshment Break

IMPROVING AND MEASURING SITE AND STUDY QUALITY

Shared Session between *Forecasting, Integrating Clin Ops Data,* and *Site-Study Activation*

1:15 Chairperson's Remarks
Greg Koski, Ph.D., M.D., Co-Founder & President, ACRES; former Director, Office for Human Research Protections, U.S. Department of Health and Human Services

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Marina Malikova, Ph.D., Executive Director, Surgical Translational Research: Operations and Compliance, Surgery, Boston University Medical Center
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2:10 Performance Metrics You Can Use and Believe
Michael Howley, Ph.D., Clinical Associate Professor, Business, LeBow College of Business, Drexel University
In this presentation, we review and critique current approaches to performance assessment, describe a new approach, and describe the results of the Clinical Trials Outsourcing Performance (C-TOP) study.

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3:00 Chairperson's Closing Remarks

3:05 Close of Conference

Patient-Centered Technologies for Post-Marketing and Real World Data Research:

Enabling Non-Interventional and Peri-Approval Studies

February 5-6, 2014

SCOPEsummit.com/RealWorld-Studies

WEDNESDAY, FEBRUARY 5

12:15 pm Bridging Luncheon Presentation between *Technologies for Post-Marketing* and *Managing Post-Marketing* *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

PATIENT-CENTERED RESEARCH TECHNOLOGIES

1:20 Chairperson's Opening Remarks

Kelly Hollis, MBA, Global Head, Surveys and Observational Studies, RTI Health Solutions

1:30 KEYNOTE PRESENTATION: Innovative Research Tools and Solutions to Empower Patients

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

Topics to be discussed include: harnessing the power of social and mobile as key platforms to engage and inform patients and capture data during participation, sharing data to enhance the intersection of research and healthcare, and considerations when research participants are social.

1:55 Value of the Patient Voice in Non-Interventional Studies

Carla DeMuro, Head, Patient Reported Outcomes, RTI Health Solutions

The value of patient reported outcomes (PROs) extends far beyond traditional use in clinical trials offering unique opportunities in observational studies to examine the impact of a disease or treatment on how a patient feels or functions as well as to understand patient preferences and healthcare choices. This presentation will provide real-world examples of how PRO data provide important insight for patients, payers and prescribers.

2:10 Sponsored Presentation *(Opportunity Available)*

2:45 Using EHR Data for Non-Interventional Studies: How Good is Good Enough

Meredith Nahm, Ph.D., Associate Director, Clinical Research Informatics, Biomedical Informatics Core, Duke Translational Medicine Institute

A major challenge in using EHR data for research lies in assessing the ability of the data to support research conclusions. This talk covers methods for assessing the quality of EHR data.

3:10 Refreshment Break in the Exhibit Hall

PATIENT-REPORTED OUTCOMES AND BEYOND

4:00 Chairperson's Remarks

4:05 Integrating Patient/Caregiver and Physician Surveys in Non- Interventional Studies: Survey Methodology and Best Practices

Kelly Hollis, MBA, Global Head, Surveys and Observational Studies, RTI Health Solutions

The discussion will focus on questionnaire development as well as selecting appropriate methods for the target population based on the content and objectives of the survey. Methods for designing patient and physician surveys to minimize bias and improve the accuracy and integrity of the data will also be discussed.

4:30 Technology Tools to Optimize the Management of Patient Reported Outcomes (PRO) Data

Nariman A. Nasser, CCRP, Founder, Only For Good; Digital Strategist for Product Development, Genentech

4:55 Innovative and Patient Centered Research Technologies in Late Phase Medical Device Clinical Trials

Christina Villar, MPH, Director, Clinical Affairs, Johnson & Johnson Vision Care, Inc.

This session will review ongoing efforts to engage patients in clinical development, initiatives such as e-consenting, direct to patient clinical studies, social media recruitment campaigns and other disruptive innovation that is being piloted across the industry. Companies such as Johnson & Johnson, Pfizer, and TransCelerate among others are evaluating new technologies to streamline the clinical research process while ensuring that data is accurate, real time, and patient centered.

5:20 Networking Reception in the Exhibit Hall

6:20 End of Day

THURSDAY, FEBRUARY 6

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

MORNING PLENARY KEYNOTES AND PANEL: COLLABORATION, DATA INTEGRATION AND INNOVATION

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Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceutical, Inc.

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9:40 Coffee Break in the Exhibit Hall

Patient-Centered Technologies for Post-Marketing and Real World Data Research:

Enabling Non-Interventional and Peri-Approval Studies

February 5-6, 2014

SCOPEsummit.com/RealWorld-Studies

NOVEL TOOLS FOR PHARMACOVIGILANCE

10:35 Chairperson's Remarks

10:40 Advancing Pharmacovigilance Using Unstructured Data

Nigam Shah, Ph.D., Assistant Professor, Medicine & Biomedical, Informatics, Stanford Center for Biomedical Informatics Research

We will discuss novel methods to identify contextual multi-drug risk profiles for further scrutiny. I will discuss our research on integrating complementary data sources such as Electronic Health Records, health search logs as well as physician query logs to provide unique data-driven insights into the safety profiles of drugs in their actual usage setting.

11:05 Implementing a Signaling Tool for Pharmacovigilance

Reinerio Deza, M.D., Head Global Pharmacovigilance, CDMA Management, Cubist Pharmaceuticals, Inc.

The implementation of a signaling tool coupled with best practices will significantly ensure a robust proactive system to conduct a high standard of safety signaling and risk management for your products. The case study in this presentation shows a pharmaceutical company's approach to a comprehensive signal and risk management method applied on their products in clinical development and post approval.

11:30 Engaging Everyone Responsibly in Biomedical Research

Marybeth McAfee, Associate Director of Health Information, Genetic Alliance

This session will explore the Platform for Engaging Everybody Responsibly, enabling dynamic and granular health data sharing, privacy and access preferences. This gamified system is managed by the individuals in a community, thereby building cohorts in an engaging trust environment.

11:55 CO-PRESENTATION: Approval Technology Solutions

Sponsored by PAREXEL. Right where you need us™

Peggy Schrammel, Vice President & Global Head, Portfolio Management, PACE PAREXEL

Kate Trainor, Vice President & Global Head, Project Management &Technology, PACE PAREXEL

This session will present case studies of how technology can be optimized and integrated in the peri-approval setting, with the focus on cost containment, enhanced investigator satisfaction and decreases in study timelines.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:05 End of Morning Session

> "This was my first time at SCOPE and I found the sessions and vendors participating to be very helpful. Will take many ideas back and implement some of these ideas into our current processes. Will recommend others in our group attend next year."
>
> — *Deborah K., Global Head, Study Monitoring, Roche Diagnostics*

ENHANCE PATIENT COMPLIANCE AND RETENTION THROUGH MOBILE TECH

Shared Session between *Subject Retention* and *Technologies for Post-Marketing*

1:15 Chairperson's Remarks

Lynne Nguyen, Director, Population & Community Core, Center for Community-Engaged Translational Research, MD Anderson Cancer Center

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Typical outcomes 'mega' trials are a lengthy and costly commitment. Keeping patients engaged and compliant becomes a key issue in order to identify the endpoints and the final vital status. This session will demonstrate how mobile technology can help.

2:35 From Start-Up to Post-Marketing: The Role of The Industry-Wide, Mobile Cyber-Identity in All Phases of the Clinical Trial

Mollie Shields-Uehling, President and CEO, SAFE-BioPharma Association

Use of mobile devices is exploding in all aspects of the clinical trial process. This raises questions about the authenticity of the identities of those submitting important post-marketing drug-risk data, as well as challenging the time and patience of trial personnel submitting the information.

3:00 Chairperson's Closing Remarks

3:05 Close of Conference

Cambridge Healthtech Institute's Fifth Annual

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

February 4 - 6, 2014
Hyatt Regency Miami, Miami FL

Pricing and Registration Information

	Commercial	Academic, Government, Hospital-affiliated
CONFERENCE PRICING		
BEST VALUE! - Includes access to the entire 3-day SCOPE program *(Does not include access to pre-conference short courses)*		
Registrations after January 10, 2014, and on-site	$2899	$1299
Standard Registration - Includes access to ONE conference *(Does not include access to pre-conference short courses)*		
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Tuesday - Wednesday, February 4th-5th	Wednesday - Thursday, February 5th-6th
C1 Electronic Data in Clinical Trials	C7 Integrating and Leveraging Clinical Trial Operations Data
C2 Global Site Selection, Feasibility Assessment, Operations and Site Mgmt	C8 Improving Site-Study Activation and Performance
C3 Enrollment Planning and Patient Recruitment	C9 Subject Retention and Compliance in Studies and Registries
C4 Aggregate Spend and Transparency Reporting in Clinical Trials	C10 Clinical Trial Forecasting, Budgeting and Project Management
C5 Managing Post-Marketing Studies and Registries	C11Patient-Centered Technologies for Post-Marketing and Real World Data Research
C6 Sample & Biospecimen Management in Clincial Trials	

SHORT COURSES		
One Short Course	$699	$399
Two Short Courses *(1 Afternoon Short Course + Dinner Short Course SC7)*	$999	$699

Afternoon Short Courses: 2:00 - 5:30pm

SC1 Cloud-Based Clinical Data Access and Management: Current Industry Status

~~SC2 Clinical Trial Monitoring and Compliance: The Role of the CRA in Supporting Subject Recruitment and Successful Study Conduct~~ CANCELLED

~~SC3 Innovative Approaches to Project Management: Strategic Planning, Forecasting and Quality Improvement~~ CANCELLED

SC4 Building Clinician & Patient Communities for Post-Marketing and Real World Data Research

~~SC5 Identity Crisis! An Educational Workshop and Guide to Study Branding~~

~~SC6 Clinical Trials to Establish Value of Diagnostic Tests: Design and Management~~ CANCELLED

~~**Dinner Short Course: 6:00 - 9:00pm**~~

~~SC7 Technical and Operational Considerations in Conducting a Patient-Centric Study~~ CANCELLED

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

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ADDITIONAL REGISTRATION DETAILS

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