9th Annual

SUMMIT FOR CLINICAL OPS EXECUTIVES

February 12-15, 2018
Hyatt Regency Orlando
Orlando, Florida

Event Features

- More than 1,400 participants projected for 2018
- 18 Conferences
- 3 Plenary Keynote Sessions
- Clinical Informatics News Best Practices Awards
- Participant Engagement Awards
- Dedicated Exhibit Hall Hours & Networking Functions

Register by January 5 and SAVE up to $200

SCOPEsummit.com
### Event-at-a-Glance

<table>
<thead>
<tr>
<th>Event</th>
<th>Monday, February 12</th>
<th>Tuesday, February 13</th>
<th>Wednesday, February 14</th>
<th>Thursday, February 15</th>
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</thead>
<tbody>
<tr>
<td><strong>Monday, February 12</strong></td>
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<tr>
<td>Make Space for Innovation: Trifecta InvestigatorSpace® User Forum</td>
<td>12:00 pm – 5:00 pm</td>
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<tr>
<td>Pre-Conference User Group Meetings &amp; Hosted Workshops (Opportunities Available)</td>
<td>2:30 pm – 5:00 pm</td>
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<td>SCOPE’s Kick-Off Networking Happy Hour on the Garden Terrace</td>
<td>6:30 pm – 8:30 pm</td>
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| **Tuesday, February 13**                  |                      |                       |                         |                        |
| Conference 1A Protocol Development, Global Site Selection, Feasibility and Site Management |                       |                       |                         |                        |
| Conference 2A Enrollment Planning and Patient Recruitment |                       |                       |                         |                        |
| Conference 3A Clinical Trial Forecasting, Budgeting and Contracting |                       |                       |                         |                        |
| Conference 4A Mastering an Outsourcing Strategy |                       |                       |                         |                        |

| **Wednesday, February 14**                |                      |                       |                         |                        |
| Conference 5A Implementing Risk-Based Monitoring - Part 1 |                       |                       |                         |                        |
| Conference 6A Clinical Data Strategy and Analytics |                       |                       |                         |                        |
| Conference 7A NEW Sensors, Wearables and Digital Biomarkers in Clinical Trials |                       |                       |                         |                        |
| Conference 8A Late Stage Research and Observational Studies |                       |                       |                         |                        |
| Conference 9A Biospecimen, Central Lab and Technology for Precision Medicine Trials |                       |                       |                         |                        |

| **Thursday, February 15**                 |                      |                       |                         |                        |
| Conference 1B Improving Site-Study Activation and Performance |                       |                       |                         |                        |
| Conference 2B Patient Engagement, Enrollment and Retention through Communities and Technology |                       |                       |                         |                        |
| Conference 3B NEW Resource Management and Capacity Planning for Clinical Trials |                       |                       |                         |                        |
| Conference 4B Managing Outsourced Clinical Trials |                       |                       |                         |                        |
| Conference 5B Implementing Risk-Based Monitoring - Part 2 |                       |                       |                         |                        |
| Conference 6B NEW Artificial Intelligence in Clinical Research |                       |                       |                         |                        |
| Conference 7B Clinical Technology and Innovation |                       |                       |                         |                        |
| Conference 8B Leveraging Real World Data for Clinical and Observational Research |                       |                       |                         |                        |
| Conference 9B NEW Clinical Supply Management |                       |                       |                         |                        |

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Join the Clinical Trials Ops Executives group [LinkedIn](https://www.linkedin.com), [Twitter](https://twitter.com), [#SCOPE2018](https://www.scopesummit.com)

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

Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

Podium Presentations — Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 25-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

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Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

EXHIBIT – Hall Over 90% Sold!

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- Footprint Trails
- Aisle/Meterboard Signs
- Exhibit Hall Reception
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- Padfolios
- Program Guide Advertisement

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CHI’s Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. 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:
- Live Webinars
- White Papers
- Market Surveys
- Podcasts and More!

2017 ATTENDEE DEMOGRAPHICS

For sponsorship and exhibitor information, please contact:

Ilana Quigley
Sr Business Development Manager
781-972-5457
iquigley@healthtech.com
Hotel & Travel Information

Conference Venue and Hotel:
Hyatt Regency Orlando
9801 International Drive
Orlando, FL 32819
T: 407.284.1234

Reservations: Go to the travel page of SCOPEsummit.com.

Discounted Room Rate: $249 s/d
Discounted Cut-off Date: January 9, 2018

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

After conference sessions, our attendees may enjoy:
• Complimentary internet in their guest room
• Three different swimming pools, with waterfalls and a water slide
• 24-hour state-of-the-art fitness center and spa
• First rate onsite restaurants, including upscale, pool dining, family friendly and grab-and-go options
Monday Evening:
WHERE ARE CLINICAL TRIALS HEADED FOR 2018?

5:00 - 6:15 PANEL DISCUSSION: Where Are Clinical Trials Headed for 2018?

Moderator: Christopher Rull, Principle Consultant, CR Consulting, LLC; former Vice President, Head of Business Development & Account Management, UBC

Ibraheem (Ibs) Mahmood, CEO, DrugDev

Joan Shaw, Vice President, Global Clinical Development & Operations, UBC

Greg Skalicky, Chief Enterprise Business Officer, inVentiv Health

Jeffrey Kasher, Ph.D., Founder, Patients Can't Wait; former Vice President, Clinical Innovation and Implementation, Eli Lilly and Company

As the biopharmaceutical industry increasingly turns to CROs to stay competitive and improve its efficiency, hear from senior CRO leaders as they explore where clinical trials are headed in 2018. Start off SCOPE by hearing leading CROs forecast new trends, changes in process, and partnerships and continue the discussion at our Welcome Reception. Topics to be discussed:

• What are the key trends on the horizon for clinical trials? Where will the next big pay-off be for clinical trials?
• As new technology and increasing volumes of data become more accessible to the biopharmaceutical industry, how will industry make meaningful, data-driven decisions in 2018? How will pharma put these trends to action?
• What is in store for Sponsor-CRO partnerships as mergers and acquisitions increase across the CRO landscape?
Plenary Keynotes & Panels

TUESDAY, FEBRUARY 13, 2018

Tuesday Morning:
PATIENT-CENTRIC DRUG DEVELOPMENT AND TRIAL OPERATIONS

8:20 am Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:25 Chairperson's Introduction
Jerome Chiaro, Vice President, Clinical Site Operations, StudyKIK

8:30 Keynote Kick-Off: Stop Trying to Be Innovative! Hack Your Way to Creative, Valuable Solutions
Shwen Gwee, Head of Digital Strategy, Global Clinical Operations, Biogen

At a time of unprecedented innovation disrupting almost every other industry, the healthcare and pharmaceutical industries seem to be laggards and most resistant to this change. This talk will cover three easy steps that are used by MIT Hacking Medicine, a student organization that runs health hackathons around the world, to help hack innovative solutions for medicine and healthcare. The approach draws principles and learnings from Design Thinking, Lean Startup and other innovation processes, which when applied to your organization or corporate approach, can help you hack your way to creative, valuable solutions that can engender value and drive true innovation.

8:45 Operating on a Beating Heart: Evolving Patient-Centricity End to End in Pharmaceutical Development
Roslyn Schneider, M.D., Global Patient Affairs Lead, Pfizer

People living with and trying to prevent illness expect more iterative involvement in decisions that affect their health including in development of therapies. They are no longer content with surrogates speaking for them even if they are learned, compassionate professionals. We in the pharmaceutical industry are working together with patients to understand and implement the most appropriate ways to involve patients without missing a beat in the rush to advance and support therapies that may benefit them. This keynote will address some of the experiences, opportunities and challenges in doing just that.

9:10 PANEL DISCUSSION: What Does Digital Patient Engagement Mean Today?

Moderator: Paulo Moreira, Vice President, Global Clinical Operations - External Innovation, EMD Serono
Roslyn Schneider, M.D., Global Patient Affairs Lead, Pfizer
Terrie Livingston, Pharm.D., Senior Director, Real World Outcomes, Innovative Partnerships & Insights (RIZ), Biogen
Michelle Crouthamel, Lead, Clinical Innovation & Digital Platforms Unit, GlaxoSmithKline
Gilles Frydman, Patient Advocate; Co-Founder, Smart Patients and ACOR (Association of Cancer Online Resources)

The research community has embraced patient-centricity as a driving force to improve participant experience, trial design and outcomes, but the engagement piece has many components. This panel will discuss current digital patient projects, engagement pilots, experiences with new technologies, the role of patient communities, and lessons learned to date. Key questions to be discussed by the panel and with the audience:

• What is a complete digital patient experience? What is required to make this a reality for all trials?
• What are we getting right and what are we getting wrong as we realign our processes and our research organizations around the patient-centric model?
• What technologies and capabilities do we already have in house and what pieces of the puzzle are we missing, whether low- or hi-tech?

9:45 - 10:45 Grand Opening Coffee Break in the Exhibit Hall
Plenary Keynotes & Panels

WEDNESDAY, FEBRUARY 14, 2018

Wednesday Afternoon:
NEW TECH, INNOVATION AND COLLABORATION IN CLINICAL TRIALS

1:30 Organizer’s Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

1:35 Chairperson’s Introduction
Greg Skalicky, Chief Enterprise Business Officer, inVentiv Health

1:40 Clinical Informatics News Best Practices Awards
Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News
The Clinical Informatics News Best Practices Awards recognizes outstanding examples of applied strategic innovation—partnerships, deployments, and collaborations that manifestly improve the clinical trial process. An expert panel of judges assesses entries looking for solutions that are innovative, and needed in the industry.

Learn More & Submit an Entry for 2018 at:
www.clinicalinformaticsnews.com/BestPracticeAwards/

1:50 Part 1: The Forgotten Patient
Joe Kim, MBA, Senior Advisor, Clinical Innovation, Eli Lilly and Company
Typically, all patients who volunteer for clinical research come from two places – either they are known to the investigator, or they are not. But there is a third type of patient that has long been forgotten and considered beyond our reach. And it has been our collective inability to accommodate this patient group that certainly hasn’t helped our ability to quickly deliver new medicines to the world. What will it take to reach them where they are?

2:10 Part 2: Pharma-ACO Collaboration and New Delivery Systems: Facilitating the Linkage between Healthcare’s Triple Aim and Improved Clinical Trials
Jeff James, MBA, CEO, Wilmington Health
The worlds of healthcare delivery, payment reform, medical technology and clinical research are all evolving in tandem. This presentation will share how we are facilitating a linkage between an ACO's triple aim aspirations and the need for Pharma to initiate trials that are better, faster, more predictable, more reliable and less expensive. In addition, it will illustrate the roadblocks that still need to be overcome.

2:30 PANEL DISCUSSION: Clinical Trial Technology and Innovation: Collaboration as the Key to Industry Transformation
Moderator: Dalvir Gill, Ph.D., CEO, TransCelerate BioPharma, Inc.
Ken Getz, MBA, Director, Sponsored Research Programs, Tufts CSDD; Chairman, CISCRP
Vaibhav Narayan, Ph.D., MBA, Vice President, Research and Therapeutic Area IT, Janssen
Susan Griffing, Vice President, Global Head Country Clinical Operations, Roche
Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline
Harnessing the power of collaboration can alter the healthcare landscape as we know it today. This thought-provoking session will bring together a diverse panel representing some of the industry's most influential organizations for a candid and innovative conversation about what is needed to shake up the current ecosystem and truly transform patient health. This panel discussion will address:
• What is working today, and how will the 'next generation of collaborations' be different?
• Is collaborative R&D, pooling data and insights from academia, sponsors, and CROs in our near future?
• What roles will FDA, consortiums, technology providers, and other stakeholders play?

3:00 - 4:00 Valentine's Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing
BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day’s sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

5:00 Welcome Reception in the Exhibit Hall

6:15 Close of Day
Interactive Breakout Discussions

TABLE 4: Barriers and Opportunities in Site Adoption of Clinical Trial Technology
Moderators:
Claire Sears, Director, DrugDev Data Solutions
Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)
David Vulcano, Assistant Vice President & Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)
Sean Walsh, MBA, Chief Development Officer, Raleigh Neurology Associates

• What is a complete digital patient experience? What is required to make this a reality for all trials?
• What are current digital patient projects gaining traction, engagement pilots, partnerships & insights?

TABLE 5: Strategies for Accelerating Recruitment in Complex Clinical Trials in a Resource Constrained Environment
Moderators:
Kevin Hudziak, Innovation Lead, Clinical Innovation, Eli Lilly & Company
Jerome Chiaro, Vice President, Clinical Site Operations, StudyKIK
Kate Boneck, Associate Director, Global Trial Optimization, Merck & Co.
Angela Radcliffe, Managing Director, Executive Vice President, FCBVIO
Matt Miller, Vice President, Global Patient Recruitment & Feasibility, StudyKIK

• Dealing with the Acute Patient where timing is critical
• Do traditional/past tactics still work in current environment? What tactics (new and old) work best today?
• Ensuring success for procedure driven protocols (Non-conventional administration, device and/or diagnostic intense)
• Utilization of supportive field resources to accelerate recruitment (Medical Science Liaisons & Clinical Trial Educators)

TABLE 6: Precision Feasibility in Precision Medicine-Driven Trials
Moderators:
Jill Lofftiss, Head, Clinical Operations, Oncology, MedImmune/AstraZeneca
Karina Bienfait, Ph.D., Head, Global Genomics Policy, Process and Compliance, Principal Scientist, Clinical Pharmacogenomics and Operations, Genetics and Pharmacogenomics (GpGx), Translational Medicine, Merck Research Laboratories

• The impact of precision medicine on today’s clinical trial feasibility assessment and trial planning
• The impact of competition, breakthrough FDA approval and change of standard of care
• Leverage the power of real world data and trial intelligence data to enable evidence-based trial feasibility assessment

TABLE 7: Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint
Moderators:
Christopher Conklin, Director, Feasibility Center of Excellence, Pfizer
Mark Springer, Project Lead, Clinical Innovation, Eli Lilly & Company
Maribel Hernandez, Director, Clinical Operations, Global Therapeutic Area Lead AD/Belviq, Neurology Business Group, Eisai, Inc.
Shawn Tedman, MBA, Head of Product Offerings, Clinical Trial Optimization Solutions (CTOS), QuintilesIMS

• Optimizing the site feasibility process: Improving global site feasibility assessment to identify sites that will recruit on time and within budget
• Objective country feasibility and selection: Where are the patients?
• Data-driven site selection: Understand the number of sites, their probability of success, and the impact of site non-performance

TABLE 8: Improving Both Time and Quality in Site Activation and Study Start-Up
Moderators:
Valérie Reynaert, Head, In-Country Clinical Operations for the Americas, R&D Projects Clinical Platform & Sciences, GlaxoSmithKline
Christina Brennan, M.D., Vice President, Clinical Research, Executive Research Administration, Northwell Health
Marina Malikova, Ph.D., Executive Director, Surgery, Boston University Medical Center

• Identifying and consolidating site start up activities that are redundant, inefficient and needlessly complex
• What are key learnings and opportunities for different approaches, including a centralized approach of study activation and site performance?
• How can sponsors, CROs and site streamline site activation and study start-up?

TABLE 9: Strategies for Patient-Centric Trial Design and Digital Patient Engagement
Moderators:
Lynn Hagger, Ph.D., Patient Engagement Director, Respiratory, INA & CVMD, Global Medical Affairs, Astra Zeneca
Gilles Frydman, Patient Advocate; Co-Founder Smart Patients and ACOR (Association of Cancer Online Resources)
Terrie Livingston, Pharm.D., Senior Director, Real World Outcomes, Innovative Partnerships & Insights (R12), Biogen
Amir Lahav, Digital Innovation, Rare Disease Research Unit, Pfizer

• What are current digital patient projects gaining traction, engagement pilots, new technologies, the role of patient communities?
• What is a complete digital patient experience? What is required to make this a reality for all trials?
• What are we getting right and what are we getting wrong as we re-align our processes and our research organizations around the patient-centric model?
Interactive Breakout Discussions

TABLE 10: Balancing Budgets and Performance in Resource Management and Capacity Planning
Moderators:
Chris Chan, Executive Director, R&D Finance, Finance, FibroGen, Inc.
Heather Baldwin, MPH, Principal Consultant, Frogbottom Consulting, LLC
Rajyalakshmi Nimmagadda, Global Trial Forecast Development Unit Head, Trial Forecasting and Resource Management, Novartis
- What are key factors that should be considered when developing a resource plan?
- What situations warrant a bigger focus on cost savings, and which on using other resources?
- How do training and retention programs fit into capacity planning and overall resource management?

TABLE 11: RBM in a Finance and Resource Limited Environment
Moderators:
Yiwen Sun, Senior Clinical Research Associate, Samumed, LLC
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
- How can we adopt TransCelerate’s RACT model for a resource limited company/org?
- In terms of technology, what are nice to haves vs. need to haves for implementing RBM?
- Who is involved in putting RBM in action at smaller companies?

TABLE 12: Vendor Performance Metrics and KPIs
Moderators:
Rick Morrison, Co-Founder and CEO, Comprehend Systems
Diane Miller, Director, Vendor Management, AbbVie
Aaron Fleishman, Head of Emerging Markets, BBK Worldwide
- How effective are your KPIs for measuring vendor performance and quality?
- What is your strategy for establishing KPIs and metrics?
- What are the key areas that should be evaluated for vendor performance and quality?

TABLE 13: Understanding and Implementing the New Realities of Diversity in Clinical Trials
Moderators:
David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award
Jeri Burtchell, Director, Patient Initiatives, HealthiVibe, LLC
Marisa Rackley, Director, Clinical Research Operations, Vertex Pharmaceuticals, Inc.
- What are the regulatory changes from FDA and updated requirements for ethnicity/race inclusion in trial populations?
- How do you formalize into a clinical development plan at a company level to make it part of corporate culture by educating and training teams so that they can embrace the ethnicity value?
- How do you then implement at project team level and operationalize the activities to support diversity in clinical trials?

TABLE 14: Selecting, Developing and Incorporating Novel Endpoints, Generated from Data Captured by Mobile Technologies, for Use in Clinical Trials
Moderators:
Jennifer Goldsack Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)
Rob DiCicco, Ph.D., Vice President, Clinical Innovation and Digital Platforms, GSK
Michelle Crouthamel, Digital Platform Leader, GSK
Amy Calvin, BS, MT (ASCP), MBA, Digital Strategy and Implementation, Advisor, Eli Lilly and Company
Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development
- Describe approaches to identifying mobile technology-derived outcome measures that are most valuable and warrant development
- Review approaches for optimizing the efficiency of technology-derived novel endpoint development
- Discuss how to include and position technology-derived novel endpoints to be most impactful

TABLE 15: RWE in Clinical Trial Research and Patient Recruitment
Moderators:
Jane Fang, M.D., Head, Research & Development Information for Clinical Biologics, MedImmune Biologics Science Unit, AstraZeneca
Jyotsna Mehta, Director, Economics Value Evidence and Outcomes, Alkermes, Inc.
Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation
- The impact of precision medicine on today’s clinical trial feasibility assessment and trial planning
- Leverage the power of real world data to enable evidence-based trial feasibility assessment
- RWE needs to go beyond analysis and clinical trial is calling new clinical-health service to link healthcare and clinical trial research

TABLE 16: Visual Analytics in Clinical Research
Moderators:
Charlie Romano, Senior Director, Clinical Trial Management, Clearside Biomedical
Steven Sweeney, Vice President, Clinical Development Operations, Rodin Therapeutics
- Data visualizations for clinical operations
- Focus on decision making and value
- Using the data properly
Interactive Breakout Discussions

TABLE 17: Addressing Chronic Site and CRA Turnover Issues through a Competency-Based Approach to Workforce Development
Moderators:
Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)
Divya Chadha Manek, Head, Business Development (Commercial), Clinical Research Network, National Institute of Health Research
Jeff Kingsley, CEO, IACT Health
Lisa Hegg, Ph.D., Vice President, Head Project Planning and Management, Project Management and Business Performance, GSK

- Discuss common sources and reasons for CRA turnover and why those issues arise
- Examine the role of workforce development and how a competency-based system can address turnover issues
- Discuss strategies for implementing a competency-based approach

TABLE 18: Biospecimen, Central Lab and Technology
Moderators:
Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck
Brenda Yanak, Global Head, Specimen Strategy & Innovation, End-to-End Specimen Management, Q² Solutions
Jonathan Reuter, Associate Director, Global Procurement R&D, Clinical Labs, Bristol-Myers Squibb

- Biorepositories: in house vs. outsourcing
- Advanced informatics for biospecimen management
- Central and reference labs: building the relationship
- Biospecimen and central lab considerations for risk-based monitoring

TABLE 19: Artificial Intelligence and Machine Learning: Extreme Case of Data Analytics?
Moderators:
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb
Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche

- With Machine Learning becoming needing Big data sets, how could the industry share more data in a precompetitive framework?
- As more Deep learning techniques are deployed - how can we gain confidence in “Black Box” approaches?
- In what ways, if any, will we have to change how we work with regulators?
- Will clinicians use and have confidence in ML using clinical decision support tools?
- Will a ML algorithm be part of the molecule package?

TABLE 20: Blurring the Division between Clinical and Observational Studies
Moderators:
Cathy Critchlow, Ph.D., Vice President, Center for Observational Research, Amgen
Christopher Chinn, Head, Real World Investigations, Sanofi
Mark Price, Senior Director, Surveys and Observational Studies, RTI Health Solutions

- Similarities and differences in operationalizing observational studies vs. clinical trials
- Building a continuous program that includes post-approval studies
- Integration of real world data into decision-making across the drug development cycle

TABLE 21: Driving Fully eSource Clinical Trial
Moderators:
Michelle Crouthamel, Digital Platform Leader, GSK
Jaydev Thakkar, IS Director, R&D Informatics, Amgen
Aman Thukral, Assistant Director, Data and Statistical Sciences, AbbVie

- What is the current state?
- High and low of eSource adoption, what are the drivers and barriers
- How to get to 100% eSource?
Data-driven global site selection, an optimized protocol development and feasibility assessment process, and effective site management are critical to improving clinical trial timelines and outcomes. Too often, companies fail to learn from past mistakes and take the same approach to trial planning and execution. In order to overcome challenges in clinical trial planning, operations and site management, leaders should learn from the best practices of their peers, utilize data and technology to support decision making, and improve communication and relationships between Sites, CROs, and Sponsors. CHI’s 8th Annual Protocol Development, Global Site Selection, Feasibility and Site Management will cover the topics one should consider when planning and implementing a trial.
2:00 Chairperson's Remarks
Kelly White, Director, Global Operations Oncology, Global Trial Optimization, Merck & Co.

2:05 Accelerating Drug Development through Protocol Harmonization: TransCelerate’s Common Protocol Template
Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

Increasing complexity in protocols makes implementation and reporting difficult and the lack of consistency compounds the issue. A significant opportunity exists for an improvement in quality and simplification through protocol harmonization, as all protocols rely on the same health care and regulatory infrastructure for design, review and implementation. This session will explore the collaboration between TransCelerate, FDA, and NIH to achieve alignment on a common protocol structure. It will also describe how TransCelerate’s CPT enables use of clinical data standards, as well as next steps towards automation and data traceability from protocol through to downstream processes.

2:20 PANEL DISCUSSION: Current and Emerging Protocol Optimization Design Strategies
Christopher Conklin, Director, Feasibility Center of Excellence, Pfizer
Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline
John Oidtman, Senior Vice President, Head of Global Clinical Operations, EMD Serono

A number of protocol design optimization strategies have been introduced and implemented including protocol authoring tools, feasibility review mechanisms, patient advisory boards, and pre-planning simulations. This talk touches on optimization strategies and provides data on their impact to date where available. Several protocol design optimization strategies will also be discussed including the adoption and use of adaptive designs and patient centric approaches. This introductory talk will be followed by a panel discussion among pharmaceutical and biotechnology company professionals. Panel members will discuss:
- Optimization strategies that most resonate with their respective organizations and why
- Experience with various strategies and lessons learned
- Adoption challenges and impact following implementation

2:30 CASE STUDY CO-PRESENTATION: How the Business Embedded the Tech-Enabled CPT in Our Business Process and Extended It to Extract Data for Downstream Processes
Bina Rathod, Associate Director & Business Lead, MRL IT Global Clinical Development, Merck & Co.
Mitzi Allred, Director, Clinical Research, Clinical Content Standards, Merck & Co.

This presentation will cover how our business partners leverage the tech-enabled CPT to make protocol data and metadata available to downstream clinical processes, tools and applications to optimize reusability with minimum manual intervention. We will cover from protocol creation and downstream process to clinical study report finalization.

2:55 Presentation to be Announced

3:00 Chairperson's Remarks
Kelly White, Director, Global Operations Oncology, Global Trial Optimization, Merck & Co.

3:05 Breakout Discussion Groups

3:30 Breakout Discussion Groups

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day
number of sites required by 21%, and overestimates the enrolment rate by 53%. The session will conclude with a discussion of the potential impact on the need for rescue studies, projected trial enrolment duration, country/site selection, and the benefits of cross-company sharing of CTMS.

9:45 Translating Registry & Health Informatics Data to Site Performance: Opportunities to Accelerate Feasibility & Enrollment
Earl Seltzer, Director, Global Feasibility, INC Research/inVentiv Health
In the age of burgeoning data sources and data driven clinical trial planning, many questions remain about how these data, particularly at the patient level, are actually translated to a viable trial delivery solution. This session will cover the use of patient data to facilitate trial feasibility and site selection from a CRO perspective, including lessons learned, current gaps and progress to address them globally, with a focus on understudied indications and rare diseases.

10:10 Coffee Break in the Exhibit Hall

FEASIBILITY/SITE SELECTION IN COMPETITIVE IMMUNO-ONCOLOGY TRIALS & DATA SOURCES FOR EVIDENCE-BASED PLANNING

11:10 Chairperson’s Remarks
Chairperson to be Announced, Bio-Optronics

11:15 CO-PRESENTATION: Rolling Feasibility in Competitive Immuno-Oncology Trials
Jane Fang, M.D., Head, R&D Information, Clinical Biologics, MedImmune/AstraZeneca
Jill Lofriss, Head, Clinical Operations, Oncology, MedImmune/AstraZeneca
With the rapid development of cancer immunotherapy drug development, competition in the immuno-oncology (IO) trials is fierce. The precision medicine behind trial design is driving rapid change in the way of traditional feasibility assessment. As a result, the innovative approach of Rolling Precision Feasibility has been developed to provide ongoing comprehensive analyses covering trial competitive landscape, patient population, disease epidemiology, precision recruitment rate, regulatory approval landscape, country and site selection strategy, impact of standard of care change, etc.

11:40 PANEL DISCUSSION: Evidence for Success: Which Data Sources and Data Elements to Use in Study Planning and Site Selection
Moderator: Elisa Cascade, President, Data Solutions, DrugDev
Panelists:
Julie Argento, Principal Data Scientist, Center for Design and Analysis, Amgen Inc.
Shawn Tedman, MBA, Head, Product Offerings, Clinical Trial Optimization Solutions (CTOS), QuintilesIMS
When it comes to data to plan clinical trials, drive country selection, predict
enrollment, and find sites, more may be better, but each data source often adds cost, time, and complexity to the process. While the published literature cites 4 factors for predicting successful site performance: investigative site focus, experience, past performance, time to randomize first subject, actual best practice doesn't necessarily match the theory published in the literature. In this session, industry experts will review in detail which specific data sources and data elements they use to support evidence-based planning, and the relative importance and sequence in which these sources/elements are used.

• Understand data sources and elements available to support study planning and site selection
• Identify strategies for maximizing return while minimizing cost and burden
• Gain insight into which data sources/elements are most powerful in an evidence-based approach

12:05 pm Session Break

12:10 Bridging Luncheon Presentation: Approaches to Evidence Based Site Planning in Trial Design

Gavin Coney, Head, Clinical, Clarivate Analytics

We will explore approaches to ensuring that your study planning is based on the broadest evidence base. We will demonstrate how additional manually curated intelligence can complement existing data sources to identify relevant insights based on similar studies and provide specific insights into critical trial design and planning decisions.

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Improving Site-Study Activation and Performance. Click here for details.
Patient recruitment and up-front enrollment planning are critical to drug development programs. Patient recruitment, if not adequately planned for, can extend your development timeline by a number of years. Retention of patients throughout the life of a clinical trial is essential in order to have complete data sets for your analysis and subsequent filings. In order to optimize both, you have to have a plan. CHI’s 11th Annual Enrollment Planning and Patient Recruitment will cover the topics one should consider when drafting and strategically implementing a patient recruitment plan for a clinical development program.

**MONDAY, FEBRUARY 12**

9:00 am - 7:30 pm Registration Open

5:00 - 6:15 Pre-Conference Plenary Keynote Panel (click here for details)

6:30 – 8:30 SCOPE's Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis

8:30 Close of Day

**TUESDAY, FEBRUARY 13**

7:15 am Registration Open and Morning Coffee

8:20 Opening Plenary Keynotes (click here for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

**INCORPORATING DATA AND PATIENT INSIGHTS INTO ENROLLMENT PLANNING AND TRIALS**

10:45 Chairperson's Remarks

10:50 Leveraging Data and Analytics for Enrollment Planning and Trial Execution

11:15 Patient Voice Plans in R&D: Improving the Patient Experience and Clinical Trial Success

11:40 Bringing the Patient Voice and Community into the Drug Development Process

12:05 pm Learning from Other Industries

12:30 Session Break

12:40 Luncheon Presentation to be Announced

1:20 Coffee and Dessert Break in the Exhibit Hall
EXPANDING THE REACH OF TRIALS AND RECRUITMENT BEYOND TRADITIONAL METHODS: TELEMED, EMRs & RWD

2:00 Chairperson's Remarks

Chairperson to be Announced, WIRB-Copernicus Group

2:05 Pharma Bands Together to Activate a New Audience: HealthCare Providers

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

It's no secret that attempts to inspire and enable health care providers to refer their patients into clinical trials have often failed. Reasons for this have been documented in peer reviewed literature and felt first hand by study teams in real world campaigns. Come learn about a key component of TransCelerate's Clinical Research Awareness and Access workstream where they look to go beyond incentive models and skill building. Learn about a unique photojournalism campaign that seeks to activate the hearts of HCPs in a way that will make them believe in the benefit of research for patients, tomorrow and today.

2:30 Data-Driven Patient Recruitment with Real World Data at Roche pRED

Liping Jin, Data-Driven Recruitment Lead, Pharmaceutical Research & Early Development, Roche Innovation Center New York

With the increasing use of Real World Data (RWD) in the pharma industry, Data-Drained Recruitment (DDR) team at Roche Pharm Research & Early Development (pRED) would like to share our experience of integrating RWD (e.g. insurance claims, EMR) with trial metrics data to optimize study protocol design and target patient recruitment strategy. While the team has received positive feedback from our business partners (translational medicine, clinical program teams, and study leaders) we would like also to share the challenges to expanding the effort in broader US and international settings.

2:55 PANEL DISCUSSION: Innovation in Recruitment Is Not a 4-Letter Word

Kevin Hudziak, Innovation Lead, Clinical Innovation, Eli Lilly and Company

Mark Springer, Project Lead, Clinical Innovation, Eli Lilly and Company

Taylor Wong, LRL Procurement, Medical and Regulatory, Eli Lilly and Company

Rahlyn Gossen, Founder & Principal, Rebar Interactive

Patient recruitment methods and execution have become stale. In the typical full-service model, a sponsor chooses one full-service supplier, who may not have expertise in all aspects of digital patient recruitment. To innovate in this space, Lilly Clinical Innovation sought to determine if creating a new patient recruitment sourcing solution would benefit the digital patient recruitment ecosystem. By analyzing each aspect of the ecosystem, we looked to identify the best in class vendors for each aspect of digital patient recruitment (e.g., creative, outreach, microsites, etc.) using Lilly TrialGuide as the centerpiece. This panel will examine the innovation and will represent the voices of Clinical Innovation, Research Procurement, and a supplier involved in the process. Our process for determining selected suppliers will be explored including defining the "Pitch Match" method for determining final suppliers. Communication, processes, challenges, best practices, and insights from all sides of the table will be explored and audience participation is encouraged.

3:20 Real World Data Meets Real World Evidence in Patient Recruitment and Engagement

Bonnie Brescia, Founding Principal, BBK Worldwide

Today we have access to multiple health databases containing myriad data points that can be integrated, correlated and mined. The expectation is that these data will help researchers to better define target patient populations, improve protocol design, and enhance site selection. But will these efforts advance patient recruitment and retention? Using data from multiple global trials, we explore RWE pointing to the decisive role of support and engagement programs in recruiting and retaining study participants.

BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups

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11th Annual
Enrollment Planning and Patient Recruitment
Strategic Enrollment Planning, Data-Driven Recruitment and Forecasting, and Central Campaign Management

February 13-14, 2018
8:30 Deploying Patient Recruitment Websites: Behind the Scenes in Big Pharma
Paul Whitehead, Ph.D., Head, Early Development Workflows, Roche
This talk will focus on the heroic efforts that go into getting a patient recruitment website progressed from a study team request to production deployment. There are many factors to consider when deploying a new trial recruitment website in a global organization and these will be discussed in the context of actual use cases: the good, the bad and the ugly.

8:55 Increasing Enrollment While Reducing Sites
Speaker to be Announced, Acurian

9:20 Lessons Learned from Rare Disease Trials: Community, Engagement, Recruitment and Retention
Marisa Rackley, Director, Clinical Research Operations, Vertex Pharmaceuticals, Inc.
Although late-phase costs of conducting orphan drug development are smaller when compared to non-orphan drugs, rare disease clinical trials encounter many challenges in patient recruitment and retention. What lessons can experts in trial planning and operations learn, whether they are running rare or non-rare disease trials, and apply to improve engagement, recruitment and retention?

9:30 SCOPE’s 2018 Participant Engagement Award
Design to inspire innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials, this award embodies the values and personal accomplishments of Jerry Matczak, who sadly passed away soon after receiving the 2017 award. We dedicate this award to Jerry in the hopes that it will serve as a reminder of his ideals and accomplishments. We welcome submissions from every aspect of the industry including, but not limited to, Sites, CROs, e-Patient Advisors, Agencies, Start-Ups, and Sponsors to submit their best work in the Patient Recruitment and Retention communications field.

Learn More & Submit an Entry for 2018
Event Designers:
Kelly McKee, Advisor, Clinical Innovation, Eli Lilly and Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award
Jeri Burtchell, Director, Patient Initiatives, HealthiVibe, LLC
Shwen Gwee, Head of Digital Strategy, Global Clinical Operations Biogen
Angela Radcliffe, Managing Director, Executive Vice President, FCSVIO
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)
There are many reasons a clinical trial can be delayed, but many of these can be prevented through proper forecasting, budgeting, and contracting strategies. As clinical trials become more complex, with a number of CROs, third-party vendors, and sites getting involved, sponsors must evolve their strategies and take advantage of technology to streamline these processes and set clear expectations from the get-go. Cambridge Healthtech Institute's 8th Annual Clinical Trial Forecasting, Budgeting and Contracting conference shares case studies and best practices on effective budgets and clear contracts, as well as metrics and key performance indicators of their success.

11:15 Cost, Time, and Quality Trade-Off in Clinical Trials
Ozgur Ozkan, Decision Science Director, Biometrics and Information Sciences, AstraZeneca Pharmaceuticals
This presentation will report on a novel approach to estimate trial costs at the country level and how it is used within a simulation tool to visualize cost, time and quality trade-offs between alternative recruitment scenarios. We will give an overview of the analysis on the operational/financial data and demo the tool to show how it informs decision making in Clinical Operations.

11:40 CO-PRESENTATION: Clinical Trial Budgeting/Forecasting
SMACK-DOWN: Investigator Sites vs. Sponsors – Budgeting Issues
Chris Chan, Executive Director, R&D Finance, Finance, FibroGen, Inc.
Al Peters, President, Clinical Operations and Finance, BTC Network
Although theoretically teammates with common goals, when Sponsors and Investigator Sites interact over budget and money issues, conflicts often arise in the form of miscommunications or even animosity that would make the Hatfields and McCoys blush. This session will explore some common conflicts as well as possible resolutions.

12:05 pm Presentation to be Announced

12:30 Session Break

12:40 Luncheon Presentation: An Easy 4-Step Process That Will Make You a CTMS Evaluation Hero
Jens B. Thuesen, CTMS Business Development, BSI Business Systems Integration AG
Is your CTMS evaluation process outdated? Using scorecards to evaluate solutions based on features alone can be frustrating. And knowing the right questions to ask that go beyond basic features can be daunting. You don’t have to be an IT expert to choose a CTMS that will serve you well for years to come. Learn how a concise 4-step process can get you on your way to a solution that fits your organization perfectly.

1:20 Coffee and Dessert Break in the Exhibit Hall

WORKING WITH SITES: BUDGETING AND PAYMENTS

10:50 Budget Forecasting and Tracking: Teamwork and Transparency
Kenneth Olovich, Chief Financial and Procurement Officer, Chorus
This talk will discuss how the application of budgetary and invoicing models can lead to increased trust. What do sponsors really need to help them manage CRO and trial related expenses? Some budgetary models require more effort to set up than others; when is it worth the investment? The timing of spend and the accurate projection of the same is just as important as the total spend – this talk will discuss finding the balance.

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SMACK-DOWN: Investigator Sites vs. Sponsors – Budgeting Issues
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grant budget. Standard of Care plays an important role in the US, and some countries; this needs to be factored into the budget templates. When all is complete for the site level template, we will evaluate how this can be utilized to build a forecast for total investigator grants and what is factored into these calculations. We will also look at how this feeds into a typical full clinical trial budget and forecast.

2:30 CO-PRESENTATION: Merck's Site Ready Team: Integrating Capabilities to Provide a Centralized Approach and User Experience for Investigators Budget and Payment Process
Cathy Carfagno, Associate Director, MRL IT, Merck & Co., Inc.
Rochelle Redding, Associate Program Manager, MRL, Merck & Co., Inc.
This talk will present an overview of the strategy that Merck would like to take in changing its global budget and payment process and our thoughts on enabling a more integrated collaboration and interaction with our investigative sites. In order to maintain strong and effective investigator relations and to enhance our site performance, while ensuring meeting FDA compliance rules, we have started to map out a simplified process for creating and negotiating our budgets as well as improving our payment controls, all while operating in a very budget-conscious environment.

2:55 PANEL DISCUSSION: Budgeting with Sites: Bottlenecks, Challenges, and Opportunities
Moderator: Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer
Panelists: Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University
Kenneth Olovich, Chief Financial and Procurement Officer, Chorus
Cathy Carfagno, Associate Director, MRL IT, Merck & Co., Inc.
During site budget negotiations, don’t you often want to just ask the other party “Are you crazy or just being stubborn?” We all have different end games during negotiations, and it’s important to understand the dynamics of the Sponsor, Site and CRO triad. As this triad continues to be dominant in our industry, it’s important that we learn to predict each other’s reactions in order to avoid “show-down” meetings where all are frustrated and ready to walk away. We all think we are right, but ultimately, it’s about the final negotiated budget, how we get there, and creating a win-win-win scenario for all.

3:20 Presentation to be Announced

BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

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

WEDNESDAY, FEBRUARY 14

7:15 am Registration Open
7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It
Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

STRATEGIES FOR EFFICIENT NEGOTIATION AND CONTRACTING

8:25 Chairperson's Remarks
Chairperson to be Announced, Strategikon Pharma

8:30 Contracts and Budgeting for Studies Involving Special Populations and Adaptive Designs: Evolving Challenges with Precision Medicine Trials
Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University
In-human (FIH) studies now routinely contain several parts with multiple cohorts with increased dose flexibility and accelerated dose escalation paradigms, each of which might have been previously a separate clinical trial. Sponsors, CROs and investigators struggle to minimize risks and avoid serious consequences, and yet, there remains real risk in an FIH study. Understating challenges associated with the use of special populations is critical to ensure that the study design will allow for the timely and successful completion of the project, while minimizing individual exposure to the risks of participating subjects, planning and implementing budgets, forecasting, managing costs, and assessing safety profile.

8:55 Streamlining CTA Negotiations beyond the Legal Language
Débora Araujo, Associate Director, Site Budgets and Payments (US Group Head), Boehringer Ingelheim Pharmaceuticals, Inc.
It is widely known that legal language is one of the main pain points threatening the timely execution of CTAs. The issue has prompted much-needed industry focus and related initiatives in recent years in an effort to standardize legal language and thus streamline CTA negotiations. However, to effectively address the overall delays in CTA execution, some other aspects of the negotiation process must be dealt with as well. In this presentation, we will explore the top aspects of the negotiation process threatening an expeditious CTA execution and some practical ways to counter each of them.

9:20 Strategies to Reduce Time to Contract Approval: A Site Perspective
JoAnn Pfeiffer, DrSc., Director, Clinical Research Management, Arizona State University
How can sites accelerate the CTA review process for quicker approval of a fair and balanced contract? This session covers strategies and practical tips to speed up the CTA review and approval process. Topics include preparation, contract pitfalls, language, contract editing, common contract challenges between the site and sponsor, and leveraging site data and metrics.

11:15 PANEL DISCUSSION: Resource Allocation and Its Effect on Contracting between CROs and Sponsors
Greg Skalicky, Chief Enterprise Business Officer, inVentiv Health
Ratan Ratnesh, Director & Head, Clinical Outsourcing, Otsuka
David Freschi, Senior Director, R&D Procurement and Clinical Outsourcing, Regeneron
Tara Dubois, MBA, Head, Clinical Trial Cost Management, Business Operations, Pfizer
Procurement, contracting, and clinical operations teams need transparency with their CRO partners in order to properly understand a CRO’s allocation of resources and costs, especially when contracting key deliverables. This panel will address, from the Sponsor’s and CRO’s perspective, resource allocation considerations during the contracting process: potential challenges, what CROs wish pharma knew, and pitfalls to avoid.

11:10 Chairperson’s Remarks
Chairperson to be Announced, Strategikon Pharma

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12:05 pm Session Break
First time experience and came away with a head buzzing full of ideas for our team!

- Vitaflo International Ltd.

Understanding outsourcing needs and optimizing the selection process of vendors lays the foundation for an efficient, cost-effective clinical trial. Cambridge Healthtech Institute's 2nd Annual Mastering an Outsourcing Strategy conference provides a new perspective on the vendor selection process and challenges attendees and speakers to reimagine the standard vendor selection process for improved efficiency on both the Sponsor and Vendor side of the relationship. The 2018 program focuses on case studies and interactive discussion on outsourcing strategy, the RFP and bid defense process, vendor selection, as well as contracting with outsourced partners and vendors, including sites, CROs, suppliers, and other vendors.

MONDAY, FEBRUARY 12
9:00 am - 7:30 pm Registration Open
5:00 - 6:15 Pre-Conference Plenary Keynote Panel (click here for details)
6:30 – 8:30 SCOPE's Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis
8:30 Close of Day

TUESDAY, FEBRUARY 13
7:15 am Registration Open and Morning Coffee
8:20 Opening Plenary Keynotes (click here for details)
9:45 Grand Opening Coffee Break in the Exhibit Hall

OUTSOURCING TRENDS & STRATEGY: WHERE ARE WE HEADED?

10:45 Chairperson's Remarks
Charlotte French, Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas

10:50 Outsourcing Revolution: Where We Were to Where We Are
Ian Lauf, Head, Clinical Business Operations, Shionogi, Inc.

As clinical trials and outsourcing become more expensive, many in the pharma industry are evaluating their outsourcing practices. This presentation will discuss current outsourcing trends, what is affecting outsourcing trends, and where we are headed as an industry.
2:30 PANEL DISCUSSION: Request for Information (RFI) to Bid Defense – How Do Pharma and CROs Obtain the Most Value during This Process?
Moderator: Charlotte French, Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas
Panelists:
Frank Carnevale, Senior Outsourcing Lead, Takeda
Christopher Rull, Principle Consultant, CR Consulting, LLC; Former Vice President, Head of Business Development & Account Management, UBC
Jeff Van Noy, Vice President, Global Proposal Development and Business Information, ICON
Jay Zinni, Associate Director, Procurement, Incyte Pharmaceuticals
Today this is a very time consuming and resource intense activity at both Pharma and CROs. This panel discussion will be focused on how we jointly become more innovative in approaching these activities. We will explore:
- How to develop the most effective RFI to deliver the key information required to determine which CROs are short-listed for the Bid Defense meeting
- How Pharma/CRO determine the participants at the Bid Defense meeting
- What are the key deliverables for a CRO at a Bid Defense meeting?

3:20 Sponsored Presentation (Opportunity Available)

BREAKOUT DISCUSSION GROUPS

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7:15 am Registration Open

7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It
Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

UNDERSTANDING THE OUTSOURCING FUNCTION & YOUR CHOSEN SUPPLIERS

8:25 Chairperson’s Remarks

8:30 Outsourcing versus Procurement: Is There a Difference?
Charlotte French, Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas
Today it can be difficult to navigate the various functions within Pharma, in particular relating to the roles and responsibilities of Outsourcing functions versus Procurement functions. In some instances, these are combined, but are there differences? And, if so, what are these? We will explore the advantages and disadvantages of separating these two functions within Pharma and review differences in the skill set that they should offer to an organization. Additionally, we will review how these functions work together, or in some instances, incorporate the vendor oversight responsibilities that are required under ICH E6. We will also discuss CRO’s response to the ICH E6 guidelines when providing third party contracting and oversight for additional services.

8:55 Choosing & Maintaining the Best Suppliers/Partners
Carrie Lewis, MS, Associate Director, Clinical Operations, Lupin Research, Inc.
This presentation will discuss how to select the best Supplier/Partner for your company needs. This will include a case study of how Lupin set-up their initial Governance with all CROs at the table. Discussion will also include when to select a niche supplier over preferred vendor and the process. Lastly, the talk will discuss how to maintain relationships with preferred vendors.

CONSTRUCTING YOUR CONTRACT FOR MAXIMUM BENEFIT

9:20 Contracting with CROs to Optimize Working Relationship and to Guarantee On-Time Study Starts
Richard O’Hara, Associate Director, Clinical Outsourcing, Endo Pharmaceuticals
This presentation will focus on the best strategies to ensure a smooth study start from a contracting perspective. It will address agreement construction and helpful terms. Also addressed will be optimal lead times as well as governance and communication strategies.

9:45 Three Key Elements to Operationalizing CRO Oversight: A Sponsor’s Story
Rick Morrison, Co-Founder and CEO, Comprehend Systems
Learn how a leading sponsor revolutionized its relationship with its CROs. Understand the best practices they put in place to continuously manage study quality and achieve milestones on-time and on-budget across their portfolio of trials. This, combined with real-time data delivery, enabled them to expand their...
portfolio of trials and build new relationships with more CROs, all at the same rapid pace of business.

10:10 Coffee Break in the Exhibit Hall

CONSTRUCTING YOUR CONTRACT FOR MAXIMUM BENEFIT

11:10 Chairperson's Remarks

11:15 PANEL DISCUSSION: Resource Allocation and Its Effect on Contracting between CROs and Sponsors

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12:05 pm Session Break

12:10 Bridging Luncheon Presentation to be Announced

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Close of Conference
Poor quality and risk management of clinical trials significantly impacts the success, timeliness and cost-effectiveness of clinical trials. Cambridge Healthtech Institute’s 4th Annual Implementing Risk-Based Monitoring — Part 1: Integrating Quality into Clinical Trials conference provides guidance on how to holistically and proactively build quality standards into clinical trials with emphasis on the latest quality standards and guidelines, including the recent ICH-E6 R2 addendum changes, thereby ensuring higher quality clinical trials and laying the foundation for successful risk-based monitoring.

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8:30 Close of Day

TUESDAY, FEBRUARY 13

7:15 am Registration Open and Morning Coffee

8:20 Opening Plenary Keynotes (click here for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

THE TRUE COST OF CLINICAL TRIAL QUALITY

10:45 Chairperson's Remarks
Janis Little, Vice President, Global R&D Quality, Allergan

10:50 PANEL DISCUSSION: The Total Cost of Quality: Finding the Balance between Investing in Quality and the Cost of Fixing Quality Problems
Moderator: Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC
Panelists:
- Armelde Pitre, MBA, Head, Quality Performance Analytics, Clinical Development Quality, Global Product Development, Pfizer, Inc.
- Janis Little, Vice President, Global R&D Quality, Allergan
- Brian Nugent, Executive Director, Clinical Solutions and Compliance, Ultragenyx

Few organizations have a complete understanding of the financial impact of poor clinical trial quality. With better understanding of poor quality on an organization’s bottom line, it can improve buy-in for proactively investing in quality to avoid costly quality problems. In this panel, representatives from across pharma will come together to discuss the sources of poor clinical trial quality (ex. protocol amendments, low/non-enrolling sites, subjects dropping out, data quality issues, etc.), the challenges of estimating poor quality costs, current quality cost estimate techniques including the Cost of Poor Quality Estimator Tool developed by the MCC Study Quality Trailblazer Group, and how improved access to data about the cost of poor quality is impacting risk management and quality investment decisions.

CLINICAL QUALITY IN ACTION

11:40 Quality by Collaboration: Practical Applications
Jolie Weintraub, Executive Director, TA Head Oncology, MRL Quality Assurance, Merck

This presentation will discuss how quality is implemented within Merck, including the importance of collaborating with various quality functions at all levels of the organization. It will provide a holistic approach to supporting and achieving quality proactively throughout the clinical trial process. In addition, case studies will be shared on how this principle has been put into practice and steps to take to foster the collaborations.

12:05 pm The Value of Centralized Monitoring on Monitoring Visits—Increasing Quality and Decreasing Costs
Nicole Stansbury, Executive Director, Adaptive and Intelligent Monitoring, Clinical Development Services, PPD

As regulatory authorities embrace change and the industry focuses on reducing costs, increasing data integrity and patient safety, the importance of centralized monitoring increases. PPD combines centralized monitoring with site health assessments to enhance site performance. Learn how our CRAs are moving from finding to fixing issues and becoming experts in process improvement to help sites become more engaged and efficient—ultimately reducing risk, increasing safety, ensuring quality and reducing the costs of drug development.

12:30 Session Break
4th Annual
Implementing Risk-Based Monitoring — Part 1
Integrating Quality into Clinical Trials

February 13-14, 2018

12:40 Luncheon Presentation to be Announced

1:20 Coffee and Dessert Break in the Exhibit Hall

CLINICAL QUALITY IN ACTION (CONT.)

2:00 Chairperson's Remarks
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC

2:05 TransCelerate's Clinical QMS
Janis Little, Vice President, Global R&D Quality, Allergan

The presentation will cover what a Clinical QMS is, and what the benefits are to sponsors in having a Clinical QMS defined and in place in alignment with ICH E6 (rev 2) requirements in Section 5. Audience will recognize and understand the flexibility of the TransCelerate Conceptual Framework for a Clinical QMS that will help sponsors design a customized CQMS for their specific needs. The presentation will dispel myths that exist on what a Clinical QMS "is" and what it is not, and it will cover what TransCelerate QMS publications and tools are currently available to industry. The presentation will also take a deep dive into a newly available tool for sponsors to assess a clinical quality management system (if they have implemented in alignment with the TransCelerate CQMS Conceptual Framework).

2:55 Envisioning a Quality Management System to Address the ICH E6 R2 Changes
Andy Lawton, Director and Consultant, Risk Based Approach Ltd.

The changes in ICH E6 R2 impact the fundamental basis of how quality should be addressed by a sponsor. This presentation will take a holistic look at the Regulatory background, and the tools that can be used to address the critical issues of Quality Tolerance Limits, Quality by Design, and Continuous Quality Improvement.

3:20 Risk-Based Monitoring Strategies for Improved Clinical Trial Performance
Henry Galio, Senior Director, Vault CTMS, Veeva Systems

A strategic, risk-based approach to clinical trial management can aid sponsors and CROs in early detection and mitigation of risks that could affect the quality and safety of a study and its subjects. However, risk mitigation strategies have little value unless they are executed, monitored, and analyzed continuously throughout the trial's lifecycle. This session explores how cloud-enabled solutions can be leveraged to gain real-time insights and actionable analytics to improve clinical trial safety and performance.

BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups

Concurrent break out discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will gain a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 14

7:15 am Registration Open

7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It
Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

ICH E6 R2 & ITS IMPACT ON CLINICAL TRIAL QUALITY

8:25 Chairperson's Remarks
Nithya Ananthakrishnan, CEO, Algorics

8:30 Presentation to be Announced

8:55 CO-PRESENTATION: The Impact of Technology on Clinical Trial Oversight to Ensure Quality and Meeting ICH E6 R2 Requirements
Brian Nugent, Executive Director, Clinical Solutions and Compliance, Utragenyx
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences

Today there is an array of technological solutions bringing change to the processes involved in conducting clinical trials. This change is impacting everything from study start-up activities, data collection, and analysis of clinical trial data, to the monitoring of clinical trials. The big question is how is this technology really ensuring quality in clinical trials. During this presentation, we will be discussing the following:

• What is Quality Management, and how can we ensure quality in clinical trials?
• What are the specific Quality Management requirements in ICH E6 R2 that sponsor companies should pay close attention to when evaluating technologies for use in a clinical trial?
• How has E6 impacted the use of homegrown risk systems?
• Has technology increased the overall operational complexity and cost, or has it enabled us to provide cost effective trial management and oversight?
ICH E6 R2 & ITS IMPACT ON CLINICAL TRIAL QUALITY (CONT.)

11:15 PANEL DISCUSSION: ICH E6 and How the Industry Is Tackling Things Head On
Moderator: Andy Lawton, Director and Consultant, Risk Based Approach Ltd.
Panelists:
Jonathan Rowe, Ph.D., Executive Director & Head, Quality Performance and Risk Management, Pfizer
Eva Bush, Senior Director, QA Lead, Americas Audit Excellence Quality Assurance Team (AEQAT), Global Clinical Quality Assurance, QuintilesIMS

With the passage of ICH E6 (R2) addendum, the pharma industry is taking a closer look at how they approach clinical trial quality and oversight with their partners. This panel will cover how individual organizations are approaching ICH E6 R2 addendum changes, the struggles and challenges they faced or continue to face, and how they are working with other stakeholders (their CRO partners, stakeholders across different departments, etc.).

12:05 pm Session Break
12:10 Bridging Luncheon Presentation: Extracting Data from the EHR Dramatically Reduces the Need for Manual Monitoring. New Standards Make This Possible
Keith Howells, CTO, Omnicomm
12:50 Coffee and Dessert Break in the Exhibit Hall
1:30 Close of Conference

Stay on and attend Implementing Risk-Based Monitoring – Part 2. Click here for details.
E-clinical technology is changing the landscape of the clinical research industry and healthcare IT in general. Digitalization of healthcare data, mobile data capture technologies, and cloud storage of data are a few of the main technological advances that influence clinical research informatics. The technological advances have been coupled with novel data visualization solutions, and this powerful duo is helping to develop a new paradigm of data-driven clinical trials. Cambridge Healthtech Institute's 10th Annual Clinical Data Strategy and Analytics conference is designed to bring together clinical research informatics experts to discuss the challenges and find solutions necessary to navigate and thrive in this rapidly changing environment.

**MONDAY, FEBRUARY 12**

9:00 am - 7:30 pm **Registration Open**

5:00 - 6:15 **Pre-Conference Plenary Keynote Panel** (click here for details)

6:30 – 8:30 **SCOPE's Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis**

8:30 **Close of Day**

**TUESDAY, FEBRUARY 13**

7:15 am **Registration Open and Morning Coffee**

8:20 **Opening Plenary Keynotes** (click here for details)

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

**INTEGRATED TECHNOLOGY PLATFORMS**

10:45 **Chairperson's Remarks**

Jaydev Thakkar, IS Director, R&D Informatics, Amgen

10:50 **SPECIAL OPENING PRESENTATION: Integrated Technology Platforms and the Implications to Our Clinical Organizations**

Rehbar Tayyabkhan, Vice President, Global Data Strategies & Solutions, Global Clinical Operations, Bristol-Myers Squibb

As capabilities emerge with e-clinical technology platforms, esource, analytics, etc., clinical operations organizations have no choice but to adapt and realign our capabilities. This presentation will provide some context for some high-impact emerging changes and share some practical approaches taken to realize the value from these technological advancements.
February 13-14
Protocol Development, Global Site Selection, Feasibility and Site Management
Enrollment Planning and Patient Recruitment
Clinical Trial Forecasting, Budgeting and Contracting
Mastering an Outsourcing Strategy
Implementing Risk-Based Monitoring-Part 1
Clinical Data Strategy and Analytics
Sensors, Wearables and Digital Biomarkers in Clinical Trials
Late Stage Research and Observational Studies
Biospecimen, Central Lab and Technology for Precision Medicine Trials
February 14-15
Improving Site-Study Activation and Performance
Patient Engagement, Enrollment and Retention through Communities and Technology
Resource Management and Capacity Planning for Clinical Trials
Managing Outsourced Clinical Trials
Implementing Risk-Based Monitoring-Part 2
Artificial Intelligence in Clinical Research
Clinical Technology and Innovation
Leveraging Real World Data for Clinical and Observational Research
Clinical Supply Management
Sponsor & Exhibit Opportunities
Hotel & Travel Information
Registration Information

10th Annual
Clinical Data Strategy and Analytics
Enabling Data Driven Clinical Trials

February 13-14, 2018

2:05 Analytics to Drive Better Decisions in Clinical Development
Angelique Hopkins, MPH, Associate Director, Clinical Trial Analytics, Business Insights and Analytics, Bristol-Myers Squibb Company
Integrated, predictive analytics can help drive R&D strategy and execution, with clear benefits to operational costs and long-term financial success. Analytics in trial planning and execution are often viewed as drivers of delay rather than acceleration and analytics is rarely used effectively to drive decisions in planning. This presentation will discuss how embedding analytics into clinical development process can alleviate challenges and build trust with stakeholders for faster, better decisions.

2:30 From the Trenches: Technical Strategies for Start-Up and Virtual Pharma/BioTech Companies
Steven Sweeney, Vice President, Clinical Development Operations, Rodin Therapeutics
This presentation will focus on the technology stack utilized for clinical development in the start-up and virtual pharma/biotech sector. It will include a review of popular start-up models and overlay considerations for the use of technology to improve efficiency and vendor oversight and obtain scientific and medical insights.

2:55 Clinical Data Integration from Translational Modeling Using Machine Learning Approach
Raj Bandaru, Senior Director, Data Sciences Strategy, Translational Medicine, Sanofi
Use of clinical data for translational modeling and trial simulation is key capability to transform the pharma industry to more data and model-driven drug development. At Sanofi, we have developed some elegant machine learning approaches to integrate clinical study data and make it available for clinical research. This approach reduces the manual effort and thus enabling real time analytics and simulation of trial results.

3:20 Visual Analytics for Medical Data Review: A Physician's Perspective
Anthony Everhart, MD, FACP, Vice President, Medical Informatics, Covance

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vie some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 14

7:15 am Registration Open

7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It
Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

8:25 Chairperson's Remarks
Chairperson to be Announced, Oracle Health Sciences

8:30 Harnessing Digital Technology and Big Data in Clinical Trials and Beyond
Vaibhav Narayan, Ph.D., Vice President, Research and Therapeutic Area IT, Janssen
Measuring physiological and activity-based parameters remotely and continuously via unobtrusive on/off-body sensors or smartphones has the potential to revolutionise our ability to monitor patients between clinic visits and develop objective markers that track disease trajectory. How can we harness such advances in digital technology and big data analytics to enable more informative and efficient clinical studies and develop patient-centric digital solutions that improve outcomes in the real world?

8:55 Digital Biomarker Implementation, Presentation and Comparability
Amy Calvin, BS, MT (ASCP), MBA, Digital Strategy and Implementation, Advisor, Eli Lilly and Company
Over the past few years, data generation is beginning to take a new form. It's moving from subjective to more objective, from episodic to contemporaneous, and is being generated through connected digital tools that can be used to quantitatively explain or predict physiological, behavioral, and functional health measures and outcomes. These digital measures are known as digital biomarkers. This presentation utilizes learnings from pilot examples to examine the implementation, presentation and comparability of digital biomarkers.

9:20 Wearables and Sensors Are Changing the Clinical Trial Process, but What's the Return on Investment for This Dramatic Change in People, Process and Technology?
Deborah Profi, Ph.D., Vice President, Otsuka Information Technology
The advent of wearables and sensors in clinical trials is changing the paradigm...
of trial designs, clinical teams, outsourcing practices, and ultimately patient engagement. However, what value does sensor/wearable data and these new trial practices bring, and how quick is the return of investment to the various stakeholders? Otsuka Pharmaceutical Development and Commercialization, Inc. is on the cutting edge of the trial and technology reform, and will share some critical learnings from "the road less traveled".

9:45 Presentation to be Announced

10:10 Coffee Break in the Exhibit Hall

FROM THE TRENCHES: THE CASE STUDIES

11:10 Chairperson's Remarks
Chairperson to be Announced, ZS Associates

11:15 Data Integration Solutions: A Case Study of CSL Behring's Evolution on Managing Clinical Data
Thomas Verish, Senior Director, Data Operations & Clinical Infrastructure, CSL Behring

CSL Behring had three new molecular entity approvals in the last two years for rare diseases to treat factor eight and nine deficiencies in hemophilia, along with hereditary angioedema. How does a company go from running small rare disease studies to delivering a Phase III CV mega-trial? We will discuss how we have spent the last two years preparing to start this study in the first half of 2018.

11:40 CO-PRESENTATION: Randomization Authorization Flow (RAF): It's Not Just about Meeting Eligibility Criteria
Jody Goldstein, Senior Clinical Project Manager, Center for Human Experimental Therapeutics, University of Rochester
Susan Bennett, Senior Clinical Data Manager, Center for Human Experimental Therapeutics, University of Rochester

RAF is a review and approval process of predetermined key data points and eligibility criteria by a single point of contact (medical monitor) prior to randomization. The RAF process helps to ensure enrollment of the appropriate study-specific patient population. This gestalt review takes into account critical elements not necessarily covered by the eligibility criteria. Looking for subtle (subjective) differences between patients upfront ensures meeting the primary outcomes of the study.

12:05 pm Session Break
The clinical research industry is moving toward end-to-end digital clinical trials. The data collection should stay in line with this inevitable change, and wearables and point-of-care sensors address this need. Furthermore, digital biomarkers translate new data sources into clinically actionable insights. The inaugural Sensors, Wearables and Digital Biomarkers in Clinical Trials: Novel Data Sources and Connectivity for Virtual and Remote Trials conference, part of the 9th Annual SCOPE Summit, is designed as a knowledge and experience exchange for clinical data and clinical operations executives. The conference will feature case studies of clinical trials that already employ sensors and wearables as well as discussions of the future steps needed for digitalization of clinical trials.

MONDAY, FEBRUARY 12

9:00 am - 7:30 pm Registration Open

5:00 - 6:15 Pre-Conference Plenary Keynote Panel
(click here for details)

6:30 – 8:30 SCOPE’s Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis

8:30 Close of Day

TUESDAY, FEBRUARY 13

7:15 am Registration Open and Morning Coffee

8:20 Opening Plenary Keynotes (click here for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

WEARABLES AND SENSORS AS NEW DATA SOURCES

10:45 Chairperson’s Remarks
Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

10:50 Digital Biomarker Development at Roche pRED: How Mobile Technology Can Innovate Clinical Endpoints
Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

Merging the best of two worlds - clinical trials and real world - is now increasingly possible. Mobile sensors are rapidly becoming a part of everybody’s lives. They allow for objective, precise and continuous measurements. We share our first real world digital biomarker results based on active tests and passive monitoring data - provided by Parkinson's disease and Multiple Sclerosis patients in clinical trials.
Inaugural
Sensors, Wearables and Digital Biomarkers in Clinical Trials

NEW Novel Data Sources and Connectivity for Virtual and Remote Trials

February 13-14, 2018

12:10 pm Clinical Trial Pilots of Wearable Sensors in Diabetes and Asthma
Martin Karpefors, Ph.D., Informatics Science Director, CardioRenal, Autoimmune & Neuroscience TA Lead, AstraZeneca

Sensors offer a way to transform clinical trial results from snapshot measurements of physiological parameters to continuous remote monitoring, which will enable disease insight, increase patient engagement and control, as well as give cost savings and operational advantages. However, these promises do not come without challenges. Based on our pilot experiences from (multi-) sensor trials in diabetes and asthma, we present some scientific, analytical and operational perspectives.

2:55 PANEL DISCUSSION: Digital Technology Adoption and Implementation
Moderator: Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development
Panelists: Gahan Pandina, Ph.D., Senior Director, Compound Development Team Leader, Neuroscience, Janssen Research & Development
Aman Thukral, Assistant Director, Data and Statistical Sciences, AbbVie
Jeuan Clay, Ph.D., Group Lead Digital Endpoints, Translational Medicine, Novartis Institutes for Biomedical Research
Michelle Crouthamel, Digital Platform Leader, GSK

This panel will discuss: Wearable sensors’ impact on trials design and execution; Collecting, integrating, and analyzing wearable devices data, and Driving innovation in patient centricity and PROs.

3:20 Talk Title to be Announced
Speaker to be Announced, High Point Clinical Trials Center

DIGITAL TECHNOLOGY ADOPTION AND IMPLEMENTATION

2:00 Chairperson's Remarks
Gahan Pandina, Ph.D., Senior Director, Compound Development Team Leader, Neuroscience, Janssen Research & Development

2:05 Novel Biomarkers for Use in ASD Drug Development: State of the Science
Gahan Pandina, Ph.D., Senior Director, Compound Development Team Leader, Neuroscience, Janssen Research & Development

Autism Spectrum Disorder is a heterogeneous, complex neurodevelopmental disorder affecting 1-2% of the global population. There are currently no medications indicated for the treatment of core symptoms. Recently, research focus has shifted to the development and potential use of biomarkers to stratify the ASD population, or to assist with measuring treatment outcome change. The presentation will review the current state of the science in development of ASD biomarkers.

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day’s sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Click here for details.

2:30 Key Considerations in Integrating Wearables/Sensors Data in Sponsor's Ecosystem (AbbVie)
Aman Thukral, Assistant Director, Data and Statistical Sciences, AbbVie

In pursuit of patient-centric clinical research, sponsors are leveraging wearables and sensors devices in clinical trials. These devices shoot data at a larger volume and velocity compared to traditional systems and require different skills to collect, integrate, and manage patient data. This session will discuss key considerations in integrating wearables/sensors data in sponsor’s ecosystem.

3:50 Find Your Table and Meet Your Moderator

5:00 Welcome Reception in the Exhibit Hall

DIGITALIZATION OF CLINICAL TRIALS

8:25 Chairperson’s Remarks
Chairperson to be Announced, Oracle Health Sciences
Inaugural

Sensors, Wearables and Digital Biomarkers in Clinical Trials

Novel Data Sources and Connectivity for Virtual and Remote Trials

February 13-14, 2018

8:30 Harnessing Digital Technology and Big Data in Clinical Trials and Beyond
Vaibhav Narayan, Vice President, Research and Therapeutic Area IT, Janssen
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9:45 Presentation to be Announced

10:10 Coffee Break in the Exhibit Hall

TECHNOLOGY-DERIVED ENDPOINTS AND CASE STUDIES

11:15 Identifying, Developing and Incorporating Technology-Derived Endpoints into Clinical Trials: A ‘How-To’ Guide on the Agenda
Rob DiCicco, Ph.D., Vice President, Clinical Innovation and Digital Platforms, GSK
Mobile technologies hold enormous promise for clinical research, but uncertainty about how to use the data captured by these devices has slowed progress. This presentation will describe recommendations and tools from the Clinical Trials Transformation Initiative (CTTI) that aim to change this by providing a pathway for using information gathered from mobile technologies to accelerate the development and evaluation of urgently needed therapies.

11:40 Making Sense of Sensor Data: A Case Study in Data Quality Evaluation
Bhaskar Dutta, Principal Scientist, Advanced Analytics Center, AstraZeneca
Wearable sensor technology brings the promise of improving management of chronic diseases, identification of drug adverse effects, and use of new efficacy endpoints. Future adoption of wearable sensors in clinical studies will depend on the usability of the devices and quality of the data. Currently, several sensors are commercially available, hence, requiring a comprehensive review. We carried out a study to compare them in healthy volunteers and implemented a comprehensive data analysis strategy, which has paved the way for improved designs of future studies involving wearable sensors.

12:05 pm Session Break

12:10 Bridging Luncheon Presentation:
Streamline Clinical Trials with the Industry's Only Proven Clinical Operations Suite - DrugDev Spark™
Brett Kleger, Chief Commercial Officer, DrugDev

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Clinical Technology and Innovation. Click here for details.
Non-interventional studies are an integral part of product development plans. Product safety profiles, comparative effectiveness data, as well as health economic evidence obtained from non-interventional studies, are essential for multiple stakeholders. These stakeholders include but are not limited to regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute’s 7th Annual Late Stage Research and Observational Studies: Novel Approaches and Data Sources for Post-Approval Research conference is designed to facilitate knowledge exchange around all aspects of observational research from the designing and managing of post-approval studies, to applying the obtained data to pivotal business and medical decisions. Similarities and differences between clinical and observational studies will be addressed by the top industry experts.

**MONDAY, FEBRUARY 12**

9:00 am - 7:30 pm **Registration Open**

5:00 - 6:15 **Pre-Conference Plenary Keynote Panel**  
(click here for details)

6:30 – 8:30 **SCOPE's Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis**

8:30 **Close of Day**

**TUESDAY, FEBRUARY 13**

7:15 am **Registration Open and Morning Coffee**

8:20 **Opening Plenary Keynotes (click here for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

**ELVING ROLE OF OBSERVATIONAL RESEARCH**

10:45 **Chairperson's Remarks**  
Cathy Critchlow, Ph.D., Vice President, Center for Observational Research, Amgen

10:50 **Evolving Role for Real-World Evidence in Facilitating Regulatory, Payer and Provider Decision-Making**  
Cathy Critchlow, Ph.D., Vice President, Center for Observational Research, Amgen

Increasing use of real world evidence (RWE) to tailor health care decision-making to patients in clinical practice complements evidence obtained from the carefully selected patients enrolled in randomized clinical trials. While growing data availability and sophistication of analytic tools have transformed evidence generation, challenges impeding full realization of benefit from RWE remain. Collectively addressing these challenges and advancing suitable use cases will help guide and enable appropriate impact of RWE.

11:15 **Non-Interventional Studies and Pragmatic Clinical Trials to Support Product Value**  
Christopher Chinn, Head of RWE Strategy for Market Access Health Economics and Value Assessment, Sanofi

Real World Evidence can be defined to include both non-interventional studies - aka observational studies or registry studies – and pragmatic clinical trials. These can provide evidence of interest to payers and inform clinical guidelines. The design and delivery of such studies draws on skills required for RCTs, but raise new challenges. Study teams should be prepared to find appropriate solutions.

11:40 **Combining Safety, Efficacy and Pharmacoeconomics Endpoints**  
Durgesh Bhandary, Senior Director, HEOR, AstraZeneca

This talk will discuss the strategy and logistics of designing and executing an observational study that would incorporate multiple end points to serve major stakeholders such as epidemiologists, drug safety researchers, sales and marketing, treating physicians.

12:05 pm **Presentation to be Announced**

12:30 **Session Break**

12:40 **Luncheon Presentation to be Announced**  
Annette Stemhagen, Dr.P.H., FISPE, Senior Vice President, Safety, Epidemiology, Registries and Risk Management, UBC: An Express Scripts Company

1:20 **Coffee and Dessert Break in the Exhibit Hall**

**FEASIBILITY ASSESSMENT; DATA PARTNERSHIPS**

2:00 **Chairperson's Remarks**

2:05 **CO-PRESENTATION: Value of Conducting Feasibility Studies in Observational Research**  
Mark Price, Senior Director, Surveys and Observational Studies, RTI Health Solutions

David Richardson, Project Manager, Surveys and Observational Studies, RTI Health Solutions

This presentation will provide justification and case study examples to demonstrate why it is important to spend time and resources up front to conduct feasibility assessments in noninterventional studies and the range of feasibility approaches that could be performed to get the most out of the implementation phase.
2:30 CO-PRESENTATION: Collaborative Approach to Real World Data Collection

Ginger Spitzer, Executive Director, Foundation of Sarcoidosis Research

Winnie Nelson, Pharm.D., MS, MBA, Senior Director HEOR, Mallinckrodt Pharmaceuticals

This presentation will focus on the valuable role of non-profit disease research foundations in securing and managing real world data and collaboration with industry to access the data. The two-part presentation will include review of methods such as patient registries, clinical site networks, collaboration, wearables, and other techniques, and will feature the perspective of industry partners as both collaborators and first-line collectors of data. The "neutral third party" status of the non-profit organizations can enable industry to navigate more easily the issues in logistics to get direct real world data.

2:55 A Crawl, Walk, Run Strategy towards Virtual Studies in Real World Research

Kathleen Mandziuk, MPH, RN, Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences

This presentation will address new and exciting developments in planning and executing real world research studies virtually. Attendees will learn about the reality of conducting virtual studies on a global scale and the role mobile technology can have to optimize recruitment, engagement and retention of patients, while driving better data, decisions and outcomes more efficiently, and at a significant reduction in costs.

3:20 PANEL DISCUSSION: Meeting the Evidentiary Needs of Multiple Stakeholders by Better Non-Interventional Studies

Moderator: Cathy Critchlow, Ph.D., Vice President, Center for Observational Research, Amgen

Panelists: Speakers of the Day

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

- What are key considerations and approaches to balance scientific and commercial values of non-interventional studies?
- What are common utilizations 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)?

BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 14

7:15 am Registration Open

7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It

Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

EMBEDDING STUDIES IN PATIENT CARE

8:25 Chairperson's Remarks

Annette Stemhagen, Dr.P.H., FISPE, Senior Vice President, Safety, Epidemiology, Registries and Risk Management, UBC: An Express Scripts Company

8:30 Pragmatic Clinical Trials: Bridging the Gap between Research and Care

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

Clinical trial findings that lead widespread change in health care is relatively slow. Since many clinical trials are not relevant to clinical practice, it is difficult to translate results to the real world clinical practice. Tens of thousands clinical trials published each year, yet systematic reviews consistently find that we don't have enough evidence to effectively inform the clinical decisions. Clinical research is more than just traditional RCTs. Pragmatic research is designed with input from health systems and produces evidence that can be readily used in improve care. By engaging health systems, providers, and patients as partners, pragmatic research accelerates the integration of research, policy, and practice.

8:55 CASE STUDY: Leveraging Real World Data in Observational Research to Address Safety Risks

Younus Muhammad, Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer

Observational data from real-world setting are increasingly being used to assess safety risks with pharmaceutical products. This presentation will describe how real world data from routine clinical practice were used to address a safety risk in a special patient population including details around feasibility assessment, regulatory agency interactions, study methods and results, and impact on the product label.
9:20 CO-PRESENTATION: The Use of Real-World Data and Evidence in Clinical Research and Post-Marketing Safety Monitoring
Mary Jo Lamberti, Ph.D., Senior Research Fellow, Tufts CSDD, Tufts University
Jill Abel, MPH, Ph.D., Team Leader, Real World Evidence, Janssen
Tufts CSDD has recently conducted a study of 30 biopharmaceutical companies to examine insights on the industry’s response to this opportunity including current and planned uses of real-world data, operational issues and return on investment/performance areas impacted by real-world data use. Significant challenges are identified as well as strategies and practices that impact return on investment or performance.

9:45 Real World Evidence: Separating the Hype from the Promise
Charles Makin, Vice President & Global Head, Late Phase Research, Commercialisation & Outcomes, ICON
Increasing availability of RWE has created justifiable excitement, accompanied by confusion about its true meaning and implications for stakeholders. While RWE is neither the starting point nor the solution, it is a critical component of the value demonstration toolkit. It is not the data that counts, but the insights gained from it. Join us for best practices to ensure you are asking the right questions and using data to guide the pursuit of answers.

10:10 Coffee Break in the Exhibit Hall

11:10 Chairperson's Remarks
Emily Freeman, Ph.D., Director, Risk Management Sciences, Abbvie

11:15 Incorporating the Patient Perspective into Pharmacovigilance
Emily Freeman, Ph.D., Director, Risk Management Sciences, Abbvie
Patient engagement is a key aspect to improving health outcomes and effectiveness of risk management activities within the pharmaceutical industry. It is imperative to incorporating the patient perspective into pharmacovigilance and subsequent risk management strategies. This session strategizes how to incorporate the patient perspective to develop patient focused risk minimization activities utilizing concepts from the social/behavioral sciences that focuses on patient activation, patient measurement, and shared-treatment decision making.
The availability of high-quality biological specimens, laboratory access and diagnostics services are of utmost importance for biomarker-driven clinical trials and future research. The complexity and number of samples collected during studies has increased steadily over the years and we need to come up with best practices, operational models and IT systems to deal with this volume and complexity. The next step, the testing of the samples and various laboratory services, also requires significant managerial efforts whether they are outsourced or provided by an in-house laboratory. Cambridge Healthtech Institute's 3rd Annual Biospecimen, Central Lab and Technology for Precision Medicine Trials conference brings together leading experts to discuss challenges and identify actions to improve infrastructure for biomarker-driven clinical trials.

**MONDAY, FEBRUARY 12**

9:00 am - 7:30 pm Registration Open

5:00 - 6:15 Pre-Conference Plenary Keynote Panel (click here for details)

6:30 – 8:30 SCOPE's Kick-Off Networking Happy Hour on the Garden Terrace Hosted by CHI, DrugDev, Exostar, & Praxis

8:30 Close of Day

**TUESDAY, FEBRUARY 13**

7:15 am Registration Open and Morning Coffee

8:20 Opening Plenary Keynotes (click here for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

**ENABLING PRECISION MEDICINE TRIALS**

10:45 Chairperson's Remarks

Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck

10:50 Precision Medicine Trials, and How the Bio-Repository Can Support Biomarker and Diagnostic Development

Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck

Personalized medicine initiatives have led to a marked increase in biomarker-driven research objectives within clinical trials. This has re-defined traditional biospecimen management into a more comprehensive information management role requiring innovative technology and best practices. The ability to integrate disparate data sources into centralized systems and present the information in a way that can guide decision-making and biomarker development, will define the utility and success of the biorepository.

11:15 Clinical Biomarker Sample Management: Taking Time to Do It Right, Rather than Do It Over

Dmitri Mikhailov, Ph.D., Director, Head, Biomarker Study Coordination, Novartis

The emergence of global clinical trials with complex biomarker analyses performed at CROs pushes the industry to reconsider clinical sample management. How to mitigate risks of losing samples or compromising quality? How to maximize sample usage beyond clinical study objectives? This presentation discusses how Novartis approaches these challenges, starting with trial documentation setup, to systems used in biorepository for sample inventory and enabling additional research use of clinical samples.

11:40 Operationalizing Precision Medicine Trials in Oncology

Karina Bienfait, Ph.D., Head, Global Genomics Policy, Process and Compliance, Principal Scientist, Clinical Pharmacogenomics and Operations, Genetics and Pharmacogenomics (GpGx), Translational Medicine, Merck Research Laboratories

The immuno-oncology revolution has required many sponsors to rethink the infrastructure needed to support complex biomarker driven trials. This presentation will discuss challenges and solutions in operationalizing such trials, including governance committees, roles and responsibilities of functional areas, biomarker plan structures, and vendor alignment.

12:05 pm Sponsored Presentation (Opportunity Available)

12:30 Session Break

12:40 Luncheon Presentation: Best Practices in Clinical Trial Samples & Consent Tracking

Jian Wang, Ph.D., CEO, BioFortis, Inc.

In biomarker-driven precision medicine clinical trials, patient samples (biospecimens) are as important as patients themselves. Sample assay results often determine patient segmentation, and support primary and key secondary objectives. The lack of proper sample tracking & management escalate risks of milestone delays and regulatory scrutiny. We illustrate best practices and technology solutions that address the rise in complexity and importance of biospecimen operations, with unique perspectives from risk-based monitoring approaches.

1:20 Coffee and Dessert Break in the Exhibit Hall
SOURCING AND PROCUREMENT

2:00 Chairperson's Remarks
Jonathan Reuter, Associate Director Global Procurement R&D, Clinical Labs, Bristol-Myers Squibb

2:05 Use of Make vs. Buy Analyses and “Should-Cost” Modeling in Clinical Laboratory Procurement
Jonathan Reuter, Associate Director, Global Procurement R&D, Clinical Labs, Bristol Meyers-Squibb

Elevating the role of procurement in company decision-making. Using comprehensive analysis to enable informed sourcing decisions. Partnering with external supply base to implement cost-controlled and sustainable models in support of the clinical development cycle.

2:30 Comprehensive Bio-Inventory System to Support Clinical Biomarker Strategy
Sandra Hudgens, MT(ASCP), BS, MBA, Associate Principal Scientist, Clinical Specimen Management Operations, Merck

Precision medicine is a key component to drug development strategy. The management of clinical specimens to support genetic and biomarker testing is critical to realizing precision medicine. This includes having a biospecimen inventory management system which can seamlessly link specimens to informed consent and clinical data to appropriately select specimens for analysis. Based on established business criteria, the biospecimen inventory management system should be able to track the specimen life cycle to provide a cost-effective inventory for the organization.

2:55 Frozen Clinical Biospecimens – New Approach for Optimizing Quality, Compliance, and Cost
Robert Sever, PhD, Associate Director, Research & Development, Praxair, Inc.

This seminar will review the challenges of today’s cold chain for clinical biospecimens from kit preparation and dry ice management to sample acquisition and shipment logistics. A new approach will be described that can improve sample preservation, process compliance, and productivity while reducing overall complexity, risk, and cost.

3:10 Sponsored Presentation (Opportunity Available)

3:25 PANEL DISCUSSION: Biospecimen and Core Lab Considerations for Risk-Based Monitoring
Moderator: Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck
Panelists: Jonathan Reuter, Associate Director Global Procurement R&D, Clinical Labs, Bristol-Myers Squibb
Jian Wang, Ph.D., CEO, BioFortis, Inc.
Dmitri Mikhailov, Ph.D., Director, Head, Biomarker Study Coordination, Novartis
Karina Bienfait, Ph.D., Head, Global Genomics Policy, Process and Compliance, Principal Scientist, Clinical Pharmacogenomics and Operations, Genetics and Pharmacogenomics (GpGx), Translational Medicine, Merck Research Laboratories
- Importance of Biospecimens in Precision Medicine trials
- When patient samples are as important as the patient themselves
- Specimen-centric RBM approaches
- Inclusion of specimen KRIs (key risk indicators)
- Working with RMB colleagues to improve quality

BREAKOUT DISCUSSION GROUPS

3:50 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 14

7:15 am Registration Open

7:45 Breakfast Presentation: A New Way to Pay: SaaS Technology and Outsourcing How You Need It
Stuart Thiede, President, Payments, DrugDev

8:15 Session Break

8:25 Chairperson's Remarks
Lynn Wetherwax, Senior Manager, Biobank, Translational Sciences Operations, Amgen

8:30 CO-PRESENTATION: Clinical Sample Tracking Project Implementation: A Case Study
Ron Bourque, Associate Director, RDI, Clinical Biologics, MedImmune/AstraZeneca
Venkatraman Raman, Senior Project Manager, R&D Information, Clinical Biologics, AstraZeneca

TECHNOLOGY SOLUTIONS
We have developed a new and innovative sample management model combining MedImmune Clinical Operations with close alliance/partnership to a Central Lab. Together the technology we are employing is Labmatrix. This initiative is focused on accepting standardized data from all lab vendors. Discrepant data will be corrected at the source lab and reflected back into the tool. Labmatrix is also receiving consent data from our EDC.

8:55 Enabling Scientific Discovery and Innovation Using Biomarker Specimens by Means of Advanced Informatics

Lynn Wetherwax, Senior Manager, Biobank, Translational Sciences Operations, Amgen

Biomarker specimens may be collected with a specific purpose in mind or they may be stored until that “a-ha” moment when scientific discovery hinges on biomarker investigation. This presentation will provide an overview of biomarker specimen management strategy using informatics to track, confirm consent and search clinical data attributes related to available specimens.

9:20 Leveraging Systems and Automation to Address the Challenges in GSK’s Sample Management Strategy Implementation

Kimberly Bojczuk, Investigator, Discovery Supply - Global Biological Assets, RD Platform Technology & Science, GSK

GSK is developing a cross-functional strategy working with IT and global teams, to increase the visibility and use of human biomaterials in Discovery and Clinical. This integrated approach will increase standardization, allow GSK to maximize investment in biological materials and ensure increased compliance. An IT platform to provide a single interface to both on-site and off-site storage, as well as rapid delivery of samples from an automated sample store will facilitate addressing challenges faced.

9:45 Bringing the Trial to the Patient: Sample Collection at Home for Clinical Trials

Kevin Bateman, Distinguished Scientist, Pharmacokinetics, Pharmacodynamics and Drug Metabolism, Merck & Co.

Merck’s “Smart Trials” initiative evaluates and implements technologies bringing clinical trials to the patient. Enabling this is the ability to collect samples for pharmacokinetic/biomarker analysis away from the clinic. Dried blood collection is being investigated and learnings will be shared on hurdles met and how they are being addressed.
Clinical trial site activation and efficient study start-up are critical to drug development programs, in terms of time, cost and quality of data. To improve start-up times and outcomes, one needs an experienced clinical research investigator, motivated and capable team members and efficient communication by all. Everyone (Sponsor, CRO, Site) must communicate and execute effectively in order to improve the study feasibility process, contract and budget negotiations, standardization of source documents and other study-related materials, development of patient and staff educational materials, and development of patient recruitment and retention programs. CHI’s 5th Annual Improving Site-Study Activation and Performance will cover the topics one should consider when strategically implementing a process for rapid study start-up.

Arrive early and attend Part 1: Protocol Development, Global Site Selection, Feasibility and Site Management. Click here for details.

WEDNESDAY, FEBRUARY 14

11:30 am Registration Open

12:10 pm Bridging Luncheon Presentation: Approaches to Evidence Based Site Planning in Trial Design

Gavin Coney, Head, Clinical, Clarivate Analytics

We will explore approaches to ensuring that your study planning is based on the broadest evidence base. We will demonstrate how additional manually curated intelligence can complement existing data sources to identify relevant insights based on similar studies and provide specific insights into critical trial design and planning decisions.

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Plenary Keynotes (click here for details)

3:00 Valentine’s Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

ACHIEVING EFFICIENCY FOR THE SPONSOR, CRO, SITE AND PATIENT IN SITE ACTIVATION

4:00 Chairperson's Remarks

Shawn Tedman, MBA, Head, Product Offerings, Clinical Trial Optimization Solutions (CTOS), QuintilesIMS

4:05 Site Activation, a Balancing Act between Time and Quality: How to Avoid Paying the Price Later On

Valérie Reynaert, Head, In-Country Clinical Operations for the Americas, R&D Projects Clinical Platform & Sciences, GlaxoSmithKline

There are many processes in the site start up activities that are redundant, inefficient and needlessly complex. Our study start up timelines often slip as a result. This presentation will share learnings and opportunities on how simplification of our processes and reducing complexity can help in starting up sites on time without paying the price for it later.

4:30 Accelerating Study Start Up: A Centralized Approach

Christina Brennan, M.D., Vice President, Clinical Research, Executive Research Administration, Northwell Health

Hospitals and health system consolidations continue to be on the rise and will continue to remake the delivery system landscape over the next 10 years. Clinical research participation will be more efficient if it is approached centrally as a systemwide approach in these settings. Currently, 57% of the US hospitals are part of a system and this will continue to rise. A centralized approach to site selection and site activation will streamline this process and accelerate study start up. This will lead to improved processes with study performance.

4:55 CO-PRESENTATION: Why Is Study Startup Still so Inefficient?

Jae Chung, President & Founder, goBalto

Ken Gatz, Director, Sponsored Research Programs, Associate Professor, Tufts Center for the Study of Drug Development

An in-depth study conducted by Tufts Center for the Study of Drug Development focused on the end-to-end process of site identification through site initiation grapples with this question, and sheds light on the challenges organizations are facing, and on new tools, technologies, and approaches being developed to overcome these hurdles.

5:10 Presentation to be Announced

5:25 PANEL DISCUSSION WITH PATIENT & SITE: Why Site Buy-In Is Crucial to Improving the Trial Participant Experience

Moderator: Abbe Steel, CEO, HealthVibe, LLC

Patient: Nicole Moore

PI: Bruce Rankin, M.D., Avail Clinical (An Accel Research Site)

Site: Chris Hoyle, MBA, Executive Director, Elite Research Network

Industry-wide adoption and benchmarking of trial participant insights has the potential to truly improve clinical trial design and execution and improve the patient experience in clinical trials. But the overall success of these surveys is largely...
5th Annual
Improving Site-Study Activation and Performance
Strategically Implementing a Process and Systems for Rapid Study Start-up and Improved Site-CRO-Sponsor Interactions

February 13-14
Protocol Development, Global Site Selection, Feasibility and Site Management
Enrollment Planning and Patient Recruitment
Clinical Trial Forecasting, Budgeting and Contracting
Mastering an Outsourcing Strategy
Implementing Risk-Based Monitoring-Part 1
Clinical Data Strategy and Analytics
Sensors, Wearables and Digital Biomarkers in Clinical Trials NEW
Late Stage Research and Observational Studies
Biospecimen, Central Lab and Technology for Precision Medicine Trials

February 14-15
Improving Site-Study Activation and Performance
Patient Engagement, Enrollment and Retention through Communities and Technology
Resource Management and Capacity Planning for Clinical Trials NEW
Managing Outsourced Clinical Trials
Implementing Risk-Based Monitoring-Part 2
Artificial Intelligence in Clinical Research NEW
Clinical Technology and Innovation
Leveraging Real World Data for Clinical and Observational Research
Clinical Supply Management NEW

Sponsor & Exhibit Opportunities
Hotel & Travel Information
Registration Information

Register Online!
SCOPESummit.com

In order to make submissions faster and ensure the quality of the data, it's important best practices to the Clinical Operations team when submitting clinical documents. This presentation will be given from a Regulatory Operations perspective to provide AD/Belviq, Neurology Business Group, Eisai, Inc.

Maribel Hernandez, Director, Clinical Operations, Global Therapeutic Area Lead
Sophia Kourliouros, Senior Manager, Global Regulatory Operations, Eisai, Inc.

Integration Can Accelerate Timelines to Submission
8:55 CO-PRESENTATION: How Reg Ops and Clin Ops Business Factors and KPIs to Ensure Faster Start-Up and Better Accrual Rates
Marina Malikova, Ph.D., Executive Director, Surgery, Boston University Medical Center

The success of a trial heavily relies on the strong bond between trial operations and project management throughout the life cycle of the trial. It is important to develop a specific knowledge of the strengths, weaknesses and pitfalls of assumed risks at the inception of the project in order to devise a solid strategy to mitigate them throughout implementation phase. Systematic assessment of risk factors and key performance indicators at a start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. This session will discuss best practices to expedite start-up phase.

8:30 Chairperson's Remarks
Chairperson to be Announced, Bio-Optronics

8:35 A Systematic Approach to Study Start-Up: Identifying Risk Factors and KPIs to Ensure Faster Start-Up and Better Accrual Rates
Marina Malikova, Ph.D., Executive Director, Surgery, Boston University Medical Center

While navigating the rough seas toward study activation, advanced planning is key to staying on course. Our presenters will share insights on streamlining the study start up journey, by addressing major components such as protocol development, competitive landscape assessment, evaluating patient demand and country/site selection. We’ll touch on how combining expertise with a trusted crew, along with a few simple tech tools, will ensure smooth sailing and a timely arrival at your final destination.

9:00 Networking Coffee Break

9:25 CASE STUDY: Transforming the Site Monitoring and Management Model to Become a Sponsor of Choice for Sites and Improve Quality
Mari Maurer, Pharma Clinical Solutions Consulting LLC; former Vice President, Clin Ops, REGENXBIO

Site activation for studies in rare diseases especially those involving novel therapeutic modalities may have additional challenges due to additional regulatory review and oversight, specialized technology, novel intervention procedures, and training. We will be discussing the challenges frequently encountered during site activation in rare diseases and novel therapies and potential solutions to address them.

5:50 Close of Day

5:50 - 7:00 Track Reception (Sponsorship Opportunity Available)

THURSDAY, FEBRUARY 15

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

LEVERAGING SOUND BUSINESS PROCESSES, COLLABORATION AND TECHNOLOGY TO ACCELERATE THE PROCESS OF INITIATING A STUDY

9:10 Optimizing Site Activation in Rare Diseases and Novel Therapy Studies
Mari Maurer, Pharma Clinical Solutions Consulting LLC; former Vice President, Clin Ops, REGENXBIO

Site activation for studies in rare diseases especially those involving novel therapeutic modalities may have additional challenges due to additional regulatory review and oversight, specialized technology, novel intervention procedures, and training. We will be discussing the challenges frequently encountered during site activation in rare diseases and novel therapies and potential solutions to address them.

9:25 CASE STUDY: Transforming the Site Monitoring and Management Model to Become a Sponsor of Choice for Sites and Improve Quality

Mark Ridge, Vice President, Clinical Development Operations, CSL Behring

This session will explore an innovative site management and oversight approach to transform site relationships, enhance site quality and strengthen the overall site monitoring approach that yields successful approval of new therapies for patients. The presentation will include site survey results and lessons learned.

9:50 CO-PRESENTATION: Partnering Shared Expertise and Technology to Optimize Study Planning
Lon Branon, Director, Sitetrove/Chinatrove, Pharma Intelligence-Informa
Michael Fites, Senior Feasibility Strategist, Bayer Pharmaceuticals
Otis Johnson, PhD, Vice President, ICON Clinical Research

This session will explore an innovative site management and oversight approach to transform site relationships, enhance site quality and strengthen the overall site monitoring approach that yields successful approval of new therapies for patients. The presentation will include site survey results and lessons learned.

10:30 Chairperson's Remarks
Chairperson to be Announced, Bio-Optronics

10:45 Networking Coffee Break

E-CONSENT (EICF) IMPLEMENTATION LESSONS LEARNED BY STUDY EXPERTS

11:00 CO-PRESENTATION: How Reg Ops and Clin Ops Business Integration Can Accelerate Timelines to Submission
Sophia Kourliouros, Senior Manager, Global Regulatory Operations, Eisai, Inc.
Maribel Hernandez, Director, Clinical Operations, Global Therapeutic Area Lead AD/Belviq, Neurology Business Group, Eisai, Inc.

This presentation will be given from a Regulatory Operations perspective to provide best practices to the Clinical Operations team when submitting clinical documents. In order to make submissions faster and ensure the quality of the data, it's important...
10:35 PANEL DISCUSSION: eConsent after the Pilot: Implementation Lessons Learned by Study Experts
Moderator: Eric Delente, President, Patient Solutions, DrugDev
Scott Askin, Digital Development Director, Lead for eSource and eICF, Digital Development, Portfolio, Strategy & Innovation (PS&I), Novartis Pharma
eConsent (eICF) is a potential participant’s first real interaction as they consider participation in a clinical trial, and as such, it can be the keystone of a patient engagement strategy. Different sets of challenges and solutions appear at each stage as the implementation moves beyond early stages. In this panel-led discussion, we’ll hear perspectives from experts that start with using eICF in a pilot, then move into regulatory and quality considerations with perspectives, and finally the challenges of broader, global implementations. This discussion will also reveal some of the reasons why use of eConsent is not yet ubiquitous across the industry. The panel will include an interactive discussion, driven by questions from attendees with a goal of illuminating the path beyond pilot implementations, and attendees’ understanding of how an eConsent program can improve patient engagement.
• Understand the benefits and potential role of eConsent in Patient Engagement
• Recognize challenges of eConsent adoption across various stages of implementation from several perspectives
• Discuss potential approaches to implementation

11:00 Talk Title to be Announced
Speaker to be Announced, Bio-Optronics

11:25 Transition to Shared Session

M-HEALTH’S POTENTIAL TO IMPROVE PATIENT CENTRICITY AND THE CONDUCT OF CLINICAL TRIALS

11:35 Digital Trends Impacting Recruitment, Engagement and Retention
Shwen Gwee, Head of Digital Strategy, Global Clinical Operations, Biogen
Digital technology is connecting more people to clinical trials than ever before, and at the same time, the adoption of wearables as data collection devices in clinical trials is rising. The hope of streamlining trial operations, patient recruitment and registration is real. What technologies and approaches are having the greatest impact on recruitment, engagement and retention?

12:00 pm CASE STUDY: The Art and Science of Patient Engagement in the Digital Era – Learning from GSK PARADE Study
Michelle Crouthamel, Lead, Clinical Innovation & Digital Platforms Unit, GlaxoSmithKline
The ability to efficiently develop new medicines for patients with unmet needs is limited by the current model for clinical development. Although the emerging mHealth technologies have the potential to improve the conduct of clinical trials, the successful implementation requires careful study design and patient engagement. Data and experiences from GSK PARADE study will be summarized, highlighting the learning and opportunities in this new area of clinical development.

12:25 Mobile Clinical Trials: New Findings on Patient and Site Perspectives from the Clinical Trials Transformation Initiative
Hassan Kadhim, Business Consultant for Clinical Operations, Boehringer Ingelheim Pharmaceuticals
This presentation will discuss qualitative and quantitative research conducted by the Clinical Trials Transformation Initiative to understand the perspectives of patients and site investigators of mobile clinical trials. Discussion will include insights and advice from site investigators who have participated in trials that incorporate mobile devices to collect data for study endpoints.

12:50 PANEL DISCUSSION: Why Are There Barriers to the Adoption of Innovative Processes and Technologies at Sites?
Moderator: Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)
David Vulcano, Assistant Vice President & Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)
Sean Walsh, MBA, Chief Development Officer, Raleigh Neurology Associates
Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)
Many innovative technologies and process improvement initiatives are coming out at a rapid pace, whether from TransCelerate and other industry consortia, or from technology companies themselves. Which of these improvements actually work? How can sites implement these more effectively? Why are there barriers to adoption, and how can the innovators better understand sites’ needs?
• Discuss the reasons sites struggle with new processes and technology tools
• Determine ways to facilitate adoption

1:15 Closing Remarks

1:20 SCOPE Summit 2018 Adjourns
Enrollment planning and patient recruitment are critical to drug development programs and garner a lot of attention by study teams. However, once the hard work of identifying and recruiting a trial subject has been accomplished, they must be retained and remain in compliance. Retention of patients throughout the life of a clinical trial is essential in order to have complete data sets for your analysis and subsequent filings. There are strategies, tools and techniques such as social media platforms and mobile technology, empowered patient communities, and a more informed patient population that need to be understood and engaged. CHI’s 5th Annual Patient Engagement, Enrollment and Retention through Communities and Technology will cover the topics one should consider when planning and strategically implementing a patient retention plan in the digital age.

KEY CONSIDERATIONS WHEN ENGAGING PATIENTS PARTNERING IN THE DRUG DEVELOPMENT PROCESS: SHARED STRATEGY, PRIVACY, CONSENT

4:00 Chairperson’s Remarks
Terrie Livingston, Pharm.D., Senior Director, Real World Outcomes, Innovative Partnerships & Insights (RI2), Biogen

4:05 Top 10 Rules of Engagement to Incorporate the Voice of the Patient in Clinical Development
Paulo Moreira, Vice President, Global Clinical Operations - External Innovation, EMD Serono

The industry is making strides in its attempt to include the voice of the patient in clinical development, but much uncertainty on how to do it still exists. Successful engagement between pharma and patients requires that some basic tenets be observed. This presentation will enumerate and discuss the top 10 rules based on several years of engaging patients to seek their input into clinical trial design and protocol operational implementation.
5:50 - 7:00 Track Reception (Sponsorship Opportunity Available)

THURSDAY, FEBRUARY 15

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

Sponsored by

APPLYING INSIGHTS FROM PATIENT COMMUNITIES AND SOCIAL NETWORKS TO IMPROVE OUTCOMES

8:30 Chairperson’s Remarks
Daniel Piekarsz, Senior Vice President, Healthcare & Life Sciences Practice Leader, DataArt

8:35 **CO-PRESENTATION CASE STUDY: How Bioverativ Identified Endpoints That Matter Most to Patients**
Briana Cox-Buckley, Pharm.D., Executive Director, US Field Medical and Value Based Outcomes, Bioverativ
Christopher O’Brien, Vice President, Strategic Partnerships, myHealthTeams

More and more patients have become reliant upon and trust online information and they have access to more information than ever before. What have we learned from the patient communities, and how can we apply those insights into better outcomes for our clinical trials? This co-presentation will share a case study with a specific example from a hemophilia patient population.

9:00 **Inclusion of Patient Reported Outcomes (PROs) in Rare Disease Trial Design: How Social Networks Can Enhance Patient Engagement and Patient Experience**
Terrie Livingston, Pharm.D., Senior Director, Real World Outcomes, Innovative Partnerships & Insights (RI2), Biogen

This presentation is given from the perspective of someone who understands clinical research both as a member of industry, but also as a patient. It will cover: Developing meaningful patient reported outcomes by gathering information about their disease journey through an independent social network, whether PROs will be used to run 3b trials to produce further evidence to support approval, strategies and tools to enhance patient engagement and patient experience.

9:25 **PANEL DISCUSSION: Understanding the Power of Social Networks to Facilitate Engagement, Education, Research and Recruitment**
Moderator: Pablo Graiver, Co-Founder & CEO, Antidote
Helen Kellar-Wood, Ph.D., Lead, Immunoscience Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb
Eric Peacock, Co-Founder & CEO, myHealthTeams
Gilles Frydman, Patient Advocate, Co-Founder Smart Patients and ACOR

10:30 Chairperson’s Remarks
Sandra Shpilberg, CEO & Founder, Seeker Health

Helen Kellar-Wood, Ph.D., Lead, Immunoscience Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb
Mary Murray, Associate Director, Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb

Patient engagement does not always look and feel the same from internal and external perspectives. How can patient engagement strategies be developed to perpetuate an ongoing and robust conversation with patients as partners? The speakers will address this question, sharing examples and unexpected experiences from the past few years that have led to the development of a new approach.

11:00 **Patient Engagement Strategies to Increase Clinical Study Awareness, Interest, and Referrals Across Indications**
Barbara B. Zupancic, MS, MBA, Director, Global Patient Recruitment and Retention, Worldwide Clinical Trials

11:25 Transition to Shared Session

**M-HEALTH’S POTENTIAL TO IMPROVE PATIENT CENTRICITY AND THE CONDUCT OF CLINICAL TRIALS**

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Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)
Many innovative technologies and process improvement initiatives are coming out at a rapid pace, whether from TransCelerate and other industry consortia, or from technology companies themselves. Which of these improvements actually work? How can sites implement these more effectively? Why are there barriers to adoption, and how can the innovators better understand sites’ needs?
- Share sites’ perspective on the evolving clinical research landscape
- Discuss the reasons sites struggle with new processes and technology tools
- Determine ways to facilitate adoption

1:15 Closing Remarks
1:20 SCOPE Summit 2018 Adjourns
# Inaugural Resource Management and Capacity Planning for Clinical Trials

**Metrics and Strategies for Efficient Resource Forecasting and Management**

February 14-15, 2018

Resource management and capacity planning is an essential step in setting up clinical trials. As protocols become more complex and as more partners are being used to execute them, the need to properly manage staff, workload, and outsourced partners is more essential than ever to run efficient clinical trials and get programs executed on time and within budget with as little variance as possible. Resource managers and capacity planners must gather input from executives in finance and those at the portfolio level, as well as from those in clinical operations and at the project level in order to understand the scope of projects in the pipeline, the effect complex protocols have on planning and timelines, and where internal and external resources may fall short. Operations managers and the budget team must ultimately be able to find the balance between cost savings and high performance. Cambridge Healthtech Institute’s Inaugural Resource Management and Capacity Planning for Clinical Trials conference will share case studies and best practices on clinical trial finance and capacity planning, metrics for resource management algorithms, maximizing efficiency of internal-external resources, optimizing staff, and managing changes and delays.

### WEDNESDAY, FEBRUARY 14

- **11:30 am** Registration Open
- **12:10** Bridging Luncheon Presentation to be Announced
- **12:50** Coffee and Dessert Break in the Exhibit Hall
- **1:30** Plenary Keynotes (click here for details)
- **3:00** Valentine’s Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

### ANALYTICAL STRATEGIES FOR RESOURCE PLANNING, FORECASTING, AND BUDGETING

- **4:00** Chairperson’s Remarks
- **4:05** An Analytical Approach to Making Informed Decisions around Resource Management
  - Geoff Kremer, Director, CMR Informatics, Strategy & Operational Effectiveness, Novo Nordisk

Innovative tools and analytics are a key tool in enabling informed decision-making around resource management. This talk will discuss various ways to optimize resource management operations with analytics and data visualization.

### 4:30 Quantitative and Qualitative Factors for Outsourcing versus Using Internal Resources

**Chris Chan, Executive Director, R&D Finance, Finance, FibroGen, Inc.**

One very important decision that biopharmaceutical companies need to make is what outsourcing strategy to pursue. Given the enormous cost and inherent complexity of the drug development process, this decision may play a key role in determining whether a company ultimately achieves its goals. This presentation will explore both quantitative (money!) and qualitative (money isn’t everything!) factors that companies should consider when determining the right outsourcing strategy.

### 4:55 Fostering a Committed Organization for Clinical Operations

**Geert Vanhove, Partner, Bluecrux**

Bluecrux is a resource planning cloud application that targets R&D, Regulatory Affairs, Clinical Operations and Labs. On top of the “standard” features of conventional resource planning, together with clients, we work on two innovations that drastically speed up the organizational maturity and performance of PPM and resource planning. Let’s share.

### 5:10 Sponsored Presentation (Opportunity Available)

### 5:25 Predictive Clinical Resource Planning: Overview of a Bespoke Solution (SPEAR) that Converts Planned Clinical Workload to Role-Based Resource Requirements

**Grant Morgan, Ph.D., PMP, Senior Vice President & Head of Portfolio Planning, R&D Finance, Systems & Analytics, Portfolio & Project Management, BTG PLC**

The SPEAR Tool is used to analyze simple study information inputs to outputs that help resource managers better plan for the future workload.

### 5:50 Close of Day

SCOPE sets the bar for what a conference should be. A great opportunity for Sponsors, Sites and suppliers to connect and discuss truly innovative ways to improve the clinical trial process.

- **Associate Director, BMS**

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Inaugural
Resource Management and Capacity Planning for Clinical Trials
Metrics and Strategies for Efficient Resource Forecasting and Management
February 14-15, 2018

5:50 - 7:00 Track Reception (Sponsorship Opportunity Available)

THURSDAY, FEBRUARY 15

7:15 am Registration Open
7:45 Breakfast Presentation to be Announced

CONSIDERATIONS FOR EFFECTIVE CAPACITY PLANNING AND RESOURCE MANAGEMENT FOR SITES

8:30 Chairperson's Remarks

8:35 Resource Management in a Managed Network at a National Level: Lessons from the NIHR Clinical Research Network
Diya Chadha Mane, Head of Business Development (Commercial), Clinical Research Network, National Institute of Health Research
The NIHR Clinical Research Network is a government-funded research network that faces unique challenges related to resource management at a national level. This talk will discuss how resources are moved throughout the business and across sites in order to properly support hundreds of clinical trials. We will also review how the finance model affects decision-making around resource planning and optimizing the efficiency of clinical trials across the UK.

9:00 CO-PRESENTATION: Workforce Resource Management: Managing Onboarding and Training for Key Functional Area Roles
Erika Stevens, MA, Vice President, Research, Northwell Health
Liz Wool, RN, BSN, CCRA, CMT, Global Head of Training, Barnett International
In today's fast paced clinical research industry with heightened expectations of quality and qualified staff, effective on-boarding (beyond company orientation) requires a systematic review and analysis of key functional roles in order to strategically align and allocate resources for the development of efficient-reproducible on-boarding practices across the enterprise. This session reviews methods and analysis practices for deployment of on-boarding and training to include re-alignment when necessary, based upon organizational needs.

9:25 PANEL DISCUSSION: What Sponsors and CROs Need to Know about Site Capacity Planning
Moderator: Jim Kremidas, Executive Director, Association of Clinical Research Professionals
Panelists: Jeff Kingsley, CEO, IACT Health
David Morin, Director, Research, Holston Medical Group
John Neal, Founder and Chairman, PCRS Network
Sites have a unique set of challenges when developing a resource management plan for their clinical trials, a process that evades many sponsors and CROs. This panel discussion will address a number of ways sites do capacity planning, how it differs from a sponsor or CRO strategy, and what sites wish these partners knew in order to close the gap in understanding. This panel will provide strategies for sponsors and CROs to improve their own budgets and resource management based on this information.

• Discuss methods sites use to estimate staffing requirements
• Review tools to drive site efficiency
• Discuss the implications on current site payments (fee for service) vs. performance-based payment structures

9:50 Sponsored Presentation

10:15 Networking Coffee Break

10:30 Chairperson's Remarks

10:35 Project Level Resourcing: A Journey of Resource Management
Lisa Hegg, Ph.D., Vice President, Head Project Planning and Management, Project Management and Business Performance, GSK
The drug development process is complex and expensive, and the ability to accurately forecast project resource is critical to identifying and managing key touch points across a portfolio of projects. We will discuss how improving resource capacity forecasting and integrating with planning across projects will enable us to effectively move resources and enable effective decision-making across the business to support a dynamic portfolio of medicines.

11:00 Sponsored Presentation (Opportunity Available)

11:25 Brief Session Break
11:35 Driving Accountability for Resource Efficiencies in Clinical Development
Tara Dubois, MBA, Head, Clinical Trial Cost Management, Business Operations, Pfizer
Teams and business leaders often have great ideas about how to make clinical trial execution more efficient and reduce spend. As budgets get tighter, there is an increasing need to hold leaders accountable to delivering those efficiencies and ensuring they translate to the bottom line. This presentation will focus on how to connect the dots from idea to implementation and assess the impacts on contracts, budgets and resource algorithms in a large complex organization.

12:00 pm Achieving Agile Resource Management in Big Pharma in Early Clinical Trials: Challenges and Successes in AstraZeneca Early Clinical Development
Charles O'Donnell, Director, Early Clinical Development Portfolio, AstraZeneca
The Early Clinical Development (ECD) group in AstraZeneca is novel and forming, with a need to be agile, pioneering and collaborative. I will describe the history, challenges and successes in managing capacity and resource in a large Pharma. Specifically, approaches to building and using resource algorithms will be described and our evolving approach to different clinical trial delivery models which utilize resource that is both internal and external. In addition, the presentation will provide insight into some of the cultural challenges faced by a small clinical group that has hatched out of a big clinical organization.

12:25 Human-Centered Design in Clinical Trial Operations: Setting Your Team Up for Success
Heather Baldwin, MPH, Principal Consultant, Frogbottom Consulting, LLC
Solutions to challenges in clinical research operations must be Business Viable, Technology Feasible, and Human Desirable to create real and lasting impact. Using Human-Centered Design in clinical trial operations engages the team at the heart of operations to come up with a range of solutions to the challenges they face each day. Sponsors, CROs and sites that use HCD with their operations team would benefit by increasing job-ownership and satisfaction, decreasing turn-over and training costs, decreasing start-up and enrollment periods, and decreasing team performance redundancies.

12:50 Closing Remarks
1:00 SCOPE Summit 2018 Adjourns
Managing Outsourced Clinical Trials
Forming Effective and Quality Partnerships

As more clinical trial activities are outsourced to contract research organizations (CROs) and other third-party vendors, sponsors and their partners must form effective and quality partnerships. Effective management of outsourced clinical trials requires realistic and explicit expectations from each partner in the outsourcing relationship as well as effective oversight and the ability to measure partnership and project performance and quality. Cambridge Healthtech Institute's 4th Annual Managing Outsourced Clinical Trials conference features case studies and lessons learned from sponsors and CROs on vendor quality and performance in light of the new ICH E6 R2 changes, as well as the outsourcing partnership and working with third party suppliers to achieve more efficient clinical trials.

Arrive early and attend Part 1: Mastering an Outsourcing Strategy. Click here for details.

**WEDNESDAY, FEBRUARY 14**

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12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Plenary Keynotes (click here for details)

3:00 Valentine's Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

**VENDOR QUALITY AND PERFORMANCE**

4:00 Chairperson's Remarks

Walter Young, External Partner Engagement & Governance Lead, CSL Behring

4:05 Sponsor Oversight of Service Providers: Thoughts from a Quality Perspective

Joanne Spallone, Global Development Quality Audit Head, Franchise Operations and Strategy, Novartis

Within our industry, every clinical trial employs third party services to some extent. Everyone knows that the trial sponsor must provide appropriate oversight for the external service providers. But how do we define "appropriate oversight"? What is "effective oversight"? This talk will provide a QA perspective, having observed examples from Sponsors’ and Health Authorities’ perspectives.

4:30 Sponsored Presentation (Opportunity Available)

4:55 PANEL DISCUSSION: Vendor Quality and Oversight in Light of the New ICH E6 R2 Changes

Joanne Spallone, Global Development Quality Audit Head, Franchise Operations and Strategy, Novartis

Diane Miller, Director, Vendor Management, AbbVie

Richard O’Hara, Associate Director, Clinical Outsourcing, Endo Pharmaceuticals

Panelist to be Announced, Advanced Clinical

With increased pressure of the ICH E6 R2 addendum changes on quality and oversight in clinical trials, Sponsors and CROs are concerned with ensuring quality partnerships. This panel will discuss KPIs for vendor quality, quality metrics, and how Sponsors and CROs are approaching their relationships with quality in mind.

5:50 Close of Day

5:50 - 7:00 Track Reception (Sponsorship Opportunity Available)

**THURSDAY, FEBRUARY 15**

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

**BUILDING MORE EFFECTIVE PARTNERSHIPS**

8:30 Chairperson's Remarks

Sagarika Bollini, Director, Head of Clinical Partner Management, Central Clinical Planning and Solutions, Global Clinical Operations, Bristol-Myers Squibb

Discuss key components to CRO/sponsor relationship management and building a framework of trust within the partnership. Can we create a culture...
Managing Outsourced Clinical Trials

Forming Effective and Quality Partnerships

February 13-14

Protocol Development, Global Site Selection, Feasibility and Site Management
Enrollment Planning and Patient Recruitment
Clinical Trial Forecasting, Budgeting and Contracting
Mastering an Outsourcing Strategy
Implementing Risk-Based Monitoring - Part 1
Clinical Data Strategy and Analytics
Sensors, Wearables and Digital Biomarkers in Clinical Trials NEW
Late Stage Research and Observational Studies
Biospecimen, Central Lab and Technology for Late Stage Research and Observational Studies
Clinical Trials NEW

February 14-15

Improving Site-Study Activation and Performance
Patent Engagement, Enrollment and Retention through Communities and Technology
Resource Management and Capacity Planning for Clinical Trials NEW
Managing Outsourced Clinical Trials
Implementing Risk-Based Monitoring - Part 2
Artificial Intelligence in Clinical Research NEW
Clinical Technology and Innovation
Leveraging Real-World Data for Clinical and Observational Research
Clinical Supply Management NEW

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4th Annual

Making Meaningful Supplier Segmentation

Understanding the true business levers and drivers to make meaningful supplier segmentation. Careful consideration should be given to levers that encompass inherent business risk as well as those that drive value. The segmentation or classification process should be made distinct to clearly drive the message as to the oversight and management of the classification. Meaningful classification translates into recognizable benefits to internal stakeholders.

9:25 Supplier Segmentation and Classification: How to Make It Meaningful
Marija Nikolic, Associate Director, Vendor Management, Contracts & Outsourcing, Astellas Pharma Global Development

This presentation will focus on how to go about understanding the true business levers and drivers to make meaningful supplier segmentation. Careful consideration should be given to levers that encompass inherent business risk as well as those that drive value. The segmentation or classification process should be made distinct to clearly drive the message as to the oversight and management of the classification. Meaningful classification translates into recognizable benefits to internal stakeholders.

9:50 Sponsored Presentation (Opportunity Available)

10:15 Networking Coffee Break

10:30 Chairperson's Remarks

10:35 Establishing a Common Process for the Management and Escalation of Supplier Performance: From Manufacturing to Drug Development
Marisa Bower, Director, Global Supplier Management & Supply Business Development, Merck

The session will highlight implementation of an end-to-end supplier performance management process that ensures reliable and compliant supply and service delivery. It will outline the commercial importance of deploying consistent methodology, developed by the direct side of our business, to align all categories across a large, global procurement organization. The methodology results in creation of a framework that ensures optimal performance from key suppliers, scorecards to enable consistent supplier evaluation, and supports a common way of working across categories, suppliers and stakeholders. Criteria for segmentation must be established and agreed by all impacted stakeholders. The management of all suppliers in a specific segment must be consistent in terms of governance, corrective action planning, VOC data collection and frequency of segmentation. The process for managing suppliers who support multiple areas of business must be well-structured in order for data to be meaningful and can have benefit to procurement colleagues and stakeholders through the business.

11:00 Sponsored Presentation (Opportunity Available)

11:25 Brief Session Break

11:35 Contracting Dilemmas - Should the Sponsor or CRO Contract with Third Parties?
Lan Bandara, Director, Pharmaceutical Contract Management Group (PCMG); Director, Clinical Outsourcing, Medicines Development Centre, Coordination Department, Eisai Limited

The talk covers 1. Different contract models, 2. Pros and cons of each model with reference to new ICH E6 R2 guidelines, 3. Lessons learned from recent case studies.

12:00 pm PANEL DISCUSSION: Where Is the Industry Headed with 3rd Party Suppliers?
Christopher Rull, Principle Consultant, CR Consulting, LLC; Former Vice President, Head of Business Development & Account Management, UBC Charlotte French, Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas
Craig Coffman, Executive Director, Clinical Business Operations & Outsourcing, Nektar Therapeutics

As CROs are tasked with outsourcing more services on behalf of Sponsor companies, where is the industry headed with this practice? This panel will address the following questions: Are CROs equipped to effectively outsource for additional service providers? When Sponsors outsource to CROs, is the CRO’s capability to outsource additional services a factor in deciding to partner with a particular CRO? How is oversight and accountability of deliverables being handled? What are some best practices and lessons learned when CROs are outsourcing multiple services?

12:50 Closing Remarks

1:00 SCOPE Summit 2018 Adjourns
Risk-based monitoring (RBM) approaches promise to improve clinical trial efficiency while ensuring data quality. As industry adoption of RBM increases, it is clear that although RBM takes many forms – remote, centralized, and risk-based monitoring – successful risk-based monitoring implementation requires developing new roles, analytics and processes among the stakeholders in RBM. Cambridge Healthtech Institute's 4th Annual Implementing Risk-Based Monitoring – Part 2: Ensuring Effective and Efficient Monitoring and Data Quality conference offers case studies and practical solutions from across pharma and TransCelerate member organizations on effectively implementing clinical quality and RBM as well as a prospective look into the future of RBM.

Arrive early and attend Implementing Risk-Based Monitoring – Part 1. Click here for details.

**Wednesday, February 14**

11:30 am Registration Open

12:10 pm Bridging Luncheon Presentation: Extracting Data from the EHR Dramatically Reduces the Need for Manual Monitoring. New Standards Make this Possible

Keith Howells, CTO, Omnicomm

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Plenary Keynotes (click here for details)

3:00 Valentine's Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

**CASE STUDIES ON HOW PHARMA IS TACKLING THE CHALLENGES OF RISK-BASED MONITORING**

4:00 Chairperson's Remarks

4:05 PANEL DISCUSSION: A Cross-Functional Look at RBM from Abbott Nutrition's RBM Task Force

Moderator: Sonya Verrill, Manager, Clinical Projects, Clinical Operations, Abbott Nutrition

Panelists:

- Geraldine Baggs, Ph.D., Principal Research Statistician, Statistical Sciences, ANRD Scientific and Medical Affairs, Abbott Nutrition
- Dione Smart, Research Data Coordinator, Clinical Data Management, Abbott Nutrition
- Xiaosong (Sue) Zhang, MS, MAS, Staff Statistical Analyst, Clinical Program & System Support, Abbott Nutrition

8:30 Chairperson's Remarks

**Thursday, February 15**

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

**RBM: WHERE ARE WE AND WHAT IS NEXT?**

8:30 Chairperson's Remarks

**Andy Lawton, Director & Consultant, Risk Based Approach Ltd.**

8:35 Best Practices and Observations from Implementing TransCelerate's Risk-Based Monitoring Model Framework

**Suzanne Lukac, Director, Risk-Based Monitoring Implementation, Merck**

Although Regulators were urging companies to move to a risk-based approach, no model framework existed to enable organizations to successfully deploy and scale risk-based monitoring. To address this, a collaboration of 18+ Sponsor Companies worked in an unprecedented way to develop a model approach for
Implementing Risk-Based Monitoring – Part 2
Ensuring Effective and Efficient Monitoring and Data Quality

risk-based monitoring. This session will share the latest work of this initiative, including new tools to assist implementation, best practices for adoption, and post-adoption metrics and observations.

9:00 Developing a Risk Repository
Adrienne Strickler, Associate Director, Risk Management-Central Monitoring, Janssen
What comes next after your Risk-Based Monitoring process is established? Process improvement! After 4 years of RBM at Janssen R&D, our portfolio has grown to include well over 150 trials and we are now able to gain efficiencies by applying lessons learned across similar studies. One key way to do so is through a central risk repository that can be used to streamline RBM set-up and implementation for new trials.

9:25 CO-PRESENTATION: The Quality Journey - A Small Companies Approach to the Implementation of ICH E6 and RBM
Yiwen Sun, Senior Clinical Research Associate, Samumed, LLC
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
This presentation will be in two parts, firstly examining the overall quality imperative within the clinical trial arena and the second part will focus on Samumed’s ICH E6 and RBM journey to current status and future direction. Key points: 1. Understand the quality requirement expected of sponsors, 2. What can be achieved by a small company, current status, and 3. Future direction.

10:15 Networking Coffee Break

10:30 Chairperson’s Remarks
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

10:35 RBM: A Larger Sponsor’s Approach
Taras Carpiac, Director, Global Development Operations, Amgen
Amgen began its RBM journey in 2012. In the years since, Amgen has continued to make investments in its RBM process and tools in order to align with regulations and in response to industry developments. This presentation will examine the principles of Amgen’s RBM model and highlight areas of new focus.
Artificial intelligence (AI) and machine learning (ML) have propelled many industries toward a new highly functional and powerful state. Now they are starting to make their way into the clinical research realm. Many pharmaceutical companies and larger CROs are starting projects involving some elements of AI, ML and robotic process automation in clinical trials. To facilitate the discussion and to accelerate the adoption of these approaches in clinical trials, Cambridge Healthtech Institute presents the Inaugural Artificial Intelligence in Clinical Research conference, part of 9th Annual SCOPE Summit.

**Wednesday, February 14**

**11:30 am Registration Open**

**12:10 pm Bridging Luncheon Presentation:** Centralizing Data to Address Imperatives in Clinical Development  
*Munther Baara, Senior Director, Development Business Technology, Pfizer*

**12:50 Coffee and Dessert Break in the Exhibit Hall**

**1:30 Plenary Keynotes (click here for details)**

**3:00 Valentine’s Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing**

**BLOCKCHAIN, ML, AI**

**4:00 Chairperson’s Remarks**

Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb

**4:05 Blockchain Disruption: How Blockchain Will Change Our Industry**

Munther Baara, Senior Director, Development Business Technology, Pfizer

Imagine a solution that makes it easy to aggregate health data in a secure, trusted, automated, and error-free way, a solution which enforces rules, privacy, and regulations in a mutually agreed upon manner, resulting in a smart-contract between patient and healthcare stakeholders. This enables patients to aggregate their data from diverse health sources and share what they choose to with their physicians and researchers. All this puts the patient in control of their health and well-being, rather than being along for the ride: How it works, key benefits, empowering the patients with control over their data.

**4:30 Exploration of Where Machine Learning Will Help in the Product Development Process in the Pharmaceutical Industry**

Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche

The talk will explore how Machine Learning is and will change how Product Development is carried out in the industry from improving efficiencies, gaining more insights on products, improved surveillance of products, especially safety, and its use in IoT devices.

**4:55 Leveraging Digital Transformation to Unify Data and Process and Boost Clinical Operations**

Evi Cohen, Vice President, Global Pharma & Life Sciences, Appian

Conducting and managing a successful, safe clinical trial is complicated. With massive data and complex processes at the core, it’s no surprise innovation in Business Process Management (BPM) is behind many successful trials.

**5:25 Intelligent Clinical Trial Design, Planning and Conduct**

Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb

As technology evolves and AI solutions become more sophisticated, there is a natural demand to test and apply them in areas that were traditionally expert opinion-guided. This presentation is about early experiences and challenges of applying technology - including AI and ML - that are starting to apply AI in the R&D space to promote precision oncology, identify targets, design and plan trials and translate strategy to efficient operational execution.

**5:50 Close of Day**

**5:50 - 7:00 Track Reception (Sponsorship Opportunity Available)**

**Thursday, February 15**

**7:15 am Registration Open**

**7:45 Breakfast Presentation to be Announced**

**AI AND ML IN CLINICAL TRIALS**

**8:30 Chairperson’s Remarks**

Vikram Gupta, Technology Innovation Senior Manager, Amgen

**SCOPEsummit.com | 54**
8:35 CO-PRESENTATION: AI and Machine Learning for Clinical Trials
Vikram Gupta, Technology Innovation Senior Manager, Amgen
William Wang, Technology Strategy, Innovation Senior Manager, Amgen
While technology will probably never completely replace HCPs, machine intelligence (Machine Learning, Natural Language Processing (NLP), and Artificial Intelligence (AI)) is transforming healthcare by improving outcomes and changing the way healthcare professionals think about providing care and manage clinical trials.

9:25 Clinical Trials Innovations in the Age of Big Data and Advanced Analytics
Kaushik Raha, Ph.D., Associate Director, Head, Emerging Analytics and Advanced Visualizations, Data Sciences Pharma IT, Janssen Pharmaceuticals
This talk will share advanced analytics approaches in clinical research. Examples and case studies will be shared to demonstrate some strategic points and approaches.

9:50 AI Guided Patient Selection to Elevate the Clinical Trial Efficiency and Accelerate Positive Outcomes
Slava Akmaev, PhD, Senior Vice President & Chief Analytics Officer, BERG
Drug development is well positioned to benefit from data driven approaches integrating disparate data types and delivering actionable insight with a commercial impact. The BERG AI driven platform, Interrogative Biology® identifies novel biochemical markers in phase I/II clinical studies for patient selection in registrational trials increasing the likelihood of success.

10:05 Presentation to be Announced

11:00 CO-PRESENTATION: Semi Automated CSR Narratives
Avanti Karandikar, Senior Manager, Clinical Business & System Analysis RDIS, MedImmune (AstraZeneca Biologics)
Dorian Zoumplis, M.S. Biotechnology, Senior Innovation Project Manager, Technology Innovation & Delivery Excellence, AstraZeneca
This presentation will include topics such as: Create quality CSR narratives that are consistent across a therapeutic area and/or compound, scope, save time and effort on behalf of the author; reduction in cost associated with (e.g. costs associated with service providers) writing narratives from scratch, create narratives based on a template with specifics to protocol and/or compound, allow for collected data points to be pre-populated to avoid mistakes in study day calculations, event onset/resolution dates, etc.

10:20 Networking Coffee Break

11:35 CO-PRESENTATION: AI - Machine Learning for Clinical Data Management, a Pilot Case Study
Abhay Jha, Principal, Business Technology Lead, R&D Excellence Practice, ZS Associates
Venkat Sethuraman, MBA, Ph.D., Associate Principal, ZS Associates
Machine Learning can aid Clinical Data Management with smart and early detection of anomalies in patient data from sites, thereby reducing the need to unlock databases frozen for submission. To explore this hypothesis, ZS used univariate and multivariate analytics and fraud detection techniques to identifying anomalies that slip through the standard data quality checks. In this session we will share our case study results including lessons learned and future plans.

12:00 pm PANEL DISCUSSION: How to Make All the Data Machine Learnable?
Moderator: Munther Baara, Senior Director, Development Business Technology, Pfizer
Panelists: Kaushik Raha, Ph.D., Associate Director, Head, Emerging Analytics and Advanced Visualizations, Data Sciences Pharma IT, Janssen Pharmaceuticals
Vikram Gupta, Technology Innovation Senior Manager, Amgen
William Wong, Technology Strategy, Innovation Senior Manager, Amgen
Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb
• Leveraging data for machine learning projects
• Implementing robust data standards
• Analyzing big data using machine learning algorithms
12:50 PANEL DISCUSSION: Why Are There Barriers to the Adoption of Innovative Processes and Technologies at Sites?

Moderator: Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)

Panelists: David Vulcano, Assistant Vice President & Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)
Sean Walsh, MBA, CDO, Raleigh Neurology Associates
Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)

Many innovative technologies and process improvement initiatives are coming out at a rapid pace, whether from TransCelerate and other industry consortia, or from technology companies themselves. Which of these improvements actually work? How can sites implement these more effectively? Why are there barriers to adoption and how can the innovators better understand sites’ needs?
• Share sites’ perspective on the evolving clinical research landscape
• Discuss the reasons sites struggle with new processes and technology tools
• Determine ways to facilitate adoption

1:15 Closing Remarks
1:20 SCOPE Summit 2018 Adjourns
Digital technology, mobile solutions, novel data collection modalities and integrative systems are becoming game-changing features of modern clinical trials. However, the adoption of novel technology solutions to improve overall outcomes and garner operational efficiencies has been slower than expected. Cambridge Healthtech Institute’s 7th Annual Clinical Technology and Innovation conference will feature a broad array of topics such as blockchain technology, machine learning, digital trends, and their adoption and implementation in clinical research. We are looking forward to hosting a practical and productive knowledge and experience exchange.

**WEDNESDAY, FEBRUARY 14**

11:30 am **Registration Open**

12:10 pm **Bridging Luncheon Presentation:** Streamline Clinical Trials with the Industry’s Only Proven Clinical Operations Suite - DrugDev Spark™

Brett Kleger, Chief Commercial Officer, DrugDev

12:50 **Coffee and Dessert Break in the Exhibit Hall**

1:30 **Plenary Keynotes (click here for details)**

3:00 Valentine’s Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

**BLOCKCHAIN, ML, AI**

4:00 **Chairperson’s Remarks**

Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb

4:05 **Blockchain Disruption: How Blockchain Will Change Our Industry**

Munther Baara, Senior Director, Development Business Technology, Pfizer

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4:30 **Exploration of Where Machine Learning Will Help in the Product Development Process in the Pharmaceutical Industry**

Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche

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4:55 **Leveraging Digital Transformation to Unify Data and Process and Boost Clinical Operations**

Evi Cohen, Vice President, Global Pharma & Life Sciences, Appian

Conducting and managing a successful, safe clinical trial is complicated. With massive data and complex processes at the core, it’s no surprise innovation in Business Process Management (BPM) is behind many successful trials.

5:25 **Intelligent Clinical Trial Design, Planning and Conduct**

Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb

As technology evolves and AI solutions become more sophisticated, there is a natural demand to test and apply them in areas that were traditionally expert opinion-guided. This presentation is about early experiences and challenges of piano companies - including BMS - that are starting to apply AI in the R&D space to promote precision oncology, identify targets, design and plan trials and translate strategy to efficient operational execution.

5:50 **Close of Day**

5:50 - 7:00 **Track Reception (Sponsorship Opportunity Available)**

**SCOPE was the perfect conference to attend! The conference size was just right that allowed for great learning from a variety of organizations. The topics were relevant to the current issues being discussed today. And, majority of the attendees were in management level positions which allowed for even better interactions and discussions during the sessions due to the level of experience shared from everyone. It’s a conference you don’t want to miss!**

- Clinical Operations Consultant, Gilead Sciences, Inc.
7th Annual
Clinical Technology and Innovation
Disruptive Technologies for Data and Trial Management

February 14-15, 2018

THURSDAY, FEBRUARY 15

7:15 am Registration Open
7:45 Breakfast Presentation to be Announced

REMOTE TRIALS AND DIGITAL TECHNOLOGY

8:30 Chairperson's Remarks
Julie Dietrich, MS, Director, Development Design Center, Amgen

8:35 Remote Data Monitoring: Ideal Model versus Current Practices
Charlie Romano, Vice President, Global Clinical Operations, Peachtree Bioresearch Solutions

This presentation will discuss qualitative and quantitative research conducted by the Clinical Trials Transformation Initiative to understand the perspectives of patients and site investigators of mobile clinical trials. Discussion will include insights and advice from site investigators who have participated in trials that incorporate mobile devices to collect data for study endpoints. Key findings from a survey of patients in four therapeutic areas will also be presented, focusing on factors important to the design and conduct of clinical trials involving mobile devices.

9:00 CO-PRESENTATION: How Technology Can Enable Patient-Centric Clinical Research
Julie Dietrich, MS, Director, Development Design Center, Amgen
Sindhya Govind, Specialist Business Systems Analyst, Amgen

Presentation highlights will include: Opportunities for technology to be part of a patient-centric strategy and improve patients’ experience with clinical research.

9:25 Talk Title to be Announced
Theodora Sarver, Manager, Product Management, Almac Clinical Technologies

9:50 Real World Innovation and Application in Pipeline Data Approaches
Amelia Wall Warner, Ph.D., RPh, CEO & Founder, Global Specimen Solutions

Pharmaceutical companies have collected vast amounts of data during a clinical trial, yet only ~20% of the data is used. Disparate data sources, unaligned data, and incomplete data sets prevent in-life interventions, lead to delays in go to market, and can lead to non-compliance with regulations. In this presentation, we will discuss case studies that empowered translational medicine and clinical operations teams to make decisions that advanced drug development.

10:15 Networking Coffee Break

REMOTE TRIALS AND DIGITAL TECHNOLOGY (CONT.)

10:30 Chairperson's Remarks

10:35 CO-PRESENTATION: Incubating Digital Innovation Across the Clinical Trial Process
Leyla Rich, IT Business Partner, Digital Health, Information Technology, Bristol-Myers Squibb
Erin Rossi, Category Manager, Clinical Core Technologies, Global Procurement, Bristol-Myers Squibb

Our internal working group is executing a number of proof-of-concepts (POCs), pilots, and tests in 2017 to evolve the digital clinical trials landscape at Bristol-Myers Squibb aligned to our enterprise strategy and with a focus on patient and site experience. These POCs focus on telemedicine, Quality of Life (QoL) metrics via wearables and sensors, and the use of digital technologies for adverse event reporting in Clinical Trials. As part of the session we will also share the outcomes from these experiments.

11:00 CO-PRESENTATION: Zero UI: The Next Generation of IVR
Chris Watson, Director, Product Strategy, Digital Patient, ERT
Gavin Birchall, Senior Solutions Consultant, Digital Patient, ERT

Voice assistants and conversational AI platforms are ushering in a new era of global data collection, overcoming barriers to this and opening up participation to broader patient populations, including those with physical disabilities, declining dexterity and different literacy levels. Embracing intelligent voice assistant technology not only offers new ways of capturing data, it's a powerful -- and cost effective -- way to increase patient engagement, improve care coordination, enhance education and deliver real-time insights.

11:25 Transition to Shared Sessions

M-HEALTH’S POTENTIAL TO IMPROVE PATIENT CENTRICITY AND THE CONDUCT OF CLINICAL TRIALS

11:35 Digital Trends Impacting Recruitment, Engagement and Retention
Shwen Gwee, Head, Digital Strategy, Global Clinical Operations, Biogen

Digital technology is connecting more people to clinical trials than ever before and at the same time the adoption of wearables as data collection devices in clinical trials is rising. The hope of streamlining trial operations, patient recruitment and registration is real. What technologies and approaches are having the greatest impact on recruitment, engagement and retention?
12:00 pm CASE STUDY: The Art and Science of Patient Engagement in the Digital Era – Learning from GSK PARADE Study
Michelle Crouthamel, Lead, Clinical Innovation & Digital Platforms Unit, GlaxoSmithKline
The ability to efficiently develop new medicines for patients with unmet needs is limited by the current model for clinical development. Although the emerging mHealth technologies have the potential to improve the conduct of clinical trials, the successful implementation requires careful study design and patient engagement. Data and experiences from GSK PARADE study will be summarized, highlighting the learning and opportunities in this new area of clinical development.

12:25 Mobile Clinical Trials: New Findings on Patient and Site Perspectives from the Clinical Trials Transformation Initiative
Hassan Kadhim, Business Consultant for Clinical Operations, Boehringer Ingelheim Pharmaceuticals
This presentation will discuss qualitative and quantitative research conducted by the Clinical Trials Transformation Initiative to understand the perspectives of patients and site investigators of mobile clinical trials. Discussion will include insights and advice from site investigators who have participated in trials that incorporate mobile devices to collect data for study endpoints.

12:50 PANEL DISCUSSION: Why Are There Barriers to the Adoption of Innovative Processes and Technologies at Sites?
Moderator: Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)
David Vulcano, Assistant Vice President & Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)
Sean Walsh, MBA, Chief Development Officer, Raleigh Neurology Associates
Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)
Many innovative technologies and process improvement initiatives are coming out at a rapid pace, whether from TransCelerate and other industry consortia, or from technology companies themselves. Which of these improvements actually work? How can sites implement these more effectively? Why are there barriers to adoption, and how can the innovators better understand sites’ needs?
• Share sites’ perspective on the evolving clinical research landscape
• Discuss the reasons sites struggle with new processes and technology tools
• Determine ways to facilitate adoption

1:15 Closing Remarks
1:20 SCOPE Summit 2018 Adjourns
The abundance of data generated during routine health care is growing in significance and should be re-used for clinical and observational research. Patient electronic records, registries, data from pharmacy and social media, and wearable sensors have been increasingly used as eSources. This process requires strategizing, utilizing novel data technologies, as well as close collaboration between pharmaceutical companies and organizations that possess the data. CHI’s 3rd Annual Leveraging Real World Data for Clinical and Observational Research will discuss challenges and solutions with secondary use of existing healthcare data for assessing the effectiveness and safety of medical products.

**Arrive early and attend Part 1: Late Stage Research and Observational Studies. Click here for details.**

**WEDNESDAY, FEBRUARY 14**

**11:30 am Registration Open**

**12:10 pm Bridging Luncheon Presentation: Achieving Evidentiary Equilibrium**

David Thompson, Ph.D., Senior Vice President, Real-World & Late Phase, INC Research/inVentiv Health

Achieving Evidentiary Equilibrium - Generating the Right Evidence for the Right Stakeholders at the Right Time Throughout the Clinical/Commercial Continuum

**12:50 Coffee and Dessert Break in the Exhibit Hall**

**1:30 Plenary Keynotes (click here for details)**

**3:00 Valentine's Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing**

**RWE TO INFORM STUDY DESIGN AND EXECUTION**

**4:00 Chairperson's Remarks**

Sean Mooney, Ph.D., Chief Research Information Officer, UW Medicine

**4:05 Systematic Approach to Use RWD to Inform Trial Design: Going beyond Simple Feasibility**

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

We developed a structured framework to guide the use of RWD to inform clinical trial design. This framework consists of three dimensions: recruitability, efficacy endpoint impact and risk impact. Each major criterion in the trial inclusion/exclusion criteria can be assessed on how it would impact the size of patient pool, the efficacy endpoints and risks. This framework was validated via its application on pre-authorization pivotal trials.
THURSDAY, FEBRUARY 15

7:15 am **Registration Open**

7:45 **Breakfast Presentation to be Announced**

**INTEGRATING EHR THROUGHOUT THE LIFE CYCLE OF DRUG PRODUCTS**

8:30 **Chairperson’s Remarks**
*Chairperson to be Announced, Omnicomm*

8:35 **Optimize Your Clinical Trials Using Electronic Health Records: The Case of EHR4CR**
*Xia Wang, Ph.D., Director, Health Informatics, Global Medicines Development Unit, R&D, AstraZeneca*

This talk presents the AZ coordinated IMI project EHR4CR (Electronic Health Records for Clinical Research). The objective of EHR4CR is to research and develop a trustworthy technical platform and services to allow re-use of EHR data to support clinical research in Europe. We will also share our experiences to test and evaluate the EHR4CR InSite platform for protocol feasibility and recruitment services on a growing hospital network.

9:00 **Platform-Based Approaches in RWE: Approaches, Methodologies and Examples**
*Jyotsna Mehta, MS, B.Pharm., Principal and Owner, KevaHealth*

9:25 **Building Credibility with the Audience: Methodology**
*Elizabeth MacLean, Pharm.D., Director, Global Health and Value/Outcomes & Evidence, Pfizer*

Interest in the use of real world evidence to inform decision making in healthcare is growing. Importantly, concerns have been raised in the scientific and decision making communities regarding the reproducibility of observational studies using large healthcare databases. This presentation will review the concepts of reproducibility and transparency and efforts to guide researchers in this regard.

9:50 **Presentation to be Announced**

10:15 **Networking Coffee Break**

RWD IN EUROPE AND POC TRIALS IN US

10:30 **Chairperson’s Remarks**
*Chairperson to be Announced, Omnicomm*

10:35 **RWD from Europe to Optimize Clinical Research Processes: Creating Value for Patients, Hospitals and Sponsors/CROs**
*Tine Lewi, Ph.D., MBA, Scientific Director, Quantitative Sciences/Real World Evidence Partnerships, Janssen Global Research & Development*

This presentation will provide an in-depth understanding of platform-based approaches in real world evidence and provide examples to show its usefulness and value in drug development throughout the life cycle of drug products. It will also provide a framework of how and when to consider these for your studies and explain pros and cons through the use of examples.

9:25 **Building Credibility with the Audience: Methodology**
*Elizabeth MacLean, Pharm.D., Director, Global Health and Value/Outcomes & Evidence, Pfizer*

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10:15 **Networking Coffee Break**

Attention Pharma! 25 for 25 Special Offer

If you are an employee of the following TOP 25 Pharmaceutical companies as cited by Pharmaceutical Executive*, you may attend this meeting at a 25% discount off the current rate. Enter Keycode TOP25 when registering for SCOPE on-line.

Group registrations are encouraged and we suggest calling:

**Melissa Dolen**
*Account Manager, Cambridge Healthtech Institute*

T: 781-972-5418 | E: mdolen@healthtech.com

Get your team to Orlando at special company rates.

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10 Amgen
11 AstraZeneca
12 Allergan
13 Teva Pharmaceutical Industries
14 Bristol-Myers Squibb
15 Eli Lilly
16 Bayer
17 Novo Nordisk
18 Boehringer Ingelheim
19 Takeda
20 Celgene
21 Astellas Pharma
22 Shire
23 Mylan
24 Biogen
25 Daiichi Sankyo

The European Real World Data (RWD) scene is developing at full speed. Multiple new approaches to RWD and Big Data emerge to optimize the clinical research process. An overview of the state of the art on RWD for clinical research in Europe will be provided, with a special focus on RWD from EHRs. Use cases demonstrate the value of RWD to optimize protocol design, accelerate feasibility for site selection and ultimately support the patient recruitment. These use cases will also demonstrate benefits to the patient, the hospital, the research sponsors and CROs.

11:00 Presentation to be Announced

11:25 Brief Session Break

11:35 Conducting and Translating Research in Real-Time at Point of Care: Designing a Clinical Research Enterprise Infrastructure

Uli Chettipally, M.D., MPH, CTO, CREST Network, Division of Research, Kaiser Permanente

Improvements in information technology have provided better tools to conduct research. Electronic health records and mobile technology are now ubiquitous in care delivery environments. The design of a clinical research enterprise infrastructure should take into account these factors. This talk will discuss the design, development, and deployment of such a system at a large integrated health system.

12:00 pm Embedding Clinical Trials in the Electronic Medical Record: Challenges of Integrating Research into Clinical Care

Ryan Ferguson, Sc.D., MPH, Director, VA Cooperative Studies Program Coordinating Center

Point-of-care clinical trials (POC-CT) are a pragmatic trial design intended to reduce the burden of research for both patient and provider and to support the learning healthcare system within the VA Healthcare System. Trials are fully embedded in the electronic medical record and use only data that can be found in the corresponding data warehouse, Medicare, and the National Death Index. With this innovative design come a number of challenges associated with regulation and implementation. We will discuss these challenges and their solutions in an active clinical trial.

12:25 Enhancing Clinical Research with Data and Technology at an Academic Health System

Sean Mooney, Ph.D., Chief Research Information Officer, UW Medicine

At the University of Washington, there are many clinical research touch points with our health system, UW Medicine. Not surprisingly, this is especially relevant in activities surrounding data and information technology. In this presentation, I will discuss our efforts to leverage data and IT platforms to support research activities throughout the enterprise.
Successful, patient-centric clinical trials depend upon streamlined clinical trial supply processes that ensure that the study drug is properly handled and delivered to the right patient whether at the trial site, pharmacy, or in their home. Cambridge Healthtech Institute's Inaugural Clinical Supply Management conference offers case studies and practical solutions from across pharma focusing on effective clinical supply management from handling the study drug to direct-to-patient distribution.

**Arrive early and attend Part 1: Biospecimen, Central Lab and Technology for Precision Medicine Trials. Click here for details.**

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**Wednesday, February 14**

11:30 am Registration Open

12:10 pm Luncheon Presentation to be Announced

12:50 Coffee and Dessert Break in the Exhibit Hall

1:30 Plenary Keynotes (click here for details)

3:00 Valentine's Day Celebration in the Exhibit Hall, Last Chance for Exhibit Viewing

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**CLINICAL SUPPLY MANAGEMENT & STRATEGY**

4:00 Chairperson’s Remarks

4:05 Building an Effective End-to-End Cold Chain Supply Management Process

Doug Meyer, MBA, RPh, Associate Director, Clinical Drug Supply, Biogen, Inc.

This presentation will discuss: 1. What tools and technologies can you leverage to protect the product and avoid costly temp excursions? 2. How can you build efficient processes that ensure drug is always available for patient dosing? 3. What strategies should you adopt in your stability program to enable an efficient and scalable supply chain for temperature sensitive products?

4:30 Clinical Trial Supply Chain Strategy – Minimizing Risk and Cost

Ajay Gupta, Associate Director, Clinical Supplies, Merck

This presentation will discuss strategies and techniques that can be used to minimize risk and cost along the clinical trial supply chain. Issues related to oversight, tracking, and waste will be addressed.

4:55 Talk Title to be Announced

Paddy Hanlon, Vice President, Global Key Accounts, Marken

**Thursday, February 15**

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:30 Chairperson's Remarks

8:35 Supply Chain Integrity; Technology Tools for Tracking and Tracing Clinical Supplies

Tom Skienzdzielewski, Associate Director, Clinical Supply, Shire

This presentation will discuss: 1. Benefits of ERP system application in Clinical Supply Management (in-source vs. out-source), 2. Scoping your IRT to optimize benefit, reduce risk, and increase compliance, 3. Comprehensive Technology-Based Time Out of Environment (TOE) Management, 4. Analyzing RFID utilization in the Clinical Supply Chain, and 5. The Last Link of the Clinical Supply Chain – Site Level Management

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**Overall great event. Full of insight and food for thought!**

- Lead UX, Medidata Solutions
Clinical Supply Management
Building an Effective End-to-End Clinical Supply Strategy

9:00 IRT Considerations for Managing Clinical Supplies
Carol Lee, Associate Director, Clinical Drug Supply, Logistics, & IRT, Regeneron
This presentation will discuss: 1. Exploring methods through which IRT technology can improve clinical supply logistics, 2. Pinpointing how IRT technology can be set up to improve your logistical planning, 3. Exploring the benefits of creating your own in-house IRT system versus using a base-line vendor model, 4. Recognizing the value of IRT in clinical supply ordering and distribution, and 5. Emphasizing ways through which IRT systems can become more effective for your different trials.

9:25 IRT Data Integration Provides Big Benefits
Aaron Harlett, Director, Supply Chain Systems and Related Services, Eli Lilly and Company
It's obvious an IRT makes conducting a clinical trial more efficient and secure; from study drug forecasting and distribution to treatment group assignment and blinding. But using an IRT can provide benefits in many other aspects of trial execution. IRT allows near real-time data capture that can seamlessly integrate with multiple systems and functions while safeguarding sensitive data through automation. And combining data from an IRT with patient data from other systems can allow information alignment and facilitate reconciliation. And sharing a consistent data flow from an IRT can reduce vendor cost and play a critical role in bringing an asset to market in less time.

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9:50 Sponsored Presentation (Opportunity Available)

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10:15 Networking Coffee Break

10:30 Chairperson's Remarks

10:35 FEATURED PRESENTATION: Patient Centered Clinical Trial Material Design and Delivery
Janelle Sabo, Pharm.D., RPh, MBA, Senior Group Director, Product Delivery, Eli Lilly and Company
We will explore areas for patient-centered design and delivery in CT material, including formulation/drug product, kitting, delivery and technology. Practical current examples and inspirational goals will both be discussed to frame where we are today but where the future opportunities lies within clinical supplies.

11:00 Presentation to be Announced

11:30 Brief Session Break

11:35 The Near-Term Viability and Benefits of eLabels for Clinical, Sites and Patients
Jodi Smith-Gick, RPh, Senior Advisor, Product Delivery and Supply, Eli Lilly and Company
This session will speak to the options and benefits of utilizing eLabeling to enhance site efficiency and enhance patient centricity. Specifically discussed will be approaches, considerations when planning a study, and potential add-on technologies which can further improve productivity at sites. Specific feedback received from patients and sites on these concepts will be shared. In addition, this session will de-bunk some of the misconceptions around the near-term viability for an eLabel solution.

12:00 pm PANEL DISCUSSION: Direct-to-Patient Distribution: Meeting the Patient's Needs
Moderator: Sascha Sonnenberg, MBA, Vice President, Commercial Operations Americas & EMEA, Marken
Panelists: Gerald Finken, CSO/Founder and Innovator, Clinical Supplies Management
Janelle Sabo, Pharm.D., RPh, MBA, Senior Group Director, Product Delivery, Eli Lilly and Company
As the pharma industry moves towards more patient-centric initiatives for clinical trials, direct-to-patient distribution is growing in popularity, but many challenges still remain. Topics discussed in this panel include: 1. Investigator and site buy-in and support for direct-to-patient initiatives, 2. Logistical, cost and regulatory considerations; and 3. Challenges with patient handling of IMPs.

12:50 Closing Remarks

1:00 SCOPE Summit 2018 Adjourns