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10TH ANNUAL

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

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February 18-21, 2019
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Orlando, Florida

1,700+ PARTICIPANTS PROJECTED FOR 2019

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Event-at-a-Glance

Monday, February 18 PM	Tuesday, February 19 AM & PM	Wednesday, February 20 AM	Wednesday, February 20 PM	Thursday, February 21 AM & PM
2:00 – 5:00 pm Monday Afternoon Pre-Con User Group Meetings & Hosted Workshops **(Sponsorship Opportunities Available)**	**SITE ACTIVATION**	Conference 1A **Protocol Development, Global Site Selection, Feasibility, and Site Management**		Conference 1B **Improving Site-Study Activation and Performance**
	RECRUITMENT	Conference 2A **Enrollment Planning and Patient Recruitment**		Conference 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**
	BUDGETING & RESOURCES	Conference 3A **Clinical Trial Forecasting, Budgeting and Contracting**		Conference 3B **Resource Management and Capacity Planning for Clinical Trials**
	OUTSOURCING	Conference 4A **Mastering an Outsourcing Strategy**		Conference 4B **Managing Outsourced Clinical Trials**
	QUALITY & MONITORING	Conference 5A **Implementing Risk-Based Monitoring (Part 1)**		Conference 5B **Implementing Risk-Based Monitoring (Part 2)**
5:00 – 6:15 pm Monday Evening Kick-Off Plenary Keynote & Participant Engagement Awards	**DATA**	Conference 6A **Clinical Data Strategy and Analytics**		Conference 6B **Artificial Intelligence in Clinical Research**
	TECHNOLOGY	Conference 7A **Sensors, Wearables and Digital Biomarkers in Clinical Trials**		Conference 7B **Clinical Technology and Innovation**
	REAL WORLD EVIDENCE	Conference 8A **Late Stage Research and Observational Studies**		Conference 8B **Leveraging Real World Data for Clinical and Observational Research**
6:15 – 7:15 pm SCOPE's Kick-Off Networking Happy Hour	**BIOMARKERS & BIOSPECIMENS**	Conference 9A **Clinical Biomarkers Innovation and Operations**		Conference 9B **Clinical Biospecimen & Central Lab Solutions**
	CLINICAL SUPPLY	Conference 10A **Clinical Supply Management**		

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Plenary Keynote Program

Celebrating its 10th successful year, SCOPE Summit 2019 takes place February 18-21 in Orlando, FL. Over the course of four stimulating days of in-depth discussions in 19 different conferences, 3 plenary keynote sessions, and the ever-popular interactive breakout discussions, the programming focuses on advances and innovative solutions in all aspects of clinical trial planning, management and operations, including: Site Selection and Management, Patient Engagement, Recruitment and Retention, Protocol Optimization, Feasibility, Data Strategy & Analytics, Artificial Intelligence (AI), Sensors and Wearables, Project Management, Outsourcing, Forecasting, Budgeting and Contracting, Quality (QbD) in Trial Conduct, Risk-Based Monitoring, Post-Marketing Studies, Observational Research, Clinical Biomarker Strategy, Clinical Supply Chain, Precision Medicine, and Biospecimens and Central Lab Solutions. SCOPE attracted 1,700 leaders in clinical operations and research in 2018, and each of our conference tracks will feature best practice case studies relevant to clinical operations experts and those new to the field.

MONDAY, FEBRUARY 18

MONDAY USER GROUPS, KICK-OFF KEYNOTE, PARTICIPANT ENGAGEMENT AWARDS

2:00-5:00 pm User Group Meetings & Hosted Workshops *(Sponsorship Opportunities Available)*: www.SCOPEsummit.com/pre_conference_user_group_meetings

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 Pre-Conference Plenary Keynote Opening Remarks

James Riddle, MCSE, CIP, CPIA, CRQM, Executive Vice President, Kinetiq, a Division of Quorum Review IRB

5:05 Empowering Humans to Own Their Own Data

Scarlet Shore, Product Manager & Platform Lead, Project Baseline, Verily

Project Baseline is developing tools and strategies to empower everyday people to better understand and manage their health through the return of individual research results. Launched in April 2017, Project Baseline will recruit 10,000 participants to better characterize health and the transition to disease. Scarlet will briefly present an overview of Project Baseline and some of the insights from their efforts to-date.

PARTICIPANT ENGAGEMENT AWARD
SCOPE 2019

Underwriter Sponsorship Available

5:30 SCOPE's 2019 Participant Engagement Awards Introduction
Speaker to be Announced

5:35 SCOPE's 2019 Participant Engagement Awards
In Memory of Jerry Matczak #BeLikeJerry #SCOPE2019

Creativity and Engagement in Recruitment and Retention Communications

Designed 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.

Deadline for submission is November 30th, 2018
SCOPEsummit.com/participant-engagement-award

Chairperson: David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

Angela Radcliffe, R&D Practice Lead, Life Science, Capgemini Invent

Kelly McKee, Head, Patient Recruitment, Vertex; Co-Creator of the SCOPE Participant Engagement Award

Shwen Gwee, General Manager, Digital Accelerator, Global Drug Development, Novartis

David Fuehrer, CEO, GRYT Health, Two-Time Cancer Survivor

Joseph Kim, MBA, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly

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

6:15 SCOPE's Kick-Off Networking Happy Hour Hosted by CHI *(Sponsorship Opportunities Available)*

7:15 Close of Day

Plenary Keynote Program

TUESDAY, FEBRUARY 19

DIGITAL TRENDS CHANGING HEALTHCARE EXPERIENCE & DOCTOR-PATIENT-CAREGIVER PERSPECTIVES ON TRIALS AND ENGAGEMENT

8:15 am Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:20 Chairpersons' Introduction
Matt Miller, President, Co-Founder, StudyKIK
Jerome Chiaro, Chief Patient Advocate, Co-Founder, StudyKIK

8:25 Keynote Kick-Off: Digital Trends That Are Changing the Healthcare Experience
Emmanuel Fombu, MD, MBA, Global Commercial Strategy and Digital Innovation, Johnson & Johnson

AI and Machine Learning. Blockchain. Chatbots and Voicebots. As technology continues to advance at a rapid pace, the biopharma industry, and in particular the clinical development area, struggles to keep up and adopt/integrate these novel platforms with how they operate. This talk will cover some of the current digital trends that are changing the clinical trial experience, including examples from within and outside the biopharma industry, as well as some of the external forces from other industries that are shifting customer expectations.

8:45 Do Engagement Tools Live Up to Their Hype? Doctor and Patient Perspectives on Study Participation
Moderator: Bonnie Brescia, Founding Principal, BBK Worldwide
Gerald Dryden, Jr., MD, PhD, Division of Gastroenterology, Hepatology and Nutrition, University of Louisville
Linda Glaser, MD, PhD, Medical Director, Coastal Biomedical Research, Inc.
Annie Finstein, Patient

It is generally thought that engagement programs (e.g. apps, travel, and reimbursement tools) enhance the patient and site experience within a clinical research study. But do they really? This interactive session will feature a doctor and a patient who can provide first-hand insight into using these engagement tools and what their effectiveness truly is. This session will be part of BBK Worldwide's Pharma15 Live! web series that tackles some of today's most compelling issues and brings them to the forefront for discussion.

- Perspectives from a doctor and a patient regarding usage of engagement tools – i.e. travel and reimbursement apps
- Shifting the conversation from return-on-investment to return-on-impact.

9:05 INTERACTIVE PANEL: Why Do We Need Caregivers in Clinical Trials; Exploring Real-Life Applications in Engagement and Retention
Moderator: Lynne Becker, Senior Data Analyst, Enterprise Intelligence & Data Solutions (EIDS) Program Management Office (PMO), Deputy Assistant Director Information Operations, Defense Health Agency (DHA)
Thérèse Johnsen, Associate Director, Patient Engagement Management, Novartis
Chris O'Brien, MBA, Vice President, myHealthTeams, Board Member, MHE Research Foundation
Stuart Williams, Impact Ecosystems Architect, Inplace Impact
Elizabeth Allardice, Family Advisory Board, Concussion Legacy Foundation
Alyssa Lanzi, Ambassador & Researcher, Patient-Centered Outcomes Research Institute (PCORI)

Why do we need caregivers in clinical trials? We have oversimplified our lifestyles in many areas but burdened our healthcare. Persons became doctors or nurses to care for others, delivering empathy to their patients. Technology is inhibiting, perhaps limiting these touchpoints, leaving patients to search for compassionate care. Caregivers are quickly becoming essential to a person's healthcare, as well as to complex, confusing and overwhelming clinical trials. How do we integrate this new and essential component in helping us achieve successful clinical trial experiences?

- What a caregiver is not: Are caregivers an extension of a healthline or a patient? Are there legal or ethical implications?
- How involved can a caregiver be? Should they be compensated?
- Who chooses a caregiver? What are the HIPPA or IRB challenges?

9:35-10:35 Grand Opening Coffee Break in the Exhibit Hall

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Plenary Keynote Program

WEDNESDAY, FEBRUARY 20

OPPORTUNITIES AND CHALLENGES IN ARTIFICIAL INTELLIGENCE (AI), PATIENT CENTRICITY, PRIVACY

2:10 pm Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

2:15 Chairperson's Introduction
Jackie Kent, Senior Vice President, Head, Product, Medidata

2:20 INTERACTIVE PANEL: Welcome, Pharma, to AI. Here's What You Have Been Missing.
Moderator: David Vulcano, MBA, Vice President, Research Compliance & Development, Hospital Corporation of America (HCA)
Niall O'Connor, Chief Technology Officer, Genospace (Sarah Cannon, the Cancer Institute of HCA Healthcare)
Ron Williams, CEO, Global Business Evolutions
Balazs Flink, MD, Head, Clinical Trial Analytics, Bristol-Myers Squibb
Artificial intelligence (AI) has been utilized in other industries outside of life sciences with varying degrees of sophistication. As pharma learns AI's place in the life sciences industry, it may benefit from learning what other large companies have accomplished with AI and their lessons learned.

- How are healthcare delivery systems using AI to better deliver care and improve efficiencies?
- What similar problems have non-healthcare industries solved with AI?

2:50 INTERACTIVE PANEL: Patient Centricity and Data Permissions
Moderator: Munther Baara, MS, Head, New Clinical Paradigm, Pfizer
Michelle Shogren, Head of Innovation in Portfolio and Operations, Bayer
Lauren Bataille, Senior Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research
Laurie Myers, Global Health Literacy Director, Merck (MSD)
The Patient Centricity and Data Permissions panel will feature technologies and approaches to enable patient centricity of clinical trials and to ensure the patient data rights and good practices.

- Building a patient-centric framework that is both effective and compliant
- Converging patient-facing technology capabilities, the real challenges
- Streamlining direct-to-patient activities and creating a user experience to improve research and outcomes
- Creating the infrastructure to comply with best practices for patient data rights and permissions

3:20-4:05 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

Interactive Breakout Discussions

TUESDAY, FEBRUARY 19

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 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. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. 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.

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

Patient Engagement and Recruitment

What Is Holding Back the Adoption of eConsent?

- Is eConsent for every trial? Discuss when eConsent is or isn't appropriate
- Understand IRB and regulatory feedback on the eConsent process
- Discuss how eConsent technology integrates with other systems
- Review a typical implementation timeline and how it impacts all stakeholders

Strategies for Aligning and Accelerating Recruitment in Complex Clinical Trials in a Resource-Constrained Environment

- 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)

Strategies for Patient-Centric Trial Design and Digital Patient Engagement

- 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?

TABLE: Shiny New Objects: Can Traditional Recruitment Mediums Merge With Technology Driven Solutions for Better Engagement?

- What is at the intersection of conversational ai/chatbots and "old school" techniques such as call centers in last mile recruitment strategies?
- What can traditional media (TV, Print and Radio) teach digital about storytelling?
- Who is succeeding in marrying technology solutions to identify patients with traditional outreach tactics?

Interactive Breakout Discussions

Protocol Optimization and Trial Design

Embracing Best Practices in Protocol Design to Reduce Protocol Amendments and Improve Trials

- What are the updated metrics on the prevalence and causes of protocol amendments and what does this mean for us?
- How can we as an industry improve our process of protocol development?
- What are some community initiatives and individual company approaches to finding success?

How to Start from Scratch to Get Patient Input into Clinical Trial Design

- Speaking to objections from senior leadership
- Discuss how to partner with advocacy organizations in order to obtain patient input
- How to work within timelines to get input from patients

Feasibility and Site Selection

Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint

- 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

Study Start Up and Operations

Barriers and Opportunities in Site Adoption of Clinical Trial Technology

- What site facing technology is critical to improving clinical trials?
- What is holding sites back from adopting this technology?
- What can be done to minimize the burden of technology for sites?
- What opportunities exist to streamline and integrate technology in clinical trials?

Identifying and Alleviating Burdens Inherent in Clinical Trials (for Patients, Sites, Caregivers, Investigators and Trial Managers)

- Identifying study requirements that may be burdensome
- Transportation to and from study visits – how can sponsors help
- Helping research sites to alleviate their internal burdens

Partnering with Qualified Investigators and Study Teams for Improved Site Performance, Efficiency, and Execution of Clinical Trials

- Identify inefficiencies in current approaches to investigator training and learn how they impact the conduct and timelines of clinical trials
- Discuss strategies for developing a culture of collaboration between sponsors/CROs and site teams in preparing investigators and their delegates for the quality conduct of clinical trials
- Describe approaches to combining "qualification" and "preparation" activities for site teams

Improving Both Time and Quality in Site Activation and Study Start-Up

- 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?

Data and Technology

Wearable Devices in Clinical Trials

- What is the value, beyond scientific interest?
- Where do we want to be in 5 years (and why we are not there already!)?
- Key challenges for industry uptake?
- Opportunities for industry-wide collaborations

Digital Data Transfer and Virtual Trials

- The Digital Health eco-system and its impact on clinical trials
- EHR2EDC: how to implement and advance
- Mastering collaborations between pharma companies and academic medical centers

Artificial Intelligence and Machine Learning: Extreme Case of Data Analytics?

- Will data science and machine learning disrupt the provision of clinical evidence or compliment it?
- With Machine Learning needing big data sets, how can 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?

Technologies to Enable Patient-Centered Trials

- Innovative digital technologies
- Technologies to capture patient experience
- Framework for converging patient-facing technologies

Clinical Analytics Strategy

- Implementing analytics on top of existing operating model
- Study Start Up Methodology to Adopt a Clinical Analytics Strategy
- Data analytics in outsourced trials

Monitoring and Quality

RBM in a Finance and Resource Limited Environment

- How are you assessing risk and developing an appropriate quality and risk plan?
- In terms of technology, what are nice-to-haves vs. need-to-haves for implementing RBM?
- Who are the stakeholders involved in putting RBM in action at smaller companies?

Interactive Breakout Discussions

RBM and Critical Reasoning Skills
- How are central monitoring activities different than traditional monitoring?
- How do you train people to do critical problem solving around data?
- How do you uncover root causes of data issues instead of just fixing data afterwards?

Vendor Performance Metrics and KPIs
- How effective are your KPIs for measuring vendor performance and quality?
- What is your strategy for establishing KPIs and metrics? Who are the stakeholders developing performance metrics?
- What are the key areas that should be evaluated for vendor performance and quality?

Building a Clinical Quality Management System (CQMS) from the Ground Up
- What are the minimum requirements for a CQMS?
- What do you need to build a CQMS?
- How to build a CQMS with limited resources and budget
- Learn from each other's current experiences with building a CQMS

Budgeting, Contracting and Resource Management

Coordinating Contracting and Payments to Enhance Efficiencies
- Understand how contracting and investigator payments are connected
- Review standard terms to use on both ends of the contracting process
- Discuss how to improve and implement a plan to streamline operations

Budgeting and Contracting for Remote and Digital Trials
- Understand budgeting needs for remote and digital trials and how they are different from traditional site-driven trials
- Review differences in contracting: Needs, models, and language
- Discuss how to improve and implement a plan to streamline budgets and negotiations

Balancing Budgets and Performance in Resource Management and Capacity Planning
- 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?

Developing Resource Management Tools for Complex Trials and Diverse Portfolios
- Understand the important factors that need to be tracked to successfully capacity plan and how to integrate them into a tool
- Discuss how to get buy-in from key stakeholders by demonstrating value, cost savings, and efficiency
- Discuss change management and how to roll out a new tool or process

Addressing Current and Future Workforce Challenges
- What competencies are most lacking in the workforce today?
- How are you addressing these challenges?
- What more can and should the industry be doing to create a more skilled and sustainable workforce?

Clinical Supply and Logistics

Clinical Supply in Virtual Trials
- How does clinical supply fit in with the industry trend towards virtual/site-less trials?
- What does clinical ops need to know about direct-to-patient distribution before embarking on a virtual trial?
- What are the logistical, cost and regulatory considerations of direct-to-patient distribution?

Biospecimen and Central Lab Management

Biospecimen, Central Lab and Technology
- Biorepositories: In-house vs. outsourcing
- Advanced informatics for biospecimen management
- Central and reference labs: Building the relationship
- Informed consent and data sharing

Integrating Sample Management into Clinical Trial Cycle
- Regulatory Compliance
- Site Selection Considerations
- RBM Considerations

RWE

RWE to Support Regulatory Decisions and the Medicine Lifecycle
- Leverage the power of RWD to enable evidence-based trial feasibility assessment and patient recruitment
- How can RWD support Clinical Operations and the Medical organization overall?
- What opportunities exist to collaborate between Medical and Commercial on RWD assets and insights?
- Which functions can help bridge and facilitate the ingestion of RWD for actionable insights?
- RWE needs to go beyond analysis and clinical trial is calling new clinical-health service to link healthcare and clinical trial research

RWD To Accelerate Design and Execution of Clinical Trials
- RWD to improve the efficiency of clinical trials
- RWD to accelerate site selection and patient recruitment
- RWD sources and analytics
- RWD to supplement clinical trials

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Pre-Conference User Group Meeting & Hosted Workshops

February 18, 2019
2:00-5:00 pm

Shared Investigator Platform User Forum

Sponsored by Cognizant

The Shared Investigator Platform (SIP) is the success story of TransCelerate BioPharma's collaborative vision brought to reality through a digital platform. SIP is delivering tangible, measurable benefits to sponsors and sites as more and more studies are onboarded and user adoption accelerates exponentially.

Beginning in February 2019, SIP will be available to sponsors outside of TransCelerate membership, as well as directly to CROs. The SIP User Forum is open to anyone whose organization is a current user of the platform or considering its adoption, including technology partners. Investigators and site personnel, who are able to join SIP at any time at no charge, are encouraged to attend.

- Understand the plan for SIP to transition from TransCelerate's incubation to become a Cognizant product in 2020
- Hear from current SIP adopters on the benefits being realized
- See the new features of Version 3.1 and the product roadmap of future releases
- Provide your input on current and future features and functions of SIP

To learn how to register for the Shared Investigator Platform User Forum, please contact Jill Notte at jill.notte@cognizant.com or 862-217-7080.

Trifecta Annual User Group Forum

Sponsored by trifecta

Trifecta is a global leader — and a trusted partner — with decades of experience in clinical trial technology solutions. From accelerating study start up for trials of all sizes to organizing and distributing all critical training and safety data, Trifecta offers a fully integrated, totally comprehensive platform built from the ground up. And through it, we consistently deliver more trial and less error across an entire portfolio of studies. We are proud to be hosting our annual user group meeting at SCOPE.

To learn how to register for the Trifecta Annual User Group Meeting, please contact Karen Olszewski at karen.olszewski@trifectaclinical.com.

Host a User Group on Monday, February 18

Co-locate your User Group meeting with SCOPE Summit. CHI will help market the event & manage logistical operations. We will co-market to prospective attendees and extend your users a discount to attend.

For Partnering & Sponsorship Information, contact:

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9th Annual

Protocol Development, Global Site Selection, Feasibility, and Site Management

Improving Outcomes through Strategy, Relationships, Data and Execution

February 19-20

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 protocol development, trial planning and execution. To overcome challenges in clinical trial planning, operations and site management leaders, should learn from the best practices of their peers, utilize data and analytics to support decision making, and improve communication and relationships between Sites, CROs, and Sponsors. CHI's 9th Annual "Protocol Development, Global Site Selection, Feasibility and Site Management" will cover the topics one should consider when planning and implementing a trial.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

IMPROVING YOUR APPROACH TO STUDY PLANNING, PROTOCOL DEVELOPMENT, FEASIBILITY AND SITE SELECTION

10:35 Chairperson's Remarks
Laura Galuchie, Director, Global Clinical Trial Operations, Merck & Co., Inc., and TransCelerate Program Lead

10:40 CO-PRESENTATION: Evidence-Based Site Selection Profiles
Jonathan Rowe, PhD, Executive Director, Head of Clinical Development, Quality Performance and Risk Management, Pfizer
Oriol Serra Ortiz, MBA, Senior Director, Head Site Intelligence & Selection, Study Optimization, Clinical Development & Operations, Pfizer
Historical site GCP quality performance data can be a useful decision point in combination with other site metrics for future site identification. A model incorporating a number of variables that reflect site performance, start up and site's GCP status will be described along with real examples of its utility in site identification and performance predictions.

11:10 Feasibility for Early Stage Studies in Oncology
Michael Fites, Senior Feasibility Strategist, Global Clinical Trial Services, Bayer
Early stage trials (First in Human, Basket Trials) present a unique design with adaptive planning. As such, feasibility in early stage trials requires a tailored and flexible approach in order to identify the optimal sites for study conduct. This presentation will share details and key learnings.

11:40 INTERACTIVE PANEL: Study Planning, Site Identification and Feasibility: Strategies for Success in Centralised and De-Centralised Organizations
Moderator: Elisa Cascade, President, Data Solutions, DrugDev
Lorena Gomez, Director, Global Study Start Up & Essential Documents, Global Site Management Operations, Allergan
Sylvia Eberhardt, Business Lead, Shared Investigator Platform and Investigator Registry, Hoffmann-La Roche
Laura Galuchie, Director, Global Clinical Trial Operations, Merck & Co., Inc., and TransCelerate Program Lead
This panel discussion will take a look at study planning, site identification and feasibility in 3 different companies, with a focus on strategies for success in companies that have largely centralised functions governing these processes vs. those that have a more de-centralised model with local responsibility for such tasks. In addition, the session will provide input on tactics (successful and unsuccessful) for driving standardization and evidence-driven activities.

Topics to be discussed:

- Understand the different organizational structures that inform approaches to study planning, site identification and feasibility
- Identify challenges and opportunities that arise from both a centralized and a de-centralized approach
- Based on these insights, discuss best practices for strategies for study planning, site identification and feasibility based on organizational structure

12:10 pm Optimize Your Recruitment Efforts for Highly Competitive Patient Populations *Sponsored by* Pharma intelligence informa
Loni Branon, Senior Director, Sitetrove Citeline, Informa – Pharma Intelligence
Otis Johnson, PhD, Vice President, Feasibility and Informatics, ICON Clinical Research
Are you making the best possible decisions as you design and plan your next clinical trial? Come join us to review strategies in protocol development and implementation. Hear how you can leverage data and technology to optimize patient enrollment, drive quicker trial completion, and mitigate the risks of failure.

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12:40 Transition to Lunch

12:45 Key Learnings from the PROTECT Registry

Sponsored by SYNEXUS

Dawie Wessels, MBA, MBChB, Chief Medical Officer, Synexus Clinical Research Limited

The PROTECT online clinical registry platform, run by the University of Exeter, follows a network of patients (baseline 17,000 expanding to 55,000) > 50 years old without dementia to determine genetic and environmental factors associated with cognitive decline and onset of Alzheimer's Disease as well as the effect of various interventions in this population. We discuss the most recent findings to-date and the challenges of implementing and managing such a unique clinical trials asset.

1:25 Coffee and Dessert Break in the Exhibit Hall

USING MULTIPLE DATA SOURCES AND ANALYTICS TO IMPROVE FEASIBILITY AND QUANTIFY PATIENT BURDEN

2:05 Chairperson's Remarks

Lorena Gomez, Director, Global Study Start Up & Essential Documents, Global Site Management Operations, Allergan

2:10 CO-PRESENTATION: Applying a Data-Centric Approach to Feasibility and Site Selection

Sandra Smyth, Director, Central Feasibility and Recruitment Group, AstraZeneca
Michele Teufel, Patient Engagement Lead, Clinical Operations, AstraZeneca

This presentation will report AstraZeneca's recent transformation initiative focusing on patients, sites, and data-centric approaches to improve feasibility and site selection in late-stage studies. We will talk about the data sources involved, and other tools and strategies implemented for site selection and continuous predictive forecasting. We will share learnings from our experiences in terms of using historical and RWD data balanced with local insights to inform site selection decisions in a global organization.

2:40 Using RWE and Data Analytics for Enhanced Feasibility and Site Selection Strategies

Michelle Everill, Senior Director, Head of Global Feasibility, Janssen

As more varied data sources are becoming available across multiple industries, the potential to merge, overlay, and analyze data is proving to increase the ability to be predictive in achieving better operational and recruitment outcomes. Case studies utilizing RWE and varied data sources will be shared to highlight how insights were derived and applied to increase success and risk mitigation strategies.

3:10 INTERACTIVE PANEL: Quantifying Patient Burden to Improve Clinical Trial Planning and Execution

Moderator: Diane Carozza, Managing Senior Engagement Consultant, Medidata Solutions
Steve Schwager, Professor Emeritus, Cornell University
Ashley Williams, Associate Director, Global Clinical Operations, Biogen
T.J. Sharpe, Patient Advisor, Starfish Harbor, LLC

The burden of a trial and its procedures on a patient has the potential to substantially impact patient retention in a study. Sponsors have traditionally relied on subjective measures to understand this patient burden. New tools are available that provide an objective framework for quantifying and visualizing the burden on the patient from a procedure, a visit, and the overall protocol. Learn from our panel how clinical operations professionals are taking a data-driven approach to making patient-centric modifications to trial designs.

Topics to be discussed:

- What is the value of incorporating patient burden into study design and strategies to improve patient retention?
- What are data-driven tools that can provide an objective framework for patient burden and its use by clinicians and patient experience teams to bolster patient retention?
- How can clinical operations and protocol designers make the important shift from subjective, often ad hoc assessment of patient burden to an objective, data-driven approach to improve patient-centricity in clinical trials?

3:40 Using Data Science and Technology to Design and Deliver Better Clinical Trials

Sponsored by IMS Health & Quintiles are now IQVIA

Allen Kindman, MD, Vice President, Clinical Planning and Analytics, IQVIA

Access to data and innovative technology developments are enabling better protocol design and more efficient execution of clinical trials. In this presentation we will discuss how you can: - Assess and optimize your protocol using real-world data to avoid protocol amendments - Create precise and predictable study strategies - Provide seamless operational deployment, at scale, to deliver enrollment and high quality.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

Sponsored by IQVIA

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Eric Delente Head, Patient Consent, IQVIA Technologies
This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

CHOOSING DATA SOURCES, RESCUE SITES AND FOOLPROOF FEASIBILITY

8:20 Chairperson's Remarks
Chairperson to be Announced

8:25 CO-PRESENTATION: Unknown Unknowns: Leveraging Technology to Identify Blind Spots in Country and Site Feasibility Data
Mary-Anne Tomas, Director, Site Intelligence & Selection, Study Optimization, Pfizer Inc.
Claire Sears, Director, Product Communications, Data Solutions, IQVIA Technologies
Lisa Jarosek, Senior Data Architect, CfDA (Center for Design and Analysis), Amgen
Increasingly sophisticated data sources are becoming more readily available to site and country selection teams for use in feasibility assessments. As teams look to add to their tool kits, there are necessary trade-offs that must be made due to limited resources – and some very expensive data options. Where do teams get the best return on their data investment? It's valuable for these tradeoffs to be informed by an understanding of the feasibility data landscape and the value added by each category of data.

8:55 Landscape Analysis: Site Activation and Enrolment Patterns
Lorena Gomez, Director, Global Study Start Up & Essential Documents, Global Site Management Operations, Allergan
The burden of adding rescue sites during a study to pharma companies is considerable in terms of time and cost, and yet understanding the landscape of rescue sites is limited. This session will present a framework for benchmarking use of rescue sites and associated findings from an analysis of shared CTMS from 13 different pharma companies. Specifically, we leveraged this data to investigate the distribution of sites activated and patients enrolled overall, and at the country and therapy level.

9:25 Foolproof Feasibility: Matching Standard of Care with Clinical Feedback and Site Intelligence
Matt Cooper, PhD, Director, Business Development & Marketing, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre
In the UK the National Institute for Health Research (NIHR) has developed a unique national strategy for delivering reliable feasibility reports using a three-pronged approach to be presented in detail. This foolproof approach to achieving accurate feasibility information is underpinning research delivery success in the UK and has contributed to record-breaking 'time and target' performance results (74%) for commercial contract research (74% figure is based on 466 commercial studies that closed in financial year 2017/18, 346 of which recruited 100% of their target within planned timescales).

Sponsored by HIGH POINT CLINICAL TRIALS CENTER

9:55 Right-Sizing Technology in Early Clinical Development
Lorraine Rusch, PhD, President, High Point Clinical Trials Center
Clinical trials are driven by the industry's need to innovate and provide decision making data rapidly. For compounds with measurable endpoints and wide toxicity windows adaptive Proof of Concept (POC) studies are the gold standard where safety and efficacy are evaluated in healthy volunteers and patients. This discussion addresses design and execution of POC studies incorporating technology to drive data collection in a way that safeguards efficacy evaluations from patient noncompliance due to technology burnout.

10:25 Coffee Break in the Exhibit Hall

IMPROVING SITE AND INVESTIGATOR SELECTION AND PERFORMANCE THROUGH COLLABORATIVE APPROACHES

11:20 Chairperson's Remarks
Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)

11:25 Partnering with Qualified Investigators and Study Teams for Improved Site Performance, Efficiency, and Execution of Clinical Trials
Kathy Goldstein, PharmD, Senior Director, Head, Quality Management Lead, Regeneron Pharmaceuticals
Current approaches to investigator qualification make it difficult for sponsors and CROs to identify study teams that are well-prepared for the quality conduct of clinical trials. This session will report recommendations from the Clinical Trials Transformation Initiative (CTTI) that are intended to disrupt current approaches to investigator qualification, resulting in 1) more streamlined and efficient learning, and 2) improved execution of study protocols. For example, reduced recruitment timelines, improved patient retention, and less time spent resolving discrepancies.

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11:55 INTERACTIVE PANEL: The Missing Ingredient that Most Impacts Successful Site Performance

Moderator: Beth Harper, MBA, Workforce Innovation Officer, Association of Clinical Research Professionals (ACRP)

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

Doug Schantz, Executive Director, Clinical Operations, AstraZeneca

Jennifer Byrne, Founder/President, Greater Gift, CEO, Javara, Inc.

What matters most in clinical research is the people doing the work; however, staff qualifications are often not considered when it comes to site selection. There is a growing body of evidence to support the impact that more highly-qualified staff have on performance and the operational efficiencies that can be gained when these sites are used.

Topics to be discussed:

- Current site selection processes and gaps in the data collected
- The value of site staff qualification analysis and standardization of competencies
- Industry issues associated with variance in site staffing training, development and assessment

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Metrics, Standards & Technology: How to Harness Digital to Transform Protocol Creation

Sponsored by Cognizant

Bob Brindle, Venture Leader, Life Sciences, Cognizant

How much effort do you waste during clinical trial protocol creation? How do you know? How do you fix it? In this increasingly digital world, it's frustrating to be constrained by traditional word processing tools, but making the shift to a digital process can be daunting. Join this session to discover the practical steps that will set you up to transform your process - and get a peek at what a digital protocol will enable.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Improving Site-Study Activation and Performance. See page 43 for details.

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12th Annual

Enrollment Planning and Patient Recruitment

Strategic Enrollment Planning, Data-Driven Recruitment and Forecasting, and Central Campaign Management

February 19-20

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. To optimize both, you have to have a plan and effectively leverage analytics and technology without losing site of the participant's user experience. CHI's 12th Annual "Enrollment Planning and Patient Recruitment" will cover the topics one should consider when drafting and strategically implementing a patient recruitment plan for a patient-centric clinical development program.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

DIGITIZING TRIALS AND PATIENT RECRUITMENT TO IMPROVE PATIENT EXPERIENCE AND RETENTION

10:35 Chairperson's Remarks
Mark Summers, President, Patient Engagement, WCG

10:40 CO-PRESENTATION: The Changing Face of Digital Patient Recruitment: Better Data-Driven Decisions
Amy McCormick, Innovation Lead, Patient Experience and Design Innovation, Eli Lilly & Co.
Kevin Hudziak, Consultant, Innovation Lead, Patient Experience and Design Innovation, Eli Lilly & Co.
This talk will focus on new approaches to digital patient recruitment. It will focus on real-world examples using data-driven decisions to adapt recruitment and retention strategies. Examples on how to provide patients and caregivers with useful information to help guide them through their journey.

11:10 CO-PRESENTATION: Treating Patients Like Customers: Changing the Paradigm of Clinical Trial Recruitment *Sponsored by* ICON
Gretchen Goller, Global Head, Patient Recruitment and Retention, Clinical Research Services, ICON plc
Kelly McKee, Head, Patient Recruitment, Vertex

11:40 CO-PRESENTATION: Digitizing a Patient-Focused Clinical Trial Experience
Stephen Yates, Clinical Program Director, UCB
Kelley Erb, Lead, TransCelerate's Novel Digital Endpoints; Director, Digital Medicine, Pfizer
During this interactive session, leaders from TransCelerate Member Companies will candidly share their experiences collaborating to create solutions that will bring about innovative change, and address some of our industry's greatest challenges. They will discuss the four key initiatives that, using innovative digital efforts, have the potential to transform clinical trials. The audience will learn how the use of patient technologies, eConsent, eLabels, and electronic health records (EHRs) can advance clinical research and create the patient experience of the future.

12:10 pm Virtual Interactions: Effective Patient Recruitment Strategies in the Digital Era *Sponsored by* UBC
Matthew Kratz, Senior Manager, Patient & Physician Services, UBC
This session will focus on employing the best global and US-centric practices around patient recruitment and harnessing digital tools to target potential patients. The session will address how using digital outreach has impacted rare disease trials and how important response mechanisms are to any recruitment effort. Will also discuss regulatory and legal considerations when using digital tactics and the use of patient platforms to offer more to trial participants and improve retention and brand loyalty.

12:40 Transition to Lunch

12:45 LUNCHEON PRESENTATION: Bringing the Trial to the Patient: Virtual Trials and the Promise of Patient Engagement *Sponsored by* IQVIA
Josh Rose, Vice President, Global Head, Strategy, Research and Development Solutions, IQVIA
The shift to virtual trials is upon us. With it comes a myriad of benefits to both the patient and sponsor. This presentation will share how early adopter studies are delivering more rapid patient enrollment, higher retention, better data quality and overall faster cycle times.

1:25 Coffee and Dessert Break in the Exhibit Hall

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ENGAGEMENT, RECRUITMENT AND RETENTION LESSONS LEARNED FROM COMPLEX, GLOBAL & RARE DISEASE STUDIES

2:05 Chairperson's Remarks
Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer

2:10 Lessons Learned from a Successful Phase 3 Program in Japan: Culture, Engagement, Recruitment and Retention
Julie Dubourg, MD, Medical Director, Clinical Development, Poxel
This talk will focus on patient recruitment and retention in the settings of a first-in-class registration program in Japan. There are many factors to consider when planning a registration program in Japan from a European biotech company perspective and efficient strategies will be presented.

2:40 Can Historical Data and Analytics be Used for Recruitment Planning in Rare Diseases?
Angela Dimitrova, MD, Senior Director, Feasibility Group Lead Rare Diseases, Study Optimization, Pfizer
Rare disease studies are more difficult to enroll because of the much smaller patient pools. Planning enrollment durations for rare diseases is also more challenging and complicated due to rarity of data. In this presentation we will review the opportunities to use evidence-based and data-driven approaches to better plan enrollment in rare diseases.

3:10 CO-PRESENTATION: The Digital Clinical Trial Recruitment Landscape: Insights and a Fireside Chat
Shwen Gwee, General Manager, Digital Accelerator, Global Drug Development, Novartis
Jeff Greene, Vice President, Digital Strategy & Insights, Decision Resources Group
More than ever, patients feel empowered to play an active role in their health decisions. That extends to their participation in clinical trials - and digital advances have made it a lot easier. Over 30% of U.S. patients have expressed interest in going online to find clinical trials. Among rare disease patients willing to participate in a clinical trial, nearly 60% have accessed prescription drug information from social media. But many pharma companies struggle to integrate digital solutions into their clinical trial recruitment strategies. Come join this interactive session where we'll highlight DRG Digital's latest study, The Digital Clinical Trial Recruitment Landscape. This session will also end with a brief fireside chat that discusses what clinical can learn from marketing to develop better digital strategies that enhance and accelerate trial recruitment.

3:40 Myth, Urban Legend and an Element of Truth: Dispelling Commonly Held Beliefs about Clinical Study Participation
Sponsored by bbk
Aaron Fleishman, Director, Market Development, Business Development Innovation and Market Expansion, BBK Worldwide
Are site staff overburdened by multiple systems? Can an app really increase patient engagement? There's no shortage of opinions of what makes patient recruitment and engagement for a clinical study effective. Leveraging data from BBK's Study Voices survey of over 3,000 patients, site staff, and study personnel, this presentation will challenge common myths and legends and determine their veracity.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

5:00 Welcome Reception in the Exhibit Hall
Sponsored by ADVARRA

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Sponsored by IMS Health & Quintiles are now IQVIA
Eric Delente Head, Patient Consent, IQVIA Technologies
This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

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INNOVATIVE DIGITAL APPROACHES TO PATIENT IDENTIFICATION AND ENGAGEMENT

8:20 Chairperson's Remarks
Neil Weisman, Executive Vice President, Continuum Clinical

8:25 Active Patient Identification: The Power of Patients and the Role of Grit in Pre-Determining Retention
Lynne Becker, Senior Data Analyst, Enterprise Intelligence & Data Solutions (EIDS) Program Management Office (PMO), Deputy Assistant Director Information Operations, Defense Health Agency (DHA)
Patient engagement implies a variety of methods that is differentiated amongst organizations and its application is becoming confused, perhaps diluting its intent. Patients are being bombarded with a plethora of technology, social media, wearables and now concierge services to become "engaged"; but engagement for a hospital administrator differs from a clinical trial sponsor, which differs from the clinician and even further differs from the actual patient. Our position is to pre-identify the grittiness of a clinical trial candidate before they are overwhelmed with these services. Then appropropriately apply your engagement resources in a more efficient manner to improve the clinical trial's return on investment.

8:55 A New Ecosystem for Clinical Trials Recruitment: Go Where the Patients Are
Pravin Jadhav, PhD, Senior Director, Corporate Projects, R&D Innovation, Otsuka Pharmaceutical Development and Commercialization (OPDC)
Almost two-thirds of clinical sites do not meet patient recruitment targets. There have been a number of approaches explored to boost clinical trial recruitment with some mixed success. While there are tools with promising visuals by leveraging big data analytics, most tools do not provide any actionable insight for study teams to implement in areas "where the patients are." An example of leveraging smart data analytics combining real world data, internal clinical operations data and publicly available resources will be discussed that supported development of a novel and actionable targeted recruitment approach.

9:25 CO-PRESENTATION: Creating a Connected Patient Engagement Platform through Innovative Digital Approaches
Carolyn Brehm, Associate Director, BMS Study Connect Business Lead, Bristol-Myers Squibb
Mano Das, IT Business Partner, Clinical Patient and Site Operations, Bristol-Myers Squibb
Through global expansion and innovative digital approaches, BMS has created an industry-leading patient engagement platform dedicated to increasing clinical trial awareness, participation and engagement. BMS Study Connect is a comprehensive clinical trial resource for patients and caregivers to learn about and find clinical trials, and connect with others. The platform delivers an experience that empowers patients, provides transparency, and supports patients and caregivers before, during and after a clinical trial.

9:55 Patient Engagement: Treating Patients Like Customers
Sponsored by SubjectWell
Ivor Clarke, CEO, SubjectWell
You're a consumer. As such, what do you look for when choosing a product or service to meet your needs? Price? Quality? Convenience? Customer Service? All of the above? Patients are consumers too and they, just like you, are accustomed to being able to engage providers with ease. In this session, get insights into how other industries inform and engage consumers and explore how you can apply those same techniques to your next study.

10:25 Coffee Break in the Exhibit Hall

11:20 Chairperson's Remarks
Paul Ivsin, Managing Director, PEP Trials, The Patient Experience Project

11:25 Implementing Patient-Facing Technology in Clinical Trials: How to Overcome Industry's Biggest Challenges to Benefit Patients, Sites and Sponsors
Hassan Kadhim, MBA, Director, Head of Clinical Trial Business Capabilities, Bristol-Myers Squibb Company
Patient-facing digital technologies (also called 'Patient Technology') have the potential to serve a variety of functions in clinical trials, such as capturing clinical endpoints, engaging patients, and facilitating remote study conduct. However, these technologies are not yet accepted as mainstream research tools, and the opportunities, challenges, and facilitators associated with their implementation in clinical trials have not been fully characterized. The audience will gain an understanding of factors associated with implementation and this session will also explore the assets developed by the TransCelerate Patient Technology Initiative freely available to clinical research professionals to address these opportunities.

11:45 How Roche is Planning to Use eConsent to Retain Patients for a Complex Oncology Trial
Olaf Danner, Global Studies Manager, Roche
This session will tell the story of a recent multi-cohort oncology study conducted by Roche. Specifically, it will identify how and why Roche developed targeted education and videos for each oncology cohort group, using eConsent, and how that improved engagement, enrollment, and retention. The talk will share: How eConsent was deployed to address each cohort group; the process for identifying, developing, and implementing each educational video; the benefits of Roche's approach and why patients better understood the risks and needs of the trial.

12:05 CASE STUDY: Building a Patient-Centric Platform for Improved Recruitment and Retention
Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer
Communications and trial support of patients before, during, and after trial

participation is challenging, yet will positively support enrollment and retention efforts of our clinical trials. And while we have ways to solve each of these, how do we make the process simple for our study volunteers? By building a single platform solution that will allow each study volunteer to obtain information and support based on their individual needs.

12:25 pm Transition to Lunch

Sponsored by

PRAXIS

12:30 BRIDGING LUNCHEON PRESENTATION: Leveraging Analytics and the Patient Voice to Optimize Patient Recruitment & Retention Campaigns

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis Communications, LLC

As the world becomes more and more digital, it is important to tap into the endless amounts of data and conversations being shared on the Internet to glean patient insights and understanding. As we have lunch, we'll explore case studies and discuss how our industry can utilize data and analytics to craft and optimize efficient and effective patient-centric enrollment campaigns.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Patient Engagement, Enrollment and Retention through Communities and Technology. See page 46 for details.

Clinical Trial Forecasting, Budgeting and Contracting

Innovative Strategies for Cost-Efficient Trials

As clinical trials become more complex and take on innovative designs, it is more critical than ever to develop proper strategies for forecasting, budgeting, negotiating, and contracting both internally and externally with sites, CROs, and other partners. Finance and operations teams must continue to evolve and adapt, especially in light of new and changing regulations and laws. CHI's 12th 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.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

BUDGETING: NON-TRADITIONAL CLINICAL TRIALS AND NON-TRADITIONAL STRATEGIES

10:35 Chairperson's Remarks
Debora Araujo, Founder & CEO, ClinBiz

10:40 Exploring the Budgetary Challenges and Opportunities in Remote and Digital Trials
Debora Araujo, Founder & CEO, ClinBiz
With the age of remote and digital clinical trials upon us, it bears asking: how will these studies impact the bottom line in organizations? In addition to the patient-centricity aspect and competitive advantages, like efficiency and speed that remote and digital clinical trials present to sponsors, do these trials also present cost-saving opportunities or can additional costs be expected? In this presentation, we will explore the challenges and opportunities remote and digital trials can present from a budgetary perspective.

11:10 Planning for Non-Traditional Trials: Lessons Learned with Real World Evidence (RWE)/Pragmatic Clinical Trials
Maryanne Santilli, Director, North America Clinical Finance & Operations, Novo Nordisk
This talk will discuss the importance of input from clinical operations, HEOR, medical, finance, and legal departments in budgeting for non-traditional clinical trials at Novo Nordisk. I will highlight the differences in budgeting and contracting in traditional trials vs. real-world evidence trials.

11:40 UK's One Contract, One Costing Assessment, All Sites: Impact on Budgets and Delivery of Clinical Trials
Matt Cooper, PhD, Director, Business Development & Marketing, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre
Currently in the UK, the NIHR is implementing a new initiative that will allow industry to negotiate one contract and set of costings with one site, and all sites thereafter partaking in the trial would abide by that contract and costing assessment. This will have a significant impact on clinical trials at large, with the biggest impact on budgeting and improved set-up times. This talk will discuss the current impact of site budgets on the delivery of clinical trials, and how this initiative will change that.

12:10 pm Clinical Trial Financial Forecasting with Predictive Subject Enrollment *Sponsored by* medidata
Perry Steinberg, Vice President, Product Management, Medidata
The industry is fraught with disparate systems that prohibit effective financial forecasting critical for clinical financial management. CROs and sponsors need to anticipate site grant payments and the financial impact of drug supply costs and logistics. Learn how predictive subject enrollment models, when applied correctly, can inform financial forecasting for appropriate budgeting.

12:40 Transition to Lunch

12:45 LUNCHEON CO-PRESENTATION: Assembling the eClinical Suite: Lessons from the Road *Sponsored by* bsi
Jens Thuesen, CTMS Business Development, BSI Business Systems Integration AG
Pamela Penman, CTMS Business Development, BSI Business Systems Integration AG
Software that helps the clinical development process has become commonplace, but what's the best way to go about assembling a clinical suite to automate and optimize the clinical development process? What are the advantage when choosing multiple applications from the same vendor? Can "Best of Breed" applications really provide the best user experience, aid efficiency, and help to reduce risk? Explore common myths and misconceptions regarding integration and get insight into selecting an eClinical System.

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1:25 Coffee and Dessert Break in the Exhibit Hall

STRATEGIES FOR FINANCIAL FORECASTING

2:05 Chairperson's Remarks
Chris Chan, Executive Director, R&D Finance, Fibrogen

2:10 Financial Considerations When Contracting with a CRO
Keith Jones, Director, Financial Planning and Analysis, Ovid Therapeutics
Finance functions at small and medium sized sponsors tend to have a greater reliance on CROs. To ensure compliance with GAAP and minimize external audit issues, CRO contracts should include specific language.

2:40 The Seven Wondrous Ways to Immediately Improve Your R&D Financial Accruals Process
Chris Chan, Executive Director, R&D Finance, Fibrogen
Any biopharma professional who has ever endeavored to generate financial accruals for clinical trials and other R&D activities knows how frustrating and time-consuming the process can be. Not only is the task itself fundamentally challenging, numerous entities conspire to make life even more exquisitely painful for you, including pushy auditors, impatient managers, and personnel generally unclear on the concept. This presentation strives to enrich your lives by making your financial accruals efforts significantly less painful by discussing "The Seven Wondrous Ways to Immediately Improve Your R&D Financial Accruals Process."

3:10 INTERACTIVE PANEL: Fair Market Value and the Role it Plays in Clinical Trial Budgeting and Forecasting
Moderator: Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine
Maryanne Santilli, Director, North America Clinical Finance & Operations, Novo Nordisk
Debora Araujo, Founder & CEO, ClinBiz
Kelly Loughner, Senior Associate Director, Site Enablement, Boehringer Ingelheim
This panel discussion will focus on fair market value, what it is, how it is determined, and the role it plays in clinical trial budgeting and forecasting. Panelists will discuss common misconceptions about FMV, interpretation challenges, and the burden of sponsor vs. site. They will discuss how FMV affects not only budgeting and forecasting, but also resource utilization.

3:40 Finding the Right Forecasting Model with the Right Technology
Sponsored by bio-optronics
Kelly Smith, CCRP, Senior Solutions Consultant, Bio-Optronics
This talk will discuss the common pitfalls that come with correctly forecasting complex, multi-site clinical trials, and how the right ClinOps tools can help provide the right frameworks for better tracking budgets, monitoring, completed patient visits and payments. What's more, attendees will learn how to properly leverage reporting and business intelligence to better identify immediate action areas, better collaborate with stakeholders and leverage past data for enhanced performance on future studies.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

5:00 Welcome Reception in the Exhibit Hall
Sponsored by ADVARRA

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Sponsored by IQVIA
Eric Delente Head, Patient Consent, IQVIA Technologies
This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

FINANCES AND CONTRACTING FOR LONG-TERM PARTNERSHIPS

8:20 Chairperson's Remarks
Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine.

8:25 CO-PRESENTATION: Marriage Pitfalls & How to Avoid them: Clinical Finance & Strategic Outsourcing
Jennifer Goldman, Director, Clinical Business Operations, Deciphera
Shawne J. Moran, Senior Director, Strategic Development, IQVIA
Choosing a CRO to be your partner is a lot like a marriage, it has the good days and

bad days. Two industry veterans share what they have learned;. Why Sponsors are reducing vendors and partnering more. What it takes to make these relationships work. How to weather the bumpy times, avoid divorce and celebrate successes. Understanding the importance of contracting right, communicating more and having the processes in place for when you hit bumps in the road.

CONTRACTING AND NEGOTIATION CONSIDERATIONS FOR SITES, CROS, AND VENDORS

8:55 Strategies for Successfully Negotiating CRO Contracts

Bella Sessoms, MPH, Director, Portfolio Sourcing Management, Portfolio Sourcing and Relationship Management, Astellas Pharma Global Development

The CRO contracting process is a critical component in achieving Sponsor timeline and financial goals. This presentation will review common challenges in the CRO contracting process and offer solutions for expediting the contracting process while maintaining quality in the final contractual deliverables.

9:25 Hybrid Contracting Models for Sites and Vendors

Kelly Loughner, Senior Associate Director, Site Enablement, Boehringer Ingelheim

Sponsors are continuously changing the process by which they manage clinical trials, specifically in the start-up phase. This session will take a deep dive into the different models for negotiating in start-up – fully outsourcing negotiations, a hybrid outsourced/in-house negotiation model, and a fully in-house negotiation strategy. We will discuss the highs and lows of each model and where industry is trending and why.

9:55 Site-Centric Payments: Developing a Strategy That Pays Off

Sponsored by
BIOCLINICA
SEE MORE CLEARLY

Meghan Harrington, Vice President, Head, Payments, Site and Patient Payments, Bioclinica

With drug and device development costs climbing, it's important to know the status of investments from beginning to end in a clinical trial. If you're uncertain exactly where the money is going, whether you're getting the most from those investments, or if you worry about inaccurate reconciliation -- join this informative session. Learn reasons behind slow and inaccurate payments, factors essential to implementing a site-centric approach, the role of technology in unlocking data, analytics, reporting, and forecasting capabilities. 10:25 Coffee Break in the Exhibit Hall

THE IMPACT OF NEW REGULATIONS AND LAWS ON CLINICAL TRIAL NEGOTIATION AND BUDGETING

11:20 Chairperson's Remarks

Rick Morrison, Founder & President, Comprehend Systems, Inc.

11:25 The Impact of GDPR on Contracting and Negotiating Clinical Trial Agreements

David Posselt, Director, Global Contract Management - Drug Development Operations, Allergan

General Data Privacy Regulations (GDPR) was adopted in April 2016 and became enforceable in May 2018 in the EU. In this session we will explore the impact and challenges which the new GDPR regulations have had on negotiating clinical trial agreements in the EU. We will review some of the approaches which have been used to shorten and simplify the negotiation timelines.

11:55 The Impact of Final ICH GCP E6 Guideline and R2 Addendum in Globalization Environment: Changes Affecting Budgeting and Resource Management in Clinical Trials

Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine

This talk will explore the changes to provide a better understanding of how the final ICH GCP E6 Guideline and R2 Addendum impacts conduct of clinical trials, budgeting, and resource allocation. Practical information and a systematic approach in assessing organizational, processes and practices for contracts, budgeting, cost estimation and forecasting resources as well as designing modifications to assist with implementation will also be provided.

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Resource Management and Capacity Planning for Clinical Trials. See page 49 for details.

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3rd Annual

Mastering an Outsourcing Strategy

Defining Your Sourcing Strategy & Ensuring Harmony between All Stakeholders

February 19-20

Understanding outsourcing needs and optimizing the selection process of vendors lays the foundation for an efficient, cost-effective clinical trial. CHI's 3rd Annual "Mastering an Outsourcing Strategy" conference provides a new perspective on key considerations for defining an organization's sourcing strategy. The 2019 program focuses on case studies and interactive discussions with sponsors, CROs, suppliers, and sites on outsourcing strategy, working with third party suppliers, and effective site sourcing.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

CONSIDERATIONS FOR DEFINING YOUR SOURCING STRATEGY

10:35 Chairperson's Remarks
Charlotte French, Principal, CAF Consulting LLC; Former Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas

10:40 Considerations for Defining Your Sourcing Strategy
Charlotte French, Principal, CAF Consulting LLC; Former Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas

In today's world of significant pressure to deliver cost effective clinical trials in a highly competitive and fast paced environment, biopharmaceutical companies face many competing influences in developing the appropriate sourcing strategy that appropriately balances risk, reward and cost. Understanding that small biopharmaceutical companies through mid-to-large size pharmaceutical companies have different requirements, this presentation will outline an approach to evaluating the various areas to consider when developing a strategic sourcing strategy. These include a deep dive into your organization to include an evaluation of the portfolio, review of current personnel, competencies, roles and responsibilities, and commitment across the entire organization to implement the sourcing strategy.

11:10 INTERACTIVE PANEL: Considerations for Defining Your Sourcing Strategy
Moderator: Charlotte French, Principal, CAF Consulting LLC; Former Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas
Ratan Ratnesh, Director, Head, Clinical Outsourcing, Otsuka
Hansu Dong, Director, Outsourcing, MedImmune
Julie VanOrsdel Daves, MSHS, Director, Clinical Contracts & Outsourcing, miRagen Therapeutics, Inc.
David Burnham, Senior Vice President, Strategic Alliance Management, Syneos Health
Eric Forsthoffer, Global VP, Business Development, Bioclinica
Mary Dixon Drake, CEO & Founder, Innovenn

Stakeholders from small, large and mid-sized pharma/biotech as well as their CRO and service provider counterparts will come together to discuss how to successfully meet their outsourcing needs. Topics to be discussed include:

- Defining an organization's sourcing strategy
- How to successfully implement a new sourcing strategy

12:10 pm Harmonizing Clinical Partnership Strategy and Procurement for Better Delivery *Sponsored by* Syneos Health
Mark Scullion, Executive Vice President, Strategic Resourcing, Clinical Solutions, Syneos Health

Innovative partnerships between sponsors, CROs and tech companies are often misaligned with standard procurement process, characterized by broad criteria and comparison measures. This can negatively impact clinical solutions development from the start. We'll discuss how partners can work with procurement to move from the standard bid defense and single POC buying mold to make space for more expert level collaboration to deliver better value clinical solutions.

12:40 Transition to Lunch

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12:45 LUNCHEON CO-PRESENTATION: Global Site Payment Transformation

Sponsored by greenphire

Jim Murphy, CEO, Greenphire
Joe Robbins, Senior Manager, Global Clinical Pricing & Payments, Amgen

Attend this joint presentation to learn how Amgen chose Greenphire's eClinicalGPS to automate its site payments for a more transparent, reliable process that eliminated as many manual points of intervention as possible.

1:25 Coffee and Dessert Break in the Exhibit Hall

MANAGING MIXED OUTSOURCING MODELS & THIRD PARTY SUPPLIERS

2:05 Chairperson's Remarks

Charlotte French, Principal, CAF Consulting LLC; Former Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas

2:10 INTERACTIVE PANEL: How are Patient-Centric Trials Changing How the Industry Is Working with Third Party Suppliers?

Moderator: Melissa Bomben, Vice President, Key Account Management, Syneos HealthMelissa Hurst, MBA, Clinical Outsourcing Manager, CSL Behring Melissa Hurst, MBA, Clinical Outsourcing Manager, CSL Behring

Hansu Dong, Director, Outsourcing, MedImmune

Adam Halbridge, Principal of Digital Health, PRA Health Sciences

As clinical trials become more patient-centric, there is increased pressure on CROs to deliver specialized services that they currently don't offer. This panel will address the following questions:

- How are CROs addressing the demand for specialized services?
- How are sponsors and CROs approaching the need for third party suppliers?
- How are CROs aligning themselves with specialty vendors and niche providers?
- Is this the new industry trend?
- How is oversight and accountability of deliverables being handled?
- What are some best practices and lessons learned when sponsors are outsourcing multiple services?

3:10 Biotech vs. Big Pharma Outsourcing Strategies in Practice

Richard Scaife, Chair, Pharmaceutical Contract Management Group (PCMG)

A change in outsourcing strategies and practice are emerging from the increased funding available to Biotechs globally. Once forced to partner with Pharma early in the clinical development pathway due to financial and subsequent resource constraints, more Biotechs are now developing concepts into Phase II and beyond. Yet these often scientifically-led companies can lack the expertise to comprehensively develop and manage an outsourcing strategy and its implementation. This can increase sponsor dependency on CROs who are now acting as outsourcing managers on behalf of their smaller sponsors. Where is this trend heading and what are the implications in terms of strategy, budget and resource management in a constantly consolidating CRO marketplace?

3:40 RFPs and Bids Slowing You Down? New Strategies Can Help Speed the Outsourcing Process

Sponsored by ORACLE Health Sciences

Julie Smiley, Senior Director, Life Sciences Product Strategy, Oracle Health Sciences

Outsourcing your trials to CROs can be difficult since each trial has its own set of assumptions, and RFP creation and management generally requires manual effort. Additionally, each vendor organizes tasks and resources differently, so evaluating bids is like comparing apples to oranges. These challenges can ultimately lead to study start delays and change orders because tasks were left out, misunderstood, or under-bid.

What if you were able to significantly shorten your RFP and bid management cycle times? In this session, we will discuss not only how to gain efficiencies in your outsourcing processes, but also how you can determine the optimal outsourcing model for your trial and leverage industry intelligence for better negotiations.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

5:00 Welcome Reception in the Exhibit Hall

Sponsored by ADVARRA

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent

Sponsored by IMS Health & Quintiles are now IQVIA

Eric Delente Head, Patient Consent, IQVIA Technologies

This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

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EFFECTIVE SITE SOURCING

8:20 Chairperson's Remarks
Katie Gaiek, Account Executive, Bio-Optronics

8:25 An Outsourcing Manager's Role in Site Contracting and Site Oversight
Jennifer Trevor, PhD, Sr. Portfolio Sourcing Manager, Portfolio Sourcing and Relationship Management, Astellas Pharma

Outsourcing managers play a pivotal role in parlaying their knowledge, skills, and abilities to oversee the execution of site contracts facilitated by a CRO. As an integral member of the study team, and a triage point for the sponsor, the outsourcing manager provides the internal Astellas stakeholders with historical country or provision-related knowledge and risk to provide context for the stakeholder. This enables the stakeholder to provide rapid, compliant, and informed decisions to drive negotiations further. Tracking and trending site escalations allows the sponsor to improve template language and develop improved fallback language and positions. Finally, the outsourcing manager has the leverage of representing the sponsor in difficult negotiations for which the site and the CRO have reached an impasse.

8:55 INTERACTIVE PANEL: Ensuring Harmony between All Stakeholders – Sponsor, CRO, and Site – When Site Sourcing
Moderator: Ly Kawaguchi, Senior Director, DBO-Outsourcing, Site Budgets, and Business Analytics, MyoKardia, Inc.
Jennifer Trevor, PhD, Sr. Portfolio Sourcing Manager, Portfolio Sourcing and Relationship Management, Astellas Pharma
Carlos Orantes, CEO, Accel Research Sites
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC
Natalia Grassis, Vice President, Clinical Operations, Parexel

Topics to be discussed:

- Working with stakeholders on setting appropriate site budgets, site contracting, site identification, selection of sites, and site oversight/ management

9:55 Talk Title to be Announced
Sponsored by Quest Diagnostics
David Freeman, GM Ventures, Ops Admin/Clinical Data Support, Quest Diagnostics
Rich Franco, Vice President, Clinical Strategy, Quest Diagnostics

10:25 Coffee Break in the Exhibit Hall

BECOMING A PREFERRED SPONSOR AMONG SITES

11:20 Chairperson's Remarks
Brett Kleger, Chief Commercial Officer, DrugDev, An IQVIA Company

11:25 INTERACTIVE PANEL: How Emerging Biotechs Can Compete with Big Pharma and Become a Preferred Sponsor Among Sites
Moderator: Brett Kleger, Chief Commercial Officer, DrugDev, An IQVIA Company
Adam Simmons, Clinical Program Manager, Alkermes
Brenda Medina, Director, Development Science Business Operations, BioMarin
Jennifer Heckman, Senior Director, Clinical Trial Logistics, Incyte

This panel will explore how small to mid-size pharma and biotech can leverage technology to even the playing field between themselves and "big pharma." The panel will demonstrate how an outsourcing model that employs best-in-class technology together with the CRO of choice can help attract research sites to their studies and in turn make them a sponsor of choice.

Topics to be discussed include:

- The different types of clinical trial technologies and service models for smaller organizations
- What to look for when picking clinical trial technology
- Client success stories and real-world examples of how technology helped them become a sponsor of choice

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Managing Outsourced Clinical Trials. See page 51 for details.

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5th Annual

Implementing Risk-Based Monitoring (Part 1)

Integrating Quality into Clinical Trials

February 19-20

Poor quality and risk management of clinical trials significantly impacts the success, timeliness and cost-effectiveness of clinical trials. CHI's 5th Annual "Implementing Risk-Based Monitoring – Part 1: Integrating Quality into Clinical Trials" conference provides lessons learned, case studies, and ample discussion on building and maintaining proper clinical quality management systems 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.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

REALIZING RISKS WITH YOUR CLINICAL QUALITY MANAGEMENT SYSTEMS

10:35 Chairperson's Remarks
Angie Maurer, MBA, Clinical Quality & Risk Management Consultant, GRAIL, Inc.

10:40 CO-PRESENTATION: Build a Clinical Quality Management System from The Ground Up
Brian Nugent, Senior Director, Clinical Compliance, GRAIL, Inc.
Angie Maurer, MBA, Clinical Quality & Risk Management Consultant, GRAIL, Inc.
During this session we will discuss a case study where we built a CQMS from the ground up. We will discuss our evaluation, planning and implementation process. Also, we will share the findings and the steps we took to build the department, current status and plans for the future. included in this presentation will be: 1. Background of the company, 2. Evaluation process of the company's quality group, 3. Plan developed based on the evaluation findings, 4. Implementation of a CQMS and an overall Quality Management System (QMS), and 5. Lessons learned.

11:40 A Risk Management Case Study: Evolution of Pfizer's Integrated Quality Risk Management Plan and Realization of Risks
Sheri Kuss, Director, Clinical Quality Management, Pfizer
With clinical trial experience and the release of ICH E6 Revision 2, our Risk Management approach has evolved from the initial use of an excel-based plan to the creation of an electronic risk management system with reduced questions, risks and the addition of Quality Tolerance Limits. The speaker will provide an example of studies where the prospective risks identified were analyzed for risk realization post-study. The retrospective look at the risks and identified study issues has had an impact on risks, mitigations and controls of future studies as well as the overall risk management approach.

12:10 pm RBx: A Complete Risk-Based Approach to Clinical Trials - How ICH E6 (R2) is Driving the Industry to Realize Hope and Overcome Fear *Sponsored by* CluePoints
Francois Torche, CEO, CluePoints SA
Since the initial publication of the ICH guidelines, the way clinical trials operate has changed significantly. The ICH E6 (R2), encourages sponsors to develop a prioritized, risk-based approach to both quality management & monitoring. This session will shed light on how to achieve the "gold standard" for monitoring, study execution, and oversight, in line with ICH guidance.

12:40 Transition to Lunch

12:45 Transforming Data Quality using Machine Learning *Sponsored by* medidata
Stacey Yount, Vice President, Product, Medidata
Learn how to set your organization on a path to improved data quality across the clinical trial process using machine learning.

1:25 Coffee and Dessert Break in the Exhibit Hall

OPERATIONALIZING CLINICAL TRIAL QUALITY

2:05 Chairperson's Remarks
Angie Maurer, RN, Clinical Quality & Risk Management Consultant, GRAIL, Inc.

2:10 CO-PRESENTATION: Operationalizing Quality
Alana Wriggins, Head, Site Management, Allergan
Ann Hegarty, Executive Director, GSMO, Head PLs, CRO Oversight & Ph I Site Management, Allergan
We all have great ideas of what quality looks like in clinical trials and we have regulations and guidances as support. However, it seems the challenge remains

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in how and IF we operationalize quality. This session will focus on inspection readiness from the beginning - from incorporating RBM to outsourcing strategies, all in the hopes of keeping the surprises at bay!

3:10 Solving Key Protocol Deviations Challenge to Improve Data Quality
Laura Galuchie, Director, Global Clinical Trial Operations, Merck & Co., Inc. & TransCelerate Program Lead
Currently, clinical research sponsors and sites are struggling to interpret certain elements of the ICH E3 and the associated guidelines related to protocol deviations. Based on input from investigational CROs and sites, as well as research sponsors themselves, the TransCelerate Protocol Deviations Initiative is engaging health authorities to create a Protocol Deviation Management Toolkit to ultimately improve patient safety, reliability of study data, human subjects' protections and data quality.

Sponsored by ERT

3:40 Beyond Risk-Based Monitoring: Employing Risk-Based Management
Rob Bolduc, Director, Product Management, ERT
Discussion highlights include: 1) Exploring process, resource, and technology challenges in implementing risk-based management 2) Overcoming challenges in data source variability and data aggregation
3) Moving beyond risk-management, into performance management: Incorporating study start-up metrics, milestone tracking, and other KPIs 4) Complying with ICH E6 guidance: Sponsor / CRO roles in risk-based management and oversight 5) Finding the best model and solution for your organization: Maturing into risk-management, the value of pilots and proofs of concept (POCs)

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups
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Sponsored by ADVARRA

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

Sponsored by IQVIA

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Eric Delente Head, Patient Consent, IQVIA Technologies
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8:15 Session Break

THE INTERSECTION OF QUALITY AND RBM

8:20 Chairperson's Remarks
Venkat Sethuraman, Associate Principal, ZS

8:25 The Use of Predictive Models, Quality Tolerance Limits and Anomaly Detection to Drive and Oversee RBM
Jonathan Rowe, PhD, Executive Director & Head, Quality Performance and Risk Management, Pfizer
ICH E6 R2 calls for a systematic, prioritized, risk-based approach to monitoring clinical trials that is tailored to the specific human subject protection and data integrity risks of the trial. A methodology for establishing the risk level of a protocol, identifying risks to critical trial processes and data, and establishing quality tolerance limits will be described that enables the requirements of ICH.

8:55 CASE STUDY: How Alkermes Created a Risk-Based Data Quality Oversight Framework
Amy Neubauer, Associate Director, Data Management, Alkermes, Inc.
Many CROs are offering RBM capabilities, but what is the sponsor's role in oversight of RBM for outsourced studies? This session will take a look at the roles, tools, partnership model, internal framework, high-level results, lessons learned, and future plans that Alkermes' Clinical Data Sciences team is taking in leading the clinical study teams in an effective risk-based data quality oversight approach.

9:25 RBM-Where Have We Come? From the 2011 FDA Draft Guidance to the Finalization of ICH E6 (R2)-Lessons Learned, Best Practices and Process Improvements
Mary Arnould, Director, Clinical Science Operations and RBM Lead, Astellas
This session will discuss challenges and best practices in the 8 years since RBM

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was recommended by the FDA. The evolution in people, process and technology will be discussed, including risk assessment evolution, central monitoring capabilities, adaptive monitoring strategies and the introduction of Quality Tolerance Limits.

9:55 CO-PRESENTATION: A New Approach to RBM Using Total Trial Management (TTM)

Sponsored by COVANCE SOLUTIONS MADE REAL

Kristin Stallcup, Director, Central Monitoring Operations, Covance
Olivia Feiro, PMP, Associate Director, Central Monitoring Operations, Covance

Today, managing risk in a clinical trial is more about the balance of people, process and technology. It's about a holistic approach to RBM and a combination of quality risk management, site and central monitoring. It's about delivering ICH GCP R2 compliant processes utilizing quality by design throughout the trial from start to finish. Learn how Covance uses a powerful technology solution, Xcellerate® Informatics, to implement total trial management to manage risk and increase quality.

10:25 Coffee Break in the Exhibit Hall

EXTENDING RISK-BASED MONITORING PRINCIPLES TO BIOSPECIMEN MANAGEMENT

11:20 Chairperson's Remarks

Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories

11:25 Specimen-Centric Considerations for Possible Extensions of Risk-Based Monitoring (RBM) Principles

Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories

Clinical trials play a central role in the development and delivery of breakthrough diagnostics for patient care, and specimens collected in these trials are becoming increasingly significant and subject to regulatory compliance. As biomarker data continues to drive an increasing number of trial decisions and clinical endpoints, a specimen-centric focus needs to become part of any comprehensive clinical trial monitoring process. As Risk-Based Monitoring (RBM) matures and adoption becomes more widespread, the extension of the established principles to include specimen-centric elements seems like a reasonable path forward.

11:45 CO-PRESENTATION: What Can We Learn from RBM to Enhance the Utillity of Biospecimens in Clinical Trials?

Matt Harlin, Associate Director, Clinical Pharmacology, Otsuka Pharmaceutical Companies
Sharin Roth, Director, Clinical Pharmacology, Bioanalysis, Otsuka

Establishing business processes to govern the life cycle of biospecimens collected in clinical trials is essential to any drug developer. Leveraging existing risk-based monitoring (RBM) systems can enhance the utility of biospecimens, ensuring they are of high quality, consented properly, accounted for, and easily selected for analysis. RBM system attributes that are specific to biospecimens will be evaluated.

12:05 pm Biospecimen Tracking as an Integral Part of Risk Based Monitoring

Morten Thorup Pedersen, Risk Based Monitoring Specialist, Centralised Monitoring Unit, Clinical Systems, Data & Trial Management, Novo Nordisk A/S

Novo Nordisk has implemented Risk Based Monitoring with biospecimen tracking being an integral part of the approach. With biospecimens being the primary endpoints in many trials, we took the approach of centrally monitoring the collection and analysis of these to be able to do a targeted follow up with the sites where results of biospecimen samples were missing. Combining data from several sources, we have set up a system to predict where the risk may emerge and do a proactive targeted follow-up.

12:25 pm Transition to Lunch

12:30 BRIDGING LUNHEON PRESENTATION: How Artificial Intelligence and Machine Learning with Advanced Analytics are Driving New Levels of RBM Efficiencies

Sponsored by IMS Health & Quintiles are now IQVIA™

Rajneesh Patil, Global Head, Process Design and Analytics, Clinical Operations, IQVIA

RBM continues to evolve. This presentation will highlight the evolution of advanced analytics and how the application of contemporary statistical science can strengthen risk-based strategies, share learnings from practical models that help reduce white noise/false positives in signal detection deployed for RBM, and provide insights on where machine learning and artificial intelligence models have potential application in clinical monitoring to address risks based on study design and patient population.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Implementing Risk-Based Monitoring – Part 2. See page 53 for details.

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E-clinical technologies have changed 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 data management and analytics. These 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. CHI's 11th 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 the rapidly changing environment.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI *(Sponsorship Opportunities Available)*

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

DIGITAL DATA TRANSFER

10:35 Chairperson's Remarks
Tine Lewi, PhD, MBA, Scientific Director, Janssen R&D, Clinical Innovation

10:40 Building a 21st Century Data Backbone
Jerry Whaley, Senior Director, Development Business Technology, Pfizer
Clinical development organizations are changing how they collect, manage and analyze clinical data and new measures of clinical outcome are being adopted. Data will be the fuel that powers machine learning and AI. As a result we must re-imagine what is required to create a data powered organization that unlocks value and insights. We will explore how information supply chains, elastic infrastructure, tools for data science, and automation enable a 21st century data backbone accelerating the delivery of new medicines to patients.

11:10 Digital Data Transfer (From EHR to EDC) and Inter-related Issues
Kyle Holen, MD, Head, Development Design Center, AbbVie
With the increased use of electronic medical records world-wide, the clinical trial process of collecting, verifying, and analyzing relevant data to assess the impact of our interventions requires a re-visit into a process that is less manual labor intensive and allows for the ability to gain insights beyond the limitations of stated endpoints. Collaborations between AbbVie and academic medical centers as well as between AbbVie and data collection companies have initiated systems that will solve some of these challenges. The presentation at SCOPE will show some of the learnings gained from these collaborations and demonstrate a path where we can achieve a non-touch solution to clinical data transfer for all future trials.

11:40 CO-PRESENTATION: EHR2EDC, an Innovative European Public/Private Project to Optimize EDC Processes
Marija Todorovic, Bridges Associate, Hospital Engagement Lead/Data Sciences, Janssen R&D, Clinical Innovation
Tine Lewi, PhD, Scientific Director, Janssen R&D, Clinical Innovation
EHR2EDC is a newly launched eIT-funded consortium project that aims at facilitating the data extraction for applications used during trial execution, e.g. prefilling of CRF reports. With the EHR2EDC project, we aim to avoid double data entry and source data verification, to collect subject data as soon as it is available, which will lead to continuous monitoring, but also to reduce data management costs, to convert data to a form suitable for analytics software and promote the reuse of the data.

12:10 pm The Future of Automation in Managing Clinical Data and Operations *Sponsored by* Veeva
Richard Young, Vice President, Vault CDMS, Veeva Systems
Clinical Research of the future will be driven by personalization and data, increasing the demands on clinical data and operations teams. This presentation looks at how automation can transform our approach to trial design and execution, by modernizing data management to reflect the experiences we have in our everyday lives. Join this presentation for a look into how harmonized data exchange and process automation will revolutionize the work of our clinical data and operations teams.

12:40 Transition to Lunch

Organized by
Cambridge Healthtech Institute
A Division of Cambridge Innovation Institute

12:45 LUNCHEON PRESENTATION: Maximizing the Use of Data Hubs to Streamline Clinical Operations

Sponsored by Cognizant

Sundaram Ramakrishnan, Venture Leader, Life Sciences, Cognizant

Data is your most valuable asset, but are your data management systems helping you improve decisions - or holding you back? In this session, we'll discuss the most common data hub problems - and how to solve them. We'll use a combination of best practices and case studies to help you discover how your data hub should improve your decision-making and streamline operations.

1:25 Coffee and Dessert Break in the Exhibit Hall

TECHNOLOGY TO ENABLE PATIENT CENTRICITY

2:05 Chairperson's Remarks

Aman Thukral, Assistant Director, DSS, AbbVie

2:10 Patient Experience Captured through Digital Technology

Michelle Shogren, Head, Innovation, Portfolio and Operations, Pharma Development, Bayer

In light of recent new FDA draft guidance around adding patient experience to the label, we need to think about what that means to Pharma and how we design clinical trials to be able to have the necessary data to support it. Join this session to learn more about this guidance and what could be done.

2:40 Create a Single Data Collection Hub to Promote Interoperability and Seamless Integration of Direct-to-Patient Activity

Munther Baara, MS, Head, New Clinical Paradigm, Pfizer

Innovative digital technologies are starting to disrupt the highly regulated and conservative biopharmaceutical industry. - Learn how a single data hub can be utilized to harmonize recruitment, eConsent, patient outcomes and other relevant systems that must be simplified for direct-to-patient trials; - Capitalize on opportunities to remotely administer wearables and other trial activity; - Develop understanding in the vendor community of the adaptations they need to make to their standards, systems and processes to utilize emerging hubs; - Craft an implementation plan and develop cross industry buy-in and support

3:00 Converging Patient-Facing Technology Capabilities: The Pinnacle of Patient Centricity

Aman Thukral, Assistant Director, DSS, AbbVie

Biopharmaceutical sponsors are experimenting multifold technologies to achieve patient centricity. This is increasing pressure on patients to use multiple sensors, apps and devices during clinical trials. The goal of this presentation to provide the framework for converging patient-facing technologies.

3:20 Enabling Patient-Centric Clinical Trials via Digital Health Technologies

Jyoti Shah, Associate Director, Data Development, Merck

Digital technologies provide an opportunity to modernize the current site-centric clinical trial model by enriching the quality of data collected and enabling real-time decision making, thereby increasing probability of success. At Merck, we have conducted clinical pilots to determine this feasibility and our results demonstrated the feasibility and subject acceptance of these technologies for future clinical trial use.

3:40 Using Data and Technology to Design a Trial that Patients WANT to do!

Sponsored by COVANCE SOLUTIONS MADE REAL

Veronica Alcine, Director, Global Patent Recruitment and Engagement, Covance

It's a well-known fact that obtaining the right patients has long been a challenge for clinical trials. However, the real challenge comes from the ability to design a trial that patients actually choose to participate in. Covance has developed a methodology to use technology to realistically pinpoint accurate patient populations and design trials that patients actually want to do. Join us and learn to design trials effectively and efficiently.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

5:00 Welcome Reception in the Exhibit Hall

Sponsored by ADVARRA advancing better research

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent

Sponsored by IMS Health & Quintiles are now IQVIA

Eric Delente Head, Patient Consent, IQVIA Technologies

This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track

ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

CLINICAL ANALYTICS STRATEGY

8:20 Chairperson's Remarks
Kenneth Massey, Chief Life Sciences Officer, Saama

8:25 Leveraging the Lean Start-Up Methodology to Adopt and Scale the Data and Clinical Analytics Strategy
Nareen Katta, Director, Operations Analytics, Data Sciences, Data and Statistical Sciences, AbbVie
The case study discusses the need for organizations to reimagine the operating model in order to unleash the full value of the clinical analytics, and the opportunity cost of implementing analytics on top of existing operating model.

8:55 Smart Dashboards: Our Journey to Building Interactive Process Performance Analytics Using Machine Learning
Faye O'Brien, Director, Metrics and Performance, GMD, AstraZeneca
The Operational Excellence team at AstraZeneca piloted artificial intelligence tools to create a new interactive performance measurement dashboard for key clinical and regulatory processes. The machine learning tools ingest and process data from different access points across the business, make the data available for intuitive querying using natural language and create dashboards from results. During this session, we will walk you through this pilot including an overview of the technology and its benefits.

9:25 CO-PRESENTATION: Using Metrics and Visualizations to Change the Way We Work
Kevin Ott, Clinical Operations Data Analyst, Clinical Affairs, Cardiovascular Systems, Inc.
Kyle Christopherson, Director of Clinical Affairs, Cardiovascular Systems, Inc.
In less than 18 months, the Clinical Affairs team at CSI swiftly evolved into a datadriven organization with over 20 tools and visualizations created to support the execution of their clinical portfolio. Join the presenters as they walk you through their journey of how this small team defined critical needs, developed compelling metrics, introduced new tools, and integrated metrics into the organizational workflow for action and decision making.

9:55 Traditional Methods of Clinical Risk Management are Breaking Down
Sponsored by comprehend
Rick Morrison, Founder & President, Comprehend Systems, Inc.
The complexity of managing clinical trials is accelerating, as new technologies are introduced and vendor fragmentation occurs among suppliers. As the number of moving parts multiplies, clinical teams are forced to be reactionary and end up continually falling behind. This session will explain how clinical teams can overcome challenges related to improving study performance and minimizing clinical trial risk through several case studies that show what works and what doesn't.

10:25 Coffee Break in the Exhibit Hall

DIGITAL ENDPOINTS & TECHNOLOGIES

11:20 Chairperson's Remarks
Hugh Levaux, PhD, Founder and CEO, Protocol First

11:25 The Future of Healthcare: Humans and Machines Partnering for Better Outcomes
Emmanuel Fombu, MD, MBA, Global Commercial Strategy and Digital Innovation, Johnson & Johnson
We live in a world where data can help us make more informed decisions about how to navigate traffic, who to date, what to buy, who to network with and how to better manage our finances. But when it comes to our personal health and wellness, we have no roadmap. We need something to show us where we are in terms of our health, with landmarks for risks and opportunities. A GPS that makes it easier to move toward our personal health goals. A new way to look at health and life.

11:55 The Digital Health Ecosystem: The "New" People, Technologies and Processes Needed to Scale Up the Use of Digital Health in Pharmaceutical Development
Rick Franckowiak, Senior Director, Pharma R&D Digital Innovation, Janssen R&D
It is becoming increasingly valuable to leverage digital technology in a clinical trial environment to differentiate therapy, provide rapid insights and provide patient centric solutions. This talk will aim to discuss how to move beyond ongoing digital health "pilot-itis" and describe the ecosystem of functions and capabilities that are needed to scale the use of digital technologies in clinical operations.

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Portfolio Risk Mitigation
Sponsored by saama
Amit Gulwadi, Senior Vice President, Clinical Innovations, Saama Technologies

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Artificial Intelligence in Clinical Research. See page 55 for details.

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Sensors, Wearables and Digital Biomarkers in Clinical Trials

Digital Endpoints and Connectivity

February 19-20

The clinical research industry is moving toward end-to-end digital clinical trials. 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. CHI's 2nd Annual "Sensors, Wearables and Digital Biomarkers in Clinical Trials" conference 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 18

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(Sponsorship Opportunities Available)

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TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

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9:35 Grand Opening Coffee Break in the Exhibit Hall

WEARABLES AND SENSORS AS DATA SOURCES

10:35 Chairperson's Remarks
Michelle Crouthamel, Digital Platform Leader, GSK

10:40 Moving beyond Patient Engagement to Human-Centered Design in Digital Health
Greg Silvesti, Head, Digital Health & Innovation, AbbVie
Digital health tools, like smart devices and IoT have the power to revolutionize healthcare by unlocking untapped objective data and translating it into clinically relevant information. As the industry is maturing, technology is increasingly getting commoditized and experience is becoming a differentiator. Patient-centricity and "engagement" has taken us so far in digital health, it's time we start to discuss what it means to be human-centric and why that matters.

11:10 Digital Biomarker Development at Roche: Are Clinical Endpoints from Mobile Sensor Data in Reach?
Timothy Kilchenmann, Digital Biomarker Scientist, Roche
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.

12:10 pm Using AI and Computer Vision Technology to Capture, Measure, and Modify Patient Behavior in Clinical Research *Sponsored by* AiCure
Michelle Marlborough, Chief Product Officer, AiCure
Advances in computer vision and AI technology are allowing us to capture and analyze an unprecedented amount of data from patients around their actions and responses to medical conditions. This is fundamentally changing how drug developers keep their patients engaged and optimized to treatment in clinical trials. Learn how sites and clinical operations teams are leveraging these behavioral insights today to better support patients, improve data quality, and increase the likelihood of trial success.

12:40 Transition to Lunch

12:45 Plug-Me-In Clinical Research – Innovating at Scale *Sponsored by* ORACLE Health Sciences
Jonathan Palmer, Senior Director, Digital Trials, Oracle Health Sciences
Clinical research is about to change beyond recognition. Simply plugging in the patient to a variety of sensors/wearables/apps can deliver high-quality, objective data, to provide deep understanding of efficacy and safety profiles. This presentation will explore digital trial use cases, and associated enabling technologies, and consider how best to scale adoption of these innovative paths to maximize the resultant new data streams to rapidly gain insight into trial progress and patient outcomes.

1:25 Coffee and Dessert Break in the Exhibit Hall

IMPLEMENTING WEARABLE DEVICES IN CLINICAL STUDIES

2:05 Chairperson's Remarks
Philippe Verplancke, PhD, Global Head, Business Development, XClinical GmbH

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2:10 Implementing Wearable Devices in GSK Clinical Studies
Luis Garcia-Gancedo, PhD, Director, Clinical Sensors and Data Analytics, GSK
In this talk I will give an overview of our main considerations for choosing and deploying wearable technologies in clinical trials. As an example, I will explain how we went about introducing a specific wearable in some of our ongoing studies, and the impact that the data we are collecting is expected to make in assessing treatment efficacy and adding value to our medicines.

2:40 Validating Novel Digital Endpoints: What's the Right Development Model?
Kelley Erb, PhD, Director, Digital Medicine, Early Clinical Development, Pfizer
Novel digital endpoints are transforming drug development. Their successful validation in time to impact clinical development requires the right evidence, from the right studies, at the right time. With the range of options including clinical trial pilots to large multi-stakeholder collaborations, what's the right model to deliver fit-for-purpose outcome measures? Data, experiences, and key lessons learned from Pfizer's efforts to develop and validate novel outcomes for Parkinson's disease will be discussed.

3:10 INTERACTIVE PANEL: Novel Digital Endpoints in Clinical Research: Technology, Infrastructure, Regulatory Considerations
Moderator: Michelle Crouthamel, Digital Platform Leader, GSK
Kelley Erb, PhD, Director, Digital Medicine, Early Clinical Development, Pfizer
Luis Garcia-Gancedo, PhD, Director, Clinical Sensors and Data Analytics, GSK
Timothy Kilchenmann, Digital Biomarker Scientist, Roche
Greg Silvesti, Head, Digital Health & Innovation, AbbVie

- Where we are with NDE currently compare to 3 years ago? Are we making progress?
- What are the barriers?
- How should industry advance NDE development, standardization, validation, approval
- Audiences' thoughts

Sponsored by
modus stepwatch

3:40 StepWatch™ Accuracy, Reliability, and Adherence Means Greater Probability to Detect Improvements in Real World Walking
Teri Chou, PhD, CEO, Modus Health
The accuracy of walking monitors vary widely from consumer products such as Fitbit™ to medical devices such as StepWatch™. This presentation emphasizes how monitor accuracy and reliability can affect number of study participants needed to detect walking improvements. Adherence results in an ongoing pharmaceutical trial will also be discussed.

3:55 Sponsored Presentation *(Opportunity Available)*

BREAKOUT DISCUSSION GROUPS

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Sponsored by
ADVARRA advancing better research

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent

Sponsored by IQVIA

Eric Delente Head, Patient Consent, IQVIA Technologies

This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

STANDARDIZATION AND REGULATORY CONSIDERATIONS

8:20 Chairperson's Remarks

Daniel Karlin, MD, Director of Biotech Ventures, CEAi, Inc.

8:25 Regulatory Considerations during Mobile Medical App Development for Commercial and Clinical Trial Use

Michael Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision & Digital Medicine, GSK

Mobile medical apps are defined as medical devices from their intended use. Mobile medical app regulation is health risk-based to balance patient safety and barriers to technological innovation. Medical device patient risk analysis is a critical prerequisite prior to sensor/app inclusion within a clinical trial. Key components of quality management systems for mobile medical apps include: software requirements/specifications, user acceptance testing, software post-market surveillance, software version control and medical device adverse event reporting.

8:55 Data Integrity Playbook: Risk-Based, Analytics-Driven Approach to Monitor Data Integrity

Gian Prakash, Assistant Director, Data and Statistical Sciences, Abbvie

Technology is changing the paradigm of how clinical data is collected and analyzed, with the increase in the volume of data and complexity of clinical technologies, there is a need to ensure appropriate controls are in place to govern and monitor the data integrity throughout the life cycle of the clinical data. Data Integrity Playbook provides a solution to implement a cross-functional technical approach to perform audit trail reviews for ensuring data integrity.

9:25 A Standardized Approach for Assessing Endpoints through Mobile Technology Collection: A Pfizer Perspective

Joe Mather, Executive Director, Head of Advanced Science and Collaboration Group, Pfizer

This presentation will take a brief look at the standardized approach that Pfizer has developed to build remote monitoring platforms using biosensors to quantitatively assess disease relevant physical and physiological phenomena. A review of this methodology will focus on endpoint identification, biosensor and device evaluation and analytics development.

9:55 CO-PRESENTATION: Re-Imagine Clinical Trials with Trust

Sponsored by KPMG

Arun Ghosh, Principal, US Blockchain Leader, KPMG LLP

Richard Bergstrom, Vice President, Life Sciences, Guardtime

Digital technologies provide significant opportunity to modernize clinical trials. During this session, KPMG will provide its perspective on applying the Internet of things (IoT) and Blockchain technologies for clinical trials to validate the precision and accuracy of patient data captured from smart sensors, improve consistency and reliability of data to garner insights and provide the trust trial participants, clinicians and regulators need for transparency and compliance with data privacy and security regulations. KPMG will also present a framework to enhance the efficacy of patient care, improve reporting cycles, optimize drug development lifecycle, and advance innovation in Life Sciences.

10:25 Coffee Break in the Exhibit Hall

DIGITAL ENDPOINTS & TECHNOLOGIES

11:20 Chairperson's Remarks

Hugh Levaux, PhD, Founder and CEO, Protocol First

11:25 The Future of Healthcare: Humans and Machines Partnering for Better Outcomes

Emmanuel Fombu, MD, MBA, Global Commercial Strategy and Digital Innovation, Johnson & Johnson

We live in a world where data can help us make more informed decisions about how to navigate traffic, who to date, what to buy, who to network with and how to better manage our finances. But when it comes to our personal health and wellness, we have no roadmap. We need something to show us where we are in terms of our health, with landmarks for risks and opportunities. A GPS that makes it easier to move toward our personal health goals. A new way to look at health and life.

11:55 The Digital Health Ecosystem: The "New" People, Technologies and Processes Needed to Scale Up the Use of Digital Health in Pharmaceutical Development

Mark Sapp, Product Line Owner, Digital Health, Janssen R&D

It is becoming increasingly valuable to leverage digital technology in a clinical trial environment to differentiate therapy, provide rapid insights and provide patient-centric solutions. This talk will aim to discuss how to move beyond ongoing digital health "pilot-itis" and describe the ecosystem of functions and capabilities that are needed to scale the use of digital technologies in clinical operations.

12:25 pm **Transition to Lunch**

Sponsored by
Clinical Ink

12:30 **BRIDGING LUNCHEON PRESENTATION: Configuration in ePRO: Making Design More Collaborative and Delivering Better Results**

Kyle Hogan, Director, eClinical Solutions, Clinical Ink

You will learn how the authoring tool allows Clinical Ink project managers to focus on continuous collaboration in design and iterative improvements starting with early decisions and regular feedback. You will see how rapid and regular prototyping supports that feedback cycle, improves sponsor study team confidence and delivers better quality ePRO solutions with fully integrated patient engagement experiences.

1:10 **Coffee and Dessert Break in the Exhibit Hall**

2:10 **Close of Conference**

Stay on and attend Part 2: Clinical Technology and Innovation. See page 20 for details.

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8th Annual

Late Stage Research Strategy and Operations

RWE for Regulatory Decisions, Market Access and Pharmacovigilance

February 19-20

Real world evidence solutions have changed the design and execution of peri-approval and post-marketing research. Real time real world data generation, pragmatic trials, next generation databases open new opportunities for post-marketing research as well as regulatory and market access needs. Data generated in peri-approval real world data based studies is essential for multiple stakeholders within and outside pharmaceutical companies, such as regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's 8th Annual "Late Stage Research Strategy and Operations" conference is designed to facilitate knowledge exchange around all aspects of peri-approval studies and major application of their outcomes/generated data.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings **(see page 11 for details)**

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Trifecta Annual User Group Forum *Sponsored by* trifecta

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7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes **(see page 5 for details)**

9:35 Grand Opening Coffee Break in the Exhibit Hall

RWD TO SUPPORT REGULATORY DECISIONS

10:35 Chairperson's Remarks
Charles Makin, Global Head, Real World Evidence Strategy, Biogen

10:40 RWD: Studies for Formulary Decision Making and Health Technology Assessment – A US Perspective
Martin Marciniak, PhD, Vice President, US Medical Affairs, Customer Engagement, Value, Evidence & Outcomes, GSK
HTA is heavily dependent on real world data (RWD) in part because of its focus on measuring outcomes that extend past that offered by traditional clinical trial data or systematic reviews. RWD, in its many forms (e.g., pragmatic, observational, social media, other) is increasingly viewed as an important part of this process, particularly outside of the United States. What does this mean for the US, and its nascent HTA infrastructure?

11:10 Considerations for Use of Real World Evidence to Inform Regulatory Decisions
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen
Real world evidence (RWE) will be increasingly used in regulatory submissions seeking approval for a new indication, label expansion, or new product marketing authorization. The 21st Century Cures Act places additional focus on the use of RWE in regulatory decision making. While growing availability of data and sophistication of analytic tools have transformed RWE generation, challenges impeding full realization of benefit from RWE involve issues such as data quality and what constitutes "substantial evidence" when using RWE as supporting or pivotal evidence. Considerations to help ensure the advancement of suitable RWE use cases to enable appropriate impact of RWE in regulatory decision making will be discussed.

11:40 Use of Real World Data (RWD) to Assess Cardiovascular Safety of Prucalopride to Support a New Drug Application in the US
William Spalding, MS, Director, Outcomes Research-Epidemiology, Shire
Prucalopride belongs to the 5HT4 agonist drug class, and 2 previously approved 5HT4 agonist drugs have been removed from the market for increased risk of adverse cardiovascular (CV) events. Shire, in agreement with the FDA, sponsored a CV safety study based on RWD from clinical use of prucalopride in European markets where prucalopride has been marketed since 2009. This talk discusses rationale for use of RWD to assess drug safety.

12:10 pm Using Technology to Maximize Patient Choice While Minimizing Burden in Post-Approval Research *Sponsored by* ERT
Chris Watson, PhD, Director, Product Strategy, Digital Patient Product Management, ERT
With the rise in importance of prospective patient data capture as part of real-world evidence analysis how can we make it simpler and easier for patients to participate - and remain engaged - in post-approval research? What role does technology play and how can advances in consumer technology simplify the process for patients, investigators and sponsors?

12:40 Transition to Lunch

12:45 LUNCHEON PRESENTATION to be Announced *Sponsored by* Syneos Health

1:25 Coffee and Dessert Break in the Exhibit Hall

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RWD TO SUPPORT REGULATORY DECISIONS (CONT.)

2:05 Chairperson's Remarks
Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals

2:10 A Practical Paradigm of Using RWE for Seeking Regulatory Decisions in Label Expansion or New Indication
Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals

21st Century Cure Act required the FDA to provide a framework and guidance for evaluating RWE in the context of drug regulation to support approvals of new indications for previously approved drugs and to support or fulfill post-approval study requirements. We established a practical paradigm to guide drug projects teams in developing high-quality RWE proposals to the FDA for these two areas.

2:40 Enhancing the Credibility of Real-World Evidence to Expand it Usage by Decision Makers
Marc Berger, MD, Chair, Real World Evidence Advisory Committee, SHYFT Analytics

3:10 Accelerating Clinical Research by Mining and Leveraging Electronic Health Records Data
Sponsored by OPTUM™
Todd Johnson, MD, MBA, Senior Vice President, Clinical Research, Optum

We've all heard the statistics. Half of all clinical trials miss their timelines. Eleven percent of trial sites don't enroll a single patient. It can cost $2-3 billion dollars to bring a new drug to market. This is an incredibly challenging area that is ripe for new ideas and approaches. Optum is now ready to launch a solution that will significantly change the way clinical research is done. It's called the Digital Research Network and its goal is to combine EHR data (80+ million lives), leading-edge cloud-based technology, study design expertise and our existing relationships with research-ready provider groups in a way that only Optum can. The result will be an entirely new way to conduct clinical research that will shorten time to market and reduce the overall cost of clinical research.

3:40 A Dialogue on FDA Draft Framework for Real-World Evidence Programs
Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, CDER, FDA

The session is dedicated to a discussion on the FDA Draft Framework for Real-world Evidence Programs that was issued in December, 2018.

Q&A Moderator: Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals

BREAKOUT DISCUSSION GROUPS

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5:00 Welcome Reception in the Exhibit Hall
Sponsored by ADVARRA

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Sponsored by IMS Health & Quintiles are now IQVIA™
Eric Delente Head, Patient Consent, IQVIA Technologies

This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

RWD SOURCES AND ANALYTICAL APPROACHES

8:20 Chairperson's Remarks
Ken Light, Executive Vice President, Corporate Strategy, OmniComm Systems

8:25 Real World Considerations for Using Real World Common Data Models and Rapid Analytics
Guo Li, Director, Real World Evidence (RWE) Analytics, Novartis

Use of real world data (RWD) has evolved over the last several decades to a point where the body of evidence for any research question can easily be addressed across multiple databases with the use common data models (CDMs). These

CDMs can enable rapid insight generation by improving interoperability across different data types and different geographies, but also come with some important practical limitations.

8:55 Using Data and Analytics to Synthesize Real-World Evidence
Victoria Gamerman, Associate Director, Biostatistics, Head, Health Informatics & Analytics, Boehringer-Ingelheim Pharmaceuticals, Inc.
In this presentation, learn about an integrated approach to understanding real-world evidence needs throughout the medical organization. Two case studies will be highlighted: (1) an observational US-based registry in a rare disease to capture the real-world patient journey; and (2) a global survey of patients and physicians in a chronic condition. A future outlook on RWD standards and the role of Big Data in RWE generation will be shared.

9:25 Identifying Breast Cancer Stage and Biomarker Status in Administrative Claims Data Using Predictive Modeling
Cynthia de Luise, PhD, Senior Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer, Inc.
Claims databases lack stage and receptor status to identify cancer populations. From Anthem's Cancer Care Quality program validation sample, we used regression and machine learning techniques to construct a predictive model to identify advanced stage ER+/HER2- breast cancer (ASBC) patients. The model (c-statistic=0.93; PPV=91%; Sensitivity=54%) was applied to the HealthCore Integrated Research Database (HIRD) to identify an ASBC cohort. Predictive modeling can identify cancer stage and receptor status in claims.

9:55 The Role of RWD After Safety Signals are Identified: Analytic Approaches to Refining a Safety Signal
Sponsored by UBC
Irene Cosmatos, Senior Research Specialist, Database Analytics Automation, UBC

10:25 Coffee Break in the Exhibit Hall

INTERNAL CONSIDERATIONS AND OPERATIONAL CHALLENGES

11:20 Chairperson's Remarks
Sean Zhao, PhD, Head, US Patient Safety Surveillance, US Medical Affairs, AstraZeneca Pharmaceuticals, Inc.

11:25 Considerations and Challenges Associated with the Implementation of an Integrated Value-Based Pharmaceutical Data and Evidence Strategy
Tony Hebden, PhD, Vice President, Health Economics & Outcomes Research, AbbVie
Pharmaceutical companies have identified the need to define value to key access stakeholders as critical to ensuring appropriate patient access to new medications. This approach requires that companies not only define value in terms of the classical RCT evidence required to obtain regulatory approval, but also develop new processes, infrastructure and governance to ensure less traditional types of evidence are generated and leveraged appropriately.

11:55 Cross-Company Coordination of Post Marketing Research Efforts
Sean Zhao, PhD, Head, US Patient Safety Surveillance, US Medical Affairs, AstraZeneca Pharmaceuticals, Inc.
There are many types of post marketing research activities, including clinical trials, patient registries, epidemiology studies, health economic and outcome researches, etc., having been used for multiple purposes, i.e., fulfilling regulatory post marketing requirements (PMRs), supporting in risk management activities, closing clinical evidence gaps, generating real life clinical evidences in supporting formulary decisions, etc. It is important to strategically plan and implement these studies and activities through a cross-company coordination. The presentation will discuss how to involve cross-company functions in post marketing research activities and when a post marketing research activity's scientific purposes can be combined with commercial goals and when they should be separated.

12:25 pm Transition to Lunch

12:30 pm BRIDGING LUNCHEON PRESENTATION: Sharper Images: How Rollover Studies Can Mitigate Post-Market Study Commitments
Sponsored by PRA Health Sciences
Meg Richards, PhD, MPH, Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences
Over the past decade, the FDA has increasingly approved new products based on fewer and shorter trials. This reflects a lifecycle evaluation approach, which stresses continued monitoring of safety and effectiveness after the product has been marketed. Sponsors can be assigned numerous post-market commitments whose delay may result in real-world safety and effectiveness challenges. Properly designed rollover studies can provide a wealth of information about the product well in advance of marketing.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Leveraging RWD for Clinical and Observational Research . See page 60 for details.

Clinical Biomarkers Strategy and Innovation

Enabling Precision Medicine Trials

The concept of personalized or precision medicine has brought to life several types of clinical trials that involve biomarkers and require biospecimen collection and management. Effective management of these trials can be complicated and requires specific operational approaches. CHI's 4th Annual "Clinical Biomarkers Strategy and Innovation" conference is designed to exchange solutions to overcome operational and scientific challenges with various types of studies, including trials with biomarker-based stratified trials, biomarkers as end points, etc. Informed consent, innovative solutions for biospecimen management and other important topics will be discussed by leading experts from top pharmaceutical companies.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

BIOMARKER DRIVEN TRIALS: STRATEGY AND INNOVATION

10:35 Chairperson's Remarks
Caoimhe Vallely-Gilroy, Director, Global Head, Clinical Trials Biosample Management, Global Clinical Operations, Merck KGaA

10:40 Implementation of GSK's Biological Sample Management Strategy
Mohan Bangalore, Global Head, BioAsset Management, GSK

GSK is implementing a biological sample management strategy to increase the visibility and use of human biological samples in discovery and clinical R&D. This cross-functional strategy is leveraging systems and automation to increase efficiency, reduce manual effort and ensure increased compliance in biospecimen management. An integrated IT platform is being developed to create a master sample repository with links to automated sample stores.

11:10 The Challenges of Implementing 10 Years of Industry Advancement in 1 Year!
Caoimhe Vallely-Gilroy, Director, Global Head, Clinical Trials Biosample Management, Global Clinical Operations, Merck KGaA

It is rare in the industry to get the "luxury" of implementing a function within an established pharmaceutical company, so when the opportunity presents itself, it is not one to easily turn down! This presentation will give an overview of the highs (and lows!) of establishing the function of Clinical Trial Biosample Management in a reputable clinical operations organization.

11:40 Challenges of Clinical Specimen Management in the Era of Precision Medicine
Debra Reinhard, Head, Translational Medicine Enabling Solutions, Bristol-Myers Squibb Company

In the era of precision medicine in the pharma industry, historical paradigms for clinical operations are giving way to new structures designed for maximum flexibility and speed. Biospecimen management is fundamental to the biomarker research informing our translational strategy. Traditional operations are no longer sufficient to respond to this need for speed and agility to pivot as scientific insights are revealed. Learn about how BMS is addressing this challenge.

12:10 pm Biomarker Management in Immuno-Oncology Clinical Trials: Operationalizing Biomarker Assessments
Maria Tverskoy, PhD, Biomarker Operations Program Leader, Product Development Global Operations, Genentech

Clinical trials are becoming more complex by shifting to personalized medicine, looking at mechanisms of actions of immuno-oncology (I-O) agents and evaluating responses to new immunotherapy combinations. Inclusion of biomarkers has been critical to understanding the underlying biological response in clinical trials. This talk will focus on specific challenges in biomarker management and strategies that can be used for successfully operationalizing biomarker assessments in I-O clinical trials.

12:40 Transition to Lunch

12:45 LUNCHEON PRESENTATION: Clinical Trial Biospecimen Lifecycle Management *Sponsored by* BIOFORTIS a QIAGEN Company
Jian Wang, PhD, CEO, BioFortis

Biomarker-driven clinical trials are the foundation for precision medicine. In these trials, sample collection, consent, transportation, and testing, involving multiple CROs, vendors, and labs, must be carefully designed and executed. Deviation from design must be quickly accounted for to allow continuous improvement; otherwise,

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trials risk milestone delays and regulatory non-compliance. Here we showcase our "complete biospecimen lifecycle management" approach that has proven to increase trial execution efficiency and reduce regulatory risk at numerous R&D organizations.

1:25 Coffee and Dessert Break in the Exhibit Hall

INFORMED CONSENT AND DATA PERMISSIONS

2:05 Chairperson's Remarks
Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck

2:10 Consent for Biospecimens: The Basics
Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck
Obtaining consent for research with biospecimens in global clinical trials is complex. This presentation will provide an understanding of the basics of consent for biospecimens, a background and several influential cases which have shaped the way we consent today, and an overview of today's global challenges in obtaining consent for research use of biospecimens.

2:40 Returning Data and Results to Clinical Trial Participants
David Leventhal, Senior Director, Clinical Innovation, Global Product Development, Pfizer
Clinical trials rely on the participation of patients who are willing to have data collected about them, as these complete results are posted online and published in scientific journals. Little, however, is routinely given back to the patient to acknowledge their contribution. Pfizer has pioneered the returning of data to patients by making plain-language summaries of study results available to participants as well as returning individual patient data to clinical trial volunteers.

3:10 Real World Sample-Based Approach for Qualification of GLDH as a Liver Specific Biomarker of Liver Injury
Jiri Aubrecht, PhD, Scientific Director, Translational Biomarker Research, Takeda
Diagnosis of the onset of liver injury in subjects with underlying muscle impairments is an unmet medical need. We have evaluated glutamate dehydrogenase as a liver specific biomarker of hepatocellular damage. The presentation will introduce a translational biomarker development paradigm based on real world samples. We will discuss biomarker qualification study design and feedback from regulatory agencies.

3:40 Sponsored Presentation *(Opportunity Available)*

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See website for details: www.SCOPEsummit.com/breakouts.

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

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Eric Delente Head, Patient Consent, IQVIA Technologies
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8:15 Session Break

TECHNOLOGY TO ADDRESS SAMPLE AND BIOMARKER LOGISTICS & BEST PRACTICES

8:20 Chairperson's Remarks
Chairperson to be Announced

8:25 Clinical Sample Tracking: Switching from Project to BAU and Providing Enhancements Including a Dashboard
Jane Fang, MD, Head, Clinical Business Management & Analytics, MEDI Biologics Unit, AstraZeneca
Once clinical sample tracking was implemented, our goal was to allow the business to take it on. This would be about the processes and the guidance we as an implementation team provided to the business for them to take on the daily functionality. And as an enhancement, provide simple inventory feedback to a larger audience through an existing clinical dashboard.

8:55 Innovations along the Specimen Management Value Chain

Brenda Yanak, Former Global Head, Specimen Strategy and Innovation, Q2 Solutions, a Quintiles Quest Joint Venture

When the term "specimen management" is used, people generally think of biobanking, although recently more and more companies are starting to take a cross-functional viewpoint. This talk describes a vision in which the term "specimen management" is further expanded to encompass an end-to-end approach. Innovation along the end-to-end drug development value chain and how it will impact operations and technology of specimen management within future clinical trials will be discussed.

9:25 Patient Friendly Biomarkers: Utility of Minimally Invasive Blood Sample Collection Technologies in Clinical Trials

Dmitri Mikhailov, PhD, Biomarker Development, Novartis Institutes for BioMedical Research, Inc.

Most clinical blood samples are obtained via venipuncture which can be unpleasant to the subject and requires a trip to a clinical site. The emergence of minimally invasive and patient friendly procedures can facilitate subject recruitment, improve retention, and promote simplification of trial design and conduct. Such technologies allow clinical trials to reach a broader patient population and enable collections of follow-up samples from patients for an extended period of time, including post-study conduct.

9:55 Sponsored Presentation *(Opportunity Available)*

10:25 Coffee Break in the Exhibit Hall

INTEGRATING SAMPLE MANAGEMENT INTO CLINICAL TRIAL CYCLE: RBM CONSIDERATIONS

11:20 Chairperson's Remarks

Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories

11:25 Specimen-Centric Considerations for Possible Extensions of Risk-Based Monitoring (RBM) Principles

Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories

Clinical trials play a central role in the development and delivery of breakthrough diagnostics for patient care, and specimens collected in these trials are becoming increasingly significant and subject to regulatory compliance. As biomarker data continues to drive an increasing number of trial decisions and clinical endpoints, a specimen-centric focus needs to become part of any comprehensive clinical trial monitoring process. As Risk-Based Monitoring (RBM) matures and adoption becomes more widespread, the extension of the established principles to include specimen-centric elements seems like a reasonable path forward.

11:45 CO-PRESENTATION: What Can We Learn from RBM to Enhance the Utility of Biospecimens in Clinical Trials?

Matt Harlin, Associate Director, Clinical Pharmacology, Otsuka Pharmaceutical Companies

Sharin Roth, Director, Clinical Pharmacology, Bioanalysis, Otsuka

Establishing business processes to govern the life cycle of biospecimens collected in clinical trials is essential to any drug developer. Leveraging existing risk-based monitoring (RBM) systems can enhance the utility of biospecimens, ensuring they are of high quality, consented properly, accounted for, and easily selected for analysis. RBM system attributes that are specific to biospecimens will be evaluated.

12:05 pm Biospecimen Tracking as an Integral Part of Risk Based Monitoring

Morten Thorup Pedersen, Risk Based Monitoring Specialist, Centralised Monitoring Unit, Clinical Systems, Data & Trial Management, Novo Nordisk A/S

Novo Nordisk has implemented Risk Based Monitoring with biospecimen tracking being an integral part of the approach. With biospecimens being the primary endpoints in many trials, we took the approach of centrally monitoring the collection and analysis of these to be able to do a targeted follow up with the sites where results of biospecimen samples were missing. Combining data from several sources, we have set up a system to predict where the risk may emerge and do a proactive targeted follow-up.

12:25 Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Where in the World Are My Specimens? (And How Do I Fetch Them?)

Sponsored by eurofins | BioPharma Services

Kevin Smith, Vice President, Technology & Data Solutions, Eurofins Central Laboratory

With the ever-increasing complexity of each clinical trial being conducted globally, a universal challenge faced by the industry is specimen visibility as it proceeds through the processing pathway from point of collection, to shipment to central laboratory, to potential aliquoting and disbursement to long term storage, third party laboratories or specialty laboratories within your vendor organization. When you add the potential for discrepancies in shipping manifests, demographics contained in multiple databases/systems and queries generated from paper-based requisitions, you add the additional real-world risk of database lock delays. Please come share in a case study of technology utilization to mitigate all of these operational risks and engage with your colleagues in an exploration of best practices.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Clinical Biospecimens and Central Lab Solutions. See page 18 for details.

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2nd Annual

Clinical Supply Management

Streamlining Clinical Supply Tracking, Management & Distribution for Patient-Centric Trials

February 19-20

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. CHI's 2nd Annual "Clinical Supply Management" conference offers practical solutions for effective clinical supply management. The program focuses on the intersection of clinical supply and clinical operations, offering best practices and case studies on partnering with clinical ops to streamline the process, the role of clinical supply in virtual, siteless trials, and tech tools to enable proper tracking and tracing of clinical supplies.

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7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

PARTNERING WITH CLINICAL OPS FOR CLINICAL TRIAL SUPPLY OPTIMIZATION

10:35 Chairperson's Remarks
Jon Paras, Senior Manager, Electronic Trials Operations, Amgen

10:40 CO-PRESENTATION: Don't Reinvent the Wheel: Leveraging Robust Enrollment Planning to Inform Clinical Supply Management
Christine Crandall, Head of Strategic Clinical Planning, Study Start Up, RD Projects Clinical Platforms & Sciences, GSK
Tony Porter, Associate Director, Consultative Solutions, IQVIA Technologies
Clinical supply budgets remain a big area of untapped potential efficiencies for both sponsors and CROs. While suppliers have focused on improving accuracy of their estimates, it's usually in isolation and is often impacted by unexpected activities of upstream stakeholders. We'll share details of a collaborative approach that allows a clinical supply organization to leverage existing clinical technology for enrollment and timeline planning to inform their supply strategy.

Sponsored by MARKEN

11:40 Trends and Innovative Solutions for Optimizing Your Clinical Supply Chain
Paddy Hanlon, Vice President, Commercial Operations, Marken LLP

Sponsored by ALMAC

12:10 pm The Next Frontier: New GCP Expectations of Sponsors & Suppliers for the eClinical Landscape
Todd Kole, RPh, Vice President, Clinical Project Services, Almac Clinical Technologies
Global regulatory agencies are exhibiting greater scrutiny over both sponsor and vendor processes during eClinical system development and deployment. This session will shed light on the new areas of interest by regulators, and includes actionable insight on how to ensure both sponsor and vendor processes align with new expectations being set.

12:40 Transition to Lunch

Sponsored by

12:45 LUNCHEON PRESENTATION: Achieving Extended Enterprise Supply Chain Maturity Within a Clinical Supply Environment
Oliver Cunningham, Director, Client Enablement, CRF Bracket
Clinical supply chains are well known to be immature within the industry, and some way behind their commercial counterparts. This session will explore the different stages of evolution within clinical supply chains, and some key indicators to enable you to determine the level of maturity your company is at.

1:25 Coffee and Dessert Break in the Exhibit Hall

TRANSFORMING CLINICAL SUPPLY CHAIN PLANNING

2:05 Chairperson's Remarks
Jon Paras, Senior Manager, Electronic Trials Operations, Amgen

2:10 INTERACTIVE PANEL: Current Challenges in Demand and Supply Planning
Moderator: Bill Coakley, Senior Director, Global Supply Chain Planning, BioMarin Pharmaceutical Inc.
Jan Pieter Kappelle, Vice President, Strategy, 4G Clinical
Jon Paras, Senior Manager, Electronic Trials Operations, Amgen
Topics covered include:

- What are the best available technology solutions for clinical demand and supply planning? Are they different from commercial planning solutions? What are the must-have features planning tools need to satisfy for clinical supply chain professionals? How aligned is your CSC with your company's commercial planning processes and tools?
- What role does Clinical Supply Chain plan with respect to drug accountability

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and reconciliation? What role does Clinical Operations Play? Who has overall responsibility? How is that achieved?
- What are some best practices on ensuring that clinical supply is meeting requirements of blinded studies? Is your CSC blinded or unblinded? Do they interact with study teams? Patient sites?

3:10 Navigating Clinical Trial Supply Optimization Vendors and IRT ROI
Constantine Ward, Owner & Supply Chain Consultant, Optimal
How much do I need to label & package? Explore the various clinical trial supply chain optimization software packages in the market. Do they work with budget IRT systems? Do they work with sophisticated highly bespoked IRT systems? How do they compare to commercial systems? How is the supply chain Optimization market coping with new IRT functionality?

Sponsored by Catalent CLINICAL SUPPLY

3:40 Turning Up the Heat: The Effect of Pipeline Success on Clinical Supplies
Eva Allen, Senior Clinical Supplies Manager, Clinical Supply Services Business Solutions, Catalent
For many sponsors, advancing promising investigational medicines from Phase I to Phase II means the introduction of complex protocols and design elements such as blinding, arms, placebos, comparators and more that can quickly increase the potential for significant clinical supply-related issues. Sponsors with young pipelines moving into Phase II or Phase III for the first time are particularly at risk of encountering clinical supply challenges that can delay studies and waste limited resources.

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups
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Sponsored by ADVARRA advancing better research

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8:15 Session Break

TECH INITIATIVES TO ENHANCE CLINICAL SUPPLY CHAIN MANAGEMENT

8:20 Chairperson's Remarks
Jan Pieter Kappelle, Vice President, Strategy, 4G Clinical

8:25 How Can Blockchain Improve Traceability of Clinical Trial Supply Chain?
Basker Gummadi, IT Strategy & Digital Transformation, Digital Innovation, Bayer U.S. LLC
Blockchain technology has the potential to positively impact clinical trial supply chains by improving the traceability of medications from active pharmaceutical ingredient (API) to patient. The chain between a clinical study sponsor, study patient, and site is long and involves the use of multiple IT systems. In a world where all parties are linked via a blockchain, it would be possible to leverage encryption and access control so that the members (trusted participants) could get confirmation of the receipt of the product without having access to protected patient information and, in turn, provides the ability to validate patient identity.

8:55 Cross-Industry Collaboration Evaluating How Blockchain Can Transform the Pharmaceutical and Healthcare Industry, Part of Emerging Trends & Technology PhUSE Workgroup
Adama Ibrahim, Associate Director, Clinical Operations, Biogen
This presentation will describe the current landscape in the pharma and healthcare settings, exploring the areas where Blockchain could be used and presenting two detailed use cases (a. Drug Supply Chain using Smart Contracts; b. Patient Data Access/Transparency) to support future development and implementation for an upcoming proof of concept.

9:25 Diving into Innovations that Will Change Your Clinical Trials
Matthew Moyer, Director, Clinical Supply Technology, Merck
This presentation will review innovations expected to change the landscape of clinical trial supply and conduct in the years to come, and the efforts within and across industry to support their installation. This includes use of mobile healthcare technology to enable siteless clinical trials and improved patient monitoring, opportunities for use of Blockchain to secure data sharing and communication between all the parties involved in trials, and the potential for social robotics to play a role in patient engagement.

9:55 Utilization of Drug Pooling to Optimize Complex Drug Management
Sponsored by medidata
Kevin Collier, Senior Director, Product Management, Medidata
Despite the potential to deliver significant efficiencies and cost savings, pooling inventory across clinical studies has more often been an approach discussed in our industry than applied in practice. This presentation will cover how drug pooling at the site and depot levels was applied to an innovative oncology program, enabling for the implementation of a complex adaptive design while decreasing costs, shortening timelines, and, ultimately, leading to better treatments for patients sooner.

10:25 Coffee Break in the Exhibit Hall

DIRECT-TO-PATIENT CONSIDERATIONS OF CLINICAL TRIAL SUPPLY

11:20 Chairperson's Remarks
Gerald Finken, CEO, Center Point

11:25 INTERACTIVE PANEL: Clinical Supply in Virtual Trials – Direct-to-Patient Distribution
Moderator: Gerald Finken, CEO, Center Point
Michael Sparozic, RPh, Lead Trial Supply Operations Manager, Clinical Supplies Chain Operations, Distribution, Sanofi

As the pharma industry moves towards virtual trials and more patient-centric initiatives for clinical trials, one challenge that is often overlooked is direct-to-patient distribution of clinical supplies. Topics discussed in this panel include:

- Technologies that can offer solutions in tracking and tracing supplies direct to patients
- Investigator and site buy-in and support for direct-to-patient initiatives
- Logistical, cost and regulatory considerations
- Challenges with patient handling of IMPs.

12:25 pm Transition to Lunch

12:30 LUNCHEON PRESENTATION: Putting the Patient at the Center: A New Approach to System Change Requests (SCRs)
Sponsored by CENDUIT
Andrew Rohrbaugh, Director, Client Delivery, Cenduit
Clinical studies are not a one-size fits all approach. A purely "configured based system" is a myth. This session focuses on the evolving role of system change request (SCRs): putting the patient at the center. 1) Hear an academic review on protocol amendment impact in clinical studies 2) Learn how an agile, configurable approach can reduce timelines, keeping patient benefit at the forefront 3) Understand an Operational Excellence (OpEx) approach to IRT system changes.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Clinical Biospecimens and Central Lab Solutions. See page 63 for details.

Improving Site-Study Activation and Performance

Strategically Implementing Process and Systems for Rapid Study Start-Up and Improved Site-CRO-Sponsor Interactions

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 to improve: the study feasibility process, site investigator's experience, consent process, rollout and implementation of technologies across a study, contract and budget negotiations, payments, standardization of source documents and study-related materials, and development of patient recruitment and retention programs. Understanding and planning for the challenges faced by your study participants, investigators, sites and industry partners is the key to improving trial efficiencies and outcomes. CHI's 6th 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. See page 12 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Metrics, Standards & Technology: How to Harness Digital to Transform Protocol Creation

Sponsored by Cognizant

Bob Brindle, Venture Leader, Life Sciences, Cognizant

How much effort do you waste during clinical trial protocol creation? How do you know? How do you fix it? In this increasingly digital world, it's frustrating to be constrained by traditional word processing tools, but making the shift to a digital process can be daunting. Join this session to discover the practical steps that will set you up to transform your process – and get a peek at what a digital protocol will enable.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

UNDERSTANDING THE LATEST CHALLENGES FOR STUDY START-UP AND SITE ACTIVATION IN US, EU AND ROW

4:05 Chairperson's Remarks

John Makowski, Head, Clinical Operations, Audentes Therapeutics

4:10 New EU-Clinical Trials Regulation: Industry Preparation via Pilot Procedures

Thorsten Ruppert, MD, Senior Manager, Research, Development and Innovation, Association of Research-Based Pharmaceutical Companies (vfa)

The Regulation (EU) No 536/2014 on clinical trials in medicinal products for human use (EU-CTR), which will apply from 2020, will fundamentally change the procedures for approving and evaluating applications for clinical trials in Europe – e.g. a purely electronic application via an EU portal or a joint assessment between EU-Member State with involvement of national-level authorities and ethics committees. In preparation for the approach introduced by the EU-CTR, different pilot phases have been started in Europe with the aim of fundamentally testing this new process. The presentation will describe the experience of industry and learnings made for the preparation for the new authorization system in Europe.

4:40 Study Start Up Practices and Cycle Times among Sponsors and CROs

Mary Jo Lamberti, PhD, Professor, Associate Director, Sponsored Research, Tufts CSDD

Tufts CSDD conducted a comprehensive survey among over 400 pharmaceutical and biotechnology companies and contract research organizations examining the processes of site identification, site selection and study start up. The survey examined site selection practices and decision-making, study start up timelines, and site feasibility, and also explored the implementation of specific tools and resources that impact cycle time, cost, and performance. Tufts also assessed those factors contributing to poor site selection; and improvements made to the site selection and start up processes. Key performance metrics (e.g. cycle time) were gathered for site selection, site identification and study start up activities, and comparisons were made between those companies using new vs. repeat sites, sponsors and CROs, and those companies with varying investment levels in technology.

5:10 Disassembling Endemic Silos in Pharma Pivotal to Improving the Clinical Trial Continuum

Sponsored by ORACLE Health Sciences

Jae Chung, President & Founder, goBalto

Workflow-based technology coupled with executive authoritative power encourages process optimization in the clinical trial continuum, helping to break down silos, enhance operational performance and ensure quality in the electronic trial master file.

5:25 EnForeSys – A Simulation Tool for Enrollment Planning

Sponsored by Cytel

Hrishikesh Kulkarni, Principal Statistician, QA and Pre-Sales Support, Cytel

A majority of clinical trials experience delays in enrollment, which can lead to discontinuation and loss of revenue. EnForeSys, a sophisticated tool for enrollment planning, makes this task more manageable. In this talk, we will explore useful

options to incorporate a trial planner's experience into a simulation based approach.

5:40 CASE STUDY: The Sites First Initiative: Understanding Patients and Site Relationships to Improve Trials
Marisa Rackley, Director, Clinical Development Execution, Vertex Pharmaceuticals
This presentation will share Vertex's site-focused initiatives and our journey to put sites first. How did the initiative start? What were the obstacles? In addition to describing the other parts of the initiative, the talk will focus on the installation of our new Regional Site Advocate group and share data from the sites on how this role has helped to bring value to the sites.

6:10 – 7:10 Networking Reception *Sponsored by* DrFirst

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach *Sponsored by* medidata
Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging
Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

IMPROVING START-UP TIMES: UNDERSTANDING SITE INVESTIGATORS' EXPERIENCE, INFORMED CONSENT, PAYMENTS

8:20 Chairperson's Remarks
Chris Crucitti, Chief Commercial Officer, CRF Bracket

8:25 Re-Defining the Site Investigator Experience
Lisa Moneymaker, CTMS Process Architect, Amgen
Imagine a world where Site Investigators could use a centralized point of access for all study-related tasks and study information, rather than many portals and platforms, to access studies with every Sponsor they work with. Imagine if Sponsors could quickly search for and download their latest study documents, and easily access a registry of Investigator profiles to assess feasibility for new studies. The Shared Investigator Platform (SIP) was launched with these goals in mind and continues to evolve with new functionality. This session will provide real-world observations and learnings from the SIP's first major wave of adoption.

8:45 Site Management Approaches in Gene Therapy & Rare Disease Clinical Trials: A Collaborative Approach to be a Sponsor of Choice
John Makowski, Head, Clinical Operations, Audentes Therapeutics
There is significant complexity, sensitivity and timely logistics to most effectively execute gene therapy, rare disease clinical trials. The importance of a Clinical Operations organization to have a well-established collaborative approach with Investigators, Internal Medical Science Liaisons and Advocacy Groups is key to successful execution of these complex studies. The ability to simplify and innovate around a sponsor's Site Management approaches can increase your ability to be a sponsor of choice in this competitive and exciting area of drug development. We will review several different approaches and strategies to consider to position a team for success in this space.

9:05 Transforming Informed Consent: Current Landscape and Tools to Enable the Future of eConsent
Cassandra Smith, MBA, Associate Director, Investigator and Patient Engagement, Janssen
While the shift to digital technologies is pervasive across multiple industries, the informed consent process for clinical trials remains primarily paper-based. Further, the increasing complexity in clinical trial-informed consent language and longer paper consent forms are increasing the importance of efforts to enhance patient comprehension, which may in turn contribute to increased study compliance, and fewer withdrawals from a study. TransCelerate's eConsent initiative stands to transform the informed consent process by using an array of patient-focused, multi-media components to improve understanding of a study and create process efficiencies for sites and sponsors. This session will share how the initiative has created the first cross-industry perspective, developed over a period of 2 years with input from over 14 global pharmaceutical companies.

9:25 Improving Site-Study Activation and Study Timelines through Harmonizing Budgeting, Contracts, Data, and Payments
Trent Farmer, Contract Manager, Attorney, CSL Behring
Site activation timelines and site payments both remain key industry issues. Simplifying and streamlining processes provides benefits for both sites and sponsors. This session covers how approaching the budgeting and contracting phases with both data and payments in mind can improve site activation timelines while creating a better foundation for prompt, accurate, and timely site payments.

9:55 Presentation to be Announced *Sponsored by* MENDEL
Wael Salloum, CSO & Co-Founder, Mendel Health

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

Improving Site-Study Activation and Performance

Strategically Implementing Process and Systems for Rapid Study Start-Up and Improved Site-CRO-Sponsor Interactions

BUILDING CAPABILITIES FOR IMPROVED SITE ACTIVATION AND CYCLE TIMES

11:10 Chairperson's Remarks
Chris Crucitti, Chief Commercial Officer, CRF Bracket

11:15 CASE STUDY: GSK's Journey of Launching a Formal Study Start-Up Department

Christine Crandall, Head of Strategic Clinical Planning, Study Start Up, R&D Projects Clinical Platforms & Sciences, GSK

In mid-2018, GSK established a Study Start Up Department bringing together core functions: Clinical Planning, Investigator Contracts & Benchmarking, Technology & Innovation and Study Start-up Leads. This Case Study will provide insight to our vision, capabilities and delivery methodology of providing subject matter expertise to enable quicker and more efficient study start-ups in a complex, global environment.

11:45 Transforming Study Start-Up

Sponsored by Veeva

Ashley Davidson, Director, Vault Study Startup, Strategy, Veeva

The industry sees tremendous opportunity to simplify and streamline study start-up processes. In a recent survey, 83% of respondents said their organizations have an initiative underway to do so.

Join Veeva to learn how a unified clinical operating model eliminates costly study start-up delays and speeds execution. Explore what other organizations are doing to streamline study start-up processes from site identification to site activation. Identify and quantify the value of improvements for your organization.

12:15 pm Transition to Shared Sessions

OPTIMIZING SITE-CRO-SPONSOR INTERACTIONS: UNDERSTANDING PATIENTS, SITES, PROCESS & TECHNOLOGY TO IMPROVE TRIALS (SHARED SESSION)

Chairperson's Remarks (continued from morning session)

Kyle Hogan, Director, eClinical Solutions, Clinical Ink

12:20 Focus on the Worst? A Weak-link Approach to Improving Site Performance and Accelerating Clinical Trials

Angelique Hopkins, Director, Clinical Trial Analytics, Business Insights and Analytics, Bristol-Myers Squibb Company

There are weak link sports (soccer) and strong link sports (basketball), the best method for improving performance in each situation depends on whether investing in the worst component of a team or the greatest strength on a team makes the biggest difference. For years the preferred method for accelerating clinical trials and improving site performance has been to focus on the highest performing sites. Using trial simulation and modeling techniques, we can see how a "weak link' approach to site performance (focusing middle and lower tier sites) may be a better although less intuitive method for increasing performance and accelerating timelines.

12:50 INTERACTIVE PANEL: Moving from Technology Indigestion to Workable Solutions

Moderator: David Vulcano, MBA, Vice President, Research Compliance & Development, HCA

Stephanie Abbott, PharmD, Clinical Research Program Director, Western Washington Medical Group

Jeewa Perera, CEO, Champ IT Solutions

Brenda Yanak, Former Global Head, Specimen Strategy and Innovation, Q2 Solutions a Quintiles Quest Joint Venture; Former Precision Medicine Lead, Pfizer

Matt Moyer, MBA, Director, Clinical Supply Technology, Merck

Multiple technologies are advancing healthcare delivery each and every day. This not only pertains to better utilizing both data at rest and data in motion, but also pertains to communication technologies breaking down the traditional boundaries of medicine. As clinical trial site operations are often dwarfed by the larger healthcare delivery ecosystem, how can pharma leverage that already-developing ecosystem so that they don't have to recreate the wheel?

- What technologies are out there right now that are underutilized by pharma in clinical trials?
- What regulatory or operational issues need to be either "myth busted" or challenged to make this happen?

1:20 Transition to Lunch

1:25 LUNCHEON PRESENTATION: The Secret to Unlock Adoption of eClinical Solutions

Sponsored by

Jeff Lee, President, eCOA & Patient Engagement, CRF Bracket

Technologies such as eConsent and ePRO are well-known by many researchers and have many case studies demonstrating their value. And yet, they are still used by a minority of studies. Why is this? This session will explore some hidden opportunities that lead to higher adoption of eClinical technologies. This session includes an open discussion format, so please bring all your thoughts and concerns on this topic!

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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Patient Engagement, Enrollment and Retention through Communities and Technology

Patient Centric Approaches to Optimize Clinical Trials and Participant Engagement

February 20-21

Enrollment planning, patient recruitment and a more patient-centric approach to study planning and execution 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 and continued engagement throughout the life of a clinical trial is essential to have complete data sets for your analysis and subsequent filings. There are strategies, tools and data-driven 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 6th 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.

Arrive early and attend Part 1: Enrollment Planning and Patient Recruitment. See page 16 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Leveraging Analytics and the Patient Voice to Optimize Patient Recruitment & Retention Campaigns

Sponsored by PRAXIS

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis Communications, LLC

As the world becomes more and more digital, it is important to tap into the endless amounts of data and conversations being shared on the Internet to glean patient insights and understanding. As we have lunch, we'll explore case studies and discuss how our industry can utilize data and analytics to craft and optimize efficient and effective patient-centric enrollment campaigns.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

CLOSING THE GAP BETWEEN THE PATIENT AND SPONSOR VIA SOCIAL MEDIA, COMMUNITIES, APPS & PATIENT-FOCUSED CONTENT

4:05 Chairperson's Remarks

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis Communications, LLC

4:10 CO-PRESENTATION: From Patient Voices to Real Solutions - Industry Examples Guided by Online Patient Interactions

Kevin Hudziak, Consultant, Innovation Lead, Patient Experience and Design Innovation, Eli Lilly & Co.

Leigh Anne Naas, Community Manager, Patient Experience and Design Innovation, Eli Lilly & Co.

Lilly maintains an active social media presence with @LillyTrials to ensure we are continually engaging with and listening to patients and caregivers to gain insights into the clinical trial journey. We will provide real world examples of how we have converted those insights into actions. These actions are centered around the Lilly TrialGuide ecosystem.

4:40 CASE STUDY: Insights from the Introduction of a Patient App to Improve Clinical Trial Engagement and Retention

Christie Fry, Therapeutic Area Lead Oncology, Patient & Investigator Relations, AbbVie

AbbVie introduced a pilot program for patient apps to improve compliance and retention in a few clinical trials. From this pilot program, we learned how an app can help and where we need to improve in the development of future apps. I will present real data from our experience which led to important insights. These will be helpful for others that are considering apps for use in clinical trials.

5:10 Patient Engagement & Retention "It's Not Just About the Patient"

Sponsored by PRA HEALTH SCIENCES

Claire Russell, Executive Director, Patient Experience, PRA Health Sciences

To design a truly patient-centered trial requires the development of a comprehensive patient persona- this includes an understanding of anyone that surrounds the patient. Personas tell us when, where and how to engage with a potential study participant. Removing study participation barriers extends to those that care for the study participant. While the patient is at the heart of the study – it's their care circle that impacts the participants decision to enroll in a study.

5:40 Creating a Platform to Connect Directly with Patients Now and in the Future

Maura Snyder, MBA, Director, Patient Engagement Strategy & Portfolio, Janssen

More than 90% of study participants never learn about study-specific results and recent data show 81% of patients want their own data and results above all other information. There is an opportunity to create a direct interface between

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the patient and sponsor to stay connected and share information. This interface also empowers patients by providing access to data, information, research opportunities to create engagement and a long-term partnership build on transparency, trust and awareness.

6:10 – 7:10 Networking Reception *Sponsored by* DrFirst

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach *Sponsored by* medidata
Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging
Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.8:15 Session Break

OVERCOMING ENGAGEMENT AND PROCESS CHALLENGES WITH VIRTUAL/REMOTE TRIALS AND PATIENT-CENTERED FRAMEWORKS

8:20 Chairperson's Remarks
Michael Stadler, CEO & Co-Founder, Clariness

8:25 Incorporating the Patient Voice into Drug Development & Gaining Buy-In from Leadership on Patient-Centricity Efforts
Beth Zaharoff, Senior Director, Patient Focused Engagement and Partnerships, TESARO
Engaging patients – people who know what it's like to live with the diseases that our protocols hope to enroll – can help to improve study feasibility, enhance convenience, create greater relevance and build commitment. This presentation will share how our Clinical Operations department made changes to incorporate the patient voice into the work that we do. Equally important, the presentation will share strategies for gaining support from senior leadership. The audience will have concrete examples to take back to their organizations.

8:55 Virtual Trials & Remote Trials: Efficiencies and Challenges
Antonieta Sosa, Director, Clinical Innovation, Janssen
The concept of virtual (site-less) and remote trials may seem like an efficient method to conducting a clinical trial, and in many ways, it is. There are however, many internal challenges we face as sponsors to discuss and address. Given that we continue facing challenges with recruitment and enrollment, site activations, etc., discussions around novel trial conduct is essential.

9:25 CO-PRESENTATION: Applying a Consistent Patient-Centered Framework for Patient Insight and Engagement Tools
Michele Teufel, Patient Engagement Lead, Clinical Operations, AstraZeneca
Sandra Smyth, Director, Central Feasibility and Recruitment Group, AstraZeneca
This presentation will review a consistent Patient-Centered Framework and offer a discussion on various patient insight sources to inform protocol design. In addition to learning about protocol design this insight is used to shape the patient engagement tools for support during the conduct of study. Discussion will include an analysis of the insights used and the impact on the conduct of studies.

9:55 Bridging the Empathy Gap: A Human-Centric Approach to Engagement *Sponsored by* BIOCLINICA
Heather Swech, MBA, Head, Marketing, Patient Recruitment & Retention, Bioclinica
Building lasting relationships with patients and caregivers requires a holistic view that considers the entire patient experience. Through deep understanding and insights, our online communities and programs, support and empower patients and caregivers, by providing ongoing engagement, tools and resources throughout their study journey and beyond. The result is an authentic, trusted partnership for continuous interaction and feedback. Patients who engaged through our communities were approximately 1/3 more likely to be retained in the trial.

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

HARNESSING TECHNOLOGY FOR IMPROVED PATIENT ENGAGEMENT, RECRUITMENT & RETENTION

11:10 Chairperson's Remarks
Kyle Hogan, Director, eClinical Solutions, Clinical Ink

11:15 iSTEP: First of Its Kind Smart Trial and Engagement Program Implemented in Janssen Clinical Trials
Jason LaRoche, Clinical Innovation Leader, Janssen Research & Development
This talk will share a flexible platform designed to accommodate the unique needs and complexities of individual studies with the core features of patient app, kit tracking and smart packages. We will share preliminary results of a first Phase II study with Alzheimer's patients, and discuss the benefits experienced in the first in-clinic use of a novel smart trial and engagement platform. The sharing of lessons learned from this first in-clinic experience will provide valuable guidance in how to approach patient engagement with novel technologies.

11:45 Digital Patient Finding Platform for Clinical Trial Enrollment

Sponsored by seeker HEALTH

Sandra Shpilberg, MBA, CEO, Seeker Health

This session will discuss an end-to-end solution to digital clinical trial enrollment including online pre-screening and patient lead management, to accelerate clinical trial enrollment.

12:00 pm Working Together to Understand the Needs of Patients

Sponsored by faze

Mark Evans, Managing Director, Faze - Havas Lynx

Clinical trials are complex, difficult experiences involving uncertainty, uncomfortable procedures, multiple stakeholders, agencies, vendors and healthcare professionals. How often do we work together as a group to create a connected solution? Is there a better model for collaboration to benefit our studies and our patients?

12:15 Transition to Shared Sessions

OPTIMIZING SITE-CRO-SPONSOR INTERACTIONS: UNDERSTANDING PATIENTS, SITES, PROCESS & TECHNOLOGY TO IMPROVE TRIALS (SHARED SESSION)

Chairperson's Remarks (continued from morning session)

Kyle Hogan, Director, eClinical Solutions, Clinical Ink

12:20 Focus on the Worst? A Weak-link Approach to Improving Site Performance and Accelerating Clinical Trials

Angelique Hopkins, Director, Clinical Trial Analytics, Business Insights and Analytics, Bristol-Myers Squibb Company

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12:50 INTERACTIVE PANEL: Moving from Technology Indigestion to Workable Solutions

Moderator: David Vulcano, MBA, Vice President, Research Compliance & Development, HCA

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Sponsored by

Jeff Lee, President, eCOA & Patient Engagement, CRF Bracket

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1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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2nd Annual

Resource Management and Capacity Planning for Clinical Trials

Metrics and Strategies for Efficient Resource Forecasting and Management

February 20-21

Resource management and capacity planning is as complex as the clinical trial protocol itself – and the need to properly manage staff, workload, and outsourced partners is more important than ever to execute trials on time and within budget. To properly understand resource needs, the scope of the pipeline, and the types of complex protocols to be expected, resource managers need input and information from the project to the portfolio level, from finance and operations teams. All teams must ultimately find the best balance between cost savings and high performance. CHI's 2nd Annual "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.

Arrive early and attend Part 1: Clinical Trial Forecasting, Budgeting and Contracting. See page 19 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

RESOURCE MANAGEMENT INITIATIVES, SYSTEMS, AND TOOLS

4:05 Chairperson's Remarks
Davina Touchton, Regional Associate Director, Clinical Operations, ProTrials Research, Inc.

4:10 Resource Estimation Driving Resource Planning, Allocation, and Related Finance Processes at Bayer Pharma
Piet Theisohn, Director, Resource Management, R&D - Portfolio & Operations, Bayer Pharma
Bayer is using an internally developed Resource Estimation system for clinical development. This is organized by roles and continuously refined from plan-actual comparison and process changes. It works based on the Project Management system and the CTMS. It feeds various finance and resource management processes, including the FTE allocation, budgeting for resources, and project costing.

4:40 CO-PRESENTATION: The Clinical Planning Journey: Keys to Capacity Planning
Jamie Cash, Section Manager, Clinical Planning & Resource Management, Abbott Nutrition
Gisele Paule, Contract Coordinator, Clinical Planning & Resource Management, Abbott Nutrition
Please join us as we present our journey through resource management optimization. The journey will wind through the bumpy road of long-time culture and old process to the high summit of change and new understanding. Using a variety of techniques to gain alignment, improve accuracy, and empower employees, a transition was implemented to provide a convenient way to track time and provide consistent categorization. We will define the resource management cycle by demonstrating the relationship between better inputs, accurate actuals and improved forecasting data. We will share our roadmap as we adjusted our course and found success!

5:10 Decentralized Trials and Mobile Healthcare Professionals - Flexibility Improves Resource Requirements *Sponsored by*
Gail Adinamis, Founder & CEO, GlobalCare Clinical Trials, LLC
Decentralized clinical trials offer innovative and proven ways to reduce overall resource requirements and shorten development timelines. Learn what the regulatory requirements are for DCTs and what services can be conducted at home. See examples of case studies that successfully incorporated these services creating win-win benefits for all stakeholders.

5:40 How the Adoption of a New Planning Platform Lead to an Evolution in Resource Management at UCB: A Mid-Sized Pharma Case Study
Paul Andrews, Planning and Resource Management Head, Business Excellence, UCB Biosciences
UCB recently adopted a new global planning solution (Planisware version 6.2) for Research & Development. We took the opportunity to also EVOLVE how we conduct resource planning and overall program management across the pipeline and all R&D departments. This presentation will be a case study of both the challenges and solutions encountered over the one-year agile development project.

6:10 – 7:10 Networking Reception *(Sponsorship Opportunity Available)* **or Close of Day**

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach *Sponsored by* medidata
Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging
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data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 **Session Break**

SPONSORS, CROs, AND SITES: CAPACITY PLANNING IN A COMPLEX CLINICAL TRIAL LANDSCAPE

8:20 **Chairperson's Remarks**
Piet Theisohn, Director, Resource Management, R&D - Portfolio & Operations, Bayer Pharma

8:25 **Clinical Trial Complexity Drives Staff Capacity: The Development of a Capacity Assessment Tool**
Alexa Richie, DHSc, Research Operations Manager, Research Administration, Mayo Clinic
Determining the capacity of your staff, whether a coordinator or CRA, can be challenging. We have developed a tool to measure the complexity of a clinical trial through a scoring system. Through the scoring process, we are able to determine the capacity of each team member to better allocate resources, balance workloads and implement a predictive staffing model.

8:55 **INTERACTIVE PANEL: What Sponsors, CROs, and Sites Need to Know about Each Other for Effective Capacity Planning**
Moderator: Jim Kremidas, Executive Director, Association of Clinical Research Professionals
David Morin, Director, Research, Holston Medical Group
Paul Evans, Formerly Corporate Vice President, Global Site Solutions, Parexel
Jamie Cash, Section Manager, Clinical Planning & Resource Management, Abbott Nutrition
Sponsors, sites, and CROs all have their own set of challenges in developing resource management plans for clinical trials – challenges that each partner may not be aware of. This panel discussion will address how each group approaches capacity planning, how they differ in strategy, and what each group should know about the other to close the gap in understanding. Walk away from this panel with strategies for improving budgets and resource management, as well as relationships with your partners.

9:55 **What Issues Are Top of Mind for Smaller Biotech and Emerging Biopharma Companies?**
Sponsored by Grant Thornton
Pat Shafer, Managing Director, Regulatory Risk & Quality Effectiveness, Grant Thornton LLP
As a firm proceeds from start-up phase through rapid growth of its operations, it will face many critical decisions along the way. This session will explore a number of these critical decisions and provide guidelines, so they may have a better understanding of factors to be considered when making decisions that may have significant impact on the future of their growing firms.

10:25 **Networking Coffee Break** *(Sponsorship Opportunity Available)*

SOURCING MODELS AND IMPLICATIONS FOR RESOURCE MANAGEMENT

11:10 **Chairperson's Remarks**
Chairperson to be Announced

11:15 **CO-PRESENTATION: Implementing a High-Functioning FSP Model at a Small or Mid-Sized Sponsor**
Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals
Richard O'Hara, Associate Director, Clinical Outsourcing, Endo Pharmaceuticals
This presentation will cover the following: Assessing core competencies and building FSP(s) to complement, portfolio transparency to provide as much lead as possible to all providers, building a meaningful and effective governance with providers, and dynamic resource planning.

11:45 **CO-PRESENTATION: Sourcing Models and Implications on Resource Management**
Jonathan Cohen, Executive Director, Business Operations, Regeneron
Paul D'Ambrosio, Senior Director, Business Operations, Regeneron
Rehbar Tayyabkhan, Executive Director, Clinical Sourcing, Regeneron
This presentation will provide a review of internal resource needs versus outsourcing. There will be an assessment of needs using resource, performance and budget data that is available.

12:15 pm **Brief Session Break**

12:20 **INTERACTIVE PANEL: What Does Your Sourcing Model Mean for Your Resource Management Process?**
Moderator: Anca Copaescu, CEO, Strategikon Pharma
Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals
Chris Chan, Executive Director, R&D Finance, Fibrogen
Paul D'Ambrosio, Senior Director, Business Operations, Regeneron
Jonathan Cohen, Executive Director, Business Operations, Regeneron
Catherine Deacon, Director, Finance Global Development and CEI, Takeda
Topics to be discussed:
- How to effectively align resources to meet outsourcing needs
- Approaches for accurately forecasting resource demands
- Impact of resourcing on financial forecasting
- How to quickly get your organization to adapt to changing resource needs

1:20 **Transition to Lunch**

1:25 **LUNCHEON PRESENTATION** *(Sponsorship Opportunity Available)*

1:55 **Closing Remarks**

2:00 **SCOPE Summit 2019 Adjourns**

5th Annual

Managing Outsourced Clinical Trials

Building Successful Partnerships with Effective Oversight, Risk Mitigation & Resource Management

February 20-21

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. CHI's 5th 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 how to build beneficial partnerships that effectively mitigate and manage risks and resources.

Arrive early and attend Part 1: Mastering an Outsourcing Strategy. See page 22 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

RBM, VENDOR QUALITY & OVERSIGHT

4:05 Chairperson's Remarks
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

4:10 INTERACTIVE PANEL: CRO Oversight, RBM and ICH E6 R2
Moderator: Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
Susanne Gronen, Senior Vice President and Head, Data Science, Astellas
Sarah Bednarski, Associate Director, Strategic Monitoring, Sunovion
Ann Hegarty, Executive Director, GSMO, Head PLs, CRO Oversight & Ph I Site Management, Allergan
Jill Collins, Executive Director, Global Operations Management, Syneos Health
David Nickerson, Head, Clinical Quality Management, Global Clinical Operations, EMD Serono

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:

- What does ICH E6 R2 mean for risk-based monitoring?
- How is the industry approaching the ICH E6 R2 addendum changes: the struggles and challenges they have faced or continue to face
- What does a sponsor expect the CRO to handle on its behalf?
- How are sponsors and CROs collaborating to ensure clinical quality risk management?
- How are sponsors and CROs handling oversight, especially when CROs subcontract to third party vendors?

Sponsored by medidata

5:10 Practical Considerations of a Successful RBM Implementation
Gary Thompson, Vice President, Strategic Consulting, Medidata

RBM is not a one-size fits all. Yet, RBM carries a value proposition for everyone. Learn how to be successful with your RBM implementation by seeking different value propositions than others.

5:40 What Should CROs Do to Protect Sponsors Undertaking RBM Trials
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

This presentation will examine the ICH GCP (E6) requirements for oversight and RBM, including central monitoring. Proposals will be given for a model framework for ensuring sponsor oversight. Using a CRO appears to be the common model in the industry for clinical trials using RBM methods, and so it should be a well established model for CROs to give information to sponsors to ensure oversight. Judging by continued inspection findings, it is an area that deserves more review.

6:10 – 7:10 Networking Reception *(Sponsorship Opportunity Available)* **or Close of Day**

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach

Sponsored by medidata

Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging

Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

RISK MITIGATION PLANNING & ENSURING THAT TIMELINES ARE MET

8:20 Chairperson's Remarks

Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals

8:25 Clinical Analytics Innovation 2.0 - Measurement that Matters

Ankit S. Lodha, MS, MBA, Associate Director, Clinical Analytics & Innovation, Global Development Operations, Shire, part of Takeda Pharmaceuticals

Clinical analytics and insight can be leveraged to address a wide range of operational questions in variety of settings. It is often utilized for purposes that are beyond the original intent of these data points. At Shire, we have developed industry best practices in measuring multiple CROs performance consistently i.e. apple to apple comparison for all our CRO partners. We are applying best practices, but also taking a fresh approach to develop a world-class clinical analytics metrics that will enhance our partnerships across our therapeutic areas. The goal of this presentation is to review the capability of several analytical approaches and to demonstrate how these insight can be incorporated into all phases of a clinical development program. This presentation will also share advances from previous analytical solutions and from scaling up our clinical analytics suite of metrics in developing KPIs to measure clinical trial performance.

8:55 INTERACTIVE PANEL: What Can Sponsors and CROs Do When Timelines/Milestones Aren't Met for Study Start-Up?

Moderator: Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc.
Erin O'Boyle, Senior Director, Clinical Contracts and Outsourcing, FibroGen, Inc.
Pat Kenney, Director, Strategic Partnering, UCB Biosciences
Holger Liebig, Senior Director, Strategic Partnerships, PAREXEL International

Topics to be discussed:

- How are CROs responding to missed timelines and milestones around patient enrollment, site selection, and study start-up?
- How are CROs addressing risks such as site staffing shortages, patient recruitment issues, etc. that may delay clinical trials? What type of risk mitigation planning is happening?
- How can sponsors proactively ensure timely study start-up? How can sponsors hold CROs more accountable? Do contract incentives work?

9:55 Presentation to be Announced

Sponsored by medidata

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

SOURCING MODELS AND IMPLICATIONS FOR RESOURCE MANAGEMENT

11:10 Chairperson's Remarks

Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals

11:15 CO-PRESENTATION: Implementing a High-Functioning FSP Model at a Small or Mid-Sized Sponsor

Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals
Richard O'Hara, Associate Director, Clinical Outsourcing, Endo Pharmaceuticals

This presentation will cover the following: Assessing core competencies and building FSP(s) to complement, portfolio transparency to provide as much lead as possible to all providers, building a meaningful and effective governance with providers, and dynamic resource planning.

11:45 CO-PRESENTATION: Sourcing Models and Implications on Resource Management

Jonathan Cohen, Executive Director, Business Operations, Regeneron
Paul D'Ambrosio, Senior Director, Business Operations, Regeneron
Rehbar Tayyabkhan, Executive Director, Clinical Sourcing, Regeneron

This presentation will provide a review of internal resource needs versus outsourcing. There will be an assessment of needs using resource, performance and budget data that is available.

12:15 pm Brief Session Break

12:20 INTERACTIVE PANEL: What Does Your Sourcing Model Mean for Your Resource Management Process?

Moderator: Anca Copaescu, CEO, Strategikon Pharma
Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals
Chris Chan, Executive Director, R&D Finance, Fibrogen
Paul D'Ambrosio, Senior Director, Business Operations, Regeneron
Jonathan Cohen, Executive Director, Business Operations, Regeneron
Catherine Deacon, Director, Finance Global Development and CEI, Takeda

Topics to be discussed:

- How to effectively align resources to meet outsourcing needs
- Approaches for accurately forecasting resource demands
- Impact of resourcing on financial forecasting
- How to quickly get your organization to adapt to changing resource needs

1:20 Transition to Lunch

1:25 LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)*

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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Implementing Risk-Based Monitoring (Part 2)

Ensuring Effective and Efficient Monitoring and Data Quality

Risk-based monitoring (RBM) approaches promise to improve clinical trial efficiency while ensuring data quality. As industry adoption of RBM increases, it is critical to reflect on lessons learned to refine the process as well as focus on leveraging RBM data for clinical operations. CHI's 5th 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 on effectively implementing clinical quality and RBM as well as a prospective look into the future of RBM.

Arrive early and attend Part 1: Implementing Risk-Based Monitoring – Part 1. See page 25 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: How Artificial Intelligence and Machine Learning with Advanced Analytics are Driving New Levels of RBM Efficiencies

Sponsored by IMS Health & Quintiles are now IQVIA

Rajneesh Patil, Global Head, Process Design and Analytics, Clinical Operations, IQVIA

RBM continues to evolve. This presentation will: Highlight the evolution of advanced analytics and how the application of contemporary statistical science can strengthen risk-based strategies. - Share learnings from practical models that help reduce white noise/false positives in signal detection deployed for RBM. - Provide insights on where machine learning and artificial intelligence models have potential application in clinical monitoring to address risks based on study design and patient population.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

RBM, VENDOR QUALITY & OVERSIGHT

4:05 Chairperson's Remarks

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

4:10 INTERACTIVE PANEL: CRO Oversight, RBM and ICH E6 R2

Moderator: Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
Susanne Gronen, Senior Vice President and Head, Data Science, Astellas
Sarah Bednarski, Associate Director, Strategic Monitoring, Sunovion
Ann Hegarty, Executive Director, GSMO, Head PLs, CRO Oversight & Ph I Site Management, Allergan
Jill Collins, Executive Director, Global Operations Management, Syneos Health
David Nickerson, Head, Clinical Quality Management, Global Clinical Operations, EMD Serono

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Sponsored by medidata

5:10 Presentation to be Announced

5:40 What Should CROs Do to Protect Sponsors Undertaking RBM Trials

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

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6:10 – 7:10 Networking Reception *(Sponsorship Opportunity Available)* **or Close of Day**

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach

Sponsored by medidata

Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging

Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

CENTRALIZED MONITORING APPROACHES

8:20 Chairperson's Remarks
Victor Lobanov, PhD, Vice President, Informatics, Covance

8:25 A Guide to Avoiding Major Pitfalls in Your Central Monitoring Solution Implementation in Your RBM Program
John Kim, Senior Manager, Clinical Development & Operations Business Technology, Pfizer
Implementing a central monitoring solution has many challenges. This presentation will review some insights into key pitfalls including working in a multi-tenant software as a service, vendor relationships, security, compliance, change management and support. I will also share how Pfizer faced implementation challenges.

8:55 How to Build a Resourceful, Economical, and Agile Model for Internal or Oversight Central Monitoring & Where to Begin the Journey?
Sarah Bednarski, Associate Director, Strategic Monitoring, Sunovion
Centralized Monitoring is not a one-size-fits-all concept. Some key factors include: level of company experience, budget and/or appetite to purchase software, level of statistical sophistication desired, and outsourcing model. For those not ready or able to make the leap to a state of the art system, there may still be a gap to fill to ensure regulatory compliance. One way to fill this gap is to implement an internal model that can leverage reporting software already available at your present company. A proposed series of steps, a tool for defining a study dashboard, example graphics, and lessons learned will be shared.

9:25 Transitioning from Operational to Clinical Data in RBM Strategies
Marcin Makowski, Head, Risk Based Monitoring & Standards, UCB
Initially centralized monitoring approaches concentrated on operational data and a small stable subset of clinical data. This evolved to approaches based on clinical data – especially pertaining key efficacy objectives. These newer strategies proved to generate more value to studies and projects. The presentation will give examples of the transition from operational to clinical data in RBM strategies. Opportunities and risk related to the transition will also be discussed.

9:55 Reframing RBM: Thinking Beyond Centralized Monitoring
Sponsored by Advanced Clinical
Kimberly Wanick, Executive Director, Compliance and Quality, Advanced Clinical
Within the past decade, our industry has made successful progress in implementing RBM programs through centralized monitoring. However, improving quality must start with a comprehensive quality management system, and cannot be achieved through study oversight and monitoring alone. During this presentation, explore a risk-based approach to clinical trial conduct beyond centralized monitoring, and learn how to use the same principles to develop an overarching risk management system that improves clinical trial quality.

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

USING PREDICTIVE ANALYTICS ON RBM DATA TO DRIVE CLINICAL OPS DECISION-MAKING

11:10 Chairperson's Remarks
Victor Lobanov, PhD, Vice President, Informatics, Covance

11:15 Leveraging RBM Data to Drive Study Quality
Nechama Katan, Associate Director, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer
We will explore how RBM data can be used to drive study quality. Both technical/analytical as well as organizational challenges will be addressed. The talk will include real experience implementing both KRIs and full clinical data analysis on over 70 RBM studies. Participants will leave the talk with key insights that they can apply to their RBM implementation.

11:45 INTERACTIVE PANEL: How Is Data Collected from RBM Affecting Study Quality/Integrity and Driving Site Selection Decisions?
Moderator: Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
Amy Neubauer, Associate Director, Data Management, Alkermes, Inc.
Francois Torche, CEO, CluePoints SA
Marcin Makowski, Head, Risk Based Monitoring & Standards, UCB
Mary Arnould, Director, Clinical Science Operations and RBM Lead, Astellas
Kimberly Wanick, Executive Director, Compliance and Quality, Advanced Clinical
Topics to be discussed:
- Based on RBM data and statistical monitoring, are data trends emerging across sites and studies?
- Where is the industry headed in optimizing and adopting use of RBM data for predictive analytics and clinical ops decision-making?
- How are pharma/biotech and CRO companies leveraging the wealth of data that they are collecting from RBM for clinical ops decisions, especially around study quality, data quality/integrity, site selections, and site capabilities?
- What are the current challenges in using RBM data for predictive analytics? What would improve the ability to use RBM data for predictive analytics?
- How is RBM data being combined with other technologies and data sources to enhance clinical trial decision-making? What are future uses of RBM data?

1:20 Transition to Lunch

1:25 LUNCHEON PRESENTATION *(Sponsorship Opportunity Available)*

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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2nd Annual

Artificial Intelligence in Clinical Research

Machine Learning, Robotics, Advanced Analytics and More

February 20-21

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, CHI presents the 2nd Annual "Artificial Intelligence and Machine Learning in Clinical Research" conference, part of the 10th Annual SCOPE Summit.

Arrive early and attend Part 1: Clinical Data Strategy & Analytics. See page 28 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 BRIDGING LUNCHEON PRESENTATION: Portfolio Risk Mitigation
Sponsored by saama
Amit Gulwadi, Senior Vice President, Clinical Innovations, Saama Technologies

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

AI TO SUPPORT CLINICAL TRIAL DECISION MAKING

4:05 Chairperson's Remarks
Balazs Flink, MD, Head, Clinical Trial Analytics, Bristol-Myers Squibb

4:10 The Dos and Don'ts of AI in Clinical Trial Planning and Execution
Balazs Flink, MD, Head, Clinical Trial Analytics, Bristol-Myers Squibb
In the past years, BMS dedicated tremendous efforts to explore and implement novel analytics solutions to advance drug development and deliver innovative products that show unprecedented features. During these projects, we have gained experiences with AI solutions and this presentation will discuss our early findings with concrete use cases.

4:40 Machine Learning – Influencing the Clinical Evidence Paradigm
Francis Kendall, Director, Biostatistics & Programming, Cytel, Inc.
This talk will examine the factors why machine learning techniques are getting traction in the life science industry, which include what machine learning approaches are useful in life sciences, new data dynamics e.g. ownership, new emerging data sources and easier access to data sources which can give greater insight into products and new diagnostics/evaluation techniques. It will also include what the future of clinical evidence may look like for regulators.

5:10 Presentation to be Announced
Sponsored by MENDEL

5:40 Artificial Intelligence and Machine Learning: Extreme Case of Data Analytics? Summary of Round Table 14
Francis Kendall, Director, Biostatistics & Programming, Cytel, Inc.

6:10 – 7:10 Networking Reception
Sponsored by DrFirst

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach
Sponsored by medidata
Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging
Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

CASE STUDIES

8:20 Chairperson's Remarks
Michelle Marlborough, Chief Product Officer, AiCure

8:25 Intelligent Automation Opportunities in Pharmacovigilance
Songlin Xue, MD, PhD, Executive Vice President, Global Head, Pharmacovigilance, Astellas
Given the wide variety of global regulatory requirements, managing the volume, variety and velocity of Pharmacovigilance data presents a significant challenge. Operations that are repetitive in nature and of relatively low business value are ripe for automation to gain efficiencies and reduce costs. TransCelerate's newest Intelligent Automation initiative focuses on identifying how intelligent automation technologies can be used to better support execution of Pharmacovigilance activities/processes. By conducting an impact assessment and working with global health authorities to verify risks/issues with their use, this initiative will provide guidance, as appropriate, on applications of new technology in Pharmacovigilance practice.

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8:55 From Real World Data Hype to AI Hype
Professor Dr. Dorothee B. Bartels, Chief Digital Science Officer, BI X GmbH, Boehringer Ingelheim
The real world data (RWD) hype caused high expectations, including how RCTs might only play a minor role in future drug development. RWD help to define target populations, and are key for drug utilization, safety and effectiveness studies. They are complementary to RCTs but cannot replace them. The same is true for artificial intelligence: AI is a tool applicable in different stages of drug development, supporting RCTs as well as RWD studies to generate evidence.

9:25 Using Machine Learning to Analyze Clinical Trials that Fail to Meet Primary Endpoints
Sean Grullon, PhD, Machine Learning Data Scientist, Data Centre of Excellence, GSK
Factors that cause clinical trials to fail their primary endpoints can be difficult to uncover with traditional statistical methods. Modern machine learning techniques can discover features which cause the primary endpoints to fail in historical clinical trial data. Insights on features that drive primary endpoint failure can be used to inform better clinical trial study design in the future.

9:55 Practical Applications of Natural Language Processing
Sponsored by saama
Malaikannan Sankarasubbu, Vice President, AI Research, Saama Technologies

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

RPA IN CLINICAL TRIALS

11:10 Chairperson's Remarks
Michelle Marlborough, Chief Product Officer, AiCure

11:15 The Use of RPA (Robotic Process Automation) within Data Management at Novartis
Sarah Clark, BSc, Stats and Computing, Global Head, Data Management, Novartis
As the digital age progresses, how are companies using technology to increase throughput and reduce/eliminate monotonous tasks? What processes can be automated and what are the benefits from a time and cost perspective and employee retention perspective? This presentation will examine the use of RPA within Data Operations at Novartis.

11:45 Enhancing Serious Adverse Event Detection Through Artificial Intelligence
Sponsored by medidata
Jingshu Liu, MSc, Lead Data Scientist, Medidata
To protect the rights and welfare of patients in a clinical trial, information concerning adverse events--especially serious adverse events (SAE)--must be communicated among site investigators, institutional review boards, trial sponsors and regulatory agencies, such as the FDA, in a timely manner.

12:15 pm Transition to Shared Sessions

BLOCKCHAIN: GAMECHANGER IN CLINICAL RESEARCH?

Chairperson's Remarks
Ronald S. Waife, President, Waife & Associates

12:20 Blockchain Opportunities for Patient Data Donation & Clinical Research
Munther Baara, MS, Head, New Clinical Paradigm, 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.

12:40 Blockchain and Pragmatism: A Necessary Marriage
Ronald Waife, MPH, President, Waife & Associates, Inc.
Biopharma is improving its track record in adopting advances in software and work process. However, the use of blockchain technologies may be too immature and unproven to expect rapid incorporation into clinical research. A productive approach for biopharma may be to select a focused business problem. For instance, the "mining" of data from RWD sources could be more feasible with blockchain security. But biopharma will need to follow best practices for technology evaluation, process impact, compliance assurance, vendor management and user acceptance

1:05 INTERACTIVE PANEL: Blockchain in Clinical Research
Moderator: Ronald S. Waife, President, Waife & Associates
Panelists: Munther Baara, MS, Head, New Clinical Paradigm, Pfizer
Professor Dr. Dorothee Bartels, Chief Digital Science Officer, BI X GmbH, Boehringer Ingelheim
Greg Plante, Principal, Digital Health & Technology, IQVIA
The most significant costs to clinical trials are in time and resources to insure the com-pleteness, accuracy and integrity of patient data. Blockchain technology has the potential to transform and simplify the exchange of data among business partners in clinical re-search. Can blockchain solutions be applied to reduce the time to bring new biopharmaceu-tical products to market while reducing the cost of achieving that objective? The presenta-tions and discussion will address this

opportunity and the path to its implementation.

- What is the realistic path for the adoption of innovations such as blockchain for sponsors, sites and CROs?
- Do service providers (CROs) play a leading or trailing role in the facilitating for the industry and why?
- Unlike EDC, blockchain technology requires sites to take an active role rather than waiting for sponsors/CROs to deliver the capabilities. How does that impact adoption?
- Thoughts on global adoption
- Thoughts on business process implications and feasibility for transition

1:20 Transition to Lunch

Sponsored by accenture

1:25 LUNCHEON PRESENTATION: Intelligent Operations: Envisioning a Better Way to Deliver R&D Outcomes

Jennifer Duff, Managing Director, Life Sciences, Accenture

The research and development landscape is changing and new technology is presenting complex challenges to traditional ways of working. In order to successfully navigate this change, the industry needs to transform their core ways of working. Accenture will share perspective on how these forces are shaping the future of R&D Operations, elaborate on how Accenture is partnering with the industry to enable the pivot, and how this transformation is key to long-term success and improved outcomes.

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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8th Annual

Clinical Technology and Innovation

Disruptive Technologies for Data and Trial Management

February 20-21

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. CHI's 8th 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.

Arrive early and attend Part 1: Sensors, Wearables and Digital Biomarkers in Clinical Trials. See page 31 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Configuration in ePRO: Making Design More Collaborative and Delivering Better Results

Sponsored by Clinical Ink

Kyle Hogan, Director, eClinical Solutions, Clinical Ink

You will learn how the authoring tool allows Clinical Ink project managers to focus on continuous collaboration in design and iterative improvements starting with early decisions and regular feedback. You will see how rapid and regular prototyping supports that feedback cycle, improves sponsor study team confidence and delivers better quality ePRO solutions with fully integrated patient engagement experiences.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

NEXT-GENERATION CLINICAL TRIALS

4:05 Chairperson's Remarks

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

4:10 The Hitchhiker's Guide to MountainView – A True Story about an Exciting Journey

Kirstin Holzapfel, Head, Clinical Data Process Technology, Data Sciences & Analytics, Bayer AG

What if you found yourself in a world where system integrations are coming out of one hand, patient data collected by mobile devices floating seamlessly into your data repository, data flow processing and transformations happening, meta data driven and being triggered in an instant manner, searches delivering comprehensive overviews covering data and associated documents, and support is given to keep you on top of your clinical study? Bayer's Mountain View Program is striving to make this picture real.

4:40 CO-PRESENTATION: Under the Hood of Investigator Grant Budgeting

Sponsored by IQVIA

Shelley Douros, Associate Director, Design & Planning, IQVIA Technologies

Brenda Medina, BBA, Director, Development Science Business Operations, Biomarin

This session will review and highlight best practices of the protocol into finances, including using consistent benchmarks and automating the site budget execution process. In addition, it will highlight how to create holistic budgets using benchmarks while effectively tracking the financial lifecycle through API adoption.

5:10 Changing the Clinical Paradigm: Striving for End to End Automation

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

Players in the drug development industry are actively looking at ways to apply a plethora of technologies to improve quality, speed up the process and focus on the patient. Is this really changing the paradigm? The new clinical paradigm will be fed by data intelligence, based on standards and driven by automation. We'll share plans and experiences in driving change in several areas including data ingestion, site relationships, study optimization and intelligent document generation.

5:30 Future Perfect: Personalized Homes and Personalized Medicine

Peter Bergethon, Vice President, Quantitative Medicine & Clinical Technologies, Biogen

In the near future, sufficient numbers of sensors will be found throughout houses, cars, clothes and everyday objects to enable multiple orthogonal views of each person over varying time intervals. Individuals in their personal spaces will be evaluated and their clinical state captured and characterized and then mathematically cross-referenced to create populations of highly correlated but distinct individual entities. This digital future will enable remote clinical diagnosis, trials and therapeutics.

5:50 Telemedicine in Clinical Trials

Nina Spiller, Vice President, Clinical Management, Otsuka Pharmaceutical Companies

This talk will feature experiences to date with telemedicine use in clinical trials, including considerations for protocol design, study startup activities and trial oversight. Vendor landscape (current capabilities and wish list for future offerings) and anticipated future use in clinical trials will be discussed.

6:10 – 7:10 Networking Reception *(Sponsorship Opportunity Available)* **or Close of Day**

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach

Sponsored by medidata

Troy Schneider, Director, Imaging Strategy, Medidata

Sarah Halek, Head, Innovation Design, ICON Medical Imaging

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8:15 Session Break

DIGITAL HEALTHCARE TO RESHAPE CLINICAL TRIALS

8:20 Chairperson's Remarks

Chairperson to be Announced, Omnicomm

8:25 Real World Insights & Collaboration in Protocol Development

Rob DiCicco, Deputy Chief Health Officer, IBM Watson Health

Today the cost of a poorly developed protocol is reflected in expensive amendments, delayed study start-up and recruitment periods, and ultimately delays to file and launch. Utilization of real-world data and insights early in protocol development is an opportunity to optimize selection criteria and avoid costly delays across the study and product development life-cycle.

8:55 How We Know What We Know in Clinical Trials

Daniel Karlin, MD, Director of Biotech Ventures, CEAi, Inc.

The ubiquity of mobile technologies that contain sensors capable of collecting clinical quality data, the emergence of novel analytical techniques, the availability of transmission and storage resources to support the collection of huge amounts of data, and computational resourced to execute demanding models have brought us toward the integration of latent and trial data, but have also revealed the limits of our current understanding of the relationships between what we have been able to measure and the underlying physiological processes. Dr. Karlin will discuss the opportunities and obstacles we have encountered on this journey into a new era of data, information, and knowledge in clinical trials.

CASE STUDIES OF DIGITAL ENDPOINTS

9:25 Using Janssen Autism Knowledge Engine to Measure Facial Affect: An Example of Implementation of Biosensors in Clinical Trials

Abi Bangerter, DEdPsy, Clinical Research Manager, Janssen Research & Development

Biosensors can be used to detect clinical population differences, and may be useful for stratification and outcome measurement. For example, facial expression of affect is impaired in autism spectrum disorder (ASD). With the Janssen Autism Knowledge Engine (JAKE®), we measured posed and spontaneous facial expressions in ASD and a reference sample via automated facial expression analysis software. Significant group differences suggest facial affect may be useful in ASD clinical trials.

9:40 CASE STUDY: Tele-visits, Wearables, Sensors, the New Landscape of Clinical Trials

Elise Kayson, Director, Clinical and Strategic Initiatives, the Center for Health + Technology (CHeT); Assistant Professor of Nursing and Senior Associate in Neurology, University of Rochester

The study objective was to develop, implement, and evaluate a model for long-term observation of Parkinson's disease (PD) clinical trial cohorts using smartphone-based assessments, web-based surveys, and virtual research visits (tele-visits). Demonstrating platform accuracy will facilitate tele-health outcomes as digital biomarkers of PD progression. A remote model represents an opportunity to streamline study conduct, reduce participant burden, and allow the collection of data beyond the usual episodic, in-clinic assessments.

9:55 CO-PRESENTATION: Streamline Clinical Operations with End-to-End Processes

Sponsored by Appian

Evjatar Cohen, Vice President, Global Life Sciences and Healthcare, Appian

Greg Ferrao, Global Regulatory Affairs, Labeling Implementation Manager, Sanofi

With complex data and processes, an innovative and streamlined approach to Clinical Operations is required. Appian is facilitating innovation in the clinical space through a powerful low-code application platform, enabling the creation of solutions that can support pre-clinical and clinical success. In this session, Evi Cohen, VP of Global Life Sciences & Healthcare, Appian and Greg Farrao, Labeling Implementation Manager, Sanofi will delve into how Appian's platform helped transform Sanofi's pre-clinical operations.

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

CASE STUDIES OF DIGITAL ENDPOINTS (CONT.)

11:10 Chairperson's Remarks

Anthony Costello, Vice President, mHealth, Medidata

11:15 Exploiting the Digital Armamentarium to Fight Heart Failure: Challenges & Opportunities

Kinjal Patel, Senior Study Manager, Research & Development, Bayer

Worldwide, approximately 26 million people suffer from heart failure (HF). The disease has a high impact on patients' quality of life and life expectancy with an annual mortality of approximately 30%. The use of emerging technologies, which allow remote and continuous patient monitoring, will lead to a paradigm shift in the conduct of clinical trials in HF. Opportunities and challenges in this field will be discussed in the presentation.

11:30 Remote Autonomous Cardiac Monitoring - Applicability in Clinical Trials

David Fauvart, PMP, Associate Director, Janssen Clinical Innovation, Johnson & Johnson

ECGs are an often-used assessment in many Clinical Trial Protocols. The golden standard for ECGs is the 12-lead ECG, which requires study participants to go to the site and which can be quite time consuming for site personnel. Several devices are currently available on the market which allow for consumers to autonomously capture ECGs. Janssen Clinical Innovation is currently testing and developing such a device for usage in a clinical trial setting and in this presentation will cover the initial results and learnings.

11:45 New Clinical Research Technologies: The Perspective of the Clinical Research Site

Teresa Hines, Associate Director, Clinical Management, Otsuka Pharmaceutical Development and Commercialization

In today's clinical research environment there is a progression toward the use of fully paperless technologies like electronic source and e-consent. These technologies have significant operational impacts on sponsors and CROs, but also on clinical research sites. Having deployed several trials that are virtually paperless, we will summarize the key findings from sites on the advantages and challenges of the new technological environment, and speak to the implications for deploying new technologies in clinical research.

12:15 pm Transition to Shared Sessions

BLOCKCHAIN: GAMECHANGER IN CLINICAL RESEARCH?

Chairperson's Remarks

Ronald S. Waife, President, Waife & Associates

12:20 Blockchain Opportunities for Patient Data Donation & Clinical Research

Munther Baara, MS, Head, New Clinical Paradigm, 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.

12:40 Blockchain and Pragmatism: A Necessary Marriage

Ronald Waife, MPH, President, Waife & Associates, Inc.

Biopharma is improving its track record in adopting advances in software and work process. However, the use of blockchain technologies may be too immature and unproven to expect rapid incorporation into clinical research. A productive approach for biopharma may be to select a focused business problem. For instance, the "mining" of data from RWD sources could be more feasible with blockchain security. But biopharma will need to follow best practices for technology evaluation, process impact, compliance assurance, vendor management and user acceptance

1:05 INTERACTIVE PANEL: Blockchain in Clinical Research

Moderator: Ronald S. Waife, President, Waife & Associates

Panelists: Munther Baara, MS, Head, New Clinical Paradigm, Pfizer

Professor Dr. Dorothee Bartels, Chief Digital Science Officer, BI X GmbH, Boehringer Ingelheim

Greg Plante, Principal, Digital Health & Technology, IQVIA

The most significant costs to clinical trials are in time and resources to insure the com-pleteness, accuracy and integrity of patient data. Blockchain technology has the potential to transform and simplify the exchange of data among business partners in clinical re-search. Can blockchain solutions be applied to reduce the time to bring new biopharmaceu-tical products to market while reducing the cost of achieving that objective? The presenta-tions and discussion will address this opportunity and the path to its implementation.

- What is the realistic path for the adoption of innovations such as blockchain for sponsors, sites and CROs?
- Do service providers (CROs) play a leading or trailing role in the facilitating for the industry and why?
- Unlike EDC, blockchain technology requires sites to take an active role rather than waiting for sponsors/CROs to deliver the capabilities. How does that impact adoption?
- Thoughts on global adoption
- Thoughts on business process implications and feasibility for transition

1:20 Transition to Lunch

Sponsored by
accenture

1:25 LUNCHEON PRESENTATION: Intelligent Operations: Envisioning a Better Way to Deliver R&D Outcomes

Jennifer Duff, Managing Director, Life Sciences, Accenture

The research and development landscape is changing and new technology is presenting complex challenges to traditional ways of working. In order to successfully navigate this change, the industry needs to transform their core ways of working. Accenture will share perspective on how these forces are shaping the future of R&D Operations, elaborate on how Accenture is partnering with the industry to enable the pivot, and how this transformation is key to long-term success and improved outcomes.

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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Leveraging RWD for Clinical and Observational Research

Data Integration and Real-Time RWE Generation

The abundance of data generated during routine health care is growing in significance and should be 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 4th Annual Leveraging RWD for Clinical and Observational Research conference will discuss challenges and solutions with secondary use of existing healthcare data to support the medicine lifecycle.

Arrive early and attend Part 1: Late Stage Research Strategy and Operations. See page 34 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Late Stage Research Strategy and Operations
Sponsored by
Meg Richards, PhD, MPH, Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

RWD TO ACCELERATE THE DESIGN AND EXECUTION OF CLINICAL TRIALS

4:05 Chairperson's Remarks
Marc Berger, MD, Chair, Real World Evidence Advisory Committee, SHYFT Analytics

4:10 Using Learning Health Systems to Capture Real World Data in Routine Care
Charles Makin, Global Head, Real World Evidence Strategy, Biogen
As the availability and use of RWD continues to increase rapidly, demand is outpacing supply. While a variety of data sources abound, individual data gaps and lack of interconnectedness create unique challenges for users vying for precise insights. In this evolving scenario, learning health systems are emerging as a comprehensive source of patient-level data, combining patient information that traditionally resides in discrete verticals. This session discusses the best practices, challenges and limitations of this approach.

4:40 Challenges and Opportunities with Use of Real World Evidence in Drug Development
Demissie Alemayehu, PhD, Head, Vice President, Biostatistics, Pfizer
With the growing demand for new medicines to meet critical healthcare needs with speed and efficiency, it has become essential to explore novel approaches and data sources. Thanks to the prevailing digital revolution, and advances in predictive analytics and computing platforms, a new frontier has emerged to enhance the drug development process. We elucidate pertinent aspects of the use of real world evidence in regulatory settings, with emphasis on study design, analytical strategies, data quality and regulatory requirements.

5:10 Automation Beyond CRF Population. Why a Disruptive Platform to Support Multiple Data Sources Will Future Proof Your Clinical Trials
Sponsored by ORACLE Health Sciences
Greg Jones, Enterprise Strategy Architect, Life Sciences, Oracle Health Sciences
Please join this provocative session to discover how preparing your clinical research platform for EHR as a data source to automate population of CRFs can serve as a catalyst for full disruption of your clinical research approach. Implementing strategies to manage expanding data sources is the path to the future of conducting clinical trials. Join this session to understand how you can prepare for this new world. Why planning beyond CRF automation, and looking at full scale data management of legacy and emerging data sources, as well data sources we haven't imagined yet, will help future-proof your clinical development.

5:40 RWD Strategies for Improving Development and Access to Innovative Therapeutics
Gregory Daniel, PhD, Deputy Center Director, Duke-Margolis Center for Health Policy, Duke University
This presentation will include an overview of the requirements on FDA, established by the sixth reauthorization of PDUFA and the 21st Century Cures Act, to consider the use of RWE. This session will also include emerging recommendations by stakeholders regarding a framework and approaches for evaluating data quality, improving observational studies, and how broader RWE might be considered along with other factors to reach regulatory evidentiary requirements.

6:10 – 7:10 Networking Reception
Sponsored by DrFirst

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach *Sponsored by* medidata
Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging
Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

LEARNING FROM EU: SALFORD STUDY AND BEYOND

8:20 Chairperson's Remarks
Kyle Ricketts, Marketing Manager, Bio-Optronics

8:25 Creating the Extensible Data Platform of the Future to Better Leverage Real World Data (RWD)
John Yonchuk, Manager, Digital Clinical Trials, GlaxoSmithKline
With the ever expanding number and types of real world data (RWD) sources, it is more critical than ever for Pharma to be able to analyze, interpret, and act upon RWD in a fast, efficient, interoperable, and extensible manner. Creating a data model and a data platform across a clinical operations organization presents opportunity but also challenges that Pharma must get right in order to succeed.

ADVANCES IN RWD ANALYTICS

9:00 CO-PRESENTATION: Real-World Data & Analytics Empowered Clinical Trials Design
Xia Wang, PhD, Director, Health Informatics & Global Medicines Development, AstraZeneca
Jane Fang, MD, Head, Clinical Business Management & Analytics, MEDI Biologics Unit, AstraZeneca
Patient-centric drug product development starts with a characterization of the targeted patient population. Real world evidence data (RWD) provides a new way to gain such insights. Incorporating RWD-use into current study planning process will advance and innovate trial design, conduct and patient recruitment. The talk will feature a RWD-empowered trial feasibility and patient recruitment process that has joined the expertise from different fields such as feasibility function, informatics and data scientists, study teams, technologists and sites.

9:35 Data-Driven Patient Recruitment with Real World Data
Liping Jin, Data-Driven Patient Recruitment Lead, Pharma Research and Early Development, pREDi Early Development Workflows, Roche
With the increasing use of Real World Data (RWD) in the pharma industry, Data-Driven 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 also like to share the challenges to expanding the effort in broader US, Europe and international settings.

9:55 Leveraging RWD for Clinical and Observational Research *Sponsored by* PRA Health Sciences
Jane Quigley, Senior Vice President, Real World Evidence, PRA Health Sciences
When will be ready for the real world? Let's find out together!

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

SUPPLEMENTING CLINICAL TRIALS IN ONCOLOGY WITH REAL WORLD EVIDENCE

11:10 Chairperson's Remarks
Marion Brayer, Head, Clinical Operations, SOPHiA GENETICS

11:15 Supplementing Clinical Trials in Oncology with Real World Evidence
Kavita Sail, PhD, Associate Director, Health Economics and Outcomes Research, AbbVie
Real world evidence is growing in importance and can be used effectively in oncology to test sub-populations, identify risk groups and even inform the right population prior to conducting a clinical trial. Studies using big data require expertise in handling and pose unique challenges related to potential bias and complex data management strategies. It's important that these studies are conducted with expert data scientists alongside medical and clinical reviewers for correct data interpretation.

11:45 Talk Title to be Announced *Sponsored by* SOPHiA™ SOPHIAGENETICS.COM
Marion Brayer, Head, Clinical Operations, SOPHiA GENETICS

12:15 pm Transition to Shared Sessions

BLOCKCHAIN: GAMECHANGER IN CLINICAL RESEARCH?

Chairperson's Remarks
Ronald S. Waife, President, Waife & Associates

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1:20 Transition to Lunch

Sponsored by
accenture

1:25 LUNCHEON PRESENTATION: Intelligent Operations: Envisioning a Better Way to Deliver R&D Outcomes

Jennifer Duff, Managing Director, Life Sciences, Accenture

The research and development landscape is changing and new technology is presenting complex challenges to traditional ways of working. In order to successfully navigate this change, the industry needs to transform their core ways of working. Accenture will share perspective on how these forces are shaping the future of R&D Operations, elaborate on how Accenture is partnering with the industry to enable the pivot, and how this transformation is key to long-term success and improved outcomes.

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

Clinical Biospecimens and Central Lab Solutions

Managing Biospecimens and Partnering with Biorepositories & Labs

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. CHI's 4th Annual "Clinical Biospecimens and Central Lab Solutions" conference brings together leading experts, representing clinical sponsors as well as biorepositories, to discuss challenges and identify actions to improve infrastructure for biomarker driven clinical trials.

Arrive early and attend Part 1: Clinical Biomarkers Strategy and Innovation. See page 37 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Where in the World Are My Specimens? (And How Do I Fetch Them?) *Sponsored by* eurofins | BioPharma Services

Kevin Smith, Vice President, Technology & Data Solutions, Eurofins Central Laboratory

With the ever increasing complexity of each clinical trial being conducted globally, a universal challenge faced by the industry is specimen visibility as it proceeds through the processing pathway from point of collection, to shipment to central laboratory, to potential aliquoting and disbursement to long term storage, 3rd party laboratories or specialty laboratories within your vendor organization. When you add the potential for discrepancies in shipping manifests, demographics contained in multiple databases/systems and queries generated from paper based requisitions, you add the additional real world risk of database lock delays. Please come share in a case study of technology utilization to mitigate all of these operational risks and engage with your colleagues in an exploration of best practices.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

NEXT-GENERATION SAMPLE MANAGEMENT

4:05 Chairperson's Remarks

Brenda Yanak, Former Global Head, Specimen Strategy and Innovation, Q2 Solutions, a Quintiles Quest Joint Venture

4:10 Overcoming Challenges in Sample Collection for Biomarker-Driven Trials

Caoimhe Vallely-Gilroy, Director, Global Head, Clinical Trials Biosample Management, Global Clinical Operations, Merck KGaA

As clinical trial design becomes more biomarker-driven, and biomarker sampling becomes more complex, the challenge of converting these protocols into an operational success looks like a science in its own right. This presentation will look at examples of challenges experienced, what actions were taken to mitigate the risks, and processes developed to prevent the issues in the future.

4:40 Considerations for Secondary Use of Biospecimen Data to Enable Scientific Discovery and Data-Driven Decision Making

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

Clinical trial data is a treasure trove of information that has value to the scientific community well beyond the clinical study report. With improved access to aggregated data and user-friendly tools, scientists can answer questions related to safety, disease mechanisms, underlying conditions, and adverse event triggers. We will review a case study involving a data platform where this was accomplished successfully while maintaining required privacy and data protection.

5:10 Sponsored Presentation *(Opportunity Available)*

5:40 Pharma and Central Laboratory Collaboration to Customize and Enhance the Execution of the Laboratory Manual

Melissa Rawley-Payne, Executive Director, Biospecimen Operations, Celgene

To enhance the execution and customization of the Laboratory Manual, Celgene and Covance have partnered cross-functionally across and within their respective organizations to develop standardized collection guidelines that include graphical representations of the collection and processing procedures. These enhancements are meant to facilitate the development process of the document and to ensure that sites receive all required information in one comprehensive document.

6:10 – 7:10 Networking Reception *(Sponsorship Opportunity Available)* **or Close of Day**

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach *Sponsored by* medidata

Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging

Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

VENDOR QUALIFICATION AND OPERATIONAL CHALLENGES

8:50 Chairperson's Remarks
Dianna Blessington, MEd, Research Expert, Translational Sciences, Laboratory & Biospecimen Operations, Incyte Research Institute

8:55 The Evolution of a Sample Management Infrastructure in a Growing Biopharmaceutical Company
Dianna Blessington, MEd, Research Expert, Translational Sciences, Laboratory & Biospecimen Operations, Incyte Research Institute

Since its inception less than 20 years ago, Incyte Corporation has brought together rigorous drug discovery and development, leading to the identification of novel therapies for patients with significant unmet medical needs. As the development pipeline has expanded, and the number and complexity of clinical trials has grown, so has the number and different types of samples associated with each of these studies. This presentation will focus on the *de novo* development of a sample management organization to manage the receipt and tracking of samples collected to conduct translational research.

9:25 CO-PRESENTATION: Clinical Sample Vendor Qualification and Process Management
Mary Zuniga, Consultant, Translational Science, Immunology, Eli Lilly and Company
Anita Pascarella Cole, Consultant, LRL Sourcing, Eli Lilly and Company

This presentation will walk participants through the vendor qualification process and the process management related to the use of clinical samples in research, taking into consideration appropriate risk levels when selecting and qualifying vendors, along with the vendors' capabilities for assay development, validation, and data delivery.

9:55 Sponsored Presentation *(Opportunity Available)*

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

LARGE BIOREPOSITORIES TO ENABLE CLINICAL RESEARCH

11:10 Chairperson's Remarks
JoachimSilber,ScientificDirectorofOperations,PrecisionPathologyBiobankingCenter,MSKCC

11:15 Precision Pathology: Taking Clinical Trials and Biomarkers to the Next Level
Joachim Silber, Scientific Director of Operations, Precision Pathology Biobanking Center, MSKCC

The role of pathology in modern precision clinical trials has grown very rapidly. Specimen-centered, biomarker-based therapeutic development and precision measurements of treatment response and resistance are novel key developments. My talk will show examples of these exciting developments and will highlight examples of exciting collaborations between academic pathology and the diagnostic and pharma industries that reshape the path towards precision healthcare.

11:45 Kaiser Permanente Research Bank: Core Resource for Collaborative Research
Alexander Lituev, MD, Practice Leader, Biorepository Head, Kaiser Permanente Research Bank

The Kaiser Permanente Research Bank (KPRB) is a research-ready resource that supports the scientific community inside and outside of Kaiser Permanente in a wide variety of health conditions and diseases. With over three-hundred thousand enrolled members, KPRB is one of the largest and most diverse biobanks in the US. Background, technical, and operational structure and access policies will be presented.

12:15 pm Brief Session Break

OPTIMIZING SITE-CRO-SPONSOR INTERACTIONS: UNDERSTANDING PATIENTS, SITES, PROCESS & TECHNOLOGY TO IMPROVE TRIALS (SHARED SESSION)

Chairperson (continued from morning session)
Kyle Hogan, Director, eClinical Solutions, Clinical Ink

12:20 Focus on the Worst? A Weak-link Approach to Improving Site Performance and Accelerating Clinical Trials
Angelique Hopkins, Director, Clinical Trial Analytics, Business Insights and Analytics, Bristol-Myers Squibb Company

There are weak link sports (soccer) and strong link sports (basketball), the best method for improving performance in each situation depends on whether investing in the worst component of a team or the greatest strength on a team makes the biggest difference. For years the preferred method for accelerating clinical trials and improving site performance has been to focus on the highest performing sites. Using trial simulation and modeling techniques, we can see how a "weak link' approach to site performance (focusing middle and lower tier sites) may be a better although less intuitive method for increasing performance and accelerating timelines.

12:50 INTERACTIVE PANEL: Moving from Technology Indigestion to Workable Solutions

Moderator: David Vulcano, MBA, Vice President, Research Compliance & Development, HCA

Stephanie Abbott, PharmD, Clinical Research Program Director, Western Washington Medical Group

Jeewa Perera, CEO, Champ IT Solutions

Brenda Yanak, Former Global Head, Specimen Strategy and Innovation, Q2 Solutions a Quintiles Quest Joint Venture; Former Precision Medicine Lead, Pfizer

Matt Moyer, MBA, Director, Clinical Supply Technology, Merck

Multiple technologies are advancing healthcare delivery each and every day. This not only pertains to better utilizing both data at rest and data in motion, but also pertains to communication technologies breaking down the traditional boundaries of medicine. As clinical trial site operations are often dwarfed by the larger healthcare delivery ecosystem, how can pharma leverage that already developing ecosystem so that they don't have to recreate the wheel?

• What technologies are out there right now that are underutilized by pharma in clinical trials?

• What regulatory or operational issues need to be either "myth busted" or challenged to make this happen?

1:20 Transition to Lunch

1:25 LUNCHEON PRESENTATION: The Secret to Unlock Adoption of eClinical Solutions

Jeff Lee, President, eCOA & Patient Engagement, CRF Bracket

Sponsored by

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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Host a User Group on Monday, February 18

Co-locate your User Group meeting with SCOPE Summit. CHI will help market the event & manage logistical operations.

Additional sponsorship & branding opportunities include:

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- Footprint Trails
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- Padfolios / Notebooks
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- Luncheon Presentations – now offered all 3 days!

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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:

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For additional information, please contact:

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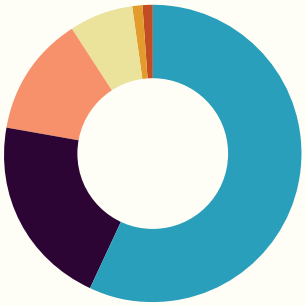
(Companies P-Z)
Patty Rose,
Sr. Business Development Manager
(+1) 781.972.1349
prose@healthtech.com

2018 ATTENDEE DEMOGRAPHICS

Company Title



Executive/Director	57%
Sales & Marketing	21%
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Scientist/Technologist	7%
Professor	1%
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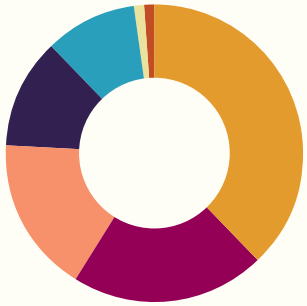
Company Type



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Pharma	17%
Healthcare/Hospital	12%
Services/Societies	10%
Academic	1%
Other	1%

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Cambridge Healthtech Institute
A Division of Cambridge Innovation Institute

Hotel & Travel Information

Conference Venue and Hotel:

Hyatt Regency Orlando
9801 International Drive
Orlando, FL 32819
T: 407.284.1234

Reservations: Go to SCOPEsummit.com/hotel-and-travel
Discounted Room Rate: $284 s/d (Price Includes Resort Amenities)*
Discounted Room Rate Cut-off Date: January 22, 2019

Why Stay at the Hyatt Regency Orlando?

- Complimentary Wi-Fi in guestrooms
- Located on International Drive, stop #21 on the I-Ride Trolley: Situated across the street from the Orange County Convention Center, and moments away from dining, shopping, and entertainment
- No Commute - Conference takes place at the hotel
- 50% Discount off self-parking for overnight guests when booked within the group block
- Eclectic dining: Seven on-site restaurants, serving coastal Floridian fare, poolside snacks and cocktails, rustic Italian food and steaks, and much more
- Plenty of places to relax after conference sessions: Two tropical-inspired pools, a separate kiddie pool, a luxurious spa and salon, and a 24-hour gym with studio spaces and fitness classes

Transportation:

- The Hyatt Regency Hotel is only 15 minutes from the Orlando International Airport, with multiple transportation options to get to the hotel and around Orlando. Go to SCOPEsummit.com/hotel-and-travel to see all transportation options.

**Resort Amenities Include: 24-hr gym and fitness classes, pool activities, bicycle rentals, two daily tickets for the I-Ride Trolley, offering direct transportation to International Drive locations such as SeaWorld Orlando, 10% savings on spa and salon services at The Spa, two bottles of water daily. (Resort fee covered amenities are subject to change)*

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

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Cambridge Healthtech Institute
A Division of Cambridge Innovation Institute

Pricing & Registration Information

CONFERENCE PRICING

	Commercial	Academic, Government, Hospital-affiliated
BEST VALUE! *Includes access to the entire 3-day SCOPE event, plus Monday Evening's Pre-Conference Plenary Keynote Panel and Kick-Off Networking Happy Hour*		
Advance - Registration Rate Until January 18, 2019	$2,799	$1,299
Registrations After January 18, 2019 and On-Site	$2,999	$1,399
BASIC CONFERENCE PRICING *Includes access to ONE Conference*		
Advance - Registration Rate Until January 18, 2019	$1,799	$929
Registrations After January 18, 2019 and On-Site	$1,999	$1,029

TUESDAY, FEBRUARY 19 - WEDNESDAY, FEBRUARY 20	WEDNESDAY, FEBRUARY 20 - THURSDAY, FEBRUARY 21
1A: Protocol Development, Global Site Selection, Feasibility, & Site Management	1B: Improving Site-Study Activation and Performance
2A: Enrollment Planning and Patient Recruitment	2B: Patient Engagement, Enrollment & Retention through Communities & Tech
3A: Clinical Trial Forecasting, Budgeting and Contracting	3B: Resource Management and Capacity Planning for Clinical Trials
4A: Mastering an Outsourcing Strategy	4B: Managing Outsourced Clinical Trials
5A: Implementing Risk-Based Monitoring (Part 1)	5B: Implementing Risk-Based Monitoring (Part 2)
6A: Clinical Data Strategy and Analytics	6B: Artificial Intelligence in Clinical Research
7A: Sensors, Wearables and Digital Biomarkers in Clinical Trials	7B: Clinical Technology and Innovation
8A: Late Stage Research and Observational Studies	8B: Leveraging Real World Data for Clinical and Observational Research
9A: Clinical Biomarkers Innovation and Operations	9B: Clinical Biospecimen & Central Lab Solutions
10A: Clinical Supply Management	

CONFERENCE DISCOUNTS

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

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Melissa Dolen at (+1) 781-972-5418

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

ADDITIONAL REGISTRATION DETAILS

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

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

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

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

How to Register: SCOPEsummit.com

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

Please use keycode SCOPE F when registering