11th Annual

SUMMIT FOR CLINICAL OPS EXECUTIVES

February 18-21, 2020 • Hyatt Regency Orlando • Orlando, FL

Register by January 10 and Save up to $200!

- 2,000+ Participants
- 180+ Exhibits
- 300+ Presentations
- 20 Conferences

Driving Innovation in Clinical Trials and Digital Health

PRE-CONFERENCE EVENTS
- Pre-Conference User Group Meetings & Hosted Workshops
- Kick-Off Plenary Keynote & Participant Engagement Awards

STUDY PLANNING & ACTIVATION
- Protocol Development, Global Site Selection, Feasibility and Site Management
- Improving Study Start-Up, Site Activation and Trial Performance

RECRUITMENT & ENGAGEMENT
- Enrollment Planning and Patient Recruitment
- Patient Engagement, Enrollment and Retention through Communities and Technology

BUDGETING & RESOURCES
- Clinical Trial Forecasting, Budgeting and Contracting
- Resource Management and Capacity Planning for Clinical Trials

OUTSOURCING
- Mastering an Outsourcing Strategy
- Managing Outsourced Clinical Trials

CLINICAL SUPPLY
- Clinical Supply Management

DATA
- Clinical Data Strategy and Analytics
- Artificial Intelligence in Clinical Research

TECHNOLOGY
- Sensors, Wearables and Digital Biomarkers in Clinical Trials
- Clinical Technology and Innovation

REAL WORLD EVIDENCE
- Accessing and Generating RWD
- Leveraging Real World Data for Clinical and Observational Research

BIOMARKERS & BIOSPECIMENS
- Clinical Biomarkers Operations and Innovation
- Clinical Biospecimens Technology and Outsourcing

QUALITY & MONITORING
- Implementing Risk-Based Monitoring (Part 1)
- Implementing Risk-Based Monitoring (Part 2)

MED DEVICE TRIALS
- Medical Device Clinical Trial Operations and Regulations

+ NEW
- China Clinical Development Partnering Forum
- The SCOPE Scientific Symposium

SCOPEsummit.com

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Signature Sponsors: ALMAC, IQVIA, medidata, Dassault Systèmes, Oracle, saama
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- Medical Device Clinical Trial Operations and Regulations

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TUESDAY, FEBRUARY 18, 2020

Pre-Conference User Group Meetings, Hosted Workshops, Science Symposium, China Partnering Forum, Kick-Off Keynote, Participant Engagement Award & Happy Hour

2:00 - 5:00 pm User Group Meetings & Hosted Workshops (Sponsorship Opportunities Available)
Host a User Group, Workshop or Company Meeting

9:00 am - 5:00 pm Shared Investigator Platform User Group Meeting Full Day
The first official Shared Investigator Platform (SIP) User Group Meeting will unite sites, sponsors, research organizations, technology providers, and product leadership as we continue to evolve the SIP ecosystem together. Whether you are a new user, veteran, or just beginning to evaluate SIP for your organization, join our User Group Meeting as we share the SIP roadmap, ideate new features, and exchange best practices for successful collaboration across the clinical research community. To register, please contact priya.iyer@cognizant.com, or +1 (513) 802-3681.

12:00 – 3:00 pm Applying Artificial Intelligence to Protocol Design, Feasibility Testing, and Patient Recruitment
Cedar Health Research, a clinical trial Site Network, partnered with Aspen Insights, a machine learning technology provider, invite you to attend their debut at the 2020 SCOPE Conference. Aspen Insights has developed a cutting-edge artificial intelligence platform designed to streamline clinical trial design, feasibility testing, and enrollment through the matching of patients to clinical trials at a level of precision and speed not previously possible. Join us to see a demonstration of this technology and learn how it can accelerate your clinical programs. Refreshments and lunch will be provided. To register, please contact dmccool@korenvaes.com

2:00 - 5:00 pm Trifecta Annual User Group Forum
Trifecta is pleased to host the 3rd annual User Group Forum to be held on Tuesday. Sponsor and CRO leaders from the industry, as well as sites leadership, are invited to take part in this highly interactive and engaging session focused on how Trifecta’s InvestigatorSpace® training and communication platform along with the SafetyVigilance® online safety letter delivery can transform critical site communication and documentation processes. Hear from our senior executive team on best practices, key success stories and the road ahead for driving innovation to drive positive outcomes across the industry. To register, please contact joseph.shafer@trifectaclinical.com

3:00 - 5:00 pm

*Must be a Best Value registered attendee.

2:00 - 5:00 pm

*Must be a Best Value registered attendee.

5:00 Evening Plenary Keynote Opening Remarks
Matt Miller, President, Co-Founder, StudyKIK
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

5:05 INTERACTIVE PANEL: Taking the Plunge, Why Now is the Time to Invest in eConsent and Patient Engagement
Moderator to be Announced, Signant Health
Increased willingness to take a patient-centric approach to technology adoption to improve data capture, patient understanding, and patient engagement is needed to drive real return on investment for retention, compliance, protocol adherence, and overall study timelines.

• Why isn’t the pharmaceutical industry moving more quickly to adopt solutions that patients—and sites and study teams—want?
• What are the key barriers to digitally focused patient-centricity (uncertainty over regulators’ expectations, data safety, privacy concerns)?
• How do you identify and deploy the right talent to support a patient-centric ecosystem?

5:35 SCOPE’s 2020 Participant Engagement Awards Introduction
Joseph Kim, MBA, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly

5:40

In Memory of Jerry Matczak, #BeLikeJerry, #SCOPE2020
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.

Submit your work now: http://www.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
Joseph Kim, MBA, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly
Lilly Stairs, Patient Advocate; Board Member, AARDA; Head, Client Relations, Savvy Cooperative
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

6:20 SCOPE’S Kick-Off Networking Happy Hour

7:30 Close of day
This keynote will describe JCI's view on innovation, key elements of its innovation framework, as well as some remaining challenges which are of interest to the broader industry.

Janssen Clinical Innovation (JCI) was established in 2012 with the goal to address several common challenges in clinical trials. It is an autonomous innovation team, having introduced a number of successful innovations – some of which have an impact beyond Janssen. To support its operations, JCI has developed a framework to effectively and efficiently bring innovations all the way from ideation to implementation.

In taking a patient-centric approach to the design of clinical studies, what methodologies should we consider in seeking meaningful patient perspectives? What are the considerations for implementing this approach in an organization to utilize patient perspectives as an input into trial design and operational planning? In this session, you can learn from patients in a panel discussion about their opinions on clinical trials. In addition, the panel will discuss how patient perspectives can be used as an input to feasibility and clinical trial design.

- Selecting the right tactics to get the patient feedback that you need
- Considerations for patient insight data as an input into study design
- Messaging the value proposition for taking time in planning for patient insight development
- Which types of study can this approach have the most impact in patient-centric

**INNOVATION METHODOLOGY & DIGITAL HEALTHCARE TO RE-SHAPE TRIALS**

**2:40 FIRESIDE CHAT: Digital Healthcare to Re-Shape Clinical Trials**
Moderator: Jacob LaPorte, PhD, Co-Founder & Vice President, Global Head of BIOME – The Digital Innovation Lab, Novartis
Emmanuel Fombu, MD, MBA, Global Strategy and Digital Innovation Leader, Johnson & Johnson

Over a decade of increasing cost and complexity in R&D has driven the pharmaceutical business model to the brink of unsustainability. Digital technologies have the power to fundamentally transform the pharmaceutical development and commercial model, significantly increasing the efficiency and effectiveness of developing new medicines and creating more holistic solutions to deliver more meaningful experiences and outcomes for patients in need. This brave new paradigm, however, will require a fundamental shift in program strategy, organization, and culture to achieve. Come find out from two experts how to drive transformational change in your organization to effectively harness the power of these new digital technologies.

- What are the key challenges in the development of new medicines; what is pushing the development/commericalization model to the brink of unsustainability?
- What are the key technology trends to enable transformational changes in how we develop and commercialize medicines?
- What are some early indicators that people are starting to put these things together in a meaningful way to drive transformation change in their development model?

**3:10 Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing**
Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

**Podium Presentations — Available within Main Agenda!**
Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

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

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

Additional branding & promotional opportunities include:
- Track Reception
- Footprint Trails
- Aisle Signs
- Exhibit Hall Reception
- Focus Groups

Looking for additional ways to drive leads to your sales team?
CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program!

Opportunities include:
- Live Webinars
- White Papers
- Market Surveys
- Podcasts and More!

### 2019 Attendee Demographics

**Company Title**
- Executives: 52%
- Sales & Marketing: 24%
- Managers: 15%
- Scientists & Technologists: 7%

**Company Type**
- CRO: 35%
- Biotech: 20%
- Pharma: 20%
- Healthcare/Hospital: 12%
- Services/Societies: 10%

For sponsorship and exhibitor information, please contact:

**Companies A-K**
Ilana Quigley
Senior Manager, Business Development
781-972-5457
iquigley@healthtech.com

**Companies L-Z**
Patty Rose
Senior Manager, Business Development
781-972-1349
prose@healthtech.com
Current Sponsors

Corporate Sponsors

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### Event at-a-Glance

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#### Tuesday, February 18
- 2:00 – 5:00 pm
  - Tuesday Afternoon
  - Pre-Con User Group Meetings & Hosted Workshops
- 5:00 – 6:20 pm
  - Tuesday Evening
  - Kick-Off Plenary
  - Keynote & Participant Engagement Awards
- 6:20 – 7:30 pm
  - SCOPE’s Kick-Off Networking Happy Hour

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**Special Offer**

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

1. Pfizer
2. Roche
3. Novartis
4. Johnson & Johnson
5. Merck & Co.
6. Sanofi
7. AbbVie
8. GlaxoSmithKline
9. Amgen
10. Gilead Sciences
11. Bristol-Myers Squibb
12. AstraZeneca
13. Eli Lilly
14. Bayer
15. Novo Nordisk
16. Takeda
17. Celgene
18. Shire
19. Boehringer Ingelheim
20. Allergan
21. Teva Pharmaceuticals
22. Mylan
23. Astellas Pharma
24. Biogen
25. CSL

**Notes:**
- Group registrations are encouraged and we suggest calling: Melissa Dolen, Account Manager. T: (+1) 781-972-5418 E: mdolen@healthtech.com
- Get your team to Orlando at special company rates.

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Pre-Conference Events

Tuesday, February 18

Arrive Early for

2:00 – 5:00 pm
- Pre-Conference User Group Meetings & Hosted Workshops (Opportunities available)
- The NEW SCOPE China Clinical Development Partnering Forum
- The NEW SCOPE Scientific Symposium (SSS)

5:00 – 6:20 pm
- Tuesday Evening Kick-Off Plenary Keynote & Participant Engagement Awards

6:20 – 7:30 pm
- SCOPE’s Kick-Off Networking Happy Hour

Host a User Group, Workshop, or Company Meeting

Co-locate your User Group, a Workshop, or even your company’s Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market to prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point!

For information, contact:
Melissa Dolen
Account Manager
T: (+1) 781-972-5418
E: mdolen@healthtech.com

Group Discounts Available!

For information, contact:
Ilana Quigley
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(+1) 781.972.5457
iquigley@healthtech.com

Companies A-K

Patty Rose
Sr. Business Development Manager
(+1) 781.972.1349
prose@healthtech.com

Companies L-Z

Cognizant

Trifacta Annual User Group Forum
To learn how to register for the Trifacta Annual User Group Meeting, please contact Joseph Shafer at joseph.shafer@trifactaclinical.com

Applying Artificial Intelligence to Protocol Design, Feasibility Testing, and Patient Recruitment
To learn how to register for Applying Artificial Intelligence to Protocol Design, Feasibility Testing, and Patient Recruitment Meeting, please contact Deena McCool at dmcool@korenvaes.com

Shared Investigator Platform User Group Meeting Full Day
To learn how to register for the SIP User Group Meeting, please contact Priya Iyer at priya.iyer@cognizant.com, or +1 (513) 802-3681.
Pre-Conference Events

SUBMIT YOUR SPEAKING PROPOSAL!

China Clinical Development Partnering Forum

February 18

The new China Clinical Development Partnering Forum at SCOPE provides a focused forum to connect Chinese clinical development leaders and experts with their counterparts from the US, as well as the rest of the world. The forum will provide a great opportunity for global and China-based pharmaceutical companies, biotech companies, academic research centers, CROs, consultancies, and other service providers involved in the conduct of drug development and clinical trials to share best practices for developing and bringing new therapies to market in the West and in China.

SCOPEsummit.com/precon-China

SEE PAGE 11 FOR FULL AGENDA

SCOPESummit.com/precon-SSS

SCOPESummit.com/precon-China

SCOPESummit.com/precon-SSS

CREATIVITY AND ENGAGEMENT IN RECRUITMENT AND RETENTION COMMUNICATIONS: WHAT IS IT?

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 Award in 2017. We dedicate this award to Jerry in the hopes that it will serve as a reminder of his ideals and accomplishments. SCOPE’s 2020 Participant Engagement Award program is brought to you by Cambridge Healthtech Institute (CHI)’s SCOPE Summit.

SCOPEsummit.com/participant-engagement-award
The new China Partnering Forum at SCOPE provides a focused forum where Global and Chinese-based pharmaceutical companies, biotech companies, academic research centers, CROs, consultancies and other service providers involved in the conduct of drug development and clinical trials can share best practices for developing and bringing new therapies to market here in the West and in China. The stakeholders may be US or European sponsors interested in partnering with up-and-coming Chinese biotech companies, or they may be Chinese innovators looking for US-based CROs or licensing partners to expand their market and reach. This is not simply about “outsourcing”! This is about research-based innovators on both sides trying to figure out a win-win and trying to help one another navigate a two-way partnership. The forum will feature case studies, “how to” panel discussions, and networking. The atmosphere will be casual and interactive, though the topic is very important and somewhat complicated at this moment in time. Speaking proposals and panel proposals are being accepted, but they must include actual best practices and leaders who can offer accurate advice on how best to find partners on both sides.

新的SCOPE中国伙伴论坛将在2020年2月18日在美国佛罗里达州欧伦达市（Orlando, FL, USA）举行。这个论坛是2020 SCOPE年会的一部分，它的目的是为全球和中国的药物企业，生物公司，研究中心，CRO，和其他的药物研究和临床试验的服务公司提供一个好的平台来分享它们在从药物开发到在东、西方国家及中国上市的成功经验。目前很多美国及欧洲的药企非常感兴趣与中国的企业及CRO建立合作伙伴关系。这不仅仅是“外包”，它也是东、西方药物研究创新者们试图找出互相帮助的双赢方法的尝试。从另外一个角度，中国的企业也希望与美国及其他西方国家的公司，企业和研究机构建立合作关系，以将中国的药物及研发工作扩展到美国或其他西方国家。这个论坛将利用一些实例和专家讨论帮助参与者建立广泛关系网。论坛将是一个非正式的交流场合。希望您或您的公司能够参加这个论坛。论坛现在已经开始接受参与者和论坛讨论者，如果您希望分享您的成功经验及开展东西方合作的心得，请同组织者直接联系。

CHINESE PHARMA INDUSTRY CHALLENGES AND OPPORTUNITIES & NEW CHINESE DRUG DEV REGULATIONS

1:30 pm Registration
2:00 Organizers’ Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)
Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)
2:05 Chinese Pharmaceutic Industry and Its Future Direction: Challenges and Opportunities
Walt Cao, PhD, President, Zeta Therapeutics, Inc.
Yue Yang, PhD, Director, International Center for Food and Drug Policy and Legal Research, Shenyang Pharmaceutical University

CONDUCTING TRIALS IN CHINA & COMPARE AND CONTRAST HOW CROS IN CHINA & US OPERATE IN DRUG DEVELOPMENT

2:45 Opportunities and Challenges of Conducting Clinical Trials in China (vs North America and Europe)
Amanda Fu, MD, MBA, Founder and CEO, RedBud Pharma
3:05 Panel Discussion: Compare/Contrast CROs in China & CROs in US – How We Operate in Drug Development
Moderator: Jane Fang, MD, MS, Director, Leader of Digital Clinical Innovations, RWD/RWE for Clinical Trials, AstraZeneca
Dan Zhang, CEO, Fountain Medical Development Ltd.
Yue Yang, PhD, Director, International Center for Food and Drug Policy and Legal Research, Shenyang Pharmaceutical University

US-CHINA INDs and NDAs & ESTABLISHING CHINA-US ALLIANCES

4:05 US-China Comparison on IND, NDA and Conduct of Clinical Trials
Dan Zhang, MD, Executive Chairman, Fountain Medical Development Ltd.
4:20 Panel Discussion: How to Establish China and US Collaborative Alliance in Drug Development
Moderator: Jane Fang, MD, MS, Director, Leader of Digital Clinical Innovations, RWD/RWE for Clinical Trials, AstraZeneca
Dan Zhang, CEO, Fountain Medical Development Ltd.
Amanda Fu, MD, MBA, Founder and CEO, RedBud Pharma
Yue Yang, PhD, Director, International Center for Food and Drug Policy and Legal Research, Shenyang Pharmaceutical University
3:35 Networking Break
4:50 Chairperson’s Closing Remarks: Next Steps for Chinese, US, European and RoW Life Sci Companies to Further Partnerships in and with China
Sean Zhao, PhD, Head, US Patient Safety, AstraZeneca
4:55 China Forum Ends, Transition to SCOPE Evening Keynote and Happy Hour
The new SSS provides a forum where academics, sponsors, CROs, and other parties who share a common interest in the conduct of clinical trials can discuss the latest and most promising research that advances how we run clinical trials. We are focusing on research to improve a process that in many ways is outdated and in dire need for efficiencies. The panelists will discuss promising research and technologies that can bring data-driven, scientific practices to clinical research design and execution. These improvements should result in better decisions in new drug evaluations; providing patients with broader and more rapid access to novel medications. The panel discussion will feature the committee members below, all thought leaders, sharing ideas in a collegial atmosphere.

PROGRAM COMMITTEE AND PANELISTS

**Kyle Holen, MD,**
*Head, Development Design Center, Research & Development, AbbVie*

**Michelle Crouthamel, PhD,**
*Director, Digital Health & Innovation, AbbVie*

**Mary Jo Lamberti, PhD,**
*Associate Director and Research Assistant Professor, Tufts Center for the Study of Drug Development (CSDD)*

**Craig Lipset, MBA,**
*Former Head, Clinical Innovation, Pfizer; Venture Partner, Boston Millennia Partners (BMP) & FundRx; Advisor, People-Centered Research Foundation (PCRF)*

**Gabriela Feldberg,**
*Leader, Advanced Analytics Center of Excellence, AstraZeneca Pharmaceuticals Inc*

**Antonieta Sosa,**
*Director Clinical Innovation, Clinical Innovation, Janssen R&D LLC*

**Oriol Serra Ortiz,**
*MBA, Senior Director & Head, Global Site Intelligence & Selection, Pfizer Inc*

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

**Adama Ibrahim, EMBA,**
*Associate Director Performace Operational Capabilities, Global Clinical Operations, Biogen Ltd*

**Carrie Melvin,**
*Vice President & Head, Global Clinical Operations, TESARO*

**Balazs Flink, MD,**
*Head, Clinical Trial Analytics R&D Business Insights, Bristol Myers Squibb Co*

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

**Marina Filshtinsky, MD,**
*Executive Director, Conferences, Cambridge Healthtech Institute (CHI)*

Attending: There is no added cost to attend this event at SCOPE, but Attendees and Speakers must be registered as a “Best Value” SCOPE conference participant (using discount code SSS). If you would like to attend, please save your seat by registering with Melissa Dolen at mdolen@healthtech.com or (+1) 781-972-5418 or online at https://register.healthtech.com/reg?SCO20&ID=19798&CO=0
Analytics-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 design, planning, operations, and 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 10th Annual “Protocol Development, Global Site Selection, Feasibility and Site Management” will cover the topics one should consider when planning and implementing a data-driven and patient-centered trial.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*
*Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE’s Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

10:40 Chairperson’s Remarks
Venkat Sethuraman, PhD, MBA, Global Clinical Lead, R&D Excellence Practice, ZS Associates

10:45 The Direct-to-Patient Approach for Trial Design and Planning: The Feasibility of Adopting a DTP Model
Antonieta Sosa, Director, Janssen Clinical Innovation
Explore key factors that need further understanding in the direct-to-patient model and look at what aspects of the model have to be vetted with key functional groups such as regulatory, legal, quality, and health care compliance. Revisit key factors to determine when a virtual, hybrid or traditional model is the best approach or fit for a clinical trial, therapeutic area and overall success of the trial.

11:15 CO-PRESENTATION: Augmented Reality (AR)/Virtual Reality (VR) Simulations to Incorporate Site and Patient Insights on Protocol Design
Brendan O’Neill, Senior Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer
Site Partner, Speaker to be Announced
In this presentation, Pfizer will share their approach on incorporating site and patient input into protocol designs using protocol simulations. Protocol simulations have provided key insights to avoid study operation pitfalls and prepare our sites for study execution. Pfizer has partnered with sites around the globe to build this capability and will co-present with a site to share their experience to date.

11:45 The Benefits of Cloud-Based, Digital Protocol Development
Kyle Holen, MD, Head, Development Design Center, Research and Development, AbbVie
Digitizing a protocol into discrete common core elements and making it available in a cloud-based environment allows for seamless transfer of information as well as customized analytics on how the process can be improved. Further, data on protocol development can also be used to create predictive algorithms to inform the risk of protocol amendments, post production changes, delays in budgets and ethics approvals.

12:15 pm CO-PRESENTATION: Are your Traditional Protocol Design and Recruitment Methods Missing the Mark?
Earl Seltzer, Senior Director, Global Feasibility at Covance, Covance
Loni Branon, Senior Director, Citeline’s Sitetrove and Citeline Engage, Pharma Intelligence-Informa
Rising clinical trial protocol complexity and competition for sites, investigators, and patients are contributing to increasing trial timelines and costs. Identifying strategies for optimizing a trial protocol at all stages is essential to ensuring your protocol is feasible and on the path to success. Please join us in reviewing how protocol feedback and customized recruitment tactics can help keep your clinical trial on track.

12:45 Transition to Lunch

12:50 Luncheon Presentation to be Announced
Sponsored by

1:20 Coffee and Dessert Break in the Exhibit Hall

IMPLEMENTING DATA-DRIVEN SITE SELECTION USING ADVANCED ANALYTICS, DATA SCIENCE MODELING, AND CLINICAL INSIGHTS

2:15 Chairperson’s Remarks
George Tiger, Vice President, Global - Business Development, Almac Group
2:20 CO-PRESENTATION: Designing a Feasibility Intelligence Platform to Merge Advanced Analytics, Data Science Modeling, and Clinical Insights
Michelle Everill, Senior Director, Head of Global Feasibility, Janssen
Miruna Sasu, PhD, Clinical Operations and Data Science, Janssen
This co-presentation will share a case study that details the building of a feasibility intelligence tool that merges advanced analytics, data science modeling, and clinical insights. The reasons behind it, the roadblocks encountered during development and implementation, and the successes achieved will be shared by two members of the team, each of whom had a different role in the story.

2:50 CO-PRESENTATION: Challenges and Successes in Building and Implementing a Data-Driven Site Selection Approach
Sandra Smyth, Global Feasibility & Site Intelligence Director, AstraZeneca
Gabriela Feldberg, Practice Leader, Applied Analytics & Artificial Intelligence, AstraZeneca
In an environment of growing complexity, the need to utilize advanced analytical techniques is more pressing now than ever to ensure selection of the optimal investigators for a study. This presentation will be a lively discussion sharing the challenges and successes in building and implementing data-driven site selection to ensure the teams have the meaningful information needed, at the time needed, to make the best decisions for their studies.

3:20 Paradigm Shifters for Site Selection: Are We Looking at the Right Site Attributes to Build Predictive Algorithms and Analytics Platforms?
Oriol Serra, MBA, Head, Site Intelligence & Selection, Global Product Development, Pfizer
Are past historical site metrics a good predictor of future performance? Can we look at other site attributes traditionally not factored into feasibility analysis? This presentation will provide a real-world demonstration on how a new methodology can improve transparency and collaborative efforts to optimize study execution and build new relationships with otherwise often overlooked investigators.

3:50 Presentation to be Announced

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 Concurrent 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share
Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

IMPROVING FEASIBILITY AND SITE SELECTION WITH PATIENT FEEDBACK, EHR STRATEGY & STRATEGIC PHARMA-SITE-CRO RELATIONSHIPS

8:20 Chairperson’s Remarks
John Musante, Senior Vice President, Head, Clinical Business Development, QPS

8:25 Engaging with Patients in Design and Execution of Trials: Ways to Make Clinical Trials More Patient-Centric
Lani Hashimoto, Clinical Program Benchmark Manager, Patient Engagement & Recruitment, Novartis
To provide more effective ways to engage with patients in the design and execution of clinical studies, TransCelerate’s Patient Experience Initiative developed tools in collaboration with Patients, Sites, Sponsors and CROs. Learn more about how the publicly-available Patient Protocol Engagement Toolkit and Study Protocol Feedback Questionnaire Toolkit may lead to greater patient engagement and partnership between patients and sponsors to design and execute clinical protocols that create better patient experiences.

8:40 Protocol Development in Collaboration with Educated Patient Advocates
Daniela Shikova, General Manager, FindMeCure Foundation
Eupati (European Patients’ Academy) and FindMeCure Foundation are working on a mutual project to help match experienced patient advocates with sponsors and CROs who are looking for help with protocol development. We identified the clear need for preparing the industry for gathering feedback and a way to implement it, and at the same time educate patients on how to provide actionable feedback. The synergy between both will bring new generation protocols that are better aligned with patients’ needs.

8:55 CO-PRESENTATION: EHR Trial Strategy, Implementation and Case Studies
Jane Fang, MD, MS, Director, Leader of Digital Clinical Innovations, RWD/RWE for Clinical Trials, AstraZeneca
Marie Eckerd, Feasibility and Recruitment Partner, Director, AstraZeneca
Electronic health records (EHR) are the new norm to drive decision making from early data mining through patient recruitment in clinical trials. End-to-end experience is limited as both sponsors and sites initiate new workflows covering site engagement, data queries, resources, and geographic presence. AZ will present a year-long overview of how EHR is embedded throughout clinical development to drive patient-centered decisions.
SCOPE was very well moderated and managed topics. Very real, valuable, actionable work done by clin ops across Bio-pharma. A good balance of executives from Bio-pharma/Bio and CRO.

- Ankit L. Associate Director, Clinical Analytics, Takeda
Clinical trial site activation and efficient study start-up for both site-based and remote/de-centralized trials 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, 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. Knowing when and where to use and to effectively scale technology is now a must in the age of digital trials. CHI’s 7th Annual “Improving Study Start-Up, Site Activation and Trial Performance” will cover the topics one should consider when strategically implementing a process for rapid study start-up, whether with sites or for de-centralized trials.

SITE ENGAGEMENT DURING FEASIBILITY PROCESS & IMPROVING START-UP TIMELINES WITH ADVANCED PLANNING FOR EARLY AND LATE-STAGE TRIALS

4:10 Chairperson’s Remarks

4:15 Site Engagement During the Site Feasibility Process and Impact on Study Start-Up Timelines
Mary-Anne Tomas, Director, Site Intelligence & Selection, Study Optimization, Global Product Development, Pfizer
This presentation will look into the impact of insourcing site intelligence and site engagement for site feasibility from a sponsor point of view. It will examine the impacts of site relationships on study start-up timelines and success. It will also highlight approaches with respect to site architecture, therapeutic alignment, and methods of approach.

4:45 Presentation to be Announced

5:15 Avoid Rescue Studies, Reduce Costs and Timelines, and Accelerate Clinical Operations with Metrics
Elvin Thalund, Director, Industry Strategy, Oracle Health Sciences, Oracle, Inc
You can’t manage what you don’t measure. Granular real-time metrics provide operational insights allowing you to take control of your studies by being proactive instead of reactive. Drive competitive performance and operational excellence by focusing your resources on bottlenecks and processes ripe for optimization. Introduce efficient resource allocation and parallelization of operational activities that can significantly compress operational timelines, improve downstream quality and regulatory compliance, while speeding entry to market.

5:45 INTERACTIVE PANEL: Sponsor and Site Interactions in Phase 1 Site Selection, Recruitment and Contract Negotiations
Kristi Womack, Director, Clinical Pharmacology Operations, Allergan
Mark Scheetz, Associate Director, Program Lead for Phase I Studies, Allergan
Carol Miller, Senior Director, Business Development, Spaulding Clinical Research
Phase 1 doesn’t fit into the late Phase mold. Start-up is much quicker and procedures differ for these studies. Study enrollment goals and duration are much shorter than most late phase studies. Discussions pertaining specifically to Phase 1 are lacking and there is a need for discussion on these topics within the clinical operations community. This panel is an open dialogue between Sponsor representatives and site representatives sharing “what works” and the lessons are relevant to those working in both early and late phases:
• Site selection process from the sponsor point of view
• Meeting recruitment and retention goals: How Phase 1 centers distinguish themselves to retain a healthy volunteer database, and how do we find the special patient populations?
• Maintaining strong sponsor and site relations: How does contracting play a role?

6:15 Networking Reception

7:15 Close of Day
FRIDAY, FEBRUARY 21

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

IMPROVING SITE SELECTION, ENGAGEMENT AND PROCESS: CONSENT, EHR PLATFORMS, CONTRACTING & DATA-DRIVEN COURSE CORRECTION

8:20 Chairperson’s Remarks

8:25 CASE STUDY CO-PRESENTATION: Create and Control: BI’s Move to a DIY Consent Process
Kristen Signs, Senior Associate Director, Clinical Operations, Boehringer Ingelheim

Eric DeLente Head, Patient Consent, IQVIA Technologies

Boehringer Ingelheim took a major step and insourced their consent process with a SaaS technology so they could create, manage, distribute, control and report on consent documents all in-house. BI will discuss their journey, including why they decided to go this direction, managing change within their organization, reactions from sites and ethics committees, the successes and struggles of their implementation and pilot trials, and the importance of early adopters in driving transformational change.

8:55 CO-PRESENTATION: Lessons Learned in Site Selection and Site Engagement Using EHR Platforms
Doug Schantz, Executive Director, Clinical Operations, AstraZeneca
Chrysalis Oley, Associate Director, Site Partnerships, AstraZeneca

In 2019 AstraZeneca began to explore how to make smarter site selection decisions by leveraging electronic health record systems capability to pre-identify potential participant clusters. We discovered that the success of this strategy is rooted in three primary drivers: technology platform capabilities, data access across multiple institutional platforms and institutional line-of-site across the patient care delivery system. Our findings suggest that although the technology capabilities are important, the drivers are the human factors: leadership support of cross institutional database access and institutional line of site into patient care access points. Successful implementation of an EMR strategy is achievable but awareness of an individual site’s commitment to this process is essential to converting the numeral data to patient lives impacted by clinical research.

9:25 Navigating the Study Start-Up Labyrinth: The Importance of Upfront Planning and Cross-Functional Alignment to Efficient Site Contracting
Christina Greene, Esq., Associate Director, Global Site Agreements, Merck Sharp & Dohme Corp.

CTA execution is an essential element to activating an industry-sponsored clinical trial at a clinical site, yet site contracting and budgeting remain one of the top reasons for delayed site activation. What are the root causes and how can it be avoided? Which techniques and approaches should we apply to avoid excessive delays in study start-up? What are we (sponsors, CROs, sites) doing together to avoid unnecessary delays and what are we missing? Learn about efficiency improvement opportunities in contracting aspects of study start-up.

9:55 Reducing the Administrative Burden on Sites
Larissa Comis, Product Lead, Shared Investigator Platform Life Sciences Products & Platforms, Cognizant

Every sponsor wants to make life easier for investigators, but what are the initiatives that are delivering measurable benefits today? This session will share the practices that are truly making a difference. Use cases of solutions that have proven to reduce investigator frustration, burnout, and drop-out will be explored.

10:25 Networking Coffee Break

SITE-LEVEL TRIAL ACCELERATION AND DATA-DRIVEN COURSE CORRECTION

10:55 Chairperson’s Remarks
Linda Glaser, MD, PhD, Medical Director, Coastal Biomedical Research

11:00 When Data Drives Intervention: An Analytics Approach to Site Level Acceleration and Trial Course-Correction
Angeline 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 depending 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.
11:30 Why Effective Site Regulatory Doc Oversight is the Key to Stress-Free Inspection Readiness
JT Tan, Pharma/CRO Innovation Lead, Complion
At its core, Inspection Readiness is straightforward: everyone’s been doing what they should be doing, so there’s nothing wrong with taking a look, right? Yet that pit in your stomach tells a different story - why? In this talk, we will unpack the challenges behind effective regulatory document oversight and introduce a new, pro-active approach to TMF quality through automation.

12:00 pm Transition to Shared Sessions

FACILITATING THE TRIALS OF THE FUTURE NOW VIA THE CONNECTED PATIENT & DECENTRALIZED TRIALS
(SPECIAL SHARED SESSION)

Chairperson’s Remarks
Neil Weisman, President, Continuum Clinical

12:05 The Connected Patient: A “One Stop Shop” for Trial Information and Data
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Learn how we are creating a connected experience for trial participants before, during and after the trial where patients can access meaningful information, their individual data to share with their EHR, aggregate study results and provide ongoing feedback and insights to ensure a better experience for patients, caregivers and the site teams. Explore the possibilities to remain connected via communities to raise awareness around trials. The audience can gain insights as to the ins and outs of how we managed to create a platform to share data directly with patients—from legal, privacy, regulatory and other key stakeholder hurdles to our vision for broadening the scope of data sharing across industry.

12:35 INTERACTIVE PANEL: Translating Virtual to Reality: Decentralized Trial Transformation
Moderator: Jane Myles, Head, Operational Intelligence and Innovation, Roche
Panelists:
Bardia Akbari, PharmD, Senior Vice President, Clinical Operations, Science37
Carrie Melvin, Vice President, Global Clinical Sciences and Delivery TA Head of Oncology, GSK/TESARO
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Our expert panel will include a variety of perspectives and the aim is to provide pragmatic solutions and actionable advice to make virtual trials a realistic option for your study needs. We’ll discuss strategic and tactical needs to help you determine how to navigate and implement virtual and decentralized options to drive your pipeline goals. Topics to be discussed include:

• Discuss the settings for virtual trials and help define best fit options for study needs.
• How and when does the regulatory strategy get set to enable a successful filing?
• What are the challenges to drive both site and patient participation in virtual trials?
• What are the timeline and cost differences in planning for and executing virtual trial components?
• What are the key lessons learned from those who have been early adopters and champions?

1:05 Transition to Lunch

1:10 Send Off Luncheon Presentation to be Announced

1:40 Closing Remarks

1:45 SCOPE Summit 2020 Adjourns
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 sight of the participant’s user experience. One must take into account the needs of different patient populations, the importance of diversity, how to use digital tech, challenges of consent processes, direct-to-patient models, and many other factors.

CHI’s 13th 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 and inclusive clinical development program.

**TUESDAY, FEBRUARY 18**

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*

*Sponsored by

5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)

6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

**WEDNESDAY, FEBRUARY 19**

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

**PATIENTS, DATA, DIVERSITY, TECHNOLOGY: OPERATIONALIZING PATIENT-CENTRIC ENROLLMENT USING DIGITAL TECH AND DIRECT-TO-PATIENT MODELS**

10:40 Chairperson’s Remarks
*Diana Foster, PhD, CEO, Total Clinical Trial Management

10:45 Data and Diversity: The Need for Increased Representation across Clinical Trials
*Charlotte Jones-Burton, MD, Vice President, Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization, Inc.

Despite known differences in disease prevalence and therapy response across ethnicities and genders, women and minority groups have been historically underrepresented in clinical trials, limiting findings on response from the full breadth of potential patients. How can we ensure that our commitment to addressing unmet need is reflected in complete, diverse patient datasets? The solution begins long before the first patient is enrolled in a trial. This talk will discuss the urgent need for increased diversity within the clinical trials space at every level, from initial study design through final read-out.

11:15 The Intersection of Patients and Technology: Innovating Clinical Trials with Patients in Mind
*Michelle Shogren, Director of Innovation, Pharma R&D Clinical Operations, Bayer

We are all working to design and execute truly patient-centered drug development and trials. At the same time we are onboarding a myriad of new technologies, from advanced analytics to wearables. So, how do you innovate while keeping the patient at the center? This presentation will share examples of design thinking principals put to use when bringing in new technology and will suggest how we can set our new way of working up for success.

11:45 SPECIAL CASE STUDY: What’s the Perfect Wearable Device for Research and Patient-Centric Trials?
*Joseph Kim, MBA, Senior Advisor, Translational Technology & Innovation, Digital Health, Eli Lilly and Company

Digital approaches can transform research beyond just participant engagement and enrollment. The rapid evolution of wearable devices and mobile health (mHealth) technology in clinical trials combined with patient-centric data generation provides the potential for better science in drug development measures. But which device is the best? They all are – depending on what you’re trying to do. The lack of know-how to understand and validate devices, data, algorithms are slowing the integration as novel endpoints into clinical trials.

12:15 pm Presentation to be Announced
12:45 Transition to Lunch

12:50 LUNCHEON PRESENTATION: The (Not So Distant) Future State of Patient Recruitment
*Neil Weisman, President, Continuum Clinical

Join this fast-paced, inspiring presentation that will leave you feeling energized about the future of patient recruitment. Learn about how and when to start incorporating next-gen technology into your patient recruitment strategies.

1:20 Coffee and Dessert Break in the Exhibit Hall
PROVEN METHODOLOGIES FOR CONNECTING PATIENTS WITH TRIALS & SUPPORTING RECRUITMENT AT PROGRAM AND STUDY LEVEL

2:15 Chairperson’s Remarks
Chair to be Announced, Clarityness

2:20 Let’s Talk Options and Scalability: Exploring the Evolution of Patient-Centric Technologies in Clinical Trials
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb

Patient technology is proliferating at a fast pace in the healthcare industry, but it is still slow at scaling in the clinical research arena. This talk will explore strategies at scaling patient-centric technologies in clinical trials to enable wider adoption while benefitting patients in the way they want to be engaged.

2:50 Talk Title to be Announced
Sponsored by EVERSANA

3:05 Patients are a Virtue: How to Find the Right Participants for Your Trial
Mark Joing, MBA, Vice President, Clinical Operations, Menlo Therapeutics Inc.

Leading patient recruitment experts and organizations are finding new ways to connect patients to trials and are tackling the thorniest of patient recruitment challenges. What hurdles do they have in common and what solutions are worth investing time and money in? This talk will share qualitative research, consisting of interviews with leading patient recruitment experts, innovators, and service providers to understand the trends, latest tools, technologies, and other recent innovations impacting the patient recruitment landscape. It will also share a simple yet powerful framework, called S4, as a tool for anyone looking to improve patient recruitment in any trial.

3:20 Supporting Clinical Trial Recruitment – Program versus Study Level
Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Pfizer

This presentation will discuss the pros and cons of supporting clinical trial enrollment efforts at the program level versus the study level. It will look at how operational and financial efficiencies are impacted, as well as the risks involved in these approaches.

3:50 CO-PRESENTATION: Talk Title to be Announced
Sponsored by greenphire

Kyle Cunningham, Chief Product Officer, Greenphire
Denisa McKnight, Senior Operations Insights Analyst, Business Insights & Analytics (Clinical Development), Roche Products Limited

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 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 investigation and problem solving, and most importantly, participate in active idea sharing. See pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share
Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

IMPROVING TRIAL PLANNING AND ENROLLMENT UTILIZING AI/ANALYTICS & ENGAGING PATIENTS FOR DIGITAL HEALTH TRIALS

8:20 Chairperson’s Remarks
Chair to be Announced, WIRB Copernicus Group

8:25 CO PRESENTATION: What Do Healthcare Consumers Really Care About? How Can We Leverage New Insight for Clinical Trial Enrollment Success?
Aaron Fleishman, Director, Market Development, BBK Worldwide
Jessica Kim, Director, Research, Digital Strategy, BBK Worldwide

This session will leverage findings from BBK’s Study Voices survey, designed to gain insight into the new healthcare consumer. Market Development Director Aaron Fleishman will share findings from more than 1,000 survey respondents and provide insight into what drives healthcare consumer behavior and how study sponsors can harness it for enrollment success. Research and Digital Strategy Director Jessica Kim will share ways to leverage insight in the planning and execution of recruitment and engagement campaigns.

8:55 SPECIAL CASE STUDY: Operationalizing Patient-Centric Enrollment Using Digital Tech and Direct-to-Patient Models
Eric Hajjar, Associate Director, Innovation, Global Development Operation, Novartis

Medicines can spend years in the development pipeline held back by a lack of suitable patients at clinical sites, yet we know the patients exist and are desperately waiting for the right medicines. Digital approaches can transform recruiting by adopting direct-to-patient models with these approaches, enabling access to a wider pool of potential patients and the ability to explore new responses to diseases. We will share our vision for an end-to-end clinical trial recruitment capability based on a modular and partnership approach, and also highlight the problems and pitfalls that can be encountered when developing Outreach Electrónica.
9:10 “Patients didn’t join my trial.”
We asked 4,000 patients why.
Laurent Schockmel, DVM, MBA, CEO, Antidote
Finding the right patients at the right time requires a deep understanding of the patient experience. This presentation will share results of a groundbreaking survey examining motivations for and barriers to participation in research, and dive into what these findings mean for your recruitment strategies.

PRACTICAL DATA-DRIVEN APPROACHES TO PARTICIPANT RECRUITMENT & LEVERAGING RWD TO OPTIMIZE ELIGIBILITY CRITERIA

11:20 Chairperson’s Remarks
Ivor Clarke, President & CEO, SubjectWell

11:25 Utilizing RWD to Enable Data-Driven Enrollment Planning and Recruitment
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen
Using a data-driven approach, investigators can optimize recruitment activities and efficiently reach potential participants. This talk will discuss tools available to collect data on recruitment activities, including: claims data, EHR data, Google analytics, Facebook pixel, trackable links and phone numbers and survey data. There is no shortage of data sources! Turning that into knowledge and a guide to improved recruitment is the challenge. This talk will share a few successes and failures that informed our RWD strategy at Amgen.

11:55 How to Use RWD to Optimize Eligibility Criteria and Enhance Recruitment
Jack Sheehan, MBA, PhD, Director, Real-World Value and Evidence, Neuroscience, Janssen Scientific Affairs (JSA)
This presentation will outline best practices to leverage EHR and claims data for recruitment and eligibility in clinical trials. Attendees will learn about CTTI’s newly released recommendations that provide practical models and operational guidance for the use of RWD to facilitate RCT planning and execution.

12:25 pm Transition to Lunch

2:00 Close of Conference
Stay on and attend Part 2: Patient Engagement, Enrollment and Retention through Communities and Technology. See pages 18-20 for details.
Patient engagement, 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. More importantly, industry should be actively listening, engaging and garnering insights from the volunteers who are the foundation and purpose of all of the research. The engagement, continuous exchange of knowledge, 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 and diverse patient population that need to be understood and engaged.

CHI's 13th Annual "Patient Engagement, Enrollment and Retention through Communities and Technology" will cover the topics one should consider when planning and strategically implementing a patient engagement strategy and retention plan in the digital age.

Arrive early and attend Part 1: Enrollment Planning and Patient Recruitment. See pages 15-17 for details.

THURSDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON CO-PRESENTATION: Putting Patients & Caregivers First: An In-Depth Look at Strategic Partnerships in Executing a Successful Clinical Trial

Tricia Barrett, Senior Vice President, Managing Director, Praxis Communications, LLC

Samantha Rogers, Patient Recruitment & Retention Lead, Takeda

Join us as we pull back the curtain to review strategies from a case study that highlights a patient-centric approach to drug development. We'll discuss how to craft a strategic plan that resonates with both the patient and caregiver. This session will focus on tactics that were successfully executed as well as mid-study adjustments that were implemented in order to optimize patient recruitment and retention.

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

ENABLE EMPOWERED PATIENTS IN CLINICAL TRIALS BY INTEGRATING THE PATIENT VOICE, HEALTH LITERACY AND CULTURAL SENSITIVITY

4:10 Chairperson's Remarks

Chris Crucitti, Chief Commercial Officer, Signant Health

4:15 CO-PRESENTATION: Enable Empowered Patients in Clinical Trials by Integrating Health Literacy and Cultural Sensitivity

Laurie Myers, MBA, Global Health Literacy Director, Global Population Health, Merck & Co., Inc.

Alicia Staley, MBA, Trial Volunteer & Cancer Survivor

Health literacy is an essential tool to help empower patients to: find clinical trial information, understand the potential risks of a trial, know their commitment (time, visits), and improve the participation of underrepresented populations. This session will provide the perspectives of a patient advocate and a pharma health literacy leader, each of whom has been personally overwhelmed by clinical trial information. It will also highlight the importance of cultural sensitivity and of use of the “teach-back method” in reaching patients and training investigators.

4:45 CO-PRESENTATION: Partnering with Patients to Tackle Engagement Together

Lely Saadat-Lajevardi, Team Leader, Clinical Insights & Experience Group, Janssen R&D

Alyson Gregg, MBA, Director, Patient Insights, Janssen R&D

As we know, the patient voice is critical to ensuring that the solutions that are put in place are meeting an actual need, alleviating a burden and/ or are fit for purpose. In this presentation, we will discuss how we have adopted different methods to obtain that patient voice early across multiple therapeutic areas. We will also discuss what we have learned and what we have done as a result of these learnings to create a better experience for our most important stakeholders in clinical trials, the patients who volunteer their time and data for the better outcomes for all.

5:15 Patient Centricity By Design: Clinical Trial Solutions Designed By Patients For Patients

Alicia Staley, Senior Director, Patient Engagement, Medidata, a Dassault Systèmes company

Patient advocates are partnering with Medidata as informed collaborators who can provide meaningful input into product design features and functionality that matter the most. Medidata has taken an innovative approach by engaging and collaborating with patient communities to infuse the patient perspective throughout the software development process. This session will review Medidata’s Patient Centricity By Design Framework and how incorporating patients into the product development process will help improve the overall patient experience.

PATIENTS USING AI/DIGITAL TECH TO PERSONALIZE ENGAGEMENT/DO BENEFIT-RISK ASSESSMENT & UNDER-REPRESENTED COMMUNITY ENGAGEMENT

5:45 Patients Embracing Artificial Intelligence and Relevant Technologies in Clinical Trials to Personalize Engagement and Do Benefit-Risk Assessment

Raj Pallapothu, mHealth Global Business Lead, Bayer Pharmaceuticals; mHealth Global Advocate

Patients are ready to integrate new tech and AI into their healthcare experiences, alongside numerous other digital patient engagement technologies, when it comes to personalized patient engagement. Patient engagement, which prioritizes the patient experience during trials, removes obstacles to treatment and helps patients take more ownership over their health during the course of the study. So, the desire to connect with
patients and solicit their feedback is there, but many trials struggle to find an efficient means to do so. In addition, developing a better trial design for patients and benefits were at the top of their lists. Because patients benefit from effective treatments while also bearing the risks, their perspectives must be at the heart of trial design and benefit-risk assessment.

6:00 CASE STUDY: Under-Represented Community Engagement to Reach, Raise Awareness and Educate on Clinical Trial Participation
Narinder Chopra, Director, Patient Feasibility, Enrollment & Retention Optimization, Global Clinical Operations, Biogen
Investing in relationships with trusted partners to enhance community engagement and participant outreach that raises awareness of clinical trial participation. However, beyond the hype are some operational challenges that must be understood before investing in digital approaches, technology or altering budgets/timelines with overly-optimistic expectations. This talk will share a specific application of traditional and digital engagement with under-represented patient communities to enhance awareness and education, ultimately to present research opportunities in these communities.

6:15 Networking Reception
Sponsored by IBM Watson Health.

7:15 Close of Day

FRIDAY, FEBRUARY 21

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:20 Chairperson's Remarks
Jim Lane, Chief Business Officer, Longboat Clinical

8:25 INTERACTIVE CO-PRESENTATION: Moving the Mountain: A Large Pharma Approach to Tech-Enabled Site and Patient Trial Engagement
April Lewis, Senior Director, R&D Technology, GSK
Alexandra Charge, Senior Director, DevOps, AstraZeneca
Rose Holub, Head, Regulatory Affairs & Compliance, Clinical Operations, Circuit Clinical
This presentation will review how large pharma is taking steps to undergo technology enablement of critical and strategic site and patient engagement strategies. AZ and GSK will discuss their approaches to site and patient technology modernization, including adoption strategies, data and system orchestration, and change management. 1) Expected improvement in pharmacology to site/patient engagement, 2) organizational challenges and successes in technology adoption, and 3) overview of blue-sky future state.

8:55 CO-PRESENTATION: The Mutual Benefits of Active Listening
Michele Teufel, Patient and Site Engagement Lead, Development Operations, AstraZeneca
John Linnell, Clinical Trial Participant and Member of AZ’s Patient Partnership Program
This discussion will be an opportunity to provide details on the interactions we, Sponsors-Patients, have had over the years and how both AstraZeneca and the patients have benefited. How has listening to and understanding the patient enhanced AstraZeneca’s ability to help patients? Why does active listening allow for a mutually beneficial partnership between the patient and sponsor companies?

9:25 CASE STUDY: Collaborating with Advocacy Organizations to Integrate Patient Perspective into Research
Mary McGowan, Executive Director, The Myositis Association
This talk will share the why and the how of the development of a training manual for home care nurses that integrated the patients’ perspective and experiences to enhance the clinicians’ understanding of the lived experience by someone who endures the pains and challenges that come with a myositis diagnosis. The manual includes details on the day to day activities of patients and care partners, what it’s like living with the disease, and information on how the disease impacts one’s life. This information was integrated into the routine nurse protocol training for the clinical trial. TMA will demonstrate how prospectively integrating this information into home nurses’ training process results in a better patient clinical trial experience.

9:55 Presentation to be Announced

10:25 Networking Coffee Break

PARTNERING WITH PATIENT ADVOCACY GROUPS TO IMPROVE PATIENT ENGAGEMENT ACROSS DRUG DEVELOPMENT

10:55 Chairperson's Remarks
Neil Weisman, President, Continuum Clinical

11:00 Partnering with Patient Advocacy Groups to Create Meaningful Patient Engagement across the Drug Development Continuum
Christina Román, Senior Community Engagement Manager, Community Partnerships, Cystic Fibrosis Foundation
Including the patient perspective in drug development can improve study feasibility, reduce burden and ensure that research projects are directed toward questions that matter most to patients. This presentation will highlight innovative and practical approaches to developing collaborations between patients and the research community at every stage of drug development. In addition, the presentation will describe how patient advocacy groups can create and formalize opportunities for patients to meaningfully engage in research activities.

11:30 Presentation to be Announced

12:00 pm Transition to Shared Sessions
FACILITATING THE TRIALS OF THE FUTURE NOW VIA THE CONNECTED PATIENT & DECENTRALIZED TRIALS
(SPECIAL SHARED SESSION)

Chairperson’s Remarks
Neil Weisman, President, Continuum Clinical

12:05 The Connected Patient: A “One Stop Shop” for Trial Information and Data
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Learn how we are creating a connected experience for trial participants before, during and after the trial where patients can access meaningful information, their individual data to share with their EHR, aggregate study results and provide ongoing feedback and insights to ensure a better experience for patients, caregivers and the site teams. Explore the possibilities to remain connected via communities to raise awareness around trials. The audience can gain insights as to the ins and outs of how we managed to create a platform to share data directly with patients—from legal, privacy, regulatory and other key stakeholder hurdles to our vision for broadening the scope of data sharing across industry.

12:35 INTERACTIVE PANEL: Translating Virtual to Reality: Decentralized Trial Transformation
Moderator: Jane Myles, Head, Operational Intelligence and Innovation, Roche
Panelists:
Bardia Akbari, PharmD, Senior Vice President, Clinical Operations, Science37
Carrie Melvin, Vice President, Global Clinical Sciences and Delivery TA Head of Oncology, GSK/TESARO
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Our expert panel will include a variety of perspectives and the aim is to provide pragmatic solutions and actionable advice to make virtual trials a realistic option for your study needs. We’ll discuss strategic and tactical needs to help you determine how to navigate and implement virtual and decentralized options to drive your pipeline goals. Topics to be discussed include:

• Discuss the settings for virtual trials and help define best fit options for study needs.
• How and when does the regulatory strategy get set to enable a successful filing?
• What are the challenges to drive both site and patient participation in virtual trials?
• What are the timeline and cost differences in planning for and executing virtual trial components?
• What are the key lessons learned from those who have been early adopters and champions?

1:05 Transition to Lunch

The sessions, exhibit floor and peer interactions validated that SCOPE is the place to understand trends in drug development innovation.

- Otis J., PhD, MPA, VP, Feasibility & Clinical Informatics, ICON Clinical Research
Companies large and small are taking on more clinical trials and with new designs, it is more critical than ever to develop effective 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. Cambridge Healthtech Institute's 10th Annual Clinical Trial Forecasting, Budgeting and Contracting conference will showcase case studies and best practices on effective budgets and clear contracts, finding harmony among all stakeholders, and using innovative tools to streamline the process.

**TUESDAY, FEBRUARY 18**

9:00 am - 7:15 pm Registration Open

2:00 - 5:00 pm User Group Meetings

2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*

*Separate registration required. Must be a Best Value registered attendee.

5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)

6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour

7:30 pm Close of Day

**WEDNESDAY, FEBRUARY 19**

7:15 am Registration Open and Morning Coffee

8:15 Morning Opening Plenary Keynotes (See page 4 for details.)

9:40 Grand Opening Coffee Break in the Exhibit Hall

10:40 Chairperson's Remarks

Maryanne Santilli, Senior Director, Scientific Alliance Management, Novo Nordisk

10:45 Budgeting and Forecasting in Large vs. Small Companies

Kenneth G. Olovich, Director, Sourcing and Finance, Chorus Division, Eli Lilly and Company

With continued pressure on operating expenses and cash flow, both large and small pharma companies depend on accurate clinical trial forecasts and predictive cost models. This presents an excellent opportunity for CROs and service providers to deliver timely invoices and routinely updated cost projections. CROs who help their sponsors do this well will be favored and will appear as good, trustworthy partners who are also good stewards of money.

11:15 INTERACTIVE PANEL: Budgeting & Negotiating Across Stakeholders

Moderator: Rick O'Hara, Director, Clinical Business Operations, Clinical Operations, Endo Pharmaceuticals, Inc.

Panelists: Kenneth G. Olovich, Director, Sourcing and Finance, Chorus Division, Eli Lilly and Company

Mike Eveland, Executive Director, Business Development, PRA Health Sciences

Kelly Willenberg, President, Kelly Willenberg, LLC

This panel will discuss the process of budget negotiations across all of the various stakeholders that contribute to a clinical trial. We'll discuss navigating stakeholders, such as Senior Management, R&D, Finance, Commercial, Legal and Regulatory. We'll also explore external stakeholders, such as providers, HCPs and the FDA.

12:15 pm Sponsored Presentation (Opportunity Available)

12:45 Transition to Lunch

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:20 Coffee and Dessert Break in the Exhibit Hall

**REVAMPS BUDGETING AND CONTRACTING STRATEGIES**

2:15 Chairperson's Remarks

2:20 Budget Templates...What Is Standard Practice?

Jamie Cash, Section Manager, Clinical Planning & Resource Management, Abbott Nutrition

Have you ever wondered what industry would consider “standard” for a clinical study budget template? Do you charge by time, by procedure, or a hybrid of both? This discussion will look at some information we found (or couldn’t find!) regarding the “right” way to budget. We will look at the diverse ways to build a budget template and look for input from the audience on perspectives and feedback.

2:50 CASE STUDY: Sample Contracts and Recommendations for Remuneration for Germany-Based Clinical Trials

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

The time factor plays an important role for clinical trials internationally and so is relevant for the competitiveness of a trial location. To start a clinical trial as early as possible, the contracts between the parties involved should be completed quickly, simply and comprehensively. Sample contracts are a new development in Germany and were developed by the German university clinics, coordination centres for clinical trials and the pharmaceutical
industry. The associated recommendations for remuneration are helpful if the potential partners in the contract have (in their respective negotiations) recommendations available that identify examples of recurrent cost items for the accurate determination of a fair remuneration in clinical trials.

3:20 INTERACTIVE PANEL: Vertex Innovation in Vendor Budgeting & Contracting Strategy
Moderator: Heidi Shea, Senior Director, Clinical Development Execution, Vertex
Panelists: Leah McCarthy, Director, Outsourcing, Vertex
Gina Carbone, Associate Director, Clinical Budget Management, Vertex
Sandra O’Sullivan, Associate Director, Vendor Management, Vertex
Vertex panel comprised of leaders in vendor management, contracting, forecasting and budget management. Discussion will include Vertex’s innovative approaches and tools for managing the related processes, resulting in inspection steadiness. Panelists’ combined industry experience of over 60 years.

3:50 Presentation to be Announced
4:05 Presentation to be Announced

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator
4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall
6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open
7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share
Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

USING TOOLS TO STREAMLINE PROCESSES AND STUDY START-UP

8:20 Chairperson’s Remarks
Anca Copaescu, CEO and Founder, Clinical Maestro by Strategikon Pharma

8:25 CO-PRESENTATION: Lessons Learned in Facilitating Expedited Timelines and Working through Delays with Internal and External Customers
Kelly Loughner, Senior Associate Director, Site Enablement, Boehringer Ingelheim
Justin Bandura, JD, Contract Manager, Clinical Operations, Boehringer Ingelheim
In today’s climate of increasingly compressed timelines, there is an enhanced focus on start-up metrics in regard to contracts and budgets. What ways is the industry addressing delays in contract negotiation and what tricks and tools have we implemented to address our customers’ KPI asks?

8:55 Leveraging Start-Up Tools to Manage Contract Negotiations
Dave Posselt, Global Director, Contract Management and Monitoring Operations, Allergan
There are a number of start-up tools currently available in the market today. In this session, we will explore how to use these tools to help manage contract negotiations, reduce bottlenecks, measure team performance and speed up negotiations.

9:25 Amgen’s Approach to Clinical Trial Patient Cost Financial Planning
Joe Robbins, Senior Manager, Clinical Pricing & Payments, Amgen
This presentation will describe how to design clinical trial patient cost/investigator grant budgets to inform life of study cost accruals. We’ll discuss budget design considerations to facilitate an efficient payments process and to enable adjustment to planned budget/accruals through clinical trial start-up and conduct.

9:55 CO-PRESENTATION: End-to-End Workflow Automation: From Budget Creation to Payment Execution
Catherine Click, Director, Pricing Analysis, Greenphire
Jenn Hill, Director, Site Contracts, Synteract
- Identifying key challenges of site budget development and negotiation
- Introducing technology to accelerate study start-up
- Optimizing the clinical trial lifecycle, resulting in increased efficiency, quality and scalability
10:25 Coffee Break in the Exhibit Hall

**NAVIGATING SITE SOURCING AND CONTRACTING**

**11:20 Chairperson's Remarks**  
Debora Araujo, Founder & CEO, ClinBiz

**11:25 Site Contracting Oversight Strategy for Outsourced Trials**  
Debora Araujo, Founder & CEO, ClinBiz  
The right CRO or functional service provider (FSP) can be an excellent and strategic partner in helping sponsors have a wider and farther reach. This is no different when it comes to outsourced site contract negotiations. As the CRO/FSP is an extension of the sponsor's brand and reputation, it is vital that study sponsors develop, execute and train on an appropriate oversight strategy for all outsourced work, including site contract negotiations, and apply it consistently. In this session, we’ll explore the main components of this site contracts oversight strategy.

**11:55 CO-PRESENTATION: SPAR WARS*: The Sponsor Menace vs. The Revenge of the Site**  
Chris Chan, Executive Director, R&D Finance, Fibrogen  
Carlos Orantes, CEO, Meridien Research  
*(Site and Pharma Arguing Relentlessly). This will be a discussion on significant budgeting, contracting and payment issues within the site-sponsor relationship.

12:25 pm Transition to Lunch

12:30 Bridging Luncheon Presentation  
(Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference


SCOPE is always a fantastic event for talks, workshops, and meeting all the who’s who of the industry. Always a pleasure to attend.

- Jivan A., Principle Adoption RISM, Medidata
Companies large and small are taking on more clinical trials and with new designs, it is more critical than ever to develop effective 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. Cambridge Healthtech Institute's 10th Annual Clinical Trial Forecasting, Budgeting and Contracting conference will showcase case studies and best practices on effective budgets and clear contracts, finding harmony among all stakeholders, and using innovative tools to streamline the process.

**Arrive early and attend Part 1: Clinical Trial Forecasting, Budgeting and Contracting. See pages 22 & 23 for details.**

**THURSDAY, FEBRUARY 20**

11:30 am Registration Open

12:30 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

**EVALUATING AND UPDATING CLINICAL RESOURCE MANAGEMENT**

4:10 Chairperson's Remarks

Jeff Kingsley, DO, MBA, CPI, FACRP, Chief Executive Officer, IACT Health


Piet Theisohn, Director, Head, Resource Management in Clinical Operations, R&D-ClinOps - Business Excellence & Innovation, Bayer AG Pharma Division

In 2019, Bayer evaluated the Resource Management approach in Clinical Operations with regards to processes and organization. The functional leadership teams in CO were interviewed and an enhanced design presented to management for decision and implementation. We will share the key feedback and what Bayer’s enhanced Resource Management approach looks like.

4:45 Clinical Resource Planning & Management: What’s The Benefit?

Giselle Paule, Contract Coordinator, Clinical Planning & Resource Management, Abbott Nutrition

Once your resource management process is optimized, what’s next? You aligned teams, changed culture and overhauled processes. Now it’s time to use the data. We will discuss the ongoing relationship between better inputs, accurately reported effort and improved forecasting. We will demonstrate outputs we used to create meaningful reporting for team managers, directors and VPs. Finally, we will debate the longstanding question - what is the benefit of resource planning?

5:15 Investigator Training and Engagement Data as Resources to Prevent Clinical Trial Delays

Jennifer Tontini, Vice President, Global Business Development, Educational Measures

Poor quality data and inappropriate patient selection are key causes of clinical trial delays. Effective training of site teams at investigator meetings can mitigate the underlying causes. In this session, we cover how to leverage interactive content and participant engagement as resources to improve knowledge retention of study protocol, patient selection, informed consent and standards for data collection. Capturing and assessing participant engagement data closes the gap by identifying areas where additional training is needed.

5:45 Shared Resources with Competitors as a “Relief Valve” for Workload Volatility

Jeff Kingsley, DO, MBA, CPI, FACRP, CEO, IACT Health

The clinical trial pipeline is highly volatile, resulting in significant peaks and troughs for staff workload. Adding team members for a peak will result in losses during a trough. However, shared resources amongst research organizations can balance the needs of all. Dr. Kingsley will suggest solutions, resulting in variable costs and improved performance.

6:15 Networking Reception (Sponsorship Opportunity Available)

7:15 Close of Day

**FRIDAY, FEBRUARY 21**

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

**USING ADVANCED ANALYTICS AND METRICS TO DRIVE RESOURCING**

8:20 Chairperson's Remarks

8:25 CO-PRESENTATION: Effectively and Efficiently Driving the Resourcing Discussion Using Analytics and Collaboration

Laila Mork, Senior Manager, Systems, Analytics & Reporting, Business Operations, Allergan

Joseph Yi, Systems, Analytics & Reporting Administrator, Allergan

Resource planning requires not only the right tools, but also the right conversations at the right time. This presentation will cover all three aspects, including: practical methods for resourcing within and across business units, powerful ways to visualize resourcing needs with different levels of granularity, and frequency and alignment of resourcing activities. Attendees will see real-world examples of resource planning and visualizations that drive conversation and decision making.

9:25 What Sponsors and CROs Need to Know about CRC Performance Metrics Before Site Selection

David J. Morin, MD, FACP, CPI, FACRP, Director of Research, Clinical Research, Holston Medical Group
Essential to the success of a study are highly functional Clinical Research Coordinators (CRCs). How CRCs perform depends on their intrinsic abilities, concomitant workload and site structure. We will review how these elements are measured and applied to resource capacity planning through the use of novel metrics. When a new study is considered, the Sponsor/CRO should confirm that the CRC has the capacity to successfully complete the study if assigned.

9:55 Leveraging the EHR in Clinical Trials Fulfillment
Roy Jones, MD, PhD, Professor, Medicine, MD Anderson Cancer Center
The capability to leverage EHR data in the fulfillment of clinical trials has arrived and the return on investment can be substantial. In this session, the panelists describe their experience implementing an EHR2EDC solution from both the research site and sponsor perspectives.

10:25 Networking Coffee Break

IMPLICATIONS OF RESOURCE AVAILABILITY ON OUTSOURCING AND OPERATIONS

10:55 Chairperson's Remarks
Audrey Rossow, Principal, A Rossow Consulting, LLC

11:00 How Many Internal ClinOps Resources Should You Have for Study Start-up?
Audrey Rossow, Senior Director, Clinical Operations, Pulmatrix, Inc.
In most biotech companies, budgets are small and timelines are as tight as possible in order to get the data needed to support the next round of funding and the next step in your clinical development program. The best way to achieve the next step is proper planning ahead. This presentation will focus on proper resourcing of a sponsor’s internal Clinical Operations team to support a clinical trial during startup.

11:30 Sponsored Presentation (Opportunity Available)

12:00 pm Transition to Shared Sessions

12:05 Transparency is Key to Successfully Enable Vendor Partnerships Align on Resource Demands
Eric Lawrence, MBA, MS, Associate Director, Clinical Biomarker Specialty Lab Alliance Lead, Bristol-Myers Squibb
Successful execution of a study supported by third party vendors begins with transparency of expectations. When a strategic partner is selected by multiple study teams with no visibility for competing resources from an enterprise perspective, the opportunity for risks to the portfolio become evident. Strategies to mitigate pitfalls with external providers to ensure successful execution and success for the partnership will be reviewed.

12:35 INTERACTIVE PANEL: How Varying Resource Availability Affects Outsourcing, Operations and Pressures in Large vs. Small Pharma
Moderator: Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc.
Panelists: Erin O’Boyle, Senior Director, Clinical Operations, Rezolute, Inc.
Wes Bonner, Vice President, Strategic Development, Meridian Clinical Research
Piet Theisohn, Director, Head, Resource Management in Clinical Operations, R&D-ClinOps - Business Excellence & Innovation, Bayer AG Pharma Division
This panel will highlight key differences in how large and small pharma companies address clinical operations due to varying amounts of resources. Panelists will address questions, such as:
• How does resource availability affect the outsourcing strategy?
• How do small and large pharma companies work with CROs on timelines, deliverables and meeting targets?
• How do different-sized companies prioritize milestones, and what types of risk mitigation are put into place?

1:05 Transition to Lunch

1:10 SCOPE Send Off Luncheon Presentation (Sponsorship Opportunity Available)

1:40 Closing Remarks

1:45 SCOPE Summit 2020 Adjourns
4th Annual
Mastering an Outsourcing Strategy
Defining Your Sourcing Strategy & Ensuring Harmony between All Stakeholders

The landscape of how sponsors approach their outsourcing strategy continues to adapt as new methods and technologies become available. CHI’s 4th Annual Mastering an Outsourcing Strategy conference provides a number of perspectives on approaching an overall outsourcing strategy and will address how both internal considerations and external forces can influence the process. The program will also offer case studies and discussions with input from sponsors, CROs, sites and suppliers on navigating the outsourcing process.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*
*Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

UPDATING OUTSOURCING STRATEGIES IN A CHANGING LANDSCAPE

10:40 Chairperson’s Remarks
Todd Reul, Associate Director, Global Strategic Sourcing, BioMarin Pharmaceutical Inc.

10:45 How Evolving Technology Influences Sourcing Strategy
Reb Tayyabkhan, Head, R&D Sourcing and Procurement, Merck
Sourcing approaches which to date have been isolated based on functional area or scope of services needs to be evolve, as there is a clear interplay between technology and services; and with the rapid evolution in technology, the ability to look ahead is more important than ever when considering your sourcing strategy.

11:15 Leveraging Category Management to Inform Clinical Outsourcing Strategy
Todd Reul, Associate Director, Global Strategic Sourcing, BioMarin Pharmaceutical Inc.
This presentation will explore the what and why of Category Management and meeting the needs of all stakeholders, from operations, finance, and compliance to legal and executive management. We’ll discuss the relationship to Strategic Sourcing and how Category Management informs Clinical Outsourcing strategy by defining and prioritizing service categories, examining elements of a holistic Category Management Plan and exploring synergies with Supplier Management.

11:45 Double Vision – Lessons From the Biotech Outsourcing Perspective that Larger Pharma Can Learn From
Richard Scaife, Chair, Pharmaceutical Contract Management Group (PCMG)
The volume of program-level clinical trials that Biotech companies are outsourcing is increasing. Is this due to increased availability of funding or also because Biotechs are more effective in their outsourcing and trial management? Decision-making, contracting, trust, payment, interaction and limited resource to micro-manage are just some of the different perspectives between leaner, meeker Biotech companies and bigger sponsors. This session will explore some essential the truths and myths of outsourcing at the sharp end of the spectrum. Lessons that can be viable for both sponsors and providers.

12:15 pm CO-PRESENTATION: Evolved FSP Models are Meeting the Industry Need for Organizational Agility
Eleanore Doyle, Executive Vice President, FSP Strategic Solutions, Syneos Health
Shaun Williams, Executive Director of Investigator Management Solutions, Syneos Health
As customers look to consolidate outsourced Clinical Solutions, typical static outsourcing models fail to meet their increasingly complex scientific and operational needs. Rather than think of outsourcing or insourcing as single function engagements, sponsors can combine the stability and infrastructure of a full service organization and a flexible FSP team to quickly respond to evolving development needs. Syneos Health will provide a case study that demonstrates, improved efficiencies and cost reductions by leveraging multifunction FSP models to support the growing need for organizational agility.

12:45 Transition to Lunch

12:50 LUNCHEON CO-PRESENTATION: The Importance of Open Systems in eClinical Technology
Jan Nielsen, Community Manager, Life Sciences, BSI Business Systems Integration AG
Jens Thuesen, Business Development, BSI Business Systems Integration AG
An open system, in the context of computing, is a computer system that combines portability and interoperability, and makes use of open software standards. It typically refers to a computer system that is interoperable between different vendors and standards, allowing for modularity so that hardware and software need not to be attached to a single vendor or platform. This presentation focus on the importance of selecting Open Systems when evaluating new eClinical technologies

1:20 Coffee and Dessert Break in the Exhibit Hall

CONSIDERATIONS FOR CHOOSING AND IMPLEMENTING AN OUTSOURCING STRATEGY

2:15 Chairperson’s Remarks
Gretchen Voolich, Associate Director, R&D External Operations, R&D Quality, Operations & Performance, Biogen

February 19-20
2:20 To Strategize or Not to Strategize: That is the Question!  
Scott Sawicki, R&D Sourcing Consultant, Adare Pharmaceuticals
Size does matter: in terms of volume, volume in terms of number of assets and planned studies within a given portfolio, which should definitely drive whether or not an outsourcing strategy is needed. The presentation will cover the different sourcing models, key differences in defining and developing a strategy in a large pharma vs a small pharma, what works well and not so well in both environments, and ways to deal with the adversity that may exist in both environments.

2:50 PANEL DISCUSSION: Considerations for Choosing and Implementing an Outsourcing Strategy
Moderator: Ratan Ratnesh, Director, Head, Clinical Outsourcing, Otsuka
Panelists: Hansu Dong, Director, Outsourcing, AstraZeneca
Ly Kawaguchi, Senior Director, Head, Outsourcing and Procurement, MyoKardia
Reb Tayyabkhan, Head, R&D Sourcing and Procurement, Merck
Anca Copaescu, CEO and Founder, Clinical Maestro by Strategikon Pharma
Choosing, updating and implementing an outsourcing strategy is a daunting task with so many methodologies, business needs and resource needs to consider. Stakeholders in outsourcing will discuss key considerations for defining outsourcing needs, choosing an effective outsourcing strategy and implementing the strategy across the organization.

3:50 Talk Title to be Announced
Gail Adinamis, CEO, Founder, GlobalCare Clinical Trials

4:05 Sponsored Presentation (Opportunity Available)

THURSDAY, FEBRUARY 20

7:15 am Registration Open
7:45 Breakfast Presentation to be Announced
8:15 Session Break

REALIZING YOUR SPONSOR OF CHOICE STRATEGY

8:20 Chaiperson's Remarks
Mike Keens, COO, Firma Clinical Research

8:25 Being a Sponsor of Choice
Rosalie Filling, Vice President, Clinical Operations, Research and Development, Endo Pharmaceuticals
This talk will be outlining what it takes to not only be a sponsor of choice for personnel joining your organization, but also for vendors and partners.

8:55 Investigator Payments: A Critical Component in Realizing Your Sponsor of Choice Strategy
Geri Masessa, Senior Resource Manager, Clinical Operations, Bayer Healthcare
Feedback from Bayer's clinical sites delivered the news loud and clear: investigator payments were one of the most pressing and enduring clinical operations challenges. Investigator payment cycle times, payment transparency and traceability had a direct link to site satisfaction and retention. We will highlight the key initiatives undertaken to reduce the administrative burden associated with managing the site payment process in the US, and increase site satisfaction because of the improved payment transparency and accuracy of on-time payments. We will discuss how the implementation of a new investigator site payment solution will not only further Bayer's sponsor of choice initiative by increasing site satisfaction, payment accuracy and cycle times, but will drive operational efficiencies within the company, and has already driven other departments to start their own sponsor of choice initiatives.

9:25 INTERACTIVE PANEL: Sponsor of Choice – Small Company, Different Needs, Same Desires
Moderator: Ly Kawaguchi, Senior Director, Head of Clinical Outsourcing, Site Budgets/CTAs, and Business Analytics, Outsourcing and Procurement, MyoKardia
Panelists: Adrienne Robinson, Associate Director, Clinical Outsourcing, MyoKardia
Audrey White, Associate Director, Clinical Site Budgets/CTAs, MyoKardia
Janet Pak, Senior Manager, Business Analytics and Resource Management, MyoKardia
The panelists will share their perspectives on Sponsor of Choice and how they go about leading this effort within each function.

9:55 Embracing the Future in Research & Development Operations
Jennifer Duff, Global Operations, R&D, Lead, Managing Director, Global Operations, Accenture

10:25 Coffee Break in the Exhibit Hall
NAVIGATING SITE SOURCING AND CONTRACTING

11:20 Chairperson's Remarks  
*Debora Araujo, Founder & CEO, ClinBiz*

11:25 Site Contracting Oversight Strategy for Outsourced Trials  
*Debora Araujo, Founder & CEO, ClinBiz*

The right CRO or functional service provider (FSP) can be an excellent and strategic partner in helping sponsors have a wider and farther reach. This is no different when it comes to outsourced site contract negotiations. As the CRO/FSP is an extension of the sponsor’s brand and reputation, it is vital that study sponsors develop, execute and train on an appropriate oversight strategy for all outsourced work, including site contract negotiations, and apply it consistently. In this session, we’ll explore the main components of this site contracts oversight strategy.

11:55 CO-PRESENTATION: SPAR WARS*: The Sponsor Menace vs. The Revenge of the Site  
*Chris Chan, Executive Director, R&D Finance, Fibrogen*  
*Carlos Orantes, CEO, Meridien Research*  
*(Site and Pharma Arguing Relentlessly). This will be a discussion on significant budgeting, contracting and payment issues within the site-sponsor relationship.

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Data Certainty from Source to Submission: Addressing Disparate Data Challenges with eSource  
*Jonathan Andrus, Chief Business Officer, Clinical Ink*

Poor clinical trial data collection can delay decisions that help study stakeholders confidently move products to market. This presentation covers:

• The benefits of direct data capture using eSource technologies
• How eSource solutions improve data capture, access and interoperability
• How eSource helps companies enable true risk-based and remote monitoring approaches
• How ePRO and eCOA improve site and patient engagement
• Why investing in a disruptive solution both decreases study cost and creates a new revenue stream

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Managing Outsourced Clinical Trials. See pages 28 & 29 for details.
As more clinical trial activities are outsourced to CROs and other third-party vendors, and as those CROs and vendors grow in their capabilities, it is more important than ever for sponsors and vendors to develop strong partnerships and establish themselves as partners of choice. CHI’s 6th Annual Managing Outsourced Clinical Trials conference features case studies and lessons learned from sponsors and CROs on managing relationships, vendor quality and performance in light of the new ICH E6 R2 changes, and how to build beneficial partnerships that effectively manage resources.


THURSDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Data Certainty from Source to Submission: Addressing Disparate Data Challenges with eSource

Jonathan Andrus, Chief Business Officer, Clinical Ink

Poor clinical trial data collection can delay decisions that help study stakeholders confidently move products to market. This presentation covers:

• The benefits of direct data capture using eSource technologies
• How eSource solutions improve data capture, access and interoperability
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• How ePRO and eCOA improve site and patient engagement
• Why investing in a disruptive solution both decreases study cost and creates a new revenue stream

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

BEST PRACTICES IN MANAGING RELATIONSHIPS

4:10 Chairperson’s Remarks

Rosalie Filling, Vice President, Clinical Operations, Research and Development, Endo Pharmaceuticals

4:15 The Value of Supplier Relationship Management: CROs vs. Technology Outsourcing

Krista Emmons, Associate Director, Portfolio Relationship Management, R&D Procurement, Astellas Pharma

This talk will discuss how Supplier Relationship Management can bring value to the business beyond savings and describe tailoring your approach to a range of suppliers, from CROs to technology solutions. We’ll cover lessons learned from sitting on both sides of the table – from both the sponsor and vendor perspective.

4:45 Managing Offshore Outsourcing of Clinical Trial Research

Minji Bae, Associate Director, Vendor Management, AbbVie

This presentation will describe how to operationally ready when onboarding offshore providers in BRIC countries, including the outcomes and models utilized to ensure successful sustainability of the offshore engagements, as well as lessons learned from challenges and opportunities.

5:15 Presentation to be Announced

5:45 INTERACTIVE PANEL: Supplier Relationship Management: Various Journeys in Supplier Relationship Management “SRM” & Vendor Management “VM”

Moderator: John Santacruz, Director, Portfolio Relationship Management, R&D Procurement, Astellas Pharma

Panelists: Amanda Hovda, MBA, Associate Director, Business Strategy & Operations, Analytics and Data Sciences, Biogen

Gretchen Voolich, Associate Director, R&D External Operations, R&D Quality, Operations & Performance, Biogen

Liz Wool, President, Wool Consulting Group

Hear stories from the panel on various journeys in Supplier Relationship Management “SRM” & Vendor Management “VM”, including:

• Various Models & Value Propositions
• Launches & Sustainability
• Lessons Learned & Best Practices in Value Creation & Capture

6:15 Networking Reception

7:15 Close of Day

FRIDAY, FEBRUARY 21

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

VENDOR OVERSIGHT: METRICS, KPIs AND ICH E6 R2

8:20 Chairperson's Remarks

Chairperson to be Announced, Adaptive Clinical Systems

8:25 Defining Metrics for Quality Vendor Oversight

Keith Dorricott, Ambassador, Metrics Champion Consortium; Director, DMPI Ltd.

ICH E6 R2 highlights the importance of CRO and third-party vendor oversight. Measuring whether timelines are met and financial aspects is relatively easy, but measuring quality can be much more challenging. While developing a set of metrics for quality oversight of CROs and vendors, an industry consortium of sponsors and vendors have uncovered many learnings from the bringing together of experiences across the industry. This presentation aims to share some of the key learnings and provide an overview of the metrics developed.
8:55 **CO-PRESENTATION: Right-Sizing an R&D Approach for Optimizing Vendor Oversight**  
_Amanda Hovda, MBA, Associate Director, Business Strategy & Operations, Analytics and Data Sciences, Biogen_  
_Gretchen Voolich, Associate Director, R&D External Operations, R&D Quality, Operations & Performance, Biogen_  

R&D outsourcing strategies are a highly discussed, highly debated, current topic within our industry with organizations utilizing slightly different approaches. At Biogen, oversight of R&D vendors is a shared responsibility using a risk-based model for the routine and watchful management of how we engage with our critical external relationships. The purpose of this presentation is to share Biogen's approach of how everyone within the GxP and non-GxP environments owns oversight to drive internal accountability and vendor performance.

9:25 **Sponsor Oversight in a Fully Outsourced Model: Small Biopharma Perspective**  
_Michael McLaughlin, Associate Director, Clinical Operations, Dermavant Sciences, Inc._

9:55 **CO-PRESENTATION: A Multi-level Approach to Systematic Portfolio Oversight in a Sponsor-CRO Partnership**  
_Holger Liebig, Senior Director, Strategic Partnerships, Parexel_  

An effective sponsor-CRO oversight model is risk-driven, lean, objective and based on mutual respect. UCB and Parexel have developed a well-functioning oversight model with these attributes. Metrics, KPIs and communication play an important part where stakeholder management is key to a successful partnership. In this presentation, we will share our experience of the co-development of a model that supports real time access to high level trial data using a sponsor driven visualization tool.

10:25 Networking Coffee Break

**IMPLICATIONS OF RESOURCE AVAILABILITY ON OUTSOURCING AND OPERATIONS**

10:55 **Chairperson’s Remarks**  
_Audrey Rossow, Principal, A Rossow Consulting, LLC_

11:00 **How Many Internal ClinOps Resources Should You Have For Study Startup?**  
_Audrey Rossow, Principal, A Rossow Consulting, LLC_

In most biotech companies, budgets are small and timelines are as tight as possible in order to get the data needed to support the next round of funding and the next step in your clinical development program. The best way to achieve the next step is proper planning ahead. This presentation will focus on proper resourcing of a sponsor’s internal Clinical Operations team to support a clinical trial during startup.

11:30 **Sponsored Presentation (Opportunity Available)**

12:00 pm **Transition to Shared Sessions**

**IMPLICATIONS OF RESOURCE AVAILABILITY ON OUTSOURCING AND OPERATIONS (CONT.)**

12:05 **Transparency is Key to Successfully Enable Vendor Partnerships Align on Resource Demands**  
_Eric Lawrence, MBA, MS, Associate Director, Clinical Biomarker Specialty Lab Alliance Lead, Bristol-Myers Squibb_

Successful execution of a study supported by third party vendors begins with transparency of expectations. When a strategic partner is selected by multiple study teams with no visibility for competing resources from an enterprise perspective, the opportunity for risks to the portfolio become evident. Strategies to mitigate pitfalls with external providers to ensure successful execution and success for the partnership will be reviewed.

12:35 **INTERACTIVE PANEL: How Varying Resource Availability Affects Outsourcing, Operations and Pressures in Large vs. Small Pharma**  
_Moderator: Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc._  
_Panelists: Erin O’Boyle, Senior Director, Clinical Operations, Rezolute, Inc.  
_Wes Bonner, VP, Strategic Development, Meridian Clinical Research  
_Piet Theisohn, Director, Head, Resource Management in Clinical Operations, R&D-ClinOps - Business Excellence & Innovation, Bayer AG Pharma Division_

This panel will highlight key differences in how large and small pharma companies address clinical operations due to varying amounts of resources. Panelists will address questions, such as:

- How does resource availability affect the outsourcing strategy?
- How do small and large pharma companies work with CROs on timelines, deliverables and meeting targets?
- How do different-sized companies prioritize milestones, and what types of risk mitigation are put into place?

1:05 **Transition to Lunch**

1:10 **SCOPE Send Off Luncheon Presentation (Sponsorship Opportunity Available)**

1:40 **Closing Remarks**

1:45 **SCOPE Summit 2020 Adjourns**
Successful patient-centric clinical trials are underpinned by efficient, streamlined clinical trial supply processes that ensure the investigational drug is properly handled and delivered to the right patient, whether it be at the trial site, pharmacy or at home. Cambridge Healthtech Institute's 3rd Annual Clinical Supply Management meeting focuses on the partnership of clinical supply and clinical operations. This meeting shares case studies and best practices that emphasize the critical role of clinical supply management for ever-more complex trials.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open

2:00 - 5:00 pm User Group Meetings

2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*

*Separate registration required. Must be a Best Value registered attendee.

5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)

6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour

7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Morning Opening Plenary Keynotes (See page 4 for details.)

9:40 Grand Opening Coffee Break in the Exhibit Hall

AUTOLOGOUS THERAPIES: END-TO-END SUPPLY LOGISTICS

10:40 Chairperson's Remarks

Disa Lee Choun, Head of Innovation, Global Clinical Sciences and Operations, UCB

10:45 The N=1 Clinical Supply Chain


Autologous therapies, such as CAR-T, have challenged us to re-evaluate our clinical supply chains to accommodate the needs of personalized manufacturing: harvesting raw material from the patient and tracking material through the production process until the drug product is infused back into the patient. This talk discusses the challenges and opportunities of building a personalized logistics network in this novel therapeutic modality, including new stakeholders and differing capabilities in hospital networks, while reducing vein-to-vein time and maintaining an end-to-end chain of custody.

11:15 Presentation to be Announced

11:45 Navigating the Supply Chain and Supplier Challenges in Cell Therapy

Alan K. Smith, PhD, Executive Vice President, Technical Operations, Bellicum Pharmaceuticals, Inc.

Developing a supply chain required to develop and manufacture GMP cell therapy products presents some unique challenges to typical biologics or small molecule drugs. Identification and qualification of suppliers and consideration of best practices is essential. Successful strategies in negotiating supply and quality agreements, establishing and managing lead times and supply inventory considerations are also critical to the successful manufacture and release of cell therapy products for clinical use.

12:15 pm Direct to Patient: Choosing the Right Distribution Model for Your Study

Jennifer Fenwick, Director, Project Management, Americas

• Direct to Patient
• HHC
• Protocol Considerations
• Operational and Regulatory Factors to consider

12:45 Transition to Lunch

12:50 LUNCHEON PRESENTATION:
Cumulative Live Meta-Analyses for Understanding Real-World Trial Outcomes and Driving Protocol Design

Nikhil Gopinath, Associate Director, Product Management, Saama Technologies

1:20 Coffee and Dessert Break in the Exhibit Hall

BLOCKCHAIN: SUPPORTING EFFICIENCY AND VISIBILITY ACROSS THE CLINICAL TRIAL

2:15 Chairperson's Remarks

Adama Ibrahim, EMBA, Associate Director, Global Clinical Operations, Biogen

2:20 CO-PRESENTATION: Blockchain Clinical Trials: Truth or Dare?

Disa Lee Choun, Head of Innovation, Global Clinical Sciences and Operations, UCB

Adama Ibrahim, EMBA, Associate Director, Global Clinical Operations, Biogen
In this presentation, we will show how blockchain can be used for the design and implementation of faster, less onerous user identification processes through permissioned access to a federated database pointing to a variety of traditionally siloed sources (inc. EMR, wearables, IoT, etc.) We will also describe how a blockchain-powered health wallet could support greater efficiencies across the clinical trial process.

2:50 Can We Use Blockchain for Clinical Trial Efficiency?  
Basker Gummadi, MS, PMP, PgMP, Director, Technology and Innovation, Celgene  
The healthcare clinical trials domain is ripe to leverage core benefits of blockchain technology. We must also identify challenges and map blockchain solutions based on a 'fit-for-purpose' approach. Some of the most pressing challenges in clinical trials include access and management of clinical trial data; data integrity and provenance for regulatory purposes; updating and maintaining patient consent; and patient recruitment. We will describe blockchain approaches to address clinical trial management challenges and illustrate the variety of blockchain designs.

3:20 Transforming Clinical Supply with Blockchain  
Ben Taylor, Member, Clinical Supply Blockchain Working Group & CEO, LedgerDomain  
With active clinical studies on the rise and personalized medicine on the horizon, clinical pharmacies are struggling to keep up with growing demand. The sheer number of systems used by sponsors and CROs means that many sites have fallen back on paper documentation. This talk explores a landmark pilot program in which a working group with broad industry participation scoped, developed, and tested a collaborative blockchain solution aimed at delivering a win for patients awaiting new medicines.

3:50 Presentation to be Announced  

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:05 Sponsored Presentation (Opportunity Available)  

4:20 Find Your Table and Meet Your Moderator  

4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall  

5:45 Close of Day  

THURSDAY, FEBRUARY 20

7:15 am Registration Open  

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share  
Mike Nolte, Chief Executive Officer, Signant Health  

8:00 Session Break  

8:15 DIRECT TO PATIENT (DTP): END-TO-END SUPPLY MANAGEMENT  

8:20 Chairperson's Remarks  
Gerald Finken, CEO, Center Point Clinical Services, LLC  

8:25 DTP Case Study: Planning, Implementation, Ensuring On-Going Success and Lessons Learned  
Sarah Halmrast, Vice President, Global Project Management, Clinical Supplies Management, Inc.
A Clinical Supplies discussion on planning packaging & labeling, delivery, storage and return of supplies for clinical trial that will have a positive impact on patients participating in a DTP study. We will also discuss challenges encountered to successfully get medication in the patients' hands throughout the study.

8:50 Clinical Patient Management for Specialty Pharmaceuticals  
Jeremy Faulks, PharmD, Director, Specialty Pharmacy and Pharmacy Procurement, Pharmacy Operations, Thrifty White Pharmacy  
This presentation will cover Specialty Pharmacy Patient Management Programs for a variety of medications. These programs include benefit investigation, insurance and funding support, clinical patient counseling and ongoing patient assessment and management through clinical surveys and data analysis. We currently offer 200+ clinical protocols, each specific to the medication therapy and disease state undergoing treatment. These clinical protocols support gathering of real-world evidence and patient outcomes from their medication therapy.

9:10 Clinical Trials from the Patient Perspective: What Matters Most?  
Jasmine Benger, Senior Project Manager, Research Services, Center for Information and Study on Clinical Research Participation (CISCRP)
Excerpts from CISCRP’s 2019 Perceptions and Insight Study: A Global Online Survey of Patients and Public. Take a deep dive into the findings from CISCRP’s most recent study. What are patient’s thoughts on remote trial models? How can trials be designed to reduce the burdens associated with participation? Learn about patient preferences around medicine being delivered to their home, thoughts on the use of technology and more.

9:50 Presentation to be Announced  

10:05 BOARD BREAK  

10:20 Welcome to the Exhibit Hall  

10:30 Networking in the Exhibit Hall  

10:50 Presentation to be Announced  

11:00 General Session Kickoff/Celebration (Opportunity Available)  

11:15 Welcome Reception in the Exhibit Hall  

11:45 Interactive Breakout Discussion Groups

4:05 Sponsored Presentation (Opportunity Available)  

4:20 Find Your Table and Meet Your Moderator  

4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall  

5:45 Close of Day

36|SCOPEsummit.com  
REGISTER!
3rd Annual
Clinical Supply Management
Streamlining Clinical Supply Tracking, Management & Distribution for Patient-Centric Trials

9:25 PANEL DISCUSSION: Patient-Focused Clinical Supplies
Moderator: Gerald Finken, CEO, Center Point Clinical Services, LLC
Panelists:
Jasmine Benger, Senior Project Manager, Research Services, Center for Information and Study on Clinical Research Participation (CISCRP)
Jeremy Faulks, PharmD, Director, Specialty Pharmacy and Pharmacy Procurement, Pharmacy Operations, Thrifty White Pharmacy
Sarah Halmrast, Vice President, Global Project Management, Clinical Supplies Management, Inc.

Topics to be discussed:
• Best Practices for Patient-Focused Supplies
• Packaging and Labeling/Dispensing
• Delivery – Site Dispensing/DTP
• Storage
• Returns
• Patients and Their Medication – Ensuring Adherence, Compliance and Therapeutic Outcomes
• Packaging and Labeling Site's Role
• Clinical Site's Role
• Dispensing Pharmacy’s Role

9:55 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall

ADOPTING DATA TECHNOLOGY:
PATIENT & PRODUCT MONITORING

11:20 Chairperson's Remarks

11:25 Analytical Risk-Based Approach to Investigational Product Monitoring Activities: A Practical Case
Julian Ortiz, Associate Director, Risk Management and Central Monitoring, Infectious Diseases and Vaccines, Integrated Data Analytics and Reporting, Janssen Research and Development
ARBM methodology allowed the use of centrally available drug accountability data to guide the CRAs to perform tailored review and targeted verification of IP processes. IP TSDV methodology was implemented to verify data of 10% of subjects. IP SDR was implemented in sites with possible issues, based on centrally calculated number of unaccounted for bottles and possible missing/overdoses. After ARBM IP implementation, the data quality and OSVM efficiency were increased.

11:45 Electronic Labels in Clinical Supplies: Understanding the Benefit for Patients, Sites and Sponsors
Nicohle J. McGeorge, Senior Lead Project Manager, Clinical Supply Operations P&L, Bristol-Myers Squibb

12:05 Change Management Clinical Supply Chain Considerations for Digitally Enabled Patient-Centric Clinical Trials
Matthew Moyer, MS, MBA, PMP, Director, Clinical Supply Technology, Global Clinical Supply, Merck & Co., Inc.
This presentation will focus on considerations when leveraging new digital health and supply chain technologies to improve clinical trial planning and execution, and how we are engaging internal (sponsor) and external (regulators, clinical sites, patients) stakeholders to drive and manage change, and accelerate adoption of these new technologies. A vision for trials of the future will also be shared.

12:25 pm Transition to Lunch

12:30 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Managing Outsourced Clinical Trials. See pages 28 & 29 for details.
Interactive Breakout Discussions

Wednesday, February 19

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.

**WEDNESDAY, FEBRUARY 19**

**BREAKOUT DISCUSSION GROUPS**

4:20 Find Your Table and Meet Your Moderator

4:25 Interactive Breakout Discussion Groups

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

**Patient Experience and Patient-Centric Trial Design**

**TABLE: How Can We Improve the Patient Experience in Clinical Trials?**
Moderators:
Kelly McKee, Head, Patient Recruitment, Vertex Pharmaceuticals Incorporated
Jane Myles, Former Head, Operational Intelligence and Innovation, Roche
Bernadette Tosti, Quest Diagnostics

- How can we learn from other industries?
- Advocating for both high tech and high touch solutions
- The role of storytelling and patient communities

**TABLE: Including Patients in Clinical Trial Design**
Moderators:
Christina Román, Senior Community Engagement Manager, Community Partnerships, Cystic Fibrosis Foundation

- What do you currently do at your organization?
- What are the perceived risks and benefits?
- How do you overcome these risks?

**TABLE: Strategies for Patient-Centric Trial Design and Digital Patient Engagement**
Moderators:
Daniela Shikova, General Manager, FindMeCure Foundation

- 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?

**Patient Engagement and Recruitment**

**TABLE: Shiny New Objects: Can Traditional Recruitment Mediums Merge with Technology Driven Solutions for Better Engagement?**
Moderators:
Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis Communications, LLC

**TABLE: eCOA, ePRO, BYOD: Strategies for Improving Study Convenience and Compliance**
Moderators:
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb
Kyle Hogan, Director, Outcome Solutions, Clinical Ink
Matt Noble, Vice President, Product Management, Medidata, a Dassault Systèmes company

- Discuss how eCOA supports accurate and timely clinician and patient data collection and improves data quality and accessibility
- Talk about how ePRO enables patient data to be collected and validated electronically by patients as a part of their daily life — anytime, anywhere
- Examine how a sound BYOD approach impacts the patient experience and encourages patient engagement and compliance

**TABLE: Diving into TransCelerate's New and Free Patient Engagement Toolkits**
Moderators:
Lani Hashimoto, Clinical Program Benchmark Manager, Patient Engagement & Recruitment, Novartis

- How the Patient Protocol Engagement Toolkit (P-PET) toolkit helps prospective advisory board hosts and discussion on implementation considerations
- Common questions from early users of the Study Participant Feedback Questionnaire (SPFQ) toolkit
Access and feedback for the toolkits

**TABLE: What are the Risks of and Risk Reduction Strategies for Using Social Media in Clinical Trials?**
Moderators:
Michael McLaughlin, MS, MSED, RAC, Associate Director, Clinical Operations, Dermavant Sciences, Inc

- What are the potential risks and how to reduce risk when using social media?
- What can we learn from recent FDA Guidance on Recruiting Study Subjects using Media Advertising and recent FDA Warning Letters from monitoring Social Media?
- What are some valuable risk reduction strategies?
**Interactive Breakout Discussions**

**Wednesday, February 19**

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<th>TABLE: Integrating Health Literacy, Diversity and Cultural Sensitivity into Clinical Trials</th>
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<td><strong>Moderators:</strong></td>
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<tr>
<td>Laurie Myers, MBA, Global Health Literacy Director, Global Population Health, Merck &amp; Co., Inc.</td>
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<td>Alicia Staley, Senior Director, Patient Engagement, Medidata, a Dassault Systèmes company</td>
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<td>Alicia Staley, MBA, Senior Director, Patient Engagement, Medidata; Trial Volunteer</td>
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<td>Charissa Barger, MS, Recruitment Specialist, Alzheimer’s Therapeutic Research Institute, University of Southern California</td>
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<td>• Gain sponsorship from senior management and legal</td>
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<td>• Move from concept to action: Identify pilots and coordinate across internal groups</td>
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<td>• Include the perspectives of patients across a range of health literacy levels and from different cultural backgrounds</td>
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<td>• Train investigators in teach back and cultural sensitivity</td>
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<th>TABLE: Operationalizing Diversity and Inclusion into Your Clinical Trials</th>
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<tr>
<td><strong>Moderators:</strong> Cassandra Smith, MBA, Associate Director, Diversity and Inclusion in Clinical Trials Lead, Janssen R&amp;D</td>
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<tr>
<td>• What are the barriers to operationalizing diversity and inclusion?</td>
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<td>• How do you improve enrollment of underserved and underrepresented populations in clinical trials to ensure that all patients have access to innovative and high-quality care regardless of race or ethnicity?</td>
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<td>• Key strategies to ensure the patient population in a trial is representative of the actual incidence of the disease itself</td>
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<th>TABLE: Embracing Best Practices in Protocol Design to Reduce Protocol Amendments and Improve Trials</th>
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<td><strong>Moderators:</strong> Rob DiCioccio, Deputy Chief Health Officer, IBM Watson Health</td>
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<td>Sunny Reed, Offering Manager, IBM Watson Health</td>
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<td>• What are the updated metrics on the prevalence and causes of protocol amendments and what does this mean for us?</td>
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<td>• How can we as an industry improve our process of protocol development?</td>
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<td>• What are some community initiatives and individual company approaches to finding success?</td>
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<th>TABLE: Building and Implementing a Data-Driven Site Selection Approach</th>
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<td><strong>Moderators:</strong> Sandra Smyth, Global Feasibility &amp; Site Intelligence Director, AstraZeneca</td>
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<td>Gabriela Feldberg, Practice Leader, Applied Analytics &amp; Artificial Intelligence, AstraZeneca</td>
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<td>• Opportunities and challenges of utilizing different types of data sources (internal, external public and commercial, etc.) for site selection</td>
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<td>• Challenges in shifting an organization towards a more data driven culture when the data is imperfect</td>
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<td>• Discussion on how to best leverage internally built tools on outsourced studies</td>
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<th>TABLE: Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint</th>
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<td><strong>Moderators:</strong> Maya Zlatanova, Co-founder, FindMeCure Foundation</td>
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<td>Daljit Cheema, Managing Director, PHARMASEAL</td>
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<td>• Optimizing the site feasibility process: Improving global site feasibility assessment to identify sites that will recruit on time and within budget</td>
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<td>• Objective country feasibility and selection: Where are the patients?</td>
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<td>• Data-driven site selection: Understand the number of sites, their probability of success, and the impact of site non-performance</td>
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<th>TABLE: Ask a Site – Tips, Tricks and Trends in Site Operations, Compliance and Site Sponsor Relationships</th>
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<tbody>
<tr>
<td><strong>Moderators:</strong> Tamara O’Black, JD, Senior Director, Compliance, Quality &amp; Regulatory, Minneapolis Heart Institute Foundation (MHIF)</td>
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<tr>
<td>Lisa Tindell, RN, Senior Director, Clinical Research Operations, Minneapolis Heart Institute Foundation (MHIF)</td>
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<tr>
<td>• Study feasibility and start-up – getting to a 90-day launch</td>
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<td>• Working with IRBs – myths of central IRB review</td>
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<td>• Site-Sponsor relationships – the good, the bad &amp; the ugly: how sites and sponsors can work more effectively together</td>
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<tr>
<td>• Auditing &amp; monitoring – whether it’s sponsor monitors or the FDA, how sites and sponsors can partner for quality</td>
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<th>TABLE: Barriers and Opportunities in Site Adoption of Clinical Trial Technology</th>
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<tbody>
<tr>
<td><strong>Moderators:</strong> Raj Pallapothu, mHealth Global Business Lead, Bayer Pharmaceuticals; mHealth Global Advocate</td>
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<tr>
<td>• What site facing technology is critical to improving clinical trials?</td>
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<td>• What is holding sites back from adopting this technology? What can be done to minimize the burden?</td>
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<tr>
<td>• What opportunities exist to streamline and integrate technology in clinical trials?</td>
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</tbody>
</table>
Interactive Breakout Discussions

Wednesday, February 19

TABLE: Improving Both Time and Quality in Site Activation and Study Start-Up (Sponsor, CRO and Site Perspectives)
Moderators:
Linda Glaser, MD, PhD, Medical Director, Coastal Biomedical Research
- 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 startup?

Risk-Based Monitoring and Quality Management

TABLE: Using eSource, eConsent and Other Technologies in Trials
Moderators:
Laura Whitmore, Head, Clinical Operations, Oversight, Cerevel Therapeutics
Hilde Vanaken, Senior Industry Advisor, TCS Life Sciences and Healthcare, Tata Consultancy Services
- Barriers to eTrials
- Best practices
- Future of eTrials

TABLE: Building a Clinical Quality Management System (CQMS) from the Ground Up
Moderator:
Jonathan Rowe, PhD, Executive Director, Head of Clinical Development, Quality Performance and Risk Management, Pfizer
- 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

TABLE: Quality Monitoring and Quality Tolerance Limits
Moderators:
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
Ruma Bhagat, MPH, MBBS, Senior GCP Strategy Lead, Site Innovation Group Lead, Genentech, Inc.
Janis Little, Vice President, Global R&D Quality, Allergan
- How many QTLs do we need?
- What areas should we apply QTLs for?
- Should the QTLs be set at failure points or reasonable expectations of the quality?
- What other benefits could QTLs give us?
- Are your QTLs linked to your QbD initiative?

Budgeting, Contracting, and Resource Management

TABLE: Coordinating Contracting and Payments to Enhance Efficiencies
Moderators:
Debora Araujo, Founder & CEO, ClinBiz
Chris Chan, Executive Director, R&D Finance, Fibrogen
Kelly Willenberg, President, Kelly Willenberg, LLC
- 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

TABLE: Contracting Strategies and Tools for Speedy Study Start-Up
Moderators:
Christina Greene, Esq., Associate Director, Global Site Agreements, Merck Sharp & Dohme Corp.
Ly Kawaguchi, Senior Director, Head, Outsourcing and Procurement, MyoKardia
- Discuss barriers to speedy study start-up
- Review contracting strategies: standard templates, language, culture
- Share tools and processes that speed time-to-contract and study start-up

TABLE: Navigating New Laws and Regulations in Clinical Trial Contracts
Moderators:
John Conley, JD, PhD, Professor, Law, University of North Carolina School of Law
- Strategies for navigating the revised Common Rule, the US-EU Privacy Shield, and California privacy laws
- Exploring EU-based regulations, including GDPR
- How these laws and regulations affect clinical trial design, operations, and execution

TABLE: Developing Resource Management Tools for Complex Trials and Diverse Portfolios
Moderators:
Piet Theisohn, Director, Head, Resource Management in Clinical Operations, R&D-ClinOps - Business Excellence & Innovation, Bayer AG Pharma Division
Laila Mork, Senior Manager, Systems, Analytics & Reporting, Business Operations, Allergan
Anca Copaescu, CEO and Founder, Clinical Maestro by Strategikon Pharma
- 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
Interactive Breakout Discussions

Wednesday, February 19

Outsourcing, Strategic Partnerships, and KPIs

TABLE: Vendor Performance Metrics and KPIs
Moderators:
Keith Dorrictott, Ambassador, Metrics Champion Consortium; Director, DMPI Ltd.
- How effective are your KPIs for measuring vendor performance and quality?
- What is your strategy for establishing KPIs and metrics?
- What are the key areas that should be evaluated for vendor performance and quality?

TABLE: Strategies for Becoming a Partner of Choice
Moderators:
Rosalie Filling, Vice President, Clinical Operations, Research and Development, Endo Pharmaceuticals
Wes Bonner, Vice President, Strategic Development, Meridian Clinical Research
Kenneth Olovich, Director, Sourcing and Finance, Chorus Division, Eli Lilly and Company
Justin Bandura, JD, Contract Manager, Clinical Operations, Boehringer Ingelheim
- What initiatives can different departments take on to enhance the experience of working with partners?
- How do small vs. large sponsors, CROs, and sites compete?
- What strategies exist to stand out in a dense market?

TABLE: FSP vs. Hybrid vs. Strategic Partnership Outsourcing – Choosing an Appropriate Model
Moderators:
Todd Reul, Associate Director, Global Strategic Sourcing, BioMarin Pharmaceutical Inc
Erin O'Boyle, Senior Director, Clinical Operations, Rezolute, Inc.
Minji Bae, Associate Director, Vendor Management, AbbVie
- Strategies for choosing an appropriate outsourcing model for individual trials vs. the entire portfolio
- Determining pros and cons of each model – cost, resources, performance, study start-up
- Determining sourcing needs vs. budget vs. relationships with previous and new partners

Digital Tech, Wearables, and Digital Biomarkers

TABLE: Building a Personalized Logistics Network with Tech to Enable Patient-Centered Trials
Moderator:
- How can we build a personalized logistics network?
- What technologies will reduce vein-to-vein time?
- What are the main barriers to new technology adoption in CAR-T trials?

TABLE: Digital Biomarkers and Endpoints
Moderators:
Michael Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline
Michelle Crouthamel, Digital Platform Leader, Abbvie
- How effective are your KPIs for measuring vendor performance and quality?
- What is your strategy for establishing KPIs and metrics?
- What are the key areas that should be evaluated for vendor performance and quality?

Matt Pipke, Chief Technology Officer, physIQ
- Appropriate application of wearables
- Identifying criteria to use digital biomarkers
- Challenges presented in digital biomarker exploration. What is the value, beyond scientific interest?
- Where do we want to be in 5 years (and why are we not there already)? Key challenges for industry uptake?

TABLE: Digital Technologies in Clinical Trials: How to Choose, Implement and Work with Vendors
Moderators:
Jaquie Finn, Global Head, Digital Health, Cambridge Consultants
Krista Emmons, Associate Director, Portfolio Relationship Management, Portfolio Relationship & Sourcing Management
Narayanan R., Chief Architect (Life Sciences and Healthcare) and Head of TCS Connect Clinical Trial platform, TCS Life Sciences and Healthcare, Tata Consultancy Services Ltd.
- Scaling technology partners for digital clinical trials
- Coming up with strategy and developing common language
- Medical vs. commercial grade devices
- Dos and don'ts of technology partnerships

TABLE: Master Trials – Pragmatic Operations for Complex Oncology Precision Medicine
Moderator:
Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML / LLS
- Key considerations in program set-up and execution
- Benchmarks/Performance – Toss conventional oversight metrics?
- NextGen clinical trial technology solutions – Do they work?

Clinical Data Management, Analytics, and AI/ML

TABLE: Advances in Clinical Data Management and Analytics
Moderators:
Dermot Kenny, Global Head, Data Operations, Novartis
Nareen Katta, Head, Clinical Analytics, AbbVie
Ozgur Ozkan, IT Director, Clinical Decision Support, The Janssen Pharmaceutical Companies of Johnson & Johnson
Charles Romano, Vice President, Global Clinical Research, Peachtree Bioresearch Solutions
- Data Operations
- Process Automation
- Innovation in Clinical Trials
- Machine Learning/AI

TABLE: Transforming Clinical Operations with a Data-Driven Approach
Moderator:
Tom Doyle, Vice President, Data Science, Acorn AI by Medidata, a Dassault Systèmes company
- Using analytics from a unified platform to inform better decision making
- Using data to identify potential problems before they become bigger issues ensuring better outcomes
- Data that drives effectiveness in clinical trial operations, not just efficiencies
### Interactive Breakout Discussions

**Wednesday, February 19**

#### TABLE: Artificial Intelligence and Machine Learning: Reporting Progress
**Moderators:**
- **Balazs Flink, MD, Head, Clinical Trial Analytics, Bristol-Myers Squibb**
- **Francis Kendall, Director, Biostatistics & Programming, Cytel, Inc.**

- Will data science and machine learning disrupt the provision of clinical evidence or compliment it?
- With Machine Learning becoming needing Big data sets, how could the industry share more data in a precompetitive framework?
- As more Deep learning techniques are deployed - how can we gain confidence in "Black Box" approaches?
- In what ways, if any, will we have to change how we work with regulators?

#### Virtual Trials, Remote Trials, and De-Centralized Trials

**TABLE: Virtual Trials: The New Ecosystem**
**Moderators:**
- **Pam Duffy, Senior Director & Digital Strategic Planning and Demand Lead, Pfizer**
- **Kevin Bateman, Distinguished Scientist & Scientific Associate Vice President, Merck & Co., Inc.**
- **Julia Andrews, Strategic Feasibility Manager, Program Delivery, UCB**
- **Katherine Vandebelt, Global Head, Clinical Innovation, Health Sciences Global Business Unit, Oracle**

**Moderators to be Announced, Deloitte Consulting**

- Let's discuss terminology: Site-less, de-centralized, virtual? Does it have to be one model, or can we mix (e.g. central and remote)?
- Where do retrospective/eTrials fit in? virtual control arms? Does digital technology inevitably lead to virtual trials?
- What are some specific challenges in retaining patients and investigators? What are the data science considerations in de-centralized/virtual trial?

**TABLE: Remote Trials, Digital Technology Adoption in Clinical Trials, and Patient Centricity**
**Moderators:**
- **Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb**

- Which strategies shall we use to further proliferate and scale Remote Trials?
- How to enable culture change in pharma for further innovation in clinical trials?

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### Ops and Data Ownership in Sample, Biomarker, Biospecimen Management

**TABLE: Data Ownership and Returning Results to Patients**
**Moderators:**
- **Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck**
- **David Leventhal, Senior Director, Clinical Innovation, Global Product Development, Pfizer Inc.**

- Who owns the patient data in clinical research?
- Do the patients get longitudinal choice and control of ongoing use of their data?
- Returning biomarker data to patients

**TABLE: Technologies and Partnerships to Streamline Sample/Biomarker Management in Clinical Trials**
**Moderators:**
- **Brenda Yanak, Principal, Clinical Transformation Partners**
- **Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories**

- Biorepositories: in house vs. outsourcing
- Advanced informatics for biospecimen management
- Central and reference labs: building the relationship
- Informed consent and data sharing

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### Early Phase Trial Planning and Ops, a Focus on Phase 1

**TABLE: Sponsor and Site Interactions in Phase 1 Site Selection, Recruitment and Contract Negotiations**
**Moderators:**
- **Kristi Womack, Director, Clinical Pharmacology Operations, Allergan**
- **Mark Scheetz, Associate Director, Program Lead for Phase I Studies, Allergan**
- **Carol Miller, Senior Director, Business Development, Spaulding Clinical Research**

- Sponsor representatives and site representatives sharing "what works" in Phase 1 trials
- Early phase Site Selection process from the Sponsor point of view
- Meeting recruitment and retention goals: How Phase 1 centers distinguish themselves to retain a healthy volunteer database and how do we find the special patient populations?
- Maintaining strong Sponsor and site relations: How does contracting play a role?

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### Clinical Supply and Logistics

**TABLE: Clinical Supply in Hybrid Virtual Trials**
**Moderator:**
- **Adama Ibrahim, EMBA, Associate Director, Global Clinical Operations, Biogen**
- **Abby Stephens, Project Manager II, Group Lead, Services, Suvoda**

- What is the value to stakeholders?
- What are the main barriers to adoption? How can they be addressed?
- Defining success metrics and sharing case studies
### Medical Device Clinical Trial Operations and Regulations

**TABLE: Navigating the EU MDR**

**Moderators:**
To be Announced

- Strategies for getting products already on the market approved under the EU MDR
- Tips for updating internal processes
- Long-term changes for new clinical trials

**TABLE: Pre- Vs. Post-Market Studies: Different Challenges and Strategies**

**Moderators:**
Jane Jacob, PhD, CCRP, Vice President, Research and Clinical Affairs, Orthofix, Inc
Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific Corporation

- Strategies for pre- vs. post-market studies: site identification, study start-up, etc.
- Comparing study types and their unique requirements
- Using national registries for post-market studies

**TABLE: Obstacles to Implementing RBM on Medical Device Studies & How to Overcome Them**

**Moderators:**
Stephanie Clark, Director, Risk Management-Central Monitoring, Janssen R&D (J&J)
Erin Creedon, Associate Director, Clinical Operations, Ethicon (J&J)

- Leadership and regulatory support
- Change Management concerns
- The impact of the lack of technology and resources

### Real-World Data (RWD/RWE)

**TABLE: Global Regulatory Atmosphere Surrounding Real World Data: FDA and Beyond**

**Moderators:**
Steven Draikiwicz, MD, Global Medical Bioinformatics Lead, Sanofi
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen
Gracie Lieberman, Senior Director, Regulatory Policy, Genentech

- Regulatory standards for use of real-world data (R+D and Medical Affairs)
- Challenges of international data application
- High level review and commentary of latest FDA guidelines – commentary on expanding international real-world data usage

**TABLE: Innovative RWD-Based Studies**

**Moderators:**
Charles Makin, Global Head, Real World Evidence Strategy, Biogen
David Van Brunt, PhD, Senior Research Fellow and Head, HEOR Division of Evidence and Analytics AbbVie, Inc.

- Types of studies (pragmatic, hybrid, learning healthcare, etc.)
- How to gain internal support for novel studies
- How to integrate novel studies into existing programs

**TABLE: RWD To Accelerate Design and Execution of Clinical Trials**

**Moderators:**
Xia Wang, PhD, Director, Health Informatics & Global Medicines Development, AstraZeneca
Michael Kelsh, PhD, Director, Center for Observational Research, Amgen
Jyotsna Mehta, Senior Director & Head, HEOR, Karyopharm Therapeutics

- 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

### Clinical Research as a Care Option (CRAACO)

**TABLE: Clinical Research as a Care Option (CRAACO): Changing Large Health Organizations from Bureaucratic Behemoths to Operationally Efficient Research Centers**

**Moderators:**
Jim Kremidas, Executive Director, ACRP

- Defining roles and responsibilities of academic and health system-based site staff
- Driving change to ensure operational efficiency and quality via standardized performance metrics and processes
- Ensuring career paths for site staff to drive employee engagement

### Clinical Development Partnering in China

**TABLE: Bringing New Therapies to Market in the West and in China: Clinical Development Partnering**

**Moderators:**
Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc.
Jane Fang, MD, MS, Director, Leader of Digital Clinical Innovations, RWD/RWE for Clinical Trials, AstraZeneca
Sean Zhou, PhD, Head, US Patient Safety, AstraZeneca
Wendy Wang, PhD, MD, Managing Director, Clinical Accelovance China

- Best practices for developing and bringing new therapies to market here in the West and in China
- Conducting clinical development programs in China and partnering with up-and-coming Chinese biotech companies and CROs
- Chinese innovators and CROs working with US-based CROs or licensing partners to expand their market and reach to collaborate
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 12th Annual Clinical Data Strategy and Analytics conference will be bringing together top clinical research informatics experts to discuss the challenges and find solutions necessary to navigate and thrive in the rapidly changing environment.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium* *Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

CLINICAL DATA INNOVATION: HARNESSING THE POWER OF NEW TECHNOLOGY

10:40 Chairperson's Remarks
Pam Duffy, Senior Director & Digital Strategic Planning and Demand Lead, Pfizer Inc.

10:45 Opportunities to Apply AI in the Clinical Data Environment
Demetris Zambas, Vice President and Global Head, Data Monitoring and Management, Pfizer Inc.
This presentation will discuss various applications of AI for clinical trials operations and data management.

11:15 Modern Clinical Data Concepts – Models, Technology and Regulations
Brooks Fowler, Senior Director and Global Head, Data Science, AbbVie
The variety of data sources has grown, new and sophisticated use cases are emerging, technology opportunities are many, and regulatory and legal aspects surrounding data privacy and ownership have become more conservative and complex. This presentation will explore each concept, their convergence, and describe a modern environment that breaks from legacy, domain-specific technology, skill sets and processes to address current and future realities.

11:45 Reimagining Clinical Data Operations
Dermot Kenny, Global Head, Data Operations, Novartis
Clinical Data Operations is on the cusp of a revolution. Technologies that have for some time eluded us are now beginning to have an impact and the result will be a transformation in how clinical trials are conducted. At Novartis, we are exploring how machine learning and artificial intelligence change how we build data capture solutions and how we clean clinical data. We are exploring how advanced analytics capabilities can change how we (and in the future, our regulators) analyze clinical data. We will share some of our ongoing work and our vision for the future of Clinical Data Operations.

12:15 pm Improving Study Start-Up, Site Activation and Trial Performance
Greg Jones, Enterprise Strategy Architect, Product Strategy, Oracle Health Sciences

12:50 LUNCHEON PRESENTATION: Data-Driven Site Selection and Patient Recruitment
Bennett Rosenthal, Product Manager, BioPharma, SOPHiA GENETICS
The development of personalized treatments implies that selected patient populations would benefit the most from these therapies. To date, SOPHiA GENETICS has analyzed the genetic profile of over 380,000 patients in over 1000 institutions worldwide. Thanks to the global knowledge of this community, we will present how we can contribute to increasing clinical trial efficiency by identifying sites and patients for biomarker-driven oncology trials.

1:20 Coffee and Dessert Break in the Exhibit Hall

DATA DEPARTMENTS TO ADJUST TO DIGITALIZATION OF CLINICAL TRIALS

2:15 Chairperson's Remarks
Richard Young, Vice President, Vault CDMS Strategy, Veeva Systems

2:20 Need to Un-Scale the Clinical Data and Analytics Operating Model in Order to Scale Digital Health
Nareen Katta, Head, Clinical Analytics, AbbVie
The traditional economics of scale operating models in the clinical data and analytics space are being challenged by the variety, variability and velocity of the data enabled by the Digital Health revolution. This talk explores the need to un-scale the clinical data and analytics operating models in order to adapt to the rapid innovation in the digital health space and to unleash the full potential of the new technology innovation.
The Evolution of Real-World Data Capture and Application

Steven Draikiwicz, MD, Global Medical Bioinformatics Lead, Sanofi

A review of a use case of Electronic Health Records to Electronic Data Capture (EHR2EDC), including additional information surrounding the regulatory climate, standards and Esource.

CO-PRESENTATION: Real-World Data Strategy in Accelerating Clinical Trial and Research

Xia Wang, PhD, Director, Health Informatics & Global Medicines Development, AstraZeneca

Jane Fang, MD, Head, Clinical Business Management & Analytics, MEDI Biologics Unit, AstraZeneca

This talk presents a strategic project in AstraZeneca to evaluate the landscape of real-world data, novel capabilities and partnerships in accelerating clinical trials and clinical research innovations. We will share our approaches, findings, learnings, recommendation of implementation and challenges.

Clinical Analytics & Innovation – Help Us Help You!

Ankit Lodha, MS, MBA, Associate Director, Clinical Metrics & Analytics, Global Development Operations, Takeda

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 Takeda (L-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 insights 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.

CO-PRESENTATION: Reducing the Noise and Increasing the Value We Get from Our Systems

Richard Wzorek, Director, New Products & Service, Almac Group

Kenny Kong, Director, Life Sciences & Health IT, Exostar

One of the principal goals behind the use of eClinical systems is reducing noise to allow us to hear a clear signal from the study treatment. Understanding when a process or software feature is a competitive advantage or just a standard utility is essential for achieving that goal. The utilities can become part of shared ecosystems through standards and interoperability allowing us to focus on the processes or features that give us a competitive advantage.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

Find Your Table and Meet Your Moderator

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 pages 32-37 or scopesummit.com/breakouts for details.

Welcome Reception in the Exhibit Hall

Close of Day

THURSDAY, FEBRUARY 20

Registration Open

Breakfast Presentation to be Announced

Session Break

NEW MODELS FOR IMPROVING CLINICAL DATA

Chairperson’s Remarks

Gaurav Singh, Business Process Manager, ZS

Modernizing the Drug Development Process: Streamlining Clinical Protocols

Michael Dawson, Director, Development Design Center, AbbVie

This presentation will discuss new approaches and templates designed to streamline clinical protocols. Case studies and examples of advanced analytics enabling innovative clinical protocol design will be shared.

The Curve Ahead: Dynamics of Clinical Trial Recruitment Projections

Ozgur Ozkan, IT Director, Clinical Decision Support, The Janssen Pharmaceutical Companies of Johnson & Johnson

Recruitment speed is a major concern for trial timelines, as it may put target deadlines at risk, run up costs and even put the whole study at risk of failure. Ability to better predict and adjust recruitment curves is a crucial capability in trial management. In this presentation, we will share learnings from our experience in recruitment modeling. These will include the main dynamics underlying the shape of recruitment curves and how we could use them to help with our decision making in various areas, e.g. drug supply planning. We will also touch on approaches to inform model assumptions when working with planned vs. ongoing trials.

Quality Risk Management Framework: Guidance for Successful Implementation of Risk Management in Clinical Development

Jonathan Rowe, PhD, Executive Director & Head, Quality Performance and Risk Management, Pfizer

Effective quality risk management is fundamental to ensuring the protection of human subjects and reliability of clinical trial results during the conduct of clinical trials. Risk management is a core element of an effective quality management system (QMS). An overview of a successful end to end QPP Quality Risk Management program, along with associated analytical tools to predict quality issues, will be described.
11:25 PANEL DISCUSSION: Novel Digital Endpoints in Clinical Research: Technology, Infrastructure, Relationship with Technology Providers
Moderator: Michelle Crouthamel, DBA, Director, Digital Health & Innovation, AbbVie
Panelists: Jeremy Wyatt, President, ActiGraph
Kelley Erb, PhD, Team Lead, Novel Digital Endpoints, TransCelerate BioPharma Inc.
Sina Djali, Head, Clinical and Operations Analytics, Johnson & Johnson

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Practical Applications of AI in Patient Data Analytics
Srinivasan Anandakumar, Senior Director, Clinical Analytics, Saama Technologies

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Artificial Intelligence in Clinical Research. See pages 40 & 41 for details.

AN INTERSECTION OF CLINICAL RESEARCH, ENGINEERING AND DATA SCIENCES

11:20 Chairperson’s Remarks
Fred Martin, Chief Product Officer, Medrio

11:25 FEATURED PRESENTATION: Digital Biomarkers: An Intersection of Clinical Research, Engineering and Data Sciences
Sina Djali, Head, Clinical and Operations Analytics, Johnson & Johnson

Clinical and outcome-based research are rapidly moving away from relying on traditional sources of data, such as Electronic Data Capture/Case Report Forms and laboratory outputs, to collecting data continuously in real time using different digital media. This is achieved through the use of wearables and invisible (e.g. Bluetooth) miniaturized devices, and a corpus of existing images that can collect, track and predict behavioral and physiological outcomes. These innovations have given rise to digital biomarkers as a new discipline in clinical research. Many companies and academic research institutions have dedicated Digital Biomarker teams and projects solely focused on defining digital genotypes and phenotypes relevant to their specific areas of research. This new discipline takes advantage of new deep learning models, such as convolutional (imaging) recurrent neural networks that can be used for both detection and prediction of a particular clinical outcome. The aim of this session is to provide an overview of some of the advances in this field.
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 advancing clinical operations, as well as data management. Many pharmaceutical companies and larger CROs are starting projects involving some elements of AI, ML and robotic process automation in clinical trials. CHI’s 3rd Annual Artificial Intelligence in Clinical Research conference is designed to facilitate the discussion and to accelerate the adoption of these approaches in clinical trials.

### THURSDAY, FEBRUARY 20

**11:30 am Registration Open**

**12:30 pm BRIDGING LUNCHEON PRESENTATION:** Practical Applications of AI in Patient Data Analytics
*Srinivasan Anandakumar, Senior Director, Clinical Analytics, Saama Technologies*

**1:00 Coffee and Dessert Break in the Exhibit Hall**

**2:00 Afternoon Plenary Keynotes (See page 4 for details.)**

**3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing**

**AI TO ENABLE INNOVATION IN CLINICAL TRIALS**

**4:10 Chairperson’s Remarks**
*Balazs Flink, PhD, Head, Clinical Trial Analytics, R&D Business Insights, Bristol-Myers Squibb Co.*

**4:15 AI Applications in Trial Planning and Execution**
*Balazs Flink, PhD, Head, Clinical Trial Analytics, R&D Business Insights, Bristol-Myers Squibb*

BMS have started a journey on Digital Health and Innovation a few years ago. The company has tested a lot of emerging technologies and ideas, especially to advance clinical trial design, execution and market access. This presentation will concentrate on a few use cases in these areas sharing experiences with AI and highlighting opportunities for future evolution.

**4:50 Clinical Pitfalls in Using AI for Decision Support**
*Sujay Kakarmath, MD, MS, Lead Scientist, Data Science and Artificial Intelligence, Partners Healthcare Pivot Labs*

Traditional metrics used to evaluate the performance of AI solutions suffice to establish a proof-of-concept. For real-world applications, however, these metrics are far from sufficient in establishing clinical utility. The Data Science and AI team at Partners Healthcare Pivot Labs invests a great deal of time thinking about the right questions, working out potential pitfalls and developing best practices in evaluating AI solutions for healthcare. This presentation will share insights obtained from real projects.

**5:05 Chairperson to be Announced, Saama Technologies**

**5:20 Networking Reception**

**7:15 Close of Day**

### FRIDAY, FEBRUARY 21

**7:15 am Registration Open**

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

**8:15 Session Break**

**AI TO ADVANCE CLINICAL DATA MANAGEMENT**

**8:20 Chairperson’s Remarks**
*Chair to be Announced, Saama Technologies*

**8:25 CO-PRESENTATION: Intelligent Machines Take on Clinical Data Management**
*Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer*
*Ashley Howard, Manager, Clinical Data Scientist, Pfizer*

In this session, we will discuss how Artificial Intelligence will transform Clinical Data Management. The human versus machine battle has already started in other industries. How can we leverage machines to not just perform repetitive data cleaning tasks, but take on higher complexity tasks in tandem with humans?

**8:55 Accelerating Clinical Database Set-Up Using Machine Learning & AI**
*Arun Patnaik, Director, Clinical Data Management, Data Operations, Novartis*

Have you ever wondered how to get the best experience for end users while defining data collection and reporting requirements during the study start-up phase? Does this process take too long in your company? How can technology be used to drive down timelines, improve quality, increase standardization and downstream impact? This presentation will give insights into the work being done at Novartis to achieve all these using...
Artificial Intelligence in Clinical Research

Machine Learning and AI to Advance Clinical Operations and Data Management

9:15 AI/ML – Will it Revolutionize Clinical Data Management?
Francis Kendall, Senior Director, Biostatistics & Programming, Cytel
This talk will look at AI/ML within the context of how it could revolutionize Clinical Data Management. It will outline the assumptions of how the scope of Clinical Data Management will widen and what factors will need to be in place to allow for the effective application of AI/ML. Finally, it will provide a few case studies on how AI/ML is being applied in Clinical Data Management.

9:35 The Application of Intelligent Automation Technologies in Pharmacovigilance
Robert Taylor, Director, Safety Management, Global Regulatory Affairs and Clinical Safety, Merck
The application of intelligent automation technologies to PV processes has the potential to improve quality, consistency, and efficiency with the ultimate goal of improving patient safety. Automating areas where available data continues to increase can facilitate that goal by optimizing human resources within the areas of higher value to patient safety. To accomplish this, PV organizations must continually oversee the applicability, design, deployment, performance, validation, and updating of these technologies. Our proposed validation framework seeks to build on early seminal works while incorporating best practices from other industries and TransCelerate member companies.

9:55 Presentation to be Announced

10:25 Networking Coffee Break

PREDICTING QUALITY ISSUES

10:55 Chairperson’s Remarks
Francis Kendall, Senior Director, Biostatistics & Programming, Cytel

11:00 Can Artificial Intelligence Identify Recurring Quality Issues? – A Case Study
Faye O’Brien, Director, Performance & Metrics, AstraZeneca
Joann Frazier, Lead Analyst, Operations Excellence, AstraZeneca
Mining, Categorizing and Analyzing quality data through machine learning has the potential to improve clinical trial delivery processes.

11:30 In-Silico Patients
Wael Salloum, PhD, CSO & Co-Founder, Mendel.ai
AI technologies can generate digital patients as a substitute for human subjects. Although this may sound like science fiction today, it definitely won’t in a few years. We have already achieved the first few milestones: synthesizing a digital copy of a patient journey from EHR records and building technologies to interrogate these digital replicas to generate clinical evidence. The future is patientless.

12:00 pm Transition to Shared Sessions

AI TO ENABLE DIGITALIZATION OF CLINICAL TRIALS

12:00 Chairperson’s Remarks
Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management,
Clinical Sciences and Operations, Global Product Development, Pfizer Inc.

12:05 Real World Evidence Generation for Clinical Decision Making: Can AI Solve the Challenges?
Professor Dr. Dorothee Bartels, Clinical and Real World Data Strategist, X The Moonshot Factory
Real World Evidence Generation (RWE) is continuously gaining importance, but trust in results, transparency and reproducibility are challenging. The same is true for prediction models based on learning algorithms. Questions are arising: who may be the best expert in big data analysis; who may have the appropriate skill sets; and can clinical decisions be based on real world data analysed by either traditional or artificial intelligence (AI) methods? Complementary approaches using synergies from the epidemiological and AI field may boost the field of RWE.

12:25 Re-Skilling for AI/ML: Leveraging Your SMEs
Nechama Katan, Associate Director, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer
AI/ML are very powerful tools for clinical trials. However, there is a gap between those that understand what AI/ML can do for the business and the business SME (subject matter experts) who really understand the business problems. Without strong SME engagement in solutions, technical solutions are often at risk. This talk will review successful case studies for developing “lego” employees/teams who help bridge the gaps between AI/ML technologist and the SMEs. We will discuss both the how and what that makes an AI/ML project successful in clinical trials.

12:45 PANEL DISCUSSION: AI Implementation: Technology, Data, People
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
Panelists: Balazs Flink, PhD, Head, Clinical Trial Analytics, R&D Business Insights, Bristol-Myers Squibb
Faisal Khan, PhD, Executive Director, Advanced Analytics and Artificial Intelligence, AstraZeneca
Arun Patnaik, Director, Clinical Data Management, Data Operations, Novartis
Malaikannan Sankarasubbu, Vice President, AI Research, Saama Technologies
It was proven that machine learning and AI can aid clinical development in various aspects. With evolving AI technology implementation challenges become more and more noticeable. This panel discussion will brainstorm the key pain points of AI implementation:
• What is the best technology and how to work with technology providers?
• How to make all data machine learnable and available for AI applications
• How to solve “the people puzzle”

1:05 Transition to Lunch

1:10 SCOPE Send Off Luncheon Presentation (Sponsorship Opportunity Available)

1:40 Closing Remarks

1:45 SCOPE Summit 2020 Adjourns
Clinical research industry is moving toward end-to-end digital clinical trials. The data collection should stay in line with this inevitable change and wearables and point-of-care sensors should address this need. Furthermore, digital biomarkers translate new data sources into clinically actionable insights. CHI’s 3rd Annual Sensors, Wearables and Digital Biomarkers in Clinical Trials conference is designed to feature case studies of clinical trials that already employ sensors and wearables, as well as to discuss the future steps needed for implementation of digital biomarkers and endpoints in clinical trials.

TUESDAY, FEBRUARY 18
9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium
*Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19
7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

ENABLING DIGITAL BIOMARKERS AND ENDPOINTS
10:40 Chairperson’s Remarks
10:45 Validating Novel Digital Endpoints: What’s the Right Development Model?
Kelley Erb, PhD, Team Lead, Novel Digital Endpoints, TransCelerate BioPharma Inc.
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.

11:10 Regulatory Considerations during Mobile Medical App Development
Michael Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline
This presentation will cover the following topics: 1) Mobile Medical Apps (MMAs) are defined as medical devices from their intended use shown through labeling claims, advertising, or oral or written statements; 2) MMA regulation is health risk-based to balance patient safety and barriers to technological innovation; 3) patient risk analysis is a critical activity prior to sensor/app inclusion within a clinical trial; 4) digital safety risks include data privacy, data cybersecurity, software malfunction and clinical risk from app/sensor use.

11:35 An Exploration of Effective Regulator Engagement Regarding the Use of Digital Endpoints
Suraj Ramachandran, Director, Device and Digital Health, Regulatory Affairs, Merck
This session will share and explore a set of best practices for engaging regulators on the use of digital endpoints in clinical trials. The set of shared experiences and best practices is derived from a collective set of experiences by TransCelerate’s members as well as TransCelerate Patient Technology team’s own discussions with the FDA on the topic.

11:55 Role of Connected Drug Delivery Devices in Clinical Trials
Michael Song, PhD, Senior Manager, Device Functionality Safety and Digital Connectivity, AstraZeneca
Explore connected drug delivery devices for clinical trials, as well as pitfalls and approaches in selecting and developing connected devices. With connected devices come additional considerations and regulations. We will discuss approaches to minimize organizational burden and expedite development/implementation. Not all connected devices are the same; we will explore what to consider when choosing the technology platform for your therapeutic area.

12:15 pm Talk Title to be Announced
Dawn Anderson, Managing Director, R&D Life Sciences Consulting, Life Sciences, Deloitte

12:45 Transition to Lunch
12:50 Luncheon Presentation to be Announced
1:20 Coffee and Dessert Break in the Exhibit Hall
ADVANCED ANALYTICS AND CONNECTIVITY FOR DIGITAL BIOMARKERS

2:15 Chairperson’s Remarks
Philippe Verplancke, PhD, Global Head of Business Development, XClinical GmbH

2:20 Ipredict: A Case Study in Applying Digital Sensors Technology and Machine Learning to Predict Asthma Control
Bhaskar Dutta, Principal Scientist, Advanced Analytics Center, AstraZeneca

Use of wearable sensors, home monitoring and smartphone apps have the potential to generate data that can revolutionize clinical trial and disease monitoring. Analysis and interpretation of the large volume of streaming data generated from these novel sources bring a new set of challenges. In a case study applied to severe uncontrolled asthma, we developed a machine learning framework to predict asthma events from the sensor data at population, sub-population and individual levels.

2:50 Converging Patient-Facing Technology Capabilities: The Pinnacle of Patient-Centricity
Aman Thukral, Assistant Director, Data and Statistical Sciences, AbbVie

Biopharmaceutical sponsors are experimenting with 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 is to provide the framework for converging patient-facing technologies.

3:20 Wearable Devices in Clinical Trials: AI Methodologies Making an Impact in the Cardiovascular Space
Vanja Vlajnic Statistician, Clinical Statistics, Bayer

The implementation of wearable devices in clinical trials are of interest due to their ability to continuously capture data, as opposed to traditional data collection methods which only occur at scheduled visits throughout the course of the trial. A case study examining the utilization of such devices in the cardiovascular space is presented, along with the AI/ML methodologies used to analyze the data.

3:50 Faster Recruitment, Lower Attrition, and Better Insight – Are you ready for Decentralized Trials?
Jonathan Palmer Senior Director, Product Strategy, Digital Trials Oracle Health Sciences Global Business Unit Oracle, In

Decentralized trials reduce patient burden through remote monitoring, minimizing site visits, and in turn reducing attrition. Further, the acquisition of richer datasets in the real world provides greater insight into true outcomes. Learn about the hurdles of this new approach which we as an industry must jump over, and hear how Oracle are supporting global sponsors to rapidly embed the expanding ecosystem of innovative digital sources and advanced analytics techniques to fundamentally change clinical research.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility All Technology Providers Share
Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

IMPLEMENTATION CASE STUDIES

8:20 Chairperson’s Remarks
Joe Mather, Executive Director, Head of Advanced Science and Collaboration Group, Pfizer

8:25 Digital Medicine 101
Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)

From smart pacemakers to diagnostic algorithms and digital therapeutics, medicine is becoming more digitized every year. Digital medicine tools offer the possibility of improved health outcomes, lower costs, and better access to care. But the evidence base for the safety and effectiveness of these new products has not kept pace with their development. Given the great divide between the promised benefits of digital medicine and its potential risks, we need to know — not just believe — that the tools we use are trustworthy. This presentation will provide an introduction to key terms and concepts in digital medicine and reflect on how digital medicine products can advance the quality and efficiency of clinical trials for all medical products.ification, biosensor and device evaluation, and analytics development.

8:55 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.
9:25 Utilizing Digital Tools in Clinical Research for Movement Disorders: Challenges, Successes and the Future
Cindy Casaceli, Director, Clinical Trials Coordination Center, University of Rochester Medical Center

Research has traditionally involved in-person visits at a limited number of research centers. As approved digital tools become mainstream in clinical research, distance to a participating research site is no longer a barrier to participation. Digital tools are also creating volumes of continuous data as compared to the data collected from a traditional in-clinic, episodic research visit. This presentation will provide an overview of our experience at CHET utilizing a wide variety of digital tools in our research, which include smartphone applications, tele-health, remote visits, watches, sensors and video.

9:55 Talk Title to be Announced
Matt Pipke, Chief Technology Officer, physIQ

10:10 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall

AN INTERSECTION OF CLINICAL RESEARCH, ENGINEERING AND DATA SCIENCES

11:20 Chairperson’s Remarks
Fred Martin, Chief Product Officer, Medrio

11:25 FEATURED PRESENTATION: Digital Biomarkers: An Intersection of Clinical Research, Engineering and Data Sciences
Sina Djali, Head, Clinical and Operations Analytics, Johnson & Johnson

Clinical and outcome-based research are rapidly moving away from relying on traditional sources of data, such as Electronic Data Capture/Case Report Forms and laboratory outputs, to collecting data continuously in real time using different digital media. This is achieved through the use of wearables and invisible (e.g. Bluetooth) miniaturized devices, and a corpus of existing images that can collect, track and predict behavioral and physiological outcomes. These innovations have given rise to digital biomarkers as a new discipline in clinical research. Many companies and academic research institutions have dedicated Digital Biomarker teams and projects solely focused on defining digital genotypes and phenotypes relevant to their specific areas of research. This new discipline takes advantage of new deep learning models, such as convolutional (imaging) recurrent neural networks that can be used for both detection and prediction of a particular clinical outcome. The aim of this session is to provide an overview of some of the advances in this field.

11:45 PANEL DISCUSSION: Novel Digital Endpoints in Clinical Research: Technology, Infrastructure, Relationship with Technology Providers
Moderator: Michelle Crouthamel, DBA, Director, Digital Health & Innovation, AbbVie
Panelists: Jeremy Wyatt, President, ActiGraph
Kelley Erb, PhD, Team Lead, Novel Digital Endpoints, TransCelerate BioPharma Inc.
Sina Djali, Head, Clinical and Operations Analytics, Johnson & Johnson

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION: Navigating the Inclusion of Wearables in Clinical Trials: Considerations with Different Patient Populations
Christina Fawcett, Senior Director, Operations, PRA Health Sciences

What types of studies do wearables seamlessly integrate and when do the complications outweigh the benefits? Are all types of patients ready to embrace wearables and are we ready to support the change?

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Clinical Technology and Innovation. See pages 46 & 47 for details.
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 9th Annual Clinical Technology and Innovation conference will be featuring a broad array of topics, such as digitalization of clinical trials, machine learning, implementation and adoption strategies, and more.


THURSDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Navigating the Inclusion of Wearables in Clinical Trials: Considerations with Different Patient Populations
Christina Fawcett, Senior Director, Operations, PRA Health Sciences
What types of studies do wearables seamlessly integrate and when do the complications outweigh the benefits? Are all types of patients ready to embrace wearables and are we ready to support the change?

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

DIGITAL HEALTHCARE TO RESHAPE CLINICAL TRIALS

4:10 Chairperson’s Remarks
Craig Lipset, Independent Advisor, Former Head of Clinical Innovation, Pfizer Inc.

4:15 Predictive Medicine: Artificial Intelligence and Its Impact on the Future of Healthcare
Emmanuel Fombu, MD, MBA, Global Commercial Strategy and Digital Innovation, Johnson & Johnson
The true benefits of artificial intelligence, machine learning, natural language processing, robotics and data will be seen when we move away from our current fee-for-service model of healthcare and towards preventative medicine. The idea is simple: instead of waiting for people to get sick and then trying to treat their symptoms (reactive medicine), we can head illnesses off at the pass, intercept and stop them from becoming a problem in the first place. Artificial intelligence is making the art and science of predictive medicine cheap and realistic.

4:35 How Will Digital Transform Clinical Trials: Lessons from the Private Sector
Jacob LaPorte, PhD, Co-Founder & Vice President, Global Head of BIOME – The Digital Innovation Lab, Novartis
Implementing digital solutions is harder than it looks. One of the key reasons for that is lack of global regulatory standards. The digital challenge can overwhelm the sites and it requires investment to test & validate the technology. Digital technologies will lead to data explosion and more targeted clinical studies.

4:55 Digital Health Dreams vs. Digital Health Reality: Realities of Building Innovative Patient-Centric Capabilities for Clinical Trials
The hyped-up potential of digital health technology to transform pharma shouts from every industry news source and at every crowded conference. But, the truth is that technology invention and innovation have always preceded technology adoption by many years, in every industry. This is especially true in life sciences R&D, where the frictions to innovation adoption – powerful regulatory constraints, long timelines to execute trials and the misaligned incentives of the healthcare system itself – have resulted in especially slow progress bringing new technologies into clinical trial conduct.

5:15 Presentation to be Announced

5:45 PANEL DISCUSSION: Scaling Innovation
Moderator: Craig Lipset, Independent Advisor, Former Head of Clinical Innovation, Pfizer, Inc.
Panelists: Tammy Guld, Global Lead, Janssen Clinical Innovation

Speakers of the Session
Digital tools can generate a great deal of buzz and attention, but most companies today are exploring and experimenting with similar digital solutions. What will set companies apart is not whether they can find digital tools or pilot solutions, but which companies are able to implement and scale digital solutions across their development organization.

• Explore how companies are organizing themselves to scout, pilot and scale digital solutions
• Identify strengths across various models – from centralized digital and innovation teams to capabilities being embedded with business owners
• Share best practices to move innovation “beyond the pilot”

6:15 Networking Reception

7:15 Close of Day
FRIDAY, FEBRUARY 21

7:15 am Registration Open
7:45 Breakfast Presentation to be Announced
8:15 Session Break

VIRTUAL AND REMOTE TRIALS

8:20 Chairperson's Remarks
Jeff Kozloff, CEO, TrialScope

8:25 Virtual Trials from A to Z: Operations, Technology, Data Analytics
Pam Duffy, Senior Director & Digital Strategic Planning and Demand Lead, Pfizer
Virtual trials bring studies directly to patients, increasing participation and boosting your cycle times. Combining technology, data science and clinical expertise, they speed patient recruitment, heighten retention and enhance data quality—at lower cost.

8:55 CO-PRESENTATION:
Understanding the Data Journey in Virtual Trials
Adama Ibrahim, Associate Director, Clinical Operations, Biogen
Andrew Kornberg, Associate Professor & Senior Neurologist, The Royal Children's Hospital Melbourne
Virtual trials promise to improve clinical research. New methods of data collection and usage also bring new challenges. This forum will model the journey of data in a virtual trial, identify key challenges and offer solutions for sponsors and CROs.

9:25 AI in Clinical Trials:
From Big Sky to Practical Application
Jim Reilly, Vice President, Vault Clinica, Veeva Systems
Artificial Intelligence (AI) has made its way into the realm of clinical trials and is reshaping how studies are conducted. This presentation looks at the practical ways AI and process automation are being used effectively today to optimize trial design and execution. Join this presentation for a look into how technology is revolutionizing the clinical operations landscape—from the smallest biotech to big pharma.

9:55 Presentation to be Announced

10:25 Networking Coffee Break

10:55 Chairperson's Remarks
Craig Lipset, Independent Advisor, Former Head of Clinical Innovation, Pfizer, Inc.

11:00 PANEL DISCUSSION: Virtual Trials: State of the Union
Moderator: Craig Lipset, Independent Advisor, Former Head of Clinical Innovation, Pfizer, Inc.
Panelists: Speakers of the Session
- Let's discuss terminology: Site-less, de-centralized, virtual?
- Does it have to be one model, or can we mix (e.g. traditional and remote)?
- Does digital technology inevitably lead to virtual trials?
- What are some specific challenges in retaining patients and investigators?
- What are the data science considerations in de-centralized/virtual trial?

11:30 Presentation to be Announced
12:00 pm Transition to Shared Sessions

AI TO ENABLE DIGITALIZATION OF CLINICAL TRIALS

12:00 Chairperson's Remarks

12:05 Real World Evidence Generation for Clinical Decision Making: Can AI Solve the Challenges?
Professor Dr. Dorothee Bartels, Clinical and Real World Data Strategist, X The Moonshot Factory
Real World Evidence Generation (RWE) is continuously gaining importance, but trust in results, transparency and reproducibility are challenging. The same is true for prediction models based on learning algorithms. Questions are arising: who may be the best expert in big data analysis; who may have the appropriate skill sets; and can clinical decisions be based on real-world data analysed by either traditional or artificial intelligence (AI) methods? Complementary approaches using synergies from the epidemiological and AI field may boost the field of RWE.

12:25 Re-Skilling for AI/ML: Leveraging Your SMEs
Nechama Katan, Associate Director, Data Monitoring and Management, Pfizer
Al/ML are very powerful tools for clinical trials. However, there is a gap between those that understand what AI/ML can do for the business and the business SME (subject matter experts) who really understand the business problems. Without strong SME engagement in solutions, technical solutions are often at risk. This talk will review successful case studies for developing “lego” employees/teams who help bridge the gaps between AI/ML technologist and the SMEs. We will discuss both the how and what that makes an AI/ML project successful in clinical trials.

12:45 PANEL DISCUSSION: AI Implementation: Technology, Data, People
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer
Panelists: Balazs Flink, PhD, Head, Clinical Trial Analytics, R&D Business Insights, Bristol-Myers Squibb
Faisal Khan, PhD, Executive Director, Advanced Analytics and Artificial Intelligence, AstraZeneca
Arun Patnaik, Director, Clinical Data Management, Data Operations, Novartis
Malai Kannan Sankarasubbu, Vice President, AI Research, Saama Technologies
It was proven that machine learning and AI can aid clinical development in various aspects. With evolving AI technology implementation challenges become more and more noticeable. This panel discussion will brainstorm the key pain points of AI implementation:
- What is the best technology and how to work with technology providers?
- How to make all data machine learnable and available for AI applications
- How to solve “the people puzzle”

1:05 Transition to Lunch
1:10 SCOPE Send Off Luncheon Presentation (Sponsorship Opportunity Available)
1:40 Closing Remarks
1:45 SCOPE Summit 2020 Adjourns
Real-world evidence solutions have changed the design and execution of clinical trials and post-marketing research. Data generated in 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. CHI’s 9th Annual Accessing and Generating RWD conference is designed to facilitate knowledge exchange around all aspects of real-time, real-world data generation, its quality and applications.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*
*Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall

ROLE OF RWE AND INNOVATION AROUND REGULATORY GRADE RWD

10:40 Chairperson's Remarks
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen

10:45 Role of Real-World Evidence in Comprehensive Product Evidence Generation Plans
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen

Evidence generation is a key deliverable and an important strategic capability to enable efficient drug development and commercialization across the product lifecycle. Real-world evidence (RWE) effectively complements data generated from clinical trial programs and is rapidly growing in importance to evaluate medicine safety, effectiveness and value. A common understanding of RWE approaches to address key questions supporting regulatory and reimbursement agency needs and patient access does not exist. A RWE playbook to guide and support these activities can introduce efficiencies in resource allocation and help insure that the necessary evidence is generated. Growing availability of data and sophistication of analytic tools have transformed RWE generation. The appropriate use of real-world data and analytic tools, and associated challenges impeding the full realization of benefit from RWE, will be discussed.

11:10 Outcomes Ascertainment at the Speed of Digital: The Hugo Experience
Harlan M. Krumholz, MD, SM, Director, Yale-New Haven Hospital Center for Outcomes Research and Evaluation

The digital transformation holds the possibility of disrupting labor-intensive, expensive and slow research data collection and engaging participants as partners in the process. The 21st Century Cures Act is providing an impetus for change in the research enterprise and there are applications in discovery research, trial recruitment, trial conduct, post-market surveillance and label expansion. Thus, there is a window of opportunity to transform the research landscape and provide real-time clinical, participant-generated and participant-reported information about outcomes that matter.

11:35 Transparent and Replicable ‘Real World’ Evidence from ‘Real World’ Data
Shirley Wang, PhD, Assistant Professor, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School

Regulatory and Health Technology Assessment (HTA) organizations are increasingly looking toward use of ‘real world’ evidence (RWE) from ‘real world’ data sources, such as healthcare utilization databases, to support decision-making. However, they need to be able to effectively and efficiently distinguish between studies of high versus low validity. The REPEAT Initiative is focused on improving transparency, reproducibility and validity of database research. One project involves replication of 150 published database studies.

11:55 Making the (Regulatory) Grade: Approaches to Data Quality in RWE
Emily Castellanos, MD, Associate Medical Director, Research Oncology, Flatiron Health

The credibility of real-world evidence (RWE) for a specific use case depends upon both the quality of the underlying real-world data (RWD) as well as the analytic methods. This discussion will focus upon evolving approaches to fit for use quality of RWD. Standardized reporting of quality measures can inform the analytic approach, to minimize bias and generate confidence in regulatory decisions supported by RWE. Considerations important for measuring, monitoring, and addressing dimensions of RWD fit for use quality will be described.

12:15 pm Synthetic Control Arms (SCAs): The End of Placebos, or Not Quite a Silver Bullet?
Meg Richards, Executive Director, Real World Solutions, PRA Health Sciences

Synthetic Control Arms (SCAs): The End of Placebos, or Not Quite a Silver Bullet? Considerations in design, conduct, analysis and reporting of SCAs.

12:45 Transition to Lunch
12:50 LUNCHEON PRESENTATION: Going Virtual in Real-World Research: Opportunities & Challenges

David Thompson, PhD, Senior Vice President, Real World and Late Phase, Syneos Health

Real-world research is proving to be a useful setting to pilot test new technologies and process innovations for use in RCTs. One such area is mobile technologies, which hold promise to enable conduct of so-called “virtual” studies that significantly reduce the need for site-based patient recruitment, enrollment, and data collection. This presentation will highlight the opportunities and challenges for going virtual in real-world research, using an ongoing fully-virtual prospective cohort study as a case example.

1:20 Coffee and Dessert Break in the Exhibit Hall

RWD TO SUPPORT TRIAL DESIGN

2:15 Chairperson’s Remarks

Chair to be Announced, Syneos Health

2:20 Considerations on the Use of Real-World Data in Trial Design

Demissie Alemayehu, PhD, Vice President, Biostatistics, and Head of Statistical Research and Data Science, Pfizer

When traditional randomized controlled trials are not feasible for operational or ethical reasons, use of external control arms constructed from historical clinical trial or real-world data may be viable options. However, the validity of the evidence generated from such trials is dependent on several factors, including data quality, disease natural history, study design, analytical approaches and similarity of data sources. In this talk, we highlight some of the issues that arise in the design and analysis of trials with external control arms, with emphasis on trending topics in the statistical and regulatory spaces.

2:50 Leveraging Electronic Health Records to Inform Protocol Design and Accelerate Enrollment in Clinical Trials

John Yonchuk, Manager, Digital Clinical Trials, GlaxoSmithKline

One of the key challenges facing Pharma is the ability to identify and recruit the best participants to enroll and complete clinical trials. As these participants become more highly sought after and harder to find, it becomes critical to be able to quickly and correctly identify and recruit such participants. The recent trend of looking to electronic health record data, and using artificial intelligence to analyze it, holds great promise to help improve identification and recruitment in clinical trials.

3:20 The Use of Real-World Evidence in Clinical Design to Support Regulatory Decision-Making

Elodie Baumfeld Andre, PhD, Senior Director, Epidemiology Strategy & Policy Lead, Worldwide Safety and Regulatory, Pfizer

Real-World Evidence (RWE) could have a significant impact on how pharmaceutical and biotech companies conduct clinical development and pursue regulatory approval of new treatments. Due to three major drivers: 1) increased regulator acceptance of RWE designs; 2) availability of new data types/sets; and 3) broad availability of advanced data analysis capabilities, RWE approaches are gaining traction industry-wide, which might lead to more efficiencies in drug development and better medical outcomes for patients. The objective of this presentation is to provide the audience with a baseline understanding of key RWE concepts and its application to regulatory decision-making in the life sciences industry, as well as an opportunity to discuss the vision for the future.

3:50 Organizing EMR data with AI

Karim Galli, CEO & Cofounder, Mendel.ai

Mendel built the world’s first AI machine that can ingest any data type from different EMR systems and decipher it to generate analytics-ready datasets in near real-time. The company will showcase a live demo and a side-to-side comparison to standard manual data extraction methods.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share

Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

DEMystifying FIT-FOR-PURpOSE DATA

8:20 Chairperson’s Remarks

Chair to be Announced, United BioSource Corporation

8:25 Demystifying Fit-for-Purpose Data

Gracie Lieberman, Senior Director, Regulatory Policy, Genentech

Technological advancement has raised expectations that data collected in routine clinical practice could be utilized for regulatory decision-making. Hence, understanding RWD quality requirements for regulatory use became key. In December 2018, the FDA published a Framework for FDA’s Real-World Evidence Program and underscored the need for the data to be “fit for regulatory use.” This talk will examine the individual components contributing to data fitness and discuss key considerations.
8:55 Demonstrating and Communicating Real World Data (RWD) Reliability to Support Fitness-for-Use for Regulatory Decision-Making
Christina Silcox, PhD, Managing Associate, Duke-Margolis Center for Health Policy, Duke University

In December 2018, FDA released the framework on its Real-World Evidence Program including whether RWD are fit-for-use. Fit-for-use RWD is multifaceted concept, including reliability. One way to systematically assess and communicate RWD reliability is to use a standardized set of verification checks. However, it may not be feasible to identify a standardized set of checks to assess all aspects of reliability due to heterogeneity within and between RWD. Instead, a minimum set of standardized verification checks used to assess some aspects of reliability across all data sources could be identified and adopted as a first step. Because data curation is a dynamic process, this minimum set of verification checks should be assessed continuously based on initial review and on findings during analysis.

9:25 CASE STUDY: Successes, Challenges and Lessons Learned Conducting a Multi-Country RWD-Based External Control Arm Study
Leanne Larson, Corporate Vice President, WW Head, Real-World Evidence, Parexel

As indicated by regulatory agencies, RWD is recognized as a source to be used as an external control arm in clinical trials. To ensure success, many considerations must be addressed, including scientific, clinical, informatics, data management, etc. We present a case study of an FDA-approved, multi-country, external RWD control arm used for a rare disease. We discuss lessons learned related to the assessment of RWD sources, technological solutions and translation to a common data model.

9:55 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall

SUPPLEMENTING CANCER RESEARCH WITH RWD

11:20 Chairperson’s Remarks
Leanne Larson, Corporate Vice President, WW Head, Real-World Evidence, Parexel

11:25 RWD in Oncology and Immuno-Oncology Research
Michael Kelsh, PhD, Director, Center for Observational Research, Amgen

This talk will discuss RWD applications in early- and late-stage cancer research. Case studies and examples, as well as relationships with the companies owning the data will be discussed.

11:55 Risk-Based Safety Monitoring for Oncology Clinical Trials
Sean Zhao, MD, PhD, Head of US Patient Safety, AstraZeneca Pharmaceuticals LP, US Medical Affairs

There are great differences between oncology and non-oncology clinical trials. For example, the nature of the illness of study subjects in oncology clinical trials are more likely severe, life-threatening, and have relatively short survival time periods than those in non-oncology trials. The investigational medicinal product (IMP) in oncology trials are more likely new, innovated treatments and their safety profile may not be fully assessed. Many of these IMPs have specific toxicities, such as general cytotoxic effect, on- or off-target toxicity effects. Combination treatment of two or more oncology products, which are commonly used in oncology clinical trials, may express different levels of toxicity in frequency, severity and duration. A risk-based safety monitoring approach will allow patient safety professionals to proactively protect the rights, safety and well-being of human subjects involved in oncology clinical trials and assure the quality, reliability and integrity of the safety data collected.

12:25 pm Transition to Lunch

12:30 BRIDGING LUNCHEON PRESENTATION:
Supercharge Study Design and Feasibility: AI with Integrated RWD and Cross-Industry Clinical Trial Data/Metrics
Jef Benbanaste, Senior Director, Product Lead, Acorn AI by Medidata, a Dassault Systèmes company

While RWD can support both clinical and operational trial planning, its value is maximized when analyzed together with data and metrics from a large set of cross-industry clinical trials. This session will share perspectives on how to select fit-for-use RWD sources, manage and transform RWD, and apply analytics in conjunction with clinical trial data for use cases such as Synthetic Controls, protocol optimization, and site feasibility.

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Leveraging RWD for Clinical and Observational Research. See pages 51 & 52 for details.
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, implementing novel data technologies, as well as close collaboration between pharmaceutical companies and organizations that possess the data. CHI’s 5th Annual Leveraging RWD for Clinical and Observational Research conference will discuss innovative approaches and technologies for RWD-based clinical and observational studies.


THURSDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm Bridging Luncheon Presentation to be Announced

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

INNOVATIVE RWD-BASED STUDIES

4:10 Chairperson’s Remarks

Marc Berger, MD, Scientific Advisor, Medidata, a Dassault Systèmes Company

4:15 Hybrid Approaches for Data Collection in RWD

Charles Makin, Global Head, Real World Evidence Strategy, Biogen

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.

4:45 Real-World Evidence Complements and Supplements Clinical Trial Designs

David Van Brunt, PhD, Senior Research Fellow and Head, HEOR Division of Evidence and Analytics AbbVie, Inc.

Regulators, notably FDA, increasingly recognize that real-world data (RWD) can improve the efficiency and effectiveness of clinical trials and can strengthen the regulator’s understanding of the benefit-risk presentation of molecules under consideration for approval. Use cases of RWD informing trial designs and being used in FDA decisions will be described, highlighting the diversity of RWD and its applications.

5:15 Improving Clinical Study Performance with Collaboration and Data during Protocol Development

Rob DiCicco, Deputy Chief Health Officer, IBM Watson Health

Decisions made in clinical trial protocol design can have significant financial impacts during product development and commercialization. This session discusses the factors affecting protocol design and decision making and will present concrete ways to leverage the power of collaboration and data to overcome these challenges.

5:45 Hi-Lo: Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis

Andy MacKelfresh, Project Leader, Clinical Research Informatics, Duke Clinical Research Institute

The goal of this project is to determine whether less stringent control of serum phosphate versus the current standard approach will result in non-inferior rates of all-cause hospitalization among patients with ESRD undergoing hemodialysis. This presentation will describe the trial design and approach leveraging eConsent, source data from eHR, harmonization of data from multiple sources, involvement of dietitians, and reporting.

6:15 Networking Reception

7:15 Close of Day

FRIDAY, FEBRUARY 21

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

RWD AS A CONTROL ARM

8:20 Chairperson’s Remarks

Karim Galil, CEO & Co-Founder, Mendel.ai

8:25 External Control Arms for Trial Development

David Tabano, PhD, MA, Associate Director, Center for Observational Research & Data Sciences (CORDS), Business Insights & Analytics, Bristol-Myers Squibb

The presentation will summarise the key methodologies used for external controls, distributing those into categories where statistical adjustment is provided to generate external control groups, and those where more simplistic selection criteria are applied to historic controls. For the purposes of this presentation, both techniques will fall under the remit of external study controls for consistency with regulatory and scientific literature surrounding this topic.

8:50 CASE STUDY: Use of Real-World Control Arm for Single Arm Trial Studies in Cancer

Jyotsna Mehta, Senior Director & Head, HEOR, Karyopharm Therapeutics

Jatin Shah, MD, CMO, Karyopharm Therapeutics

This case study will describe the definition of a real-world control arm, how to design a study using it alongside a single arm trial, and do's and don'ts of this approach. It will provide examples of recently approved drugs and explain the scenarios where such approaches can be used.
PATIENT VOICE IN RWD-BASED RESEARCH

9:10 Chairperson's Remarks
Virginia Spitzer, Executive Director, Foundation for Sarcoidosis Research

9:15 Fox Insight: Driving Discovery with the Patient Voice
Lindsey Riley, MPH, Senior Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research

Patient reported outcomes (PRO) data complements traditional ad
cis research with scale & accessibility, as well as patient-centricity. The Fox Insight (FI) study aims to gather the world’s largest dataset on the day-to-day experience of living with PD, from 125,000 participants across the globe. This comprehensive dataset holds the power to help researchers better understand patients’ unmet needs, redefine therapeutic priorities and optimize clinical trial design.

Virginia Spitzer, Executive Director, Foundation for Sarcoidosis Research

This presentation would focus on an underutilized resource of RWD - the patient advocacy community. By reviewing how IRB-approved patient registries, observational studies, validated tools measuring patient experience, and other PROs collected can be utilized for industry, regulatory, and academic projects, RWD can be expanded to include the direct patient voice.

9:55 Leveraging Real World Data in Clinical Trials and Observational Research, Focusing the Patient Experience
Claire Russell, Executive Director, Patient Experience, PRA Health Sciences

Real world evidence is underutilized in interven
tional and observational studies. As a result, protocols are less patient-centric; patient recruitment timelines are being extended and promising drugs are not reaching patients fast enough. Due to this missed opportunity, patients are unable to access potentially life-saving treatment options.

10:25 Networking Coffee Break

AI FOR RWD APPLICATIONS

10:55 Chairperson’s Remarks
Jyotsna Mehta, Senior Director & Head, HEOR, Karyopharm Therapeutics

11:00 Machine Learning with Real World Data
John Page, MD, ScD, Medical Director and Lead of Predictive Analytics, Center for Observational Research, Amgen, Inc.

RWD provides opportunities to study drug utilization/safety of pharmaceutical products. Machine learning (ML) allows the development of automated algorithms for classification/prediction using data. ML offers opportunities to mine RWD for classification of medical images and prediction of medical events. However, RWD currently has a number of limitations, including incomplete and faulty data. The performance of ML in RWD is discussed and some solutions are offered.

11:30 The Role of Emerging Technology in Improving the Patient Experience & Generating PROs
Chris Watson, PhD, Director, Product Strategy, Product Management, ERT

Real-World Data generated through Patient Reported Outcomes play an increasingly important role across the Drug Development Lifecycle. In a hyper-connected world, learn how patients’ own technologies enable effective ways of capturing ‘new data’ to deliver high-quality PROs.

12:00 pm Transition to Shared Sessions

AI TO ENABLE DIGITALIZATION OF CLINICAL TRIALS

12:00 Chairperson’s Remarks
Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.

12:05 Real World Evidence Generation for Clinical Decision Making: Can AI Solve the Challenges?
Professor Dr. Dorothee Bartels, Clinical and Real World Data Strategist, X The Moonshot Factory

Real World Evidence Generation (RWE) is continuously gaining importance, but trust in results, transparency and reproducibility are challenging. The same is true for prediction models based on learning algorithms. Questions are arising: who may be the best expert in big data analysis; who may have the appropriate skill sets; and can clinical decisions be based on real world data analysed by either traditional or artificial intelligence (AI) methods? Complementary approaches using synergies from the epidemiological and AI field may boost the field of RWE.

12:25 Re-Skilling for AI/ML: Leveraging Your SMEs
Nechama Katan, Associate Director, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.

AI/ML are very powerful tools for clinical trials. However, there is a gap between those that understand what AI/ML can do for the business and the business SME (subject matter experts) who really understand the business problems. Without strong SME engagement in solutions, technical solutions are often at risk. This talk will review successful case studies for developing "lego" employees/teams who help bridge the gaps between AI/ML technologist and the SMEs. We will discuss both the how and what that makes an AI/ML project successful in clinical trials.

12:45 PANEL DISCUSSION: AI Implementation: Technology, Data, People
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.

Panelists: Balazs Flink, PhD, Head, Clinical Trial Analytics, R&D Business Insights, Bristol-Myers Squibb
Faisal Khan, PhD, Executive Director, Advanced Analytics and Artificial Intelligence, AstraZeneca
Arun Patnaik, Director, Clinical Data Management, Data Operations, Novartis Malaikannan Sankarasubbu, Vice President, AI Research, Saama Technologies

It was proven that machine learning and AI can aid clinical development in various aspects. With evolving AI technology implementation challenges become more and more noticeable. This panel discussion will brainstorm the key pain points of AI implementation:

- What is the best technology and how to work with technology providers?
- How to make all data machine learnable and available for AI applications
- How to solve “the people puzzle”

1:05 Transition to Lunch

1:10 SCOPE Send Off Luncheon Presentation (Sponsorship Opportunity Available)

1:40 Closing Remarks

1:45 SCOPE Summit 2020 Adjourns
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 5th 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.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open

2:00 - 5:00 pm User Group Meetings

2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*

*Separate registration required. Must be a Best Value registered attendee.

5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)

6:20 - 7:30 pm SCOPE’s Kick-Off Networking Happy Hour

7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Morning Opening Plenary Keynotes (See page 4 for details.)

9:40 Grand Opening Coffee Break in the Exhibit Hall

OPERATIONALIZING PRECISION MEDICINE TRIALS

10:40 Chairperson’s Remarks
Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories
Brenda Yanak, Principal, Clinical Transformation Partners

10:45 Specimen Management and Innovation as an Integral Part of Biomarker and Drug Discovery
Steven Piccoli, PhD, Senior Director, Precision Medicine, Experimental Medicine Unit, GlaxoSmithKline

Patient samples are the lifeblood (literally!) of successful clinical trials in the pharmaceutical/biotechnology industries. It is rare in the industry to acquire an efficient biobanking function without implementing serious changes. This presentation will overview the highs (and lows!) of establishing that function of Clinical Trial Biospecimen Management in reputable clinical organizations, including best practices and pain points, and how this enables facile patient testing for drug development.

11:10 Maximizing Specimen Assets in Oncology Clinical Trials
Michael Tanen, MBA, Director, Clinical Biomarker Specimen Management, Merck Research Laboratories

Immuno-oncology clinical trials have shifted toward more innovative clinical trial designs, such as Basket, Umbrella and Adaptive methodologies that create increased complexity and demands on supporting functions. These trial designs are frequently biomarker-intensive and need to be managed with a specimen-centric perspective to maximize collected bio-specimen assets. Innovative bio-specimen management approaches are becoming an essential part of empowering clinicians and researchers to better understand the individualized connections between biomarkers and human disease.

11:35 Operational Management of Biomarker Analysis for Submission-Ready Data
Deborah Shepard, PhD, Senior Manager, Biomarker Assay Specialist, Global Product Development, Oncology, Pfizer Inc.

Generation of high-quality biomarker data for a clinical trial requires more than selecting a lab and assay and transferring the data. It requires careful selection and qualification of the lab, fit-for-purpose assay validation, and ongoing oversight of analysis and data. Aligning expectations and building a collaborative relationship between the sponsor and the lab is the key to success.

12:00 pm Biomarker-Driven Clinical Trials: Challenges and Solutions: The Beat AML Master Trial – Simplifying Complex Precision Medicine with a Focus on Sample Flow and Laboratory Information
Len Rosenberg, PhD, RPh, Head, Clinical Operations, The Leukemia & Lymphoma Society/Beat AML LLC

AML is a heterogeneous disease with mutational heterogeneity and different rare genetic subtypes. The challenge is to apply precision-based enrollment to evaluate new targeted therapies in an efficient manner. This presentation will illustrate the complexity of the trial by mapping the flow of samples and information to support centralized treatment assignments to eleven sub-studies and then continue to process ongoing laboratory data for dose-escalations, cohort expansions or futility benchmarks.

12:15 Presentation to be Announced

12:45 Transition to Lunch

12:50 LUNCHEON PRESENTATION: Talk Title to be Announced

David Lanham, BSc (Hons), MSc, Principal Scientific Director, Eurofins Pharma Bioanalysis Services UK Limited, Eurofins BioPharma Services

1:20 Coffee and Dessert Break in the Exhibit Hall
SUPPORTING INNOVATIVE AND VIRTUAL TRIALS

2:15 Chairperson's Remarks
Brenda Yanak, Principal, Clinical Transformation Partners

2:20 Considerations for Biomarker Research in a Gene/Cell Therapy Clinical Trial
Heather Hirsch, PhD, Senior Director, Translational Pharmacology, Head of Clinical Biomarkers and Exploratory Research, CRISPR Therapeutics
Translational research can provide key insight into the activity of a therapeutic in a clinical trial. In this session, we will discuss strategies for implementing biomarker work within the context of a gene/cell therapy clinical trial. We will also focus on important considerations specific to gene/cell therapies that differ from traditional small molecule therapeutics.

2:50 Patient-Centric Sample Collection to Enable Virtual Trials
Kevin Bateman, Distinguished Scientist & Scientific Associate Vice President, Merck
Traditional approaches for measurement of drug exposure in clinical trials involve having the patient travel to a clinical site for collection of venous blood. This puts a burden on the patient while also limiting the opportunities for assessment of drug exposure or other measurements to these clinical visits. The ability to collect samples at home would provide a more patient-centric approach, enabling remote/virtual trials. This talk will share results from recent clinical pilot studies employing at-home sampling technologies.

3:20 CO-PRESENTATION: Biospecimen Collection in Virtual Clinical Trials
Matt Harlin, Associate Director, Clinical Pharmacology, Otsuka Pharmaceutical Companies
Sharin Roth, Director, Clinical Pharmacology, Bioanalysis, Otsuka Pharmaceutical Companies
As the pharmaceutical industry begins the transition to virtual or “siteless” clinical trials, how will routine clinical trial procedures, such as blood sample collection, be performed in a consistent and reliable manner? This talk will share experiences to date, including what has worked and areas for future improvement.

3:50 Sponsored Presentation (Opportunity Available)

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 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, yet some ideas with your peers, be a part of group interrogation and problem solving, and most importantly, participate in active idea sharing. See pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share
Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

INFORMED CONSENT AND RETURN OF RESULTS POLICY

8:20 Chairperson's Remarks
Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck

8:25 Challenges in Returning Individual Results in Global Clinical Trials
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.

8:55 Experiences in Individual Study Participant Clinical Data Return
Jennifer Ribeiro, Informed Consent Process Lead, Global Clinical Documentation & Submissions, Global Clinical Operations, Bristol-Myers Squibb
This presentation will review the experiences that BMS has had in the last 2 years returning clinical trial data to individual study participants.

9:25 Return of Research Results to Participants in Clinical Trials - Case Studies and Associated Challenges
Delphine Lagarde, PhD, Ethics Lead in Biosample & Repository Management, F. Hoffmann-La Roche AG
The growing demand from Ethics Committees & review bodies, patient advocates, policy makers and country regulations to provide study participants access to their genomic results led Roche to rethink their position on return of research results. This talk will present three examples where Roche has either returned research results or set up a process that could be implemented in Roche clinical trials to return genomics research results to study participants.
9:55 Returning Data and Results to Clinical Trial Participants
David Leventhal, Senior Director, Clinical Innovation, Global Product Development, Pfizer Inc.
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.

10:25 Coffee Break in the Exhibit Hall

DATA OWNERSHIP AND RETURN OF RESULTS POLICY

11:20 Chairperson's Remarks
Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck

11:25 What Should Industry do in Sharing Data/Results with Study Participants?
Jessica Scott, MD, JD, Head, R&D, Patient Engagement, Takeda
Hearing rumbles from patients, patient organizations and even other pharmaceutical companies? Better understand what is the buzz and why you need to start thinking about your approach. Navigating the return of individual data/results is nuanced, but doable. How you can better understand the benefits and also the challenges.

11:45 Return of Individual Research Results: Recommendations of the National Academies of Science, Engineering and Medicine
Jeffrey Botkin, MD, Professor, Pediatrics and Medical Ethics, University of Utah
The return of individual research results to research participants raises a complex and controversial set of issues for investigators, participants, sponsors and research institutions. The benefits of disclosure and the desire for greater transparency by many participants must be balanced with concerns over the validity of research results and the burdens associated with the oversight and disclosure process. The National Academies of Science, Engineering and Medicine convened a consensus committee that published a report on these issues in 2018. This presentation will provide an overview of the issues and recommendations addressed by the NASEM report.

12:05 PANEL DISCUSSION: How Can Industry Enable Responsible Sharing of Individual Biomarker Data in Sponsored Clinical Trials?
Moderator: Karina Bienfait, PhD, Principal Scientist & Head, Global Genomics Policy, Process & Compliance, Merck
Panelists: David Leventhal, Senior Director, Clinical Innovation, Global Product Development, Pfizer Inc.
Jennifer Ribeiro, Informed Consent Process Lead, Global Clinical Documentation & Submissions, Global Clinical Operations, Bristol-Myers Squibb
Jessica Scott, MD, JD, Head, R&D, Patient Engagement, Takeda
- Who owns the patient data in clinical research?
- How can Sponsors facilitate the return of biomarker data?
- What are the opportunities for transparent sharing of biomarker data?

12:25 Transition to Lunch

12:30 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Clinical Biospecimens Technology and Outsourcing. See pages 56 & 57 for details.
The availability of high-quality biological specimens, laboratory access and diagnostics services are of the utmost importance for biomarker-driven clinical trials and future research. The complexity and number of samples collected and analyzed during studies has increased steadily over the years and we need to come up with best practices, operational models and IT solutions to deal with this volume and complexity. CHI’s 5th Annual Clinical Biospecimens Technology and Outsourcing conference brings together leading experts, clinical trial sponsors and CROs to discuss challenges and identify actions to improve infrastructure for biomarker-driven clinical trials.


**THURSDAY, FEBRUARY 20**

11:30 am Registration Open

12:30 pm Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

**CLINICAL SPECIMEN MANAGEMENT IN THE ERA OF PRECISION MEDICINE & TECHNOLOGICAL ADVANCEMENTS**

4:10 Chairperson’s Remarks
Debra Reinhard, Head, TM Enabling Solutions, Translational Medicine, Bristol-Myers Squibb

4:15 Challenges of Clinical Specimen Management in the Era of Precision Medicine
Debra Reinhard, Head, TM Enabling Solutions, Translational Medicine, Bristol-Myers Squibb

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.

4:45 Implementation of GSK’s Biological Sample Management Strategy
Mohan Bangalore, Global Head, BioAsset Management, GlaxoSmithKline

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 samples.

**5:15 Patient Focused Clinical Trial Sample Collection, Management and Tracking**
Stephanie Weber, Director, Advanced Therapy Services, LabConnect

Labconnect has led the industry in providing innovative strategies and solutions to simplify the ever growing complexities of clinical trial virtual sample management. To address the parallel growth in advanced therapies and in clinical trial patient centric services, LabConnect will discuss the challenges and strategies for a patient focused sample management plan. Topics will include the integration of home health care visits, solutions for virtual sample and product tracking, patient scheduling, and logistical solutions.

**5:45 Performing Research during a Clinical Trial: Managing the Biospecimens**
Matthew Nguyen, Manager, Clinical Biospecimen Operations, BioMarin Pharmaceutical Inc.

BioMarin Pharmaceutical Inc. has developed an on-line approval process that leverages our inventory tracking and process management IT system to ethically manage, efficiently triage and prioritize competing business needs for using residual consented biospecimens to support our research efforts. This approach allows our researchers to actively pursue cutting-edge science while BioMarin concurrently runs a clinical trial. Our presentation will describe the review, approval and fulfillment process that is documented in our IT system.

**6:15 Networking Reception (Sponsorship Opportunity Available)**

7:15 Close of Day

**FRIDAY, FEBRUARY 21**

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

**OUTSOURCING AND PARTNERING STRATEGIES**

8:20 Chairperson’s Remarks
Mary Zuniga, Consultant, Translational Science, Immunology, Eli Lilly and Co.

**8:25 Collaboration of Major Stakeholders (CRO, Laboratory and Sponsor) to Support Biomarker-Driven Clinical Trials—Operation**
Mary Zuniga, Consultant, Translational Science, Immunology, Eli Lilly and Co.

Developing biomarkers is key to delivering medicines that improve patient’s lives. Good biomarkers have the potential to confirm that the compound/study drug affects the intended biological pathway and confirm the mechanism of action and help with dose setting. Novel biomarker assays are developed by the sponsor and transferred to a performing qualified lab...
to have a fully qualified assay for a global clinical trial. Partnering between the sponsor, the CRO managing the trial, and the central lab to successfully meet timeline deliverables is a well-orchestrated production requiring open communication and flexibility.

8:55 Innovations along the Specimen Management Value Chain
John Smutko, Manager, Biospecimen Operations, Clinical Biomarker Innovation and Development, Takeda Pharmaceuticals
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 Biobanking Strategy Using Advanced Informatics to Enable Scientific Discovery and Innovation
Lynn Wetherwax, Senior Manager, BSM & Biobank, Research Operations, Amgen
Sophisticated specimen management tools are crucial to answer key questions that will enable advancement of translational medicine. Systems that can be easily queried will help manage the size of the collection, track consent and identify any storage or use restrictions. Specimen management tools must also adapt to innovative trial designs. This talk will focus on specimen management systems and recent upgrades to adapt to the changing clinical trial landscape.

9:55 Talk Title to be Announced
Jason Attanucci, Senior Director, Sales/Partnerships, BioFortis (a Q2 Solutions Company)

10:25 Networking Coffee Break

TECHNOLOGY TO ADVANCE BIOMARKER AND BIOSPECIMEN MANAGEMENT

10:55 Chairperson's Remarks
Brenda Yanak, Principal, Clinical Transformation Partners

11:00 PANEL DISCUSSION: Innovations along the Specimen Management Value Chain
Moderator: Brenda Yanak, Principal, Clinical Transformation Partners
Panelists: Debra Reinhard, Head, TM Enabling Solutions, Translational Medicine, Bristol-Myers Squibb
Mohan Bangalore, Global Head, BioAsset Management, GlaxoSmithKline
Jane Fang, MD, Head, Clinical Business Management & Analytics, MEDI Biologics Unit, AstraZeneca
Multiple technologies are advancing healthcare delivery and clinical trials. How does this process involve biospecimen and biomarker management?

11:30 Sponsored Presentation (Opportunity Available)

12:00 pm Transition to Shared Sessions

FACILITATING THE TRIALS OF THE FUTURE NOW VIA THE CONNECTED PATIENT & DECENTRALIZED TRIALS

Chairperson's Remarks
Neil Weisman, President, Continuum Clinical

12:05 The Connected Patient: A “One Stop Shop” for Trial Information and Data
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson
Learn how we are creating a connected experience for trial participants before, during and after the trial where patients can access meaningful information, their individual data to share with their EHR, aggregate study results and provide ongoing feedback and insights to ensure a better experience for patients, caregivers and the site teams. Explore the possibilities to remain connected via communities to raise awareness around trials. The audience can gain insights as to the ins and outs of how we managed to create a platform to share data directly with patients – from legal, privacy, regulatory and other key stakeholder hurdles to our vision for broadening the scope of data sharing across industry.

12:35 INTERACTIVE PANEL: Translating Virtual to Reality: Decentralized Trial Transformation
Moderator: Jane Myles, Head, Operational Intelligence and Innovation, Roche
Panelists:
Bardia Akbari, PharmD, Senior Vice President, Clinical Operations, Science37
Carrie Melvin, Vice President, Global Clinical Sciences and Delivery TA Head of Oncology, GSK/TESARO
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCDO, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson
Our expert panel will include a variety of perspectives and the aim is to provide pragmatic solutions and actionable advice to make virtual trials a realistic option for your study needs. We'll discuss strategic and tactical needs to help you determine how to navigate and implement virtual and decentralized options to drive your pipeline goals. Topics to be discussed include:
• Discuss the settings for virtual trials and help define best fit options for study needs.
• How and when does the regulatory strategy get set to enable a successful filing?
• What are the challenges to drive both site and patient participation in virtual trials?
• What are the timeline and cost differences in planning for and executing virtual trial components?
• What are the key lessons learned from those who have been early adopters and champions?

1:05 Transition to Lunch

1:10 Send Off Luncheon Presentation to be Announced

1:40 Closing Remarks

1:45 SCOPE Summit 2020 Adjourns
Integrating Quality into Clinical Trials

Implementing Risk-Based Monitoring – Part 1

February 19-20

Poor quality and risk management of clinical trials significantly impacts the success, timeliness, and cost-effectiveness of clinical trials. CHI’s 6th Annual Implementing Risk-Based Monitoring – Part 1 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 recent changes to ensure higher-quality clinical trials and laying the foundation for successful risk-based monitoring. The program will focus on successful RBM implementation tactics employed by large, small, and mid-sized organizations. A special session is designed to discuss RBM in medical device trials.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*
*Seperate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall
10:40 Chairperson's Remarks
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium (MCC)

10:45 FEATURED PRESENTATION: The (R)evolution of Risk-Based Monitoring: A Tale of Two Deployments
Michael Walega, Head, Global Data Management & Centralized Monitoring, Bristol-Myers Squibb

11:25 Review of ICH E8 R1 – The Developing Regulatory Direction and How to Address
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
The release of ICH E8 R1 (draft) has cemented the direction that the Regulatory bodies want us to follow; that is towards a Quality by Design process, rather than “Quality by Accident” as some regulators have expressed. A background of the Regulatory presentations, guidances and discussions at meetings will be brought together to give their path of attack initially via RBM and now cemented in a compelling need for QbD. This presentation will take you stepwise through the following topics
- Regulatory background from "crumbs on the ground" to clear direction
- From early presentations from 2000 to recent (2019) Regulatory Guidance
- What is Quality by Design
- What QbD means to different areas of clinical development
- How can QbD principals be incorporated into RBM

11:45 Leveraging Process Control
Nechama Katan, Associate Director, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer

Risk Based Monitoring (RBM) is focused on eliminating errors that matter. Statistical Process Control (SPC) is a proven method for finding errors and systems that are out of control. SPC has been around for 100 years and has been applied to many different fields. This talk will explore the convergence of RBM and SPC.

12:15 pm Measuring Success of a Quality Risk Management Approach
Kristin Stallcup, Senior Director, Xcellerate Customer Success, Covance
ICH GCP E6 R2 introduced the risk-based approach in designing and conducting clinical trials and use of risk management and centralized monitoring tools has been increasingly recognized and adopted within the industry. During the research process, multiple metrics and indicators have been analyzed to determine the impact of the Risk Management Approach. Tools utilized and results presented could serve as a reference for the industry in setting up goals for successful quality risk management.

12:45 Transition to Lunch
12:50 LUNCHEON PRESENTATION: Using Advanced Risk-Based Monitoring Models to Improve Endpoint Data Quality
Todd Everhart, Clinical Vice President, Internal Medicine, Signant Health
Combining clinical insights with data analytical approaches significantly enhances the ability of risk-based monitoring programs to detect anomalous data and improve signal detection.
In this session, we will demonstrate the use of advanced risk-based analytics to detect and prevent data quality issues such as fraud, compliance with protocol, procedure violations, site staff lacking knowledge of study instruments used, etc. with real-life data across a number of therapeutic area indications.

3:50 Presentation to be Announced

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:20 Find Your Table and Meet Your Moderator

4:25 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 pages 32-37 or scopesummit.com/breakouts for details.

5:10 Welcome Reception in the Exhibit Hall

6:45 Close of Day

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: Navigating the Patient Journey: A Responsibility all Technology Providers Share

Mike Nolte, Chief Executive Officer, Signant Health

8:15 Session Break

RISK-BASED MONITORING FOR MEDICAL DEVICE TRIALS

8:20 Chairperson's Remarks

Francois Torche, CEO, Management, CluePoints

8:25 Novel Approaches to Risk-Based Monitoring for Medical Device Trials

Michelle Wetherby, MS, CCRP, Associate Director, Clinical Operations, Abbott Laboratories

As organizations become increasingly savvy about the implementation of risk-based monitoring, it is critical to evaluate current practice and make adjustments accordingly. This presentation will describe one organization's evolution in the practice of risk-based monitoring.
8:55 CO-PRESENTATION: Risk-Based Monitoring at Johnson & Johnson: From Pharma to Medical Device Clinical Trials
Stephanie Clark, Director, Risk Management-Central Monitoring, Janssen
R&D (J&J)
Erin Creedon, Associate Director, Clinical Operations, Ethicon (J&J)
RBM has been an industry buzz word for over 6 years now, but is the methodology relevant only for pharmaceutical clinical trials? Could there be benefits for medical devices studies? Join to hear how J&J is leveraging its success with RBM in pharma studies on a variety of medical device trials to learn more about global regulatory support for RBM, lessons learned from pharma and early experience with medical device studies, and the future of RBM in the medical devices space – the realization of value.

9:25 Risk-Based Quality and Compliance Management in Clinical Trials with Combination Products
Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine
A risk-based approach requires not only a strategy but also tools to define key indicators to measure specific risks. As reference from the recent FDA’s and EMA’s recently updated guidelines, Key Risk Indicators (KRIs) and Key Quality Indicators (KQIs) metrics should focus on “what really matters” and safety of research subjects and data integrity should be emphasized. Combination products, due to their specific nature, can increase risks while being tested in clinical trials. These critical metrics should be linked to particular processes within development programs for combination products.

9:55 Overcoming the Operational ‘Gap’ in RBQM
Duncan Hall, CEO, TRI
The RBQM conversation is moving from ‘why?’ to ‘how?’. The biggest challenges are operational change management and the creation of integrated strategic monitoring plans (ISMPs). ‘Critical to quality’ requires moving from routine monitoring and 100% SDV to focusing on data to be monitored, how, when and by who. Duncan shows you how to overcome these challenges, use big data analytics to do much of the monitoring ‘heavy-lifting’, and how to build ISMPs for your organization.

10:25 Coffee Break in the Exhibit Hall

11:25 Risk-Based Monitoring: A Joint Focus on Meaningful Risk Signal Detection and a Process for Action
Erin Reynolds, Manager, Clinical Analytics, Data and Statistical Science, Research & Development, Abbvie
There is a fundamental challenge with defining Risk-Based Monitoring (RBM): Is it a technology problem, a process problem, or an analytics problem? Abbvie approached RBM as a process and analytics problem. The KRIs were paired with a robust process, which was the key to realizing the potential of RBM – a culture shift that empowered all functions to use critical thinking to direct our efforts to the areas of greatest need.

11:45 CO-PRESENTATION: Statistical Surveillance Build & Grow – Adding a New Layer to RBM at Janssen
Christine Mazzucco, Global Trial Manager, The Janssen Pharmaceutical Companies of Johnson & Johnson
Dolly Ugi, Manager, Central Statistical Surveillance, The Janssen Pharmaceutical Companies of Johnson & Johnson
Statistical Surveillance is an internally developed statistical program that provides an additional layer of oversight as part of the analytical risk-based monitoring strategy. The review detects otherwise hard-to-identify data anomalies, allowing for intervention at a particular investigator site, or trial as a whole. This provides an additional layer of protection for subject safety and data quality. We will describe the launch of this new capability across all Janssen RBM trials.

12:05 pm Building an eTrial
Laura Whitmore, Head, Clinical Operations, Oversight, Cerevel Therapeutics
As a start-up, Cerevel was able to begin with a blank slate. We’ll share lessons learned as we incorporated various eTrial technology in Phase I, II and III trials within a year of start-up.

12:25 Transition to Lunch

12:30 Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Close of Conference

Stay on and attend Part 2: Implementing Risk-Based Monitoring – Part 2. See pages 60 & 61 for details.
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 6th Annual Implementing Risk-Based Monitoring – Part 2 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.


THURSDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm Bridging Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Coffee and Dessert Break in the Exhibit Hall

2:00 Afternoon Plenary Keynotes (See page 4 for details.)

3:10 Booth Crawl & Refreshment Break in the Exhibit Hall. Last Chance for Exhibit Viewing

IMPLEMENTATION CHALLENGES AND SOLUTIONS

4:10 Chairperson’s Remarks
Lewis Hower, Director, Risk Management-Central Monitoring, Janssen Pharmaceuticals

4:15 Quality Tolerance Limits: Achieving High Quality with a Tolerance for Imperfection
Lynne Cesario, Risk Based Monitoring Program Lead, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
ICH GCP R2 and Transcelerate definitions of Quality Tolerance Limits (QTLs) will be discussed and key differences between QTLs, risk indicators and action thresholds will be presented. An approach to QTL set-up, both in terms of selection of a parameter and identification of a tolerance limit, will be proposed.

4:45 Taking RBM for a Test Drive – How Trying before You Buy It Can Optimize Deployment Success
Rachel Lewis, Director, Project Management, Project Management Office, Global Clinical Trial Operations, Merck & Co., Inc.
Selection of the optimal RBM technology solution to ensure clinical data quality and maximum efficiency is critical for implementation success in any company. However, with the rapid growth in solutions available, how do you choose the right one? We will discuss the advantages, disadvantages and considerations for conducting a pilot of multiple solutions using internal study data to drive sound selection and optimize deployment success.

5:15 Presentation to be Announced

5:45 PANEL DISCUSSION: Moving Past the “i” in RBM: Partnership, Oversight, and Achieving Common Goals between Sponsor, CRO and Vendor
Co-Moderators: Sarah Bednarski, Associate Director, Strategic Monitoring, Clinical Operations, Sunovion Pharmaceuticals Inc.
Gayle Hamilton, Associate Director, Risk Based Monitoring, Project Operations and Business Performance, IQVIA
Panelists: Speakers of the Day
There are a variety of factors that may be complicating how sponsors, CROs and vendors work together in the RBM space: the formalized R2 requirement for “oversight”, the continuous evolution of RBM, the move past home-grown pilots, etc. There’s more than one right way to implement RBM, but in the outsourced model, establishing a common goal and a way to work together are both critical to success.
• What are your goals with RBM? This is an interesting opportunity to hear how goals differ between CROs, vendors and sponsors.
• If you were to go back to when you first starting working with your CRO/vendor/sponsor knowing what you know now, what would you do differently? E.g. Hold a combined training session; hold an expectations meeting with best practices from prior experiences; etc.
• What successes have you had? What are you still working on improving?
• In a collaboration between sponsor and CRO/vendor, what roles are important? E.g. Study team roles, specific functions, process-level roles across studies, etc.
• What, if any, limitations on transparency exist from CRO/vendor to sponsor or from sponsor to CRO/vendor, and have those limitations been overcome in some way?

6:15 Networking Reception

7:15 Close of Day
FRIDAY, FEBRUARY 21

7:15 am Registration Open
7:45 Breakfast Presentation to be Announced
8:15 Session Break

SESSION-PANEL: RBM AS A SPECTRUM

8:20 Chairperson’s Remarks
8:25 Risk-Based Monitoring in 2020: What Practical Lessons Can Veteran Companies Share?
Moderator: Laurie Halloran, CEO, Halloran Consulting Group, Inc.
Panelists: Carrie Melvin, Vice President, Global Clinical Sciences and Delivery TA Head of Oncology, GSK/TESARO
Vinod Parthasarathy, Senior Director, MC2 Global Monitoring & Clinical Operations (Japan & China), Medtronic
Cary Unger, Senior Clinical Operations Standards and Innovation Manager, Clovis Oncology
Laura Whitmore, Head, Clinical Operations, Oversight, Cerevel Therapeutics

The FDA’s guidance on Risk-Based Monitoring has been in use since August 2013, and the ICH E6 R2 has recently pushed the issue of using risk-based approaches to streamline the overly complex processes that cost life sciences sponsors so much and add so little. But, given that we tend to wrestle with “the way it’s always been done” – how has the adoption been progressing in both early adopters and companies new to the more expanded use of technology to enhance their adoption of risk-based approaches? On our panel, we will discuss how companies have fared and what practical lessons can be shared to facilitate adoption by other companies using the right-sized approach.

• How has trial design evolved in a risk-based approach?
• What is different in start-up: selection of sites and vendors, training of the entire team?
• If you aren’t doing it now, what is holding you back?
• The centralized monitoring role: What should we know to set up and manage the effort?
• Are there lessons learned and best practices that can be shared around remote site and even remote patient visits?

9:55 Sponsored Presentation (Opportunity Available)

PREPARING FOR FUTURE RENOVATIONS

10:05 Chairperson’s Remarks
Janis Little, Vice President, Global R&D Quality, Allergan

11:00 Assessing Your Clinical Quality Management System: A Comprehensive Review of TransCelerate’s CQMS Assessment Tool
Janis Little, Vice President, Global R&D Quality, Allergan

This session will help attendees assess clinical Quality Management Sessions to adhere to ICH E6R2 and prepare for future renovations and modernization of E6 and E8.

11:30 Sponsored Presentation (Opportunity Available)

12:00 pm Transition to Shared Sessions

FACILITATING THE TRIALS OF THE FUTURE NOW VIA THE CONNECTED PATIENT & DECENTRALIZED TRIALS

Chairperson’s Remarks
Neil Weisman, President, Continuum Clinical

12:05 The Connected Patient: A “One Stop Shop” for Trial Information and Data
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCD, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Learn how we are creating a connected experience for trial participants before, during and after the trial where patients can access meaningful information, their individual data to share with their EHR, aggregate study results and provide ongoing feedback and insights to ensure a better experience for patients, caregivers and the site teams. Explore the possibilities to remain connected via communities to raise awareness around trials. The audience can gain insights as to the ins and outs of how we managed to create a platform to share data directly with patients – from legal, privacy, regulatory and other key stakeholder hurdles to our vision for broadening the scope of data sharing across industry.

12:35 INTERACTIVE PANEL: Translating Virtual to Reality: Decentralized Trial Transformation
Moderator: Jane Myles, Head, Operational Intelligence and Innovation, Roche
Panelists:
Bardia Akbari, PharmD, Senior Vice President, Clinical Operations, Science37
Carrie Melvin, Vice President, Global Clinical Sciences and Delivery TA Head of Oncology, GSK/TESARO
Hassan Kadhim, Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers Squibb
Megan McBride, MPH, Associate Director, Janssen Clinical Innovation, GCD, R&D, Janssen, The Pharmaceutical Companies of Johnson & Johnson

Our expert panel will include a variety of perspectives and the aim is to provide pragmatic solutions and actionable advice to make virtual trials a realistic option for your study needs. We’ll discuss strategic and tactical needs to help you determine how to navigate and implement virtual and decentralized options to drive your pipeline goals. Topics to be discussed include:

• Discuss the settings for virtual trials and help define best fit options for study needs.
• How and when does the regulatory strategy get set to enable a successful filing?
• What are the challenges to drive both site and patient participation in virtual trials?
• What are the timeline and cost differences in planning for and executing virtual trial components?
• What are the key lessons learned from those who have been early adopters and champions?

1:05 Transition to Lunch
1:10 Send Off Luncheon Presentation to be Announced
1:40 Closing Remarks
1:45 SCOPE Summit 2020 Adjourns
Conference Venue & Hotel

Hyatt Regency Orlando
9801 International Drive, Orlando, FL 32819
T: 407-284-1234

Discounted Room Rate: $294 s/d (Price includes Resort Amenities)*
Discount Cut Off Date: January 22, 2020

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  Situated across the street from the Orange County Convention Center,
  and moments away from dining, shopping, and entertainment
- 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: Two tropical-inspired pools, a separate kiddie pool, a luxurious spa and salon, and a 24-hour gym with studio spaces and fitness classes
- No Commute - Conference takes place at the hotel

Go to the travel page of SCOPEsummit.com for additional info.

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The medical device industry comes with its own set of unique challenges when it comes to clinical trials, especially in light of the new medical device regulation coming out of the EU. CHI’s Inaugural Medical Device Clinical Trial Operations and Regulations conference will offer insight into navigating this new regulation ahead of the May 2020 deadline, as well as insights into pre- and post-market studies. The conference will also take a deep dive into risk-based monitoring for device trials and the impact of ICH E6 R2.

TUESDAY, FEBRUARY 18

9:00 am - 7:15 pm Registration Open
2:00 - 5:00 pm User Group Meetings
2:00 - 5:00 pm The NEW SCOPE China Clinical Development Partnering Forum and The NEW SCOPE Scientific Symposium*  
*Separate registration required. Must be a Best Value registered attendee.
5:00 - 6:20 pm Evening Kick-Off Plenary Keynote and Participant Engagement Awards (See page 3 for details.)
6:20 - 7:30 pm SCOPE's Kick-Off Networking Happy Hour
7:30 pm Close of Day

WEDNESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee
8:15 Morning Opening Plenary Keynotes (See page 4 for details.)
9:40 Grand Opening Coffee Break in the Exhibit Hall
10:40 Chairperson’s Remarks
Jane M. Jacob, PhD, CCRP, Vice President, Research and Clinical Affairs, Orthofix, Inc.

10:45 “The New Normal” – Are You Ready for Life under the Medical Device Regulation?  
Bill Bourdeau, Global Director, Clinical Operations, Biostatistics and Clinical Data Management, Clinical Affairs, Zimmer Biomet

We now have only a few months remaining before the entry into force of the European Medical Device Regulation (MDR). While manufacturers have been scrambling to gather clinical evidence and documentation to keep existing products on the EU market after May 26, 2020, once the dust has settled we must all adjust our mindset and business practices to the “new normal” under MDR/IVDR.

11:15 The Interplay Between the MDR and Data Protection Law  
Cécile van der Heijden, LLM, Attorney-at-law, Axon Lawyers

The MDR explicitly requires adherence to data protection law. As a consequence thereof, medical devices companies are obliged to take the GDPR into account when applying the MDR. This presentation will focus on what the interplay between MDR and GDPR means in practice, with a focus on the impact the GDPR has on the design requirements, incident reporting and the regime applicable to clinical investigations under the MDR.

11:45 INTERACTIVE PANEL: Navigating the EU MDR and Other Regulations  
Moderator: Cécile van der Heijden, LLM, Attorney-at-law, Axon Lawyers
Panelists: Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific Corporation
Additional Panelists To Be Announced

This panel will discuss strategies in finalizing device companies’ preparedness for the impending European Medical Device Regulation, and how this new regulation will – or will not – affect larger changes around the FDA’s regulations.

12:15 pm Sponsored Presentation (Opportunity Available)
12:45 Transition to Lunch
12:50 Luncheon Presentation (Sponsorship Opportunity Available)  
or Enjoy Lunch on Your Own
1:20 Coffee and Dessert Break in the Exhibit Hall

NAVIGATING THE EUROPEAN MEDICAL DEVICE REGULATION

PRE- VS. POST-MARKET STUDIES

2:15 Chairperson’s Remarks

2:20 Pre- and Post-Market Studies: Addressing Challenges Unique to Medical Devices  
Jane M. Jacob, PhD, CCRP, Vice President, Research and Clinical Affairs, Orthofix, Inc.

Medical device studies, either pre- or post-market, are unique compared with drug studies. Knowing what those similarities and differences are, and how to tackle them, is the key to running successful studies. In this presentation, I will discuss some of the strategies I have found that work for both IDE and post-market studies in terms of site identification, qualification, start-up and follow-up, and suggest different approaches one can take to (hopefully) achieve success.

2:50 Pre- and Post-Market Studies: Use of Real Word Data (RWD)  
Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific Corporation
Navigating Regulations and Operational Challenges for Quality Medical Device Clinical Trials

THURSDAY, FEBRUARY 20

7:15 am Registration Open

7:45 Breakfast Presentation to be Announced

8:15 Session Break

RISK-BASED MONITORING FOR MEDICAL DEVICE TRIALS

8:20 Chairperson's Remarks
Steve Young, CSO, Management, CluePoints

8:25 Novel Approaches to Risk-Based Monitoring for Medical Device Trials
Michelle Wetherby, MS, CCRP, Associate Director, Clinical Operations, Abbott Laboratories
As organizations become increasingly savvy about the implementation of risk-based monitoring, it is critical to evaluate current practice and make adjustments accordingly. This presentation will describe one organization's evolution in the practice of risk-based monitoring.

8:55 CO-PRESENTATION: Risk-Based Monitoring at Johnson & Johnson: From Pharma to Medical Device Clinical Trials
Stephanie Clark, Director, Risk Management-Central Monitoring, Janssen R&D (J&J)
Erin Creedon, Associate Director, Clinical Operations, Ethicon (J&J)
RBM has been an industry buzz word for over 6 years now, but is the methodology relevant only for pharmaceutical clinical trials? Could there be benefits for medical device studies? Join to hear how J&J is leveraging its success with RBM in pharma studies on a variety of medical device trials to learn more about global regulatory support for RBM, lessons learned from pharma and early experience with mMedical device studies, and the future of RBM in the medical device space – the realization of value.

9:25 Risk-Based Quality and Compliance Management in Clinical Trials with Combination Products
Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine
A risk-based approach requires not only a strategy, but also tools to define key indicators to measure specific risks. As reference from the recent FDA's and EMA's recently updated guidelines, Key Risk Indicators (KRIs) and Key Quality Indicators (KQIs) metrics should focus on "what really matters", and safety of research subjects and data integrity should be emphasized. Combination products, due to their specific nature, can increase risks while being tested in clinical trials. These critical metrics should be linked to particular processes within a development program for combination products.

9:55 Sponsored Presentation (Opportunity Available)
THE ROLE OF CLINICAL DATA IN BRINGING MEDICAL DEVICES TO MARKET

11:20 Chairperson’s Remarks
Glenda Guest, President, Assured of Quality Consulting & Training

11:25 INTERACTIVE PANEL: Medical Device Pathways to Market in the US and the Role of Clinical Data
Moderator: Glenda Guest, President, Assured of Quality Consulting & Training
Panelists: Chris Cain, Vice President, Clinical & Regulatory Affairs, Conformal Medical, Inc.
Patti Connolly, Executive Vice President, Product Development, RenalytixAI
Victor Chen, Managing Director, Clinical Trials Program, Kaiser Permanente Northern California
Additional Panelists To Be Announced
As EU Device Regulations become more harmonized with the FDA there is a greater focus on the role clinical trial data in the US. Following an overview of the major pathways to market and the role of clinical data for devices in the US (Premarket Notification, Premarket Approval, Humanitarian Device Exemptions) the panel will discuss trends, FDA’s new breakthrough device designation and global harmonization challenges. Audience participation will be encouraged.

12:25 pm Transition to Lunch