

April 6-8, 2020 • Hyatt Regency Cambridge • Cambridge, MA



Cambridge Healthtech Institute's 9th Annual

Clinical Trial Innovation SUMMIT

Technology • Data • Operations • Oversight

5 Concurrent Conferences

**REGISTER BY MARCH 6
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3 Plenary Keynotes

**Workshops Included
Pre-Conference**

300+ Global Delegates

**Interactive Breakout
Discussions**

**Join Executive
Leaders from:**

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Plus! Patients and Patient Advocacy Groups

ClinicalTrialSummit.com

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About the Event

From the producers of SCOPE: Summit for Clinical Ops Executives, is CHI's 9th Annual Clinical Trial Innovation Summit to be held on April 6-8, 2020, in Cambridge, MA. Hear from clinical ops leaders & clinical research innovators from pharma, biotech and academia for the perfect blend of high-quality presentations and intimate networking. Through case studies, workshops, panel & roundtable breakout discussions and an active exhibit hall, the summit delivers the real-world experiences and best practices needed to optimize clinical trial innovation, planning and management.

5 Concurrent Conferences



Feasibility &
Site Selection



Data &
Technology



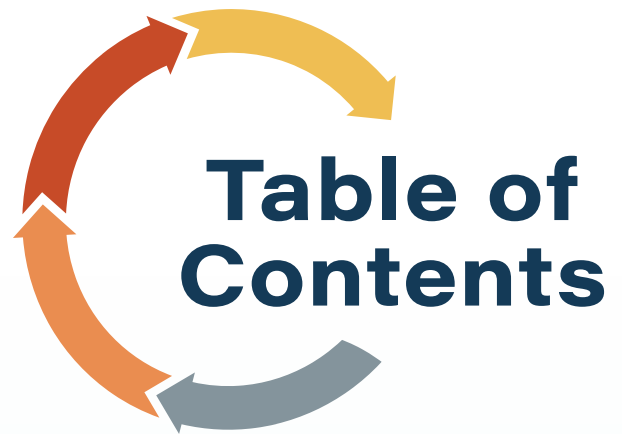
Engagement
& Enrollment



Risk-Based
Monitoring



Budgeting &
Outsourcing



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Cambridge Healthtech Institute's 9th Annual

Clinical Trial Innovation SUMMIT

April 6-8, 2020 · Cambridge, MA
Hyatt Regency Cambridge

**EVENT AT
A GLANCE**

DAY 1 » Monday, April 6

Workshops (*Sponsorship Opportunity Available*)

DAY 2 » Tuesday, April 7

Opening Plenary Keynote:

Real World Data, Artificial Intelligence & Analytics to Reshape Clinical Development

Grand Opening Coffee Break (*Sponsorship Opportunity Available*)

Feasibility &
Site Selection

Data &
Technology

Engagement
& Enrollment

Risk-Based
Monitoring

Budgeting &
Outsourcing

Luncheon Presentation (*Sponsorship Opportunity Available*)
or Enjoy Lunch on Your Own

Dessert Coffee Break in Exhibit Hall (*Sponsorship Opportunity Available*)

Afternoon Plenary Keynote:

Why Do Trials Succeed & Why Do They Fail? Insights from Industry & Academia

Welcome Reception in the Exhibit Hall (*Sponsorship Opportunity Available*)

DAY 3 » Wednesday, April 8

Feasibility &
Site Selection

Data &
Technology

Engagement
& Enrollment

Risk-Based
Monitoring

Budgeting &
Outsourcing

Coffee Break in the Exhibit Hall (*Sponsorship Opportunity Available*)

Interactive Roundtable Breakout Discussions

Community Networking Lunch in the Exhibit Hall (*Sponsorship Opportunity Available*)

Closing Keynotes: Understanding the Patient Journey to Improve Trials

Sponsorship, Exhibit & Lead Gen Information

Sponsorship & Exhibit Opportunities

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

Chairperson and Client Case Study Presentations

— Available within Main Agenda!

Chair a session with 10-minutes opening remarks or showcase your solutions to a guaranteed, targeted audience. Presentations within the agenda should be given a Subject Matter Expert (SME) or an executive in Clinical Innovation/Operations/Analytics/etc. and not a Marketing or Business Development representative. Sponsorships include a 15-minute presentation in the scientific agenda, exhibit space, branding, full conference registrations, use of the event mailing list and more.

Luncheon Presentations

Opportunity includes a 25-minute podium presentation in the main session room. Client case study presentations are highly encouraged. Lunch will be served to all delegates in attendance. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

One-on-One Meetings

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.

Invitation-Only Dinners / Hospitality Suites

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending invitations, to venue suggestions, CHI will deliver your prospects and help you make the most of this invaluable experience.

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve your exhibit with sponsorship today!

Additional Opportunities Available for Sponsorship Include:

- Pre- or Post-conference Workshop
- Reception
- Focus Group
- User Group Meeting
- Conference Tote Bags
- Badge Lanyards
- Conference Notebook
- ...and More!

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 over 800,000 life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- White Papers
- Webinar
- Custom Market Research Survey
- Podcasts

2019 Attendee Demographics

TO SPONSOR & EXHIBIT, CONTACT:



Companies A-K

Ilana Quigley

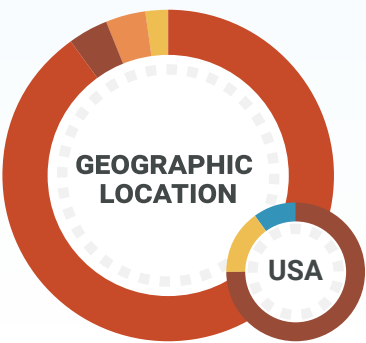
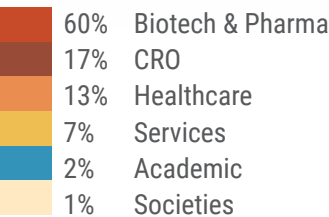
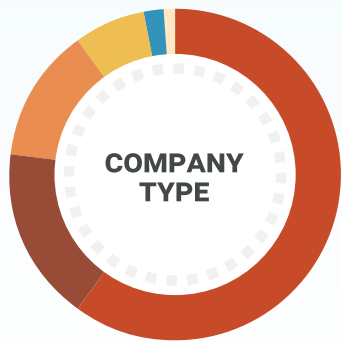
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Companies L-Z

Patty Rose

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Workshops

Monday, April 6 | 2:30 – 5:30 pm

Arrive Monday afternoon with your team to join any of the in-depth workshops below. The workshops are designed for experts as well as for those new to the topic area. The workshops are included in your conference registration, but we ask you to please RSVP to reserve your seat.

WORKSHOP 2:

Digital Clinical Development: Tutorial, Case Studies, and Future Readiness

Munther Baara, PhD, Vice President, Product Strategy and Innovation,
EDETEK

WORKSHOP 3:

Inspection Readiness in Changing Global Regulatory Environment

Marina Malikova, PhD, Executive Director, Surgical Translational Research:
Operations and Compliance, Boston University School of Medicine
Julia Martinisi, Project Director, Clinical Operations Consultant, JM
Pharma Consulting

Are you a young researcher in rare disease? Join us in Cambridge in April!

Uplifting Athletes and Cambridge Healthtech Institute are proud to include some new young researchers in rare disease at this conference. They are our future partners. Advocacy groups interested in nominating young researchers for the Uplifting Athletes Young Investigator Draft can submit to: www.upliftingathletes.org/rare-disease-research; **Nominations open on November 21, 2020.**

If you are a young researcher interested in attending this event as a special guest to participate in the discussions, network with others from industry, CROs, academia and patient communities, and to share information about your research and your teams at the event, please submit your information, a link to your lab and/or research, and why you would like to attend to mlieberman@healthtech.com. We will be reviewing the applications and will reply to you directly.



Hotel & Travel

CONFERENCE VENUE & HOST HOTEL:

Hyatt Regency Cambridge

575 Memorial Drive
Cambridge, MA 02139
(617) 492-1234

Go to the travel page of
ClinicalTrialSummit.com
for more information

Discounted Room Rate:
\$249 s/d

Discounted Room Rate Cut-off Date:
March 10, 2020



Feasibility & Site Selection

MONDAY, APRIL 6

2:30-5:30 PM PRE-CONFERENCE WORKSHOPS

Workshop 2: Data-Driven Clinical Development: Tutorial and Case Studies

Workshop 3: Inspection Readiness in Changing Global Regulatory Environment

**Workshops are included in your registration. However, please RSVP to reserve your seat. See page 5 for details.*

TUESDAY, APRIL 7

8:15 am Registration and Morning Coffee

REAL WORLD DATA, ARTIFICIAL INTELLIGENCE AND ANALYTICS TO RESHAPE CLINICAL DEVELOPMENT

9:00 Organizer's Opening Remarks

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

9:05 Chairperson's Remarks (Sponsorship Opportunity Available)

9:10 Digitalization of Clinical Trials: Breakthroughs in Technologies and Data

Peter Bergethon, MD, Vice President, Head of Digital and Quantitative Medicine, Biogen

Medicine as systems science characterizes the health state by measurable properties. Changes in state over time (dynamics) define trajectories through growth, health and disease. Dynamic transitions define trajectories between health, illness and therapeutic interventions. Capturing time dependence is the power of digital technology. Herein lies the power of digital medicine. We will review specific cases showing how this paradigm is transforming our clinical trial landscape.

9:30 CO-PRESENTATION: The Role of Real-World Data in Creating New Pathways to Biopharma Industry Transformation

Alan Louie, PhD, Research Director, Life Sciences, IDC Health Insights

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

In parallel to other industry best practices, the biopharmaceutical industry is embracing digital transformation as it seeks to better leverage data across the life science ecosystem. In conjunction with these efforts, increasingly available real-world data (RWD) promises to bring new patient-specific data and insights to the industry, data which bring researchers closer to understanding patient-level treatment responses while also opening new channels to engagement. With strong support from regulators, real-world evidence offers significant potential to accelerate new drug discovery and development, improve process efficiencies, and improve patient outcomes over the near term.

9:50 AI in Human Health – Connecting Data Modules from Discovery Biology to Clinical Development

Rangaprasad Sarangarajan, PhD, CSO & Senior Vice President, Clinical and Translational Sciences, Research & Development, BERG

Drug development programs in companies are predicated on biological insights supporting a hypothesis of target and its role in disease etiology. This presentation will focus on the data modules essential for linking discovery biology to early/late stage clinical development and the leveraging of AI in the integration of the various dataflow to make data-driven informed decisions and ensure success. It will outline how to utilize data, AI analytics with RWD-based support for planning drug development to propel products all the way through the clinic.

10:10 Grand Opening Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

PROTOCOL OPTIMIZATION & FEASIBILITY ASSESSMENT

11:10 Chairperson's Remarks (Sponsorship Opportunity Available)

11:20 Data Science in Protocol Optimization

Beth Mahon, Global Feasibility Therapeutic Area (TA) Head, Feasibility Center of Excellence (FCoE), Clinical Insights and Experience, Oncology, Janssen

Potential to merge, overlay, and analyze data is proving to increase the ability to be predictive in achieving earlier and better outcomes in the area of protocol optimization. Janssen is using natural language processing in the development of benchmarks for computing patient burden and site burden and the correlation of trial burden, trial costs, and actual enrollment with design parameters and amendments. Ultimately, this allows for protocol design with better consideration of patient and site voice and fewer protocol amendments.

11:50 PANEL DISCUSSION: Incorporating Site Input into the

Protocol Development Process

Moderator: Christina Brennan, MD, MBA, Vice President, Clinical Research, Northwell Healthcare

Panelists: MarieElena Cordisco, MA, APRN, NP-C, NuVance Health; Director Clinical Trials, Western Connecticut Health Network; Interim Director, Division of Research, Health Quest

Jane Hart, Vice President, Global Clinical Affairs, 3M Health Care

Beth Mahon, Global Feasibility Therapeutic Area (TA) Head, Feasibility Center of Excellence (FCoE), Clinical Insights and Experience, Oncology, Janssen

We've all experienced the frustration of an "ideal" sponsor protocol that is challenging for sites to execute or for patients to participate in. This panel discussion will provide interactive insights into how sites and industry can partner together more effectively to design relevant clinical trial protocols and optimize study execution for all stakeholders.

12:35 pm Transition to Luncheon Presentation

12:40 Luncheon Presentation (Sponsorship Opportunity Available)



Feasibility & Site Selection

or Enjoy Lunch on Your Own

1:25 Coffee & Dessert Break in the Exhibit Hall (Sponsorship Opportunity Available)

INNOVATIONS TO IMPROVE STUDY SUCCESS

2:00 Chairperson's Remarks (Sponsorship Opportunity Available)

2:10 PANEL DISCUSSION: Building and Implementing an IT Ecosystem for Master Trials

Moderator: Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML/LLS

Panelists: Hugh Levaux, Founder and CEO, Protocol First

Rick Arlow, CEO, Complion, Inc.

We are in the age of information, but we don't necessarily use, analyze, or share data in the most effective way. What would happen if pharma routinely participated in Master Trials managed by non-profits as an alternative to traditional clinical trials? Should it be a core element of their pipeline strategies? A centralized resource to quickly and efficiently examine drug candidates. What if our collaborative efforts would streamline decision-making so that the most effective drugs could be fast-tracked into clinical trials? Could we save time, money, and other resources if our go/no-go decisions were made in months instead of years? This panel will describe a novel approach to genomic-based decision-making to optimize breakthrough therapeutics. This drug development model combines scientific innovation and next-gen e-clinical technologies to radically change the drug development landscape.

2:40 Simplifying and Modernizing Clinical Trials

Sponsored by
teckro

WHY DO TRIALS SUCCEED AND WHY DO THEY FAIL? INSIGHTS FROM INDUSTRY AND ACADEMIA

3:35 Organizer's Opening Remarks

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

3:40 Chairperson's Remarks (Sponsorship Opportunity Available)

3:45 BEST CLI Trial: Lessons Learned From Execution Of A Complex Multicenter RCT

Alik Farber, MD, Chief, Division of Vascular and Endovascular Surgery, Associate Chair for Clinical Operations, Department of Surgery, Boston Medical Center; Professor of Surgery and Radiology, Boston University School of Medicine

The BEST-CLI trial is the largest RCT ever undertaken to evaluate strategies for treatment of critical limb ischemia (CLI). This study is an international, multispecialty, prospective, multicenter, randomized comparative effectiveness trial of endovascular versus open surgical revascularization in patients with CLI who are candidates for both procedures. The study has been performed at 134 sites and has enrolled 1843 patients. Its execution had had multiple obstacles and challenges that the trial leadership team has successfully navigated.

at Cancer Research Site Networks

Cayce Drobek, Director, Clinical Operations, Teckro

Teckro is currently collaborating with large oncology research institutions to help to modernize and simplify cancer research. Join this session to learn more about how Teckro is working with site networks to simplify the conduct of trials and make them more transparent and inclusive for investigators, site staff, and patients.

2:55 PANEL DISCUSSION: The Tried and True Traditional vs. the AI Enabled Promise: Compare and Contrast

Moderator: Jane Myles, Founder and Director, JemTech; Former Head, Operational Intelligence and Innovation, Roche

Panelists: Brandon Maggio, Associate Director, Global Clinical Operations, Boehringer Ingelheim Pharmaceuticals

Ronald Dorenbos, PhD, Head, Innovation Management & Scouting, Innovation & Technology Science, Takeda

Gabriela Feldberg, Practice Leader, Applied Analytics & Artificial Intelligence, AstraZeneca

In this session our panel will offer real life examples of using our tried and true approaches to solving problems for clinical trials and compare them to AI-enabled solutions for similar problems. The intent is to help the audience understand what might be an appropriate problem for AI support and what the challenges are in implementing that. If possible we'll compare outcomes for the problems that were tackled.

3:25 Transition to Keynote

4:15 CO-PRESENTATION: What Causes Studies to Fail? Understanding Causal Drivers of Operational Success Using Machine Learning

Marcy Kravet, BS, MBA, Head, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany
Sylvia Marecki, PhD, Design Analyst, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany

It is currently unknown what drives successful study enrollment despite extensive analysis conducted across the industry, which largely has focused on correlations. The Operational Design Center at EMD Serono has leveraged causal machine learning to analyze hundreds of variables across thousands of clinical trials with the objective of identifying causal drivers of enrollment success, which can be optimized to conduct faster, less expensive trials. Early insights will be shared.

4:45 Welcome Reception in the Exhibit Hall (Sponsorship Opportunity Available)

5:45 End of Day



Feasibility & Site Selection

WEDNESDAY, APRIL 8

7:45 am Breakfast Presentation (*Sponsorship Opportunity Available*)
or Morning Coffee

NEW TRENDS AND INNOVATIONS IN SITE SELECTION

8:25 Chairperson's Remarks

Chairperson to be Announced, Teckro Ltd.

8:35 Improving Clinical Trial Site Selection Using Advanced Analytics

Kaitlin Folweiler, PhD, Data Scientist, R&D Data Science, Analytics and Insights, Janssen

Determining which sites will achieve on-time and on-target patient enrollment is one of the most difficult aspects of clinical trial site selection. Relying solely on historical performance has been shown to be a weak predictor of future site performance and of overall trial timelines. To deliver robust predictions of site enrollment, we developed an advanced analytics pipeline using big data analytics and machine learning to assist with site selection internal trials. We will explore approaches to scaling our pipeline to the entire portfolio of clinical trials and will highlight recent successes and the challenges that lie ahead.

9:00 Shifting the Paradigm in Building Evidence-Driven Site Profiles for Clinical Trial Participation

Justin Hensperger, MS: Clinical Trial Science, Site Intelligence Lead – Associate Director, Internal Medicine, Pfizer

Can we challenge the status quo to effectively develop predictive algorithms to build an ideal site profile based on key indicators on performance, start-up, quality and competitive intelligence? This presentation will provide a real-world demonstration on how a new methodology can improve transparency and collaborative efforts to optimize study execution. We have developed an innovative approach that aims to change the paradigm in site selection.

9:25 CO-PRESENTATION: Challenges and Successes in Building and Implementing a Data-Driven Site Selection Approach

Sandra Smyth, Head, Global Feasibility & Site Intelligence, 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 that teams have meaningful information needed, at the time needed, to make the best decisions for their studies.

9:50 Coffee Break in the Exhibit Hall (*Sponsorship Opportunity Available*)

TOOLS AND STRATEGIES TO IMPROVE SITE ACTIVATION & STUDY START-UP

10:40 Chairperson's Remarks

 (*Sponsorship Opportunity Available*)

10:50 Expediting Study Start-Up in Global Clinical Trials

Amanda Hayden, Senior Director, Global Clinical Services, Clinical Operations, Alkermes

When planning for study start-up in Ex-US countries, sponsors focus on regulatory approvals, site level clinical trial agreements, study drug shipment availability and study equipment readiness to allow for timely site activations. Sometimes there are hurdles in regulatory pathways that delay start-up whereas other times there could be issues with shipping equipment or drug supply. As a sponsor company, one needs to stay on top of the changing regulatory and compliance landscape and clinical site level complications for study conduct. CROs play a vital role in overseeing local activities supporting start-up and partnering with them effectively is key to ensure sponsor companies meet start-up objectives and goals. This presentation will share obstacles in planning Ex-US clinical studies and how to plan efficiently to meet your site activation goals.

11:15 Accelerating Study Start-Up – A Site Perspective

Lale Akka, MBA, CCRA, Executive Director, Clinical Trials Unit, University of Louisville

Both sponsors and sites have a common goal: a successful trial. Success can only be achieved if multiple perspectives are considered. A collaborative approach in site selection leads to increased success in study enrollment. After being selected as a site by the sponsor, UofL Clinical Trials Unit uses its own sponsor questionnaire to evaluate the project from the site perspective. The goal is to make sure that the study is the right one both for the sponsor and the site.

11:40 Transition to Breakout Discussions

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

(See pages 27 & 28 for details)

11:45 Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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

12:30 pm Community Networking Lunch in the Exhibit Hall
(*Sponsorship Opportunity Available*)

1:40 Transition to Plenary Keynote



Feasibility & Site Selection

UNDERSTANDING THE PATIENT JOURNEY TO IMPROVE TRIALS

1:45 Organizer's Opening Remarks

Kaitlin Searfoss Kelleher, Senior Conference Director, Cambridge Healthtech Institute

1:50 Chairperson's Remarks (Sponsorship Opportunity Available)

1:55 The Journey from Patient to Advocate to Leader: Changing the Clinical Research Game

Rob Long, Executive Director, Uplifting Athletes

I will talk about my journey from Division I football and top NFL prospect to cancer patient. My experience of undergoing chemo and radiation and fighting through a battle with brain cancer has enabled me to leverage my story to make a difference in the lives of those affected by rare diseases. The attendees will gain insights into what it means to be a volunteer at the front lines of oncology research and clinical trials. New approaches to partnering with advocates, disease communities and young researchers will be shared. In addition, we will discuss the future of rare disease research and outreach and illustrate where industry and the patient community can go together in collaboration.

NOTE: Uplifting Athletes and Cambridge Healthtech Institute are proud to include some new young researchers in rare disease at this conference. They are our future partners. Advocacy groups interested in nominating young researchers for the Uplifting Athletes Young Investigator Draft can submit to: <https://www.upliftingathletes.org/rare-disease-research>; Nominations open on November 21, 2020. See page 5 for additional information on applying for a guest pass directly.

2:10 PATIENT CO-PRESENTATION: The Patient's Point of View: Clinical Trial Perceptions and Experiences

Annick de Bruin, MBA, Director, Research Services, Center for Information & Study on Clinical Research Participation (CISCRP)

Phyllis Kaplan, Trial Volunteer and Patient with T1D

Results from a large-scale global study conducted in 2019 among patients and the public offer robust insights into the latest perceptions of clinical research and enrollment barriers, as well as patient engagement preferences (exploring patient receptivity to virtual trial models and the latest technologies). The 2019 CISCRP Perceptions & Insights study is the largest global study of its kind (over 12,400 responses from around the world, including experiences of 3,600+ prior study participants), offering robust global insights that audience members can directly apply within their own organizations. Learn what information is critical to support the participation decision-making process from the patient's point of view. Identify key participation elements which matter most to patients and their support network. Determine which convenience-enhancing solutions create the biggest impact on overall experiences.

2:30 CASE STUDY CO-PRESENTATION: Co-Creating with Patients to Create a Better Clinical Trial Experience

Jackie Zimmerman, Patient Advocate

Maura Snyder, MBA, Global Head, Clinical Trial Engagement, Clinical Insights and Experience, Janssen Pharmaceuticals

Janssen, in partnership with one of our patient advocates, will co-present on an initiative established in 2019 to bring the global patient perspective and input into the Janssen patient engagement plans in immunology. While it's important to hear about the strides that the industry is making in the areas of patient engagement – it's more important to hear directly from the patients about their perspective on this. This discussion will provide the audience practical, tangible ways to approach patient engagement. There are a variety of methodologies to approach this patient voice work and we will share one way that we have found to be very beneficial and successful.

2:55 Closing Remarks

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

3:00 Close of Conference

Free Patient & Caregiver Registrations are Available!

We have 15 scholarships for patients or caregivers who have participated in a clinical trial and are interested in contributing to the summit. A complimentary registration is not available to those with a commercial interest. Cambridge Healthtech Institute is not responsible for hotel or travel expenses.

To apply for a special patient/caregiver pass, please email your contact information and a little background about your role in clinical research to:



Micah Lieberman
Executive Director, Conferences
Cambridge Healthtech Institute (CHI)
mlieberman@healthtech.com

For help with general registration, group registration, and company-wide discounts, please email:



Melissa Dolen
781-972-5418
mdolen@healthtech.com



Data & Technology

MONDAY, APRIL 6

2:30-5:30 PM PRE-CONFERENCE WORKSHOPS

Workshop 2: Data-Driven Clinical Development: Tutorial and Case Studies

Workshop 3: Inspection Readiness in Changing Global Regulatory Environment

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TUESDAY, APRIL 7

8:15 am Registration and Morning Coffee

REAL WORLD DATA, ARTIFICIAL INTELLIGENCE AND ANALYTICS TO RESHAPE CLINICAL DEVELOPMENT

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9:05 Chairperson's Remarks (Sponsorship Opportunity Available)

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9:50 AI in Human Health – Connecting Data Modules from Discovery Biology to Clinical Development

Rangaprasad Sarangarajan, PhD, CSO & Senior Vice President, Clinical and Translational Sciences, Research & Development, BERG

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10:10 Grand Opening Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

eDATA, BLOCKCHAIN, ADAPTIVE TRIALS

11:10 Chairperson's Remarks

Chairperson to be Announced, Complion, Inc.

11:20 DMD Phase II and Phase III Study Lessons Learned with Various eData Collection

Susan Bornstein, MPH, Senior Director, Data Monitoring and Data Management, Global Product Development, Pfizer Inc.

The Phase II study collected 12 types of eData, including activity monitoring (wrists and ankles), ePRO, biomarkers, immunogenicity, imaging, labs and biopsy data. This presentation will review the process of how Pfizer decides on the data collection strategy through the data analysis. With >70% of the data collected in our trials coming direct from source, we need to change how we manage our data. This presentation will highlight how we work today and where we are going.

11:45 Simulating Patient Matching to Clinical Trials Using a Property Rights Blockchain: A Study in Applying Blockchains to Biomedical Data Processing

Jay Bergeron, Director, Pfizer Digital, Pfizer Inc.

Biomedical data processing typically requires the secure stepwise transfer of sensitive personal information across multiple parties. In an effort to explore alternatives without supplemental peer-to-peer communications, the Bitmark property rights blockchain was used to design and simulate the process of assessing the suitability of individuals to enroll in specific clinical trials.



Data & Technology

12:10 pm CO-PRESENTATION: Advances in Personalized Medicine: How Technology Based on Predictive Power Can Advance Clinical Trials

Matt De Silva, Founder and CEO, Notable

Don Berry, PhD, Founder & Senior Statistical Scientist, Berry Consultants, LLC; Professor, Biostatistics, University of Texas MD Anderson Cancer Center

Effective treatment and time-to-treatment are both essential elements of fighting cancer. Advances in personalized medicine now make it possible to analyze samples for individual patients and point physicians and patients towards the drugs, drug combinations and clinical trials that are likely to be most effective for their unique cancer. New technology platforms and techniques have the potential to drastically improve the way physicians treat cancers and save more lives.

12:35 Transition to Luncheon Presentation

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:25 Coffee & Dessert Break in the Exhibit Hall (Sponsorship Opportunity Available)

DIGITAL TECHNOLOGIES TO RESHAPE CLINICAL TRIALS

2:00 Chairperson's Remarks (Sponsorship Opportunity Available)

2:10 PANEL DISCUSSION: Accelerating Adoption of Digital Biomarkers and RWE in Clinical Research

Moderator: Robert Wilson III, Consultant, Wilson Digital Health Consulting

Digital clinical endpoints derived from wearables and other mobile and remote sensors hold great promise to improve clinical trial efficiency and patient

outcomes. However, real issues regarding scientific validation, operational deployment, regulatory oversight and patient engagement and compliance pose significant challenges that must be overcome. In addition, real-world evidence (RWE) from remote sensors can be combined with other data streams in the health ecosystem (EMR, lab, claims, genomic data) to help improve patient care and clinical trial efficiency and effectiveness. What can we learn from what has been done to date and how do we position ourselves to accelerate the adoption of these tools in the future?

Panelists:

The Small and Big Picture – An Example of Remote Device and Digital Data Adoption Considerations in Clinical Trials and a View on How Pharma Can Transform Their Approach to Digital Adoption

Jake LaPorte, Co-Founder & Global Head of the Novartis Biome, Novartis

Considerations in Adoption of Remote Digital Patient Data Capture in Clinical Trials

Peter Bergethon, Vice President, Head of Digital and Quantitative Medicine, Biogen

RWE Created by Sensors: The Use of Sensor Technologies in Clinical Trials

Judith Kornfeld, MBA, Chief Business and Operations Officer, ORCATECH, Oregon Health and Sciences University

Reducing Friction in Adaption of RWE and Remote Sensors in Clinical Trials

Sam Roos, Co-Founder, Head of Life Sciences, Datavant

3:10 Sponsored Presentation (Opportunity Available)

3:25 Transition to Keynote

WHY DO TRIALS SUCCEED AND WHY DO THEY FAIL? INSIGHTS FROM INDUSTRY AND ACADEMIA

3:35 Organizer's Opening Remarks

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

3:40 Chairperson's Remarks (Sponsorship Opportunity Available)

3:45 BEST CLI Trial: Lessons Learned From Execution Of A Complex Multicenter RCT

Alik Farber, MD, Chief, Division of Vascular and Endovascular Surgery, Associate Chair for Clinical Operations, Department of Surgery, Boston Medical Center; Professor of Surgery and Radiology, Boston University School of Medicine

The BEST-CLI trial is the largest RCT ever undertaken to evaluate strategies for treatment of critical limb ischemia (CLI). This study is an international, multispecialty, prospective, multicenter, randomized comparative effectiveness trial of endovascular versus open surgical revascularization in patients with CLI who are candidates for both procedures. The study has been performed at 134 sites and has enrolled 1843 patients. Its execution had had multiple obstacles and challenges that the trial leadership team has successfully navigated.

4:15 CO-PRESENTATION: What Causes Studies to Fail? Understanding Causal Drivers of Operational Success Using Machine Learning

Marcy Kravet, BS, MBA, Head, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany
Sylvia Marecki, PhD, Design Analyst, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany

It is currently unknown what drives successful study enrollment despite extensive analysis conducted across the industry, which largely has focused on correlations. The Operational Design Center at EMD Serono has leveraged causal machine learning to analyze hundreds of variables across thousands of clinical trials with the objective of identifying causal drivers of enrollment success, which can be optimized to conduct faster, less expensive trials. Early insights will be shared.

4:45 Welcome Reception in the Exhibit Hall (Sponsorship Opportunity Available)

5:45 End of Day



Data & Technology

WEDNESDAY, APRIL 8

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

IMPACT OF AI ON CLINICAL TRIALS

8:25 Chairperson's Remarks (Sponsorship Opportunity Available)

8:35 AI in Pharma & Clinical Trials

Ronald Dorenbos, PhD, Head, Innovation Management & Scouting, Innovation & Technology Science, Takeda

The presentation will discuss how AI-related approaches are changing the way clinical trials are executed. The patient's perspective on implementation of AI in clinical trials will briefly be reviewed and the presentation will highlight implementation of AI in a variety of areas within the pharma value chain. The presentation will be concluded with a brief look into the future.

8:50 Your Brain at Your Fingertips

Ijah Mondesire-Crump, MD, Research Director, nQ Medical Inc

At nQ medical we have discovered a powerful source of information in the way we interact with our personal devices. Typing is a complex task that relies on intact motor and cognitive pathways. Impairments in any part of these pathways (such as motor impairments seen in neurodegenerative diseases) are detectable through the way our fingers interact with a computer keyboard or a smartphone screen. As personal devices become more and more frequent, we now have the opportunity to evaluate ourselves on-the-go with continuous, objective and passive monitoring.

9:05 CO-PRESENTATION: The Future is Now: Using Predictive Algorithms and Machine Learning to Identify the Best Sites for Your Studies

Liz Beatty, Chief Strategy Officer, Inato

Robert Howal, US Site Partnership Manager, Oncology, Sanofi

Industry reports estimate that by 2020, medical data will double every 73 days and there could be \$100 billion in annual savings by leaning on big data as well as the artificial intelligence and machine learning tools to process it. To test these new approaches for study planning, Sanofi partnered with Inato to deploy its algorithm across several studies in order to predict site performance. The algorithm was able to accurately tier sites by performance, which provides the opportunity to significantly reduce the number of sites needed to meet the trial timelines and reduce study costs.

9:20 PANEL DISCUSSION: AI for Clinical Trials: Adaptation, Hurdles and Advantages

Moderator: Ronald Dorenbos, PhD, Head, Innovation Management & Scouting, Innovation & Technology Science, Takeda

Panelists:

Ijah Mondesire-Crump, MD, Research Director, nQ Medical Inc

Liz Beatty, Chief Strategy Officer, Inato

Eric Gildenhuys, Vice President, Business Development, Deep 6 AI

Topics to be discussed: How do you see adaptation of AI in clinical trials from perspective of Patients, Health care providers, Regulatory agencies? What are the biggest hurdles for implementation of novel tools based on AI and ML? Apart from increased efficiency and lowering the costs, what other advantages does AI bring to the clinical trials and the various stakeholders?

Where do you see the biggest impact? Can you share with us some of the concerns that you, or the people you are working with, may have in relation to the use of AI in clinical trials? What will the clinical trials look like 5 years and 15 years from now?

9:50 Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

RWD IN CLINICAL DEVELOPMENT

10:40 Chairperson's Remarks (Sponsorship Opportunity Available)

10:45 Digital Transformation as It Seeks to Better Leverage Data across the Life Science Ecosystem

Alan Louie, PhD, Research Director, Life Sciences, IDC Health Insights

This presentation will discuss key applications of RWD such as: improving patient recruitment for clinical trials, creating synthetic control arms in clinical trials, fulfilling the regulatory requirements for post-approval Phase IV trials and uncovering new uses for existing drugs (and potentially using RWD to accelerate label extensions).

11:05 Advancing Real-World Evidence to Incorporate Patient-Generated Health Data

Deborah Kilpatrick, PhD, Evidation Health

The talk will highlight how patient-generated health data is the RWD that is more reflective of actual day-to-day health and outcomes. Patient-generated data helps us understand what works for whom, how much it works and when. For companies across the health care ecosystem, claims and EHR data have been bedrock data sources, but they are not sufficient to change how health is measured and how diseases are diagnosed, treated, and monitored.

11:25 Sponsored Presentation (Opportunity Available)

11:40 Transition to Breakout Discussions

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

(See pages 27 & 28 for details)

11:45 Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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

12:30 pm Community Networking Lunch in the Exhibit Hall (Sponsorship Opportunity Available)



Data & Technology

1:40 Transition to Plenary Keynote

UNDERSTANDING THE PATIENT JOURNEY TO IMPROVE TRIALS

1:45 Organizer's Opening Remarks

Kaitlin Searfoss Kelleher, Senior Conference Director, Cambridge Healthtech Institute

1:50 Chairperson's Remarks (Sponsorship Opportunity Available)

1:55 The Journey from Patient to Advocate to Leader: Changing the Clinical Research Game

Rob Long, Executive Director, Uplifting Athletes

I will talk about my journey from Division I football and top NFL prospect to cancer patient. My experience of undergoing chemo and radiation and fighting through a battle with brain cancer has enabled me to leverage my story to make a difference in the lives of those affected by rare diseases. The attendees will gain insights into what it means to be a volunteer at the front lines of oncology research and clinical trials. New approaches to partnering with advocates, disease communities and young researchers will be shared. In addition, we will discuss the future of rare disease research and outreach and illustrate where industry and the patient community can go together in collaboration.

NOTE: Uplifting Athletes and Cambridge Healthtech Institute are proud to include some new young researchers in rare disease at this conference. They are our future partners. Advocacy groups interested in nominating young researchers for the Uplifting Athletes Young Investigator Draft can submit to: <https://www.upliftingathletes.org/rare-disease-research>; Nominations open on November 21, 2020. See page 5 for additional information on applying for a guest pass directly.

2:10 PATIENT CO-PRESENTATION: The Patient's Point of View: Clinical Trial Perceptions and Experiences

Annick de Bruin, MBA, Director, Research Services, Center for Information & Study on Clinical Research Participation (CISCRP)

Phyllis Kaplan, Trial Volunteer and Patient with T1D

Results from a large-scale global study conducted in 2019 among patients and the public offer robust insights into the latest perceptions of clinical research and enrollment barriers, as well as patient engagement preferences (exploring patient receptivity to virtual trial models and the latest technologies). The 2019 CISCRP Perceptions & Insights study is the largest global study of its kind (over 12,400 responses from around the world, including experiences of 3,600+ prior study participants), offering robust global insights that audience members can directly apply within their own organizations. Learn what information is critical to support the participation decision-making process from the patient's point of view. Identify key participation elements which matter most to patients and their support network. Determine which convenience-enhancing solutions create the biggest impact on overall experiences.

2:30 CASE STUDY CO-PRESENTATION: Co-Creating with Patients to Create a Better Clinical Trial Experience

Jackie Zimmerman, Patient Advocate

Maura Snyder, MBA, Global Head, Clinical Trial Engagement, Clinical Insights and Experience, Janssen Pharmaceuticals

Janssen, in partnership with one of our patient advocates, will co-present on an initiative established in 2019 to bring the global patient perspective and input into the Janssen patient engagement plans in immunology. While it's important to hear about the strides that the industry is making in the areas of patient engagement – it's more important to hear directly from the patients about their perspective on this. This discussion will provide the audience practical, tangible ways to approach patient engagement. There are a variety of methodologies to approach this patient voice work and we will share one way that we have found to be very beneficial and successful.

2:55 Closing Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute

3:00 Close of Conference

Bring your society, working group or team to the CTIS and host a reception with us!

If you would like to co-locate your user group meeting, a team meeting, your meet up group, your society or association meeting with this unique clinical research community, it is a good opportunity to broaden our shared networks. We welcome partners to co-host the evening receptions on Monday and Tuesday evening. Please ask us questions about this opportunity:

Companies A-K

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Companies L-Z

Patty Rose

Sr. Business Development Manager
(+1) 781-972-1349
prose@healthtech.com



Engagement & Enrollment

MONDAY, APRIL 6

2:30-5:30 PM PRE-CONFERENCE WORKSHOPS

Workshop 2: Data-Driven Clinical Development: Tutorial and Case Studies

Workshop 3: Inspection Readiness in Changing Global Regulatory Environment

**Workshops are included in your registration. However, please RSVP to reserve your seat. See page 5 for details.*

TUESDAY, APRIL 7

8:15 am Registration and Morning Coffee

REAL WORLD DATA, ARTIFICIAL INTELLIGENCE AND ANALYTICS TO RESHAPE CLINICAL DEVELOPMENT

9:00 Organizer's Opening Remarks

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

9:05 Chairperson's Remarks (Sponsorship Opportunity Available)

9:10 Digitalization of Clinical Trials: Breakthroughs in Technologies and Data

Peter Bergethon, MD, Vice President, Head of Digital and Quantitative Medicine, Biogen

Medicine as systems science characterizes the health state by measurable properties. Changes in state over time (dynamics) define trajectories through growth, health and disease. Dynamic transitions define trajectories between health, illness and therapeutic interventions. Capturing time dependence is the power of digital technology. Herein lies the power of digital medicine. We will review specific cases showing how this paradigm is transforming our clinical trial landscape.

9:30 CO-PRESENTATION: The Role of Real-World Data in Creating New Pathways to Biopharma Industry Transformation

Alan Louie, PhD, Research Director, Life Sciences, IDC Health Insights

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

In parallel to other industry best practices, the biopharmaceutical industry is embracing digital transformation as it seeks to better leverage data across the life science ecosystem. In conjunction with these efforts, increasingly available real-world data (RWD) promises to bring new patient-specific data and insights to the industry, data which bring researchers closer to understanding patient-level treatment responses while also opening new channels to engagement. With strong support from regulators, real-world evidence offers significant potential to accelerate new drug discovery and development, improve process efficiencies, and improve patient outcomes over the near term.

9:50 AI in Human Health – Connecting Data Modules from Discovery Biology to Clinical Development

Rangaprasad Sarangarajan, PhD, CSO & Senior Vice President, Clinical and Translational Sciences, Research & Development, BERG

Drug development programs in companies are predicated on biological insights supporting a hypothesis of target and its role in disease etiology. This presentation will focus on the data modules essential for linking discovery biology to early/late stage clinical development and the leveraging of AI in the integration of the various dataflow to make data-driven informed decisions and ensure success. It will outline how to utilize data, AI analytics with RWD-based support for planning drug development to propel products all the way through the clinic.

10:10 Grand Opening Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

LEARNING FROM PATIENTS AND ACHIEVING PATIENT-CENTRICITY TO IMPROVE ENGAGEMENT AND RECRUITMENT

11:10 Chairperson's Remarks

Jonathan Andrus, Chief Business Officer, Clinical Ink

11:20 A One-on-One Conversation: What We Can Learn from a Candid Conversation with a Clinical Trial Participant

Bonnie Brescia, Founding Principal, BBK Worldwide

Richard Brescia, Cancer Survivor and Three-Time Clinical Trial Participant

This presentation will get to the heart of the clinical trial patient experience with a one-on-one conversation between an industry expert and a family member who has participated in a clinical trial (multiple times) and it will offer first-hand insight into the clinical trial experience, including the decision to enroll, the impact on family members and loved ones, and whether

the experience matched expectations. Attendees will gain: 1) Greater understanding of the patient experience and how to leverage insights for enrollment and engagement success, 2) Insight into specific engagement challenges (e.g., travel and reimbursement, burdensome appointment schedules, caregiver responsibilities) and strategies for overcoming them, and 3) Insight into the patient narrative to ensure studies are patient-centric.

11:45 Benchmarking Patient Recruitment and Retention Practices

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

Tufts CSDD gathered recent data on nearly 90 global clinical trials from a working group of pharmaceutical companies and CROs to benchmark metrics on patient enrollment and quantify the use of patient recruitment and retention tactics. Results will show the most common patient recruitment and retention tactics used across studies as well as highlight any trends and innovation in recruitment and retention practices. Metrics on patient enrollment rates and timelines by global region and therapeutic area as well as drop out and



Engagement & Enrollment

completion rates will be shared. Comparisons will be made to a previous Tufts study benchmarking patient recruitment practices.

12:10 pm PANEL DISCUSSION: A Comprehensive Approach to Patient Centricity: Case Study and Data Review of a Joint Pharma, Advocacy, and Partner Effort

Moderator: Michael Keens, COO, Firma Clinical

Panelists:

Rodrigo Garcia, MD, Head, Clinical Innovation, EMD Serono

Hollie Schmidt, Vice President, Scientific Operations, Accelerated Cure Project for MS

This panel will discuss an innovative partnership between sponsor, advocacy, and partner companies who collectively aligned in the development of a partnership collaboration supporting community events, protocol feedback, and inclusion of a unique and comprehensive training manual for home care nurses integrating 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 rare disease diagnosis. In addition to a unique approach to actualizing patient centricity, the presentation includes perspectives from the Pharma Sponsor, patients, an advocacy organization, and partner company supporting patients. We will share a comprehensive review of a real-world approach to patient centricity in clinical trials, along with an evaluation of the method, measurements, and details of this effort. Audience members will also have an opportunity to discuss areas of improvement so they can apply this approach to their own clinical trials (regardless of role).

12:35 Transition to Luncheon Presentation

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:25 Coffee & Dessert Break in the Exhibit Hall (Sponsorship Opportunity Available)

RECRUITING DIVERSE POPULATIONS, PREDICTING ENROLLMENT, AND ACHIEVING ADHERENCE

2:00 Chairperson's Remarks

Gayle McCracken, Vice President, Market Innovation, Spencer Health Solutions, Inc.

2:10 CO-PRESENTATION: Designing and Implementing Practical Approaches to Support More Diverse Recruitment

Helen Kellar-Wood, PhD, Associate Director, Oncology and Immunoscience Lead, Diversity & Patient Engagement, Bristol-Myers Squibb

Mary Murray, Associate Director, Oncology Lead, Diversity & Patient Engagement, Bristol-Myers Squibb

The need to ensure diverse participation in clinical studies has been well documented on the FDA's Snapshots website and in many recent publications, and yet this issue has not been successfully addressed by sponsors. As we see diseases associated with western life styles become more frequent on a global scale, increasingly diverse patient populations in the US, and health authorities introducing new guidance on the significance of inclusivity

in clinical trial recruitment considerations, the need to act becomes more acute. At the same time, payers are requiring evidence-based reimbursement models. Examining the impact of these changes at the clinical study level we will address how sponsors can design and implement practical approaches to support more diverse recruitment in our research studies. We will share examples of engagement and recruitment approaches leveraged in a disease area disproportionately impacting diverse patients. We will discuss the importance of community interactions, and ways to engage the health care practitioner communities involved in clinical research.

2:35 CASE STUDY: Why Patient Engagement Is Key to Achieving 95% Medication Adherence

Gayle McCracken, Vice President, Market Innovation, Spencer Health Solutions, Inc.

What is the impact of adherence on recruitment, retention, cost for successful trial? As we consider the intersection of healthcare and research, especially in hybrid and virtual models, what is the impact of habit-forming in-home technology for clinical trials? Digital technology solves key problems for pharma as well as for the patients. It reduces patient burden (travel, time, stress), increases patient access, and by gathering data in the patient's natural environment there's greater evidence for payers to support formulary inclusion for approved drugs. This case study features 95% medication adherence and 81% engagement of chronically-ill patients applied as clinical trial simulation findings.

2:50 PANEL DISCUSSION: Impact of Technology on Rare Disease Research, Engagement and Retention (Lessons Learned BEYOND Rare Disease)

Moderator: Joan Chambers, Senior Director, Marketing & Outreach, CISCPR

Panelists:

Karen Anderson, Senior Director, Medical Affairs, Rare Genetic Disease, Agios Pharma

Nan Doyle, R&D Patient Engagement Lead, Rare Disease, Takeda

Patricia Welton, CEO/Founder, Beyond the Diagnosis

Pharma is transforming its business model with biomarker and genetic data as it is playing a more significant role on drugs being approved and drugs in active R&D. The level of biomarker and genetic data collected adds more focus to Rare Diseases and Personalized Medicine; 58% of total approvals are for Rare Disease. Companies are focusing on internal infrastructures and engaging in more partnerships and collaborations to expand the pipelines. There are more than 7,000 identified rare diseases, affecting a relatively small population. Companies are looking at new technologies and platforms to target, engage and retain Rare Disease patients and communities. The panel session will discuss the increased growth, innovations supporting this growth and the challenges.

3:25 Transition to Keynote

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health solutions



Engagement & Enrollment

WHY DO TRIALS SUCCEED AND WHY DO THEY FAIL? INSIGHTS FROM INDUSTRY AND ACADEMIA

3:35 Organizer's Opening Remarks

Marina Filshitsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

3:40 Chairperson's Remarks (Sponsorship Opportunity Available)

3:45 BEST CLI Trial: Lessons Learned From Execution Of A Complex Multicenter RCT

Alik Farber, MD, Chief, Division of Vascular and Endovascular Surgery, Associate Chair for Clinical Operations, Department of Surgery, Boston Medical Center; Professor of Surgery and Radiology, Boston University School of Medicine

The BEST-CLI trial is the largest RCT ever undertaken to evaluate strategies for treatment of critical limb ischemia (CLI). This study is an international, multispecialty, prospective, multicenter, randomized comparative effectiveness trial of endovascular versus open surgical revascularization in patients with CLI who are candidates for both procedures. The study has been performed at 134 sites and has enrolled 1843 patients. Its execution had had multiple obstacles and challenges that the trial leadership team has successfully navigated.

4:15 CO-PRESENTATION: What Causes Studies to Fail? Understanding Causal Drivers of Operational Success Using Machine Learning

Marcy Kravet, BS, MBA, Head, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany
Sylvia Marecki, PhD, Design Analyst, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany

It is currently unknown what drives successful study enrollment despite extensive analysis conducted across the industry, which largely has focused on correlations. The Operational Design Center at EMD Serono has leveraged causal machine learning to analyze hundreds of variables across thousands of clinical trials with the objective of identifying causal drivers of enrollment success, which can be optimized to conduct faster, less expensive trials. Early insights will be shared.

4:45 Welcome Reception in the Exhibit Hall (Sponsorship Opportunity Available)

5:45 End of Day

WEDNESDAY, APRIL 8

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

PARTNERING WITH PATIENTS AND ADVOCACY ORGS TO IMPROVE TRIAL DESIGN AND ADVANCE YOUR STUDY

8:25 Chairperson's Remarks (Sponsorship Opportunity Available)

8:35 CO-PRESENTATION: Utilizing Patient Expertise in Trial Design

Christina Roman, MPH, Senior Manager, Community Engagement, Community Partnerships, Cystic Fibrosis Foundation

Emma D'Agostino, CF Patient, Member of FDA Review Committee

This session will cover how the cystic fibrosis community is helping to shape clinical trial designs and inform researchers on what outcome measures are most important to researchers and the CF Foundation is facilitating meaningful partnerships between researchers and patients. It will showcase two studies with different models for patient engagement. One where broad input from the patient community was utilized in selecting PROs and another model where a small group of patients served as study advisory. The audience will be able to see how different patient engagement strategies can work for different kinds of studies. They will also get ideas for how they may be able to partner with patient organizations to improve engagement strategies and improve enrollment.

8:55 CASE STUDY CO-PRESENTATION: Learning Engagement from a National Advocacy Org and Patient Community: Communicating and Listening to Participants

Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML, a division within the Leukemia and Lymphoma Society

Leah Szumita, MSN, Associate Director, Nursing, Clinical Trial Support Center,

Beat AML, a division within the Leukemia and Lymphoma Society

This presentation will share our experience and learnings as a national organization with ties to researchers, caregivers, patients and industry. Attendees will learn how to: 1) Assist patients through cancer treatment, financial and social challenges, and give accurate, up-to-date disease and support information through experienced oncology social workers, nurses and health educators; 2) Create an online presence where patients can connect with others who are going through the same challenge; and 3) Assist family support groups where patients and their families can go and share information, education and feelings in a comfortable and caring environment.

9:15 PANEL DISCUSSION: Understanding the Role of Community Oncology in Clinical Trials & Patient Engagement

Moderator: Rose Gerber, Director, Patient Advocacy and Education, Community Oncology Alliance (COA); 3x Clinical Trial Participant

Panelist: Katie Goodman, RN, Director, Clinical Research, Florida Cancer Specialists & Research Institute

Participation in clinical trials provides great value to patients, clinicians and researchers. With community oncologists treating the majority of cancer patients in the US, their role is critical in clinical trial recruitment and enrollment. Hear from clinicians and clinical trial participants about the importance of bringing trials to where the patient is being treated. Topics to be discussed: 1) Understanding the value of clinical trials offered in the community (independent physician owned) cancer setting, 2) Learn how to engage clinical trial participants to act as ambassadors in increasing enrollment in clinical trials, and 3) Gain insight from community oncology patients and clinicians about the clinical trial experience in a community setting vs. the academic settings.



Engagement & Enrollment

ACCESSING MULTIPLE PATIENT DATA SOURCES TO ENHANCE GENERATION OF REAL-WORLD EVIDENCE, OUTCOME RESEARCH AND NON-RESEARCH EVALUATIONS

9:25 PANEL DISCUSSION: Accessing Multiple Patient Data Sources to Enhance Generation of Real-World Evidence, Outcome Research and Non-Research Evaluations

Moderator: Ian Rentsch, CEO, Clinerion Ltd.

Panelists: Keyla Deucher, Head, Clinical Trial Unit, Hospital Sao Vicente

Speaker to be Announced, Roche

Ben Illigens, MD, PhD, CEO, UniMedIT Germany; Professor, Harvard Medical School

Speaker to be Announced, AstraZeneca

Real-World Evidence (RWE) research has been positively impacted by the diversity of possibilities and rapid technology advances, but also negatively impacted by the short lifetime of some developments and, in some cases, a lack of scientific rigor. A systematic evaluation of alternatives, combined with thorough strategic planning and a flexible implementation plan, is the key to success. The goals are the achievement of better-quality evaluations, representative data, and external validity, while balancing costs and resource utilization. The lessons learned with the implementation of new tech design technology, addressing scientific requirements, creating operational solutions and developing thorough strategic planning will be discussed, and complemented with our vision of the evolution of digital health, its benefits and risks.

9:50 Coffee Break in the Exhibit Hall (*Sponsorship Opportunity Available*)

USE OF REAL-WORLD DATA (RWD) TO ENHANCE RECRUITMENT & EXPEDITING THE IMPLEMENTATION OF E-SOURCE

10:40 Chairperson's Remarks (*Sponsorship Opportunity Available*)

10:50 CO-PRESENTATION: CTTI Recommendations: Use of Real-World Data to Plan Eligibility Criteria and Enhance Recruitment

Jane Perlmutter, PhD, MBA, Independent Patient Advocate, Advisor, Patient-Centered Outcomes Research Institute (PCORI)

Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen

The growing availability of real-world data (RWD) creates opportunities to potentially improve the feasibility, efficiency, and generalizability of clinical trials. Increasingly, sponsors are turning to electronic health record, claims,

and other RWD sources to help achieve these goals. Until now, there have been few resources available to help sponsors and others optimally integrate the use of RWD into their trial design. This presentation will provide actionable tools, case studies, and multi-stakeholder recommendations developed by the Clinical Trials Transformation Initiative (CTTI).

11:15 CO-PRESENTATION: The Future Is Now: EMA Qualification Favors Clinical Trial eSource Solutions Over Outdated Processes

Jonathan Andrus, Chief Business Officer, Clinical Ink

Angela Lee, Associate Director, Data Management, Otsuka

In late September, the EMA released an important qualification opinion signaling its support of the use of eSource direct data capture (DDC) in clinical trials. Although the FDA had previously expressed support for clinical eSource solutions, the EMA had been cautious. The EMA's opinion identifies many areas where eSource DDC captures source data more efficiently than traditional electronic data capture. However, despite growing evidence to support the use of eSource solutions for clinical trials, industry acceptance has been slow — mostly due to outdated process models. Join this presentation to learn about the implications behind the EMA's qualification opinion. We'll share an Otsuka case study that articulates the benefits of using eSource solutions and discuss how the industry can expedite the implementation of eSource.

11:40 Transition to Breakout Discussions

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

(*See pages 27 & 28 for details*)

11:45 Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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

12:30 pm Community Networking Lunch in the Exhibit Hall
(*Sponsorship Opportunity Available*)

1:40 Transition to Plenary Keynote



Engagement & Enrollment

UNDERSTANDING THE PATIENT JOURNEY TO IMPROVE TRIALS

1:45 Organizer's Opening Remarks

Kaitlin Searfoss Kelleher, Senior Conference Director, Cambridge Healthtech Institute

1:50 Chairperson's Remarks (Sponsorship Opportunity Available)

1:55 The Journey from Patient to Advocate to Leader: Changing the Clinical Research Game

Rob Long, Executive Director, Uplifting Athletes

I will talk about my journey from Division I football and top NFL prospect to cancer patient. My experience of undergoing chemo and radiation and fighting through a battle with brain cancer has enabled me to leverage my story to make a difference in the lives of those affected by rare diseases. The attendees will gain insights into what it means to be a volunteer at the front lines of oncology research and clinical trials. New approaches to partnering with advocates, disease communities and young researchers will be shared. In addition, we will discuss the future of rare disease research and outreach and illustrate where industry and the patient community can go together in collaboration.

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Phyllis Kaplan, Trial Volunteer and Patient with T1D

Results from a large-scale global study conducted in 2019 among patients and the public offer robust insights into the latest perceptions of clinical research and enrollment barriers, as well as patient engagement preferences (exploring patient receptivity to virtual trial models and the latest technologies). The 2019 CISCRP Perceptions & Insights study is the largest global study of its kind (over 12,400 responses from around the world, including experiences of 3,600+ prior study participants), offering robust global insights that audience members can directly apply within their own organizations. Learn what information is critical to support the participation decision-making process from the patient's point of view. Identify key participation elements which matter most to patients and their support network. Determine which convenience-enhancing solutions create the biggest impact on overall experiences.

2:30 CASE STUDY CO-PRESENTATION: Co-Creating with Patients to Create a Better Clinical Trial Experience

Jackie Zimmerman, Patient Advocate

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Janssen, in partnership with one of our patient advocates, will co-present on an initiative established in 2019 to bring the global patient perspective and input into the Janssen patient engagement plans in immunology. While it's important to hear about the strides that the industry is making in the areas of patient engagement – it's more important to hear directly from the patients about their perspective on this. This discussion will provide the audience practical, tangible ways to approach patient engagement. There are a variety of methodologies to approach this patient voice work and we will share one way that we have found to be very beneficial and successful.

2:55 Closing Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute

3:00 Close of Conference

Group Discounts are Available

Advance your career by attending CHI's Clinical Trial Innovation Summit and boost your knowledge and business connections. We reward groups of 2 or more who attend together with generous discounts!*



For details, contact:

Melissa Dolen, Sr. Account Manager
T: +1 781.972.5418
mdolen@healthtech.com

**Group discount rate can not be combined with any Alumni, Twitter, LinkedIn, Facebook or other promotional discount*



Risk-Based Monitoring

MONDAY, APRIL 6

2:30-5:30 PM PRE-CONFERENCE WORKSHOPS

Workshop 2: Data-Driven Clinical Development: Tutorial and Case Studies

Workshop 3: Inspection Readiness in Changing Global Regulatory Environment

**Workshops are included in your registration. However, please RSVP to reserve your seat. See page 5 for details.*

TUESDAY, APRIL 7

8:15 am Registration and Morning Coffee

REAL WORLD DATA, ARTIFICIAL INTELLIGENCE AND ANALYTICS TO RESHAPE CLINICAL DEVELOPMENT

9:00 Organizer's Opening Remarks

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

9:05 Chairperson's Remarks (Sponsorship Opportunity Available)

9:10 Digitalization of Clinical Trials: Breakthroughs in Technologies and Data

Peter Bergethon, MD, Vice President, Head of Digital and Quantitative Medicine, Biogen

Medicine as systems science characterizes the health state by measurable properties. Changes in state over time (dynamics) define trajectories through growth, health and disease. Dynamic transitions define trajectories between health, illness and therapeutic interventions. Capturing time dependence is the power of digital technology. Herein lies the power of digital medicine. We will review specific cases showing how this paradigm is transforming our clinical trial landscape.

9:30 CO-PRESENTATION: The Role of Real-World Data in Creating New Pathways to Biopharma Industry Transformation

Alan Louie, PhD, Research Director, Life Sciences, IDC Health Insights

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

In parallel to other industry best practices, the biopharmaceutical industry is embracing digital transformation as it seeks to better leverage data across the life science ecosystem. In conjunction with these efforts, increasingly available real-world data (RWD) promises to bring new patient-specific data and insights to the industry, data which bring researchers closer to understanding patient-level treatment responses while also opening new channels to engagement. With strong support from regulators, real-world evidence offers significant potential to accelerate new drug discovery and development, improve process efficiencies, and improve patient outcomes over the near term.

9:50 AI in Human Health – Connecting Data Modules from Discovery Biology to Clinical Development

Rangaprasad Sarangarajan, PhD, CSO & Senior Vice President, Clinical and Translational Sciences, Research & Development, BERG

Drug development programs in companies are predicated on biological insights supporting a hypothesis of target and its role in disease etiology. This presentation will focus on the data modules essential for linking discovery biology to early/late stage clinical development and the leveraging of AI in the integration of the various dataflow to make data-driven informed decisions and ensure success. It will outline how to utilize data, AI analytics with RWD-based support for planning drug development to propel products all the way through the clinic.

10:10 Grand Opening Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

DELIVERING HIGH-QUALITY DATA FOR ICH E6 R2

11:10 Chairperson's Remarks (Sponsorship Opportunity Available)

11:20 FEATURED PRESENTATION: Developing and Driving a Robust Clinical Development Quality Risk Management Program

Jonathan Rowe, PhD, Associate Principal, ZS Associates

ICH E6 R2 calls for the establishment of a system to manage quality throughout all stages of the trial process. This presentation will describe elements of a protocol to CSR quality management process that allows sponsors/CROs to understand risks to GCP and proactively mitigate those risks.

11:45 Challenges and Solutions for Delivering High Quality Consistent Data for ICH E6 (R2)/RBM Analytics

Muhammad Ali, Central Monitoring, Pfizer

This presentation will discuss an intro into risk-based monitoring (RBM), as well as why traditional SDLC methodology is challenging, implementation approaches, conflicting priorities and perspectives, change agent networks, innovations (ex. application of AI/ML), and real-world scenarios.

12:10 Is Your Centralized/Onsite Site Monitoring Program Being Implemented per ICH E6(R2)? How Do You Know?

Linda Sullivan, Co-Founder & Executive Director, WCG - Metrics Champion Consortium

The revision to ICH E6 has spawned a transformative approach to monitoring safety and data quality at investigational sites. As new centralized/remote/site monitoring models are being implemented, organizations are considering the perplexing question about how to oversee and manage these models.



Risk-Based Monitoring

For example, what should be measured and reviewed to ensure the process is being implemented according to the plan? What metrics could be used to provide insights about the process and future process improvements? Members of an industry consortium are developing consensus-based metrics by considering the process steps, critical success factors, key performance questions, and by using the process analysis technique Failure Mode and Effects Analysis (FMEA). This session will provide insights on the progress to date and plans to obtain additional industry feedback.

12:35 pm Transition to Luncheon Presentation

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:25 Coffee & Dessert Break in the Exhibit Hall (Sponsorship Opportunity Available)

CREATING A STABLE FOUNDATION FOR QUALITY MEASUREMENTS

2:00 Chairperson's Remarks (Sponsorship Opportunity Available)

2:10 Building a Data Sciences Team for Risk-Based Study Execution

Amy Neubauer, Director, Data Quality Oversight, Alkermes

When looking to create a team to manage risk-based study execution, what are the skills and experience needed? How can roles and responsibilities be managed across the team to cover everything from performing risk assessments, KRI selection and programming, issue detection/action/escalation, QTL selection and tracking, to documentation of actions? We will share our experience and best practices in building a data sciences team and

managing risk-based study execution processes.

2:35 Increase Speed Delivery of New Treatments with RBQM Strategies

Anna Gibernau, PhD, MSc, PMP, EDP, Clinical Research Consultant & Professor Pharmaceutical Law, Clinical Operations, Clementine Global S.L./Barcelona University

In response to the changing environment of how studies are conducted, several guidance and regulations have emerged that encourage the use of a risk-based management approach. This session aims to be consistent with ICH E6 (R2) and ICH E8 (R1) to learn more about how to be compliant with the legal requirements while saving time and effort.

3:00 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
- How can QbD principals be incorporated into RBM with an example

3:25 Transition to Keynote

WHY DO TRIALS SUCCEED AND WHY DO THEY FAIL? INSIGHTS FROM INDUSTRY AND ACADEMIA

3:35 Organizer's Opening Remarks

Marina Filshitsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

3:40 Chairperson's Remarks (Sponsorship Opportunity Available)

3:45 BEST CLI Trial: Lessons Learned From Execution Of A Complex Multicenter RCT

Alik Farber, MD, Chief, Division of Vascular and Endovascular Surgery, Associate Chair for Clinical Operations, Department of Surgery, Boston Medical Center; Professor of Surgery and Radiology, Boston University School of Medicine

The BEST-CLI trial is the largest RCT ever undertaken to evaluate strategies for treatment of critical limb ischemia (CLI). This study is an international, multispecialty, prospective, multicenter, randomized comparative effectiveness trial of endovascular versus open surgical revascularization in patients with CLI who are candidates for both procedures. The study has been performed at 134 sites and has enrolled 1843 patients. Its execution had had multiple obstacles and challenges that the trial leadership team has successfully navigated.

4:15 CO-PRESENTATION: What Causes Studies to Fail? Understanding Causal Drivers of Operational Success Using Machine Learning

Marcy Kravet, BS, MBA, Head, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany
Sylvia Marecki, PhD, Design Analyst, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany

It is currently unknown what drives successful study enrollment despite extensive analysis conducted across the industry, which largely has focused on correlations. The Operational Design Center at EMD Serono has leveraged causal machine learning to analyze hundreds of variables across thousands of clinical trials with the objective of identifying causal drivers of enrollment success, which can be optimized to conduct faster, less expensive trials. Early insights will be shared.

4:45 Welcome Reception in the Exhibit Hall (Sponsorship Opportunity Available)

5:45 End of Day



Risk-Based Monitoring

WEDNESDAY, APRIL 8

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

TOOLKITS AND TECHNOLOGY

8:25 Chairperson's Remarks (Sponsorship Opportunity Available)

8:35 CO-PRESENTATION: Technology Integration- Delivering Real Time Data Access and Oversight

Amy Klawitter, Senior Manager, Clinical Management, Otsuka Pharmaceutical Development & Commercialization, Inc.

Lucien Agnant, Associate Program Manager, Otsuka Pharmaceutical Development & Commercialization, Inc.

By integrating tools such as eSource, eConsent and IRT, sites will experience efficiencies with data entry and sponsors will benefit from having access to near real-time data. The presentation will provide a brief overview of how Otsuka has worked with vendors to integrate systems, the lessons learned, and valuable outcomes.

9:05 Proactive Risk Assessment for the Development of a Robust Integrated Quality Management Plan

Sheri Kuss, Clinical Quality Lead, Clinical Development Quality, Global Product Development, Pfizer, Inc.

9:35 Solving Protocol Deviations Challenges: from Protocol Creation to CSR

Laura Galuchie, TransCelerate Program Lead, Oversight Committee, TransCelerate Biopharma Inc.

- Clarify the definition of "protocol deviation"
- Support classification of "important" and "non-important" protocol deviations
- A toolkit to support multiple processes associated with protocol deviation management from identification through reporting, including several feedback loops

9:50 Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

ADOPTING ICH E6 (R2)

10:40 Chairperson's Remarks (Sponsorship Opportunity Available)

10:50 PANEL DISCUSSION: Unicorn or Racehorse? Lessons from the Trenches in RBM

Moderator: Laurie Halloran, CEO, Halloran Consulting Group, Inc.

Panelists: Catalina Ortiz, Principal Business Operations Analyst, Vertex Pharmaceuticals

Diane Thornton Chandler, BSN, RBM/Centralized Monitoring Lead

Kevin Douglass, Associate Director, Process Excellence & Risk Management at

Daiichi Sankyo, Inc

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 talk practical applications, challenges and lessons learned from companies who've managed to break through the promise to reality. They have found their unicorns, and they will share what they did to get there. A few of the key areas for discussion will include:

- At what point does trial design need to be factored into a risk-based approach?
- How to get everyone on the same page in start-up: selection of sites and vendors, training of the entire team.
- The centralized monitoring role: What have they learned through the set up and management of the process and role?
- What did they wish they know before embarking on this path that will help others?
- What is the overall impact to time, cost and quality of the paradigm shift?

11:40 Transition to Breakout Discussions

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

(See pages 27 & 28 for details)

11:45 Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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

12:30 pm Community Networking Lunch in the Exhibit Hall (Sponsorship Opportunity Available)

1:40 Transition to Plenary Keynote



Risk-Based Monitoring

UNDERSTANDING THE PATIENT JOURNEY TO IMPROVE TRIALS

1:45 Organizer's Opening Remarks

Kaitlin Searfoss Kelleher, Senior Conference Director, Cambridge Healthtech Institute

1:50 Chairperson's Remarks (Sponsorship Opportunity Available)

1:55 The Journey from Patient to Advocate to Leader: Changing the Clinical Research Game

Rob Long, Executive Director, Uplifting Athletes

I will talk about my journey from Division I football and top NFL prospect to cancer patient. My experience of undergoing chemo and radiation and fighting through a battle with brain cancer has enabled me to leverage my story to make a difference in the lives of those affected by rare diseases. The attendees will gain insights into what it means to be a volunteer at the front lines of oncology research and clinical trials. New approaches to partnering with advocates, disease communities and young researchers will be shared. In addition, we will discuss the future of rare disease research and outreach and illustrate where industry and the patient community can go together in collaboration.

NOTE: Uplifting Athletes and Cambridge Healthtech Institute are proud to include some new young researchers in rare disease at this conference. They are our future partners. Advocacy groups interested in nominating young researchers for the Uplifting Athletes Young Investigator Draft can submit to: <https://www.upliftingathletes.org/rare-disease-research>; Nominations open on November 21, 2020. See page 5 for additional information on applying for a guest pass directly.

2:10 PATIENT CO-PRESENTATION: The Patient's Point of View: Clinical Trial Perceptions and Experiences

Annick de Bruin, MBA, Director, Research Services, Center for Information & Study on Clinical Research Participation (CISCRP)

Phyllis Kaplan, Trial Volunteer and Patient with T1D

Results from a large-scale global study conducted in 2019 among patients and the public offer robust insights into the latest perceptions of clinical research and enrollment barriers, as well as patient engagement preferences (exploring patient receptivity to virtual trial models and the latest technologies). The 2019 CISCRP Perceptions & Insights study is the largest global study of its kind (over 12,400 responses from around the world, including experiences of 3,600+ prior study participants), offering robust global insights that audience members can directly apply within their own organizations. Learn what information is critical to support the participation decision-making process from the patient's point of view. Identify key participation elements which matter most to patients and their support network. Determine which convenience-enhancing solutions create the biggest impact on overall experiences.

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2:55 Closing Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute

3:00 Close of Conference



Budgeting & Outsourcing

MONDAY, APRIL 6

2:30-5:30 PM PRE-CONFERENCE WORKSHOPS

Workshop 2: Data-Driven Clinical Development: Tutorial and Case Studies

Workshop 3: Inspection Readiness in Changing Global Regulatory Environment

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TUESDAY, APRIL 7

8:15 am Registration and Morning Coffee

REAL WORLD DATA, ARTIFICIAL INTELLIGENCE AND ANALYTICS TO RESHAPE CLINICAL DEVELOPMENT

9:00 Organizer's Opening Remarks

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

9:05 Chairperson's Remarks (Sponsorship Opportunity Available)

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Alan Louie, PhD, Research Director, Life Sciences, IDC Health Insights

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

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Rangaprasad Sarangarajan, PhD, CSO & Senior Vice President, Clinical and Translational Sciences, Research & Development, BERG

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10:10 Grand Opening Coffee Break in the Exhibit Hall (Sponsorship Opportunity Available)

Media Partners

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Web Partners



Sponsoring Publications





Budgeting & Outsourcing

STUDY BUDGET BEST PRACTICES

11:10 Chairperson's Remarks (*Sponsorship Opportunity Available*)

11:20 Peeling Back the Secrets to Successful Clinical Trial Budgeting and Negotiations

Deena Bernstein, MHS, President, Amplified Clinical Research Consulting Services, LLC

Hear from three stakeholder perspectives on clinical trial budgeting: sponsor, CRO, and site. How to meet at an agreeable negotiation point where everyone walks away satisfied and needs for cost and price are met.

11:45 Sponsor Perspective on Study Budgets

Debora Araujo, Founder & CEO, ClinBiz

This talk will address sponsor challenges, needs, and considerations when budgeting with sites and CROs. I will also address other budgeting strategies from a sponsor perspective.

12:10 pm Overall Study Best Practices

Erin O'Boyle, Senior Director, Clinical Operations, Rezolute, Inc.

This talk will explore overall study budget best practices. We will discuss questions around considerations for internal costs, outsourcing budgets, and site and patient expenses.

12:35 Transition to Luncheon Presentation

12:40 Luncheon Presentation (*Sponsorship Opportunity Available*) or

Enjoy Lunch on Your Own

1:25 Coffee & Dessert Break in the Exhibit Hall (*Sponsorship Opportunity Available*)

SELECTING AND CONTRACTING WITH EMERGING TECHNOLOGY AND SERVICE PROVIDERS

2:00 Chairperson's Remarks (*Sponsorship Opportunity Available*)

2:10 PANEL DISCUSSION: Budgeting for and Contracting with Emerging Technology and Service Providers

Moderator: Debora Araujo, Founder & CEO, ClinBiz

Panelists: Ly Kawaguchi, Senior Director, Head, Outsourcing and Procurement, MyoKardia

Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine
Scott Sawicki, R&D Sourcing Consultant, Adare Pharmaceuticals

There are so many new technologies and services being integrated into clinical trials, with many new companies popping up and many traditional service providers pivoting to address these growing needs. How can sponsors determine fair market value for these types of companies, and how does this affect overall forecasting, budgeting, and contracting activities? Panelists will discuss the impact of changing technologies and study design.

3:25 Transition to Keynote

WHY DO TRIALS SUCCEED AND WHY DO THEY FAIL? INSIGHTS FROM INDUSTRY AND ACADEMIA

3:35 Organizer's Opening Remarks

Marina Filshitsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

3:40 Chairperson's Remarks (*Sponsorship Opportunity Available*)

3:45 BEST CLI Trial: Lessons Learned From Execution Of A Complex Multicenter RCT

Alik Farber, MD, Chief, Division of Vascular and Endovascular Surgery, Associate Chair for Clinical Operations, Department of Surgery, Boston Medical Center; Professor of Surgery and Radiology, Boston University School of Medicine

The BEST-CLI trial is the largest RCT ever undertaken to evaluate strategies for treatment of critical limb ischemia (CLI). This study is an international, multispecialty, prospective, multicenter, randomized comparative effectiveness trial of endovascular versus open surgical revascularization in patients with CLI who are candidates for both procedures. The study has been performed at 134 sites and has enrolled 1843 patients. Its execution had had multiple obstacles and challenges that the trial leadership team has successfully navigated.

4:15 CO-PRESENTATION: What Causes Studies to Fail? Understanding Causal Drivers of Operational Success Using Machine Learning

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4:45 Welcome Reception in the Exhibit Hall (*Sponsorship Opportunity Available*)

5:45 End of Day



Budgeting & Outsourcing

WEDNESDAY, APRIL 8

7:45 am Breakfast Presentation (*Sponsorship Opportunity Available*)
or Morning Coffee

MANAGING RISK IN VENDOR SELECTION AND ITS IMPACT ON CONTRACTING

8:25 Chairperson's Remarks (*Sponsorship Opportunity Available*)

**8:35 PANEL DISCUSSION: Effective Contracting as a Vehicle to
Increase Quality and Mitigate Risk**

Moderator: Mai Nguyen, MPH, Senior Consultant, The Avoca Group

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

Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc.

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

Clinical trials rely on vendors and partners to carry out numerous tasks, something that comes with an inherent risk. This panel will discuss the latest trends in vendor oversight and contracting, and how to mitigate risk and build in quality by design with vendors and partners using effective contracting strategies. Panelists will discuss the pros and cons of common oversight and risk mitigation approaches supported by effective contracting including quality agreements, metrics, and incentive/penalty clauses, as well as the impact these have on the contracts process and downstream clinical operations.

9:50 Coffee Break in the Exhibit Hall (*Sponsorship Opportunity Available*)

STRATEGIES FOR STREAMLINING BUDGETS AND CONTRACTS WITH CROS AND SITES

10:40 Chairperson's Remarks (*Sponsorship Opportunity Available*)

**10:50 Implementing Agile Methodologies to Improve Contract and
Budget Cycle Times**

*Cameron McClure, PMP, PMI-ACP, CSM, CCRP, Senior Manager, Clinical
Business Operations, BeiGene*

This will be a collaborative presentation/discussion that will focus on utilizing Agile techniques to increase efficiencies within the contract and budget negotiation lifecycle. I will also focus on how this implementation can increase the productivity of a company overall. There will be a focus on vendor relationships, standard industry practices and why the need for change is imminent.

**11:15 Clinical Trial Billing Compliance for Success as a Site or a
Sponsor**

*Kelly Willenberg, DBA, BSN, CHRC, CHC, CCRP, Consultant, Kelly Willenberg,
LLC*

Discuss an overview of billing compliance in clinical trials and the risk areas involved. Review the CMS Clinical Trial Policy (NCD 310.1) and Investigational Device regulations (IDE). Explain how to enhance revenue by implementing a clinical trial billing compliance program.

11:40 Transition to Breakout Discussions

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

(*See pages 27 & 28 for details*)

11:45 Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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

12:30 pm Community Networking Lunch in the Exhibit Hall
(*Sponsorship Opportunity Available*)

1:40 Transition to Plenary Keynote



Budgeting & Outsourcing

UNDERSTANDING THE PATIENT JOURNEY TO IMPROVE TRIALS

1:45 Organizer's Opening Remarks

Kaitlin Searfoss Kelleher, Senior Conference Director, Cambridge Healthtech Institute

1:50 Chairperson's Remarks (Sponsorship Opportunity Available)

1:55 The Journey from Patient to Advocate to Leader: Changing the Clinical Research Game

Rob Long, Executive Director, Uplifting Athletes

I will talk about my journey from Division I football and top NFL prospect to cancer patient. My experience of undergoing chemo and radiation and fighting through a battle with brain cancer has enabled me to leverage my story to make a difference in the lives of those affected by rare diseases. The attendees will gain insights into what it means to be a volunteer at the front lines of oncology research and clinical trials. New approaches to partnering with advocates, disease communities and young researchers will be shared. In addition, we will discuss the future of rare disease research and outreach and illustrate where industry and the patient community can go together in collaboration.

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2:55 Closing Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute

3:00 Close of Conference

Breakout Discussions

WEDNESDAY, APRIL 8, 2020

INTERACTIVE ROUNDTABLE BREAKOUT DISCUSSIONS

11:45 am Find Your Table and Meet Your Moderator

11:50 Interactive Breakout Discussion Groups

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12:30 pm Community Networking Lunch in the Hall (Sponsorship Opportunity Available)

1:40 Closing Plenary Keynote

TABLE: Strategies for Patient-Centric Trial Design and Digital Patient Engagement

Moderators:

Helen Kellar-Wood, PhD, Associate Director, Oncology and Immunoscience Lead, Diversity & Patient Engagement, Bristol-Myers Squibb

Kristin Cummings, Director, Implementation-Clinical Operations, Spencer Health Solutions, Inc.

Mike Wenger, Vice President, Patient Engagement, TrialScope

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

TABLE: Building and Implementing an IT Ecosystem for Master Trials

Moderators:

Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML/LLS

Hugh Levaux, Founder and CEO, Protocol First

Moderator to be Announced, Complion, Inc.

- What would happen if pharma routinely participated in Master Trials managed by non-profits as an alternative to traditional clinical trials?
- Should it be a core element of their pipeline strategies? A centralized resource to quickly and efficiently examine drug candidates.
- Could we save time, money, and other resources if our go/no-go decisions were made in months instead of years through collaborative efforts?

TABLE: FSP vs. Hybrid vs. Strategic Partnership Outsourcing – Choosing an Appropriate Model

Moderators:

Mai Nguyen, MPH, Senior Consultant, The Avoca Group

Cameron McClure, PMP, PMI-ACP, CSM, CCRP, Senior Manager, Clinical Business Operations, BeiGene

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

Chuck Bradley, Vice President, Clinical Development, FibroGen, Inc.

Debora Araujo, Founder & CEO, ClinBiz

Karen McCarthy Schau, Director, Global Clinical Operations, Vertex Pharmaceuticals

Adrian Otte, MB, BCh, Principal, Clinical Center of Excellence, YourEncore

- 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

TABLE: Identifying the Right Patient Advocacy Organizations to Advance Your Study

Moderators:

Rose Gerber, Director, Patient Advocacy and Education, Community Oncology Alliance (COA); 3x Clinical Trial Participant

Katie Goodman, RN, Director, Clinical Research, Florida Cancer Specialists & Research Institute

Michael Keens, COO, Firma Clinical

Hollie Schmidt, Vice President, Scientific Operations, Accelerated Cure Project for MS

- What are the reasons to partner with patient advocates and advocacy organizations?
- How do you choose the right organizations?
- What are the next steps to onboard their insights and allow them to help advance the research?

TABLE: Vendor Performance Metrics and KPIs

Moderator:

Andy Lawton, Director & Consultant, Risk Based Approach 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: What Are the Pros and Cons of Using eSource and eConsent for Clinical Trials?

Moderators:

Amy Klawitter, Senior Manager, Clinical Management, Otsuka Pharmaceutical Development & Commercialization, Inc.

Lucien Agnant, Associate Program Manager, Otsuka Pharmaceutical Development & Commercialization, Inc.

- What are the potential challenges of using eSource and eConsent?
- What is the value to sites and sponsors of using eSource and eConsent?
- What types of sites would be more interested and successful in using these tools?

Breakout Discussions

TABLE: New Approaches to Improving Site Selection

Moderators:

Marcy Kravet, BS, MBA, Head, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany
Sylvia Marecki, PhD, Design Analyst, Operational Design Center (ODC), Global Clinical Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany

Amanda Hayden, Senior Director, Global Clinical Services, Clinical Operations, Alkermes

- Data: Novel data types and overcoming challenges to maximally leverage them
- Relationships: Collaborations with internal and external groups, success stories, new opportunities to build valuable relationships
- Wisdom: Challenges with bringing prior learnings to bear on future site selection planning and success stories in overcoming them

TABLE: Best Practices in Protocol Design to Reduce Protocol Amendments and Improve Trials

Moderators:

Jane Myles, Founder and Director, JemTech; Former Head, Operational Intelligence and Innovation, Roche

Sandra Smyth, Head, Global Feasibility & Site Intelligence, AstraZeneca

- Leveraging RWD/EHR data for I/E criteria assessment and protocol optimization
- Incorporating patient voice to inform design and conduct
- KPIs used to measure reduction in avoidable amendments and improved study execution

TABLE: Digital Technologies in Clinical Trials: How to Choose, Implement and Work with Vendors

Moderators:

Robert G. Wilson III, Consultant, Wilson Digital Health Consulting

Kelly Willenberg, DBA, BSN, Consultant, Kelly Willenberg, LLC

Moderator to be Announced, Agatha

- 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: Implementation of Clinical Development Risk Management

Moderators:

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

Jonathan Rowe, PhD, Associate Principal, ZS Associates

- Is RBM delivering?
- What is the role of proactively establishing QTLs
- Any good predictive models?

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