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Cambridge Healthtech Institute's 8th Annual

Clinical Trial Innovation SUMMIT

Patient-Centric Approaches to Data-Driven Clinical Trials
May 13-15, 2019 • The Westin Copley Place • Boston, MA

Plenary Keynote Session:

ENABLING PATIENT-CENTRIC CLINICAL TRIALS



Lisa Shipley,
Vice President, Global Digital Analytics, Merck



Laura Whitmore,
Director, R&D Innovation, Corporate Projects, Otsuka



Basker Gummadi,
IT Strategy & Digital Transformation, Digital Innovation, Bayer U.S. LLC



Linnea Olson,
Lung Cancer Patient Advocate

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Clinical Trial Innovation SUMMIT

brings together 300+ leaders from across pharma, biotech and academia for the perfect blend of high quality presentations and intimate networking. Through case studies, interactive discussions and an active exhibit hall, the summit delivers the real-world experiences and best practices needed to optimize clinical trial planning and management. Presentations span across the most complex areas of trial management, including patient recruitment, patient engagement, site selection, study start-up, data analytics, integrating data and tech into clinical trials, mobile technologies, project management, quality (QbD) in trial conduct and risk-based monitoring. The Clinical Trial Innovation Summit also explores the growing intersection of pharma and healthcare in the area of digital therapeutics.

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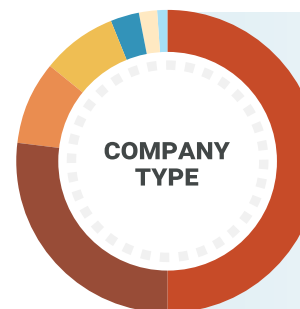
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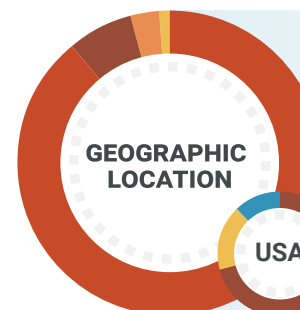
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- 50% Biotech & Pharma
- 27% CRO
- 9% Services
- 7% Healthcare
- 3% Academic, Government & Financial
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- 1% Press



- 52% Executive & Director
- 20% Manager
- 14% Sales & Marketing
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Conference & Host Hotel:

The Westin Copley Place
10 Huntington Ave
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Discounted Room Rate: \$289 s/d
Discounted Room Rate Cut-off Date: April 15, 2019

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Plenary Keynote Session

TUESDAY, MAY 14

ENABLING PATIENT-CENTRIC CLINICAL TRIALS

10:45 Chairperson Remarks: Patient-Centric Trials: How to Engage the Patients in a Clinical Study



Basker Gummadi, IT Strategy & Digital Transformation, Digital Innovation, Bayer U.S. LLC

Basker will share the results of the patients' interaction and what is important to them and what keeps them engaged in a trial. He will also share his personal vision of how Digital technologies can help in this space.

10:55 KEYNOTE PRESENTATION: Patient-Centric Trials: Moving from What's the Matter with Patients to What Matters to Patients



Lisa Shipley, Vice President, Global Digital Analytics, Merck

The overall percentage of potential patients that participate in clinical trial is very low. Engaging patients and removing barriers to patient participation in clinical trials is critically important to the development of new therapies to improve human health. Digital technologies are poised to improve patient participation and experience and shift from a site-centric to a patient-centric model. Pharmaceutical companies and CRO's are exploring a number of different paradigms deploying technologies such as, telemedicine, wearables, and home-sampling.

Dinner Short Course*

MONDAY, MAY 13 | 6:00PM-9:00PM

SC1: Central Monitoring Deconstructed from Raw Data to Monitoring Actions: An In-Depth Walk Through

Instructors: Nechama Katan, Associate Director, Central Monitoring Lead, Risk Based Monitoring, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer

Renuka Kelapure, Pfizer

Jennifer Campbell, Associate Data Analyst, CluePoints

Many organizations are still struggling to define central monitoring and the skills necessary for successful implementation. During this hands-on, dinner workshop we will discuss critical skills necessary for RBM implementation and walk through how to evaluate a RBM finding, write a signal/issue for the study team, and how a team reviews the finding before taking action.

Key Learning Objectives:

- How is Central Monitoring different that Traditional Monitoring?
 - What skills are needed to be successful in Central Monitoring?
 - Why critical reasoning skills are crucial to RBM implementation.
 - How KRIs and Statistical Data Analysis complement each other in RBM.
 - How to evaluate an RBM "result" and understand if it is an issue.
 - How to write a "Signal/Issue" for the study team.
 - How a cross functional study team reviews the whole Center before taking actions
- *Separate registration required.

11:15 KEYNOTE PANEL DISCUSSION:

Going Virtual – Moving towards Patient-Centric, Site-Less Trials



Lisa Shipley, Vice President, Global Digital Analytics, Merck



Laura Whitmore, Director, R&D Innovation, Corporate Projects, Otsuka



Linnea Olson, Lung Cancer Patient Advocate



Basker Gummadi, IT Strategy & Digital Transformation, Digital Innovation, Bayer U.S. LLC

With the rise and integration of new technologies into clinical trials – mHealth, wearables, sensors, the internet of things – there is an unprecedented opportunity for revolutionizing how the industry performs clinical trials. New technology can help move clinical trials from sites directly into patient homes.

- Virtual trials, decentralized trials, remote trials, site-less trials: What are we all talking about?
- What are the latest successes and failures?
- What are the barriers and challenges? How is the industry leveraging technology to make this a reality?
- What are patients saying about their experience with virtual trials?
- What does this mean for the future of clinical trials?

11:50 Keynote Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

Start-Up Showcase and Networking Reception

TUESDAY, MAY 14 | 5:30-7:30 PM

Start-Up Showcase and Networking Reception

As a part of the Clinical Trial Innovation Summit, attendees are welcome to attend Tuesday night's Start-Up Showcase and Networking Reception. As technological advances rapidly enter the market, it may become a challenge to keep up and ensure that your organization is effectively leveraging these technologies for improved clinical trial efficiency. Come listen to and network with new, emerging companies in the digital tech space as they provide brief descriptions of their companies and their services or products. Over cocktails in our open reception, connect with emerging products and service providers in the clinical trial space with special focus on the wearable and digital tech space.

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Mastering Risk-Based Monitoring

Integrating Quality and Effective Monitoring in Clinical Trials

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Ensuring quality from the outset of a clinical trial leads to higher quality, lower risk clinical trials. The establishment of appropriate risk assessment policies and clinical quality management systems lays the foundation for successful risk-based monitoring (RBM). CHI's "Mastering Risk-Based Monitoring" conference offers case studies, lessons learned, and practical solutions from across pharma on proactively building quality standards into clinical trials, effectively implementing RBM, scaling up roll-out of RBM as well as a prospective look into the future of RBM and its possibilities.

MONDAY, MAY 13

7:25 am Conference Registration and Morning Coffee

DEVELOPING EFFECTIVE STRATEGIES FOR RBM

8:25 Chairperson's Opening Remarks

8:30 How Smaller Pharma Achieve Compliance with ICH E6 R2 Using Risk-Based Study Execution (RBx)

Patrick Zbyszewski, Vice President, Data Management, Onconova

This session will highlight the value of a fit-for-purpose Data Surveillance & Central Statistical Monitoring solution coupled with a CRO partner that understands how to effectively leverage this central data intelligence. A Risk Based Approach to Study Execution provides value across 3 dimensions: quality, resource efficiency & timelines. The presenter will share a model to help quantify this value as well as a case study that details how a small company with limited resources should partner with their CRO to realize the value of RBx.

9:00 Developing Effective Communication Practices for Risk-Based Monitoring to Drive Improved Efficiency

Vera Pomerantseva, MS, PMP, Senior Central Monitor, Central Monitoring, Bristol Myers-Squibb

This presentation will focus on the development of an intelligent strategy for the assessment and communication of RBM issues. We will be reviewing combinational approach that could be used to determine the level of detail necessary to evaluate Key Risk Indicators (KRIs), as well as potential root causes with some business cases. The analysis will help us to distinguish the actual issues from the noise, and eventually will drive the communication, escalation and dissemination of RBM issues. The basis for this methodology will be an interleaving of RBM analysis with mind mapping (by Tony Buzan) and PMI (Project Management Institute) communication management techniques to gain RBM efficiency for improved quality and building a continuous improvement framework within the organization.

ANALYZING DATA FROM RBM & CENTRAL MONITORING

9:30 Leveraging Various Monitoring Practices to Ensure Study Quality

Laureen Dorschel, Clinical Study Risk Manager, Risk Based Monitoring, Clinical Data Operations, Technology and Standards (CDOTS), UCB Biosciences, Inc.

This presentation will focus on risk-based monitoring (RBM) approaches to building efficiencies in central monitoring by implementing new strategies to ensure data quality. The presenter will share new insights into operational data (external vendor) vs. clinical data (eCRF) by using examples of hidden data to identify potential risks within a study. In addition, the presenter will share visualizations used to build efficiencies across several studies building better ways to identify trends and analyze potential risks within a study.

10:00 Networking Coffee Break

10:30 Leveraging Statistical Process Control to Explain RBM

Nechama Katan, Associate Director, Central Monitoring Lead, Risk Based Monitoring, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer

Statistical Process Control (SPC) has been used to improve process quality for almost 100 years across multiple industries and applications. It is no longer only applied to manufacturing. SPC techniques are in hospitals, software development, administrative functions and others. Using SPC to describe RBM helps to leverage 100 years of knowledge to make drug trials more effective.

11:00 Insufficient Data for Centralized Statistical Monitoring: Strategies for Pattern and Unusual Data Detection

Michael Walega, Head of Centralized Monitoring, Global Clinical Operations, Bristol-Myers Squibb

With the advent of ICH E6(R2) and the focus on the use of Centralized Statistical Monitoring (CSM) in clinical trials, many organizations are employing CSM tools that utilize statistical approaches to assessing the health of a clinical trial. Invariably, for these tools to be of practical value, a certain amount of 'data mass' is required for effective interpretation of the results (or, in some cases, for the tools to generate any type of output). However, we still need to understand where, during early stages of a trial, issues may arise that require some actioning; what do we do when we don't have enough data to perform the 'statistical' in 'Centralized Statistical Monitoring'? This presentation will offer some ideas regarding approaches that can be considered, as well as strategies that may provide a bridge to CSM.



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11:30 Presentation to be Announced

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:45 Session Break

DATA TRENDS FROM RBM & CLINICAL OPS DECISION MAKING

1:25 Chairperson's Opening Remarks

1:30 PANEL DISCUSSION: Data Collected from RBM: Looking at Data Trends Across Sites & How the Data Affects Site Selection Decisions

Patrick Zbyszewski, Vice President, Data Management, Onconova

Amy Neubauer, Director, Data Quality Oversight, Alkermes, Inc.

Nechama Katan, Associate Director, Central Monitoring Lead, Risk Based

Monitoring, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer

Topics to be discussed:

- Based on RBM data and statistical monitoring, are data trends emerging across sites and studies?
- Where is the industry headed in optimizing and adopting use of RBM data for predictive analytics and clinical ops decision-making?
- How are pharma/biotech and CRO companies leveraging the wealth of data that they are collecting from RBM for clinical ops decisions, especially around study quality, data quality/integrity, site selections, and site capabilities?
- What are the current challenges in using RBM data for predictive analytics? What would improve the ability to use RBM data for predictive analytics?
- How is RBM data being combined with other technologies and data sources to enhance clinical trial decision-making? What are future uses of RBM data?

2:30 Grand Opening Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. 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.

4:15 Welcome Reception in the Exhibit Hall

5:30 Close of Day

5:30 Dinner Short Course Registration

6:00-9:00 Recommended Dinner Short Course*

SC1: Central Monitoring Deconstructed from Raw Data to Monitoring Actions: An In-depth Walk Through

Please see page 5 for details.

** Separate registration required.*

TUESDAY, MAY 14

7:25 am Morning Coffee

ENSURING QUALITY & RBM

7:55 Chairperson's Opening Remarks

8:00 CO-PRESENTATION: A Three-Pronged Approach to Central Monitoring to Identify Potential Risks and Ensure Data Quality

Lauren Bevivino, Manager, Risk Management and Central Monitoring, Integrated Data Analytics & Reporting, Janssen

Adrienne Strickler, Associate Director, Risk Management-Central Monitoring, Integrated Data Analytics and Reporting, Global Clinical Development Operations, Janssen R&D

Centralized Data Review is a key component of Analytical Risk-Based Monitoring. Through central oversight and regular review of real time data, signals indicating potential risks can be recognized and actioned upon in a timely manner. At Janssen R&D, we use a three-pronged approach to centralized monitoring that identifies potential risks and drives data quality. The following case studies using centralized monitoring will be shared: 1) Use of a dashboard with (standard) Key Risk Indicators to indicate potential risks in countries/sites related to data collection. 2) Use of Study-Specific Reports to indicate potential risks in countries/sites related to quality of critical data. 3) Use of Central Statistical Surveillance to identify data anomalies.

8:30 Case Study: How Alkermes Created a Risk-Based Data Quality Oversight Framework

Amy Neubauer, Director, Data Quality Oversight, Alkermes, Inc.

Many CROs are offering RBM capabilities but how should sponsors provide oversight for outsourced studies? This session will take a look at the roles, tools, partnership model, internal framework, high level results, lessons learned, and future plans that Alkermes' Clinical Data Sciences team is taking in leading the clinical study teams in an effective risk-based data quality oversight approach.

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9:00 CAPA Preventive Actions to Quality Risk Management to Reduce Systemic-Level Risks on New and Ongoing Studies

Linda Sullivan, MBA, Executive Director, Metrics Champion Consortium

This presentation will explore the link between sections 5.0 (Quality Management) and 5.20.1 (Noncompliances) in ICH E6 (R2), discuss the importance of documentation of CAPA Action Plans and Quality Management decisions and actions, describe resources developed by an industry consortium that support CAPA Management and Quality Risk Management.

9:30 Beyond Risk-Based Monitoring: Employing Risk-Based Management

Jennifer Lohan, Director, Product Management, ERT

Discussion highlights include: 1) Exploring process, resource, and technology challenges in implementing risk-based management 2) Overcoming challenges in data source variability and data aggregation 3) Moving beyond risk-management, into performance management 4) Complying with ICH E6 guidance 5) Finding the best model & solution for your organization.

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9:45 Sponsored Presentation (*Opportunity Available*)

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials

Please see page 5 for details.

11:50 Keynote Luncheon Presentation (*Sponsorship Opportunity Available*) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference. Stay on to Attend Site Activation & Study Start-Up



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4th Annual

Patient Recruitment

Data-Driven, Patient-Centric Approaches to Patient Recruitment

MAY 13-14, 2019

Delays in patient recruitment can set back drug development by years and millions of dollars. Effective patient recruitment plans that leverage the latest analytics and technologies, as well as involve patient insight, are critical to successful clinical trials. CHI's "Patient Recruitment" conference features best practices and case studies on successful patient engagement and recruitment using novel, patient-centric and data-driven approaches.

MONDAY, MAY 13

7:25 am Conference Registration and Morning Coffee

DATA DRIVEN APPROACHES TO ENROLLMENT & PATIENT RECRUITMENT

8:25 Chairperson's Opening Remarks

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

8:30 Clinical Trial Enrollment Prediction: Data Models, Action, and Impact

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

Data analytics and enrollment modeling capabilities are being explored to establish more accurate clinical trial milestones. Without fail, each study is unique in execution and appears to slowly deviate from the plan. Instead of waiting to hit or miss these milestones, can we effectively predict our future performance and better understand which operational variables are contributing to the deviation from the plan much earlier? Join us for a discussion to address this question and review the operational actions that most significantly impact performance.

9:00 Reimagining Patient Recruitment

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

The competition for right clinical trial participants is at an all-time high, especially true for precision medicine driven trials involving oncology and rare diseases. Trial recruitment has to go beyond traditional site centric approach that relies on obsolete site questionnaires. Patient-centric recruitment approach empowered by advanced data analytics of real world evidence data and trial intelligence information will provide deep insights of targeted patient population and treatment pathway for precision recruitment. The new way of patient recruitment leveraging Electronic Health Records (EHR) network platforms is also calling for new business capability in industry to bridge the worlds of healthcare providers and biopharma companies. The talk will share case studies and examples in exploring patient-centric recruitment driven by RWE and data analytics.

9:30 Talk Title to be Announced

Melaina Boyce, Director, Clinical Applications & Innovation, Biopharma, Global Clinical Operations, EMD Serono

10:00 Networking Coffee Break

ENGAGEMENT, RECRUITMENT AND RETENTION LESSONS LEARNED

10:30 Update of Data-Driven Recruitment with RWD and Advanced Analytics (e.g. Machine Learning) at Roche pRED

Liping Jin, Data-Driven Recruitment Lead, Pharmaceutical Research & Early Development, Roche

There has been an increase in use of Real World Data (RWD) and advanced analytics (e.g. machine learning) in the industry. On behalf of our Data-Driven Recruitment (DDR) team at Roche Pharm Research & Early Development (pRED), I would like to provide an update on our effort of integrating RWD with metrics data to optimize study protocol design and target patient recruitment strategy. The team has received positive feedback from our stakeholders and we have seen significant business impact. At the same time, I would also like to share the challenges of expanding the use of RWD in international settings and the potential of advanced analytics (e.g. machine learning) for the site prediction at our organization.

11:00 Optimizing Recruitment and Retention by Creating the Patient Experience of the Future

Anne Marie Inglis, PhD, Senior Director, Global In Country Clinical Operations, GSK
TransCelerate has been developing solutions to allow patients to easily find trials, understand studies and provide consent, participate in trial information exchange, utilize electronic medicine labels, provide feedback on their trial experiences, and ultimately own their digital medical records. Specifically, the session will explore the learnings, available tools, and industry impact that are being achieved by the following initiatives: Clinical Research Access & Information Exchange, Patient Technology, eConsent, eLabels, and eSource.

11:30 Presentation to be Announced

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:45 Session Break

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Patient Recruitment

Data-Driven, Patient-Centric Approaches to Patient Recruitment

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ENGAGEMENT, RECRUITMENT AND RETENTION LESSONS LEARNED CONT.

1:25 Chairperson's Opening Remarks

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

1:30 Physician Referral Programs: Case Studies of Innovative Pilots to Enhance Patient Recruitment

Charity Roddy, MBA, Senior Manager, Feasibility Enrollment Retention Optimization (FERO), Global Clinical Operations, Biogen

As recruitment for clinical trials becomes increasingly challenging, many sponsors and vendors are looking at innovative ways to support sites and help generate quality referrals for potential participation in studies. A large number of patients rely on their physician(s) to provide information on options for disease treatment, yet referrals to clinical trials from GPs and specialists continues to be lower than expected. This talk will explore why that may be while presenting three case studies of pilot programs aimed at addressing the unique challenges that may prevent physicians from referring patients to clinical trials.

2:00 Presentation to be Announced

2:30 Grand Opening Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups

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4:15 Welcome Reception in the Exhibit Hall

5:30 Close of Day

5:30 Dinner Short Course Registration

6:00-9:00 Recommended Dinner Short Course*

SC1: Central Monitoring Deconstructed from Raw Data to Monitoring Actions: An In-depth Walk Through

Please see page 5 for details.

** Separate registration required.*

TUESDAY, MAY 14

7:25 am Morning Coffee

INNOVATIVE METHODS TO ENHANCE RECRUITMENT AND RETENTION

7:55 Chairperson's Opening Remarks

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

8:00 Presentation to be Announced

Linnea Olson, Lung Cancer Patient Advocate

8:30 Presentation to be Announced

9:00 Presentation to be Announced

9:30 Leveraging Predictive Analytics to Enable Predictable Study Operations

Mark Springer, Associate Director, Consultative Services, IQVIA Technologies

Clinical supply budgets remain a big area of untapped potential efficiencies for both sponsors and CROs. While suppliers have focused on improving accuracy of their estimates, it's usually in isolation and is often impacted by unexpected activities of upstream stakeholders. This session will share details of a collaborative approach that allows a clinical supply organization to leverage existing clinical technology for enrollment and timeline planning to inform their supply strategy.

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials

Please see page 5 for details.

11:50 Keynote Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference. Stay on to Attend Patient Engagement & Retention.

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Inaugural

Site Selection & Feasibility

Strategies for Selecting High Performing Sites

MAY 13-14, 2019

The ability to identify and select high-performing sites is key to effectively launching a clinical trial. CHI's "Site Selection & Feasibility" conference features best practices and case studies on successful site selection techniques using novel, patient-centric and data-driven approaches.

MONDAY, MAY 13

7:25 am Conference Registration and Morning Coffee

ENHANCING THE FEASIBILITY PROCESS

8:25 Chairperson's Opening Remarks

8:30 Foolproof Feasibility: Matching Standard of Care with Clinical Feedback and Site Intelligence

Matt Cooper, Business Development & Marketing Director, NIHR Clinical Research Network (CRN)

In the UK the National Institute for Health Research (NIHR) has developed a unique national strategy for delivering reliable feasibility reports using a multi-pronged approach. This foolproof approach to achieving accurate feasibility information is underpinning research delivery success in the UK and has contributed to record-breaking "time and target" performance results (74%) for commercial contract research (74% figure is based on 466 commercial studies that closed in financial year 2017/18, 346 of which recruited 100% of their target within planned timescales).

9:00 Site Selection for New Indications: Enhancing the Feasibility Process for a Successful Trial

Amanda Moore, Associate Director, Clinical Operations & Development, SAGE Therapeutics

In this talk, we will look at the strategy behind finding the best sites when moving into an indication that is new for you and/or your company. Whether it's rare disease or a highly prevalent therapeutic area, the early pathway in this new space is critical to retain long-term relationships and interest. Creative approaches and operational strategy to ensure success when pioneering a program in a new indication will be explored, as well as how using these approaches can bring renewed energy into all indications.

9:30 Presentation to be Announced

10:00 Networking Coffee Break

SITE BUDGETING & CONTRACTING

10:30 Site Budgeting & Contracting under ICH GCP 6 Amendment

Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

Managing clinical trials, of any size and complexity, requires strategic planning and efficient execution. In 2016, the ICH revised the E6 guidelines to further standardize

processes in biomedical products development, decrease redundancies; and reflect the current research landscape such as increases in globalization, study complexity, and technological capabilities. This session will explore the changes to provide a better understanding of how they impact conduct of clinical trials, site budgeting and contracting. Practical information and a systematic approach in assessing organizational SOPs, processes and practices as well as designing modifications to assist with implementation will also be provided.

11:00 Talk Title to be Announced

Rakiyya E. Ali, JD, Director, Head of Site Budgets & Contracts, Business Operations, Site Budgets & Contracts Group, Regeneron

11:30 Sponsored Presentation (Opportunity Available)

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:45 Session Break

DATA TRENDS ACROSS SITES & CLINICAL OPS DECISION MAKING

1:25 Chairperson's Opening Remarks

1:30 PANEL DISCUSSION: Data Collected from RBM: Looking at Data Trends Across Sites & How the Data Affects Site Selection Decisions

Patrick Zbyszewski, Vice President, Data Management, Onconova

Amy Neubauer, Director, Data Quality Oversight, Alkermes, Inc.

Nechama Katan, Associate Director, Central Monitoring Lead, Risk Based Monitoring, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer

Topics to be discussed:

- Based on RBM data and statistical monitoring, are data trends emerging across sites and studies?
- Where is the industry headed in optimizing and adopting use of RBM data for predictive analytics and clinical ops decision-making?
- How are pharma/biotech and CRO companies leveraging the wealth of data that they are collecting from RBM for clinical ops decisions, especially around study quality, data quality/integrity, site selections, and site capabilities?
- What are the current challenges in using RBM data for predictive analytics? What would improve the ability to use RBM data for predictive analytics?
- How is RBM data being combined with other technologies and data sources to enhance clinical trial decision-making? What are future uses of RBM data?

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Site Selection & Feasibility

Strategies for Selecting High Performing Sites

MAY 13-14, 2019

2:30 Grand Opening and Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups

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4:15 Welcome Reception in the Exhibit Hall

5:30 Close of Day

5:30 Dinner Short Course Registration

6:00-9:00 Recommended Dinner Short Course*

SC1: Central Monitoring Deconstructed from Raw Data to Monitoring Actions: An In-depth Walk Through

Please see page 5 for details.

* *Separate registration required.*

TUESDAY, MAY 14

7:25 am Morning Coffee

EMPLOYING SITE METRICS AND IMPROVING SITE PERFORMANCE

7:55 Chairperson's Opening Remarks

8:00 Using Site Contracting Performance Metrics in Site Selection – Do You Have Access to the Right Data to Understand How the Site Performs?

Linda Sullivan, MBA, Executive Director, Metrics Champion Consortium

This presentation will explore why site contracting cycle times vary by country, discuss approaches organizations are using to reduce cycle time results, and review the data your organization should be reviewing to gain insights about which sites perform well in the context of local regulatory and ethical review requirements.

8:30 Creating Effective Site Partnerships to Drive Site Performance – Being the Sponsor/CRO of Choice

Dennis Salotti, COO, The Avoca Group

Execution in clinical research relies on several key interdependent relationships, most notably the interface between investigative sites, CROs and Sponsors. Avoca and ACRP have partnered on research to characterize, from the site perspective, the attributes that drive quality in clinical research when working with Sponsors/CROs. This presentation will summarize key insights that arose from this research with supporting quantitative and qualitative data.

9:00 Data Analytics for Improved Site Feasibility

Speaker to be Announced

9:30 Sponsored Presentation (Opportunity Available)

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials

Please see page 5 for details.

11:50 Keynote Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference. Stay on to Attend Site Activation & Study Start-Up



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5th Annual

Big Data Analytics, Machine Learning and Artificial Intelligence for Clinical Trials

Making Meaningful, Data-Driven Decisions in Clinical Trials

MAY 13-14, 2019

As new technology and increasing volumes of data becomes more accessible to the biopharmaceutical industry, how will the industry make meaningful, data-driven decisions aimed at improving the clinical trial process? CHI's "Big Data Analytics, Machine Learning and Artificial Intelligence for Clinical Trials" conference gathers leaders across pharma, biotech and academia to explore the use of artificial intelligence, big data analytics, machine learning, and deep learning for improving the clinical trial process and harnessing existing clinical data for new insights. Discussions and case studies will address challenges and solutions in establishing big data analytic platforms and their use in making meaningful, data-driven decisions.

MONDAY, MAY 13

7:25 am Conference Registration and Morning Coffee

MANAGING BIG DATA SETS

8:25 Chairperson's Opening Remarks

8:30 CO-PRESENTATION: Collecting and Utilizing Real World Evidence Using Teva's Digital Health Platform

Amir Kesten, Senior Director, Head of Digital Health Platform, Digital Health, Teva Pharmaceuticals

Lena Granovsky, Director, Analytics and Big Data, Teva Pharmaceuticals

As drug discovery is a complex process that requires integration of multiple data points, it is only natural that the pharmaceutical industry is turning to technology and big data analytics to streamline the process. Including digital sensors as a part of a clinical trial process allows for continuous and objective monitoring of disease symptoms, reducing errors caused by inconsistencies amongst physicians and subjective non-reliable self-reports of patients. Teva's Digital Health Platform (DHP) is a global compliant patient connectivity and data research cloud platform, supporting development and commercialization of current and future medical devices, apps and innovative digital markers. Teva's DHP is currently used for collection and sharing of patient medical device and sensor usage data globally, both in commercial settings and clinical studies. Future plans include improvement of efficiency and accuracy of clinical studies by integration with wearables and digital sensors, building a validated data backbone to support retrospective clinical studies based on Real World Evidence, and hosting patient-facing predictive algorithms.

9:30 Leveraging Real World Data through Evidence Generation for Clinical Trial Optimization

Farhan (CJ) Hameed, MD, MS, Senior Director, Global Real World Evidence Center of Excellence, Patient & Health Impact, Pfizer Inc.

Changing external environment such as passage of the 21st Century Cures Act has become a key driver for the industry to build an innovative operative model for regulatory grade evidence generation. An integrated approach to bring Randomized Clinical Trial (RCT) and evidence generated through Real World Data (RWD) together can provide the opportunities from identifying the trial population, recruitment, effectiveness prediction, trial optimization and several other growing

Real World Evidence (RWE) opportunities to improve the clinical trials execution and value generation across the organization.

10:00 Networking Coffee Break

COLLECTING, UTILIZING, AND LEVERAGING REAL WORLD EVIDENCE CONT.

10:30 Deeply-Phenotyped Individuals in Discovery and Clinical Research

Andrew Magis, PhD, Director, Research, Arivale

Response to pharmaceutical intervention in a clinical trial may be influenced by genetic predisposition, microbiome composition, and participant lifestyle, as well as other factors. Arivale has developed a platform to collect, ingest, and analyze longitudinal multi-omic data to support our research collaborations and ongoing clinical trials. We integrate genomics, clinical tests, gut microbiome sequencing, quantified-self data, metabolomics, proteomics, health history, diet, and lifestyle information within a single cohesive platform designed for data scientists.

11:00 Presentation to be Announced

11:30 Presentation to be Announced

12:00 pm Luncheon Presentation: Scaling Machine Learning for Practical Use in Clinical Trials

Luke Stewart, Senior Director, Product Management, Saama Technologies

Topics to be discussed include: 1) Current challenges in turning proofs-of-concept to production-ready implementations 2) The benefit of "Automated Machine Learning" (AutoML) for clinical trial analytics 3) Application of predictive analytics for operational risk mitigation and patient safety analytics.

12:45 Session Break

MANAGING BIG DATA SETS

1:25 Chairperson's Opening Remarks

1:30 Blockchain Network Effect for Coding Adverse Events

Basker Gummadi, IT Strategy & Digital Transformation, Digital Innovation, Bayer U.S. LLC

Blockchain technology has the potential to positively impact clinical trial supply

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5th Annual



Big Data Analytics, Machine Learning and Artificial Intelligence for Clinical Trials

Making Meaningful, Data-Driven Decisions in Clinical Trials

MAY 13-14, 2019

chains by improving the traceability of medications from active pharmaceutical ingredient (API) to patient. The chain between a clinical study sponsor, study patient, and site is long and involves the use of multiple IT systems. In a world where all parties are linked via a blockchain, it would be possible to leverage encryption and access control so that the members (trusted participants) could get confirmation of the receipt of the product without having access to protected patient information and, in turn, provide the ability to validate patient identity. The design of the blockchain has to take into consideration the nodes and participants of this blockchain: sponsor, distributor, site. Data elements to be stored in the blockchain: material number, substance name, provider, lot batch number, transaction date, time, etc.

2:00 The Application of Intelligent Automation Technologies in Pharmacovigilance

Eileen Leonard, Executive Director, Global Pharmacovigilance and Epidemiology, Bristol-Myers Squibb

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

2:30 Grand Opening Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups

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TUESDAY, MAY 14

7:25 am Morning Coffee

AI & DATA ANALYTICS

7:55 Chairperson's Opening Remarks

8:00 AI-Supported Clinical Trials

Ronald Dorenbos, PhD, Associate Director, Materials and Innovation, Takeda Pharmaceuticals

This presentation will discuss the use of AI in 1. shortening enrollment times, 2. improving patients' adherence, and 3. new ways of monitoring & diagnosing patients.

8:30 CO-PRESENTATION: The Dark Side of Data in Clinical Trials

Pablo Gersberg, Head, Digital Solutions, BlackThorn Therapeutics
Kerensa Saljooqi, Associate Director, Clinical Operations, BlackThorn Therapeutics

BlackThorn's data-driven approach to generating objective neuromarkers has allowed us to collect terabytes of data in our clinical trials. Keeping this data clean, organized, and accessible in a compliant manner is an obstacle we're overcoming by implementing innovative technology solutions. This session will present BlackThorn's lessons learned when awakening data from trials and our approach to develop a state-of-the-art, groundbreaking solution.

9:30 Sponsored Presentation (*Opportunity Available*)

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials

Please see page 5 for details.

11:50 Keynote Luncheon Presentation (*Sponsorship Opportunity Available*) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference. Stay on to Attend Data & Tech Driven Clinical Trials.

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Inaugural

Patient Engagement & Retention

Tech-Enabled, Patient-Centric Approaches to Patient Engagement

MAY 14-15, 2019

Retention and continued engagement of clinical trial participants is essential to successfully completing a clinical trial on time. With the rise of social media platforms and digital technology, the pharma industry stands to leverage these to improve patient experience, engagement, and adherence. CHI's "Patient Engagement & Retention" conference offers case studies and practical solutions on novel, patient-centric and data-driven approaches to patient engagement and retention.

TUESDAY, MAY 14

10:00 Conference Registration

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials
Please see page 5 for details.

11:50 Keynote Luncheon Presentation (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

12:35 pm Dessert Break in the Exhibit Hall

IMPROVING PATIENT EXPERIENCE IN CLINICAL RESEARCH

1:45 Chairperson's Remarks

1:50 Revitalizing Patient Experience in Clinical Research - How Data and Technology Can Help Reimagine Patients as Partners in Clinical Research?

Kamaljit Behera, MBA, Industry Analyst, Transformational Health, Frost & Sullivan

Digital health solutions are increasingly becoming a cornerstone driving the Patient Engagement moment in the overall healthcare space. More particularly, this cultural shift in patient attitude and the pervasive adoption of digital solutions such as smartphones, wearables, and social media are dramatically reshaping the clinical trial industry, demanding sponsors and researchers to view patients as partners in clinical research. As part of this interacting presentation, Frost & Sullivan thought leader will provide an unbiased prospective on how the clinical trial industry can leverage digital means to rejuvenate patient engagement and retention strategy: 1. What are the challenges with current clinical trial patient engagement and how these can be filled by emerging digital health solutions?, 2. How are these technologies being applied to patient engagement? - Select industry best practices and case studies., 3. Envisioning the Clinical Trial future with Connected Health Ecosystem, 4. Strategic imperatives for future success (Analyst prospective for key stakeholders in this space)

2:20 Adding Patient Experience to the Label- Setting Up for Success!
Michelle Shogren, Head of Innovation in Portfolio and Operations, Pharma Development, Bayer

Wondering how you can leverage the technology and newly available data you're collecting from clinical trials? Find out how patient experience can now be added to the label and set you apart from the rest.

2:50 Sponsored Presentation (*Opportunity Available*)

3:20 Refreshment Break in the Exhibit Hall

4:05 HealthCaring Conversations for Clinical ResearchSM: A Science-Based Framework for Patient-Centered Conversations

Suzann Johnson, Associate Director, Investigator and Patient Engagement Projects, Global Clinical Development Operations, Janssen R&D

In the increasingly complex clinical research environment, patients are looking for clarity, and a more personal connection with clinical site staff. Site staff are recognizing how complex communicating with patients can be, even for experienced health care providers. In response, Janssen developed HealthCaring Conversations for Clinical Research, an evidence-based framework for facilitating patient-centered conversations. The aim is to help Study Coordinators Understand, Connect and Empower each patient with the ultimate goal of improving the clinical trial experience for both patients and professionals.

PATIENT ADVOCACY AND REACHING DIFFICULT-TO-RECRUIT PATIENT POPULATIONS

4:35 Partnering with Rare Disease Patient Communities

Kim Mooney, MS, CGC, Associate Director, Patient Advocacy, Ultragenyx

Patient focused drug development requires collaboration, input & accountability from all stakeholders, including Pharma, Healthcare Providers (HCPs) and Patient Advocacy Groups (PAGs). To be successful, this requires us to challenge traditional Pharma thinking & preconceptions, as well as defining compliant roles and responsibilities for interacting with HCPs and PAGs. Additionally, new approaches on how to find, recruit & engage patients (including small, disadvantaged, or lost to follow-up populations) on a long-term basis, throughout the drug development process, will be also presented.

5:05 Session Break

5:30 Start-Up Showcase and Networking Reception
Please see page 5 for details.

7:30 Close of Day

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Patient Engagement & Retention

Tech-Enabled, Patient-Centric Approaches to Patient Engagement

MAY 14-15, 2019

WEDNESDAY, MAY 15

8:30 Interactive Breakout Discussion Groups with Continental Breakfast

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

9:25 Session Break

PATIENT ADVOCACY AND REACHING DIFFICULT-TO-RECRUIT PATIENT POPULATIONS CONT.

9:40 Chairperson's Remarks

9:45 PANEL DISCUSSION: Diversity & Inclusion in Clinical Trials

Cassandra Smith, MBA, Associate Director, Investigator and Patient Engagement, Janssen

Kim Mooney, MS, CGC, Associate Director, Patient Advocacy, Ultragenyx

Anne Marie Inglis, PhD, Senior Director, Global In Country Clinical Operations, GSK

Despite pharma's best efforts, there is still a disconnect between the makeup of the trial population compared to those affected by the disease. This discussion will address:

- What are the barriers to increasing diversity in clinical trials?
- How can pharma, academia/physicians, and advocacy groups collaborate to eliminate disparities in clinical trials?
- How can the industry leverage new tech and data approaches to increase diversity in patient recruitment?

10:45 Sponsored Presentation (Opportunity Available)

11:00 Coffee Break

DIGITAL APPROACHES TO CLINICAL TRIAL AWARENESS & PATIENT ENGAGEMENT

11:30 Digital Approaches for Optimizing Participant Retention and Compliance

Maya Hardigan, Director, Clinical Innovation & mClinical Platform Lead, Pfizer

The proliferation of smart phones and tablets has created new opportunities for robustly engaging clinical trial participants. Pfizer's mClinical platform serves as an incubation space for patient-facing mobile and digital clinical trial innovations: eConsent, mobile apps supporting protocol compliance, and flexible patient data capture models. This talk will showcase the mClinical Patient Journey and the suite of mobile and digital solutions offered to improve the experience of those

participating in Pfizer's clinical trials.

12:00 A Model for Defining and Measuring User Engagement in Digital Behavior Change Interventions

Nnamdi Ezeanochie, MD, DrPH, Senior Manager, Behavior Science, Johnson & Johnson

Researchers and practitioners of Digital Behavior Change Interventions (DBCIs) use varying and oftentimes incongruent definitions of the term engagement; thus, leading to lack of precision in DBCI measurement and evaluation. The objective of this presentation is to propose nuanced definitions for various types of user engagement and explain why precision in the measurement of these engagement types is integral to ensuring intervention effectiveness. Additionally, this presentation will describe a framework and practical steps for how engagement can be measured in practice and used to inform DBCI design and evaluation especially in the context of clinical trials.

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

1:15 Session Break

DIGITAL APPROACHES TO CLINICAL TRIAL AWARENESS & PATIENT ENGAGEMENT

2:15 Chairperson's Remarks

2:20 Talk Title to be Announced

Arian Khoshchin, MSc, Head of Digital Health Technologies, ProQR Therapeutics

2:50 PANEL DISCUSSION: Digital Strategies for Patient Engagement & Recruitment

Jiao Song, Associate Director, Janssen Clinical Innovation

Maya Hardigan, Director, Clinical Innovation & mClinical Platform Lead, Pfizer

Dennis Salotti, COO, The Avoca Group

Digital advances have made it easier for patients to find information about clinical trials online. How is pharma engaging with this digital audience and how is the industry integrating digital solutions into their clinical trial recruitment strategies? This discussion will address:

- How is pharma engaging patient and caregiver communities to enhance trial awareness and recruitment?
- How should pharma leverage social media for patient engagement and clinical trial recruitment? Are some social media platforms better than others (ex. Facebook, Instagram, Twitter, etc.)?
- What digital strategies (mobile apps, gamification, etc.) should pharma focus on to enhance and accelerate trial recruitment?

3:50 Close of Conference. Arrive early to attend Patient Engagement & Retention

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Inaugural

Site Activation & Study Start-Up

Optimizing Processes to Ensure Study Start-Up Success

MAY 14-15, 2019

Successful study start-up hinges on meeting patient recruitment goals and selecting and engaging with clinical trial sites and investigators that can effectively launch study start-up activities. CHI's "Site Activation & Study Start-Up" conference covers lessons learned, best practices and insightful conversations on optimizing study start-up processes and minimizing inefficiencies with technology. Special focus will be given to virtual and remote trials.

TUESDAY, MAY 14

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials

Please see page 5 for details.

11:50 Keynote Luncheon Presentation (*Sponsorship Opportunity Available*) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

PROCESSES TO IMPROVE STUDY START-UP & SITE ACTIVATION

1:45 Chairperson's Remarks

1:50 Digital Data Flow: Developing a Technology Solution Framework to Facilitate Full End-to-End Data Flow

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

This session will explore TransCelerate's Digital Data Flow initiative, which aims to move the drug development process from a current state of manual, study start-up asset creation (i.e. Case Report Forms, Procedure Manuals, Statistical Analysis Plans, and Schedule of Activities) to a future state of fully-automated, dynamic, study start-up readiness via an open-sourced, vendor-agnostic technical solution that will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators.

2:20 Improving Study Start-Up Practices

Carlos Orantes, CEO, Accel Research Sites

2:50 Sponsored Presentation (*Opportunity Available*)

3:20 Refreshment Break in the Exhibit Hall

4:05 A Systematic Approach to Study Start-Up: Improving Site Activation

Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

The success of a trial heavily relies on the strong bond between trial operations and project management throughout the life cycle of the trial. Systematic

assessment of risk factors and key performance indicators at a start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. This session will discuss best practices to expedite start-up phase: Develop a sound business strategy for a more efficient study start-up; Determine key performance indicators and risk factors contributing to the delays at the start-up phase; and Implement mitigation strategy in order to avoid delays and allow for successful launch of a clinical trial.

4:35 Practical Strategies for Ensuring Successful Study Start-Up

Jane M. Jacob, PhD, CCRP, Vice President, Research and Clinical Affairs, Orthofix

5:05 Session Break

5:30 Start-Up Showcase and Networking Reception

Please see page 5 for details.

7:30 Close of Day

WEDNESDAY, MAY 15

8:30 am Interactive Breakout Discussion Groups with Continental Breakfast

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

9:25 Session Break

OPERATIONAL & TECHNICAL ASPECTS OF VIRTUAL TRIALS

9:40 Chairperson's Remarks

9:45 Enabling Patient Centricity and Remote Trials in Clinical Development through At Home Sample Collection

Kevin Bateman, Scientific Associate Vice President, Merck

Traditional approaches for measurement of drug exposure in clinical trials involves

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MAY 14-15, 2019

having the patient travel to a clinical site for collection of venous blood. This puts a burden on the patient while also limiting the opportunities for assessment of drug exposure or other measurements to these clinical visits. The ability to collect samples at home would provide a more patient-centric approach, enabling remote trials. At home collection would provide benefit for 1) disease areas associated with episodic events (e.g. asthma, migraine, etc.), 2) long half-life compounds, 3) assessment of adherence, 4) developing understanding of adherence patterns for new dosing regimens (i.e. QWeekly, QMonthly), and 5) more frequent assessment of biomarkers of efficacy and toxicity. This talk will share results from recent clinical pilot studies employing at home sampling technologies.

10:15 The Next Generation of Clinical Trials

Laura Whitmore, Director, R&D Innovation, Corporate Projects, Otsuka

In 2016, Otsuka implemented an end-to-end electronic trial, reducing site burden and increasing Otsuka's access to data, enabling real time data and real time decisions. As of January 2018, 24 clinical trials have been initiated using this new ePlatform. Laura Whitmore will share Otsuka's experience and lessons learned, and how Otsuka is going farther by designing the next generation of clinical trials.

10:45 Sponsored Presentation (Opportunity Available)

11:00 Coffee Break

11:30 VCCC Teletrials Program - Clinical Trials for Regional Patients

Anne Woollett, RN, Head of Clinical Trials Programs, Victorian Comprehensive Cancer Centre

Cancer patients living in regional and rural Victoria experience several disadvantages including lower survival rates due to socioeconomic issues and access to treatment. The Victorian Comprehensive Cancer Centre (VCCC) Teletrials Program utilises the Australasian Tele-trial Model to tackle some of these disparities by allowing cancer patients to access clinical trials within their local environment. The model uses tele-health to enable clinicians from larger centres (primary sites) to enroll, consent and treat patients on clinical trials at smaller regional and rural centres (satellite sites) - a hub-and-spoke approach between a primary trial site and a satellite site(s). The first Teletrial in Victoria opened in November 2018 with Peter MacCallum Cancer Centre as the Primary Site and Border Medical Oncology Research Unit as the Satellite Site. The model will be rolled-out locally, nationally and internationally.

12:00 pm Investigating the Utility of Minimally Invasive Blood Sample Collection Technologies and Their Role in Clinical Trials

Jinming Xing, Postdoctoral PharmD Fellow, Biomarker Development, Novartis

In clinical trials, blood samples are routinely collected from study subjects to provide important data for the drug safety and efficacy. Minimally invasive and

patient centric procedures can help to facilitate subject recruitment, improve subject retention, and promote simplification of trial design and conduct. A pilot study has been conducted to evaluate a minimally invasive blood sampling technology for biomarker analysis. The aim of the study is to compare protein biomarker data obtained under home-based like collection vs. typical clinical study collection at a site. A broad range of biomarkers were examined using SOMAscan proteomic assay.

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

1:15 Session Break

ENHANCING SITE RELATIONSHIPS

2:15 Chairperson's Remarks

2:20 Site Relationships with CROs and Sponsors from A Site Perspective

Carlos Orantes, CEO, Accel Research Sites

2:50 Fostering Site Relationship: Phase 3 CNS Pivotal Study – A Case Study

Sid (Siddhartha) Chowdhury, MS, Clinical Trial Manager, Global Clinical Services, Alkermes, Inc.

I can provide sponsor insight on how site relationship is key in start-up and recruitment and what Alkermes does to maintain relationships with our sites. I can share Start-Up statistics and metrics. This presentation would be a nice takeaway for sites, CROs and sponsors planning a big phase 3 study and help them prepare for pitfalls, loopholes and challenges.

3:20 An Evolution of Sponsor-Site Collaboration in the Planning and Execution of Clinical Trials

Lisa Moneymaker, CTMS Process Architect, Amgen

For years, TransCelerate's Member Companies noted that clinical trial Sites were heavily burdened by using many different platforms, each requiring unique login credentials to perform clinical trial responsibilities and communicate with participating Sponsors. In addition to the high costs and redundant efforts involved in developing and maintaining individual Sponsor portals, the existence of disparate processes and tools within these portals increased both risk of error and support needed for Site Users. Shared Investigator Platform (SIP) was built as a cross-industry solution designed to address these challenges and ultimately enhance efficiency during clinical trial planning and execution.

3:50 Close of Conference. Arrive early to attend Site Selection & Feasibility

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Technology and data are at the forefront driving clinical trial decision-making. With further advancements in new technologies (such as mobile devices and wearables) and the rise of online communities, the pharma and biotech industries are poised to capitalize on these advancements to innovate existing clinical trial processes and systems. CHI's "Data & Tech Driven Clinical Trials" conference gathers leaders across pharma, biotech and academia for discussions and case studies on leveraging new technologies and clinical trial data to advance clinical research. Special focus will be given to the challenges, solutions, and opportunities that lie in the adoption, use, validation, and data collection of digital technologies.

TUESDAY, MAY 14

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION: Enabling Patient-Centric Clinical Trials
Please see page 5 for details.

11:50 Keynote Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

CONNECTED TECHNOLOGIES IN CLINICAL TRIALS

1:45 Chairperson's Remarks

1:50 Incorporating Digital Biomarkers in Clinical Trials

Brian Johnson, Associate Director, Corporate Projects, R&D Innovation, Otsuka

The use of digital technology and biomarkers for healthcare is growing rapidly and represents an opportunity for patient-oriented endpoints in clinical trials with the potential for real-world applications. Digital biomarkers may also represent a more objective, unbiased assessment compared to traditional subjective assessments (i.e., rating scales).

Otsuka is actively incorporating digital biomarkers in numerous trials.

2:20 Smartphones as Clinical Trial Measurement Tools

Daniel Karlin, MD, Interim General Manager, HealthMode; Former Head of Clinical, Informatics, and Regulatory Strategy, Digital Medicine and the Pfizer Innovation Research Lab

The ubiquity of mobile technologies that contain sensors capable of collecting clinical quality data, the emergence of novel analytical techniques, the availability of transmission and storage resources to support the collection of huge amounts of data, and computational resources to execute demanding models have brought us toward the integration of latent and trial data. HealthMode is leading this effort in several therapeutic areas. Dan will discuss the opportunities and obstacles we have encountered on this journey.

2:50 Presentation to be Announced

3:20 Refreshment Break in the Exhibit Hall

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DATA ANALYTICS

4:05 The Devil is in the Metadata - Lessons Learned from Data Acquisition in Digital Medicine Studies

Tomasz Adamusiak, MD, PhD, Director Medical Informatics Lead, Pfizer Innovation Research Lab, Pfizer

The mission of the Digital Medicine and the Pfizer Innovation Research (PfIRe) Lab is to solve key business problems using dynamical measures, advanced-STEM platforms and a collaborative network of external stakeholders, regulators and internal enterprise-wide colleagues to support a digital therapeutic pipeline. PfIRe Lab is an industry-leading mobile/digital technology initiative striving to utilize digital continuous remote monitoring of patients' symptoms as novel endpoints for disease diagnosis and health state assessment. This talk will focus on the takeaways from our multi-year experience of data quality management of heterogeneous non-CRF data.

4:35 Clinical Analytics Innovation 2.0 - Measurement that Matters

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

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

5:05 Session Break

5:30 Start-Up Showcase and Networking Reception

Please see page 5 for details.

7:30 Close of Day

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10:45 Sponsored Presentation (*Opportunity Available*)

11:00 Coffee Break

DIGITAL APPROACHES TO CLINICAL TRIAL AWARENESS & PATIENT ENGAGEMENT

11:30 Digital Approaches for Optimizing Participant Retention and Compliance

Maya Hardigan, Director, Clinical Innovation & mClinical Platform Lead, Pfizer

The proliferation of smart phones and tablets has created new opportunities for robustly engaging clinical trial participants. Pfizer's mClinical platform serves as an incubation space for patient-facing mobile and digital clinical trial innovations: eConsent, mobile apps supporting protocol compliance, and flexible patient data capture models. This talk will showcase the mClinical Patient Journey and the suite of mobile and digital solutions offered to improve the experience of those participating in Pfizer's clinical trials.

12:00 pm A Model for Defining and Measuring User Engagement in Digital Behavior Change Interventions

Nnamdi Ezeanochie, MD, DrPH, Senior Manager, Behavior Science, Johnson & Johnson

Researchers and practitioners of Digital Behavior Change Interventions (DBCIs) use varying and oftentimes incongruent definitions of the term engagement; thus, leading to lack of precision in DBCI measurement and evaluation. The objective of this presentation is to propose nuanced definitions for various types of user engagement and explain why precision in the measurement of these engagement types is integral to ensuring intervention effectiveness. Additionally, this presentation will describe a framework and practical steps for how engagement can be measured in practice and used to inform DBCI design and evaluation especially in the context of clinical trials.

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

1:15 Session Break

DIGITAL APPROACHES TO CLINICAL TRIAL AWARENESS & PATIENT ENGAGEMENT (CONT.)

2:15 Chairperson's Remarks

2:20 Growing Adaptation of Connected Technologies and Platforms in Clinical Trials

Raj Pallapothu, mHealth Solutions Global Lead, Bayer

This presentation will cover 1. Emergence of wearables, sensors, bio-markets in clinical trials, 2. Patient adaptation, challenges at site level, 3. Data transfers, privacy, portability growing need and associated challenges, 4. Operational challenges, 5. Value proposition, and 6. Market trends.

2:50 PANEL DISCUSSION: Digital Strategies for Patient Engagement & Recruitment

Jiao Song, Associate Director, Janssen Clinical Innovation

Maya Hardigan, Director, Clinical Innovation & mClinical Platform Lead, Pfizer

Digital advances have made it easier for patients to find information about clinical trials online. How is pharma engaging with this digital audience and how is the industry integrating digital solutions into their clinical trial recruitment strategies?

This discussion will address:

- How is pharma engaging patient and caregiver communities to enhance trial awareness and recruitment?
- How should pharma leverage social media for patient engagement and clinical trial recruitment? Are some social media platforms better than others (ex. Facebook, Instagram, Twitter, etc.)?
- What digital strategies (mobile apps, gamification, etc.) should pharma focus on to enhance and accelerate trial recruitment?

3:50 Close of Conference. Arrive early to attend Big Data Analytics, Machine Learning and Artificial Intelligence for Clinical Trials.

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SUMMIT PRICING

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Advance - Registration Rate Until April 26, 2019	\$2,599	\$1,299
Registrations After April 26, 2019 and On-Site	\$2,799	\$1,399

BASIC PRICING (Includes access to ONE conference only AND the complimentary Partnering Forum on Tuesday evening. Excludes access to the short course.)

	Commercial	Academic, Government, Hospital-affiliated
Advance - Registration Rate Until April 26, 2019	\$1,799	\$929
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MAY 13-14, 2019	MAY 14-15, 2019
C1: Mastering Risk-Based Monitoring	
C2: Patient Recruitment	C6: Patient Engagement & Retention
C3: Site Selection & Feasibility	C7: Site Activation & Study Start-Up
C4: Big Data Analytics, Machine Learning, and AI for Clinical Trials	C8: Data & Tech Driven Clinical Trials

DINNER SHORT COURSE PRICING

Short Course	Commercial	Academic, Government, Hospital-affiliated
	\$599	\$399

MAY 13, 2019 (6:00 PM - 9:00 PM)

SC1: Central Monitoring Deconstructed from Raw Data to Monitoring Actions: An In-Depth Walk Through

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