09 NOV

Le Meridien Cambridge Boston

Le MERIDIEN

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2022

New Discoveries in Technology to Enhance Remote & Virtual Approaches, Utilisation of Telemedicine To Optimise Your Clinical Operation Success

- Virtual Trials
- Tele-medicine
- Patient Recruitment
- Remote Monitoring
- Management
- AI/ML
- eCOA
- Patient Centric
- Technology
- Site Selection

Featuring Industry Leaders and Decision Makers

Frank Leu
Chief Executive Officer
Novapeutics

Dina Berdieva
VP of Clinical Operations
Arcturus Therapeutics

Amanda McEwen
Vice President, Clinical Development
Elevian Therapeutics

William Blumentals
Head of Pharmaco-epidemiology
Sanofi Genzyme

Sashka Dimitrievska
Global Therapeutic Area Head Oncology Clinical Insights
AstraZeneca

Elspeth Carnan
Senior Vice President, Clinical Development Operations
Alkermes Inc.

Jim Marshall
Associate Director, Materials Management
Alnylam Pharmaceuticals

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PROVENTA INTERNATIONAL

Proventa International's Strategy Meetings are a completely unique experience.

CLINICAL OPERATIONS
STRATEGY MEETING
EAST COAST USA 2022

09 NOV

Our Vision

To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

Our Mission

By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

Our Unique Meeting Format

ROUNDTABLE DISCUSSIONS

These interactive and informal discussion groups are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants from all over the world to share ideas, challenges and lessons learned.

PERSONALISED AGENDA

Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

INNOVATIVE SOLUTIONS

The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

STRATEGIC NETWORKING

Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

Although the pandemic response has expedited technology adoption in clinical trials, our purpose is clear in the face of changing clinical strategy:

IT'S TIME TO BUILD A BETTER SYSTEM.

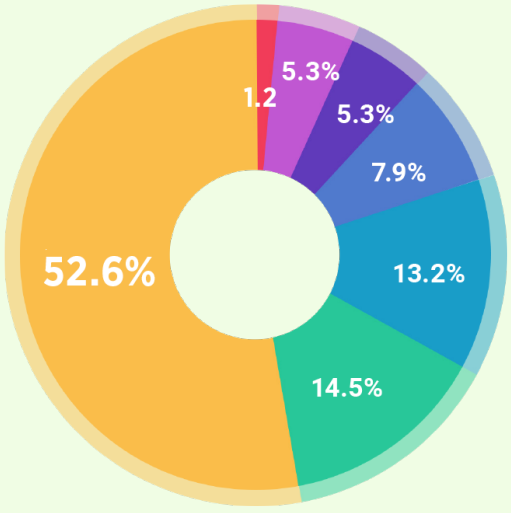
The significant changes towards decentralised, in-home patient care, along with easing regulation restrictions on centralised in-person trial execution, has created new opportunities for more patient-centric and diverse trials. Now is the time to set new industry expectations, take advantage of recent digital advancements, and assure a long-term culture shift toward patient-centric trials. We risk losing this chance to reestablish patient confidence if we do not move quickly.

From October 2023, Proventa International will be gathering senior leaders from the pharmaceutical and biotech industries, to share practical guidance on how equity, inclusion, and diversity in clinical outsourcing, site selection strategies, and digital transformation can help deliver faster, and more cost-effective trials on time and on budget whilst maintaining resilience in patient integrity.

WHY SHOULD YOU ATTEND THIS MEETING?

- To gain practical insight with Good Clinical Practice and Risk Based Quality Management strategies
- Improve diversity through patient-centric approaches, decentralized trials and new digital technologies
- Share takeaways on remote communication solutions and strategic partnerships between Sponsors and CRO's
- Enhance vendor monitoring to guarantee deliverable responsibility and to keep planning and governance frameworks in place
- Strengthen the overall global clinical operations to improve trial outcomes, and reduce costs of drug developments
- Our unique closed door round-table discussion format is exclusively designed to engage 10-15 CxO, VP and director-level individuals from pharma, biotech and thought leaders from academia, to address and find solutions to industry challenges from a strategic perspective within the Clinical community
- Facilitated by expert thought leaders, you will have the option to select and attend the round-tables that provide valuable dialogue, addressing topical issues that is currently aligned with your work
- Bespoke networking opportunities to help streamline your procurement processes, meaning the impetus for your peers attending is solely based around making business decisions at the highest level

SENIORITY OF ATTENDEES



- Director Level
- Manager
- Head
- Academia
- President / VP
- Scientist
- Team Lead

Facilitator Faculty

Aruna Adhikari Thapa
Senior Director of Product, Site Suite and Planning Suite
IQVIA

Gayle Hamilton
Director RBQM Digital Trial Management Suite,
IQVIA

Zabir Macci
Director - eCOA Business Strategy & Sales Engineering
IQVIA

John Cassidy
Global Head of Product & Commercial, eClinical
Labcorp

Adam Sullivan
Strategic Director of AI
Labcorp

Lindsey Morales
Associate Director, Site Centric Solutions
Labcorp

Reginald Swift
Head of Study Management and Monitoring
Successful Strategies for Life Sciences

Dr. Claudia Hesselmann, PhD
Co-Founder & CEO, Germany
Arensia

Jeff Repper
EVP Strategic Site Initiatives
Transformative Pharmaceutical Solutions

Ash Rishi
CEO and Co-founder,
COUCH Health
Founder,
Demand Diversity and COUCH Academy

Scott Chetham
CEO
Faro Health

Debashish Niyogi, PhD
Vice President, Product Management
Anju Software

Adrian Otte MB BCh
Executive Strategic Advisor & Board Member
KPS Life

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Frank Leu
Chief Executive Officer
Novapeutics

Oscar Segurado
Chief Medical Officer
ASC Therapeutics

Ana Sharma
Vice President, Head of Research and Development Clinical Quality Assurance
Takeda

Our Sponsors

Lead Sponsor

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry. Powered by the IQVIA CORE™, IQVIA delivers unique and actionable insights at the intersection of large-scale analytics, transformative technology and extensive domain expertise, as well as execution capabilities. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 67,000 employees worldwide. Learn more at www.iqvia.com.

VISIT WEBSITE

Associate Sponsor

Labcorp (NYSE: LH) is a leading global life sciences company that provides vital information to help doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. Through our unparalleled diagnostics and drug development capabilities, we provide insights and accelerate innovations to improve health and improve lives. With more than 70,000 employees, we serve clients in more than 100 countries. Learn more about Labcorp at www.Labcorp.com, or follow us on LinkedIn and Twitter @Labcorp.

VISIT WEBSITE

Thought Leader

Successful Strategies for Life Sciences, located in Southern CA, is a virtual information management consulting firm that specializes in developing customized regulatory and clinical operations' solutions for life sciences organizations. We also assist otherwise underrepresented patients among minority communities by providing education and guidance for participation in clinical trials with the concerted goal of achieving improved health outcomes for everyone.

VISIT WEBSITE

Co-host Sponsors

ARENSIA EXPLORATORY MEDICINE is a German operator of proprietary research clinics in Eastern Europe, dedicated to performing complex Phase Ib, IIa and PROOF-OF-CONCEPT clinical trials with novel molecules, involving patients across numerous disease areas. Given the outstanding patient recruitment rates achieved by ARENSIA clinics, we are able to substantially reduce the overall number of sites, countries and recruitment periods for any early phase patient trial.

VISIT WEBSITE

Transformative Pharmaceutical Solutions offers customized and innovative outsourcing solutions for Sponsor's clinical and site operations. These solutions are built to enhance Sponsor's relationship at the site and drive productivity across the clinical trial operations.

VISIT WEBSITE

COUCH Health is a creative health engagement agency that has purpose at its heart and that is to make health human. That means we're challenging the norm to make health experiences more inclusive, equitable, accessible and empathetic. And we can only make this happen if we understand the real-life challenges that are at play. By connecting with people — the patients, caregivers, communities and healthcare professionals — we're ensuring that we're making changes that matter.
What we do: • Health engagement • Health communications • Health equity
Are you ready to start your next project? Let's talk. **e.** hello@couchhealth.agency | **w.** https://couchhealth.agency/

VISIT WEBSITE

Faro Health is bringing clinical trials into the digital age by helping teams manage and balance the complexity of modern trial designs through a cloud native platform. The Faro platform enables study teams to design complex clinical trials using small modular building blocks and combines that with data driven insights to orchestrate and automate operationally complex trials. Faro brings balance, centricity and flexibility to protocol development through automation and integration to downstream systems and vendors, ensuring they are always up to date and correctly configured. As a result, clinical trials using Faro are operationally efficient which avoid delays due to ambiguity and generate data that can be trusted.

VISIT WEBSITE

Founded in 2010, **KPS** is a provider of FSP solutions to global biopharmaceutical companies that greatly increases the efficiencies in the execution of their clinical trials. For companies that utilize full service CROs exclusively, KPS offers a Clinical Monitoring Oversight platform to ensure the quality of the clinical data and compliance with FDA guidelines is being achieved. With over 300 employees in 28 countries, KPS offers a strategic, scalable solution that identifies and hires experienced, high quality resources that are fully dedicated to our Sponsors at a cost that represents a 35% reduction in professional fees compared to traditional CROs.

VISIT WEBSITE

Anju provides adaptive technologies for clinical trials, medical affairs, and data services with world-class customer experience. Leveraging data-driven analytics, our leading suite of solutions with application and data integration capabilities serves the worldwide pharmaceutical, biotech, and contract research Life Sciences markets. Anju is a portfolio company of Abry Partners. To learn more about Anju's technologies and services, visit http://anjusoftware.com.

VISIT WEBSITE

Inato is a global marketplace that matches community-based research sites with the right clinical trials. The marketplace allows sponsors to confidently partner with a broader range of sites, making clinical trials more accessible, inclusive and effective. Since launching in June 2020, over 1400 sites have joined the marketplace along with several top-20 sponsors. Learn more at www.inato.com

VISIT WEBSITE

ArcheMedX enables life science companies to predict and improve team and clinician performance, delivering better clinical trials and faster commercial adoption. The company's clinical trial learning and analytics platform, Ready, applies behavioral science to transform study documents and training resources into interactive learning experiences that dramatically increase preparedness and provide predictive insights that inform faster operational decisions. Trial sponsors and CROs rapidly deploy Ready to re-imagine site feasibility, study startup, and on-going site engagement; reducing cycle times and mitigating downstream risks. Learn more at www.archemedx.com

VISIT WEBSITE

Care Access is a community-centric clinical research organization accelerating the availability of new medicines and treatments by breaking down traditional barriers in clinical research for patients, sponsors, and physicians. Our innovative model brings a nationwide network of sites, decentralized trials, Sites On Demand™, Virtual PIs, and Mobile Sites to previously-unreachable patient populations to expand the impact of clinical research. Supported by top pharmaceutical and biotech partners, Care Access is scaling and globalizing its new model for clinical trial delivery, where more physicians and patients can engage in life-saving research to develop new therapies faster. Learn more at www.careaccess.com.

VISIT WEBSITE

Intimate format events where senior leadership discuss the biggest challenges facing the industry.

How it Works?

Real insights are shared in conversations, not lectures. That's why our unique **roundtable** format guarantees real learning and ensures you only attend discussions that deliver value to you.

Join as many as four roundtable discussions, each with up to 20 other subject experts, networking with top-level peers in an informal, relaxed and sociable environment.

Simply follow the steps below to select your roundtable discussions and we'll create your own personalised agenda for the day:

01 EXPLORE THE FULL AGENDA

Select which roundtable discussions you would like to join. Our sessions are divided among 6 themed tracks for easy selection - you can choose to join any session you like.

02 COMPLETE YOUR SCHEDULING FORM

Select your preferred roundtable discussion for each time slot. We will send this form out via email a few weeks before the event - be sure to get your first choice by completing the form quickly.

03 ENJOY YOUR PERSONALISED EXPERIENCE

Join your selected roundtable sessions on the day. We will give you your personalised agenda containing the time and room assignments of your chosen roundtable discussions so you won't miss it.

Agenda at a Glance

Clinical Operations Strategy Overview 9th of November, 2022 – Cambridge, Boston - Le Meridien Hotel

TIME EST	TRACK 1 RISK BASED MONITORING/RISK BASED QUALITY MANAGEMENT	TRACK 2 DIVERSITY, EQUITY AND INCLUSION IN PATIENT RECRUITMENT/ DECENTRALIZED TRIALS	TRACK 3 EMERGING BIOPHARMA	TRACK 4 CLINICAL OUTSOURCING	TRACK 5 CLINICAL DATA/ REAL WORLD EVIDENCE	TRACK 6 SITE SELECTION/ DISRUPTIVE TECHNOLOGY
ROOM ▶	Jerome C. Hunsaker C	Jerome C. Hunsaker	Jerome C. Hunsaker A	Lan Jen Chu	Margaret L.A. Macvicar	Edward Pennell Brooks
08:00 - 08:30	REGISTRATION AND WELCOME					
08:30 - 09:00	IQVIA — OPENING KEYNOTE PRESENTATION: Bringing Innovation to Clinical Development: Technology's Impact on Clinical Trials — IQVIA					
09:00 - 10:00	Finding tactical approaches that support risk-based quality management	What are the challenges organizations face in enrolling diverse populations	Design clinical trials that offers "CHOICE" to patients for in-clinic and at home (hybrid models) visits	Leveraging Outsourcing Strategies to Mitigate Rising Costs & Improve Partnerships	Incorporating real-time clinical insights in clinical development process for faster submissions and accelerated approvals	
10:00 - 10:10	REFRESHMENT BREAK					
10:10 - 10:30	NETWORKING / 1-1 MEETINGS					
10:30 - 10:50	NETWORKING / 1-1 MEETINGS					
10:50 - 11:10	NETWORKING / 1-1 MEETINGS					
11:10 - 12:10 SOLUTION	Ensuring Regulatory Compliance and Audit Readiness using RBQM Technology — IQVIA	Moving Beyond DCTs (Decentralized Clinical Trials): Next Steps in Trial Transformation — LABCORP DRUG DEVELOPMENT	Less talk, more action: How to achieve diversity, inclusion, and equity in clinical research — COUCH HEALTH	How using SiteChoice to invest in your site's workforce can transform your study outcomes and patient's experience. — TRANSFORMATIVE PHARMACEUTICAL SOLUTIONS	Effective Management of Essential Clinical Trial Documents Using eTMF Solutions — ANJU SOFTWARE	How can we use and optimize data in order to improve study start up and site cycle times — SUCCESSFUL STRATEGIES
12:10 - 12:40	labcorp Drug Development — KEYNOTE PRESENTATION: Transforming Trial Recruitment with a more Patient Centric Approach — labcorp Drug Development					
12:40 - 13:40	NETWORKING LUNCH					
13:40 - 14:10	ARENSIA EXPLORATORY MEDICINE — KEYNOTE PRESENTATION: Accelerated performance of complex exploratory patient studies: Practical insights from investigational site — ARENSIA EXPLORATORY MEDICINE					
14:10 - 15:10 SOLUTION	Bringing AI Innovations to Clinical Trials (enabling patient recruitment, design and execution, risk reduction) — LABCORP DRUG DEVELOPMENT	Understanding Site needs in managing multiple trials: An open discussion — IQVIA	Current & emerging therapeutic areas with high clinical focus & investment — SUCCESSFUL STRATEGIES	Unburdening stakeholder's lives by eCOA technology solutions — IQVIA	Industry Labor Shortage – The Post-Pandemic Workforce — KPS LIFE	How to balance scientific complexity and its inherent issues with patient-centric design of the protocol to help increase R&D efficiency in clinical trials — FARO HEALTH
15:10 - 15:20	REFRESHMENT BREAK					
15:20 - 15:40	NETWORKING / 1-1 MEETINGS					
15:40 - 16:00	NETWORKING / 1-1 MEETINGS					
16:00 - 16:20	NETWORKING / 1-1 MEETINGS					
16:20 - 17:20	Understanding the vital impact of RBM in monitoring advanced therapies in the clinical trials phase		Exploring the future of operational supply chain to meet advancing product demand	How Can Sponsors Delegate Activities and Maintain Oversight?	Accelerating Clinical Data Using Artificial Intelligence	What are the existing disruptive technologies that could be used to drive clinical operations?
17:20 - 17:50	DRINKS & CANAPES RECEPTION					

Event Day

OPENING KEYNOTE PRESENTATION

8:30 – 9:00 EST

Bringing Innovation to Clinical Development: Technology's Impact on Clinical Trials

IQVIA

Aruna Adhikari Thapa
Senior Director of Product,
Site Suite and Planning Suite
IQVIA

AFTERNOON KEYNOTE PRESENTATION

12:10 – 12:40 EST

Transforming Trial Recruitment with a more Patient Centric Approach

LABCORP DRUG DEVELOPMENT

Lindsey Morales
Associate Director, Site Centric Solutions
Labcorp

CLOSING KEYNOTE PRESENTATION

13:40 – 14:10 PST

Accelerated performance of complex exploratory patient studies: Practical insights from investigational site

- Unique model of dedicated research clinics in Eastern Europe
- Strategies for fast patient enrollment and retention
- Operational tips for flawless study conduct
- Takeaways after operating under unprecedented circumstances / case studies

ARENSIA

Dr. Claudia Hesselmann, PhD
Co-founder & CEO, Germany
Arensia

TRACK 1:
RISK BASED MONITORING/ RISK BASED QUALITY MANAGEMENT

A mix of risk assessments, analytical capabilities, and cutting-edge technology is required to provide an effective risk-based monitoring platform. Various discussions will focus on how we can include successful risk-mitigation methods and how we can fast improve patient safety to guarantee we are moving in clinical trials.

09:00 – 10:00 EST

ROUNDTABLE 1:
Finding tactical approaches that support risk-based quality management

- Using cutting-edge protocol approaches, designs, and technologies to expedite decision-making and development
- How can we use risk-based trial management and monitoring to improve the quality of your clinical data and streamline compliance processes?
- Recognizing the differences in data quality between remote and on-site monitoring

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
Ensuring Regulatory Compliance and Audit Readiness using RBQM Technology

- Understand current regulations and guidelines that support an RBQM approach to clinical trials
- Unpack common audit findings in clinical trials
- Discuss how RBQM technology can be used to support regulatory compliance and audit readiness

IQVIA

Gayle Hamilton
Director RBQM Digital Trial Management Suite
IQVIA

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
Bringing AI Innovations to Clinical Trials (enabling patient recruitment, design and execution, risk reduction)

- Are customers comfortable using AI?
- Cost versus Benefits – do sponsors see a favorable value proposition?
- Client perspectives on AI in a global regulatory environment

LABCORP DRUG DEVELOPMENT

Adam Sullivan
Strategic Director of AI
Labcorp

Event Day

16:20 – 17:20 EST

ROUNDTABLE 4:
Understanding the vital impact of RBM in monitoring advanced therapies in the clinical trials phase

- Assessing risk tolerances and SDV
  - — What percentage do you SDV and SDR for a low, medium or high risk study
  - — Are companies sticking to the Transcelerate guideline of 12% SDV?
  - — Are companies defining QTLs for phase 1 studies?
  - — Are companies including only data that supports primary or secondary analysis?
- Tools and Reports
  - — Which tools are other companies using for RBM
  - — What is the frequency they run their reporting?
  - — Who leverages the dashboards and outputs once they have been set up? The CTAs and DMs themselves?
- Challenges for introducing RBM
  - — How have risked based approaches affected the dynamic working relationship between Sponsors and CROs?
  - — What challenges have companies encountered when performing central statistical monitoring and KRIs for smaller studies?

Elspeth Carnan
Senior Vice President, Clinical Development Operations
Alkermes Inc.

TRACK 2:
DIVERSITY, EQUITY AND INCLUSION IN PATIENT RECRUITMENT/DECENTRALIZED TRIALS

Delays in patient recruitment and engagement activities can cause major setbacks and become remarkably costly. This track is aimed at identifying key pitfalls, and exploring effective patient recruitment plans that leverage the latest tools, technologies and analytical approaches to deploy into having a successful clinical trial.

09:00 – 10:00 EST

ROUNDTABLE 1:
What are the challenges organizations face in enrolling diverse populations

- When we think about diversity is it really just about race? What else?
- How do we overcome the physical barriers?
- What about the social barriers?

Dina Berdieva
VP of Clinical Operations
Arcturus Therapeutics

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
Moving Beyond DCTs (Decentralized Clinical Trials): Next Steps in Trial Transformation

- What has worked well; what has been problematic so far?
- What has the industry not yet addressed?
- Do sponsors believe the DCT value proposition, and why?

John Cassidy
Global Head of Product & Commercial, eClinical
Labcorp

LABCORP DRUG DEVELOPMENT

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
Understanding Site needs in managing multiple trials: An open discussion

- **Is technology helping or creating more challenges?**
- **How do we take all the technology applications, processes and data required to successfully conduct a trial?**
- **Considerations for making the Site experience as simple and seamless as possible**

Aruna Adhikari Thapa
Senior Director of Product,
Site Suite and Planning Suite
IQVIA

IQVIA

Event Day

TRACK 3:
EMERGING BIOPHARMA

This track will highlight important discussions to help you stay ahead of the curve and retain a competitive advantage in the industry by examining major trends that will emerge and impact the future of Clinical Operations.

09:00 – 10:00 EST

ROUNDTABLE 1:
Design clinical trials that offers "CHOICE" to patients for in-clinic and at home (hybrid models) visits

- Examine the patient journey in clinical trials to ensure flexibility and patient centricity is at the heart of decision making
- Determine how the model (in clinic vs home) is determined for your current clinical research objectives
- Leverage new technologies to enable better data collection and interoperability

Amanda McEwen
Vice President, Clinical Development
Elevian Therapeutics

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
Less talk, more action: How to achieve diversity, inclusion and equity in clinical research

- What is diversity? Learn what diversity in the context of clinical research means and why it matters
- Understand what the barriers are to diversity in clinical research
- Get practical tips so you can implement actionable strategies to ensure your studies are more diverse

Ash Rishi
CEO and Co-founder, COUCH Health
Founder, Demand Diversity and COUCH Academy

COUCH HEALTH

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
Current & emerging therapeutic areas with high clinical focus & investment

- **Neurodegenerative conditions - how we're starting to uncover underserved patient data and how it's helping shape the discovery process for therapeutics for Alzheimer's, PLS and more...**
- **Renal Disease - Underserved demographics for males and how more diseases are starting to be uncovered but also prove to provide promise to unlocking multi-purpose therapeutics**
- **Breast Cancer - Serving women and men who are diagnosed with TNBC and serving**

Reginald Swift
Head of Study Management and Monitoring
Successful Strategies for Life Sciences

SPECIALTY SOLUTIONS

16:20 – 17:20 EST

ROUNDTABLE 4:
Exploring the future of operational supply chain to meet advancing product demand

- Strategies for partnering with process development
- Strategies for partnering with suppliers in the "new normal"
- Finding opportunities in the end to end supply chain

Jim Marshall
Associate Director, Materials Management
Alnylam Pharmaceuticals

TRACK 4:
CLINICAL OUTSOURCING

The healthcare industry has seen a tremendous development of outsourcing operations after the COVID-19 outbrake. Many businesses are looking for a reason to modify their present tactics in order to achieve significant returns on their investments and better cooperation. Here we will be highlighting the importance of using different strategies to increase engagements, and what's stopping businesses from achieving diversity goals.

09:00 – 10:00 EST

ROUNDTABLE 1:
Leveraging Outsourcing Strategies to Mitigate Rising Costs & Improve Partnerships

- How to identify providers of clinical services for biopharma
- How to monitor outsourcing clinical partners
- How to link costs to deliverables of partners

Oscar Segurado
Chief Medical Officer
ASC Therapeutics

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
How using SiteChoice to invest in your site's workforce can transform your study outcomes and patient's experience.

- Removes the resourcing barriers at your sites, that cause your study to get declined or even worse, miss its milestones
- Increases enrollment productivity by having experienced, subject facing, site-based personnel that focus exclusively on your clinical trials
- Provides detailed performance reporting for the sites on your study and delivers site insights previously unavailable

Jeff Repper
EVP Strategic Site Initiatives
Transformative Pharmaceutical Solutions

TRANSFORMATIVE PHARMACEUTICAL SOLUTIONS

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
Unburdening stakeholder's lives by eCOA technology solutions

- Understand your options when implementing your eCOA requirements
- eCOA technology for trials with different designs and patterns
- If you are considering or implementing eCOA as part of you decentralized trial setup, learn participant engagement options, best approaches, efficiencies and more

Zabir Macci
Director - eCOA Business Strategy and Sales Engineering
IQVIA

IQVIA

Event Day

16:20 – 17:20 EST

ROUNDTABLE 4:
How Can Sponsors Delegate Activities and Maintain Oversight?

- Discuss the importance of delegating activities and maintaining sponsor oversight
- Share actions that can be taken to ensure appropriate sponsor oversight
- Assess how you can measure successful sponsor oversight

Ana Sharma
Vice President, Head of Research and Development Clinical Quality Assurance
Takeda

TRACK 5:
CLINICAL DATA/REAL WORLD EVIDENCE

Companies are exploring ways to accelerate artificial intelligence into clinical trials. By doing this it's critical to analyze the importance of data processing, protocol developments, technology advancements and real world evidence to mitigate potential challenges and risks that could rise.

09:00 – 10:00 EST

ROUNDTABLE 1:
Incorporating real-time clinical insights in clinical development process for faster submissions and accelerated approvals

- Realizing the value of DS&AI driving oncology trial data for existing products label extension
- Can we apply clinical data insights from early to late stage trial designs to enable smarter trial designs
- Technology and analytics enabling biomarkers data to be gathered in real time – how do we apply this data to drive clinical trial end points

Sashka Dimitrievska
Global Therapeutic Area Head Oncology Clinical Insights
Astrazeneca

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
Effective Management of Essential Clinical Trial Documents Using eTMF Solutions

- What are common operational, security and regulatory issues around the collection, management, and reporting of essential clinical trial documents?
- How can eTMF solutions help to resolve these issues, and ensure inspection-ready and regulatory compliant storage of trial content?
- How do eTMF solutions reduce business risk, improve team collaboration and productivity, reduce auditing and reporting costs, and ensure enhanced artifact quality?
- What are some major capabilities that current eTMF solutions do or do not provide?

Debashish Niyogi, PhD
Vice President, Product Management
Anju Software

ANJU SOFTWARE

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
Industry Labor Shortage – The Post-Pandemic Workforce

- Understanding and adapting to an "aging out workforce"
- Embracing a younger workforce with different expectations for work/life balance
- What outsourcing models provide higher retention and why
- Explore how oversight monitoring addresses decreased data quality resulting from high turnover

Adrian Otte MB BCh,
Executive Strategic Advisor & Board Member
KPS Life

KPS LIFE

16:20 – 17:20 EST

ROUNDTABLE 4:
Accelerating Clinical Data Using Artificial Intelligence

- Establishing an effective strategy to organise and access new data in real time to avoid data chaos, eliminate waste and enhance patient safety > Discovering how data generated from A.I & Machine Learning can assist teams to identify red flag and risks to patients
- Analyzing detractions and concerns when using technology to capture data to avoid increased timelines, and incurring costs
  — New regulations to allow systems to evolve after approval

William Blumentals
Head of Pharmacoepidemiology
Sanofi Genzyme

TRACK 6:
SITE SELECTION/DISRUPTIVE TECHNOLOGY

Due to the COVID outbreak, many companies are struggling to enrol patients in the appropriate sites that are closer to them. They're up against the task of finding the correct user-friendly data innovation in order to identify matches with different sites that will allow the study to go more quickly, as well as access to diverse locations that will offer trials to patients of various ethnicities.

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
How can we use and optimize data in order to improve study start up and site cycle times

- Mobilizing data to hyper-target patient specific environments that will enable high confidence in enrollment
- Looking at optimizing site data correlation to look at successes and failures on enrollment techniques
- How to equip clinical teams to use real-time data to help understand the patient interface that overcomes initial barriers.

Reginald Swift
Head of Study Management and Monitoring
Successful Strategies for Life Sciences

SUCCESSFUL STRATEGIES

Event Day

16:20 – 17:20 EST

ROUNDTABLE 4:
What are the existing disruptive technologies that could be used to drive clinical operations?

- What is blockchain technology and how can it be used to drive clinical operations?
- How would the clinical operations be enhanced with disruptive technologies?
- Will adapting to the disruptive technologies save cost and time?
- Will the industry be able to keep up with the changes effectively?

Frank Leu
Chief Executive Officer
Novapeutics

14:10 – 15:10 EST

SOLUTION FOCUS ROUNDTABLE 3:
How to balance scientific complexity and its inherent issues with patient-centric design of the protocol to help increase R&D efficiency in clinical trials

- Learn how clinical study teams can balance the complexity of modern trial designs with a patient's first mission.
- Discover innovative approaches to minimize patient burden and enhance site feasibility.
- Utilize data driven insights to proactively identify areas of decentralization during the initial design of your protocol.
- Discuss challenges and strategies for the current state of adoption of decentralized trials in research
- Explore the role of modern trial designs and the collaboration done by digital clinical design platforms
- Explore the role of collaborations in addressing common barriers in the research community
- Defining patient centricity in clinical trials

Scott Chetham
CEO
Faro Health

FARO HEALTH

MEETING CONCLUDE

Please contact:
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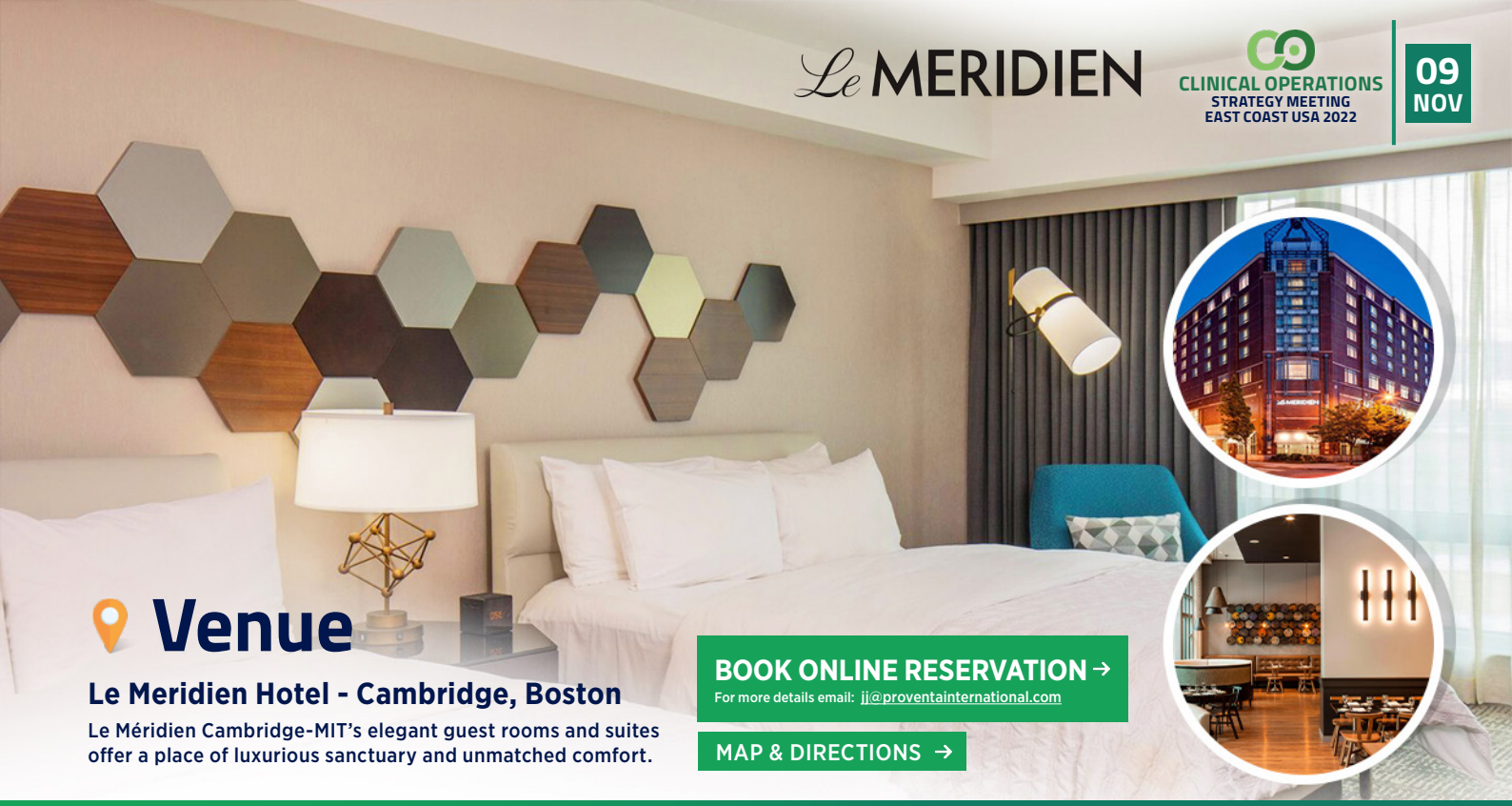

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MAP & DIRECTIONS →

OUR FACE-TO-FACE MEETING IN OCTOBER & NOVEMBER 2022

Strategy Meeting Zurich and Boston

Zurich - Europe

OCT 10 MON — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — BIOMANUFACTURING
Biomanufacturing Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 12 WED — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 13 THUR — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 10 MON — CLINICALTRIALSUPPLYCHAIN
Clinical Trial Supply Chain Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — CELLANDGENETHERAPY
Cell & Gene Therapy Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 12 WED — CHEMISTRYMANUFACTURINGCONTROL
CMC Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

Boston/Cambridge MA - US East Coast

NOV 08 TUE — ONCOLOGY
Oncology Strategy Meeting 2022
Le Meridien Cambridge

NOV 10 THUR — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Le Meridien Cambridge

NOV 15 TUE — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Le Meridien Cambridge

NOV 09 WED — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Le Meridien Cambridge

NOV 14 MON — DRUG DISCOVERY BIOLOGY
Drug Discovery Biology Strategy Meeting 2022
Le Meridien Cambridge

New Discoveries in Technology to Enhance Remote & Virtual Approaches, Utilisation of Telemedicine To Optimise Your Clinical Operation Success

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