Proventa International's 10th Annual

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

9th November 2023, Thursday | **Le Meridien Cambridge**

Effective integration of patient outcomes in clinical trial design, Overcoming under-enrollment of ethnic minorities, Employing RBQM and deep learning to your Trial knowledge

Featuring Industry Leaders and Decision Makers:

Elina Lavit
Vice President of Business Development
OncoNano Medicine

Emilio Neto
Head of US Clinical Country & Site Management, Senior Director
Biogen

Eyal Ron
Managing Partner
Sensei Ventures

George Naumov
COO & CBO
RS Oncology

Penny Carlson
Vice President, Head of Innovation & Data
Takeda Pharmaceuticals

Geraldine Briand Brucelle
Head of Clinical Study Operations Management & Academy
Novartis Institutes for Biomedical Research (NIBR)

Siew Tin Gan
Head Of Clinical Operations
Acumen Pharmaceutical

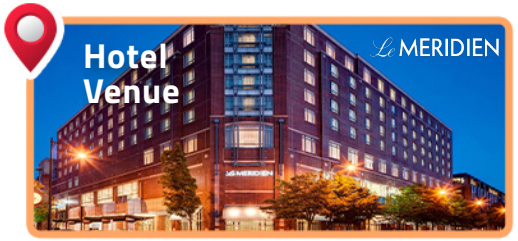
Wasfi AlAzzam
Director of Operations and Partnerships
Takeda

30 ROUNDTABLE DISCUSSIONS

6 TRACKS

2 KEYNOTE PRESENTATIONS

1 LOCATION



What Makes Our Strategy Meetings So Unique?

Proud to Partner with:

IQVIA TECHNOLOGIES | parexel | TRANSPERFECT | ELLIGO HEALTH RESEARCH | OneStudyTeam | ROSA | ObjectiveHealth | TriRadial SOLUTIONS | florence | thoughtsphere | Scout Clinical | TrialHub | PATIENT RECRUITING AGENCY LOOK NO FURTHER | 20 YEARS BOLD PATIENTRECRUITING.COM | TECHSOL LIFE SCIENCES

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

CLINICAL OPERATIONS
STRATEGY MEETING EAST COAST USA 2023

9th November 2023, Thursday | Le Meridien Cambridge

We're committed to delivering long-term value across our extensive life science network. Through our carefully crafted meetings, collaborative experiences and services Proventa International can offer you the perfect opportunity to meet your business goals, whatever they may be.

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

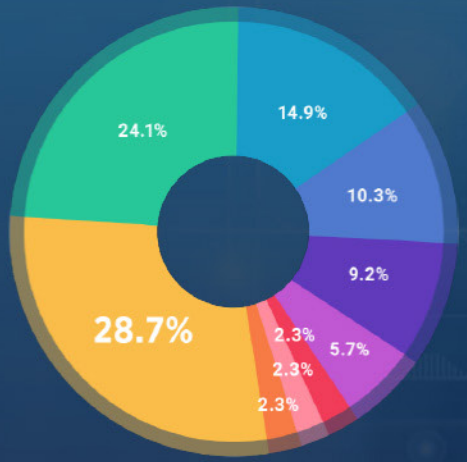
The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

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.

Seniority of Attendees

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



Clinical Operations

- Clinical Development
- Clinical Operations
- Clinical IT
- Clinical Data
- Clinical Innovation
- Early Phase Trials
- Late Phase Trials
- Risk Based Monitoring
- Biostatistics
- Study Feasibility / Site Head / Site Operations
- Patient Recruitment

Meet Investors

- Venture Capital
- Private Equity
- Large Pharma/Biotech
- Corporate Venture Capital
- Institutional
- High Net Worth
- Family Office/Private Wealth
- Government Organisation/ Sovereign Wealth Fund
- Angel

Facilitator Faculty

Wendy Morahan
Senior Director, Clinical Data Analytics
IQVIA Technologies

Julia Sundari
Senior Director, Clinical Design and Analytics
IQVIA Technologies

Nicolas Whitney
Director, Client Services, Feasibility
IQVIA Technologies

Nate Akers
Senior Vice President, Business Development
Parexel

Jimmy Brown
Senior Vice President, Business Development
Parexel

Colleen Hoke
Co-founder and CEO
Objective Health

Paige Bingham
CEO
Scout Clinical

Brian Schneider
Vice President of Business Development
Rosa & Co.

Carrie Melvin
Chief Operating Officer
Viridian Therapeutics

Elina Lavit
Vice President of Business Development
OncoNano Medicine

Emilio Neto
Head of US Clinical Country & Site Management, Senior Director
Biogen

Eyal Ron
Managing Partner
Sensei Ventures

George Naumov
COO & CBO
RS Oncology

Geraldine Briand Brucelle
Head of Clinical Study Operations Management & Academy, **Novartis Institutes for Biomedical Research (NIBR)**

Lalit Verma
Head, Artificial Intelligence CoE
Indiana University Health

Lisa Coleman
Senior Vice President, Global Inclusion and Strategic Innovation
New York University

ML Ujwal
Associate Director, Data Science
Janssen

Nancy Dubois
Head of Global Patient Safety, US Region
EMD Serono

Paul Stanley
Vice President, Head of Quality
Astria Therapeutics

Penny Carlson
Vice President, Head of Innovation & Data
Takeda Pharmaceuticals

Siew Tin Gan
Head Of Clinical Operations
Acumen Pharmaceutical

Yolanda Wan
Head of Clinical Operations
Orna Therapeutics

Wasfi AlAzzam
Director of Operations and Partnerships
Takeda

2023 Sponsors

LEAD SPONSOR

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry dedicated to creating intelligent connections that deliver unique and actionable insights. With approximately 82,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.iqvia.com. www.iqvia.com.

CO-HOST SPONSORS

Parexel Biotech works side-by-side with small and emerging biotech companies to break down the complex clinical development journey into a series of connected decisions, steps and milestones to help them meet their goals and achieve their mission. We leverage patient insights and patient-centric innovation and deliver through our global network of industry-leading capabilities, services and expertise – all while focusing on making the journey more effortless for our biotech customers.

TransPerfect Life Sciences offers global content solutions for the pharmaceutical, biotech, and medical device industries. With industry experts, specialists (like TMF, COA, medical writing, and marketing, among many others), certified linguists, and advanced technology, we accelerate the commercialization process for life sciences companies from lab through launch. Trust TransPerfect for precise, efficient, and cost-effective global content solutions. TransPerfect Life Sciences is a division of TransPerfect, a family of companies and solutions dedicated to being the world's leading enabler of global communications.

Elligo Health Research® accelerates clinical trials through healthcare with access to over 150 million known patients and their HIPAA-compliant healthcare data, our IntElligo® Research Stack technology, and our PatientSelect® identification and engagement model. Coupled with the largest Known Patient Access Network, Elligo's Site Solutions enable healthcare practices and research sites to participate in clinical trials. By adaptive engagement of known patients and physicians, we accelerate the development of new pharmaceutical, biotechnology, and medical device and diagnostic products.

Reify Health provides cloud-based software that accelerates the development of new and life-saving therapies. Reify serves the global life science industry, including thousands of clinical research sites, the most innovative biotechs, and the world's largest biopharmaceutical companies. The global healthcare system relies on clinical trials to develop new, life-saving treatments for patients. Reify Health's StudyTeam software empowers both the research sponsors who drive clinical trials forward and the doctors and research coordinators who care for patient volunteers so that they can devote more focus and time toward the work that results in successful clinical research. To learn more, visit www.reifyhealth.com.

ObjectiveHealth is an integrated research provider, partnering with physicians and healthcare organizations to establish an advanced infrastructure for research programs. The company takes an innovative approach to research that aims to improve patient outcomes at the point of care. Utilizing proprietary health-record-integrated technology, processes and trained on-site personnel, ObjectiveHealth delivers advances in clinical research.

For over 20 years, **Rosa** has utilized our PhysioPD® Research and ForecastMD™ platforms to provide actionable insights to life sciences companies that would be impossible to obtain in any other way. PhysioPD® Research is a proprietary approach that translates the physiology, disease pathophysiology and drug pharmacology of interest into a customized, interactive mathematical research platform to clarify the connection between disease mechanisms, therapeutic interventions and clinical outcomes. ForecastMD™'s key capability is to identify what product attributes will drive prescriber uptake and how a product's performance on these attributes will compare to current and future competitive options. The findings from these studies inform new product planning decisions and the quantification of a product's commercial potential.

TriRadial Solutions (www.triradial.com) is a global life sciences consultancy focused on helping companies navigate rapid growth. We develop innovative, fit-for-purpose people, process and technology solutions that deliver meaningful outcomes to improve Performance, Partnerships, and Compliance. All our solutions tie back to three core imperatives: deliver measurable performance increases, improve the value companies get from outsourcing and drive sustainable compliance across the organization. Our team of experienced domain experts are veteran professionals that bring first-hand experience confronting real-world business challenges. We have a passion for implementing transformational changes that make a positive, long-term impact on our clients and ultimately patients' lives.

Florence is the leading platform for remote connectivity and electronic document workflow management in clinical research. It is considered the industry standard, with more than 10,000 research sites, sponsors and CROs in 45 countries collaborating on its network. Florence advances clinical trials through software for managing document and data flow between research sites and sponsors. Florence solutions foster 25% faster start-up time and 40% reduced document cycle time, among other benefits. To learn about advancing research through collaboration, visit www.florencehc.com.

ThoughtSphere is a market-leading stacked platform that creates an integrated central monitoring environment to streamline RBQM, drug safety, medical, data management, and site management tasks in a single platform. Our user-friendly solution leverages Machine Learning and Artificial Intelligence to automate processes and modernize clinical trial operations from data aggregation to the generation of submission-ready datasets. Regardless of the trial design, level of patient-centricity or the diversity of data sources utilized, ThoughtSphere provides a 360º data view and a "one-stop-shop" for cross-functional end-users. Our flexible platform allows organizations the option to use all our solutions in concert or to pick specific solution(s) to fit their needs.

Scout Clinical, a member of the Meeting Protocol family, offers comprehensive services in travel, reimbursement, and payment management to ease site and patient burden. With over 25 years of industry experience and collaboration with leading pharmaceutical and biotechnology companies, Scout has successfully moved people and managed payments in over 100 countries for nearly 1,000 studies. Whether a study involves 2 patients or 20,000, Scout tailors each experience to sponsors' needs and regulatory requirements: country by country, visit by visit. With the motto "No request is too large or too small," Scout Clinical is dedicated to helping patients stick with it.

TrialHub has partnered with companies like Novartis, ICON and Boehringer. We deliver real-time clinical insights that prevent patient recruitment challenges and have supported over 6,000 global clinical trials. We are the first solution to automate Standard of Care (SoC) research and connect drug reimbursement with indications, in over 70 countries. Now, instead of spending weeks collating this information, SoC data can be displayed with a mouse click. We are also the first solution to offer patient feasibility, allowing our clients to assess if their target patient population, in specific countries, would be willing to participate in their trial. For more information, please visit www.trialhub.com

The Patient Recruiting Agency™ (TPRA) is a full-service Global Patient Recruiting & Retention Company working for Sponsors, CROs, & Investigators. Since 1999, TPRA has specialized in physician and patient outreach with a focus on diversity recruitment. Over the past 24 years, TPRA has recruited over 10,000 patients of all genders, ages, and races for over 150 indications in over 45 countries. TPRA's value proposition is that all services are performed IN-HOUSE, which provides TPRA's clients with greater synergy, cost efficiency, flexibility, quicker delivery time, as well as a single point of accountability. IN-HOUSE services include branding, content development, creative design, material fulfillment, media placement, website development, online pre-screening, & RADIUS365™ response & referral delivery, tracking, and reporting system. Experienced. Flexible. Scalable.

KEY OPINION LEADER

TECHSOL LIFE SCIENCES

Agenda at a Glance

CLINICAL OPERATIONS
STRATEGY MEETING EAST COAST USA 2023
9th November 2023, Thursday | Le Meridien Cambridge

TIME EST	TRACK 1 RISK BASED QUALITY MANAGEMENT/CENTRAL & REMOTE MONITORING	TRACK 2 DECENTRALIZED/ HYBRID TRIALS/PATIENT RECRUITMENT	TRACK 3 EMERGING BIOPHARMA / OUTSOURCING	TRACK 4 DIGITAL MEASUREMENTS/ CLINICAL DATA	TRACK 5 GLOBAL SITE SELECTION AND FEASIBILITY STUDY	TRACK 6 DIVERSITY, EQUITY, AND INCLUSION IN PATIENT ENGAGEMENT
ROOM ►	Margaret L.A. Macvicar	Edward Pennell Brooks	Jerome C. Hunsaker A	Lan Jen Chu	Jerome C. Hunsaker B	Jerome C. Hunsaker C
08:00 - 08:30	BREAKFAST & REGISTRATION					
08:30 - 09:00	OPENING KEYNOTE PRESENTATION Navigating through digital transformation and AI/ML driven insights to be well-prepared and resilient in face of global crisis situations Lalit Verma, *Head, Artificial Intelligence CoE,* Indiana University Health					
09:00 - 10:00	**Identifying strategic methods that promote risk-based quality management** Nancy Dubois, *Head of Global Patient Safety, US Region,* EMD Serono	**Decentralized Clinical Care and Patient Centric Drug Product Design at the forefront of healthcare provision** Nelio Drumond, *Associate Director - Global Manufacturing Sciences,* Takeda	**What future developments and commercial realities businesses with concentrated pipelines or single assets are facing?** Elina Lavit, *Vice President of Business Development,* OncoNano Medicine	**How can we use algorithms and other modern methods to clean and interpret data?** Lalit Verma, *Head, Artificial Intelligence CoE,* Indiana University Health	**Achieving recruitment timeline begins with Site selection and relationship building** Yolanda Wan, *Head of Clinical Operations,* Orna Therapeutics	**Describing the tactics for promoting more community participation and enhancing clinical trial diversity** Siew Tin Gan, *Head Of Clinical Operations,* Acumen Pharmaceuticals
10:00 - 10:05	REFRESHMENT BREAK					
10:05 - 10:25	NETWORKING / 1-1 MEETINGS					
10:25 - 10:45	NETWORKING / 1-1 MEETINGS					
10:45 - 11:05	NETWORKING / 1-1 MEETINGS					
11:10 - 12:10 SOLUTION			**The Evolution of Outsourcing Models: What are the Pros and Cons?** Nate Akers, *Senior Vice President, Business Development ,* Parexel Jimmy Brown, *Senior Vice President, Business Development ,* Parexel PAREXEL	**How Data Analytics and AI can help you oversee your portfolio of active trials when data are everywhere and insights are inconsistent** Wendy Morahan, *Senior Director, Clinical Data Analytics,* IQVIA Technologies IQVIA TECHNOLOGIES	**Redefining "AI" in Feasibility: Authentic Intelligence through Sponsor-Site Partnerships** Nicolas Whitney, *Director, Client Services, Feasibility,* IQVIA Technologies IQVIA TECHNOLOGIES	**How can we recognize and eliminate obstacles that prevent participation, such as historical distrust, accessibility issues and a lack of awareness?** Paige Bingham, *CEO,* Scout Clinical SCOUT CLINICAL
12:15 - 13:15	**Developing a Risk-Based Quality Management Approach to Mitigate Potential Risks and Liabilities** Penny Carlson, *Vice President, Head of Innovation & Data,* Takeda Pharmaceuticals	**Practical factors to take into account while switching to hybrid or decentralized clinical trials** Wasfi AlAzzam, *Director of Operations and Partnerships,* Takeda	**Challenges And Opportunities In Early-Stage Biotech Funding: Understand the strategies startups need to stand out from the competition** George Naumov, *COO & CBO,* RS Oncology	**Integrating Data Science and Machine Learning in Drug Discovery to Revolutionize Clinical Operations** ML Ujwal, *Associate Director, Data Science,* Janssen	**How can sponsors avoid pitfalls during the feasibility process and what are key steps that can be taken to mitigate them?** Emilio Neto, *Head of US Clinical Country & Site Management, Senior Director,* Biogen	**What obstacles do pharmaceutical and biotech businesses have to overcome in order to adequately represent various populations in clinical trials? (Topic TBC)** Carrie Melvin, *Chief Operating Officer,* Viridian Therapeutics
13:15 - 14:00	NETWORKING LUNCH					
14:00 - 14:30	AFTERNOON KEYNOTE PRESENTATION How AI and Data Analytics are transforming clinical trial oversight Wendy Morahan, *Senior Director, Clinical Data Analytics,* IQVIA Technologies					
14:30 - 14:50	NETWORKING / 1-1 MEETINGS					
14:50 - 15:10	NETWORKING / 1-1 MEETINGS					
15:15 - 16:15 SOLUTION	**Foundational Elements of RBM Steering the Future of Monitoring** Julia Sundari, *Senior Director, Clinical Design and Analytics,* IQVIA Technologies IQVIA TECHNOLOGIES		**Tackling Key Decisions in Drug Development** Brian Schneider, *Vice President of Business Development,* Rosa & Co ROSA		**Assessing technology to accelerate recruitment** Colleen Hoke, *Co-founder and CEO,* Objective Health OBJECTIVEHEALTH	
16:15 - 16:30	AFTERNOON REFRESHMENT BREAK					
16:30 - 17:30		**Improving Retention: Supporting decentralized techniques that lessen patient burden and maintain patient engagement** Nancy Dubois, *Head of Global Patient Safety, US Region,* EMD Serono	**Discussing the challenges in limited resources, inadequate infrastructure, delays in manufacturing and clinical supply, and funding concerns emerging biopharma and biotechs face** Eyal Ron, *Managing Partner,* Sensei Ventures	**Incorporating Digital Health Technologies (DHT) into Clinical Trial Design** Paul Stanley, *Vice President, Head of Quality,* Astria Therapeutics	**What tactics can we employ to successfully choose a site, do precise feasibility assessments and enhance the patient's experience? (Topic TBC)** Geraldine Briand Brucelle, *Head of Clinical Study Operations Management & Academy,* Novartis Institutes for Biomedical Research (NIBR)	**Driving Toward Health Equity: Global Diversity, Equity, Inclusion & Access (DEIA) in Patient Outreach and Engagement** Lisa Coleman, *Senior Vice President, Global Inclusion and Strategic Innovation,* New York University
17:30 - 18:30	DRINKS & CANAPES RECEPTION					

Event Day | Keynote Presentations

A great way to open the roundtable discussions is through a timely presentation from a top-tier biotech/pharmaceutical company. Listen as we hear this 30-minute exposition on this meeting's pressing topic.

08:30 - 09:00 EST **OPENING KEYNOTE PRESENTATION**

Navigating through digital transformation and AI/ML driven insights to be well-prepared and resilient in face of global crisis situations

Lalit Verma
Head, Artificial Intelligence CoE
Indiana University Health

ABOUT THE SPEAKER

Lalit Verma is an executive leader with 25+ years of progressive experience in the design, development, delivery, and management of digital technology solutions across global life-science corporations, including genomics, human & animal health, and agro-chemical industries. An advocate of human & animal health, Lalit is passionate about advancing healthy living through applied information technology, data science, and machine learning products and services. Lalit holds postgraduate degrees in Physics and Computer Science. From 1990 to 1999, he taught Electronics Honors undergraduate students at Delhi University and served as the department chair. Since 2002, he has served the life science industry as a bioinformatician and technical leader. At present, he is leading a global team of engineers, scientists, and project managers as Global Head of the Pre-clinical Sciences & Translational Safety Data Science at Janssen, the pharmaceutical division of Johnson & Johnson. He leads from the front in providing cutting-edge AI/ML/Deep Learning-based pre-clinical safety-related scientific workflow automation and data-driven decision-making, ensuring speedy regulatory submissions, first in human recommendations, and overall R&D pipeline cycle time reduction. He has authored bioinformatics and clinical algorithms, regulatory documents, and articles published in peer-reviewed journals.

14:00 - 14:30 EST **AFTERNOON KEYNOTE PRESENTATION**

How AI and Data Analytics are transforming clinical trial oversight

- The rapid evolution of AI technologies
- What is Generative AI and how are innovations like Chat GPT impacting clinical operations
- How are life sciences organizations gaining value from AI and data analytics

Wendy Morahan
Senior Director, Clinical Data Analytics
IQVIA Technologies

ABOUT THE SPEAKER

Wendy has 25+ years experience in the life sciences industry with a career spanning academic research, preclinical drug discovery, and clinical trials, culminating in a focus and passion for delivering technology solutions that help bring treatments to patients faster. Wendy is currently part of the product strategy leadership team for IQVIA Clinical Data Analytics Suite (CDAS), providing both SaaS solutions for the market as well as IQVIA's internal CRO needs. As part of the CDAS team, Wendy is responsible for strategy, product management leadership, and Go to Market activities.

Event Day

TRACK 1

Risk Based Quality Management/Central & Remote Monitoring

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.

08:00 - 08:30 EST BREAKFAST & REGISTRATION

08:30 - 09:00 EST OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 EST ROUNDTABLE 1

Identifying strategic methods that promote risk-based quality management

Nancy Dubois
Head of Global Patient Safety, US Region
EMD Serono

10:00 - 11:05 EST REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

12:15 - 13:15 EST ROUNDTABLE 3

Developing a Risk-Based Quality Management Approach to Mitigate Potential Risks and Liabilities

- Is technology required and how do companies select the right solution?
- Risk-Based Quality Management solutions – stand alone or complements to a broader clinical data/technology strategy?
- Risk-Based Monitoring as a subset of Risk-Based Quality Management – Options for technology and strategic approach; Sponsor-owned solution vs. CRO-owned solution
- Establishing cross-functional accountabilities (Clinical Operations, Site Monitoring, Clinical Quality Assurance, Statisticians and other study team functions)

Penny Carlson
Vice President, Head of Innovation & Data
Takeda Pharmaceuticals

ABOUT THE SPEAKER
Penny Carlson has 26+ years of experience in the pharmaceutical industry and is currently Head of Innovation & Data, which includes Clinical Data Management, Medical Writing, Risk Based Quality Management, GCP Operational Excellence and other clinical trial delivery functions. Penny has been with Takeda Pharmaceuticals for more than 12 years and is an executive leader in the Global Development Office, focusing on clinical trial delivery, external partnerships and innovative ways of delivering medicines to patients. Currently, she is also the Implementation Lead for the Future Fit Development Model—a transformative change to clinical development across Takeda R&D , which ultimately aims to accelerate the delivery of medicines to patients.

13:15 - 14:00 EST NETWORKING LUNCH

14:00 - 14:30 EST AFTERNOON KEYNOTE PRESENTATION
See Page 6

14:30 - 15:10 EST NETWORKING / 1-1 MEETINGS

15:15 - 16:15 EST SOLUTION FOCUS ROUNDTABLE 4

Foundational Elements of RBM Steering the Future of Monitoring

During this discussion, we will highlight the impact of RBM methodologies

- Digital transformation utilizing novel clinical technologies to strengthen the RBM model
- Patient generated data and the convergence with delivery models like decentralized clinical trials
- The increasing adoption of centralized, remote activities
- Usage of AI-driven, analytics-based processes in clinical monitoring

Julia Sundari
Senior Director, Clinical Design and Analytics
IQVIA Technologies

16:15 - 16:30 EST AFTERNOON REFRESHMENT BREAK

17:30 - 18:30 EST DRINKS & CANAPES RECEPTION

Event Day

TRACK 2

Decentralized/Hybrid Trials/Patient Recruitment

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.

08:00 - 08:30 EST BREAKFAST & REGISTRATION

08:30 - 09:00 EST OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 EST ROUNDTABLE 1

Decentralized Clinical Care and Patient Centric Drug Product Design at the forefront of healthcare provision

- Decentralized clinical trials (DCTs) are a recent reconceptualization of medical research design that embodies a patient-centric approach.
- Patient-centricity in research is also about making sure the population for whom a treatment is being developed is fairly represented and diverse.
- Collection of patient data within DCTs is far more easier to expand in a global context as compared to traditional site-based research studies.
- DCTs present opportunities for pharmaceutical industry to integrate patient-centricity in its R&D processes.

Nelio Drumond
Associate Director - Global Manufacturing Sciences
Takeda

ABOUT THE SPEAKER
Nélio Drumond is a PharmD by training with a PhD in Patient Centric Drug Product Design. He shares several years of experience in the Pharmaceutical Industry, providing scientific and strategic leadership to drug product development programs during clinical stages, including their scalability and validation for commercial use. Nélio spent the last 2 years overseeing Takeda's external supply portfolio in Germany and has recently moved to a global function in the United States supporting launch and commercialization of new innovative therapies. Dr. Drumond is a strong advocate for patient centric drug product design and is regularly invited to speak at international conferences.

10:00 - 11:05 EST REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

12:15 - 13:15 EST ROUNDTABLE 3

Practical factors to take into account while switching to hybrid or decentralized clinical trials

- Strategic Implementation: Explore the strategic considerations and methodologies for seamlessly transitioning from traditional clinical trials to hybrid or decentralized models, emphasizing the need for a well-thought-out plan.
- Operational Excellence: Discuss practical insights on optimizing operational processes, ensuring efficient trial conduct, data collection, and patient engagement while maintaining regulatory compliance.
- Patient-Centric Approach: Highlight the importance of a patient-centric approach, sharing strategies to reduce patient burden, enhance participation, and maintain a high level of patient engagement throughout the trial lifecycle.

Wasfi AlAzzam
Director of Operations and Partnerships
Takeda

ABOUT THE SPEAKER
Dr. Wasfi Alazzam brings about twenty years of pharmaceutical leadership experience to the product development and clinical operations arena. Known for his steadfast commitment to excellence, he has successfully guided cross-functional teams in various therapeutic domains and product modalities. Dr. Alazzam's impressive portfolio includes steering projects to fruition, fostering strategic innovation, and supporting regulatory submissions for multiple pharmaceutical products. His leadership is characterized by a strong dedication to ethical practices, a passion for innovation, and a consistent record of delivering meaningful outcomes. Dr. Alazzam's contributions continue to shape the landscape of clinical operations, making a lasting impact on the pharmaceutical industry.

13:15 - 14:00 EST NETWORKING LUNCH

14:00 - 14:30 EST AFTERNOON KEYNOTE PRESENTATION
See Page 6

14:30 - 15:10 EST NETWORKING / 1-1 MEETINGS

16:15 - 16:30 EST AFTERNOON REFRESHMENT BREAK

16:30 - 17:30 EST ROUNDTABLE 5

Improving Retention: Supporting decentralized techniques that lessen patient burden and maintain patient engagement

Nancy Dubois
Head of Global Patient Safety, US Region
EMD Serono

17:30 - 18:30 EST DRINKS & CANAPES RECEPTION

Event Day

TRACK 3

Emerging Biopharma / Outsourcing

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.

08:30 - 09:00 EST **OPENING KEYNOTE PRESENTATION**
See Page 6

09:00 - 10:00 EST **ROUNDTABLE 1**

What future developments and commercial realities businesses with concentrated pipelines or single assets are facing?

- After IRA act do you think that there is preference to develop specific type of assets small molecules vs biologics
- For companies with concertante assets /single assets do you think there is preference to be in certain therapeutic area
- When it comes to M&A what will be the ideal timing for acquisition for company with concentrated pipeline/ single asset

Elina Lavit
Vice President of Business Development
OncoNano Medicine

ABOUT THE SPEAKER
Elina Lavit is VP of Business Development at OncoNano Medicine. OncoNano Medicine is a privately held, clinical stage Biotech company that advances therapeutics and technology platforms for solid tumors. Elina brings over 19 years of experience in leadership roles in organizations ranging from start-ups to Fortune 100 corporations in various therapeutic areas, including oncology, neurology and cardiology. During her career, she has successfully negotiated in- and out-licensing transactions, from early-stage research technologies to clinical-stage assets. Previously, she served as Director of Program Management at Myokardia (acquired by BMS) and gained significant strategic Alliance and partnerships experience while working at Pharmacyclics, AbbVie, and Ethicon (JnJ). Elina earned a Bachelor of Science in Economics and Biology and Master of Science in Medical Science from Tel Aviv University.

11:10 - 12:10 EST **SOLUTION FOCUS ROUNDTABLE 2**

The Evolution of Outsourcing Models: What are the Pros and Cons?

Suddenly, today does not look like yesterday, let's discuss the impact of change in the context of three focus areas:

- Pace of clinical trial change is accelerating
- Cascading events lead to unavoidable impact on operation
- Outsourcing models have evolved to a bespoke continuum.

Nate Akers
Senior Vice President, Business Development
Parexel

Jimmy Brown
Senior Vice President, Business Development
Parexel

ABOUT THE SPEAKERS

Nate Akers

- A senior leader at Parexel, Nate is a clinical and regulatory strategist with experience in every stage of development and a wide spectrum of indications and therapeutic areas.
- His career spans many years in the healthcare and clinical development fields, including tenure with Lionbridge Life Sciences and Cardinal Health.
- Nate joined Parexel in 2013 and currently leads Parexel Biotech. He is responsible for partnering with clients to assist with clinical research service needs across all areas of clinical development.

Jimmy Brown

- 18+ years of clinical research experience including alliance management and account growth professional focused on supporting Biotech, Pharmaceutical and medical device companies at all stages of development.
- Member of the Biotech Leadership team and Commercial Head of Biotech Partnerships.
- Tasked with strategic growth strategy, business development and account growth and management for global strategic partnership accounts.
- Expertise includes alliance oversight and governance, internal team management, revenue forecasting and budget management.

12:15 - 13:15 EST **ROUNDTABLE 3**

Challenges And Opportunities In Early-Stage Biotech Funding: Understand the strategies startups need to stand out from the competition

George Naumov
COO & CBO
RS Oncology

14:00 - 14:30 EST **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:15 - 16:15 EST **SOLUTION FOCUS ROUNDTABLE 4**

Tackling Key Decisions in Drug Development

- Exploring the key decisions that Clinical Operations can impact
- What decision traps are we seeing?
- Step-by-step process for cultivating ideas and building consensus
- Using this tool to share and identify practical solutions we can implement

Brian Schneider
Vice President of Business Development
Rosa & Co.

ABOUT THE SPEAKER
Brian Schneider recently joined Rosa & Co. as our new Vice President of Business Development. Brian comes to Rosa after years of six years of progressive sales and sales management positions at Synthego Corporation. His previous experience includes 20+ years sales positions in the life science industry at companies including Gen9, Bio-Techne, Roche and Olympus America. Brian also spent several years running his own leadership and management skills training company. Until joining Rosa, Brian focused on getting data to successfully move assets through the drug development process. Now, the focus is helping those life science companies make better decisions with that data. He is based on the Boston area.

16:30 - 17:30 EST **ROUNDTABLE 5**

Discussing the challenges in limited resources, inadequate infrastructure, delays in manufacturing and clinical supply, and funding concerns emerging biopharma and biotechs face

- Limited Resources:
  - Financial constraints impacting operations.
  - Difficulty attracting and retaining top talent.
  - Technological limitations due to budget constraints.
- Inadequate Infrastructure:
  - Outdated or insufficient lab and manufacturing facilities.
  - Challenges in data management and compliance.
  - Struggles to meet regulatory standards with limited resources.
- Delays in Manufacturing and Clinical Supply:
  - Supply chain bottlenecks affecting production timelines.
  - Quality control challenges leading to delays in trials.
  - Logistics disrupting drug supply to trial sites.
- Funding Concerns:
  - Difficulty in attracting investment due to industry risk.
  - Vulnerability to market fluctuations impacting funding.
  - Intense competition for limited funding opportunities

Eyal Ron
Managing Partner
Sensei Ventures

ABOUT THE SPEAKER
Dr. Eyal S. Ron, a seasoned serial entrepreneur with 30+ years of experience in drug development, medical devices, and cosmeceuticals. He excels in innovative business strategies, culminating in multiple successful start-ups and product launches. Dr. Ron, a prolific author and inventor with 100+ papers and 50+ patents, leverages his scientific expertise to accelerate value inflection points. Apart from entrepreneurship, he actively engages with mentoring organizations like Biodesign, Northeastern VMN and MassChallenge. A notable speaker, Dr. Ron shares insights on establishing trustworthy collaborations, identifying a company's Minimum Viable Product (MVP) and go to market strategies.

17:30 - 18:30 EST **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 4

Digital Measurements/ Clinical Data

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.

08:00 - 08:30 EST BREAKFAST & REGISTRATION

08:30 - 09:00 EST OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 EST ROUNDTABLE 1

How can we use algorithms and other modern methods to clean and interpret data?

- What challenges industry is facing in data cleaning, data labeling and feature engineering in preparation for AI/ML production ready models.
- Impact of emerging generative AI solutions on data interpretation, reliability and trust for critical business decision making.
- How is the industry preparing for the speed of innovation opened up by the generative AI paradigm? Is the industry prepared? What are some of potential barriers and bottlenecks?

Lalit Verma
Head, Artificial Intelligence CoE
Indiana University Health

ABOUT THE SPEAKER
See page 6

10:00 - 11:05 EST REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

11:10 - 12:10 EST SOLUTION FOCUS ROUNDTABLE 2

How Data Analytics and AI can help you oversee your portfolio of active trials when data are everywhere and insights are inconsistent

- Why trying to manually oversee a portfolio of trials in today's environment is inefficient and ineffective
- How modern technologies can help aggregate, normalize and store relevant Operational and Clinical data for all your trials
- How Generative AI is transforming the future of data exploration and oversight

Wendy Morahan
Senior Director, Clinical Data Analytics
IQVIA Technologies

ABOUT THE SPEAKER
See Page 6

12:15 - 13:15 EST ROUNDTABLE 3

Integrating Data Science and Machine Learning in Drug Discovery to Revolutionize Clinical Operations

ML Ujwal
Associate Director, Data Science
Janssen

ABOUT THE SPEAKER
ML Ujwal PhD leads the PSTS/Data Science at Janssen R&D (J&J). He is a proven scientific leader with a strong pedigree in Drug Discovery and Applied Machine Learning. He has 15+ years of experience in academia, biotech, and large pharma. Before joining Janssen R&D, he co-founded and was the head of Data Sciences at Inciton, an early-stage startup that used MD simulations and ML approaches. Earlier he led predictive toxicology efforts at Eli Lilly & Co. He was on staff at the Institute for Genomic Research (TIGR). His academic credentials include MIT Engineering Management with an emphasis on systems thinking and ML frameworks. As an IIJMB Wood-Whelan fellow, he is a joint PhD in Computational Biochemistry/Biophysics from the Indian Institute of Science (IISc) and the University of Texas, Austin, followed by post-doctoral work both at Yale and Harvard. He has extensively published in peer-reviewed journals and serves on scientific advisory committees.

13:15 - 14:00 EST NETWORKING LUNCH

14:00 - 14:30 EST AFTERNOON KEYNOTE PRESENTATION
See Page 6

14:30 - 15:10 EST NETWORKING / 1-1 MEETINGS

16:15 - 16:30 EST AFTERNOON REFRESHMENT BREAK

16:30 - 17:30 EST ROUNDTABLE 5

Incorporating Digital Health Technologies (DHT) into Clinical Trial Design

- Applying DHT for improved participant experience, trial efficiencies and more comprehensive data sets
- Navigating Regulatory Authority for DHT applications in clinical trials
- Overcoming DHT generated clinical data security, integrity, management and interpretation challenges

Paul Stanley
Vice President, Head of Quality
Astria Therapeutics

ABOUT THE SPEAKER
Paul J. Stanley, member of Beta Gamma Sigma earned his MBA at the Boston College Carroll School of Management. He joined Boston based Astria Therapeutics as Head of Quality in 2021. Paul has lived the biotech experience for over 30 years, growing up at the Genzyme Corp, Framingham MA campus during the 1990s and 2000s before making the switch to clinical stage companies which have included Synageva, Visterra, Catabasis, Frequency and Astria, where product the profiles have included enzyme replacement, monoclonal antibody and small molecule based therapies as well as Class III medical devices. Much of his time has been spent developing, implementing and managing risk based GxP Quality Management Systems designed for sustainability while serving to enable effective and efficient product and clinical development. Along the way his work has simultaneously revolved around the milestones and activities inherent in INDs, BLAs, pre-approval inspections, product launches and commercial product lifecycle management. Through it all, he particularly enjoys the demands and rewards of working closely with his partners both internal and external, executing under a shared vision of bringing life changing therapies to patients in need.

17:30 - 18:30 EST DRINKS & CANAPES RECEPTION

Event Day

TRACK 5

Global Site Selection and Feasibility Study

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.

08:30 - 09:00 EST **OPENING KEYNOTE PRESENTATION**
See Page 6

09:00 - 10:00 EST **ROUNDTABLE 1**

Achieving recruitment timeline begins with Site selection and relationship building

- Where to begin in Site and Investigator identification?
- Why not let the CRO handle it all?
- What do you mean by relationship building?

Yolanda Wan
Head of Clinical Operations
Orna Therapeutics

ABOUT THE SPEAKER
Yolanda is the Head of Clinical Operations at ORNA Therapeutics, a platform-based biotech dedicated to designing and delivering a new class of fully engineered circular RNA (oRNA) therapeutics. Her industry career spanning over 20 years has included site monitoring & management, study management, compound-level project management, and regional & global-level clinical development operations leadership. Much of her experience has been focused on the development of antineoplastic agents. Yolanda has the ability to work with matrix team members towards the successful completion of project goals, with timeline and quality always as her top priorities. Prior to ORNA, Yolanda has worked at major companies like Bayer and Roche, with progressive responsibilities over time.

11:10 - 12:10 EST **SOLUTION FOCUS ROUNDTABLE 2**

Redefining "AI" in Feasibility: Authentic Intelligence through Sponsor-Site Partnerships

- What is preventing sponsors and sites from having the authentic conversations needed to build mutual trust and align needs?
- What does the industry need to build an efficient feasibility process that leads to positive site experiences?
- How can we move from a transactional approach to a site partnership model?

Nicolas Whitney
Director, Client Services, Feasibility
IQVIA Technologies

12:15 - 13:15 EST **ROUNDTABLE 3**

How can sponsors avoid pitfalls during the feasibility process and what are key steps that can be taken to mitigate them?

- Designing a patient journey that encompasses various touchpoints, from initial diagnosis through treatment and follow-up
- Crafting a robust study design while carefully considering the selection of the patient population to ensure statistically significant results balancing site and patient burden.
- Evaluating the global healthcare landscape and strategically selecting appropriate countries and clinical research sites, accounting for regulatory frameworks, patient diversity, and healthcare infrastructure to ensure the study's relevance and applicability on a global scale.

Emilio Neto
Head of US Clinical Country & Site Management, Senior Director
Biogen

ABOUT THE SPEAKER
An executive with more than 20 years of experience in Drug Development Strategy, Global Project and Team Management, Clinical Operations, and Project Finance Management globally from Phase I to Phase IV clinical trials. Experience runs through different therapeutic areas such as Rare Diseases, Respiratory, Cardiovascular, Neuroscience, Vaccines and Oncology in multiple phases (Early Clinical Development to Phase IV).As Head of US Clinical Country & Site Management, responsible for the leadership, direction and is accountable for the performance of the CCSM function in the US for all Biogen clinical trials across all phases of development and therapeutic areas. Emilio earned a PharmD degree from São Paulo University (USP - Brazil), an MBA from Getulio Vargas University (EAESP - Brazil) and complemented by a Certification in International Business Management from UCD Smurfit School (Ireland).

14:00 - 14:30 EST **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:15 - 16:15 EST **SOLUTION FOCUS ROUNDTABLE 4**

Assessing technology to accelerate recruitment

How technology can identify and prioritize patients with intelligent screening tools:

- Discuss the benefits of utilizing machine learning and precision protocol matching to streamline the recruitment process.
- Highlight the practical aspects of embedding intelligent tools into clinical research site workflows, empowering coordinators to proactively recruit eligible patients.
- Discuss the importance of real-time analytics and enhanced transparency in workflow management.

Colleen Hoke
Co-founder and CEO
Objective Health

ABOUT THE SPEAKER
Having held leadership and executive positions at clinical research organizations, specialty providers, and healthcare entities, Colleen has more than 25 years of experience in the areas of business development, organizational management, and executive team building. She was a key member of an executive team that built a successful early-phase research site that was later acquired by a major research corporation, and she has contributed to best practice standards for the Association of Clinical Pharmacology Units (ACPU). Colleen holds a bachelor's degree of science from the University of Tennessee and is a graduate of the Wharton School of Business Executive Leadership course.

16:30 - 17:30 EST **ROUNDTABLE 5**

What tactics can we employ to successfully choose a site, do precise feasibility assessments and enhance the patient's experience?

- Discuss the various feasibility databases used
- Which data to use when conducting a feasibility assessment
- How can we compare the various sites identified?
- Discuss how to select high-performing patient centric sites

Geraldine Briand Brucelle
Head of Clinical Study Operations Management & Academy
Novartis Institutes for Biomedical Research (NIBR)

ABOUT THE SPEAKER
Geraldine Briand Brucelle is a Study Operations Head at Novartis with almost 20 years of experience in pharma. She started in Portfolio Management and then moved to Clinical Sciences & Innovation (CS&I) as a Resource Manager working on study budget. Her interest in patients, countries and sites made her move to a Feasibility role that she held for 5 years. In January 2021, Geraldine took on a newly created role as CS&I Study Operations Head, supervising Study Operations Managers and Academy fellows who provide clinical trial operations support. As a member of the Study Operations and Academy leadership teams, she has provided major contributions to the building and implementation of two new organizations.

17:30 - 18:30 EST **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 6

Diversity, Equity, and Inclusion In Patient Engagement

08:00 - 08:30 EST BREAKFAST & REGISTRATION

08:30 - 09:00 EST OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 EST ROUNDTABLE 1

Describing the tactics for promoting more community participation and enhancing clinical trial diversity

Siew Tin Gan
Head Of Clinical Operations
Acumen Pharmaceuticals

10:00 - 11:05 EST REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

11:10 - 12:10 EST SOLUTION FOCUS ROUNDTABLE 2

How can we recognize and eliminate obstacles that prevent participation, such as historical distrust, accessibility issues and a lack of awareness?

- Where are we as an industry in recognizing that these are barriers in the first place?
- What are the key practical application steps that can be taken?
- How committed are we to affecting the change needed?

Paige Bingham
CEO
Scout Clinical

ABOUT THE SPEAKER
Having joined Meeting Protocol Worldwide in 1999, Paige played a pivotal role in the company's growth and expansion into numerous countries by establishing the London office and growing the European market. After many years abroad, she returned to the Dallas headquarters, at which time she was appointed Chief Operating Officer (COO), bringing with her a strong belief in cultural diversity and inclusivity. During her tenure as COO, Paige was instrumental in the creation of Scout Clinical, a market-leading patient reimbursement and concierge division. Through her passion for enhancing the patient experience she has driven adoption into the some of the Top 10 global pharmaceutical and contract research organizations.

12:15 - 13:15 EST ROUNDTABLE 3

What obstacles do pharmaceutical and biotech businesses have to overcome in order to adequately represent various populations in clinical trials? (Topic TBC)

Carrie Melvin
Chief Operating Officer
Viridian Therapeutics

13:15 - 14:00 EST NETWORKING LUNCH

14:00 - 14:30 EST AFTERNOON KEYNOTE PRESENTATION
See Page 6

14:30 - 15:10 EST NETWORKING / 1-1 MEETINGS

16:15 - 16:30 EST AFTERNOON REFRESHMENT BREAK

16:30 - 17:30 EST ROUNDTABLE 5

Driving Toward Health Equity: Global Diversity, Equity, Inclusion & Access (DEIA) in Patient Outreach and Engagement

- What steps pharmaceutical and biotech organizations might take to drive toward health equity in clinical trials.
- The obstacles that need to be addressed and the opportunities that might be leveraged in short, medium, and long-term planning and outreach efforts.
- What an engagement strategy entails when focusing on groups who have been historically and currently marginalized and underrepresented.

Lisa Coleman
Senior Vice President, Global Inclusion and Strategic Innovation
New York University

ABOUT THE SPEAKER
Dr. Lisa M. Coleman is New York University's (NYU) inaugural senior vice president for global inclusion and strategic innovation. In this role, she works with senior leaders, internal stakeholders, external partners, and constituents to advance, promote, and build capacity for strategies for Global Inclusion, Diversity, Belonging, Equity, and Access (Global IDBEA) and strategic innovation initiatives across NYU. This includes the New York, Shanghai, and Abu Dhabi campuses, as well as NYU's thirteen global sites, and numerous global research centers. Dr. Coleman is also a faculty member at the NYU Stern School of Business and teaches at NYU Abu Dhabi.

17:30 - 18:30 EST DRINKS & CANAPES RECEPTION

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

9th November 2023, Thursday | Le Meridien Cambridge

PROVENTA INTERNATIONAL

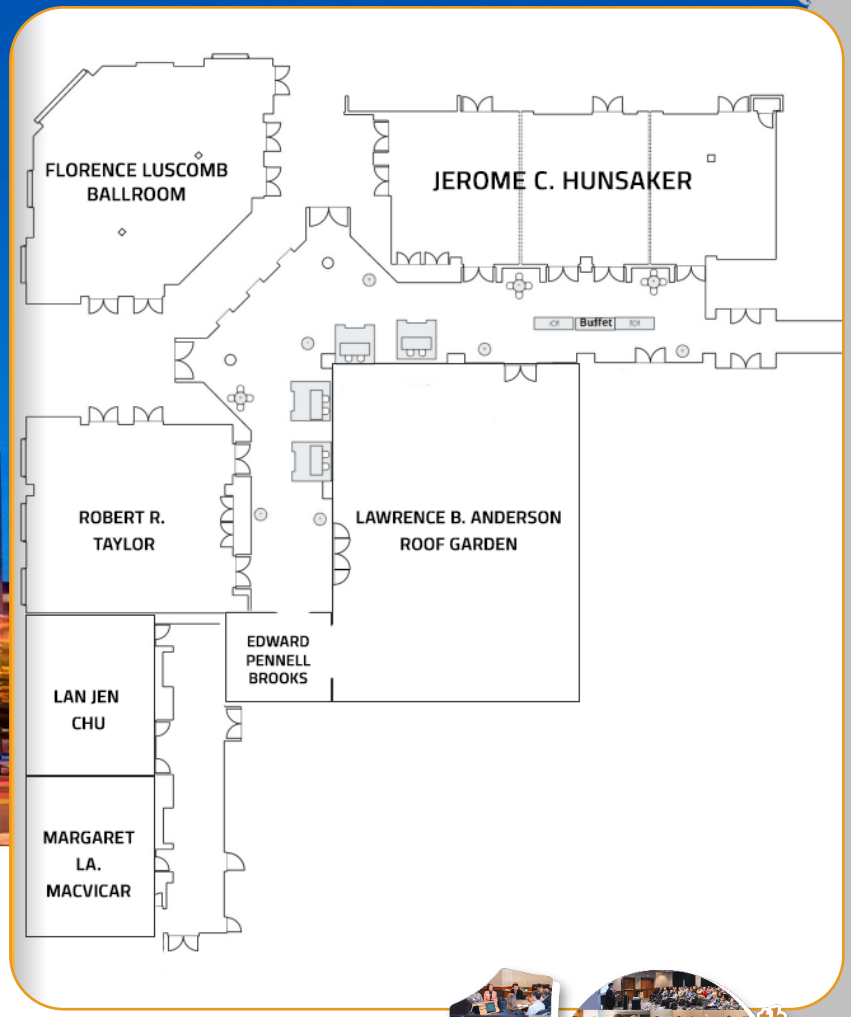
Celebrating TEN YEARS OF EXCELLENCE

• SINCE 2013 •

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

9th November 2023, Thursday Le Meridien Cambridge



Map

Transport & Getting directions from your location ➜

Check-in and Check-out (bedrooms)

Check-in: 3:00 PM
Check-out: 12:00 PM
*Featured amenites include a 24hr business center, complimentary newspaper in the lobby & dry cleaning/laundry services

Internet Access

Guest rooms: Complimentary Wireless
Lobby and public areas: Complimentary Wireless
Meeting rooms: Wireless (supplied by Proventa)

Parking at the hotel

Electric car charging stations: 2, For a fee
Self Parking Fee: USD 40 Per Day (in/out Priveleges)
Valet Parking Fee: USD 46 Per Day (in/out Priveleges)

Car Parks in the area nearby

55 Franklin St. Garage - 55 Franklin St, Cambridge, MA 02139, United States
Pilgrim Parking - 47 Erie St, Cambridge, MA 02139, United States

CONTACT US FOR MORE DETAILS: ls@proventainternational.com +1 (617) 614 0377 www.proventainternational.com

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

9th November 2023, Thursday Le Meridien Cambridge

Hotel & Venue

Le MERIDIEN

Le Méridien Boston Cambridge

Le Méridien Cambridge-MIT's elegant guest rooms and suites offer a place of luxurious sanctuary and unmatched comfort. Explore unique programs inspired by the brand's European heritage. Born in a glamorous era of travel, Le Méridien believes everyone should explore the world in style.

Hotel Details > Map & Directions >




OUR FACE-TO-FACE MEETING IN NOVEMBER 2023

Strategy Meeting Boston USA

NOV 2023

Boston/Cambridge MA - US East Coast
06th - Bioinformatics & IT Strategy Meeting
07th - Drug Discovery Biology Strategy Meeting

Boston/Cambridge MA - US East Coast
08th - Medicinal Chemistry Strategy Meeting
09th - Clinical Operations Strategy Meeting

Visit us on our website to know more about our meetings
www.proventainternational.com