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CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN

STRATEGY MEETING EAST COAST USA 2024

Thursday, 14th November 2024 | **Le Meridien Cambridge**

Effective integration of patient outcomes in clinical trial design, overcoming under-enrollment of ethnic minorities, employing RBQM, and deep learning to enhance your trial knowledge

Featuring Industry Leaders and Decision Makers:

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

Yuyi Shen
Vice President, Technical Operations
Abcuro, Inc

Allison Kemner
Vice President, Clinical Sciences and Operations
Tyra Biosciences

Uday Harle
Assistant Vice President and Head, Global Clinical Research
Kashiv Biosciences

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

Nancy Dubois
Head, Global Patient Safety, US Region
EMD Serono, Inc.

Maria Margarita Corvez
Global Program Director Hematology
AstraZenca

24 ROUNDTABLE DISCUSSIONS

6 TRACKS

2 KEYNOTE PRESENTATIONS

1 PANEL DISCUSSION

1 LOCATION

What Makes Our Strategy Meetings So Unique?

Proud to Partner with:

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

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
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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.

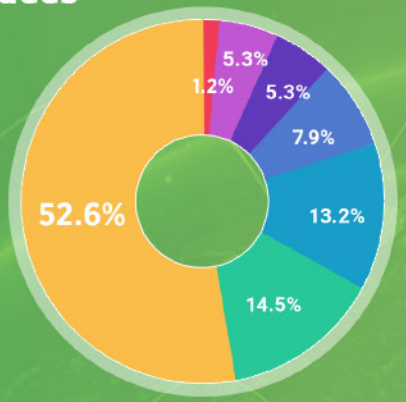
PERSONALISED AGENDA
Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

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



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

Clinical Trial Supply Chain

- CEO
- VP
- Director
- Global Clinical Program Head
- Clinical Trial Logistics
- Supply Chain
- Clinical Distribution
- Clinical Supplies Management
- Warehousing
- Cold Chain
- Quality Inspection

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

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Facilitator Faculty

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
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Michael Kleinrock
Senior Research Director, IQVIA Institute for Human Data Science
IQVIA

Naouel Baili
Director, AI Scientist
IQVIA Technologies

Charlie Pattrell
Associate Director, Solution Engineering
IQVIA

Caroline Potts
General Manager – MRN Site and Patient Services
Medical Research Network

Graham Wylie
Executive Chairman
Medical Research Network

Ed Carneglia
Business Development Manager
Peli BioThermal USA

Jamie Morisco
Vice President, Sales, Marketing & Operations
Glemser

Pawan Gandhi
Director, R&D
Glemser

Bill Jackson, Ph.D.
Founder & CEO
Base Pair Biotechnologies, Inc.

Abhishek Gupta
Senior Director, Research & Development | Quality Capabilities
BlueRock Therapeutics

Allison Kemner
Vice President, Clinical Sciences and Operations
Tyra Biosciences

Amy McCagg
Former Executive Director and Head, Patient Innovation
Sarepta Therapeutics

AnneMarie Winkler
Associate Director, Clinical Trial Optimization and Innovation
Genmab

Frank Leu
Founder & Managing Member/Managing Member
BioPharMatrix LLC/ Novapeutics LLC

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

Justin Buie
Clinical Program Manager
Candel Therapeutics

Maria Margarita Corvez
Global Program Director Hematology
AstraZeneca

Meredith Frank-Molnia
Vice President, Clinical Affairs
Vericel Corporation

Michael Tolentino
Co-Founder, Chief Innovation Officer and Board Member
Aviceda Therapeutics

ML Ujwal
Associate Director, Data Science
Johnson & Johnson

Nancy Dubois
Head, Global Patient Safety, US Region
EMD Serono, Inc.

Rakibou Ouro-Djobo
Global Clinical Supply Chain & Logistics Leader
Bill & Melinda Gates Medical Research Institute

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

Uday Harle
Assistant Vice President and Head, Global Clinical Research
Kashiv Biosciences

Yuyi Shen
Vice President, Technical Operations
Abcuro, Inc

George Naumov
Chief Operations Officer & Chief Business Officer
RS Oncology

2024 Sponsors

LEAD SPONSOR

IQVIA Clinical Technologies develops and delivers clinical trial software products providing sponsors, sites, and CROs with an operational advantage to transform the trial experience for sites and patients. We apply our expertise in healthcare-grade AI to gain efficiencies and insights in trial planning and budgeting, sponsor-site communication, patient engagement, and sponsor oversight. Our market-leading SaaS products and tech-enabled services are offered independently from our CRO services to match any business model. Explore our full line of orchestrated clinical trial technologies at iqvia.com/oct and contact us to learn more.

THOUGHT LEADER

MRN accelerates patient recruitment and improves patient engagement and retention through site-centric and patient-centric solutions. As an innovative market-leader, MRN provides customized solutions to optimize each individual protocol and create more flexible, efficient and accessible clinical trials that deliver accelerated timelines. Through integrated in-home visit delivery and a vast global network of trained, research ready sites, all empowered by MRN's digital solutions, MRN engages with and empowers diverse communities around the world to participate in and advance medical research.

CO-HOST SPONSORS

Since 1987, **Glemser** has played a critical role in developing industry-leading IT solutions and services that are essential for global life science companies to solve their most pressing challenges in quality, compliance, and efficiency. Glemser has modernized Global Labeling with ComplianceAuthorTM, a system designed to aggregate your existing RIM systems and data repositories to allow for streamlined labeling capabilities. We leverage advancements in natural language processing, machine learning, artificial intelligence, and natural language generation to make product labeling easy and content finable, accessible, interoperable, and reusable.

Pharmaceutical companies — and other organizations looking to make significant cost and quality improvements in their cold chains — are switching to Pelican BioThermal for single-use and reusable temperature-controlled packaging. Our innovative, patented technologies and consultative services ensure product quality, mitigate excursion rates, reduce packaging costs and drive TCO across your entire supply chain. Our global network of consultative cold chain experts provides our customers with consistent packaging and logistics experiences wherever they do business. While our full line of single-use and reusable packaging solutions — from parcel to pallet shippers — are competitively priced, the real economic value we bring to our customers focuses on TCO.

We can help you with concept through to commercialization by enabling:
- Accelerated speed to market
- Controlled development costs
- Development risk mitigation
- Market viability assessment

At every stage, we navigate our clients to realize efficiencies in cost and time with our integrated and comprehensive solutions.

Base Pair Biotechnologies is based just 10 miles south of the Houston, Texas Medical Center. Our team of 11 scientists has a combined 50+ person-years of experience in developing aptamers. Base Pair owns the sole worldwide rights to patents for multiplexed aptamer discovery. We have the capability to select aptamers to up to 30 protein, peptide, or small molecule targets in true competitive, multiplexed fashion. The resulting aptamers are therefore more specific for their particular targets. Using this technology, we have completed contracts from the National Cancer Institute, the CDC, and many large pharma and biotech firms and can serve as an excellent partner to help achieve your drug discovery and validation needs.

PARTNERING SPONSORS

Revvity Signals Software formerly known as PerkinElmer Informatics offers one of the most comprehensive suites of scientific software in the world. Our future-proof technology enables investigators in Life Sciences to capture and analyze their data from initial research and development of their therapeutics, through biomarker discovery & patient stratifications and ultimately live tracking of their clinical trials. From our internationally recognized flagship ChemDraw® to our Signals Research Suite (Signals Notebook, Signals VitroVivo, and Signals Inventa)to our exclusive TIBCO® Spotfire® partnership that brings scientific data analytics to visual life in both

Datacubed Health is a pioneering eClinical technology company built from the ground up by industry veterans who wanted to create a better clinical trial experience for all stakeholders. Our solutions are all infused with neuroeconomic principles designed to be inclusive, drive compliance, and greatly improve retention. We strive to deliver the best experience for you and your patients through ease of use and flexible technology configurable to your needs. Our offerings include a Decentralized Trials Platform, eCOA/ePRO, Patient Engagement, eConsent, Medication Adherence, Televisits, and Geofencing.

TOTAL Diversity Clinical Trial Management is a specialized Contract Research Organization dedicated to excellence, efficiently launching studies, enrolling diverse patients, and prioritizing quality and communication. As a full-service Contract Research Organization, we offer a comprehensive range of services including consulting, training programs, patient recruitment, retention services, and more. We are committed to reshaping the landscape of clinical research with a focus on inclusivity and accessibility through our network of capable sites and experienced researchers.

Clinical operations: - Clinical trial outcome prediction: based on 86000 clinical trials and with 350+ parameters. Used to prioritize clinical trials, give guidance on parameters lowering the POS and help design the protocol. Used as a basis for EY's immunology report, for indication prioritization etc. - Patient/site selection - Biomarker identification based on genomics data
Tool: Ontosight to help to find and explore data
Data: - Access to Onco data from >500k patients in Germany including RWD and clinical data. ->2m data in India from various hospital collaborations -Other patient data from Switzerland or South America under way

KEY OPINION LEADER

Agenda at a Glance

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2024
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TIME EST	TRACK 1 PATIENT RECRUITMENT / DECENTRALIZED & HYBRID TRIALS	TRACK 2 EMERGING BIOPHARMA / OUTSOURCING	TRACK 3 CLINICAL TECHNOLOGIES & INNOVATION	TRACK 4 GLOBAL SITE SELECTION AND FEASIBILITY STUDY	TRACK 5 DIVERSITY, EQUITY, AND INCLUSION IN PATIENT RECRUITMENT & ENGAGEMENT	TRACK 6 CLINICAL SUPPLIES / STORAGE & GLOBAL NETWORKS
BOARDROOM ►	Jerome C. Hunsaker A	Jerome C. Hunsaker B	Jerome C. Hunsaker C	Edward Pennell Brooks	Margaret L.A. Macvicar	Lan Jen Chu
08:00 - 08:30	BREAKFAST & REGISTRATION					
08:30 - 09:00	**OPENING KEYNOTE PRESENTATION:** Is Technology Delivering on its Promise to Improve Clinical Development Productivity? PRESENTER: Michael Kleinrock, *Senior Research Director, IQVIA Institute for Human Data Science,* IQVIA					
09:00 - 10:00 PHARMA/ BIOTECH	**Data Security and Privacy in the Era of Decentralized Trials: A 2024 Perspective** James Kirwin, *COO and Head, Clinical Development Operations,* SFA Therapeutics	**Managing the Complications of Collaborations: Obstacles and Resolutions in Outsourcing for Developing Biotech/ Pharma Companies** Nancy Dubois, *Head, Global Patient Safety, US Region,* EMD Serono, Inc.	**The Latest Trends in Electronic Data Capture (EDC) Systems and eClinical Solutions for Digital Transformation in Clinical Operations** Abhishek Gupta, *Senior Director, Research & Development | Quality Capabilities,* BlueRock Therapeutics	**Accelerating Clinical Trial Enrollment Through Informed Site Selection and Trial Design** Michael Tolentino, *Co-Founder, Chief Innovation Officer and Board Member,* Aviceda Therapeutics	**Implementing Diversity, Equity, and Inclusion (DEI) Initiatives: Insights from Company Case Studies and Exemplary Practices (TOPIC TBC)** Justin Buie, *Clinical Program Manager,* Candel Therapeutics	**A Strategic Discussion on Clinical Supplies, Storage Innovation, and Global Networks Reshaping the Landscape of CTM, Storage Facilities, Packaging, and Labeling in Clinical Trials** Rakibou Ouro-Djobo, *Global Clinical Supply Chain & Logistics Leader,* Bill & Melinda Gates Medical Research Institute
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	**Expanding Trial Access into New Communities for New Sites, Patients, and Researchers** Caroline Potts, *General Manager – MRN Site and Patient Services,* Medical Research Network MRN	**Protocol Designs Balancing Safety, Endpoints, and Cost** Graham Wylie, *Executive Chairman,* Medical Research Network MRN	**Transforming Clinical Data Analytics with Generative AI: The Next Frontier in Trial Efficiency and Precision** Naouel Baili, *Director, AI Scientist,* IQVIA Technologies IQVIA	**Redefining "AI" in Feasibility: Authentic Intelligence through Sponsor-Site Partnerships** Michael Kleinrock, *Senior Research Director, IQVIA Institute for Human Data Science,* IQVIA IQVIA		**Supply Chain Initiatives that Improve Accountability, Optimization, and Sustainability in IP Management** Charlie Pattrell, *Associate Director, Solution Engineering,* IQVIA IQVIA
12:15 - 13:15 PHARMA/ BIOTECH	**Is Patient Recruitment Keeping Pace with Technological Advances in the Future Years?** ML Ujwal, *Associate Director, Data Science,* Johnson & Johnson	**The Role of AI/ML in Enhancing Efficiency for Emerging Biopharma** James Kirwin, *COO and Head, Clinical Development Operations,* SFA Therapeutics	**AI and ML in 2024: Innovations Reshaping Clinical Trial Supply Chains** Meredith Frank-Molnia, *Vice President, Clinical Affairs,* Vericel Corporation	**How Can Global Site Selection Evolve to Optimize Assessments of Site Infrastructure, Ensuring Facilities, Equipment, and Resources Meet the Demands of Modern Clinical Trials?** George Naumov, *Chief Operations Officer & Chief Business Officer,* RS Oncology	**Involving Patients in Decision-Making: Exploring a Scope of Strategies, Statements, and Transformations for Engaging Underrepresented Communities and Patient Engagement** Amy McCagg, *Former Executive Director and Head, Patient Innovation,* Sarepta Therapeutics	**The Challenge and Opportunities of Sustainable Temperature Controlled Packaging for Pharmaceuticals** Ed Carneglia, *Business Development Manager,* Peli BioThermal USA PELI BIOTHERMAL
13:15 - 14:00	NETWORKING LUNCH					
14:00 - 14:20	NETWORKING / 1-1 MEETINGS					
14:20 - 14:40	NETWORKING / 1-1 MEETINGS					
14:40 - 15:10	**AFTERNOON KEYNOTE PRESENTATION:** Aptamers – Background, Recent Developments, and Their Use in Various Stages of Drug Development and Clinical Trials PRESENTER: Bill Jackson, Ph.D, *Founder & CEO,* Base Pair Biotechnologies, Inc.					
15:10 - 16:10 PHARMA/ BIOTECH	**Patient Recruitment 2.0: Strategies And Approaches for Success in Decentralized/Hybrid Trials** AnneMarie Winkler, *Associate Director, Clinical Trial Optimization and Innovation,* Genmab	**A Decentralized Trial Under Rapidly Evolving Standards Requires Disruptive Tech Adoption (Topic TBC)** Frank Leu, *Founder & Managing Member/ Managing Member,* BioPharMatrix LLC/ Novapeutics LLC	**Harnessing the Power of Digital Platforms for Enhanced Monitoring (EMC), Communication, and Decision-Making Across the Clinical Trial Ecosystem In Global Clinical Trials** Seshu Tyagarajan, *Chief Technical and Development Officer,* Candel Therapeutics	**How Can Sponsors and Researchers Harness the Power of Global Site Selection and Feasibility Studies to Anticipate Challenges and Optimize Conditions for Successful Global-Scale Trials?**	**Eliminating Health Inequities: How Can We Improve The Diverse Representation Of Clinical Trial Programs To Drive Health Equity?** Maria Margarita Corvez, *Global Program Director Hematology* AstraZeneca	**Strategies and Approaches for Seamless Integration of Clinical Supplies, Storage, Global Networks, and Regulatory Compliance through Dynamic Partnerships and Supplier Networks** Yuyi Shen, *Vice President, Technical Operations,* Abcuro, Inc
16:10 - 16:15	AFTERNOON REFRESHMENT BREAK					
16:15 - 16:45	**KEYNOTE PRESENTATION:** Overcoming clinical labeling challenges with automation PRESENTER: Jamie Morisco, *Vice President, Sales, Marketing & Operations,* Glemser PRESENTER: Pawan Gandhi, *Director, R&D,* Glemser					
16:45 - 17:45	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**

Is Technology Delivering on its Promise to Improve Clinical Development Productivity?

- The current state of industry-level productivity based on IQVIA Institute's Global Trends in R&D 2024 report
- How shifts in the funding, emerging biopharma, product portfolio, regulatory, and policy environment are changing the clinical development landscape
- Where productivity enablers appear to be having an impact and where there is additional opportunity

Michael Kleinrock
Senior Research Director,
IQVIA Institute for Human Data Science
IQVIA

IQVIA TECHNOLOGIES

ABOUT THE SPEAKER
Speaker TBC

14:40 - 15:10 EST **AFTERNOON KEYNOTE PRESENTATION**

Aptamers – Background, Recent Developments, and Their Use in Various Stages of Drug Development and Clinical Trials

Base Pair Biotechnologies' team of scientists has a combined 70+ person-years of experience in developing aptamers. Aptamers are high-affinity, highly selective affinity reagents made of single-stranded nucleic acids. Base Pair owns the sole worldwide rights to patents for multiplexed aptamer discovery, allowing Base Pair to select aptamers against up to 30 protein, peptide, or small molecule targets in true competitive, multiplexed fashion. With respect to clinical trials, Base Pair is developing a point-of-care solution to address enrollee non-compliance—an estimated $1B per year problem in the U.S. alone. Using novel aptamer-based sensors and readers similar to a glucose meter, we have demonstrated the feasibility of insuring patient compliance remotely. Secure, cloud-based data collection and patient incentives are poised to greatly decrease patient drop-out rates and improve trial data quality.

Bill Jackson, Ph.D
Founder & CEO
Base Pair Biotechnologies, Inc.

ABOUT THE SPEAKER
Speaker TBC

16:15 - 16:45 EST **PANEL DISCUSSION**

Overcoming clinical labeling challenges with automation

This presentation will explore the critical challenges facing pharmaceutical companies in clinical labeling, including the high costs of manual processes, compliance risks, and inefficiencies. Through real-world examples, Glemser will demonstrate how to leverage automation and AI to streamline the labeling process, reduce errors, and accelerate timelines. Attendees will gain insights into transforming their clinical labeling operations and improving regulatory compliance while freeing up their teams to focus on higher-value tasks.

Jamie Morisco
Vice President, Sales,
Marketing & Operations
Glemser

Pawan Gandhi
Director, R&D
Glemser

Glemser

ABOUT THE SPEAKER
Jamie serves as a Director of Sales for Glemser. In this role, Jamie draws from his extensive background in technology and business transformation to assist clients along their modernization journey. Jamie has a proven track record leading clients and team through complex technology enabled transformations delivering benefits across time, quality, cost and compliance.

Pawan serves clients as the Director of Global Research and Development. He brings along extensive experience in designing and implementing enterprise compliance solutions for life sciences clients. Pawan directs and coordinates development activities for organizational products to deliver quality solutions catering to complex regulated use cases.

Event Day

Patient Recruitment / Decentralized & Hybrid Trials

TRACK 1

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. And Delays in patient recruitment and engagement activities can cause major setbacks and become remarkably costly.

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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**

Data Security and Privacy in the Era of Decentralized Trials: A 2024 Perspective

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

ABOUT THE SPEAKER
Speaker TBC

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

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

Expanding Trial Access into New Communities for New Sites, Patients, and Researchers

Improving patient access to clinical trials has become increasingly central to the research landscape. Regulators and sponsors are more focused than ever on driving greater patient access and diversity for studies, galvanizing new and creative ways of reaching more participants. For patients without access to major medical centers that form the bedrock of clinical research, participating in a study can be challenging. Traveling extensively to a central investigator site can be burdensome, particularly for patients with limited means or complex medical conditions. Collaborating with the medical providers caring for these patients in their communities is key to democratizing clinical trial participation. This discussion will focus on working with experienced, "trial naïve", primary care and virtual sites to establish the necessary support and resources needed to conduct studies, the right clinical site can offer new participant pools to sponsors, new research opportunities for clinicians and new avenues for patients seeking treatment.

Caroline Potts
General Manager – MRN Site and Patient Services
Medical Research Network

ABOUT THE SPEAKER
Before joining MRN, **Caroline** worked in the public sector for 15 years, supporting research in hospitals and the primary care setting as well as providing support to research academics by writing funding applications, making submissions to regulatory authorities and running a large portfolio of studies to ICH-GCP requirements in clinical specialties such as stroke medicine, Parkinson's disease, orthopaedics, gastrointestinal medicine and respiratory medicine. During this time, Caroline was one of the founding members of the UKRD group as well as an executive member of the RD Forum providing R&D directors and research staff working in the public sector with strategic guidance in supporting high quality research in the NHS. In her current role, Caroline leads the development and expansion of MRN's global site network, site training programs, and on-site support services.

12:15 - 13:15 EST — **ROUNDTABLE 3**

Is Patient Recruitment Keeping Pace with Technological Advances in the Future Years?

- **Lack of awareness of appropriate clinical trials—no common portal where clinical trial information is searchable**
- **Lack of common standards for connectivity, interoperability, and HIPPA-compliant data access across EMR/EHR databases with an aggregated centralized repository**
- **The clinical trials add administrative burden—extra costs and expenses and uncertainty of insurance reimbursements**
- **The myth is that investigational treatments are not as effective as standard treatments**
- **Patient burden: humanizing technology, patient engagement through telehealth, and data capture through wearables**

ML Ujwal
Associate Director, Data Science
Johnson & Johnson

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).

13:15 - 14:40 EST — **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

14:40 - 15:10 EST — **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:10 - 16:10 EST — **ROUNDTABLE 4**

Patient Recruitment 2.0: Strategies And Approaches for Success in Decentralized/Hybrid Trials

- **Key challenges and considerations**
- **Inclusion of diverse and rural communities**
- **Overcoming barriers to decentralized/hybrid trials and keeping the human touch**
- **Balancing innovation with patient centricity**
- **Sharing success stories**

AnneMarie Winkler
Associate Director, Clinical Trial Optimization and Innovation
Genmab

ABOUT THE SPEAKER
As the Business Lead for Diversity, Equity, and Inclusion (DEI) in Clinical Trials, she is dedicated to advancing patient experience and patient-focused drug development across Research & Development (R&D). In her role at Genmab, she strives to ensure clinical trials are inclusive and representative of diverse patient populations. Prior to joining Genmab, she served as the Development Unit Lead for Patient Engagement, Equity & Transparency at Biogen. Her career also includes roles as Manager of Clinical Operations and Indication Lead for Global Trial Optimization at Syneos Health/Merck. In these positions, she specialized in end-to-end feasibility and recruitment for Tumor Agnostic Basket Studies, Novel Biomarkers, and Rare Diseases. During her tenure as Clinical Research Manager and IRB Administrator at Portsmouth Regional Hospital, she was actively involved in New Hampshire's Comprehensive Cancer Collaboration: Emerging Issues Work Group and Public Policy Education Committee. My commitment to human rights protections extended to my role as Head of Human Rights Protections and Patient Advocate at North Suffolk Mental Health. Dedication to patient advocacy and engagement underpin my approach to DEI in clinical trials, ensuring that all patient voices are heard and valued in the drug development process.

16:10 - 16:15 EST — **AFTERNOON REFRESHMENT BREAK**

16:15 - 16:45 EST — **PANEL DISCUSSION**
See Page 6

16:45 - 17:45 EST — **DRINKS & CANAPES RECEPTION**

Event Day

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TRACK 2

Emerging Biopharma / Outsourcing

A key idea in biology is that structure, to a large extent, dictates function. The rapid development of sensitive biophysical methods and emerging technologies that interrogate compound properties and mechanisms of action is transforming drug discovery.

08:00 - 08:30 EST **BREAKFAST & REGISTRATION**

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

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

Managing the Complications of Collaborations: Obstacles and Resolutions in Outsourcing for Developing Biotech/ Pharma Companies

- Ensuring outsourced partners meet quality control and local regulatory standards for clinical trials
- Verifying outsourced partners have expertise in the relevant therapeutic area and patient population
- Coordinating drug shipments, patient samples, and trial materials across regions
- Managing reduced control over trial aspects like protocol adherence, patient safety, and site management
- Balancing innovation with the need for standardized processes in outsourcing without stifling flexibility

Nancy Dubois
Head, Global Patient Safety, US Region
EMD Serono, Inc.

ABOUT THE SPEAKER
Dr. Nancy Dubois oversees Global Patient Safety for the US Region at EMD Serono. With over 20 years of expertise in healthcare and clinical trial research, she has held significant roles in both academic and sponsor environments. Over the past decade, Dr. Dubois has excelled in managing pharmacovigilance programs, implementing REMS ETASUs in healthcare settings, establishing compliant safety operations for US startups, and offering strategic insights to improve global collaboration and operational efficiency by dismantling silos. Her clinical training and extensive experience underscore her commitment to patient safety and innovation in the healthcare industry.

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

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

Protocol Designs Balancing Safety, Endpoints, and Cost

With the number of products in development drastically reduced post pandemic and the potential of delays causing millions of lost sales opportunities, it's imperative that we explore opportunities to run trials as fast as possible. Protocol design incorporating developments in solutions designed to reduce the patient workload is fundamental to maximize the key drivers of recruitment and retention. The new FDA guidance on Decentralized Clinical Trials and Digital Health Technologies supports using these solutions with some practical guidance on how to use them, supporting balancing patient workload with safety and compliance. It is possible for trial designs to meet all these regulatory, commercial and patient requirements. This discussion will focus on sharing lessons learned and best practice, especially in the light of the new guidance, utilizing our 18 years of experience in the field to accelerate clinical trials and bringing drugs to market faster.

Graham Wylie
Executive Chairman
Medical Research Network

ABOUT THE SPEAKER
Dr. Graham Wylie has been an agent of change in the pharmaceutical industry for over 34 years. His career started at Pfizer, spanning clinical trial management, development of global technology platforms, and global change management, and continued at PAREXEL as a Medical Director and then Vice President of Account Management. He formed MRN as CEO in 2006, which has since become the market leader of patient-centric and site-centric solutions for efficient, international clinical trial delivery. MRN's integrated solutions have delivered over 110,000 home trial visits across a network of over 2,600 sites in over 60 countries. In 2022, Graham became Executive Chairman for MRN. In this role, Graham is focused on continuing to find innovative ways to accelerate clinical trials, bringing drugs to market faster.

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

The Role of AI/ML in Enhancing Efficiency for Emerging Biopharma

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

ABOUT THE SPEAKER
James Kirwin is a seasoned pharmaceutical executive with over 20 years industry experience and has been involved in more than 20 NDAs. He has experience at major pharmaceutical companies such as AstraZeneca where he was Clinical Operations Team Lead for the Nexium program. He was VP of Global Clinical Development Operations at Wyeth Pharmaceuticals for the 10 years prior to its acquisition by Pfizer. Since then, he has led Clinical Development Operations at several startups, Intrexon, Intercept Pharmaceuticals, Iterum Therapeutics and Arvinas. He has been responsible for many "firsts" in clinical trial operations. While leading Global Clinical Operations at Wyeth, he was the first to implement Electronic Data Capture across all studies in the company globally. He developed the concept of the Functional Service Provider Model with RPS, implementing a US based monitoring group and also developed back-office data management and Trial Master File support in Bangalore India in partnership with Accenture.

13:15 - 14:40 EST **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

14:40 - 15:10 EST **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:10 - 16:10 EST **ROUNDTABLE 4**

A Decentralized Trial Under Rapidly Evolving Standards Requires Disruptive Tech Adoption (Topic TBC)

Frank Leu
Founder & Managing Member/ Managing Member
BioPharMatrix LLC/ Novapeutics LLC

ABOUT THE SPEAKER
Frank Leu is the Founder and Managing Member of BioPharMatrix LLC since 2010. He was also a co-founder and CEO of Novapeutics LLC, co-founded with the University of Pennsylvania to develop a first-in-class small-molecule beta-cell restoration to cure type 2 diabetes. Prior, Frank led drug development at a specialty pharma, Verto Institute, developing a class of curative antibody therapeutics for treating neuroendocrine cancer. Frank graduated from the joint pharmacology program of Memorial Sloan-Kettering Cancer Institute and the Weill Cornell Graduate School of Medical Sciences. He was the first author of five peer-reviewed publications from working in a Howard Hughes Medical Institute laboratory at Rockefeller University. He has been an adjunct professor at Thomas Jefferson University in the Department of Pharmacology since 2017.

16:10 - 16:15 EST **AFTERNOON REFRESHMENT BREAK**

16:15 - 16:45 EST **PANEL DISCUSSION**
See Page 6

16:45 - 17:45 EST **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 3

Clinical Technologies & Innovation

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.

08:00 - 08:30 ET BREAKFAST & REGISTRATION

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

09:00 - 10:00 ET ROUNDTABLE 1

The Latest Trends in Electronic Data Capture (EDC) Systems and eClinical Solutions for Digital Transformation in Clinical Operations

- Challenges in Clinical trial environment
- Need and drivers for innovation
- Use cases and case study discussion from a couple of startups/pharma

Abhishek Gupta
Senior Director, Research & Development | Quality Capabilities
BlueRock Therapeutics

ABOUT THE SPEAKER
Abhishek is a senior data, business, and technology leader with more than 2 decades of experience in building and driving digital and transformation capabilities within the pharma and biotech environments. He is primarily recognized for enterprise perspective, technical acumen, and collaborative style. Abhishek currently heads up the strategic as well as operational aspects of digital capabilities and solutions for clinical development and quality assurance at BlueRock Therapeutics. Previously, Abhishek led diverse leadership roles across Sage Therapeutics and Vertex Pharmaceuticals. Abhishek holds a master's in strategic management and a bachelor's in CS & IT. He is also an MIT fellow for systems design and management.

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

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

Transforming Clinical Data Analytics with Generative AI: The Next Frontier in Trial Efficiency and Precision

- How can Generative AI transform the way we analyze clinical data?
- What role will AI-powered assistants play in the future of clinical trials?
- Can generative models predict risks and improve trial outcomes through early signal detection
- How do we ensure AI in clinical trials is both ethical and secure?

Naouel Baili
Director, AI Scientist,
IQVIA Technologies

ABOUT THE SPEAKER
Naouel brings over 10 years of experience in the life sciences sector, with a strong focus on leveraging emerging technologies to enhance clinical trial management. She is dedicated to developing innovative solutions, from new design software to cutting-edge AI/ML capabilities. Her team has successfully created several micro-products and micro-services that can seamlessly integrate with any SaaS platform, driving greater efficiency and effectiveness in clinical operations.

12:15 - 13:15 ET ROUNDTABLE 3

AI and ML in 2024: Innovations Reshaping Clinical Trial Supply Chains

- What aspects of AI and ML do you perceive as providing current advantages in Clinical Supply Chain - Forecasting metrics
- How have you used Generative AI in Clinical Supply Chain management for the clinical trial supply process at your company?
- How does AI increase your organization's ability to better process information?
- What are the legal, ethical, and regulatory implications for the use of AI/ML?

Meredith Frank-Molnia
Vice President, Clinical Affairs
Vericel Corporation

ABOUT THE SPEAKER
Meredith joined Vericel in 2024 with more than 25 years of experience in the clinical research industry. She most recently served as Senior Director of Clinical Operations at Third Pole Therapeutics. Prior to Third Pole, Meredith also held roles of increasing responsibility at Axiom Real-Time Metrics, Advanced Clinical, Smith & Nephew, and Stryker Biotech. Throughout her career, Meredith has been involved in various aspects of clinical operations, including project management, vendor selection, implementation of new technologies, and regulatory approvals. She holds a B.S. in Biology and German Literature

13:15 - 14:40 EST NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS

14:40 - 15:10 EST AFTERNOON KEYNOTE PRESENTATION
See Page 6

15:10 - 16:10 EST ROUNDTABLE 4

Harnessing the Power of Digital Platforms for Enhanced Monitoring (EMC), Communication, and Decision-Making Across the Clinical Trial Ecosystem In Global Clinical Trials

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

ABOUT THE SPEAKER
Dr. Seshu Tyagarajan is the Chief Technical and Development Officer at Candel Therapeutics. She has two decades of technical, manufacturing and development experience in Biologics and Cell & Gene therapies. Prior to Candel, she was Global Head, CMC Strategy for CGT at Novartis where she developed the clinical and commercial manufacturing strategy for T-Charge™(CAR-T). She successfully led several BLAs and INDs and was a key contributor to the groundbreaking BLA submission for Kymriah®. Seshu held roles of increasing responsibility at Merck, Roche, Phyton, Biogen and Lilly. She holds a Ph.D. in Chemical and Biochemical Engineering (Rutgers), and MS in Bioengineering (Purdue).

16:10 - 16:15 EST AFTERNOON REFRESHMENT BREAK

16:15 - 16:45 EST PANEL DISCUSSION
See Page 6

16:45 - 17:45 EST DRINKS & CANAPES RECEPTION

Event Day

TRACK 4

Global Site Selection And Feasibility Study

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**

Accelerating Clinical Trial Enrollment Through Informed Site Selection and Trial Design

- Making sure you have the best internal (CMO, Clinical Head) and external (CRO) team to select your trial sites
- Choosing your sites by knowing your principal investigators
- Looking beyond your site feasibility studies to choose sites
- Using trial design to guide site selection
- Understanding what incentivizes a trial site as a criterion in site selection

Michael Tolentino
Co-Founder, Chief innovation Officer and Board Member
Aviceda Therapeutics

ABOUT THE SPEAKER

Dr. Tolentino is co-founder, CIO, and Director of Aviceda Therapeutics and Associate Professor of Ophthalmology/Retina Surgeon at UCF and OCOM. He invented and pioneered the use of anti-VEGF therapies for retinal diseases. He invented and took to the clinic Bevasiranib, the first RNAi therapeutic to enter human trials. He developed PRM-167, an antifibrotic drug to treat idiopathic pulmonary fibrosis and myelofibrosis. He founded CRMD clinical research, established Blue Ocean SMO, was PI for 150 trials, and was a consultant to multiple pharma companies. He recently invented AVD-104 for the treatment of AMD and fully enrolled a 300-patient Phase II/III trial in 4 months.

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

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?

Michael Kleinrock
Senior Research Director,
IQVIA Institute for Human Data Science
IQVIA

ABOUT THE SPEAKER
Speaker TBC

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

How Can Global Site Selection Evolve to Optimize Assessments of Site Infrastructure, Ensuring Facilities, Equipment, and Resources Meet the Demands of Modern Clinical Trials?

George Naumov
Chief Operations Officer & Chief Business Officer
Aviceda Therapeutics

ABOUT THE SPEAKER
Speaker TBC

13:15 - 14:40 EST **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

14:40 - 15:10 EST **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:10 - 16:10 EST **ROUNDTABLE 4**

How Can Sponsors and Researchers Harness the Power of Global Site Selection and Feasibility Studies to Anticipate Challenges and Optimize Conditions for Successful Global-Scale Trials?

Speaker TBC

ABOUT THE SPEAKER
Speaker TBC

16:10 - 16:15 EST **AFTERNOON REFRESHMENT BREAK**

16:15 - 16:45 EST **PANEL DISCUSSION**
See Page 6

16:45 - 17:45 EST **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 5

Diversity, Equity, And Inclusion In Patient Recruitment & Engagement

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.

08:00 - 08:30 EST **BREAKFAST & REGISTRATION**

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

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

Implementing Diversity, Equity, and Inclusion (DEI) Initiatives: Insights from Company Case Studies and Exemplary Practices (Topic TBC)

Justin Buie
Clinical Program Manager
Candel Therapeutics

ABOUT THE SPEAKER
Speaker TBC

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

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

Involving Patients in Decision-Making: Exploring a Scope of Strategies, Statements, and Transformations for Engaging Underrepresented Communities and Patient Engagement

- How are you currently including the patient's voice/perspective within your clinical programs?
- What are some of the challenges/success you are facing with enrolling underrepresented patients?
- How will the new FDA Guidelines for Clinical Trial Diversity (currently in draft) change your approach to recruitment? patients?

Amy McCagg
Former Executive Director and Head, Patient Innovation
Sarepta Therapeutics

ABOUT THE SPEAKER
Amy McCagg, MBA, is a biopharmaceutical leader with over 20 years of drug development management, contributing to 7 approvals and label expansions. Ms. McCagg began her career leading the clinical operations for large cardiovascular outcomes trials with the TIMI Study Group. Following her transition into industry, she focused on rare diseases and highlighted the patient voice within clinical development and commercial. She spent the last 10 years leading teams within Sanofi-Genzyme, Rhythm Pharmaceuticals, and Sarepta Therapeutics to improve patient identification, include the patient perspective within protocols, and offer services to reduce barriers to clinical trial participation.

13:15 - 14:40 EST **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

14:40 - 15:10 EST **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:10 - 16:10 EST **ROUNDTABLE 4**

Eliminating Health Inequities: How Can We Improve The Diverse Representation Of Clinical Trial Programs To Drive Health Equity?

Maria Margarita Corvez
Global Program Director Hematology,
AstraZeneca

ABOUT THE SPEAKER
Maria Margarita is a highly experienced global clinical operations professional with over 20 years of expertise in biotech, CROs, and pharmaceuticals. She has successfully led clinical development programs and studies in Oncology, Haematology, among other therapeutic indications. Maria has provided leadership to clinical operations teams and played a key role in strategic trial planning for global biotech and pharmaceutical companies, including notable contributions in enrollment acceleration, innovative patient centricity initiatives and during her spare time has organized outreach in access to medicine initiatives and has worked to develop collaborations with medical schools in Central America to train physicians on clinical research to tackle regional health care access disparities.

16:10 - 16:15 EST **AFTERNOON REFRESHMENT BREAK**

16:15 - 16:45 EST **PANEL DISCUSSION**
See Page 6

16:45 - 17:45 EST **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 6

Clinical Supplies / Storage & Global Networks

Tagline

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2024
Thursday, 14th November 2024 | Le Meridien Cambridge

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**

A Strategic Discussion on Clinical Supplies, Storage Innovation, and Global Networks Reshaping the Landscape of CTM, Storage Facilities, Packaging, and Labeling in Clinical Trials

- Supply Chain Agility: How are global disruptions and new regulations driving the need for more adaptive and resilient supply chains in Clinical Trial Material (CTM) management?
- Storage Innovation: What new technologies and innovations in cold chain storage, decentralized depots, and biorepositories are enhancing the quality and accessibility of CTM for global clinical trials?
- Packaging and Labeling Compliance: As trials become more global, how are companies addressing the complexity of multilingual labeling and regulatory requirements across different markets?
- Global Networks and Collaboration: What role are partnerships and global networks playing in streamlining the distribution of clinical supplies to emerging markets, especially in regions with limited infrastructure?
- Sustainability in Clinical Supply Chain: How are companies incorporating sustainable practices into packaging, labeling, and storage while maintaining efficiency and compliance in clinical trials?

Rakibou Ouro-Djobo
Global Clinical Supply Chain & Logistics Leader
Bill & Melinda Gates Medical Research Institute

ABOUT THE SPEAKER
Rakib Ouro-Djobo is a visionary supply chain leader with over 15 years of experience driving global impact in life sciences and biotechnology. As the Clinical Supply Chain Lead at the Bill & Melinda Gates Medical Research Institute, he leverages and implements innovative supply chain strategies that streamline clinical trial materials (CTM), packaging, and labeling for global distribution. His leadership has been instrumental in advancing cutting-edge storage technologies and fostering global networks that ensure the seamless delivery of life-saving treatments, particularly in low-income countries. Rakib is committed to leveraging his expertise to transform clinical supply chains and accelerate worldwide access to critical health interventions.

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

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

Supply Chain Initiatives that Improve Accountability, Optimization, and Sustainability in IP Management

- Improving supply chain optimization and cost efficiencies through intelligent integrations & automation
- Ensuring quality control and assurance in cold chain management
- Tools and strategies to improve drug accountability and facilitate the move to remote monitoring
- Optimizing trial processes for sites and patients with the right data and integration strategies

Charlie Pattrell
Associate Director, Solution Engineering
IQVIA

ABOUT THE SPEAKER
Speaker TBC

12:15 - 13:15 EST — **SOLUTION FOCUS ROUNDTABLE 3**

The Challenge and Opportunities of Sustainable Temperature Controlled Packaging for Pharmaceuticals

Ed Carneglia
Business Development Manager
Peli BioThermal USA

ABOUT THE SPEAKER
Ed Carneglia is an experienced Business Development Manager at Peli BioThermal, where he focuses on delivering cutting-edge cold chain solutions for clinical trials and healthcare logistics. With a BA from Siena College and an MBA in International Business from Washington State University, Ed brings a strategic perspective to optimizing cold chain operations for global clinical trial demands. His expertise in integrating robust solutions aligns with Peli BioThermal's commitment to supporting clinical and commercial operations with innovative, scalable cold chain systems and services.

13:15 - 14:40 EST — **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

14:40 - 15:10 EST — **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

15:10 - 16:10 EST — **ROUNDTABLE 4**

Strategies and Approaches for Seamless Integration of Clinical Supplies, Storage, Global Networks, and Regulatory Compliance through Dynamic Partnerships and Supplier Networks

- What are the potential challenges of clinical supplies, and how can those challenges be mitigated?
- Alleviating supply chain constraints with portfolio and vendor management and partnership
- What are your recent experiences of hardship and risk mitigation to meet the global trial supply needs and comply with regional regulations?

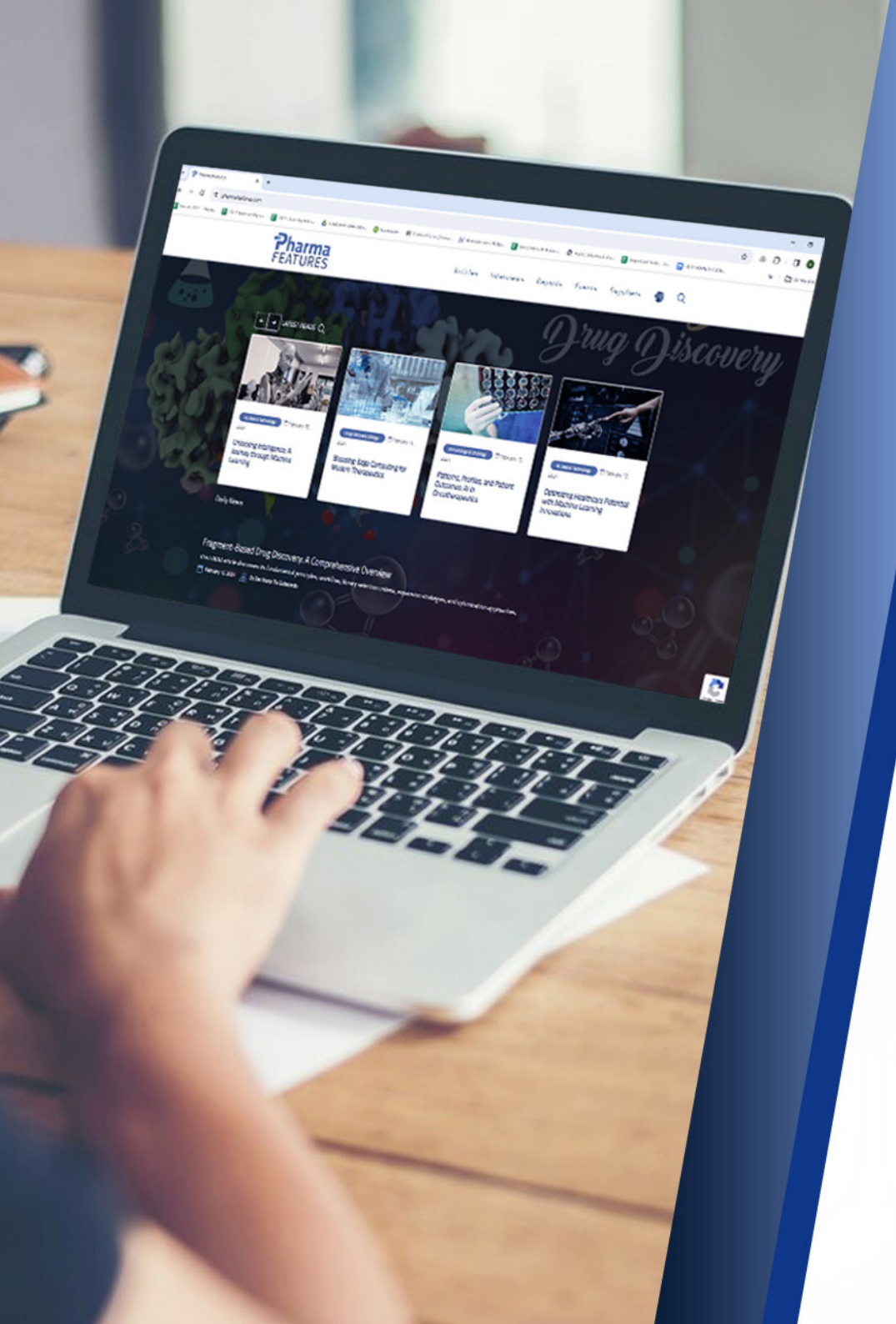
Yuyi Shen
Vice President, Technical Operations
Abcuro, Inc

ABOUT THE SPEAKER
Yuyi Shen is an inspirational CMC thought leader with management experience in biopharmaceutical development, manufacturing, and clinical supply chain. She is an accomplished program leader in the early to late phase development and commercialization of a wide range of recombinant proteins for immuno-oncology, infectious and rare disease drug platforms. She brings extensive expertise in CDMO selection and oversight, facility/team build- out, technology transfer, budget planning, partner collaboration, and CMC strategic direction of global regulatory filings. She is also an industry-recognized innovation-driven CMC expert on disruptive technology implementation, including process modeling, to deliver with high efficiency and better quality under an accelerated timeline. She served various leadership roles in CMC at large pharma to emerging biotech companies, including Bolt, XOMA, Bayer, BioMarin, and Grifols. She holds a Ph.D. degree in Chemical Engineering from the University of California, Davis.

16:10 - 16:15 EST — **AFTERNOON REFRESHMENT BREAK**

16:15 - 16:45 EST — **PANEL DISCUSSION**
See Page 6

16:45 - 17:45 EST — **DRINKS & CANAPES RECEPTION**



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Michael Klenrock
Senior Research Director, IQVIA Institute for Human Data Science

Nick Whitney
Senior Director, Trial Management Solutions

Naouel Baili
Director, AI Scientist

Helen Greta
Director, Project Managemeant

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OCT 23
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STRATEGY MEETING EAST COAST USA
Le Meridien Boston Cambridge

NOV 11
BIOINFORMATICS & IT
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