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Proventa International's 11th Annual

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN

STRATEGY MEETING EAST COAST USA 2024

Thursday, 16th May 2024 **Hyatt Regency Princeton**

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:

Brian Dole
Vice President, Global Clinical Supply Chain
Bristol Myers Squibb

Amit Gulwadi
Vice President, Head of Transformation
Alexion Pharmaceuticals, Inc.

Paresh Patel
Global Head, Clinical Intelligence
Otsuka Pharmaceutical Companies (U.S.)

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

Eve Dryer
Vice President, Patient Advocacy Emerita
Travere Therapeutics

Barry Moore
Head, Randomization and Trial Supply Managemen
GSK

Erinne Wasalski
Global Head, Regional Site Engagement
Daiichi Sankyo, Inc.

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

24 ROUNDTABLE DISCUSSIONS

6 TRACKS

2 KEYNOTE PRESENTATIONS

1 PANEL DISCUSSION

1 LOCATION

What Makes Our Strategy Meetings So Unique?

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

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN

STRATEGY MEETING EAST COAST USA 2024

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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

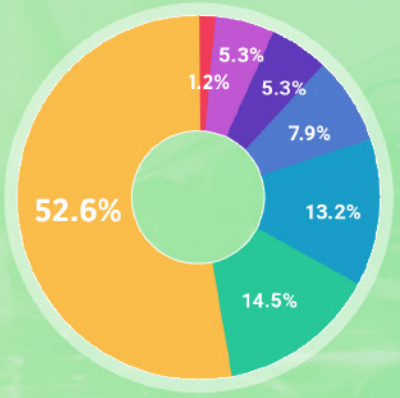
The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

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
STRATEGY MEETING EAST COAST USA 2024
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Jim DiCesare
Vice President,
Financial Management
Solutions
IQVIA Technologies

Kevin Landells
Vice President,
Business Head for IRT
IQVIA Technologies

KK Rumrill
Senior Director,
Site Suite
IQVIA Technologies

Murray Aitken
Executive Director
IQVIA Institute for Human Data Science
and Senior Vice President
IQVIA

Naouel Baili
Director, AI Scientist
IQVIA Technologies

Amit Gulwadi
Vice President,
Head of Transformation
Alexion Pharmaceuticals, Inc.

Barry Moore
Head, Randomization and
Trial Supply Management
GSK

Brian Dole
Vice President,
Global Clinical Supply Chain
Bristol Myers Squibb

Erinne Wasalski
Global Head,
Regional Site Engagement
Daiichi Sankyo, Inc.

Eve Dryer
Vice President, Patient
Advocacy Emerita
Travere Therapeutics

Kathy Machuzak
Former Director,
Patient Advocacy
Travere Therapeutics

Jackie Foster
Senior Director,
Clinical Supplies
PTC Therapeutics, Inc.

James Kirwin
COO and Head, Clinical
Development Operations
SFA Therapeutics

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

Karrie Hilsinger
Senior Director,
Head of Clinical Operations
UroGen Pharma

Paresh Patel
Global Head,
Clinical Intelligence
Otsuka Pharmaceutical Companies (U.S.)

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

How Has Our
STRATEGY MEETINGS
Benefit The Life Science Industry

> *This was a very important insightful event and I have few takeaways messages/practices which I will be implementing on my current and future projects."*
>
> **Jean-Pierre Metabanzoulou -**
> *Senior Director, CMC & RA*, **Acasti Pharma**

> *This was a very informative, significantly interactive and highly educational event. "*
>
> **Domenico Merante -**
> *VP Clinical Development*, **Sosei Heptares**

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.

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Agenda at a Glance

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2024
Thursday 16th May 2024 | Hyatt Regency Princeton

TIME / ET	TRACK 1: PATIENT RECRUITMENT / DECENTRALIZED & HYBRID TRIALS AND EMERGING BIOPHARMA / OUTSOURCING	TRACK 2: CLINICAL TECHNOLOGIES & INNOVATION	TRACK 3: GLOBAL SITE SELECTION AND FEASIBILITY STUDY	TRACK 4: DIVERSITY, EQUITY, AND INCLUSION IN PATIENT RECRUITMENT & ENGAGEMENT	TRACK 5: CLINICAL SUPPLIES / STORAGE & GLOBAL NETWORKS
ROOM ►					
08:00 - 08:30	**BREAKFAST & REGISTRATION**				
08:30 - 09:00	**OPENING KEYNOTE PRESENTATION:** **Is Technology Delivering on its Promise to Improve Clinical Development Productivity? (Topic TBC)** PRESENTER: Murray Aitken, *Executive Director,* IQVIA Institute for Human Data Science *and Senior Vice President,* IQVIA				
09:00 - 10:00 PHARMA/ BIOTECH	**Patient Recruitment 2.0: Strategies And Approaches for Success in Decentralized/ Hybrid Trials** Amit Gulwadi, *Vice President, Digital and Transformation,* Alexion Pharmaceuticals, Inc.	**The Latest Trends in Electronic Data Capture (EDC) Systems and eClinical Solutions for Digital Transformation in Clinical Operations (Topic TBC)** Paresh Patel, *Global Head, Clinical Intelligence,* Otsuka Pharmaceutical Companies (U.S.)	**An In-Depth Exploration of Emerging Trends and Cutting-Edge Best Practices in Elevating Clinical Trial Awareness and Revolutionizing Recruitment Strategies (Topic TBC)** James Kirwin, *COO and Head, Clinical Development Operations,* SFA Therapeutics	**Implementing Diversity, Equity, and Inclusion (DEI) Initiatives: Insights from Company Case Studies and Exemplary Practices (Topic TBC)** Erinne Wasalski, *Global Head, Regional Site Engagement,* Daiichi Sankyo, Inc.	**A Strategic Discussion on Decentralized Trials and the impact on Clinical Supplies** Jackie Foster, *Senior Director, Clinical Supplies,* PTC Therapeutics, Inc.
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	**Financial Empowerment: Fueling Site and Patient Engagement for Successful Clinical Trials** Jim DiCesare, *Vice President, Financial Management Solutions,* IQVIA Technologies IQVIA	**The Future of Clinical Trials: Embracing Early Signal Prediction and Simulations for Enhanced Outcomes** Naouel Baili, *Director, AI Scientist,* IQVIA Technologies IQVIA	**Making Progress in Study Start-Up in the Face of Industry Headwinds** KK Rumrill, *Senior Director, Site Suite,* IQVIA Technologies IQVIA	**Navigating The Future Involves Pioneering Strategies For Diversity, Equity, And Inclusion In Patient Recruitment And Engagement Through Comprehensive Demographic Data Collection** SPONSOR	**Supply Chain Initiatives that Improve Accountability, Optimization, and Sustainability in IP Management** Kevin Landells, *Vice President, Business Head for IRT,* IQVIA Technologies IQVIA
12:15 - 13:15 PHARMA/ BIOTECH	**How are Emerging Biopharma Firms Tackling Infrastructure Challenges to Expedite Drug Development?** Karrie Hilsinger, *Senior Director, Head of Clinical Operations,* UroGen Pharma	**AI and ML in 2024: Innovations Reshaping Clinical Trial Supply Chains** Barry Moore, *Head, Randomization and Trial Supply Management,* GSK	**Embarking on the Pinnacle of Clinical Trial Success in 2024: Unveiling Global Site Selection Strategies, Where Patient Population Precision Aligns with Study Criteria, and Ethical and Cultural Considerations Illuminate the Path to Ethical and Culturally Sensitive Trials (Topic TBC)** Erinne Wasalski, *Global Head, Regional Site Engagement,* Daiichi Sankyo, Inc.	**Involving Patients in Decision-Making: Exploring a Scope of Strategies, Statements, and Transformations for Engaging Underrepresented Communities and Patient Engagement** Eve Dryer, *Vice President, Patient Advocacy Emerita,* Travere Therapeutics Kathy Machuzak, *Former Director, Patient Advocacy,* Travere Therapeutics	**Mastery of Clinical Logistics: Unleashing the Power of Quality Control and Assurance in Clinical Supplies/Storage**
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**				
15:10 - 16:10 PHARMA/ BIOTECH	**The Role of AI/ML in Enhancing Efficiency for Emerging Biopharma** James Kirwin, *COO and Head, Clinical Development Operations,* SFA Therapeutics	**Harnessing the Power of Digital Platforms for Enhanced Monitoring (EMC), Communication, and Decision-Making Across the Clinical Trial Ecosystem In Global Clinical Trials** Amit Gulwadi, *Vice President, Head of Transformation,* Alexion Pharmaceuticals, Inc.	**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?** Uday Harle, *Assitant Vice President and Head, Global Clinical Research,* Kashiv Biosciences	**Eliminating Health Inequities: How Can We Improve the Diverse Representation of Clinical Trial Programs to Drive Health Equity? (Topic TBC)** Lisa Coleman, *Senior Vice President, Global Inclusion and Strategic Innovation,* New York University	**Strategies and Approaches for Seamless Integration of Clinical Supplies, Storage, Global Networks, and Regulatory Compliance through Dynamic Partnerships and Supplier Networks** Brian Dole, *Vice President, Global Clinical Supply Chain,* Bristol Myers Squibb
16:10 - 16:30	**AFTERNOON REFRESHMENT BREAK**				
16:30 - 17:00	**PANEL DISCUSSION:** **Investing in Health Technology Companies with a Clinical Focus in Pharma and Biotech**				
17:00 - 18:00	**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.

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

Is technology delivering on its promise to improve clinical development productivity? (Topic TBC)

Murray Aitken
Executive Director
IQVIA Institute for Human Data Science
and Senior Vice President
IQVIA

IQVIA TECHNOLOGIES

ABOUT THE SPEAKER

As head of the IQVIA Institute for Human Data Science, Murray Aitken provides policy setters and decision-makers in the global health sector with evidence, analysis, and insights that contribute to the advancement of Human Data Science to improve human health outcomes. Aitken is tasked with creating and managing a research agenda that leaders in global governments, payers, providers, academia, and the life sciences industry use to accelerate the understanding of global trends in disease patterns, data science, and technology. This research is used to foster innovation critical to evidence-based decision-making and the advancement of human health.
Register Now

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

Topic TBC

Speaker TBC

ABOUT THE SPEAKER

Speaker TBC

16:30 - 17:00 ET **PANEL DISCUSSION**

Investing in Health Technology Companies with a Clinical Focus in Pharma and Biotech

Speaker TBC

ABOUT THE SPEAKER

Speaker TBC

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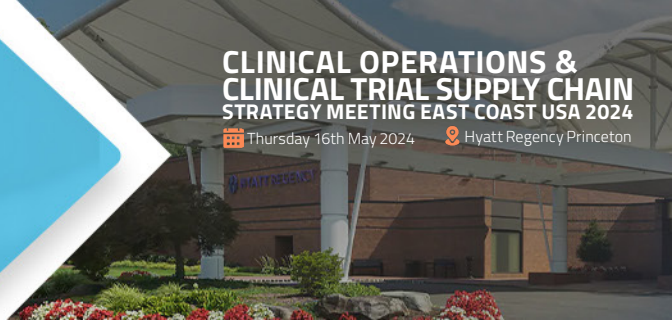

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2024
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TRACK 1 Patient Recruitment / Decentralized & Hybrid Trials And Emerging Biopharma / Outsourcing

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.

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**

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

- Challenges and opportunities to leverage decentralized/hybrid trials to reach diverse communities
- Challenges and opportunities to reach less tech-savvy patients or patients who may have challenges using technology
- Do decentralized/hybrid trials lead to better-informed patients and, thus, faster recruitment, better compliance, and better data quality?
- Any considerations for addressing patient recruitment in decentralized/ hybrid trials in emerging markets?

Amit Gulwadi
Vice President, Head of Transformation
Alexion Pharmaceuticals, Inc.

ABOUT THE SPEAKER
Speaker TBC

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

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

Financial Empowerment: Fueling Site and Patient Engagement for Successful Clinical Trials

Effective financial management is the backbone of successful clinical trials. In this discussion, we'll explore how strategic financial practices empower trial sites and engage participants, ultimately driving superior trial outcomes for sponsors. By aligning financial processes with trial objectives, we can enhance collaboration, transparency, and overall trial efficiency.

- **Aligning financial stakeholders—sponsors, CROs, sites, and patients**
- **Understanding the financial impact on patients and sites**
- **Integrating financial decisions with trial objectives**

James DiCesare
Vice President,
Financial Management Solutions
IQVIA Technologies

ABOUT THE SPEAKER
Jim DiCesare is passionate about delivering innovative Cost Benchmarking, CTA Negotiation and Site Payment services that support clinical research conducted by sponsors and CROs. With over 25 years of industry experience leading clinical operations teams at Merck, DrugDev, and now IQVIA Technologies, Jim has expertise across the contracting, budgeting, and investigator grant payment management continuum. He is a frequent speaker at industry conferences and has written for a variety of publications. He has a B.S. in Accounting from Kutztown University.

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

How are Emerging Biopharma Firms Tackling Infrastructure Challenges to Expedite Drug Development?

- **Recent drug development process is long, risky, costly and complex**
- **Growing Regulatory hurdles**
- **Biopharma vs. Large organization**
- **Competitive Marketplace**

Karrie Hilsinger
Senior Director, Head of Clinical Operations
UroGen Pharma

ABOUT THE SPEAKER
Speaker TBC

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

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

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

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

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.

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 2

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 (Topic TBC)

Paresh Patel
Global Head, Clinical Intelligence
Otsuka Pharmaceutical Companies (U.S.)

ABOUT THE SPEAKER
Speaker TBC

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

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

The Future of Clinical Trials: Embracing Early Signal Prediction and Simulations for Enhanced Outcomes

This theme captures the essence of our vision for a more efficient, secure, and ethically grounded approach to clinical trials.

- Integration of multiple data sources - the importance of leveraging diverse data sets to build predictive models that enhance safety, assess trial feasibility, and simulate trial arms with precision
- Security and privacy in data utilization - strategies to maintain high standards of data security and privacy while fostering the development of robust predictive models
- Human-machine synergy - the critical role of integrating medical reviews and human insights to refine predictive models, enhancing their reliability and ethical standards
- Future trajectory and practical use cases - exploration of real-world applications and the prospective impact of signal prediction and SIM models on clinical trial planning, monitoring, and execution

Naouel Baili
Director, AI Scientist
IQVIA Technologies

ABOUT THE SPEAKER
Naouel is an expert in emerging technology solutions, leveraging over ten years of experience in the life sciences industry to transform clinical trial management. Her proficiency in embedding sophisticated AI tools into SaaS platforms has significantly improved both user experience and operational efficiency. A holder of a Ph.D. in Computer Science, she excels in the development and design of innovative AI capabilities that streamline and optimize clinical research.

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

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

- Application of AI in clinical supplies
- Examples and Case studies
- Future Opportunities for AI
- Regulations of AI

Barry Moore
Head, Randomization and Trial Supply Management
Otsuka Pharmaceutical Companies (U.S.)

ABOUT THE SPEAKER
Barry Moore has been a clinical trial chain professional working in the field for more than 25 years. While working at both the sponsor and vendor, He has gleaned a wealth of experience in systems development and clinical supply chain management. As a recognized thought leader, Barry has been pushing for the adoption of advanced technologies across the clinical trial supplies landscape. His strategic insight and adept leadership have significantly contributed to the optimization of clinical study operations, making him a respected figure in the life sciences sector.

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

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

15:10 - 16:10 ET **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

- Platform strategy for multi-modal data across the value chain in decision making: data capture to submission
- Role of digital platforms to support data fusion for more context- and persona-aware decision-making across the value chain
- Role for AI in enhanced monitoring (e.g., safety, quality)
- How can small or emerging biopharma take advantage of such clinical digital platforms with frugal tech budgets and staffing?

Amit Gulwadi
Vice President, Head of Transformation
Alexion Pharmaceuticals, Inc.

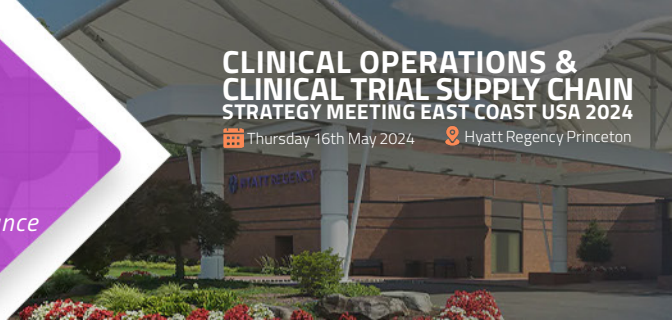
ABOUT THE SPEAKER
Speaker TBC

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day



TRACK 3

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 ET **BREAKFAST & REGISTRATION**

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

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

An In-Depth Exploration of Emerging Trends and Cutting-Edge Best Practices in Elevating Clinical Trial Awareness and Revolutionizing Recruitment Strategies

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

ABOUT THE SPEAKER
See Page 7

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

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

Making Progress in Study Start-Up in the Face of Industry Headwinds

- What sub-processes have you identified to be slowing down study start-ups?
- Is the situation with site capacity improving yet, or are budgets continuing to increase?
- What process and technology solutions for site activation have been successful and what hasn't been as effective as hoped?

KK Rumrill
Global Head Trial Management Services
IQVIA Technologies

ABOUT THE SPEAKER
KK Rumrill has more than 25 years' experience in product development, customer support, and implementation services teams in clinical trials. She was a key leader in client operations at BBK Worldwide, driving growth in global patient recruitment, site engagement, and trial optimization. In 2013, KK moved to TrialNetworks, which was acquired by DrugDev and subsequently by IQVIA in 2017. She now leads several key product teams in IQVIA Technologies' Orchestrated Clinical Trials platform.

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

Embarking on the Pinnacle of Clinical Trial Success in 2024: Unveiling Global Site Selection Strategies, Where Patient Population Precision Aligns with Study Criteria, and Ethical and Cultural Considerations Illuminate the Path to Ethical and Culturally Sensitive Trials (Topic TBC)

Erinne Wasalski
Global Head, Regional Site Engagement
Daiichi Sankyo, Inc.

ABOUT THE SPEAKER
Speaker TBC

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

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

15:10 - 16:10 ET **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?

- Clinical sites selection strategies (country, enrollment, SOC, economy, etc)
- Clinical sites with timelines mapping
- Clinical sites risk mitigations
- Clinical sites cost saving strategies

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

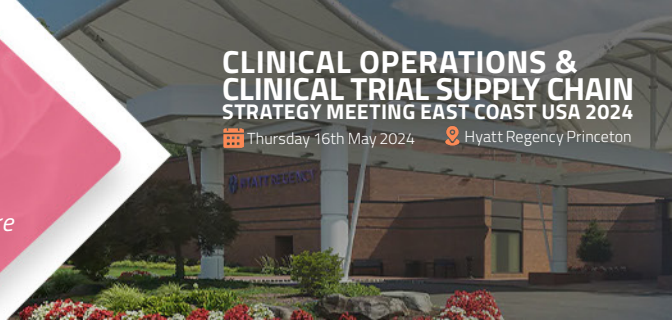
ABOUT THE SPEAKER
Uday Harle is a global clinical development leader with two decades of experience as Ex-Global Head at Abbott, Ferring Pharma, and is presently serving Kashiv Bioscience and an associated group of companies. PhD in medicine with many research publications, awards, and scientific text book authors.

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day



TRACK 4

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 ET **BREAKFAST & REGISTRATION**

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

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

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

Erinne Wasalski
Global Head, Regional Site Engagement
Daiichi Sankyo, Inc.

ABOUT THE SPEAKER
Speaker TBC

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

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

Navigating The Future Involves Pioneering Strategies For Diversity, Equity, And Inclusion In Patient Recruitment And Engagement Through Comprehensive Demographic Data Collection

Speaker TBC

ABOUT THE SPEAKER
Speaker TBC

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

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

- Early engagement with patient organizations
- Improving Diverse Recruitment through local community engagement
- Supporting PAOs in patient education focused on value of trial participation
- Eliciting patient input from development of trial concept on through Clinical Trial processes, including reimbursements for trial participation expenses
- The value of decentralized trials in engaging with communities of color and diverse geographies

Eve Dryer
Vice President, Patient Advocacy Emerita
Travere Therapeutics

Kathy Machuzak
Former Director, Patient Advocacy
Travere Therapeutics

ABOUT THE SPEAKER
Eve Dryer recently retired as Vice President, Patient Advocacy at Travere, and has served as a patient advocacy leader for more than 25 years. She is a founder of the Rare Disease Diversity Coalition, which is actively addressing delays in diagnosis and treatment of rare disease patients of color. Prior to Travere, Eve worked on rare oncology with Lexicon Pharmaceuticals, where she built the Patient Advocacy strategy and team. Working with Sisters Network, the national African American breast cancer association, she launched Teens for Pink, to engage African American teenagers in breast cancer education and family health navigation. She spent 15 years as a partner in a healthcare PR agency, Vox Medica, working with clients including AstraZeneca, GlaxoSmithKline, Eisai and Janssen. She was the Healthcare Businesswomen's Association's 2013 international STAR honoree for her efforts in mentoring up-and-coming women healthcare leaders, and was recognized in the PharmaVOICE 100 in 2008, 2016 and 2021 for her innovative work in patient advocacy and her health diversity and equity efforts.

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

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

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

Eliminating Health Inequities: How Can We Improve the Diverse Representation of Clinical Trial Programs to Drive Health Equity? (Topic TBC)

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. Prior to NYU, Dr. Coleman served as the first chief diversity officer and special assistant to the president at Harvard University for almost a decade, where she and her team developed some of the first initiatives focused on the intersections of technology, disability, and access. Before her appointment at Harvard University, she served as an administrator and faculty member at Tufts University and was later appointed to serve as the institution's first global inclusion and diversity senior executive. She earned her doctorate in Social and Cultural Analysis, American Studies from NYU, and three master's degrees in African and African American Studies; Women's, Gender, and Sexuality Studies; and Communication Studies from the Ohio State University. She also holds certificates focusing on legal theory and intercultural development and her undergraduate research foci were sociology, anthropology, and computer science. She loves to travel, is an avid photographer, gardener, cook, and soon to be (hopefully) pilot.

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 5

Clinical Supplies / Storage & Global Networks

Tagline

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**

A Strategic Discussion on Decentralized Trials and the impact on Clinical Supplies

- The setup; CDMO vs. CRO for the management of shipments from clinical sites to participants homes. Is there a benefit to one over the other?
- Sponsor's responsibility of the supply chain with shipments dispatched from a clinical site versus CDMO
- Introduction of another leg of the supply chain
- Temperature monitoring and adjudication of these shipments
- Participants receiving drugs from shippers at home versus a clinical site that has experience handling these shipments. Is training required for the participants?

Jackie Foster
Senior Director, Clinical Supplies
PTC Therapeutics, Inc.

ABOUT THE SPEAKER
Jackie Foster has been with PTC Therapeutics, Inc. since Dec. 2021 and is Senior Director, Clinical Supplies. She has over 22 years of experience in the pharmaceutical industry from both pharmaceutical companies and contract manufacturing companies. Her experience includes a wide range of roles within the clinical trial supply chain, giving her unique insight into the end-to-end clinical trial management process. In her current role, she manages a team of Clinical Supplies professionals and works with cross-functional colleagues to ensure efficiency and quality in the planning and execution of clinical trials. Jackie has her BA in Business Management from Moravian University

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

11:10 - 12:10 ET — **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

Kevin Landells
Vice President, Business Head for IRT
IQVIA Technologies

ABOUT THE SPEAKER
Kevin has over 25 years of experience in the IRT/ RTSM industry, having worked across many technical and project management leadership roles. Experienced with developing and leading global teams delivering managed services spanning Operations, Project Management, Client Partnerships and Business Transformation. Kevin is passionate about improving healthcare and utilizing technology that makes a real difference to patients' lives. Kevin holds a bachelor's degree in computer science from Hertfordshire University in the UK.

12:15 - 13:15 ET — **ROUNDTABLE 3**

Mastery of Clinical Logistics: Unleashing the Power of Quality Control and Assurance in Clinical Supplies/ Storage

Speaker TBC

ABOUT THE SPEAKER
Speaker TBC

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

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

15:10 - 16:10 ET — **ROUNDTABLE 4**

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

- What have you seen as an optimal structure for internal and external networks?
- How are you adapting your distribution networks to changing regulations ?
- What structures and tools are you using?
- How do you adapt to M&A impact on your supply chains?

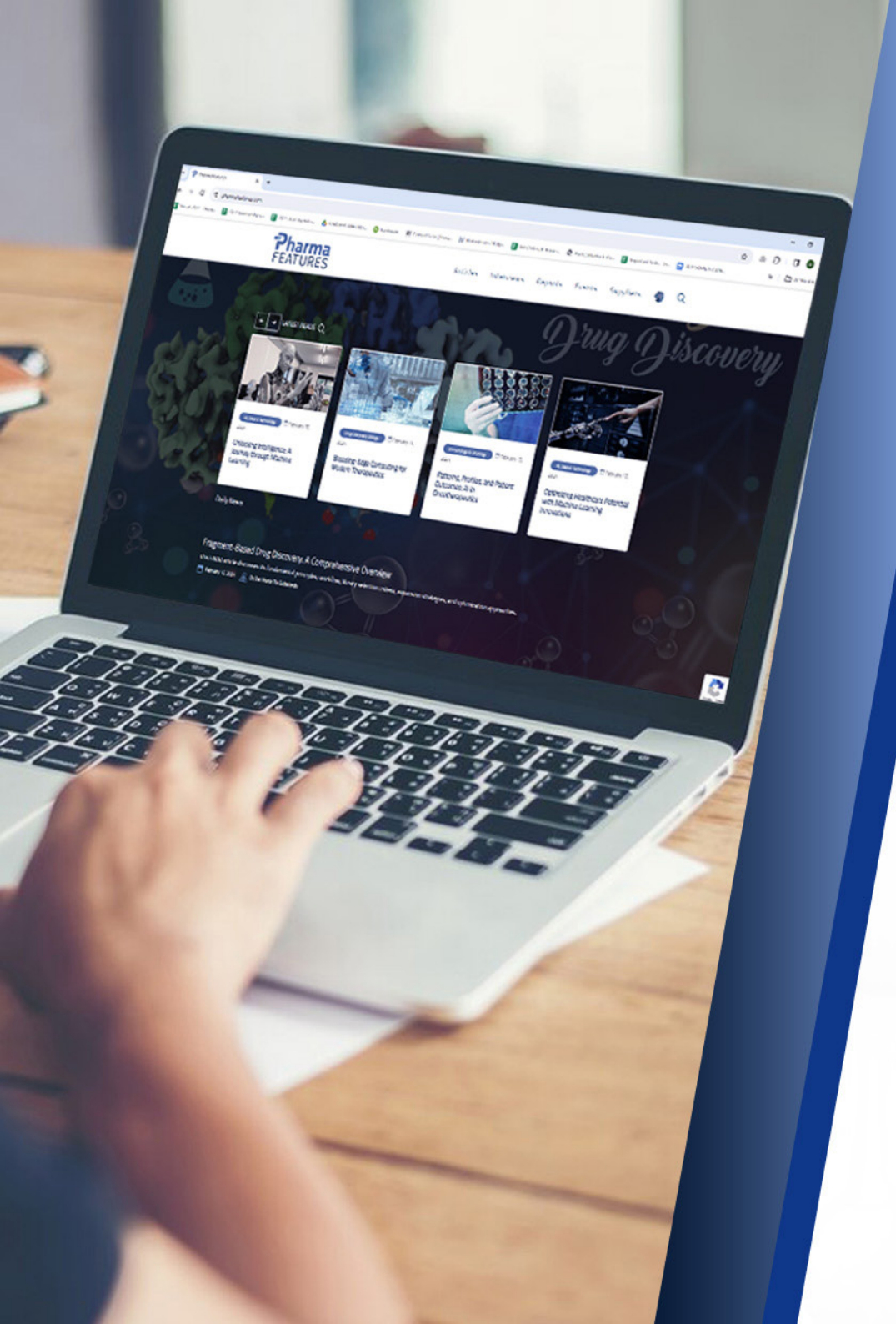
Brian Dole
Vice President, Global Clinical Supply Chain
Bristol Myers Squibb

ABOUT THE SPEAKER
Brian has over 20 years of experience in exploring and advancing game-changing supply chain and product development resource capabilities for bio-technology industry leaders. He has in-depth experience in supply chain, design thinking, next-generation technologies, technical and lean process excellence, and digital transformation. Brian leads the global clinical supply chain organization delivering on the promise to patients across the BMS global footprint. Brian brings a passion for technology and supply chain and is excited to discover, learn and grow.

16:10 - 16:30 ET ET — **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 EST — **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET — **DRINKS & CANAPES RECEPTION**



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- **MAY 15** — MEDICINAL CHEMISTRY — STRATEGY MEETING EAST COAST USA 2024
- **MAY 16** — CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN — STRATEGY MEETING EAST COAST USA 2024

STRATEGY MEETING WEST COAST USA
Hard Rock Hotel San Diego

- **MAY 21** — DRUG DISCOVERY BIOLOGY & BIOINFORMATICS — STRATEGY MEETING WEST COAST USA 2024
- **MAY 22** — MEDICINAL CHEMISTRY — STRATEGY MEETING WEST COAST USA 2024
- **MAY 23** — CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN — STRATEGY MEETING WEST COAST USA 2024

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