Proventa International's 12th Annual

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN

STRATEGY MEETING EAST COAST USA 2025

Thursday, 15th May 2025 **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.

Visit our website for future ← events

Featuring Industry Leaders and Decision Makers:

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

Sanjay Choubey
Vice President and CIO (North America), Digital & Process Excellence
Dr. Reddy's Laboratories

Radha Iyer
Senior Vice President and Head of Global Quality and Regulatory Compliance
Iveric Bio

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

Kiran Bhirangi
Head, Clinical Research & Development and Pharmacovigilance
bluebird bio

Zena Muzyczenko
Vice President, Clinical Operations
CNS Pharmaceuticals, Inc.

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

Pankaj Patel
Innovation Capability Head - Clinical Trial Diversity, Equity and Inclusion
Novartis

18 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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ARENSIA EXPLORATORY MEDICINE

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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 2025

Thursday, 15th May 2025 Hyatt Regency Princeton

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

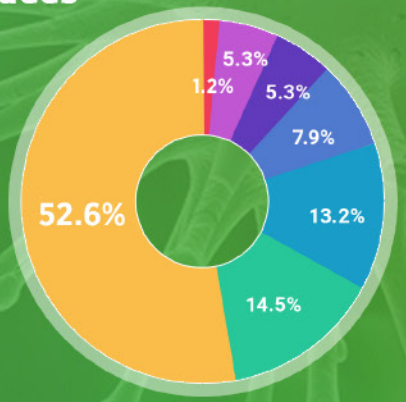
The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

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

Mohit Ahuja
Engagement Manager - Healthcare and Life Sciences
Quantiphi

Ashok Kadian
Senior Client Partner
Quantiphi

Tatiana Eidus
Director, Corporate Development North America
Arensia

Louis Smikle
Executive Director, Global Strategic Partnership
Arensia

Alex Zisson
Managing Director
H.I.G. Capital

Ashok Srivastava
Chief Clinical Officer
Autolus Therapeutics

Carl Spana
Chief Executive Offier & President
Palatin Technologies

Cheryl Roche Alexander
Executive Director
UCB

Erinne Wasalski
Senior Group Director, Clinical Programs in Early Oncology
Daiichi Sankyo, Inc

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

Irena Maksimovic
Senior Director, Strategy & Business Operations- Clinical Supply Chain
Bristol Myers Squibb

James Kirwin
COO and Head, Clinical Development Operations
SFA Therapeutics

Karrie Hilsinger
Senior Director, Head of Clinical Operations
UroGen Pharma

Pankaj Patel
Innovation Capability Head - Clinical Trial Diversity, Equity and Inclusion
Novartis

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

Robert Gabriel
Board Member, Managing Partner
Ashur Capital

Savita Bharathy
Global Clinical Operations Program Director - Community Lead
Novartis

Sanjay Choubey
Vice President and CIO (North America), Digital & Process Excellence
Dr. Reddy's Laboratories

Soumaya Abdel-Rahman
Global Head, Clinical Project Management
Eisai US

Zena Muzyczenko
Vice President, Clinical Operations
CNS Pharmaceuticals, Inc.

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

Vidhya Gedela
Head, Patient & Site Engagement Products, Drug Development IT
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ARENSIA
EXPLORATORY MEDICINE

ARENSIA Exploratory Medicine, a German-based company, is a leader in "first-in-patient" Phase IB and II/Proof-of-Concept clinical trials across a wide range of disease areas. With 14 proprietary research clinics and cutting-edge Phase I infrastructure, ARENSIA accelerates the early detection of efficacy signals for new therapies at an unparalleled speed. Its streamlined, highly efficient approach reduces patient recruitment time and costs by over 50% compared to conventional trial sites, which are often overcrowded and understaffed. This exceptional performance has resulted in a 93% repeat business rate and robust growth through collaborations with top pharmaceutical companies, biotechs, and global CROs. Headquartered in Düsseldorf, ARENSIA operates with a team of 600 professionals across 8 countries.

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Revvity Signals Software provides an extensive range of scientific solutions, empowering researchers and pharmaceutical pioneers worldwide. Our cutting-edge technology simplifies processes, speeds up experiments, and prioritizes promising compounds, redefining drug discovery. The Signals Research Suite, our flagship solution, streamlines R&D workflows with data capture, collaboration, data processing, and data-driven analytics. It includes i Signals Notebook, the only cloud-native electronic lab notebook with ChemDraw®, Spotfire® powered advanced analytics, as well as next-gen data management. In addition, we have recently introduced Signals Synergy which is designed to substantially enhance collaboration, project management, and data exchange between sponsors and CROs.

Acacium Group

As a supplier of clinical staffing and strategic outsourcing, our partnerships with life sciences organisations enable them to scale their workforce and achieve their growth ambitions. Through our specialised brands (Proclinical and R&D Partners) we support you all the way through your global clinical research challenges.

BJ Barrington James

Barrington James are an industry leading, global life science recruitment business that exclusively serves the Pharmaceutical, Biotechnology and Medical Device sectors. Our Clinical Operation division hires across the globe and covers the whole market including CRO's, Biotech, Pharma and Medical Devices of all sizes. From entry level CRCs, CTAs, CRAs through CTM/CPM up to director & (S)VP Clinical level hires on a permanent and interim basis depending on your needs as a company. Our team keep their fingers on the pulse of a constantly changing market by attending Clinical focused conferences like: ACRP, SOCRA and SCOPE as well as specialized therapeutic Area focused conferences. As well as individual hires we offer bespoke solutions from special project based Clinical team build outs (multiple hires), contingent searches and retained searches to help you find the best talent on the market for your team. Barrington James prides itself in delivering an array of best in class solutions to an industry and market place that is not one size fits all we have a true global footprint but the all-important local knowledge wherever your need is.

CROS
CLINICAL RESEARCH OPERATION SERVICES

CROS is a clinical research company offering full-service support for trials from pre-clinical to Phase I–IV, including both commercial and non-commercial studies. We specialize in site identification, protocol feasibility, study startup, contracting, and full clinical operations. Our company collaborates with pharmaceutical, biotech, and medical device companies, ensuring excellence, transparency, and regulatory adherence. With a growing network of investigators and sites, we take a strategic, data-driven approach to achieve reliable outcomes, faster timelines, and cost efficiency. CROS bring heart into every project—where science meets innovation to make a difference.

KEY OPINION LEADER

PCM TRIALS
QUALITY MOBILE RESEARCH

Agenda at a Glance

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2025
Thursday, 15th May 2025 | Hyatt Regency Princeton

TIME (EST)	TRACK 1	TRACK 2	TRACK 3	TRACK 4	TRACK 5	TRACK 6
	DEI IN PATIENT RECRUITMENT/ DECENTRALIZED & HYBRID TRIALS	EMERGING BIOPHARMA / OUTSOURCING	CLINICAL TECHNOLOGIES & ARTIFICIAL INTELLIGENCE	GLOBAL SITE SELECTION AND FEASIBILITY STUDY	EARLY PHASE CLINICAL TRIALS	CLINICAL SUPPLIES, GLOBAL NETWORKS, STORAGE & DISTRIBUTION
BOARDROOM ►	WILSON SUITE A	WILSON SUITE B	OPPENHEIMER SUITE A	OPPENHEIMER SUITE B	CLEVELAND SUITE	WEST WINDSOR SUITE
08:00 - 08:30	BREAKFAST & REGISTRATION					
08:30 - 09:00	OPENING KEYNOTE PRESENTATION: PRESENTER: Ashok Srivastava, *Chief Clinical Officer*, Autolus Therapeutics					
09:00 - 10:00 PHARMA/ BIOTECH		**The Path to Performance: Navigating Complexities of Emerging Biopharma** Zena Muzyczenko, *Vice President, Clinical Operations*, CNS Pharmaceuticals, Inc.	**AI-Driven Patient Matching and Recruitment** Vidhya Gedela, *Head, Patient & Site Engagement Products, Drug Development IT*, Bristol Myers Squibb	**Optimizing Feasibility Assessments for Effective Strategies in Global Site Selection and Management** Savita Bharathy, *Global Clinical Operations Program Director - Community Lead*, Novartis	**Navigating Regulatory Complexities: Addressing New Guidelines and Optimization of Trial Timelines (Topic TBC)** Ashok Srivastava, *Chief Clinical Officer*, Autolus Therapeutics	**Overcoming Global Logistics Challenges in Clinical Trial Supply Chains Across Borders (Topic TBC)** Sanjay Choubey, *Vice President and CIO (North America), Digital & Process Excellence*, Dr. Reddy's Laboratories
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 PHARMA/ BIOTECH	**Promoting Data Integrity and Decentralized Clinical Trials: Key Elements and Patient-Centric Approaches** Soumaya Abdel-Rahman, *Global Head, Clinical Project Management*, Eisai US		**Advanced AI Agents in Clinical Operations: Enabling Autonomous Decision-Making at Scale** Mohit Ahuja, *Engagement Manager - Healthcare and Life Sciences*, Quantiphi; Ashok Kadian, *Senior Client Partner*, Quantiphi — QUANTIPHI		**Patient Recruitment Strategies for Early Clinical Trials: A Site Perspective on What Works and What Doesn't in Europe vs. the US** Louis Smikle, *Executive Director, Global Strategic Partnerships*, Arensia; Tatiana Eidus, *Director, Corporate Development North America*, Arensia — ARENSIA	**Building Resilient Supply Chains to Manage Global Distribution and Mitigate Delays in Clinical Trials** Irena Maksimovic, *Senior Director, Strategy & Business Operations-Clinical Supply Chain*, Bristol Myers Squibb
12:15 - 13:15 PHARMA/ BIOTECH	**Operational Challenges in Diversity Action Plan (DAP) Development and Delivery** Pankaj Patel, *Innovation Capability Head - Clinical Trial Diversity, Equity and Inclusion*, Novartis	**Flexible and Modular Manufacturing Solutions: The Future of Biopharma Partnerships** James Kirwin, *COO and Head, Clinical Development Operations*, SFA Therapeutics	**Leveraging Adaptive AI Systems to Transform Compliance and Workflow Automation in Clinical Trial Design** Paresh Patel, *Former Global Head, Clinical Intelligence*, Otsuka Pharmaceutical Companies (U.S.)	**Leveraging Data Science for Enhanced Global Site Selection and Feasibility Studies (Topic TBC)** Karrie Hilsinger, *Head, Global Clinical Operations*, UroGen Pharma	**Integrating Patient-Reported Outcomes into Early Phase Clinical Trials: Enhancing Data, Patient Experience, and Long-Term Follow-Up** Erinne Wasalski, *Senior Group Director of Clinical Programs in Early Oncology*, AstraZeneca	
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	ARENSIA EXPLORATORY MEDICINE — AFTERNOON KEYNOTE PRESENTATION: Proof-of-Concept: Bold moves, big wins, and lessons learned — CHAIRPERSON: Tatiana Eidus, *Director, Corporate Development North America*, Arensia — ARENSIA EXPLORATORY MEDICINE					
15:10 - 16:10 PHARMA/ BIOTECH		**The Role of AI and Leveraging Blockchain in Emerging Biopharma Trials** Frank Leu, *Founder & Managing Member/ Managing Member*, BioPharMatrix LLC/ Novapeutics LLC	**Enhancing Efficiency and Compliance in Modern Trials Through Quality Management** Cheryl Roche Alexander, *Executive Director*, UCB	**Collaborative Approaches to Streamline Global Site Selection and Feasibility Assessments (Topic TBC)** Ashok Srivastava, *Chief Clinical Officer*, Autolus Therapeutics		**Ensuring Cold Chain Integrity: Navigating Temperature-Controlled Logistics in Global Clinical Trials** Carl Spana, *Chief Executive Offier & President*, Palatin Technologies
16:10 - 16:30	AFTERNOON REFRESHMENT BREAK					
16:30 - 17:00	PANEL DISCUSSION: CHAIRPERSON: Carl Spana, *Chief Executive Offier & President*, Palatin Technologies — PANELIST: Robert Gabriel, *Board Member, Managing Partner*, Ashur Capital					
17:00 - 18:00	DRINKS & CANAPES RECEPTION					

VENTURE CAPITAL & PRIVATE EQUITY

STRATEGY MEETING EAST COAST USA 2025

Wednesday & Thursday, 14-15th May 2025 **Hyatt Regency Princeton**

Investment Challenges and Opportunities in Emerging Biotech Markets

Featuring Industry Leaders and Decision Makers:

Allan Gobbs
Co-Founder & Managing Partner
ATEM Capital

Heather Rose
Vice President of Technology Licensing and Start-Ups
BioStrategy Partners

Rick Ewing
VP, Head of Chemistry
Rapafusyn Pharmaceuticals

CLICK HERE TO SEE FULL LIST OF SPEAKERS →

TIME EST	DAY 1 INVESTMENT IN DRUG DISCOVERY & BIOTECH
ROOM►	Witherspoon Ballroom
08:00 - 08:30	REGISTRATION AND WELCOME
08:30 - 09:00	**OPENING KEYNOTE PRESENTATION:** **Drug Discovery Approaches towards Unlocking the Hard to Drug Proteome** Rick Ewing, *VP, Head of Chemistry*, **Rapafusyn Pharmaceuticals**
09:00 - 10:00 Investor	**Navigating Financial Risks and Rewards in Biotech: Investment Trends and Strategies for 2025** Allan Gobbs, *Co-Founder & Managing Partner*, **ATEM Capital**
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 Investor	**How Biotech Startups are Leveraging Investment for Growth and Innovation through Public and Private Funding Models** Heather Rose, *Vice President of Technology Licensing and Start-Ups*, **Thomas Jefferson Health**
12:10 - 13:30	NETWORKING LUNCH
13:30 - 13:50	NETWORKING / 1-1 MEETINGS
13:50 - 14:10	NETWORKING / 1-1 MEETINGS
14:10 - 14:30	NETWORKING / 1-1 MEETINGS
14:30 - 15:30	
15:30 - 15:50	AFTERNOON REFRESHMENT BREAK
15:50 - 16:20	**PANEL DISCUSSION:** **Overcoming Investment Barriers in Biotech: R&D Costs, IP Issues, and Market Uncertainty** CHAIRPERSON: Nikolaos Tezapsidis, *President & CEO*, **Neurotez, Inc.** PANELISTS: **Arnold Lippa**, *Executive Chairman, Chief Executive Officer and Chief Scientific Officer*, **RespireRx Pharmaceuticals Inc.** **Mark Tornetta**, *VP/Director of Biologics Discovery*, **Tavotek Biotherapeutics** **Sunil Joshi**, *President & CEO*, **Protelis Bio**
16:20 - 17:20	DRINKS & CANAPES RECEPTION

TIME EST	DAY 2 INVESTMENT IN CLINICAL TRIALS
ROOM►	Witherspoon Ballroom
08:00 - 08:30	REGISTRATION AND WELCOME
08:30 - 09:00	**OPENING KEYNOTE PRESENTATION:** **Topic TBC** Ashok Srivastava, *Chief Clinical Officer*, **Autolus Therapeutics**
09:00 - 10:00	
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	
12:15 - 13:15 Investor	**Evaluating the Role of Strategic Partnerships in Mitigating Risks and Enhancing Funding or Expertise for Clinical Trials** Carl Spana, *Chief Executive Offier & President*, **Palatin Technologies**
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 Investor	**Exploring the Key Strategies for Improving the Cost-Efficiency of Clinical Trials and Increasing ROI for Investors?** Robert Gabriel, *Board Member, Managing Partner*, **Ashur Capital**
16:10 - 16:30	AFTERNOON REFRESHMENT BREAK
16:30 - 17:00	**PANEL DISCUSSION:** **Maximizing ROI in Clinical Trials: Navigating Risk, Innovation, and Opportunity** Carl Spana, *Chief Executive Offier & President*, **Palatin Technologies**
17:00 - 18:00	DRINKS & CANAPES RECEPTION

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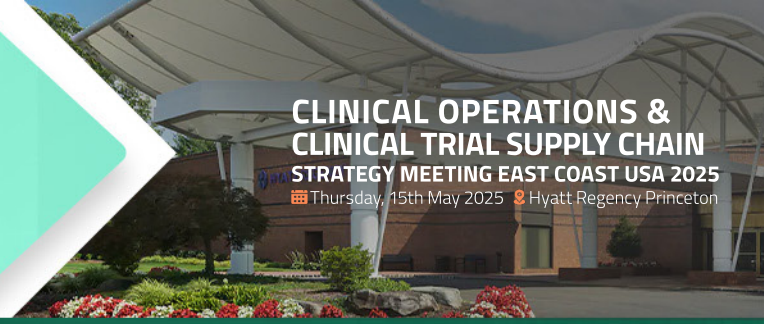
Event Day | Keynote Presentations

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 ET **OPENING KEYNOTE PRESENTATION**

Topic TBC

Ashok Srivastava
Chief Clinical Officer
Autolus Therapeutics

ABOUT THE SPEAKER
Speaker Bio TBC

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

Proof-of-Concept: Bold Moves, Big Wins, and Lessons Learned

Fast, Furious, or Never-Ending: Entertaining Case Studies on Accelerating and Unexpectedly Inflating Phase Ib/II Trial Timelines and Budgets. A Site Team Perspective.

Tatiana Eidus
Director, Corporate Development
North America
Arensia

ABOUT THE SPEAKER
Tatiana Eidus received her Master's Degree in Biophysics from Moscow State University. Entering the industry more than a decade ago, Tatiana has accumulated wide expertise in all the operational aspects of initiating and managing Phase I-III trials across Europe and US. Prior to joining ARENSIA Exploratory Medicine, Tatiana worked for GSK and Merck. Primarily focused on early-stage exploratory programs, she conducted trials in various disease areas. In her current role as Director Corporate Development, Tatiana supports ARENSIA's partners in the US, supervising cross-functional coordination throughout study planning, start-up and execution.

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

Topic TBC

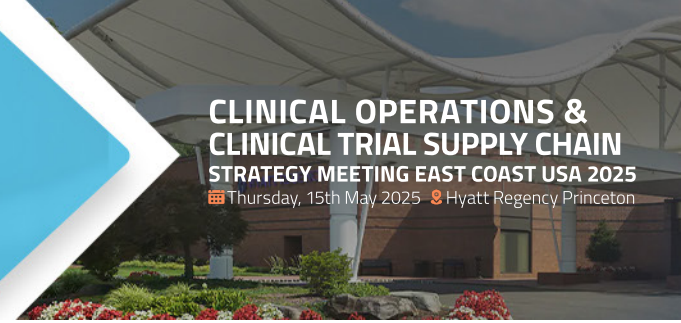
CHAIRPERSON
Carl Spana
Chief Executive Offier & President
Palatin Technologies

PANELIST
Robert Gabriel
Board Member, Managing Partner
Ashur Capital

ABOUT THE SPEAKERS
Carl Spana, Ph.D., Co-Founder of Palatin, has been the Chief Executive Officer and President since June 14, 2000. He has been a director of Palatin since June 1996 and has been a director of our wholly owned subsidiary, RhoMed Incorporated, since July 1995. From June 1996 through June 14, 2000, Dr. Spana served as an executive vice president and chief technical officer of Palatin. From June 1993 to June 1996, Dr. Spana was vice president of Paramount Capital Investments, LLC, a biotechnology and biopharmaceutical merchant banking firm, and of The Castle Group Ltd., a medical venture capital firm. Through his work at Paramount Capital Investments and The Castle Group, Dr. Spana co-founded and acquired several private biotechnology firms. From July 1991 to June 1993, Dr. Spana was a Research Associate at Bristol-Myers Squibb, a publicly held pharmaceutical company, where he was involved in scientific research in the field of immunology. Dr. Spana received his Ph.D. in molecular biology from Johns Hopkins University and his B.S. in biochemistry from Rutgers University.

Dr. Robert Gabriel has broad experience in technology and business development. He founded Genesis Aromatique and led the company for over 15 years. Prior to that, Gabriel led technology and business development initiatives at Unilever, Gillette, Clorox, and Rhone-Poulenc. In his current role as Ashur Capital's managing partner and board member, Dr. Gabriel provides strategic direction for asset allocation and capital deployment. He is also an investor and board member at Clear Protocol, a digital health startup. Dr. Gabriel earned a Ph.D. from the University of Illinois and an MBA from the Wharton School of Business. Dr. Gabriel is married and has 4 sons.

Event Day



TRACK 1

Dei In Patient Recruitment/Decentralized & Hybrid Trials

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

08:00 - 08:30 ET BREAKFAST & REGISTRATION

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

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

11:10 - 12:10 ET ROUNDTABLE 2

Promoting Data Integrity and Decentralized Clinical Trials: Key Elements and Patient-Centric Approaches

- Protocol strategy and design
- 2Operational elements to enable DCTs
- Regulatory landscape

Soumaya Abdel-Rahman
Global Head, Clinical Project Management
Eisai US

ABOUT THE SPEAKER

Dr. Soumaya Abdel-Rahman is an accomplished project management leader with over 20 years of experience in R&D, scientific research, and management consulting. As the Global Head of Clinical Project Management at Eisai, Inc., she oversees the strategic alignment, integrated planning, and execution across the Neurology and Oncology portfolios. Her team partners with international project leads to guide clinical development from clinical introduction to registration filings. A champion of innovation and process optimization, she led Eisai's decentralized clinical trials (DCTs) initiative, shaping its DCT strategy and contributing to increased diversity in Alzheimer's research. Focused on strategic insights and communication, she drives cross-functional initiatives to accelerate drug delivery. She also leads the clinical development of an early Alzheimer's compound.

12:15 - 13:15 ET ROUNDTABLE 3

Operational Challenges in Diversity Action Plan (DAP) Development and Delivery

- Factors that go into assessing if a DAP is required
- Integrating the program team to collectively write the DAP
- DAP planning and submission
- Assessing collaborative partners
- Assessing resource needs

Pankaj Patel
Innovation Capability Head – Clinical Trial Diversity, Equity and Inclusion
Novartis

ABOUT THE SPEAKER

Pankaj Patel is the Innovation Capability Head for Clinical Trial Representation at Novartis and leads efforts to drive the incubation of innovative solutions to ensure clinical trial populations robustly inform risk/benefit in the medically indicated population support. Previously he has held several leadership roles in diversity, patient advocacy, and clinical research across multiple organizations. At IQVIA, he led clinical trial representation strategy and initiatives, at Celgene he built a patient advocacy function within global clinical operations and at Bristol Myers Squibb, he managed consumer brand marketing efforts in commercials and helped create a Patient Advocacy Center of Excellence within R&D.

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

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

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 Emerging Biopharma / Outsourcing

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

08:00 - 08:30 ET BREAKFAST & REGISTRATION

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

09:00 - 10:00 ET ROUNDTABLE 1

The Path to Performance: Navigating Complexities of Emerging Biopharma

- Access to Funding
- Clinical Development Challenges
- Regulatory Complexities
- Resource Strain
- Commercialization Readiness

Zena Muzyczenko
Vice President, Clinical Operations
CNS Pharmaceuticals, Inc.

ABOUT THE SPEAKER

With over two decades of experience in drug development and operations, **Zena** is a passionate and focused leader who thrives in biotech. Her experience ranges among a broad span of therapeutic areas, prominently in oncology. Zena began her career as a CRA at a small, independent CRO before moving into a variety of roles of increasing seniority at Genmab, Inc. At Genmab, she led multiple clinical development programs, leading to the submission and approval of Arzerra. Prior to joining CNS Pharmaceuticals in 2020, Zena served in project management and leadership roles of increasing seniority at Chiltern, Inc., and Synteract, Inc.

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

12:15 - 13:15 ET ROUNDTABLE 3

Flexible and Modular Manufacturing Solutions: The Future of Biopharma Partnerships

- Outsourcing options for small and emerging biotech
- Is the FSP Model right for you?
- Internal Organizational requirements to support outsourced clinical trials
- Processes to support effective, efficient and quality outsourced clinical programs

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 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

The Role of AI and Leveraging Blockchain in Emerging Biopharma Trials

- Pragmatic use of AI automation in trials
- Blockchain utilization for transparency and security
- Humanizing technology for the best use

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. BioPharMatrix provides innovative solutions, mainly specialized in applicable decentralized processes and technologies for life sciences, is an advisor to the Pennovation Center, and is a thought leader in the directional adoption of disruptive techs (blockchain, machine learning, and artificial intelligence), with combined over 100 publications and presentations on such a topic. Frank has served as an advisor to the board, planning committee, chairman, speaker, and moderator for life sciences and drug development conferences.

16:10 - 16:30 ET AFTERNOON REFRESHMENT BREAK

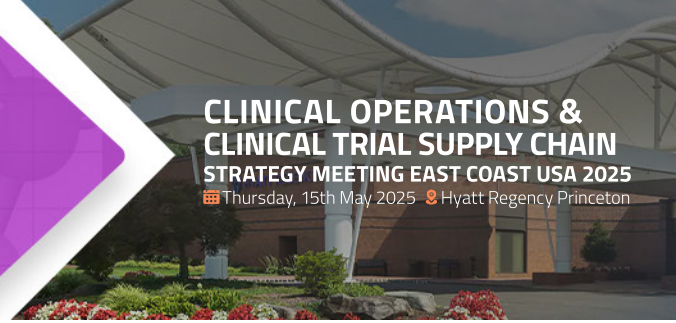
16:30 - 17:00 ET PANEL DISCUSSION
See Page 6

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

Event Day

TRACK 3

Clinical Technologies & Artificial Intelligence



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**

AI-Driven Patient Matching and Recruitment

- Advanced algorithms for identifying suitable trial participants
- Reducing recruitment with AI
- Ethical considerations in AI-driven patient selection
- Integration with existing clinical systems
- Enhancing patient engagement and retention

Vidhya Gedela
Head, Patient & Site Engagement Products, Drug Development IT
Bristol Myers Squibb

ABOUT THE SPEAKER

IT & Life-Sciences Leader enabling technology for Pharma/Biotech in R&D, Global Drug Development, and Clinical Innovation. Pragmatic, big-picture thinker, problem-solver, and hands-on leader. Engages stakeholders to meet high-value needs within budgets and constraints. Passionate about driving change through digital capabilities to optimize patient and site engagement and clinical operations. Experienced in creating and implementing business and technology roadmaps, strategic planning, and integrated business applications. Focused on building effective teams, delivering results, and managing complex enterprise technology with an emphasis on quick value delivery and sustainability. Above all, passionate about serving patients!

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

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

Advanced AI Agents in Clinical Operations: Enabling Autonomous Decision-Making at Scale

The Role of Autonomous AI Agents in clinical environments, including:

- Real-time analysis and insight generation
- Dynamic treatment plan optimization
- Supply chain adaptability based on clinical context
- Workflow Automation across clinical operations for faster decision cycles

Mohit Ahuja
Engagement Manager - Healthcare and Life Sciences
Quantiphi

Ashok Kadian
Senior Client Partner
Quantiphi

quantiphi
Solving What Matters

ABOUT THE SPEAKERS

With two decades of IT leadership under his belt, **Mohit Ahuja** has a proven track record of spearheading complex product launches, IT transformations, and AI/ML solutions within the Life Sciences sector. His expertise is well-regarded in the industry for delivering innovative solutions across clinical trials, data migration, analytics, and data sciences. Currently serving as an Engagement Manager at Quantiphi, Mohit is at the forefront of cutting-edge initiatives. This includes the establishment of an AI Center of Excellence for a major Life Science client and the development of one of the largest Agentic frameworks for a leading Contract Research Organization. Mohit's current roles underscore his continued impact on driving technological advancements in the Life Sciences domain.

With 15 years of experience in the Healthcare and Life Sciences (HCLS) service area, **Ashok Kadian** has built a strong track record across clinical trials, regulatory affairs, biomedical research, and P&L management. In life sciences, he has played a pivotal role in managing Trial Master Files (TMFs), ensuring regulatory compliance, supporting biomedical research deliverables, and managing P&L. Now, as a Senior Client Partner at Quantiphi, Ashok leverages this deep domain expertise to help pharmaceutical companies adopt AI and GenAI solutions, driving greater efficiency and faster results in R&D space.

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

Leveraging Adaptive AI Systems to Transform Compliance and Workflow Automation in Clinical Trial Design

- Expanding AI-driven prompt optimization beyond traditional regulatory frameworks to enhance flexibility in clinical trial design and execution
- Dynamic adaptation of AI models to evolving compliance standards (e.g., FDA, HIPAA, GDPR) across different trial phases and regions
- Using version-controlled AI prompt repositories to maintain consistency, auditability, and regulatory transparency in clinical trial documentation
- Real-time regulatory feedback integration to proactively adjust clinical workflows based on industry-specific updates

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

ABOUT THE SPEAKER

Paresh Patel is a visionary in Clinical Data, Systems, and Operations, pioneering advanced technologies for operational excellence. He led global initiatives like enrollment forecasting models and Covid-19 impact assessments. As a Data Science Technologist, he drove efficiency through automation and innovative review processes. His tenure saw the transformation of teams and strategic partnerships for technological advancements. Paresh has championed excellence, revenue growth, and collaborative relationships throughout his career, ensuring the highest standards in clinical research operations.

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**

Enhancing Efficiency and Compliance in Modern Trials Through Quality Management

Cheryl Roche Alexander
Executive Director
UCB

ABOUT THE SPEAKER

Speaker TBC

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

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

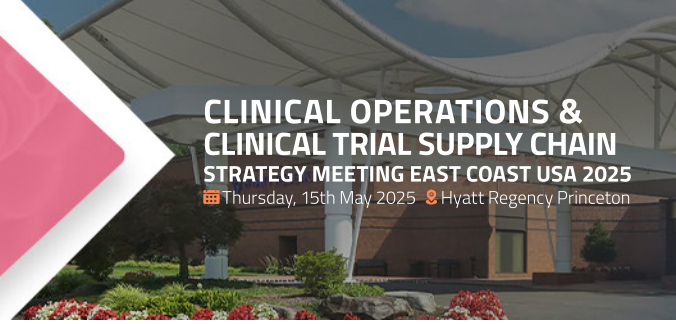
17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 4

Global Site Selection and Feasibility Study

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



08:00 - 08:30 ET — **BREAKFAST & REGISTRATION**

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

09:00 - 10:00 ET — **ROUNDTABLE 1**

Optimizing Feasibility Assessments for Effective Strategies in Global Site Selection and Management

- **Challenges with site feasibility outreach and engagement**
- **Effectiveness of data-driven approaches in enhancing site selection**
- **Balancing feasibility feedback in decision-making (Protocol optimization vs. site selection)**
- **Proactive risk identification and mitigation planning in evolving trial landscape**

Savita Bharathy
Global Clinical Operations Program Director - Community Lead
Novartis

ABOUT THE SPEAKER

Savita Bharathy is an experienced clinical research professional, including 14+ years in the pharmaceutical industry. In her current role, Savita is a clinical operations program director leading the oncology/hematology practice team responsible for early strategic planning and scenario modeling as well as overall delivery of site feasibility and recruitment planning. Savita has a strong professional focus in oncology/hematology, having held leadership positions in trial management and feasibility at Novartis for over 13 years. She is patient-focused and has been involved in numerous process-excellence initiatives and optimization of product delivery. Savita holds a Ph.D. from Rutgers University, New Jersey.

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

12:15 - 13:15 ET — **ROUNDTABLE 3**

Leveraging Data Science for Enhanced Global Site Selection and Feasibility Studies (Topic TBC)

Karrie Hilsinger
Head, Global Clinical Operations
UroGen Pharma

ABOUT THE SPEAKER

Karrie Hilsinger has over 20 years of global clinical operations leadership experience, having held leadership positions at companies such as Covance, Eisai, Hoffmann-La Roche as well as pharmaceutical startup companies such as Immunomedics and medical device organizations. Karrie, in many of her previous roles has been responsible for FDA inspection readiness and Preparedness. She has experience in all phases of Clinical Research and has a range of therapeutic experiences as well.

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**

Collaborative Approaches to Streamline Global Site Selection and Feasibility Assessments (Topic TBC)

Ashok Srivastava
Chief Clinical Officer
Autolus Therapeutics

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**

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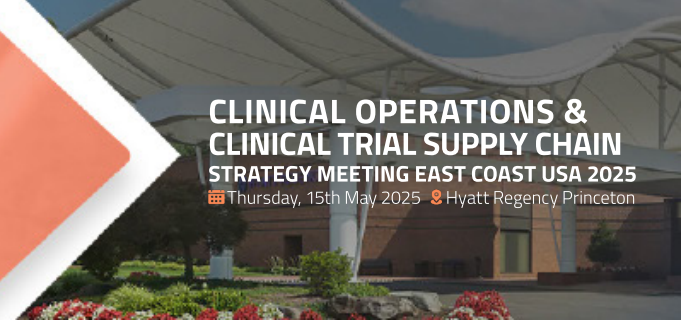
Event Day

TRACK 5

Early Phase Clinical Trials



CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN
STRATEGY MEETING EAST COAST USA 2025
Thursday, 15th May 2025 Hyatt Regency Princeton

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**

Navigating Regulatory Complexities: Addressing New Guidelines and Optimization of Trial Timelines (Topic TBC)

Ashok Srivastava
Chief Clinical Officer
Autolus Therapeutics

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**

Patient Recruitment Strategies for Early Clinical Trials: A Site Perspective on What Works and What Doesn't in Europe vs. the US

Louis Smikle
Executive Director, Global Strategic Partnership
Arensia

Tatiana Eidus
Director, Corporate Development North America
Arensia

ABOUT THE SPEAKERS
Tatiana Eidus received her Master's Degree in Biophysics from Moscow State University. Entering the industry more than a decade ago, Tatiana has accumulated wide expertise in all the operational aspects of initiating and managing Phase I-III trials across Europe and US. Prior to joining ARENSIA Exploratory Medicine, Tatiana worked for GSK and Merck. Primarily focused on early-stage exploratory programs, she conducted trials in various disease areas. In her current role as Director Corporate Development, Tatiana supports ARENSIA's partners in the US, supervising cross-functional coordination throughout study planning, start-up and execution.

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

Integrating Patient-Reported Outcomes into Early Phase Clinical Trials: Enhancing Data, Patient Experience, and Long-Term Follow-Up

- The Value of PROs in Early Phase Clinical Trials
- Operational Challenges & Best Practices
- Long-Term Safety & Patient Experience
- Regulatory & Industry Perspectives

Erinne Wasalski
Senior Group Director, Clinical Programs in Early Oncology
AstraZeneca

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

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**

Event Day

TRACK 6

Clinical Supplies, Global Networks, Storage & Distribution

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**

Overcoming Global Logistics Challenges in Clinical Trial Supply Chains Across Borders (Topic TBC)

Sanjay Choubey
Vice President and CIO (North America), Digital & Process Excellence
Dr. Reddy's Laboratories

ABOUT THE SPEAKER
Speaker TBC

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

11:10 - 12:10 ET — **ROUNDTABLE 2**

Building Resilient Supply Chains to Manage Global Distribution and Mitigate Delays in Clinical Trials

Irena Maksimovic
Senior Director, Strategy & Business Operations-Clinical Supply Chain
Bristol Myers Squibb

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**

Ensuring Cold Chain Integrity: Navigating Temperature-Controlled Logistics in Global Clinical Trials

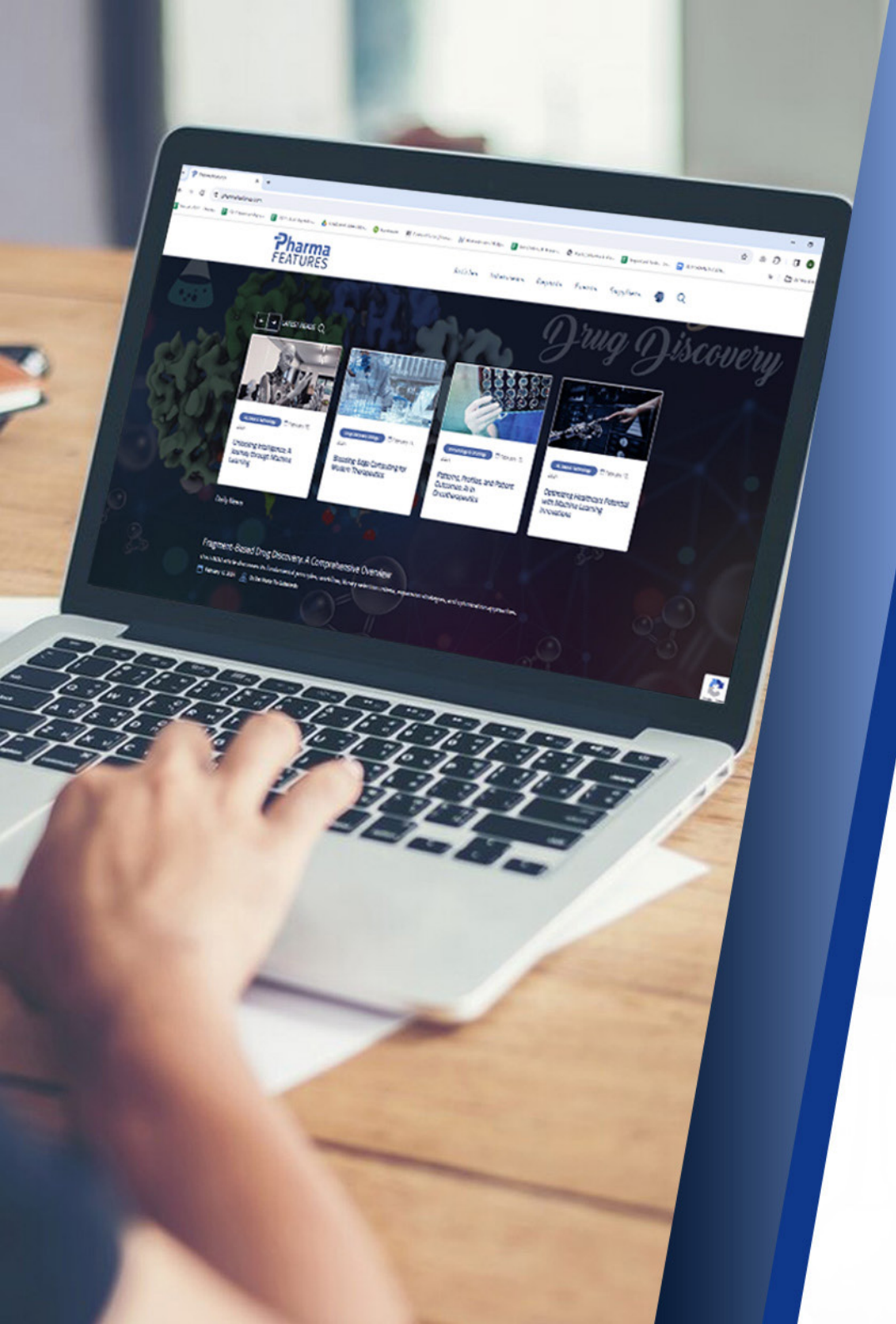
Carl Spana
Chief Executive Offier & President
Palatin Technologies

ABOUT THE SPEAKER
Carl Spana, Ph.D., Co-Founder of Palatin, has been the Chief Executive Officer and President since June 14, 2000. He has been a director of Palatin since June 1996 and has been a director of our wholly owned subsidiary, RhoMed Incorporated, since July 1995. From June 1996 through June 14, 2000, Dr. Spana served as an executive vice president and chief technical officer of Palatin. From June 1993 to June 1996, Dr. Spana was vice president of Paramount Capital Investments, LLC, a biotechnology and biopharmaceutical merchant banking firm, and of The Castle Group Ltd., a medical venture capital firm. Through his work at Paramount Capital Investments and The Castle Group, Dr. Spana co-founded and acquired several private biotechnology firms. From July 1991 to June 1993, Dr. Spana was a Research Associate at Bristol-Myers Squibb, a publicly held pharmaceutical company, where he was involved in scientific research in the field of immunology. Dr. Spana received his Ph.D. in molecular biology from Johns Hopkins University and his B.S. in biochemistry from Rutgers University.

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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Dex Marco Guibelondo
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2025 Strategy Meeting Calendar

MAY

Boston/Cambridge MA - US East Coast

MAY 7 WED
CHEMISTRY MANUFACTURING CONTROL
CMC Strategy Meeting 2025
Le Meridien Boston Cambridge

MAY 8 THUR
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Le Meridien Boston Cambridge

MAY 7-8 WED&THUR
VENTURE CAPITAL PRIVATE EQUITY
Venture Capital & Private Equity
Le Meridien Boston Cambridge

Princeton/New Jersey - US East Coast

MAY 14 WED
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Hyatt Regency Princeton

MAY 15 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Hyatt Regency Princeton

MAY 14&15 WED&THUR
VENTURE CAPITAL PRIVATE EQUITY
Venture Capital & Private Equity
Hyatt Regency Princeton

OCTOBER

London/UK - Europe

OCT 9 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Crowne Plaza, London Docklands

OCT 15 WED
BIOINFORMATICS & DRUG DISCOVERY BIOLOGY
Bioinformatics & Drug Discovery Biology Strategy Meeting 2025
Crowne Plaza, London Docklands

OCT 16 THURS
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Crowne Plaza, London Docklands

NOVEMBER

San Diego - US West Coast

NOV 12 WED
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Hard Rock Hotel San Diego

NOV 13 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Hard Rock Hotel San Diego

Boston/Cambridge MA - US East Coast

NOV 18 TUE
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Le Meridien Boston Cambridge

NOV 19 WED
BIOINFORMATICS & DRUG DISCOVERY BIOLOGY
Bioinformatics Strategy Meeting 2025
Le Meridien Boston Cambridge

CLINICAL OPERATIONS & CLINICAL TRIAL SUPPLY CHAIN

STRATEGY MEETING EAST COAST USA 2025

Thursday 15th May 2025 | Hyatt Regency Princeton

Hotel & Venue

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JUNE 24

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