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Proventa International's 10th Annual

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

25th May 2023, Thursday | 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

NEW FOR 2023:

Investment, Private Equity & Venture Capital Partnerships

Featuring Industry Leaders and Decision Makers:

Gayle Wittenberg
VP, Neuroscience Data Science and Digital Health
Janssen R&D

Kelly Clark
Head of US Partnerships and Global Site Development
Merck & Co

Michele Sharr-Hyde
Executive Director, Head Clinical Science
Daiichi-Sankyo

Alex Zisson
Managing Director
H.I.G. Capital

Victoria Gamerman
Global Head of Data Governance and Insights
Boehringer Ingelheim

Amy Neubauer
Director, GCDM Operational Excellence
Alexion Pharmaceuticals

Karen Correa
Vice President, Head Global Clinical Operations
Takeda

Craig Granowitz
Chief Medical Officer
Lexicon Pharmaceuticals

24 ROUNDTABLE DISCUSSIONS

6 TRACKS

2 KEYNOTE PRESENTATIONS

1 LOCATION

What Makes Our Strategy Meetings So Unique?

Proud to Partner with:

IQVIA TECHNOLOGIES | RegDocs365 | inato | mdgroup | thoughtsphere | inteliquet | camina MEDICAL | florence | appian

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

CLINICAL OPERATIONS
STRATEGY MEETING EAST COAST USA 2023
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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.

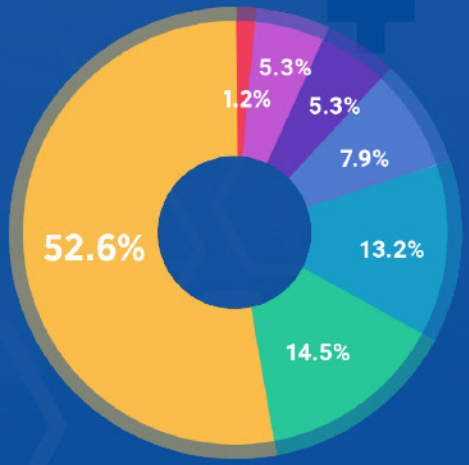
PERSONALISED AGENDA
Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

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



Clinical Operations

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

Meet Investors

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

Facilitator Faculty

CLINICAL OPERATIONS
STRATEGY MEETING EAST COAST USA 2023
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Adriana Comprelli
Therapeutic Area Head, Clinical Operations Strategy
Bristol Myers Squibb

Alex Zisson
Managing Director
H.I.G. Capital

Amy Neubauer
Director, GCDM Operational Excellence
Alexion Pharmaceuticals

Christopher J. Schaber
Chairman, President & Chief Executive Officer
Soligenx

Craig Granowitz
Chief Medical Officer
Lexicon Pharmaceuticals

Gayle Wittenberg
VP, Neuroscience Data Science and Digital Health
Janssen R&D

Jennifer Sheller
AVP Clinical Operations
Merck & Co

Karen Correa
Vice President, Head Global Clinical Operations
Takeda

Katherine Taylor
Head Risk Evaluation and Adaptive Integrated Monitoring
Merck & Co

Kelly Clark
Head of US Partnerships and Global Site Development
Merck & Co

Laura Vessey
Senior Director, Head of Early Development and Clinical Pharmacology
Janssen

Lorie Crowe
Program Director, Global Trial Optimization
Merck & Co

Mark Travers Ph.D, MBA
VP, GCTO-Regions and Regional Operations
Merck & Co

Matthew Rosenberg
Advisor
Guxi Capital

Michael Walega
Head of Centralized Monitoring
Bristol Myers Squibb

Michele Sharr-Hyde
Executive Director, Head Clinical Science
Daiichi-Sankyo

Paul Blake
Chief Executive Officer
Papyrus Therapeutics Inc

Saikat Nandi
Global Chief Business Officer
Oryzon Genomics SA

Seun Makinde
Associate Director Clinical Development
Shionogi

Srinivasan Vairavan
Director, Data Science and Digital Health
Janssen R&D

Varun Nagpal
Medical Director
Eisai US

Victoria Gamerman
Global Head of Data Governance and Insights
Boehringer Ingelheim

Aruna Adhikari Thapa
Senior Director of Product Strategy and Product Management
IQVIA Technologies

Rachael Geedey
Associate Director RBQM Technology
IQVIA Technologies

Gary Shorter
Head of Research and Development of AI into Products
IQVIA Technologies

Sarrah Val
MPH Vice President of Global Sales
MD GROUP

2023 Sponsors

LEAD SPONSOR

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

CO-HOST SPONSORS

RegDocs365 offers a suite of solutions for regulated content and collaboration, specifically streamlined for life sciences. All of our products are built on our audit-ready, compliant-cloud (ARCC).

mdgroup is a global patient services and digital technologies company with offices in the US, UK, Singapore, France, Dublin and The Netherlands. With a focus on creating remarkable patient experiences at every stage of the clinical trial, their services include patient and caregiver support, home healthcare for decentralized and hybrid clinical trials, site analysis and management, travel and logistics, expense reimbursement and patient sentiment analysis through their in-house technology platform.

Inato is a global platform that makes clinical trials more accessible, inclusive, and efficient by empowering community-based sites to match with the right trials from top pharma companies. Since launching in June 2020, Inato has quickly become a trusted two-sided platform with over 2,500 community research sites across more than 60 countries, along with a third of the top 30 sponsors. Learn more at www.inato.com

ThoughtSphere is a market-leading stacked platform that creates an integrated central monitoring environment to streamline RBQM, drug safety, medical, data management, and site management tasks in a single platform. Our user-friendly solution leverages Machine Learning and Artificial Intelligence to automate processes and modernize clinical trial operations from data aggregation to the generation of submission-ready datasets.

Regardless of the trial design, level of patient-centricity or the diversity of data sources utilized, ThoughtSphere provides a 360º data view and a "one-stop-shop" for cross-functional end-users. Our flexible platform allows organizations the option to use all our solutions in concert or to pick specific solution(s) to fit their needs.

KEY OPINION LEADER

Agenda at a Glance

CLINICAL OPERATIONS
STRATEGY MEETING EAST COAST USA 2023
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TIME (ET)	TRACK 1 RISK BASED QUALITY MANAGEMENT/CENTRAL & REMOTE MONITORING	TRACK 2 DIVERSITY, EQUITY, AND INCLUSION IN PATIENT ENGAGEMENT/ DECENTRALISED TRIALS	TRACK 3 EMERGING BIOPHARMA	TRACK 4 DIGITAL MEASUREMENTS/ CLINICAL DATA	TRACK 5 GLOBAL SITE SELECTION AND FEASIBILITY STUDY	New TRACK 6 INVESTMENT, PRIVATE EQUITY & VENTURE CAPITAL PARTNERSHIPS
ROOM ►	Wilson Suite A	Wilson Suite B	Oppenheimer Suite A	Oppenheimer Suite B	Cleveland Suite A	Cleveland Suite B
08:00 - 08:30	BREAKFAST & REGISTRATION					
08:30 - 09:00	**OPENING KEYNOTE PRESENTATION** **Navigating Through a World Crisis: Pandemic, War, Inflation, Supply Chain Disruptions and Many More Yet To Come?** PRESENTER: Mark Travers, Ph.D, MBA, *VP, GCTO-Regions and Regional Operations*, Merck & Co					
09:00 - 10:00	**Choosing The Most Effective Monitoring Strategy To Improve Participant and Site Compliance And Data Reliability** Michael Walega, *Head of Centralized Monitoring*, Bristol Myers Squibb	**Outlining the strategies for supporting more robust engagement in communities hence improving clinical trial diversity** Karen Correa, *Vice President, Head Global Clinical Operations*, Takeda	**Challenges And Opportunities In Early-Stage Biotech Funding- Understand the strategies startups need to stand out from the competition** Paul Blake, *Chief Executive Officer*, Papyrus Therapeutics Inc	**Promoting Diversity in Clinical Trials: organizational challenges and opportunities** Seun Makinde, *Associate Director Clinical Development*, Shionogi	**Identifying Your Sites by Examining Selection Criteria and Site Performance: What Selection Criteria May Inhibit Your Clinical Trial's Success?** Adriana Comprelli, *Therapeutic Area Head, Clinical Operations Strategy*, Bristol Myers Squibb Lorie Crowe, *Program Director, Global Trial Optimization*, Merck & Co	**How Wall Street's Roller Coaster Ride is Affecting the CRO/CDMO Ecosystem** Alex Zisson, *Managing Director*, H.I.G. Capital
10:00 - 10:10	REFRESHMENT BREAK					
10:10 - 10:30	NETWORKING / 1-1 MEETINGS					
10:30 - 10:50	NETWORKING / 1-1 MEETINGS					
10:50 - 11:10	NETWORKING / 1-1 MEETINGS					
11:10 - 12:10 SOLUTION	**Exploring Important Trends in RBQM: A Comprehensive Overview** Rachael Geedey, *Associate Director RBQM Technology*, IQVIA Technologies IQVIA	**Increasing diversity in clinical trials requires redesigning our approach** Sarrah Val, *MPH Vice President of Global Sales*, MD GROUP MD GROUP		**How advanced AI technologies such as Intelligent Document Review and generative AI, Chat GPT can help Pharma accelerate filings** Gary Shorter, *Head of Research and Development of AI into Products*, IQVIA Technologies IQVIA	**Overcoming Inertia to Accelerate Study Start-Up** Aruna Adhikari Thapa, *Senior Director of Product Strategy and Product Management*, IQVIA Technologies IQVIA	
12:10 - 13:10	NETWORKING LUNCH					
13:10 - 13:40	**AFTERNOON KEYNOTE PRESENTATION** **Bringing Innovation to Clinical Development: Technology's Impact on Clinical Trials** PRESENTER: Aruna Adhikari Thapa, *Senior Director of Product Strategy and Product Management*, IQVIA Technologies					
13:40 - 14:40	**A Developed Risk-Based Quality Management Approach To Mitigate Potential Risks and Liabilities** Amy Neubauer, *Director, GCDM Operational Excellence*, Alexion Pharmaceuticals	**How Can We Recognize And Eliminate Obstacles That Prevent Minority Involvement, Such As Historical Distrust, Accessibility Issues, And A Lack of Awareness** Jennifer Sheller, *AVP Clinical Operations*, Merck & Co Kelly Clark, *Head of US Partnerships and Global Site Development*, Merck & Co	**Clinical Development Perspective on: "What options are available to biopharma companies that face unique challenges due to their size and scale?** Varun Nagpal, *Medical Director*, Eisai US	**How can state of the art data analytics transform clinical trials? What obstacles exist?** Victoria Gamerman, *Global Head of Data Governance and Insights*, Boehringer Ingelheim	**Robust and Actionable Site Responses: Improve the accuracy of feasibility survey responses by Establishing a precise method to collect and analyze relevant and actionable data** Laura Vessey, *Senior Director, Head of Early Development and Clinical Pharmacology*, Janssen	**Why are CRO M&A deals on the rise? How expanding full service capabilities, through a strategic M&A process brings global efficiencies to sponsors** Matthew Rosenberg, *Advisor*, Guxi Capital
14:40 - 14:50	REFRESHMENT BREAK					
14:50 - 15:10	NETWORKING / 1-1 MEETINGS					
15:10 - 15:30	NETWORKING / 1-1 MEETINGS					
15:30 - 15:50	NETWORKING / 1-1 MEETINGS					
15:50 - 16:50	**Enhancing Trial Knowledge And Driving Better Outcomes By Using RBQM And Deep Learning** Katherine Taylor, *Head Risk Evaluation and Adaptive Integrated Monitoring*, Merck & Co	**Redesigning Clinical Trials: Patient Perspectives; Enhancing Inclusivity; Leveraging AI** Craig Granowitz, *Chief Medical Officer*, Lexicon Pharmaceuticals	**What future developments and commercial realities businesses with concentrated pipelines or single assets are facing?** Christopher J. Schaber, *Chairman, President & Chief Executive Officer*, Soligenx	**Realizing Value and Impact to Clinical Development Programs from Data Derived from Digital Technologies In Clinical Trials** Gayle Wittenberg, *VP, Neuroscience Data Science and Digital Health*, Janssen R&D Srinivasan Vairavan, *Director, Data Science and Digital Health*, Janssen R&D	**What are the biggest feasibility errors that even the most experienced sponsors occasionally make and how can we have a hands-on approach to avoid these mistakes?** Michele Sharr-Hyde, *Executive Director, Head Clinical Science*, Daiichi-Sankyo	**Why are the big Pharmas relying on partnerships and acquisitions to access new innovations and expand their pipelines?** Saikat Nandi, *Global Chief Business Officer*, Oryzon Genomics SA
16:50 - 17:50	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 ET **OPENING KEYNOTE PRESENTATION**

Navigating Through a World Crisis: Pandemic, War, Inflation, Supply Chain Disruptions and Many More Yet To Come?

Mark Travers, Ph.D, MBA
VP, GCTO-Regions and Regional Operations
Merck & Co

ABOUT THE SPEAKER

Mark joined GCTO in March 2015 as Executive Director, Head of Monitoring Excellence with a remit of building the ME Group, improving all aspects of site monitoring within Merck, re-valorizing the CRA position and making Merck partner of choice with our Investigator sites and suppliers. He implemented Risk Based Monitoring and SMART. In May 2015, Mark became interim Head for the NA Region with overall responsibility for delivering MRLs clinical trials in both Canada and the US. In June 2017, Mark was promoted to the position of VP, Head of GCTO Regions. In this position he is responsible for over 3,200 colleagues in 4 regions and 48 countries managing and monitoring all of MRL s clinical studies.

13:10 - 13:40 ET **AFTERNOON KEYNOTE PRESENTATION**

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

Aruna Adhikari Thapa
Senior Director of Product Strategy and Product Management
IQVIA Technologies

ABOUT THE SPEAKER

Aruna Adhikari is a dynamic and creative product evangelist with more than 15 years' experience in managing and building software. She leads cross-functional teams, shapes product strategy based on market research and customer feedback, justifies investment plans, and launches new products to the marketplace to solve complex business problems. At IQVIA Technologies, Aruna is responsible for cross-product strategy across the Digital Site Suite and Digital Planning Suite. Her team works closely with engineering, sales, product owners, and customers to create the roadmap, adoption strategy, and go-to-market plan. Aruna earned a Bachelor of Science degree in Network Modeling & Simulation and Statistics from Saint Cloud State University and a Master of Business Administration in Strategic Technology Management from Augsburg College in Minneapolis, MN.

Event Day

TRACK 1

Risk Based Quality Management/Central & Remote Monitoring

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

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

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

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

Choosing The Most Effective Monitoring Strategy To Improve Participant and Site Compliance And Data Reliability

- Have we achieved process maturity in developing our Monitoring Strategies?
- Where do you still see areas of opportunity?
- Are there case studies that may not have worked as well as initially anticipated that can be shared?
- What about Early Phase Trials?

Michael Walega
Head of Centralized Monitoring
Bristol Myers Squibb

ABOUT THE SPEAKER

Michael Walega is Head of Centralized Monitoring at BMS. In this capacity, he is responsible for providing protocol teams with actionable insights to achieve higher quality, ensure that monitoring processes are aligned to ICH E6 (R2), and champion risk-based approaches to monitoring clinical trials. He was previously at Covance, where he led the team responsible for development and growth of Covance's Risk-Based Monitoring (RBM) solutions, processes, and operational delivery. Additionally, he also led the Late Stage Biostatistics and Programming groups and the Process Excellence team. Mr. Walega is a qualified Biostatistician and a Six Sigma Master Black Belt.

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

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

Exploring Important Trends in RBQM: A Comprehensive Overview

- Discuss how RBQM technology can help facilitate effective hybrid trials through centralized monitoring
- Review the ways RBQM technology can help sponsors identify and address potential issues earlier in the trial lifecycle to meet regulatory oversight requirements
- Explore ways that RBQM technology can enable an adaptive monitoring approach tailored to meet the unique needs of each trial

Rachael Geedey
Associate Director RBQM Technology
IQVIA Technologies

ABOUT THE SPEAKER

Rachael brings expertise in technology training, adoption and implementation across variousclinical trial platforms. She is passionate about people, process and technology and has extensive operational experience supporting study teams in the use of RBQM technology. Rachael is currently an Associate Director supporting IQVIA's Risk Based Quality Management SaaS Solution.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 13:40 ET **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

13:40 - 14:40 ET **ROUNDTABLE 3**

A Developed Risk-Based Quality Management Approach To Mitigate Potential Risks and Liabilities

- How do study complexity, country requirements, site experience, and other key considerations factor into your risk assessments and TSDV strategy?
- Are you developing a library of study, program, indication, department, and site risks based on your experience that factor into future studies?
- How does your organization evolve as data challenges and trends are identified?
- How does communication flow throughout the organization as risks and issues are identified? What are your processes for identifying trends and notifying monitors, study team members, site auditors and other quality representatives, leadership?

Amy Neubauer
Director, GCDM Operational Excellence
Alexion Pharmaceuticals

ABOUT THE SPEAKER

Amy Neubauer serves as Director, Global Clinical Data Management Operational Excellence at Alexion, the Rare Disease Unit of AstraZeneca. Her current role focuses on the strategy, approach, and execution for quality GCDM processes, adherence to the processes, and inspection readiness. In this role she represents DM on cross-functional initiatives and provides training and compliance oversight to the DM team. Amy has served in various positions leading the strategy for R&D organizations to improve clinical trial data collection, review, compliance, visualization, sharing, access, storage, and privacy management. She has overseen relationships and strategic partnerships with vendors providing clinical trial systems, services, and software for clinical operations, and has experience building a best-in-class in-house clinical data sciences team to provide custom analytics and lead risk-based study execution activities.

14:40 - 15:50 PT **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:50 - 16:50 ET **ROUNDTABLE 4**

Enhancing Trial Knowledge And Driving Better Outcomes By Using RBQM And Deep Learning

- Grasp the evolution of RBM to RBQM- Devising a strategy to managing risk throughout clinical trial lifecycle
  - Identifying risks so they can be acted upon, and documented iteratively and staying inspection ready
  - What system capabilities are needed that can help in the decision-making process saving time and enhancing quality data?
- Change management and automating RBQM (tools/technologies)
- Understanding QbD and embedding a risk-based approach and its underlying principles
- How can deep learning be used to power central modeling across organizations. Who are key stakeholders (and what skills essential) for the adoption process
- Overcoming the complexity and numerosity of clinical trial data with the help of deep learning models
  - Understand its flexibility to work with different data formats, workflows, and processes. Empowering process simplification

Katherine Taylor
Head Risk Evaluation and Adaptive Integrated Monitoring
Merck & Co

ABOUT THE SPEAKER

Katherine (Kathy) Taylor is Head of Risk Evaluation & Adaptive Integrated Monitoring (REAIM). In her role she leads the implementation, delivery, and all aspects of Adaptive Integrated Monitoring (AIM), Global Clinical Trial Operation's (GCTO) continuous improvement initiative to further the organization's risk-based quality management (RBQM) through advanced analytics. As the head of REAIM, Kathy champions cross-functional engagement and alignment on the AIM strategy and execution of AIM activities in clinical trials. This includes development of central monitoring plans (CMPs) and clinical data specifications aligned with critical data, process, and risk assessments. She ensures execution of central analytics and monitoring activities, including Quality Tolerance Limit analysis, Key Risk Indicator analysis and Central Statistical Analytics to support identification of important study issues that require monitoring, management, and adaptation of study plans.

16:50 - 17:50 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 2

Diversity, Equity, and Inclusion in Patient Engagement/ Decentralised 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

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

Outlining the Strategies for supporting more robust engagement in communities hence improving clinical trial diversity

- Need for more concerted efforts across our industry to change how we think about and design clinical trials and how we engage and educate the public
  - — A lack of information about and awareness of clinical trials, and time and resource constraints associated with trial participation can aggravate the issue
- Create a network of clinical trial sites in underserved communities - including non-traditional locations such as community health centers and pharmacies
- Establish long-term relationships and invest in the community- building trusted relationships within diverse communities and populations
- Increasing the pool of diverse investigators and trial sites to ensure trials are culturally competent and mindful of unconscious/implicit bias
- Expanding commitment to decentralized trials which can reduce the burden on volunteers
- It is not enough just to increase diversity in clinical trials as they must represent the communities impacted by the disease targeted to address
  - —Representation of specific groups in clinical research conducted globally

Karen Correa
Vice President, Head Global Clinical Operations
Takeda

ABOUT THE SPEAKER
Dr. Karen Correa is the Vice President, Head of Global Clinical Operations at Takeda; where she is responsible for the advancement of the portfolio and execution of global clinical trials. Her 30 years of clinical research experience cover a large range of settings and venues including, benchwork, clinical site, CRO, as well as both large and small pharma organizations and has spanned across multiple therapeutic areas. She also leads the "Diversity in Clinical Trials" at Takeda and is known as an SME on this topic for the past 25 years. Dr. Correa serves as a board member of East Carolina University Alumni Board and CAMcare Health Corporation, a Federally Qualified Healthcare Center in South Jersey.

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

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

Increasing Diversity in Clinical Trials Requires Redesigning our Approach

- What IS diversity in the context of healthcare and clinical research?
- What differing approaches are required for these various groups, and where do our efforts fall short?
  - — Therapeutics areas/study indications
  - — Target populations
  - — Geographies
- What changes to clinical outsourcing strategies must be made?
- Review where gaps lie in education/execution among all involved parties and identify key factors necessary for improvement
  - — Clinical research industry – pharma, biotech, CROs, etc.
  - — Clinical outsourcing strategists
  - — Healthcare professionals
  - — Patients and local communities

Sarrah Val
MPH, Vice President of Global Sales
MD GROUP

ABOUT THE SPEAKER
Earned her Masters in Public Health from the University of Southern California after completing a dual degree in Integrative Physiology and Mathematics from the University of Colorado, Boulder. She is driven by her love for patient care, and invests her industry efforts into making clinical trials more accessible, equitable, and patient-focused. With prior experience in Medical Affairs and as a Director of Clinical Operations, she has led clinical trials from protocol design through FDA approval, driven physician education initiatives, and facilitated post-market and investigator grant research.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 13:40 ET **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

13:40 - 14:40 ET **ROUNDTABLE 3**

How Can We Recognize And Eliminate Obstacles That Prevent Minority Involvement, Such As Historical Distrust, Accessibility Issues, And A Lack of Awareness

- Discuss ways to engage with the community to raise awareness and earn trust in clinical trials
- Identify common barriers to diverse participant enrollment and ways to overcome them.
- Share strategies to increase diverse participation enrollment in clinical trials
- Discuss strategies to engage with research naïve clinical trial sites serving diverse communities

Jennifer Sheller
AVP Clinical Operations
Merck & Co

Kelly Clark
Head of US Partnerships and Global Site Development
Merck & Co

ABOUT THE SPEAKERS
Jennifer Sheller joined Merck in 2017 as an Associate Vice President, Clinical Operations. She is currently the Global Head of Monitoring Excellence, Site Partnerships / Engagement and Clinical Trial Diversity. Jennifer also serves as an R&D integration lead for multiple acquisitions. Her background includes a bachelor's degree in Molecular Biology, a Master's of Public Health in epidemiology and graduate coursework in QA/RA and Project Management. She began her career as a CRA and has worked in various roles with increasing responsibility including global program and therapeutic area leadership, functional leadership (trial operations, data management, clinical supplies) as well as serving on the front line for FDA sponsor inspections. Jennifer has over 24 years of experience in pharma, biotech and CRO companies in R&D and Medical Affairs.

14:40 - 15:50 PT **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:50 - 16:50 ET **ROUNDTABLE 4**

Redesigning Clinical Trials: Patient Perspectives; Enhancing Inclusivity; Leveraging AI

- Incorporating patient experience, preferences and needs into clinical trial design, implementation, and dissemination
- Mitigating post pandemic changes in clinical research
- Achieving patient diversity and inclusion
- Emerging opportunities for patient engagement in clinical research

Craig Granowitz
Chief Medical Officer
Lexicon Pharmaceuticals

ABOUT THE SPEAKERS
Dr. Granowitz joined Lexicon in August 2021, with deep and successful leadership experience in the pharmaceutical industry, having previously built global medical organizations at three separate companies. Prior to Lexicon, Dr. Granowitz served as chief medical officer at Amarin Corporation plc, where he was a key leader on the company's clinical development programs and held a number of other medical, safety and communications responsibilities. Prior to joining Amarin, Dr. Granowitz was senior vice president and head of global medical affairs, global human health at Merck & Co., Inc., where he developed and implemented an entirely new global medical affairs organization following Merck's merger with Schering-Plough Corporation. Prior to the merger, he held a variety of medical and commercial management positions with Schering-Plough, including group vice president, head of global medical affairs

16:50 - 17:50 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 3

Emerging Biopharma

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

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

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

- Enlisting help from one or more experienced external people who have experience in biotech and its financing
  - — Recruit industry experts that improve product positioning, and who can help with establishing strong connections within the industry
  - — Clearly define the overall development - Importance of value inflection points and establish project management in early stage companies
- How to best attract early investors? - discuss factors that make investors more cautious about investing in early stage companies than more advanced ones with easier exits -
- Need for a multi-faceted approach requiring careful planning and coordination
  - — Investor targeting for early-stage companies
  - — Attending medical and scientific meetings in-person or virtually? - Evaluating the trade-offs
  - — Publication and public relations strategies
- Strategies to explain or 'sell' a novel mechanism of drug action

Paul Blake
Chief Executive Officer
Papyrus Therapeutics Inc

ABOUT THE SPEAKER
Dr. Blake is the co-founder and Chief Executive Officer of Papyrus Therapeutics Inc., a company developing extracellular tumor suppressor therapies for multiple cancers. Until 2019 he was the Chief Medical Officer of Heron Therapeutics and before joining Heron, he had been the Chief Medical Officer of BDSI and before that he was the Chief Development Officer at Oxford BioMedica, a gene therapy company. His prior positions include Chief Medical Officer and Senior Vice President of Clinical Research and Development of Aeterna Zentaris, Inc., Senior Vice President and then Executive Vice President of Worldwide Medical and Regulatory Operations at Cephalon, Inc. From1992 to 1998, he held the position of Senior Vice President and Medical Director, Clinical Research and Development at SmithKline Beecham Pharmaceuticals (now GSK). Prior to that, he worked for ICI Pharmaceuticals (now Astra Zeneca) and G.D. Searle (now Pfizer).

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

12:10 - 13:10 ET NETWORKING LUNCH

13:10 - 13:40 ET AFTERNOON KEYNOTE PRESENTATION
See Page 6

13:40 - 14:40 ET ROUNDTABLE 3

Clinical Development Perspective on: "What options are available to biopharma companies that face unique challenges due to their size and scale?

- Exploring non-dilutive funding options and academic partnerships
- Risk-sharing approaches with CROs and other vendors
- Thoughtful incorporation of RWE/RWD and DCT elements to reduce trial costs and study timelines

Varun Nagpal
Medical Director
Eisai US

ABOUT THE SPEAKER
Speaker TBC

14:40 - 15:50 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

15:50 - 16:50 ET ROUNDTABLE 4

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

- With smaller and focused-pipeline organizations making up over 50% of clinical trials pre-COVID, what are their challenges to keep projects moving in highly concentrated pipelines
- How organizations with focused pipelines or single assets are overcoming development and commercial realities going forward
- Discuss the evolving resources that address biopharma needs during this time

Christopher J. Schaber
Chairman, President & Chief Executive Officer
Soligenx

ABOUT THE SPEAKER
Christopher J. Schaber, PhD has over 30 years experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been Soligenix's Chairman, President and Chief Executive Officer and a director since August 2006. He also serves on the board of directors for the Biotechnology Council of NJ (BioNJ), where he was a Past Chair. He has been a member of the corporate councils for both the National Organization for Rare Disorders (NORD) and the American Society for Blood and Marrow Transplantation (ASBMT). Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations.

16:50 - 17:50 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 4

Digital Measurements/ Clinical Data

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

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

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

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

Promoting Diversity in Clinical Trials: organizational challenges and opportunities

- Identifying and leveraging key tools and partners
- Developing a diversity plan and setting Enrollment goals
- Embedding and amplifying the voice of patients

Seun Makinde
Associate Director Clinical Development
Shionogi

ABOUT THE SPEAKER
Dr. Seun Makinde is an Associate Director, Clinical Development at Shionogi Inc, an organization focused on bringing benefits to patients with infectious diseases, CNS disorders and more. She has combined 16 years' experience in direct patient care, public health, clinical research, medical affairs, and clinical development. Her industry experience spans across projects in infectious disease, diabetes, oncology and rare diseases. Currently, she co-leads clinical trial diversity working group at Shionogi Inc., promoting health equity through inclusive research. Dr Makinde continues to leverage and apply her skills in opportunities that help to provide safe novel therapies to diverse patient populations, build capacity for patients and physicians through strategic relationships with experts and patient centric groups.

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

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

How advanced AI technologies such as Intelligent Document Review and generative AI, Chat GPT can help Pharma accelerate filings

- Why manual review is no longer sufficient or sustainable in today's environment
- How to stay ahead of the curve by positioning today's enterprise for tomorrow's AI solutions
- How to use AI to animate hidden content in various clinical workflows, generating faster filings with higher quality

Gary Shorter
Head of Research and Development of AI into Products
IQVIA Technologies

ABOUT THE SPEAKER
Gary pursues the use of emerging technology to provide new and more efficient capabilities to enhance clinical trial management. This includes development of new design software through to more recent advancements with AI/ML capabilities where his team has developed several micro-products and micro-services that can be plugged in and used by any SaaS solution.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 13:40 ET **AFTERNOON KEYNOTE PRESENTATION**
See Page 6

13:40 - 14:40 ET **ROUNDTABLE 3**

How can state of the art data analytics transform clinical trials? What obstacles exist?

- Reduce uncertainty, improve the probability of successes in clinical development
- Increase patient interest, adherence and engagement in the clinical trial process
- Provide evidence to accelerate submission and approval processes
- Streamline clinical trial protocols and processes
- Continual learning and feedback (applying AI/ML) from accumulating data to improve measures of safety and efficacy
- Leveraging data from both controlled clinical trial and real-world data to enable simulations and scenario-building
  - Precision predictions for market access
  - Improved representation of real world patient outcomes
  - Indicators of patient experience and healthcare access in the clinical setting
  - Evidence generation to continually improve quality, safety, efficacy + speed
  - Clinical endpoint and new indication discovery
- Obstacles in data analytics
  - Trust in technology
  - Trust in data
  - Patient privacy
  - Model and method risks

Victoria Gamerman
Global Head of Data Governance and Insights
Boehringer Ingelheim

ABOUT THE SPEAKER
Victoria Gamerman PhD is the Global Head of Data Governance and Insights at Boehringer Ingelheim, in the digital transformation center of excellence. She is accountable for shaping the pharmaceutical giant's data strategy and data governance for clinical development and operations. She was previously the company's Head of Health Informatics and Analytics, leading a team of experts in advanced statistical methodologies to generate evidence from external clinical data and real-world healthcare data to support drug development. Dr Gamerman is focused on improving healthcare by connecting the dots between patient-centricity, digital health and real-world evidence to evolve clinical research through innovation and digital transformation. She earned her master's and doctorate in biostatistics from the University of Pennsylvania's School of Medicine and has a master's in mathematics from Boston Universityennsylvania's School of Medicine, and a MA and BA in Mathematics from Boston University.

14:40 - 15:50 PT **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:50 - 16:50 ET **ROUNDTABLE 4**

Realizing Value and Impact to Clinical Development Programs from Data Derived from Digital Technologies In Clinical Trials

- How will digital health technologies add value to clinical development programs across development from Phase 1-4? What are the barriers today to realizing this value: technical, analytical, organizational?
- What is the current level of maturity in evidence generation across programs: how are we impacting internal decision making, is evidence regulatory grade, demonstrating value to payers, physicians and patients? Where do we need to advance as a field?
- How are companies addressing the challenges encountered with deployment of digital health technologies in clinical trials
  - Appropriate training and frequent training of clinical trial staff and patients on the use of these technologies
  - Availability of infrastructure support
  - Integration across multiple platforms deployed within a trial

Gayle Wittenberg
VP, Neuroscience Data Science and Digital Health
Janssen R&D

Srinivasan Vairavan
Director, Data Science and Digital Health
Janssen R&D

ABOUT THE SPEAKERS
Gayle is VP and Head of Neuroscience Data Science and Digital Health at Janssen R&D, focused on embedding data science and digital health to add value to the pipeline end-to-end across the Neuroscience portfolio. She and her team leverage molecular data, deep phenotyping, digital health and real-world data to enable decision-making and solution development for Neuroscience compounds from target identification to product launch.

Gayle has over 15 years of experience across the pharmaceutical and diagnostics industries, driving data science research into products. Gayle joined Janssen Neuroscience in 2011 as Director, Integrative Solutions and Informatics. She founded and was Head of Translational Research and Precision Medicine, Research IT in 2016. She created and led the Intelligent Automation team in Pharm IT in 2019, before moving back to the NS TA as Senior Director, Neuroscience Data Science. Prior to Janssen, Gayle was Head of Personalized Healthcare, at Siemens. She earned her doctorate linking Computational and Experimental Neuroscience at Princeton University in 2003.

16:50 - 17:50 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 5

Global Site Selection and Feasibility Study

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

08:00 - 08:30 ET BREAKFAST & REGISTRATION

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

09:00 - 10:00 ET ROUNDTABLE 1

Identifying Your Sites by Examining Selection Criteria and Site Performance: What Selection Criteria May Inhibit Your Clinical Trial's Success?

- Leveraging the power of different datasets to help determine of a site will be a good fit for trial, minimizing risks
- Indulging in open, bi-directional communication can help improve site management/engagement in the future
  - How can we employ study feasibility questionnaires? and go further than them to allow for negotiation opportunities
  - The importance of giving feedback to sites to foster relationships
- Using technology to create reproducible data
- What is the time frame between selecting and activating a site?
- How to optimize workflow between all of the trial stakeholders to ensure the research is measured with the same set of conditions

Adriana Comprelli
Therapeutic Area Head, Clinical Operations Strategy
Bristol Myers Squibb

Lorie Crowe
Program Director, Global Trial Optimization
Merck & Co

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

Overcoming Inertia to Accelerate Study Start-Up

- What are the root causes of trial start-up delays and the forces acting against acceleration?
- How are sites motivated to follow a sponsor's start-up methodology and move a new trial forward?
- What process and technology solutions for site activation have been successful and what hasn't been as effective as hoped?

Aruna Adhikari Thapa
Senior Director of Product Strategy and Product Management
IQVIA Technologies

ABOUT THE SPEAKER
See Page 6

12:10 - 13:10 ET NETWORKING LUNCH

13:10 - 13:40 ET AFTERNOON KEYNOTE PRESENTATION
See Page 6

13:40 - 14:40 ET ROUNDTABLE 3

Robust and Actionable Site Responses: Improve the accuracy of feasibility survey responses by Establishing a precise method to collect and analyze relevant and actionable data

- Right sites at the right time - determining which sites will deliver your study to your expectations
- Look at type of study – needs to be done on study by study basis
- SIPIQ or survey – do not exhaust sites asking redundant questions that each company has previously asked – verify with "boots on the ground"
  - A precise and accurate feasibility process should provide a realistic assessment of current site capabilities
  - Be backed up by historic performance data captured during previous clinical trials completed by the site organization
- How to keep updated and accurate site capabilities
- Country and site decisions to have a forum where all functions get to weigh in and whoever is funding is on board
  - Clinical therapeutic areas, Operations, local monitoring, feasibility, data sciences, and diversity plans
- Stop non-performing sites - How to make an informed decision on whether the site is truly capable of reliable performance against the trial protocol

Laura Vessey
Senior Director, Head of Early Development and Clinical Pharmacology
Janssen

ABOUT THE SPEAKER
Laura Vessey is a Senior Director and is Head of Early Development and Clinical Pharmacology Operations at Janssen where she is responsible for the operational delivery of the early development clinical portfolio. Over the past 30+ years, Laura has focused her career in Early Clinical Developmentfrom Phase 0 through Phase IIa in oncology, neuroscience, cardiometabolic, immunology, and infectious disease/ vaccine. She began her career at The Upjohn Company (now Pfizer) as a chemist in the lab and then early clinical development, she moved to Merck where she also focused on early clinical development in multiple therapeutic areas for twenty years and is now at Janssen. Laura holds a B.S degree from Hope College in Michigan and resides with her family in Princeton, NJ.

14:40 - 15:50 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

15:50 - 16:50 ET ROUNDTABLE 4

What are the biggest feasibility errors that even the most experienced sponsors occasionally make and how can we have a hands-on approach to avoid these mistakes?

- The importance of correct site selection and the repercussions of not doing so (e.g. experience in specific trial phases, phase 1 trial experience is unique)
  - Impact on patient recruitment, timelines & cost
  - Provision of resources, Principal Investor
- Collecting as much data as possible but why should you collate it yourself?
- Understanding the adherence to time - Why requests for further extensions can give a poor reflection of team managing feasibility?
- How best to ensure the highest level of quality while doing the above

Michele Sharr-Hyde
Executive Director, Head Clinical Science
Daiichi-Sankyo

ABOUT THE SPEAKER
Speaker TBC

16:50 - 17:50 ET DRINKS & CANAPES RECEPTION

new for 2023

Event Day

TRACK 6

Investment, Private Equity & Venture Capital Partnerships

Bringing together Managing Partners & C-level executives from investment firms supporting innovation in the clinical trial process, strategies from pharma companies and corporate arms with a vested interest in driving this innovation. It comes with the purpose of identifying and collaborating with potential drug development partners whilst addressing industry challenges in this area

09:00 - 10:00 ET ROUNDTABLE 1

How Wall Street's Roller Coaster Ride is Affecting the CRO/CDMO Ecosystem

- Has the slowdown in biotechnology financings impacted the outsourcing market?
- Which drugs, therapeutic areas, and types of clinical trials are most affected?
- What can CROs and CDMOs do differently?
- What are the prospects for a return of the IPO market in 2023?

Alex Zisson
Managing Director
H.I.G. Capital

ABOUT THE SPEAKER
Speaker TBC

13:40 - 14:40 ET ROUNDTABLE 3

Why are CRO M&A deals on the rise? How expanding full service capabilities, through a strategic M&A process brings global efficiencies to sponsors

- Deep diving on M&A - Understanding the reasons why companies opt for M&As instead of building the same offerings internally
  — Increased scale, geographic expansion, lower costs, and operational savings
- Gaining capabilities in niche areas - How smaller software start-ups can often solve very specific challenges in clinical trials execution
- Do mid and small biopharma sponsors get the same attention from a larger CRO as they get from a smaller one?
- Do the consolidated companies support the needs of all types of sponsors across all the stages of clinical drug development?
- How do companies with smaller budgets go for CRO services to excel in providing significant value
- There will always be attempts at consolidation, but success is less about consolidating and more about finding truly synergetic fits between two companies

Matthew Rosenberg
Advisor
Guxi Capital

ABOUT THE SPEAKER
Speaker TBC

15:50 - 16:50 ET ROUNDTABLE 4

Why are the big Pharmas relying on partnerships and acquisitions to access new innovations and expand their pipelines?

- With Innovation coming slowly in biopharma, have mergers, acquisitions, and other partnerships proven to be an existential necessity for successful companies to boost their new-product pipeline?
- The Importance of Active portfolio management is a key value driver - Companies that rotate their portfolios and pursue them programmatically typically outperform other growth strategies across industries
- When biopharma companies acquire at least partially de- risked revenue and increase their chances of R&D success - is it by buying innovation?
  — Smaller biopharma companies are expected to drive more than two-thirds of revenue growth over the next five-plus years, making partnerships and acquisitions even more attractive for larger firms
- As the industry contends with rising discovery costs and external innovation becomes a more significant component of revenues, dealmaking activity will only increase
- With the pandemic fueling the demand for data and analytics capabilities, several large biopharma players announced new partnership deals and achievements focused on data and analytics
- Why do we need a concerted effort by the C-suite and the strategy and business development teams, to maximize effective dealmaking?

Saikat Nandi
Global Chief Business Officer
Oryzon Genomics SA

ABOUT THE SPEAKER
Seasoned investment executive, business operator and entrepreneur with over 15 years of buy-side and operational experience in the healthcare, technology and finance industries. Has managed public and private investments totaling more than $1 billion and has helped build over 20 life science and technology companies. Served on the Board of Directors of Atomwise, Cullinan Oncology (NASDAQ: CGEM), ElevateBio, Fractyl Health, Roivant Sciences (NASDAQ: ROIV), SQZ (NYSE: SQZ). As Global Chief Business Officer at Oryzon, manages cross-functional teams across financing, M&A, business development and operations. As a Portfolio Manager at AIG Asset Management, oversaw AIG's healthcare & life sciences investments across venture capital, private equity, hedge fund and debt securities.

CLINICAL OPERATIONS

STRATEGY MEETING EAST COAST USA 2023

25th May 2023, Thursday Hyatt Regency Princeton

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OUR FACE-TO-FACE MEETING IN MAY 2023

Strategy Meeting San Diego, Boston & Princeton USA

MAY 2023

San Diego - US West Coast

08th - Drug Discovery Biology Strategy Meeting
09th - Medicinal Chemistry Strategy Meeting
10th - Oncology Strategy Meeting
11th - Clinical Operations Strategy Meeting

MAY 2023

Boston/Cambridge MA - US East Coast

17th - Regulatory Affairs Strategy Meeting
18th - Chemistry, Manufacturing and Controls Strategy Meeting

MAY 2023

Princeton New Jersey - US East Coast

23rd - Drug Discovery Biology Strategy Meeting
24th - Medicinal Chemistry Strategy Meeting
25th - Clinical Operations Strategy Meeting

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