BOOK NOW!

Proventa International's 5th Annual

CLINICAL OPERATIONS

STRATEGY MEETING WEST COAST USA 2023

11th May 2023, Thursday | Hard Rock Hotel San Diego

Jumpstart Clinical Operations on Patient Centricity, Innovation and Efficiency

NEW FOR 2023:
Investment, Private Equity & Venture Capital Partnerships

Featuring Industry Leaders and Decision Makers:

Bonne Adam
Chief Operating Officer
Tracon Pharmaceuticals

Moya Daniels
SVP, Regulatory Affairs, Clinical Operations and Quality
Indapta Therapeutics

Ana Krtolica
Senior Vice President, Preclinical Development
Oryn Therapeutics

Sagar Vaidya
Vice President of Clinical Development
Travere Therapeutics

Alejandra Maciel
Vice President, Clinical Affairs
Epigenomics

Ben Cadieux
Vice President of Medical Affairs
MEI Pharma

Angela Pietrofeso
Vice President, Clinical Development Operations
Oncternal Therapeutics

Christopher Mizer
President and CEO
Vivaris Capital

24 ROUNDTABLE DISCUSSIONS

6 TRACKS

3 KEYNOTE PRESENTATIONS

1 LOCATION

What Makes Our Strategy Meetings So Unique?

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

CLINICAL OPERATIONS

STRATEGY MEETING WEST 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

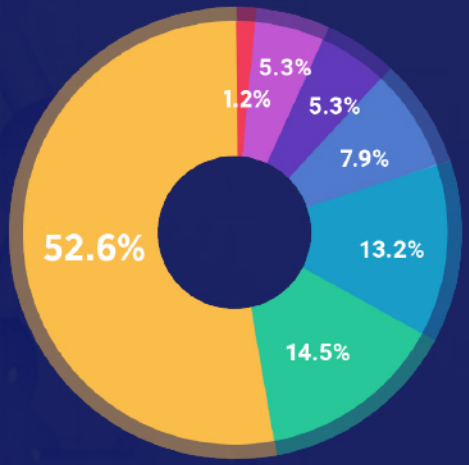
The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

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 WEST COAST USA 2023
11th May 2023, Thursday | Hard Rock Hotel San Diego

Wendy Morahan
Sr. Director, Clinical Data Analytics
IQVIA

Adrian Kizewski
Associate Director, RBQM Technology
IQVIA

Jayasri Vaidyanath
Associate Director, Product Management
IQVIA Technologies

Patrick Harrington, Ph.D.
Vice President of Elligo Solutions
Elligo Health Research®

Faith Holmes, M.D.
Medical Director, Senior Vice President of Medical Affairs
Elligo Health Research®

Chad Moore
Co-Founder & Corporate Development
Elligo Health Research®

Ana Krtolica
Senior Vice President, Preclinical Development
Oryn Therapeutics

Angela Pietrofeso
Vice President, Clinical Development Operations
Oncternal Therapeutics

Alejandra Maciel
Vice President, Clinical Affairs
Epigenomics

Arun Sivanandam
Associate Director, Global Clinical Development and Operations
Santen Pharmaceuticals

Ben Cadieux
Vice President of Medical Affairs
MEI Pharma

Bonne Adams
Chief Operating Officer
Tracon Pharmaceuticals

Christopher Mizer
President and CEO
Vivaris Capital

Daniel Gebremedhin
Partner
Flare Capital Partners

George Ng
Board Director, President & COO
Calidi Biotherapeutics

Jack Florio
Managing Director
Weild & Co

Matt Sharma
Senior Clinical Trials Manager
Arcturus Therapeutics

Melody Anderson
Executive Director, Clinical Operations
Avelas Biosciences

Moya Daniels
SVP, Regulatory Affairs, Clinical Operations and Quality
Indapta Therapeutics

Sandra Wiley
Director, Translational Sciences
MEI Pharma

Sagar Vaidya
Vice President of Clinical Development
Travere Therapeutics

How Has Our
STRATEGY MEETINGS
Benefit The Life Science Industry

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

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

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.

ASSOCIATE SPONSOR

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

CO-HOST SPONSORS

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

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

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

Current Health is a technology platform used to monitor, manage and communicate in real time with study participants while they are at home. Today, we work with Top-10 PharmaCos in phase I-IV studies for patient safety and convenience, adverse event detection, exploratory endpoint analysis and digital biomarker development. Our FDA cleared platform has continuous monitoring capability, (e.g. for CRS detection), and integrates with dozens of biometric monitoring devices that can be selected depending on the condition and acuity level. Additional services include a 24/7 clinical monitoring service and international end-to-end logistics. Current Health is a Best Buy Health company.

Global Sponsorship Opportunities

Proventa's end-to-end consulting division gather real-time business intelligence on the industry's **needs, challenges, budgets** and **investment areas**. We combine this information with your specific needs to enhance your business development strategy. With the wealth of intel we provide, Proventa guarantees tangible results for your business within twelve months of the event.

For Sponsorship Opportunites please contact:
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Agenda at a Glance

CLINICAL OPERATIONS
STRATEGY MEETING WEST COAST USA 2023
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TIME (PT)	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 ►	Encore 1	Encore 2	Encore 3	Imagine 1	Imagine 2	Watchtower
08:00 - 08:30	BREAKFAST & REGISTRATION					
08:30 - 09:00	OPENING KEYNOTE PRESENTATION Building Biotech Startup Development Strategy in the Current Investment Environment: Report From the Trenches PRESENTER: Ana Krtolica, *Senior Vice President, Preclinical Development*, Oryn Therapeutics					
09:00 - 10:00	Choosing the Best Monitoring Method to Improve Data Consistency and Quality—Centralized Monitoring vs. Remote Monitoring Melody Anderson, *Executive Director, Clinical Operations*, Avelas Biosciences	Company Case Studies and Best Practices In DEI Initiatives Implementation George Ng, *Board Director, President & COO*, Calidi Biotherapeutics		Incorporation of Novel Electronic Health Monitoring Tools in Clinical Trials Sagar Vaidya, *Vice President of Clinical Development*, Travere Therapeutics	Key reasons sites do not meet enrollment and retention criteria? Matt Sharma, *Senior Clinical Trials Manager*, Arcturus Therapeutics	Optimizing investments required for successful Clinical Trials? Jack Florio, *Managing Director*, Weild & Co
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 Adrian Kizewski, *Associate Director, RBQM Technology*, IQVIA IQVIA	FDA Diversity Requirements Patrick Harrington, Ph.D., *Vice President of Elligo Solutions*, Elligo Health Research® ELLIGO HEALTH RESEARCH	Early Detection & Diagnostics and How These Impact Research Faith Holmes, M.D., *Medical Director, Senior Vice President of Medical Affairs*, Elligo Health Research® ELLIGO HEALTH RESEARCH	How Data Analytics Can Help You Oversee Your Portfolio Of Active Trials, Insourced Or Outsourced, When Data Are Everywhere, And Insights Are Inconsistent Key Takeaways: Wendy Morahan, *Sr. Director, Clinical Data Analytics*, IQVIA IQVIA	Not Another Portal! Designing One Home for Sites Jayasri Vaidyanath, *Associate Director, Product Management*, IQVIA Technologies IQVIA	Private Equity & Venture Capital Partnerships in Clinical Research Chad Moore, *Co-Founder & Corporate Development*, Elligo Health Research® ELLIGO HEALTH RESEARCH
12:10 - 12:40	KEYNOTE PRESENTATION Bringing Innovation to Clinical Development: Technology's Impact on Clinical Trials PRESENTER: Wendy Morahan, *Sr. Director, Clinical Data Analytics*, IQVIA					
12:40 - 13:40	NETWORKING LUNCH					
13:40 - 14:10	KEYNOTE PRESENTATION The Growth of Modeling and Simulation Strategies in Pharmaceutical Research, Development and Clinical Programs PRESENTER: Mike Reed, *PhD Chief Scientist, PhysioPD® Rosa & Co*					
14:10 - 15:10	Risk-Based Monitoring, Final FDA Guidance Alejandra Maciel, *Vice President, Clinical Affairs*, Epigenomics	How Can We Recognize And Eliminate Obstacles That Prevent Minority Involvement, Such As Historical Distrust, Accessibility Issues, And A Lack of Awareness Sandra Wiley, *Director, Translational Sciences*, MEI Pharma	How can we develop more life-saving medications more efficiently? Bonne Adams, *Chief Operating Officer*, Tracon Pharmaceuticals	Utilize And Support A More Digital Environment To Stay Relevant As The Industry Changes Arun Sivanandam, *Associate Director, Global Clinical Development and Operations*, Santen Pharmaceuticals	Evolving trends and best practices in clinical trial awareness and recruitment Ben Cadieux, *Vice President of Medical Affairs*, MEI Pharma	Accessing Development Capital in the Current Environment Christopher Mizer, *President and CEO*, Vivaris Capital
15:10 - 15:20	REFRESHMENT BREAK					
15:20 - 15:40	NETWORKING / 1-1 MEETINGS					
15:40 - 16:00	NETWORKING / 1-1 MEETINGS					
16:00 - 16:20	NETWORKING / 1-1 MEETINGS					
16:20 - 17:20		Diversity, Equity, Inclusion & Patient Engagement Moya Daniels, *SVP, Regulatory Affairs, Clinical Operations and Quality*, Indapta Therapeutics	Strategic considerations for emerging Biopharma Ana Krtolica, *SVP, Preclinical Development*, Oryn Therapeutics	The Digitalized Clinical Trial—Reengineering Clinical Research Melody Anderson, *Executive Director, Clinical Operations*, Avelas Biosciences	What Are The Current Challenges With Global Site Selection/ Feasibility? Angela Pietrofeso, *Vice President, Clinical Development Operations*, Oncternal Therapeutics	Investing in Pharma / Biotech Clin Ops focused Health tech companies Daniel Gebremedhin, *Partner*, Flare Capital Partners
17:20 - 18:20	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 PT **OPENING KEYNOTE PRESENTATION**

Building Biotech Startup Development Strategy in the Current Investment Environment: Report From the Trenches

Ana Krtolica
Senior Vice President, Preclinical Development
Oryn Therapeutics

ABOUT THE SPEAKER

Ana joined Omniox in 2012 and is leading company's R&D effort. Prior to joining Omniox, Ana Krtolica co-founded, and served as CEO and CSO of StemLifeLine, Inc, an early-stage drug discovery company. Dr. Krtolica obtained her Ph.D. from University of Rochester, and did herpost-doctoral research with Dr. Judith Campisi at the Lawrence Berkeley National Laboratory. She worked as a career scientist at LBNL with joint appointment at the UCSF. Dr. Krtolica has been Principal Investigator on a number of research grants, has authored multiple patent applications and published more than 30 research papers in peer-reviewed journals, a number of reviews and book chapters.

12:10 - 12:40 PT **KEYNOTE PRESENTATION**

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

Wendy Morahan
Sr. Director, Clinical Data Analytics
IQVIA

ABOUT THE SPEAKER

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

13:40 - 14:10 PT **KEYNOTE PRESENTATION**

The Growth of Modeling and Simulation Strategies in Pharmaceutical Research, Development and Clinical Programs

- **Current state of modeling and simulation strategies in pharmaceutical research, development and clinical programs**
- **How regulators such as the FDA now view modeling and simulation approaches**
- **Case Study demonstrating how a US-based pharmaceutical company used modeling and simulation data to support an FDA approval decision for their drug**

Mike Reed
SPhD Chief Scientist, PhysioPD®
Rosa & Co

ABOUT THE SPEAKER

Dr. Reed brings 15 years of experience managing large-scale strategic collaborations with client biopharmaceutical and consumer product organizations.

At Rosa (and previously at Entelos, Inc.), his areas of expertise include metabolic diseases, oncology, central nervous system diseases, and inflammation/immunology. His efforts focus on trial design, target evaluation, competitive differentiation, and novel biomarkers, and have led to several patents and publications. Dr. Reed's work has been presented at dozens of scientific conferences worldwide.

Prior to his position at Entelos, Dr. Reed held positions in preclinical pharmacology and drug development at Shaman Pharmaceuticals Inc. and Tularik Inc. (acquired by Amgen Inc.). His contributions include the development of novel animal models for type 2 diabetes.

Dr. Reed completed his BS in Biology and MA in Exercise Physiology at The University of Texas at Austin, and a PhD in Exercise Physiology at The Ohio State University. He completed his postdoctoral fellowship at Stanford University, which focused on the mechanistic evaluation of insulin resistance in animal models.

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 PT BREAKFAST & REGISTRATION

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

09:00 - 10:00 PT ROUNDTABLE 1

Choosing the Best Monitoring Method to Improve Data Consistency and Quality—Centralized Monitoring vs. Remote Monitoring

- Is on-site monitoring dead?
- Remote vs. centralized monitoring—is it really monitoring?
- Is remote monitoring a false economy?
- How does remote monitoring impact the patient experience, compliance, etc.?

Melody Anderson
Executive Director, Clinical Operations
Avelas Biosciences

ABOUT THE SPEAKER

Melody's background in Physiology & Pharmacology from University of Illinois and The Medical Centerled to her first industry role at Abbott in 1982. Her clinical experience includes medical devices, drugs,biologics, gene therapy, combination products, and drug delivery systems. She has expertise in GCP auditing and preparing sponsors and sites for FDA inspections. In 2001 she was hired to move to AUSTRALIA to open a CRO subsidiary and serve as Managing Director. Upon returning to the USA in 2009, she had a consulting business before being lured back into industry in 2015. She is currently angelaworking on a breakthrough combination imaging drug & device with the objective to achieve clean margins during breast cancer surgery.

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

11:10 - 12:10 PT 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

Adrian Kizewski
Associate Director, RBQM Technology
IQVIA

ABOUT THE SPEAKER

Adrian brings expertise spanning R&D and clinical life sciences, business analysis, process design & improvement, and product implementation. He is currently a lead for IQVIA's Digital Trial Management Suite focused on the Risk Based Quality Management SaaS solution. Adrian holds an MBA from the McDonough School of Business at Georgetown University in addition to an MSc in Pharmacology from The Johns Hopkins University School of Medicine and a BSc in Biochemistry from Temple University

12:10 - 12:40 PT KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 PT NETWORKING LUNCH

13:40 - 14:10 PT KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 PT ROUNDTABLE 3

Risk-Based Monitoring, Final FDA Guidance

- Challenges and opportunities

Alejandra Maciel
Vice President, Clinical Affairs
Epigenomics

ABOUT THE SPEAKERS

Alejanda has 20 years of experience in Clinical Research, providing strategic and operational leadership for clinical trials for regulated medical device and diagnostic products. Proven ability to develop clinical teams, cultivate stakeholder confidence and execute high pace, high volume, multi-site clinical studies. Hands-on experience in all aspects of clinical trials, from protocol development budget planning to CRO selection and management, site qualification and study execution and clinical study reports. Subject-Matter Expert on ICH-GCP guidelines, CFRs and regulatory requirements for clinical development. Broad background spanning Academic Research, Sponsor and CRO experience. Ample experience at fast-paced start-up companies. Superb ability to adapt and execute.

15:10 - 16:20 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

17:20 - 18:20 PT DRINKS & CANAPES RECEPTION

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 PT BREAKFAST & REGISTRATION

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

09:00 - 10:00 PT ROUNDTABLE 1

Company Case Studies and Best Practices In DEI Initiatives Implementation

- Approaches to ensure DEI requirements compliance for grant-funded clinical studies
- Incorporating DEI implementation in clinical study design and company practices
- Leveraging community and non-profit partnerships for DEI implementation

George Ng
Board Director, President & COO
Calidi Biotherapeutics

ABOUT THE SPEAKER
George Ng, a seasoned life sciences industry executive, is currently Board Director, President & Chief Operating Officer at Calidi Biotherapeutics, Inc. Mr. Ng is also a partner at PENG Life Science Ventures (PENG LSV). He has founded and/or led multiple companies, includingScilex Pharmaceuticals, Inc. (now, Scilex Holding Co (NASDAQ:SCLX)), where he was Co-Founder and President, and led the company through development, clinical trials, NDA submission, FDA approval, $140 million financing, commercial launch of the company's first FDA-approved drug product, and ultimate company sale. Mr. Ng has also held various other senior management positions, including Board Director, Managing Director, Chief Administrative Officer, Chief Business Officer, Corporate Secretary, Chief Legal Officer, General Counsel, Chief Compliance Officer and Chief Intellectual Property Counsel, with publicly-traded and private, global biotechnology and pharmaceutical companies. Mr. Ng was also a past President-Elect of the Pan Asian Lawyers of San Diego (PALSD) and was previously appointed to the Leadership Development Committee of the Wake County Bar Association in North Carolina. He also earned a Juris Doctor (J.D.) degree in law from the University of Notre Dame School of Law and a Bachelor of Arts and Sciences (B.A.S.) dual degree in Biochemistry & Economics from the University of California, Davis.

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

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

FDA Diversity Requirements

- The new demographics the FDA included in their diversity action plan requirement, per FDORA, and how to reach them
- The direct and indirect impacts the diversity action plan requirements will have on sponsors
- Steps for creating and implementing a diversity action plan, including how to identify which groups to target

Patrick Harrington, Ph.D.
Vice President of Elligo Solutions
Elligo Health Research®

ABOUT THE SPEAKER
Dr. Patrick Harrington has over 25 years of scientific research and clinical experience in a broad variety of neuropsychiatric disorders. He has presented his research at professional meetings both nationally and internationally, and co-authored several publications in peer reviewed journals. Patrick has worked on numerous psychiatry trials with sponsors all around the globe. He was the leader for a Clinical Surveillance and Training team where he helped develop pre-enrollment review and a statistical analysis program to assess ongoing patient ratings. He has also created several scales used in clinical trials, collaborated with PIs on randomization decisions within the trial, and helped identify diagnostic and rating problems. In his role with Elligo, Patrick is helping to revolutionize the way clinical trials are designed and run. He holds a doctorate in clinical psychology, with a focus in clinical neuropsychology, from University of Texas at Austin. He won the American Neuropsychiatric Association Young Investigator Award in 1997. For more information, visit ElligoHealthResearch.com.

12:10 - 12:40 PT KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 PT NETWORKING LUNCH

13:40 - 14:10 PT KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 PT ROUNDTABLE 3

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

- Addressing challenges and how to mitigate the challenges to enhance participation of minorities in clinical trials

Sandra Wiley
Director, Translational Sciences
MEI Pharma

ABOUT THE SPEAKER
Sandy Wiley, PhD is the Director of Translational Sciences at MEI Pharma, Inc, a clinical stage oncology drug development company. Dr Wiley has over 25 years of experience in translational science, drug discovery, and drug development with an emphasis on cancer, autoimmune diseases, neurodegeneration, metabolic diseases, and rare diseases. Her career has included both academic and industry environments. She is part of Clinical R&D at MEI and has close cross-functional engagements with Medical Affairs, Clinical Development, and Clinical Operations

15:10 - 16:20 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 PT ROUNDTABLE 4

Diversity, Equity, Inclusion & Patient Engagement

- Sociodemographic characteristics, i.e. race and ethnicity, socioeconomic status (SES), geographic location, sexual orientation, gender identity
- Lived experiences in the context of an individual and structural social determinant of health
- Essential to have a wide range of people from different communities participate in clinical trials to reduce biases, promote social justice and health equity, and produce more innovative science

Moya Daniels
SVP, Regulatory Affairs, Clinical Operations and Quality
Indapta Therapeutics

ABOUT THE SPEAKER
Ms. Daniels has 30 years industry experience in the fields of Regulatory Affairs, Quality and Clinical Operations. She has led development programs in the regenerative medicine field such as cells, tissues and gene therapy. Ms. Daniels has previously served as Senior Vice President of Regulatory and Quality at Aruvant Therapeutics. Prior held the position of Senior Vice President of Global Quality and GxP Compliance at Orchard Therapeutics, Officer & Head of Regulatory, Quality and Clinical Operations at Histogen, and Vice President of Regulatory Affairs at Fate Therapeutics. Currently, she is SVP of Regulatory Affairs, Quality and Clinical Operations at Indapta Therapeutics. Moya resides here in San Diego with her family, three dogs and a cat.

17:20 - 18:20 PT 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 PT BREAKFAST & REGISTRATION

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

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

11:10 - 12:10 PT SOLUTION FOCUS ROUNDTABLE 1

Early Detection & Diagnostics and How These Impact Research

- The current state of healthcare ("sick care"), and why early detection and diagnostic trials are essential
- How to overcome common barriers to early detection research participation
- Tips for designing trials to meet patient needs

Faith Holmes, M.D.
Medical Director,
Senior Vice President of Medical Affairs
Elligo Health Research®

ELLIGO HEALTH RESEARCH®

ABOUT THE SPEAKER
Faith Holmes, M.D., brings more than 30 years of experience in direct patient care, and 11 years of medical practice management to her role as Elligo's Senior Vice President of Medical Affairs. Her unique perspective plays an important part in building the company's network of Research Ready physician practices and preparing them to conduct research. Holmes' rich perspective — including experience in family medicine, hospice, and palliative medicine that spans solo practice and single specialty and multispecialty group practices — allows her to build rapport with study managers, site staff, and investigators, and provide medical and scientific knowledge to support future growth.

12:10 - 12:40 PT KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 PT NETWORKING LUNCH

13:40 - 14:10 PT KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 PT ROUNDTABLE 2

How can we develop more life-saving medications more efficiently?

- When should operations be outsourced?
- At what stage should a company consider in house operations?

Bonne Adams
Chief Operating Officer
Tracon Pharmaceuticals

ABOUT THE SPEAKER
Ms. Adams joined us as our Vice President of Clinical Operations in August 2006, was promoted to Senior Vice President of Clinical Operations in July 2014, and was promoted to Executive Vice President of Clinical Operations in January 2019. Prior to joining us, Ms. Adams was a Manager of Clinical Operations at Pfizer, Inc., a pharmaceutical corporation, from 2004 to 2006 and at Biogen Idec, Inc., a biotechnology company, from 2002 to 2004. Ms. Adams managed clinical trials at Pfizer that contributed to the 2006 approval of Sutent® in renal cell carcinoma and gastrointestinal stromal tumors, and she managed clinical trials at Biogen Idec that fulfilled post-approval commitments for Zevalin® and Rituxan®. Ms. Adams has managed both early and late-stage oncology studies of small molecules as well as biologics in the areas of lymphoma, lung, colorectal, ovarian, kidney, sarcoma and breast cancers. From 2000 to 2002, she managed non-oncology programs at Quintiles Inc., a service provider for biopharmaceutical and health sciences companies, including studies in the areas of allergy and pulmonary disease. Ms. Adams received a B.A. in Kinesiology and Biology from the University of Colorado and an M.B.A. in Technology Management from The University of Phoenix.

15:10 - 16:20 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 PT ROUNDTABLE 3

Strategic considerations for emerging Biopharma

- How to build competitive programs with limited resources
- Competitive advantages and limitations of a small and nimble operations
- How to choose the indications/ clinical strategy in the context of a small company

Ana Krtolica
Senior Vice President, Preclinical Development
Oryn Therapeutics

ABOUT THE SPEAKER
Ana completed PhD at University of Rochester. As a postdoc and then, scientist at LBNL and UCSF she explored the influence of microenvironment on carcinogenesis and stem cell phenotype. Ana co-founded and led StemLifeLine, a startup focusing on cell therapy and development of the cancer drug discovery platform. After joining Omniox, Ana developed programs in oncology, ischemic stroke and critical care bringing its technology from early discovery to clinic. She currently leads translational and new indication efforts at Retrotope. Ana received >$5M in grants and serves on NIH Review Boards. She authored multiple patent applications and published >30 research papers.

17:20 - 18:20 PT 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 PT **BREAKFAST & REGISTRATION**

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

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

Incorporation of Novel Electronic Health Monitoring Tools in Clinical Trials

- What are the new tools in electronic health monitoring that can be used in clinical trials?
- How can one ensure these new tools will be operationally-feasible and meet compliance requirements?
- What are the best methods for gaining regulatory endorsement of clinical data from these tools for trial endpoints?

Sagar Vaidya
Vice President of Clinical Development
Travere Therapeutics

ABOUT THE SPEAKER
Dr. Vaidya is a rare disease drug developer and the Vice President of Clinical Development at Travere Therapeutics since 2019. Dr. Vaidya is responsible for overseeing clinical development of the company's metabolic and neurology pipeline. Previously, Dr. Vaidya served in roles in clinical development at Sangamo Therapeutics and BioMarin Pharmaceuticals, and he remains committed to developing treatments for severe and life-threatening rare diseases. Dr. Vaidya completed his Infectious Diseases fellowship at Massachusetts General Hospital, Internal Medicine/Pediatrics residency at Icahn School of Medicine at Mount Sinai Hospital, and received his M.D./Ph.D. degrees from David Geffen School of Medicine at UCLA.

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

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

How Data Analytics Can Help You Oversee Your Portfolio Of Active Trials, Insourced Or Outsourced, When Data Are Everywhere, And Insights Are Inconsistent Key Takeaways:

- Why trying to manually oversee a portfolio of trials in today's environment is inefficient and ineffective
- How modern technologies can help aggregate, normalize and store relevant Operational and Clinical data for all your trials
- How visualizing key insights for your portfolio of trials can help you make better decision, faster

Wendy Morahan
Sr. Director, Clinical Data Analytics
IQVIA

ABOUT THE SPEAKER
See Page 6

12:10 - 12:40 PT **KEYNOTE PRESENTATION**
See Page 6

12:40 - 13:40 PT **NETWORKING LUNCH**

13:40 - 14:10 PT **KEYNOTE PRESENTATION**
See Page 6

14:10 - 15:10 PT **ROUNDTABLE 3**

Utilize And Support A More Digital Environment To Stay Relevant As The Industry Changes

- Decentralized Clinical Trials – post-pandemic fad or new reality?
- Artificial Intelligence/Machine Learning Approaches to Data Review and Processing
- Digital Twin/simulated Control Arms

Arun Sivanandam
Associate Director, Global Clinical Development and Operations
Santen Pharmaceuticals

ABOUT THE SPEAKER
Arun is a Clinical Operations leader with over 10 years of experience in Site and Sponsor Global Clinical Development. Having transitioned away from a clinical career, Arun worked on Genomics, Cardiology and GI-Immuno-Oncology Investigator-Initiated through Phase 4 cooperative trials at leading Tertiary Care facilities before transitioning to Amgen as a Clinical Development Consultant. He now works as an Associate Director, Global Clinical Development and Operations leading global Phase 1 – 4 studies on innovative Ophthalmology trials at Santen, Bay Area California. Arun has a Bachelors Degree from UC-Riverside, California and a Masters Degree from Wayne State University in Michigan.

15:10 - 16:20 PT **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

16:20 - 17:20 PT **ROUNDTABLE 4**

The Digitalized Clinical Trial—Reengineering Clinical Research

- Clinical research teams of the future
- Why standardization of clinical data is critical
- Desirable characteristics of algorithms
- Automated data cleaning for analysis

Melody Anderson
Executive Director, Clinical Operations
Avelas Biosciences

ABOUT THE SPEAKER
Melody's background in Physiology & Pharmacology from University of Illinois and The Medical Centerled to her first industry role at Abbott in 1982. Her clinical experience includes medical devices, drugs,biologics, gene therapy, combination products, and drug delivery systems. She has expertise in GCP auditing and preparing sponsors and sites for FDA inspections. In 2001 she was hired to move to AUSTRALIA to open a CRO subsidiary and serve as Managing Director. Upon returning to the USA in 2009, she had a consulting business before being lured back into industry in 2015. She is currently working on a breakthrough combination imaging drug & device with the objective to achieve clean margins during breast cancer surgery.

17:20 - 18:20 PT **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 PT BREAKFAST & REGISTRATION

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

09:00 - 10:00 PT ROUNDTABLE 1

Key reasons sites do not meet enrollment and retention criteria?

- How to collect data efficiently
- Focusing on those important data points discussed in point one
- How best to analyze this data efficiently

Matt Sharma
Senior Clinical Trials Manager
Arcturus Therapeutics

ABOUT THE SPEAKERS
Matt is a Senior Clinical Trial Manager at Arcturus Therapeutics, a self-amplifying mRNA company headquartered in San Diego. Prior to joining Arcturus, he was at UCSF, PaxVax and Emergent BioSolutions. Matt has experience in biotech, global pharmaceutical, and academic clinical research. Most of his career has been focused on vaccine development including COVID, Flu, Chikungunya and Cholera.

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

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

Not Another Portal! Designing One Home for Sites

Join the discussion as we explore these questions together:

- How can we capture the benefits of clinical technologies without further complicating sites' operations?
- What could bring sponsors, CROs, and service providers together to address their valid concerns of too many systems and too many passwords?
- Why have previous efforts failed to deliver promised benefits and what needs to change to truly simplify life for sites?

Jayasri Vaidyanath
Associate Director, Product Management
IQVIA Technologies

ABOUT THE SPEAKER
See Page 6

12:10 - 12:40 PT KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 PT NETWORKING LUNCH

13:40 - 14:10 PT KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 PT ROUNDTABLE 3

Evolving trends and best practices in clinical trial awareness and recruitment

- Sponsor partnership with CROs and Advocacy Groups – when and how?
- Optimizing internal support – e.g., role(s) of Medical Affairs and Corporate Communications
- Value and challenges with clinical trial site interactions in the "new normal" post-COVID

Ben Cadieux
Vice President of Medical Affairs
MEI Pharma

ABOUT THE SPEAKER
Speaker TBC

15:10 - 16:20 PT REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 PT ROUNDTABLE 4

What Are The Current Challenges With Global Site Selection/ Feasibility?

- Are these challenges specific to small biotech or across the board?
- Share lessons learned – what worked well, what didn't work
- What tools / sources are you using?
- What is the experience with the use of AI tools?

Angela Pietrofeso
Vice President, Clinical Development Operations
Oncternal Therapeutics

ABOUT THE SPEAKER
Angela has over 20 years of extensive global expertise in biopharmaceutical and medical device industries. She has a broad range of therapeutic experience in oncology, ulcerative colitis, cardiovascular medical devices, acute pain, and infectious diseases. Before joining Oncternal, Angela held positions of increasing responsibility Pfizer, Valeant, Metabasis, Cadence Pharmaceuticals, Lithera, W.L Gore & Associates, and Gossamer Bio. Her career highlights include contributions to the successful NDA for Sutent® at Pfizer; the NDA submission for Ofirmev® at Cadence Pharmaceuticals; and the PMA approval of GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) at W.L Gore & Associates. Prior to joining industry Angela worked as a Research Nurse Manager at the Royal Free Hospital (London UK) and as a Registered Nurse in South Africa and UK. Angela holds a Bachelor of Social Science (Nursing) from University of Natal (Durban South Africa).

17:20 - 18:20 PT 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 PT ROUNDTABLE 1

Optimizing investments required for successful Clinical Trials?

- How to insure your are getting the best value for the least investment when planning and conducting clinical trials?
- Demonstrating this value to potential investors?

Jack Florio
Managing Director
Weild & Co

ABOUT THE SPEAKER
Jack Florio is a life sciences executive with 50 years of experience across the full range of pharma / biotech companies spanning early-stage company formation through capital formation, operations, and exits. This gives him a unique view of strategy and tactics across the life cycle of many companies. Jack is a Managing Director with Weild & Co. where he works on advisory, capital formation and M&A deals across the sector. He is also an angel investor with NuFund Venture Group and a Partner with Deallus, a global life sciences consultancy. Jack has held operational roles in both small and large companies across the life science space in the US and Europe including a 30 year career with Eli Lilly and Company. Jack has a BS in Pharmaceutical Sciences from Columbia University and an MBA from NYU/Stern School of Business.

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

Private Equity & Venture Capital Partnerships in Clinical Research

- The value of investment
- How VC is impacting the research industry
- Gender disparity in funding, its impact on Femtech and women's health research, and possible solutions

Chad Moore
Co-Founder & Corporate Development
Elligo Health Research®

ABOUT THE SPEAKER
Chad Moore brings over 20 years of experience to Elligo Health Research. Prior to co-founding Elligo, he was an investment banker covering the outsourced pharmaceutical services and IT sector for over a decade. Most recently, Moore was a Managing Director at Leerink Partners where he led the firm's pharmaceutical services and IT investment banking team. In addition, he founded and was the head of the Pharmaceutical Services and IT Investment Banking Practice at Robert W. Baird & Co. Earlier in his career, Moore held positions of increasing responsibilities at PRA International (now PRA Health Sciences) where he worked closely with the executive management team, oversaw PRA's merger and acquisition activities and assisted in the company's 2004 initial public offering and subsequent follow-on offering.

14:10 - 15:10 PT ROUNDTABLE 3

Accessing Development Capital in the Current Environment

- Current developments in venture capital and private equity
- Expectations for crowdfunding
- Corporate venturing
- Predictions for the next year

Christopher Mizer
President and CEO
Vivaris Capital

ABOUT THE SPEAKER
J. Christopher Mizer founded Vivaris Capital, LLC and serves as President and Chief Executive Officer. Vivaris invests in and acquires middle-market businesses in healthcare, life sciences, and technology that are leaders in their markets. Mr. Mizer serves as the chairman of each of the portfolio companies and guides strategic decisions and their execution. Mr. Mizer is a former Vice President of Key Capital Markets and certified public accountant with Ernst & Young. He has also been a member of Entrepreneurs Organization (EO) and Young Presidents Organization (YPO). He earned B.S., B.A., M.S., and M.B.A. degrees from Case Western Reserve University.

16:20 - 17:20 PT ROUNDTABLE 4

Investing in Pharma / Biotech Clin Ops focused Health tech companies

- What domain areas in the clinical trials and commercialization process are most ripe for innovative, early-stage companies?
- What product features and capabilities are required in order to serve scaled and scaling biotech / pharma companies?
- How should investors evaluate companies most poised for outsized success in the clin ops market?

Daniel Gebremedhin
Partner
Flare Capital Partnersl

ABOUT THE SPEAKER
Dan Gebremedhin, MD is a Partner at Flare Capital Partners and serves on the Board of Flare portfolio companies Somatus, Eden Health, Positive Development, Vita Health, Oui Health, and Elektra Health. Prior to joining Flare Capital, Dan served as a Medical Director at the Harvard Pilgrim Health Plan. Dan spent over 8 years as a practicing Internal Medicine Physician on the Faculty of the Massachusetts General Hospital and Instructor in Medicine at Harvard Medical School, after completing Internal Medicine Residency at the Massachusetts General Hospital in 2010. Dan served on Former Massachusetts Governor Charlie Baker's Board of Nursing Home Administrators from 2016 to 2020. He has served as a Senior Health Policy Advisor for the Campaigns of Former Governor Charlie Baker, Former Congressman Joseph Kennedy III and Congressman Jake Auchincloss. Dan earned a BS from the University of California, San Diego, an MD from the Morehouse School of Medicine, and an MBA from the Harvard Business School.

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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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