Clinical Outsourcing Group New England

Boston Marriott Burlington, MA

April 29th & 30th 2025

Previous 2024 Speakers;

Stephanie Kelly – Sr. Director, Clinical Development Operations - **Esperion Therapeutics**
Russell LaMontagne – President & CEO – **Boston Immune Technologies & Therapeutics**
Gilmore O'Neill – President & CEO – **Editas Medicine**
Jeremy Springhorn – CEO – **Nido Biosciences**
Daniel Getts – CEO & Co-Founder – **Myeloid Therapeutics**
Rahul Ballal – CEO – **Mediar Therapeutics**
Matt Wheeler – Partner – **L.E.K. Consulting**
Erin Finot - Vice President, Immuno-Oncology & CAGT - **IQVIA Biotech**
Joan Chambers – Former CEO – **Greater Gift**
Matt Britz – CEO – **AffyImmune Therapeutics**
Kalyan Obalampalli (KO) – Founder - **ClinAI**
LeeAnn Ali – Vice President, Clinical and Regulatory Development Operations - **BioBridges**
Leticia Tarilonte – Vice President, Global Clinical Operations – **Brainstorm Cell Therapeutics**
Lori Correia – Patient Advocacy Consultant – **Tenaya Therapeutics**
William Korinek – CEO – **Astrocyte Pharmaceuticals**
Mark Melton - Vice President, Scientific Operations & Development - **SLOPE**
Meredith Frank-Molina – Senior Director, Clinical Operations – **Third Pole Therapeutics**
Paul Bassett – Project Lead, Early Development Oncology – **Sanofi**
Frank Borriello – Founder & CEO – **Alloplex Biotherapeutics**
Jack Hoppin – Founder & CEO – **Ratio Therapeutics**
Colleen Cox – Director, Clinical Data Management – **Mersana Therapeutics**
Margaret Caulfield – Senior Corporate Counsel – **Mural Oncology**
Marisa Livingston - Senior Clinical Supplies Manager - **Catalent**
Justyna Lipinska – Senior Manager, Clinical Contracts & Sourcing – **Sage Therapeutics**
Judith Murphy – Executive Director, Centralized Contracting & Outsourcing – **Kura Oncology**
Delia Silva – Managing Partner – **L.E.K. Consulting**
Benedict Hirth - Global Lead Manager Supply Chain Optimization - **MYONEX**
Lynn Agata – Director, Contracts – **Vor Biopharma**
Stacey Lasser – Senior Project Manager – **Mednet**
Wessam Sonbol – CEO - **Delve Health**
Deb Kientop – Vice President, Clinical Operations – **Deka Biosciences**
Jason Berlin – Director, Clinical Operations Program Lead – **Dyne Therapeutics**
Phill Gallacher – Senior Vice President, Clinical Operations & Program Management – **Cullinan Therapeutics**
Alexander O'Leary – Director – **PBC Group**
Matt Britz – CEO – **AffyImmune Therapeutics**
Kristine Bernard – Vice President, Head of Clinical Operations – **Astria Therapeutics**
LeeAnn Ali – Vice President, Clinical and Regulatory Development Operations – **BioBridges**
Sara Johnson Davis – Senior Director, Patient Advocacy – **Editas Medicine**
Christian Rubio - Executive Director - **Everything ALS**
Eric Zhao - Head of Field & Patient Engagement - **Black Diamond Therapeutics**
Jim Lincoln - Senior Director, Clinical Operations & Regulatory - **Aixial Group**
Sofia Zhidro – Senior Director, Quality – **Vigil Neuroscience**
Corey Greene – Senior Project Manager, Research Services – **CISCRP**
Justine Holleran – Manager, Community Development & Engagement – **CISCRP**
Lucas Goren – Senior Project Manager – **CISCRP**

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Day 1: April 29th 2025

7:45	**Registration & Morning Refreshments**
8:20	**Organizer's Welcome Address** **Alexander O'Leary** – Director – **PBC Group**
8:25	**Chair's Welcome Address** **Bonnie Bain** – President/CEO, Global Healthcare – **Ipsos**
8:30	CMO Keynote Interactive Panel **Putting Patients First: Driving Patient-Centricity in Clinical Trials** *In the rapidly evolving landscape of clinical trials, patient-centricity has become not just a priority, but an absolute necessity for biopharmaceutical companies. This panel brings together a group of distinguished New England Chief Medical Officers to discuss why patient-centric approaches are critical for optimizing study designs, meeting regulatory timelines, and achieving patient recruitment and retention imperatives.* *Panellists:*
9:15	*Session Reserved for Myonex*
9:45	**Fireside Chat** **Rare Disease Trial Focus: Strategies for Finding, Recruiting & Retaining Your Patient Population** *Rare disease clinical trials present many obstacles to patient recruitment and retention. Rare diseases, by definition, affect a small number of patients. This poses unique challenges when it comes to identifying patients, getting them involved early and keeping them engaged, especially given the complex needs of these patients and the specialized nature of the trials.* In this session, Phill will focus on best practices for site activation, identifying rare disease patient populations, designing and executing trials, and addressing key considerations unique to rare disease studies. **Phill Gallacher** – Vice President, Clinical Operations & Program Management – **Cullinan Therapeutics**
10:15	*Session Reserved for SDC*
10:45	**Coffee Break**

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	Stream A **Clinical Outsourcing Confusion**	Stream B **Supply, Sites & Technology**
11:30	Interactive Debate **Implementing a Functional Service Provider vs a Fully Outsourced Model from a Small Company Perspective** *There is a growing shift towards FSP models for outsourcing, allowing sponsors to take advantage of best-fit solutions to optimise their study. However, is the FSP model a realistic option for smaller biopharma without the infrastructure required to manage multiple suppliers?* The 'For' side of the debate will argue the FSP model can be successfully implemented into smaller companies, allowing sponsors to tap into their specialized experience. The 'Against' side of the debate will argue smaller companies struggle with FSP models due to resource constraints, lack of infrastructure, and the need for close oversight. Followed by thoughts for the future. *Debate team:* *Tentative:* **Ingrid Abrahamsen** – Senior Director, Clinical Operations – **Editas Medicine**	Interactive Panel **Opportunities and Obstacles with AI in Clinical Trials: How Do We Grabble with AI as a Smaller Company?** *Whilst AI often appears all singing all dancing, this isn't always the case in the real world. Can AI streamline clinical trials by accelerating patient recruitment, and enhancing trial efficiency? What are the obstacles with implementing it and is it a realistic opportunity for small biopharma at this time?* This interactive panel will address the ClinOps and Data Management perspectives of introducing AI into a study. Our panellists will also discuss the challenges with of implementing AI in clinical trials, while asking the question: Are clinical sites and their staff also ready to embrace this technology? *Panellists:* **Phill Gallacher** – Vice President, Clinical Operations & Program Management – **Cullinan Therapeutics**
12:15	*Session Reserved for IQVIA Biotech*	*Session Reserved for Mednet*
12:45	**How to Position Yourself as a Top Priority for the CRO and Maintain the A-Team Throughout** *Due to insufficient resources and training, sponsors often find themselves working with different CRO teams than those initially selected during the bid defence. This inconsistency is negatively affecting a huge number of trials across the US and causing costly delays.* In this on-stage interview, our speaker will examine the problem from the beginning, assessing what should be put into the RPF, what to discuss with your CRO initially and how to set boundaries and expectations. X will also address how to handle situations when a team member is not pulling their weight. How can you encourage a more proactive work environment?	**Data-Driven Clinical Trials: Accelerating Site Selection & Patient Recruitment, Reducing Costs, and Gaining More Control** *The current approach to clinical trials is plagued by slow processes, missed timelines, and excessive reliance on vendors for day-to-day operations, significantly delaying the delivery of new drugs to market. By leveraging data and technology, pharmaceutical companies can accelerate the clinical trial process, streamline site selection, and ultimately bring life-saving medications to patients more quickly and efficiently.* Ernest will explore the transformative power of data, technology, and field intelligence in modernizing and accelerating clinical trials. Discussing how leveraging advanced analytics can

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		improve the accuracy of trial outcome predictions and optimize site and patient selection. *Tentative:* **Ernest Odame** – Director, Value Management Lead, R&D Technology – **Takeda**
1:15	**Lunch**	
	Stream A **Outsourcing & Controlling Costs**	Stream B **Supply, Sites & Technology**
2:15	Spotlight on Contracts **Optimising the Contracting Process and Minimizing Change Orders - A Small Biotech Case Study** *By implementing streamlined workflows, adopting clear communication strategies, and leveraging digital tools, sponsors are able to avoid delays and improve efficiency.* This case study demonstrates how proactive planning and process optimization can help smaller organizations manage resources effectively while maintaining trial quality and compliance. Head of contracts?	Spotlight on Supply **Initiatives to Enhance Accountability, Efficiency, and Sustainability in Clinical Supply Chain Management** *With affective supply chain initiatives, sponsors will see improvements on transparency through advanced tracking technologies, enabling real-time monitoring and ensuring compliance standards. Sustainability goals can also be achieved by streamlining processes and enhanced efficiency in supply chain.* This session will explore how supply chain initiatives can ensure the secure and efficient management of IP, as well as support environmental and operational goals.
2:45	**Cell & Gene Therapy Trial Set Up and Execution** *Cell and gene therapy clinical trials face several unique challenges, particularly within ClinOps and Supply Chain.* In this session our speaker will discuss the obstacles faced when setting up a gene therapy trial, and draw on their wealth of experience to share how to plan and collaborate to successfully implement the trial. *Tentative:* **Ingrid Abrahamsen** – Senior Director, Clinical Operations – **Editas Medicine**	**Leveraging High Patient Engagement in Japan & Taiwan for Effective Recruitment** *Japan and Taiwan have emerged as powerhouses in clinical research, boasting remarkably high levels of patient engagement and efficient recruitment processes. Exploring the unique landscape and incentives of clinical trials in these countries, focusing on how their cultural and healthcare environments contribute to exceptional patient participation rates.* In this session Hiroki will share insights into the factors that enable on-time and often early patient recruitment in these markets. Discussing cultural attitudes towards clinical research, healthcare

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		infrastructure, as well as high-quality data generation. *Tentative:* **Hiroki Matsushima** – Branch Manager, US – **A2 Healthcare**
3:15	Fireside Chat **Identifying Operational Efficiencies in your Study: By Continuously Evaluating and Refining Processes, Sponsors Can Drive More Efficient Trial Execution** *Finding operational efficiencies in clinical trials is crucial for accelerating timelines, reducing costs, and enhancing data quality.* X speaker will discuss how simplifying study protocols, optimizing site selection and ensuring clear communication with stakeholders can improve operational efficiency. They will also address how collaborative approaches, such as engaging with sites and CROs early to align on expectations, can prevent delays.	Interactive Panel **Clinical Trial Supply: Strategies for Vendor Selection and Effective Oversight** *Ensuring a robust and reliable clinical trial supply chain is crucial for the success of any clinical study. Selecting the right vendors and maintaining effective oversight can make the difference between a seamless trial and one plagued by delays and quality issues.* Panellists will share real-world case studies, best practices, and lessons learned from their extensive experience in managing clinical trial supply chains. *Panellists:*
3:45	**Coffee Break & Scavenger Hunt with Prizes!**	
4:15	Workshop **RFP Focus Session: Comparing Apples to Apples** *RFPs are critical for finding the best CRO for your study. However, in the complicated world of outsourcing clinical trials, using RFPs to compare CROs can be incredibly challenging.* In this session, groups will work together to identify key elements to include in an RFP and develop a basic template. Each group should list 5-10 criteria that are essential for assessing vendor qualifications to ensure we are comparing apples to apples. *Host:*	Fireside Chat **Trial Innovation - Can Smaller Companies Afford to Think This Way?** *When studies encounter problems, we often revert to familiar methods. However, with so many new options available, it's essential to explore innovative approaches to get trials back on track.* This session will examine whether smaller companies can afford the latest advancements in clinical trial innovation or if these remain out of reach. What can small companies realistically look at with regards to clinical innovation?
4:45	**Implementing Diversity, Equity, and Inclusion Initiatives in Clinical Trials: A Patient Centric Approach**	**Optimizing eDiaries in Clinical Trials: Balancing Simplicity, Efficiency, and Patient-Centricity**

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	Improving diversity, equity, and inclusion in clinical trials requires intentional strategies to address barriers to participation. This includes engaging underrepresented communities and ensuring trials are accessible to participants of all backgrounds. Partnering with Patient Advocacy Groups early on is critical for enhanced equity in clinical research. In this session X will explore real life case studies and strategies for diversity, equity, and inclusion in patient recruitment and engagement.
	Patient diaries are a critical component of a clinical trial, serving as an essential tool for collecting patient-reported outcomes (PROs). However, if the diary becomes complex, it can affect everyone involved. Overcomplicating electronic diaries can cause delayed timelines due to the extensive design and build, plus collecting excessive data can overwhelm patients. This on-stage interview will explore the advantages and challenges associated with implementing eDiaries, including the training and site burden aspect. Our expert speaker will end with key takeaways for how to simplify diaries and only collect essential data, keeping the patient front of mind.
5:15	Keynote Interactive Panel **Fuelling the Future: CEO Perspectives on Funding Clinical-Stage Biotechs** *Securing sufficient investment remains challenging for biotech companies, whether they are seeking to enter clinical trials, or seeking investment to move to later stages. Clear communication of drug/device candidate potential, as well as possible creative funding/ equity models.* This CEO panel will bring together leaders of biotechs to discuss strategies for financing clinical pipelines. Topics will include international trends in venture capital, public markets, licensing deals, local government funding, and cross-border partnerships. *Panellists:*
05:25	**Chair's Day 1 Summary** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
05:30	**Networking Drinks & Canapés Reception & Rapid-Fire Team Quiz with Prizes** ***(complementary admission to all conference participants)***

Day 2: April 30th 2025

8:15	**Registration & Morning Refreshments**
8:55	**Chair's Day 2 Welcome Address** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
9:00	Keynote Interactive Panel **Building Effective Partnerships Between Trial Sponsors and Investigators**

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Strong partnerships between trial sponsors and investigators are crucial to facilitating efficient, high-quality clinical research. Aligning priorities and effective collaboration enables successful trial execution, recruitment, and data collection.

In this panel, we will examine best practices for building robust partnerships between clinical trial sponsors and investigator sites. It will outline strategies to align priorities, incentives, and expectations to conduct high quality, efficient trials.

9:30 *Session Reserved for Versiti*

10:00 Keynote Interactive Panel

Optimizing Data Collection: New Trends for Maximizing Value

Optimizing data collection in clinical research by only capturing meaningful, high-value data points allows researchers to reduce costs, minimize patient burden, accelerate study timelines, and ultimately enhance the likelihood of uncovering insights that will benefit treatment indications.

This panel will discuss emerging approaches to optimizing clinical trial data collection. Panellists will share insights on determining high-value data points, reducing unnecessary data capture, and easing patient burden - all while maintaining scientific and regulatory standards. Key topics of discussion: Determining Essential Data, Avoiding Data Waste, Regulatory Guidance and Requirements, and Impacts on Patients and Trial Efficiency.

10:30 **Coffee Break**

11:00 Keynote Interactive Panel

Revolutionizing Clinical Trials: Innovations in Trial Design for Faster, Smarter, and More Efficient Drug Development

The landscape of clinical trials is evolving rapidly, driven by the need for faster, more efficient, and patient-centric drug development. This panel discussion will explore the latest innovations in clinical trial design, focusing on strategies that can accelerate timelines, improve data quality, and enhance patient engagement.

The panellists will explore adaptive trial designs, the integration of advanced technologies such as AI and machine learning, and the growing trend of decentralized and virtual trials. Sharing insights on the application of real-world evidence, innovative statistical approaches, and patient-reported outcomes to complement traditional randomized controlled trials. Discussing the regulatory landscape, and collaborative efforts to facilitate the adoption of innovative designs.

11:30 *Reserved for Event Sponsor*

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12:00 Keynote Interactive Panel

Building a Foundation of Excellence: Fostering a Culture of Quality in Clinical Operations

A robust culture of quality is essential for excellence in clinical operations and research. However, achieving this requires focused effort and strategy.

In this session, the panel will discuss practical ways you can promote quality behaviours and mindsets among clinical development and operational teams. Key areas of discussion will include leadership engagement, communication approaches, quality infrastructure, continuous improvement processes, and methods for recognizing and rewarding quality outcomes.

12:30 **Lunch**

1:30 Keynote

Breaking Down Barriers to Harness Real-World Evidence

Small biopharma often struggle to utilize RWE due to limited access to datasets, the cost of analyzing data, and the need for specialized expertise. Integrating RWE also requires infrastructure that smaller companies may lack.

This on-stage interview will discuss how overcoming these obstacles allows sponsors to gain valuable insights into how treatments perform in real-world populations, outside the clinical trial environment. Our speaker will explore how RWE can optimize trial designs and support regulatory approvals.

2:00 Onstage Interview

Rare Disease Trial Focus: Delving into Transportation Obstacles and the Value of PAGs

Transportation challenges in rare disease trials are significant obstacles that can affect the recruitment, retention, and overall quality of clinical research. Rare diseases, by definition, affect a small number of patients. This poses unique challenges when it comes to transportation, especially given the complex needs of these patients and the specialized nature of the trials.

In this session our expert speaker will hone in on the best practices for designing and setting up a rare disease clinical trial, with a focus on transportation, PAGs and reducing the patient burden.

2:30 Closing Keynote

Advantages and Obstacles with Exploring Unchartered Territories for Your Clinical Trial

As the number of studies in the US increases, leading to study saturation and a shrinking pool of untapped patient populations, sponsors are expanding their search to new regions. This approach helps to achieve target patient demographics, enhance diversity, and ensure that the data collected is more representative.

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	But with its own unique challenges, venturing into different locations for trials requires thorough preparation and local expertise to ensure compliance and quality standards are maintained. X will explore how embracing these new locations for your study can enhance the relevance and impact of findings on a broader scale.
3:00	**Chair's Day 2 Summary & Closing Remarks** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**

End of Conference

Extra Available Sessions

Navigating a Successful Site Start-Up: Starting on the Right Foot to Ensure an Efficient Clinical Study

The site start-up phase plays a pivotal role in setting the foundation for a successful trial. However, with ever frequent staffing issues, review delays, budget restrictions and communication challenges, this phase is proving more difficult to get right.

This session will focus on how partnering up with stakeholders and finding ways to be flexible can lead the way for a successful start-up. X will draw on their experience and give examples of how they navigate the crucial start-up phase, paving the way for a seamless clinical trial.

Strategies to Inspire Your CRO Counterpart/Teams to be Equally Committed to Achieving Objectives as Internal Teams, While Fostering a More Streamlined Operational Workflow

With CROs often managing multiple projects at one time and not always being as invested in the success of your trial, it is crucial to generate enthusiasm and engagement in the studies, ensuring CRO counterparts feel motivated to drive progress and deliver results.

X speaker will highlight strategies to encourage the CRO team to be more invested in your study, enabling earlier milestone achievements and reducing frustrations within your internal teams.

Strategies to Enhance Patient Retention, with a Focus on Leveraging the Expertise and Insights of CROs to Optimize This Process

Patient retention is vital to the success of a clinical trial, as it directly impacts the validity and overall outcomes of the study. High dropout rates can lead to delays in meeting regulatory requirements, often resulting in increased costs and extended timelines.

Our speaker will delve into best practices for patient retention, giving real-life case study examples of successful initiatives. They will also discuss the most effective ways to leverage your CROs for support.

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Interactive session – **Recruitment Pressure is Rising… What Should We Focus on Now to Target Patients More Precisely?**

Patient recruitment has always been a challenge in clinical research, but with study saturation and study criteria becoming increasingly specific, identifying patients is a harder task.
This panel will bring together experts to pinpoint best practice for a more targeted patient recruitment process. Covering patient-centric trial designs, recruitment for global sites, achieving diversity targets, and the use of tools and social media.

Involving Patients in Clinical Trial Decision Making

Keeping patients at the heart of your clinical trial is vital for recruitment and engagement success. This involves incorporating patient input during trial design, simplifying protocols to reduce participant burden, and ensuring clear communication.
Our expert speaker will address how prioritizing patient-centric practices not only enhances trust and engagement but also improves trial outcomes by fostering greater adherence and retention.

The Change in Monitoring Over Time Leading to a More Risk-Based Approach

Monitoring in clinical trials has evolved towards risk-based monitoring (RBM), focusing resources on critical data that most impact patient safety and trial integrity. Shifting away from 100% source data verification, RBM improves efficiency, reduces costs, and maintains oversight… but is this new phase of monitoring the best option for small biopharma?

Vendor Oversight Spotlight: Stop Treating it Like a One-Way Street; Focus on Maintaining and Measuring Effective Communication

For small-mid sized sponsors with no other option but to outsource, vendor oversight is a vital part of day to day life. Inefficient communication is one of the biggest obstacles with the sponsor-vendor relationship.
In this presentation X speaker will address best practices for vendor oversight including monitoring vendors against KPIs; laying out roles and expectations early on; governance structures and how technology can aide oversight. Sharing advice based on their experience of implementing effective oversight strategies and vendor management.

Diving into Early Phase Oncology Trials

This session will explore the tools available to streamline study protocols, which helps to alleviate patient burden and minimizing the need for future amendments. Our expert speaker will explore strategies to enhance clinical trial diversity whilst adhering to compliance regulations in oncology trials.

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Fireside Chat: Enhancing Sponsor-CRO Collaboration Through Technology

Strengthening Sponsor-CRO partnerships with technology can streamline clinical trials, improve data accuracy, and foster real-time communication. Both sponsors and CROs can achieve better alignment on study goals, timelines and quality standards by utilizing project management and monitoring platforms. Where delays and inefficiencies occurred, technology can step in and enable a more seamless integration of systems.

In this fireside chat X will discuss her experience with introducing technology into clinical trials and specifically how it can help the sponsor-CRO relationship.

What is the Outsourcing/ClinOps Scope in Your Company?

This panel will explore the broader responsibility of the outsourcing role in different companies, what other roles they take on and how to grow/improve your outsourcing department.

Our keynote panellists will give an overview of their role within outsourcing at their company and discuss X

Unlocking the Full Potential of RWD in Patient Referral by Developing Effective Partnerships and Overcoming Barriers

Patient referral, particularly utilizing Real-World Data (RWD), has emerged as a promising strategy to expedite clinical trial enrolment. However, the effectiveness of this approach remains largely unproven, hindered by various challenges.

This session will explore the complexities of patient referral using RWD, identify critical barriers, and proposes strategic solutions to enhance its efficacy. Our goal is to acknowledge past use cases to transform patient referral into a reliable and efficient mechanism for patient recruitment.

Achieving Equity for Women in Clinical Research: How We Can Collectively Work Towards a Healthier and More Equitable Future for All Women

Despite significant advancements in medicine, women continue to face unique healthcare challenges that are often overlooked. Achieving equity for women in clinical trials starts with study designs and recruitment strategies. This includes proactive efforts to enrol women from diverse backgrounds and address barriers early on.

Our speaker will share real-world examples of the barriers women face and the innovative solutions that are being implemented in clinical trials to drive equity.

Clinical Financing, Cash Flow and Raising Funds: A Small Company Outlook

With smaller biopharma at risk of going out of business due to mismanagement of funds, clinical financing is more important now than ever. Successful fundraising can avoid trial delays, whilst attract strategic partners, enhance credibility, and support long-term growth.

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This session will explore best practices for maximising cash flow; developing a financial road map and maximising cash as a smaller company.

Clinical Excellence from an Outsourcing Standpoint: A Small Company Perspective

Clinical excellence, from an outsourcing angle, involves partnering with specialized providers to ensure high-quality, patient-centered care while leveraging external expertise for improved efficiency. This approach enables organizations to access advanced clinical capabilities, reduce operational burdens, and maintain a focus on core strategic goals.

Our speaker will address how can you resource that outsourcing function or support as a small company, focussing on SOP development, inspection readiness, monitoring, oversight.