Clinical Outsourcing Group UK

Copthorne Tara Hotel London Kensington

4th & 5th March 2025

Rachael McTegart – Outsourcing & Contracts Director – **Barinthus Biotherapeutics**
Fiona Parker – Head of Quality Assurance - **Barinthus Biotherapeutics**
Myrthe Trompert – CEO – **Salvius Legal**
Anne Marieke Ezendam – Co-Founder – **Biozen**
Binita Patel – Diversity Strategy Lead – **Bayer**
Lavita Menezes – Director, Clinical Operations – **Silence Therapeutics**
Noemi Angelosanto – Medical Director, Clinical Development – **Ryvu Therapeutics**
Rupert Haynes – CEO – **Avata Biosciences**
Sheryl Caswell – Chief Development Officer – **Monument Therapeutics**
Alex Blyth – CEO – **Lift Biosciences**
John Boghossian – CEO – **Kadence Bio**
Lee Harle – CEO – **SolasCure**
Krzysztof Potempa – CEO & Founder – **Braincures**
George Frodsham – CEO & Founder – **MediSieve**
Julie Powell – Corporate Development Director – **Pleco Therapeutics**
Matt Kelly – Head of Clinical & Operations – **Caristo Diagnostics**
Jeff Pilot – Director, Clinical Operations – **Norgine**
Gaia Kiru – Head of Operations & Partnerships – **Imperial College London**
Ian Hodgeson – Head of Operations – **Corbus Pharmaceuticals**
Nara Daubeney – CEO & Co-Founder – **Phaim Pharma**
Melissa Sturgess – CEO – **Ananda Developments**
Karolina Afors – Medical Director – **Medherant**
Kieran Prior – Engagement & Impact Lead **– CRUK**
Yvanne Enever – CEO – **PHARMExcel**
Andy Thurstan – Senior Director, Patient Services – **Wave Life Sciences**
George Frodsham – CEO – **MediSieve**
Praveen Kumar – Director & Chief Scientific Officer – **Brinton Healthcare**

Register to attend
https://www.thepbcgroup.com/registration-page

Contact Information
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Attendance – Alexander O'Leary aol@thepbcgroup.com
Hotel/ Logistics – Samantha Drewe sam@thepbcgroup.com

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Day 1: 4th March 2025

08:00 – 08:30	**Registration & Morning Refreshments**
08:30	**Organiser's Welcome Address** **Alexander O'Leary** – Director – **PBC Group**
08:35	**Chair's Welcome Address**
08:30	Keynote Panel **Putting Patients at the Heart of Clinical Trials: Strategies for Enhancing Patient-Centricity, Diversity, and Stakeholder Collaboration in the UK** *In the rapidly evolving landscape of clinical trials, patient-centricity has emerged as a critical priority for biopharmaceutical companies in the United Kingdom. This panel brings together a group of distinguished British C-Suite executives to discuss strategies for putting patients at the heart of clinical trial design and execution within the NHS framework.* Through this interactive panel discussion, attendees will gain valuable insights into the evolving role of the C-Suite in driving patient-centricity, diversity, and stakeholder collaboration in UK-based clinical trials. The panel will discuss practical strategies and real-world examples from the British healthcare system to inspire and inform clinical development leaders as they work to bring innovative therapies to patients in need across the UK. **Binita Patel** – Diversity Strategy Lead – **Bayer** **Lavita Menezes** – Director, Clinical Operations – **Silence Therapeutics**
09:15	Keynote **RESERVED for TCR-Solutions**
09:30	Keynote **Navigating the UK Clinical Trial Landscape: Overcoming Challenges and Seizing Opportunities** *The UK offers a unique environment for clinical trials, with its robust healthcare system and world-class research institutions. However, sponsors face significant hurdles in resource allocation, contract negotiations, and regulatory approvals. Understanding these challenges and identifying strategic solutions is key to successfully conducting clinical trials in the UK.* Presenters will share their experiences in managing UK-based trials, offering practical strategies for addressing resource shortages at NHS sites, streamlining contract negotiations, and leveraging the MHRA's combined assessment system. They will also discuss approaches to navigate the complexities of NICE approvals and their impact on drug access, providing valuable insights for both newcomers and experienced professionals in the UK clinical trial landscape. **Reserved for NIHR**
10:00	Keynote **RESERVED for Aixial Group**

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10:30 **Coffee Break**

	Stream A **Clinical Outsourcing Confusion**	Stream B **International Trial Operations & Supply**
11:15	Interactive Panel **Outsourcing in Clinical Trials: Navigating FSP Models, Partnerships, and Pricing Transparency** *The shift from full-service to Functional Service Provider (FSP) models is reshaping how sponsors manage and execute clinical trials. Understanding these changes is crucial for optimizing trial oversight, cost-effectiveness, and sponsor-CRO relationships in today's competitive landscape.* Panellists will share insights on recent outsourcing trends, real-world experiences with FSP models, and strategies for enhancing partnerships and pricing transparency. They will discuss best practices for maintaining project team consistency, integrating CROs into strategic decision-making, and navigating the complexities of modern outsourcing agreements. **Yvanne Enever** – CEO – **PHARMExcel** **Andy Thurstan** – Senior Director, Patient Services – **Wave Life Sciences** **Jeff Pilot** – Director, Clinical Operations – **Norgine**	Interactive Workshop **Data Quality Challenges at European Clinical Sites: A Collaborative Workshop on Site-Level Solutions** *Clinical study sites across Europe face mounting pressures in data management and collection, leading to critical quality issues that impact trial integrity. Examining real-world challenges from sites in Poland, France, Spain, and Italy, focusing on resource constraints, common data entry errors, and their downstream effects on study outcomes.* In this hands-on workshop, Noemi will explore actual case studies of data management challenges from European clinical sites. Through facilitated group discussions, attendees will analyse root causes of data quality issues, from staffing constraints to process inefficiencies. Specific attention will be given to overcoming cultural and systemic challenges unique to different European healthcare environments. **Noemi Angelosanto** – Medical Director, Clinical Development – **Ryvu Therapeutics**
11:55	Insight **RESERVED for EMIS Health**	Insight **RESERVED for Viedoc**
12:25	Insight **Leadership Insights: Strategic Decision-Making in Clinical Development - A CEO's Perspective** As biopharma companies navigate the critical transition from pre-clinical to Phase II trials, CEOs face complex strategic decisions that shape their company's future. In this intimate fireside chat, we explore the leadership challenges, strategic considerations, and pivotal moments that define a biotech's clinical development journey.	Insight **Australia and Asia: Presenting Clinical Research Opportunities and Challenges in the Asia-Pacific Region** *The Asia-Pacific region, with its large and diverse patient populations, is becoming increasingly attractive for clinical trials. However, conducting research in this area presents unique challenges and opportunities that sponsors must navigate carefully.*

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	In this onstage interview, John will share personal insights into the strategic decision-making process behind advancing clinical programs. The discussion will explore key inflection points including go/no-go decisions, resource allocation challenges, and timing considerations for Phase II initiation. Topics will include balancing investor expectations with clinical timelines, strategic partnership evaluations, and maintaining momentum while managing risk. **John Boghossian** – CEO – **Kadence Bio**	This session will present a comprehensive case study on conducting clinical research in Australia and key Asian markets. Experienced clinical operations leaders with extensive regional expertise will share insights into the specific challenges faced when running trials in these countries. The discussion will cover critical aspects such as navigating the varied regulatory environments, managing drug supply logistics across diverse geographies, and adapting to local clinical practices and cultural nuances. **Melissa Sturgess** – CEO – **Ananda Developments**
12:55	**Lunch**	
	Stream A **Trial Efficiency**	Stream B **International Trial Supply & Supply**
14:00	Insight **Unlocking Success: Navigating Clinical Research Contracts with Sites & Vendors** *When engaging vendors & sites, successful planning and contract management can vastly improve your negotiation position and benefit your study timelines, which will drive positive management throughout the duration of clinical studies.* In this session, Myrthe will share key insights into how trial sponsors can position themselves through planning, negotiation, and contract execution to reduce costs, gain leverage, and protection against overruns. **Myrthe Trompert** – CEO – **Salvius Legal**	Case Study **Strategic Pivot in Biotech: Maximizing Value Through Partnership-Focused Development**** As the biotech landscape evolves, companies are increasingly reassessing traditional paths to market. This case study examines how one emerging biotech successfully transformed its business model from full commercial development to a partnership-focused strategy, creating enhanced value through strategic collaborations and targeted development partnerships In this revealing session, George will share MediSieve's journey of strategic transformation, exploring the decision points, challenges, and opportunities encountered during their pivot from a traditional commercialization pathway. Topics will include evaluation of partnership versus standalone commercialization, approaches to identifying and securing strategic partners, restructuring development programs for optimal partnership alignment, and insights into maintaining company valuation through the transition. **George Frodsham** – CEO – **MediSieve**
14:30	Insight **RESERVED for Premier Research**	Insight **RESERVED**
15:00	Case Study	Workshop

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Pioneering Women's Health: Inside a London-Based Phase 1 Transdermal Trial

As therapeutic innovations in women's health continue to evolve, transdermal delivery systems present unique opportunities and challenges in clinical development. This candid discussion explores the execution of a multi-cohort Phase 1 trial in London, examining operational insights and the broader context of unmet needs in women's healthcare.

In this session Karolina will explore the journey of conducting a novel Phase 1 trial investigating transdermal drug delivery in women's health. Delving into the rationale behind site selection in London, the complexities of managing multiple cohorts, and the operational nuances of conducting trials in this therapeutic area. The conversation will touch on the current landscape of off-label testosterone use in women, providing context for the development of novel delivery systems. Sharing insights into trial design considerations, participant recruitment strategies, and the practical challenges of conducting early-phase research in women's health.

Karolina Afors – Medical Director – **Medherant**

Unboxing Clinical Trial Supply: An Interactive Ask Me Anything

Dive into the intricate world of clinical trial supply in this dynamic, interactive workshop. Our panel of seasoned experts from various facets of the supply chain will be at your disposal for an enlightening "Ask Me Anything" session. Whether you're grappling with global distribution challenges, curious about the latest in temperature-controlled logistics, or seeking insights on regulatory compliance, this is your chance to get answers straight from the source.

This workshop offers a unique opportunity to:

- Engage directly with professionals who navigate the complexities of clinical trial supply daily
- Gain practical insights into real-world scenarios and best practices
- Explore innovative solutions to common and uncommon supply chain hurdles
- Network with peers and experts in a collaborative learning environment

Praveen Kumar – Director & Chief Scientific Officer – **Brinton Healthcare**

15:30 **Coffee Break**

	Stream A **Regulation & Legal**	Stream B **International Trial Operations & Supply**
16:00	Case Study **ICH E6 (R3) and the New Era of Vendor Oversight: Navigating Expanded Sponsor Responsibilities** *The recent revision of ICH E6 (R3) has introduced significant changes to vendor oversight in clinical trials, expanding sponsor responsibilities to include oversight of CRO subcontractors. This shift requires sponsors to implement more comprehensive oversight processes, potentially impacting quality assurance practices and necessitating increased audits of partners throughout the entire outsourcing chain.* Speakers will discuss the key changes in ICH E6 (R3) related to vendor oversight, exploring the implications for sponsors, CROs, and subcontractors. They will share insights on adapting to these new requirements,	Case Study **Strategic Site Selection for Early-Phase Trials: Maximizing R&D Incentives Across Global Markets** *The selection of initial trial locations for early-phase research has significant financial implications beyond operational costs. This session examines how R&D tax incentives, government grants, and regulatory pathways across key markets - Australia, UK, US, and EU - can dramatically impact both immediate trial costs and long-term development strategies.* In this session Sheryl will share a comprehensive analysis of the financial and regulatory landscape for early-phase clinical research across major markets. Participants will gain detailed insights into Australia's

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including strategies for implementing effective oversight mechanisms, developing robust audit processes, and balancing increased responsibilities with operational efficiency.

Rachael McTegart – Outsourcing & Contracts Director – **Barinthus Biotherapeutics**
Fiona Parker – Head of Quality Assurance - **Barinthus Biotherapeutics**

attractive 43.5% R&D tax rebate and streamlined regulatory pathway for Phase I trials, contrasted with the complexities and costs of the US IND process for first-in-human studies. The discussion will also explore the evolving UK and EU incentive schemes post-Brexit, providing attendees with practical frameworks for evaluating total program costs, timelines, and strategic advantages of each region.

Sheryl Caswell – Chief Development Officer – **Monument Therapeutics**

16:30 Insight

RESERVED

Insight

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Plenary
Investment: Bench to Clinic

17:00 CEO Keynote Interactive Panel
Fuelling the Future: CEO Perspectives on Funding Clinical-Stage Biopharma in the UK

Securing sufficient investment remains challenging for British biotech companies, whether they are seeking to enter clinical trials or move to later stages. Clear communication of drug/device candidate potential, as well as possible creative funding/equity models, is crucial in the UK's post-Brexit landscape.

This CEO panel will bring together leaders of UK biopharma to discuss strategies for financing clinical pipelines within the British ecosystem. Topics will include trends in UK venture capital, the London Stock Exchange and AIM markets, licensing deals with NHS trusts, funding opportunities from Innovate UK and the British Business Bank, and partnerships with European and global entities in the context of the UK's evolving relationship with the EU and other international markets.

Melissa Sturgess – CEO – **Ananda Developments**
Rupert Haynes – CEO – **Avata Biosciences**
Alex Blyth – CEO – **Lift Biosciences**
Lee Harle – CEO – **SolasCure**
Krzysztof Potempa – CEO & Founder – **Braincures**

17:50 **Chair's Day 1 Summary**

17:55 **Networking Drinks & Canapés Reception**
(complementary admission to all conference participants)

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Day 2: 5th March 2024

08:15 – 08:55 **Registration & Morning Refreshments**

08:55 **Chair's Day 2 Welcome Address**

09:00 Keynote

Meaningful Patient Engagement in Clinical Trials: Beyond Tokenism to True Value

Patient centricity has become a buzzword in clinical research, but truly incorporating patient perspectives in ways that add tangible value remains a challenge. While efforts to include patient input have increased, there's a growing need to ensure these initiatives genuinely benefit patients and enhance trial design and execution.

This presentation will explore innovative approaches to meaningfully integrate patient opinions into clinical trials. Speakers will discuss strategies that go beyond superficial involvement, examining how to incorporate patient insights into protocol design, endpoint selection, and trial execution. They will address the balance between scientific rigor and patient-centric approaches, with a focus on different therapeutic areas including rare diseases and oncology. Real-world examples will illustrate successful patient engagement initiatives that have improved trial relevance, enhanced recruitment and retention, and ultimately led to better patient outcomes. Attendees will gain practical insights on implementing patient-centric approaches that create mutual value for both patients and researchers.

Ian Hodgeson – Head of Operations – **Corbus Pharmaceuticals**

09:30 Keynote

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10:00 Keynote

Optimizing Clinical Trial Value in the UK: Insights from the NCVR Pilot Partnership

The National Clinical Value Review (NCVR) initiative, led by NIHR/NHS England, with a pilot implementation of ICVR in early phase oncology trials through the co-funded ECMC Network, represents a pioneering approach to balancing NHS research capabilities with sponsor requirements. This session explores early learnings from this innovative model designed to enhance the UK's clinical research landscape while ensuring sustainable value for all stakeholders.

In this co-presented session, stakeholders from the pilot program will share insights from the groundbreaking NCVR implementation. The presentation will examine how this collaborative approach is reshaping the evaluation of clinical trial costs and value delivery in the UK healthcare system. Topics will include the use of these standardized cost assessment frameworks in the early phase oncology environment, strategies for optimizing process between sponsors and sites, and learnings from both sponsor and site sides of the pilot.

Kieran Prior – Engagement & Impact Lead **– CRUK**

10:30 Keynote

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11:00 **Coffee Break**

11:30 Insight

Biomarker Strategy and Pre-Trial Preparation: Insights from DMX4001:T1D Phase 1b Journey

The transition from preclinical to Phase 1b demands meticulous preparation, particularly in biomarker selection and validation. This session uses the DMX4001:T1D program as a case study to explore the critical considerations in biomarker implementation, assay development, and strategic planning that underpin successful early-phase trials.

In this session, we will examine the strategic approach to pre-trial preparation through the lens of biomarker implementation. Using DMX4001:T1D as our framework, we will explore the selection and validation of key biomarkers for Type 1 Diabetes trials, including considerations for immune monitoring, beta cell function assessment, and disease progression markers. Discussions will cover practical aspects such as sample collection logistics, biomarker assay validation, data standardization, and the integration of biomarker strategies into protocol design. Participants will gain insights into timeline management for biomarker development, vendor selection for specialized testing, and strategies for maximizing the scientific value of early-phase trials through robust biomarker implementation.

Nara Daubeney – CEO & Co-Founder – **Phaim Pharma**

12:00 Insight

Strategies for Patient Recruitment & Retention for Early-Stage Biopharma: Building Foundations for Trial Success

It's never too early to begin patient engagement efforts. The power of the patient voice is essential to drive trial success and future regulatory approval. Early-stage biotechs face unique challenges in establishing meaningful patient connections while managing limited resources and evolving clinical programs.

In this comprehensive session, Julie will share Pleco Therapeutics' innovative approaches to patient engagement and their impact on clinical development strategy. The discussion will explore practical methods for establishing and maintaining relationships with patient advocacy organizations, creating effective patient panels, and incorporating patient insights into protocol design. The session will include real-world examples of how patient feedback has shaped trial design decisions, improved recruitment strategies, and enhanced retention rates.

Julie Powell – Corporate Development Director – **Pleco Therapeutics**

12:30 Insight

Academic Partnerships in Clinical Research: Leveraging UK's Educational Infrastructure for Trial Success

The unique position of academic institutions in clinical research creates powerful opportunities for enhancing trial delivery. This session explores how academic research organizations (ACROs) bridge the gap between industry sponsors, clinical sites, and traditional CROs, offering distinct advantages in the UK's research landscape.

In this session Gaia will examine the evolving role of academic institutions in delivering industry-sponsored research across the UK. Analysing the unique benefits of the ACRO model, including established site relationships, investigator trust, and integrated research networks within the NHS ecosystem. We'll explore practical considerations of academic partnerships, from operational autonomy to risk management, while examining how these collaborations can accelerate site activation and enhance recruitment.

Gaia Kiru – Head of Operations & Partnerships – **Imperial College London**

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13:00 **Lunch**

14:00 Keynote

Navigating the NHS Landscape: A Case Study in Successful Clinical Trial Implementation

Conducting clinical trials within the National Health Service (NHS) presents unique opportunities and challenges. Understanding the intricacies of the NHS framework is crucial for successful trial execution in the UK healthcare system.

This session will present a comprehensive case study of a clinical trial conducted within the NHS, offering valuable insights into the practicalities of research in this setting. Walking attendees through the entire process, from initial approvals to study completion. Discussing strategies for navigating NHS ethics committees, securing local trust approvals, and effectively collaborating with NHS staff. The session will also address challenges such as patient recruitment within NHS populations, integration with existing NHS services, and data access considerations.

Matt Kelly – Head of Clinical & Operations – **Caristo Diagnostics**

14:30 Keynote

The UK Biotech Landscape: A Founder's Vision for Clinical Innovation

In an era of evolving healthcare innovation, the UK's position as a hub for clinical research continues to adapt. This intimate discussion with a successful preclinical-stage CEO explores their journey from founding to funding, and their strategic view of the UK's future in global biotech development.

In this revealing fireside chat, we will share their firsthand experience of building and funding a preclinical-stage company in the UK's dynamic biotech ecosystem. The conversation will explore their strategic rationale for selecting the UK as their base for future clinical development, insights into accessing and leveraging local scientific talent, and their perspective on the changing landscape of biotech funding and support structures. We'll delve into their company's journey securing funding through clinical development, their views on the UK's competitive advantages and challenges in the global biotech race, and their vision for scientific innovation in the post-Brexit era.

15:00 Closing Keynote

Leveraging the NHS Primary Care Network: Optimizing Patient Identification for Clinical Research

The NHS Primary Care Network represents an untapped resource for clinical trial recruitment, offering access to diverse patient populations across the UK through established GP practices and community healthcare settings. This session explores practical approaches to utilizing this extensive network while addressing the challenges and opportunities in primary care research engagement.

In this session Andy will share real-world experiences of successful patient identification strategies through primary care collaboration. The presentation will examine innovative approaches to engaging GP practices, implementing efficient screening protocols, and building sustainable research partnerships within primary care settings. Topics will include practical solutions for integrating research activities into primary care workflows, successful models for GP practice engagement, and strategies for overcoming common barriers to primary care research participation while maintaining quality patient care.

Andy Thurstan – Senior Director, Patient Services – **Wave Life Sciences**

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15:30	**Chair's Day 2 Summary & Closing Remarks**

End of Conference