COG UK

Copthorne Tara Hotel – London Kensington

3rd – 4th March 2026

Clinical Outsourcing Group

SPEAKERS

Fiona Shields – Head of UK Clinical Operations – **Novartis**
Divya Chadha Manek – Director, Clinical Operations (ex US) – **EyeBio**
Suki Balendra – Director, Strategic Partnerships (Paddington Life Sciences) – **Imperial College NHS**
Sverre Bengtsson – CEO – **Digital Trial Solutions**
Shikta Das – Scientific Lead Real World Evidence, Oncology – **AstraZeneca**
Karolin Kroese – ECMC Programme Lead – **Cancer Research UK**
Neil Bhattacharjee – ECMC Project Manager – **Cancer Research UK**
Nara Daubeney – CEO – **Phaim Pharma**
Kingyin Lee – Head of Clinical Trials - **MHRA**
Andy Thurstan – Senior Director, Patient Services – **Wave Life Sciences**
Graeme Duncan – Head of Clinical Development – **Neurocentrx**
Jamie Cole – Director, Sales - **Optum**
Bradley Norton – VP Clinical Operations – **Gylden Pharma**
Liam Spencer – Senior Regulatory Project Manager – **Lumis International**
Joab Williamson – VP Operations – **Faron Pharmaceuticals**
Diane Chisholm – Head of Global Clinical Operations – **Owkin**
Ben Dudley – Chief Commercial Officer – **MMS**
Mireille Lovejoy – Director, Clinical Risk Management & Process Excellence – **GE Healthcare**
Karthik Maddi – Global Associate Director & Lead, Clinical Development, Medical Affairs – **Pharmanovia**
Sarah Deeley – Director, Country & Site Operations - **Biogen**
Hans-Jürgen Gruss – CMO – **Kadence Bio**
Julia Vassiliadou – VP Clinical Operations – **F2G**
Adeyemi Adeyi - Director, Medical Monitoring - **Aixial Group**
Joseph Milne – Director, Clinical Research – **Scottish Brain Sciences**
Antonella Chiucchiuini – Director, Fair Market Value Lead, Global Medical Evidence – **Takeda**
Yvanne Enever – Founder – **PHARMExcel**
Emma Kinloch – CEO – **Salivary Gland Cancer UK**
Daizy Moumi – Associate Director, Clinical Operations – **Complement Therapeutics**
Kate Greenwood - Senior Improvement Delivery Manager - **HRA**
Rebecca Cosgriff – Scientific Director, Data Partnerships & Portfolio Strategy – **LifeArc**
Tiffany Thorn – CEO – **BiVictriX Therapeutics**
Fiona Malaj - Legal Consultant - **Salvius Legal**
Nataly Hastings – CEO – **Cellestial Health**
Milena Kanova-Petrova – SVP & Global Head, General Medicine – **Premier Research**
Sam Windsor – CEO – **Ignota Labs**
David Brennan – CEO – **Aurum Biosciences**
Ryan Geiser – CEO – **Axiom Therapeutics**
Sarah Whalley – Director, Clinical Operations – **U-Ploid Biotechnologies**
Ross Breckenridge – CEO – **Arjuna Therapeutics**
Lucy Clossick Thomson – Head of Clinical Operations – **Purespring Therapeutics**
Claire Herholdt – VP Clinical Operations – **Levicept**
Deirdre Flaherty – VP Product Strategy & Clinical Operations – **Alchemab Therapeutics**
Palak Trivedi - Professor of Cholestatic & Immune-Mediated Liver Disease - **University of Birmingham**
Jay Panchmatia – Industry Consultant, Global Site Contracts, Budgets & Payments
Janette Rawlinson – Patient Advocate / Consultant
Vivek Talwar – Senior Manager, Product Management – **Medidata**
Rachel Wodarski – R&I Business Manager – **The Christie NHS Foundation Trust**
Duncan Hall – CEO – **TRI**

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DAY 1 | 3rd March 2026

07:30 **Registration & Morning Refreshments**

08:25 **Organiser's Welcome Address**
Alexander O'Leary – Director – **PBC Group**

08:30 **Chair's Welcome Address**
Sverre Bengtsson – CEO – **Digital Trial Solutions**

Strategic Foundations

08:35 **KEYNOTE PANEL**
Bringing Clinical Research Back to the UK: Capitalising on Global Opportunities

UK clinical research stands at a pivotal moment, with new geopolitical dynamics and regulatory frameworks creating unprecedented opportunities to reclaim its position as a global leader in pharmaceutical innovation. Strategic positioning requires leveraging recent political shifts, and addressing longstanding challenges in regulatory efficiency and health technology assessment.

The panel will examine how changes in US administration policies and trade relationships present new avenues for UK-based clinical research investment and collaboration. Exploring strategies for maximising the UK's unique post-Brexit regulatory positioning to attract international sponsors, while addressing critical bottlenecks in regulatory approval timelines that have historically hindered competitiveness.

Fiona Shields – Head of UK Clinical Operations – **Novartis**
Divya Chadha Manek – Director, Clinical Operations (ex US) – **EyeBio**
Suki Balendra – Director, Strategic Partnerships (Paddington Life Sciences) – **Imperial College NHS**
Lucy Clossick Thomson – Head of Clinical Operations – **Purespring Therapeutics**
Sarah Deeley – Director, Country & Site Operations – **Biogen**
Janette Rawlinson – Patient Advocate / Consultant

09:20 **KEYNOTE**
One Team, One Study: Building High-Performance Sponsor-CRO Partnerships Across the Clinical Trial Lifecycle

Clinical trial complexity continues to escalate through innovative designs, global footprints, and expanding technology ecosystems, creating acute pressure to accelerate delivery whilst maintaining quality and cost efficiency. Understanding how to structure truly integrated sponsor-CRO partnerships that eliminate operational silos from partner selection through study close-out is essential for organisations seeking faster timelines, improved cost management, and superior trial outcomes.

In this session, Adeyemi will introduce the "One Team, One Study" operating model that positions CROs as fully integrated extensions of sponsor organisations, exploring how aligned goal-setting, transparent communication frameworks, and collaborative risk management approaches impact delivery performance across the clinical trial lifecycle. Discussing partner selection criteria beyond traditional capability assessments, governance structures that enable unified decision-making, and day-to-day operational practices that break down organisational boundaries to help sponsors maximise CRO value at every study phase whilst building partnerships that consistently deliver the speed, efficiency, and quality improvements necessary to bring innovative treatments to patients more quickly and affordably in today's demanding clinical development environment.

Adeyemi Adeyi - Director, Medical Monitoring - **Aixial Group**

09:50 **KEYNOTE**

Strategic Infrastructure and Collaboration: Driving Early Phase Clinical Trial Delivery in the UK

Early phase clinical trial delivery in the UK faces challenges related to patient identification, geographical accessibility, and recruitment efficiency, factors that can significantly impact trial delivery and data quality. Strategic infrastructure development and collaborative engagement between NHS trusts, academic centres, and research networks are essential to improving trial delivery, ensuring equitable access for diverse patient populations, and optimising recruitment processes through coordinated identification and referral systems.

In this session, the ECMC (Experimental Cancer Medicine Centres) Programme Office will explore how strategic infrastructure and collaborative engagement are driving improvements in early phase clinical trial delivery across the UK. The discussion will highlight the importance of trial identification databases in supporting equitable access and enhancing recruitment efficiency, addressing geographical and demographic barriers that have historically limited participation. Real-world examples will illustrate how this collaborative model is working in practice, demonstrating the impact of coordinated approaches that connect patients with appropriate trials through systematic identification systems, multi-site partnerships, and streamlined referral pathways ultimately improving both access and recruitment outcomes across diverse UK populations.

Karolin Kroese – ECMC Programme Lead – **Cancer Research UK**
Neil Bhattacharjee – ECMC Project Manager – **Cancer Research UK**

10:15 **KEYNOTE**

Operationalizing Large-Scale Global Clinical Trials Using a Site-Centric Approach

As global clinical trials increase in size and complexity, sponsors face growing challenges translating strategic intent into consistent execution across regions, healthcare systems, and study sites. When planning does not fully reflect how studies are executed at the site level, managing large global programs becomes increasingly challenging as they scale. Grounding strategy in site-level execution provides a more durable foundation for scalable global trial delivery.

Drawing on practical operational experience, this session will explore how large global studies are structured today and how site-level insights inform country strategy, regional coordination, and global governance. Using examples from multinational programs, including mature research markets such as the UK, the discussion will focus on how sponsor and CRO roles can be aligned, communication and oversight simplified, and complexity reduced for sites while maintaining control at scale. Attendees will leave with strategic principles and practical considerations to support more predictable, efficient global trial execution.

Milena Kanova-Petrova – SVP & Global Head, General Medicine – **Premier Research**

10:45 **Morning Refreshments & Networking Break**

Partnership Strategy

11:15 **KEYNOTE**

Emerging Biopharma Vendor Selection: Strategic CRO & Vendor Partnerships

For resource-constrained biopharma companies, selecting the right vendors represents a critical strategic decision that can determine trial success, timeline adherence, and ultimately company survival. With limited budgets, lean internal teams, and intense investor scrutiny, smaller companies must navigate complex vendor evaluation processes while building partnerships that provide both operational excellence and flexible support tailored to their unique constraints and growth trajectories.

The panel will outline systematic approaches to vendor evaluation that balance cost considerations with quality requirements, helping emerging companies identify partners whose capabilities and business models align with their specific therapeutic areas and development stages. Exploring essential selection criteria beyond pricing, including cultural fit, communication protocols, and scalability factors that ensure vendor relationships can evolve with company growth and changing investor expectations.

Chair: **Nara Daubeney** – CEO – **Phaim Pharma**
Graeme Duncan – Head of Clinical Development – **Neurocentrx**
Claire Herholdt – VP Clinical Operations – **Levicept**
Bradley Norton – VP Clinical Operations – **Gylden Pharma**
Sarah Whalley – Director, Clinical Operations – **U-Ploid Biotechnologies**
Deirdre Flaherty – VP Product Strategy & Clinical Operations – **Alchemab Therapeutics**
Julia Vassiliadou – VP Clinical Operations – **F2G**

12:00 **KEYNOTE**

Transforming UK Trials: Using Primary Care Data to Transform Trials From Start to Finish

UK clinical research faces major challenges: from protocol design and study planning to set up, recruitment, delivery and retention. Each stage can introduce delays, increase workload and drive-up costs.

In this presentation Jamie will demonstrate how closer collaboration with primary care, supported by comprehensive, coded GP data, can help to address these pressures across the full trial lifecycle. Showcasing how the The Recruit solution from Optum, embedded in the UK's leading GP clinical system, strengthens site viability assessments, enables targeted cohort engagement at scale, and helps to unlock powerful real-world evidence capabilities. Leveraging primary care data through Recruit can support precise patient identification and streamline site selection. Also highlighting how Recruit helps to reduce administrative burden, unlock real-world data and ultimately lower trial costs across the UK.

Jamie Cole – Director, Sales - **Optum**

12:30 **KEYNOTE**

Achieving Diversity in Clinical Trials: Leveraging NHS Partnerships

Clinical trials have historically struggled with participant diversity, resulting in medicines that may not reflect the efficacy and safety profiles across the populations they serve. The NHS, with its universal healthcare model and access to diverse patient populations across the UK, presents a unique opportunity to address longstanding representation gaps in clinical research. Successful diversity strategies now require meaningful partnerships that go beyond transactional site relationships to embed equity considerations throughout trial design and delivery.

In this session Suki will examine how sponsors can forge effective partnerships with the NHS to enhance participant diversity in clinical trials, identifying specific barriers to diverse recruitment and practical solutions for overcoming them. Exploring strategies for engaging underrepresented communities, leveraging NHS infrastructure and patient networks, and designing trials that are accessible and relevant to diverse populations while maintaining scientific rigour and regulatory compliance.

Suki Balendra – Director, Strategic Partnerships (Paddington Life Sciences) – **Imperial College Healthcare NHS Trust**

12:55 **Lunch & Networking Break**

Vendor Selection & Site Strategy

13:55 **KEYNOTE PANEL**

Aligning Site, CRO, and Sponsor Perspectives on Fair Market Value

Misalignment between clinical trial sites, sponsors, and CROs during budget negotiations often stems from a lack of mutual understanding and transparency. Sites may propose costs based on their own models, which often don't align with sponsor/CRO benchmarks. This disconnect highlights the importance of thorough budget assessments and proactive communication with CROs in the negotiation process.

In this discussion we will discuss how contributing to a global costing task force and leveraging experience across all three perspectives—site, CRO, and sponsor—helps bridge these gaps. It also fosters a shared understanding of how each stakeholder interprets fair market value, which is essential for building sustainable, equitable site budgets.

Chair: **Antonella Chiucchiuini** – Director, Fair Market Value Lead, Global Medical Evidence – **Takeda**
Jay Panchmatia – Industry Consultant, Global Site Contracts, Budgets & Payments
Vivek Talwar – Senior Manager, Product Management – **Medidata**
Rachel Wodarski – R&I Business Manager – **The Christie NHS Foundation Trust**

14:25 **KEYNOTE**

3 Technology Use Cases Shaping the Future of Trial Design and Implementation

As clinical development grows more complex and competitive, sponsors must leverage technology not just for efficiency, but as a strategic enabler of smarter trial design, adaptive execution, and sustainable innovation. When technology is applied reactively or in isolation, its impact remains limited. Integrating advanced tools throughout the trial lifecycle - from design through delivery - creates the foundation for more predictable outcomes and scalable operational models.

Drawing on emerging industry practices, this session will explore three critical use cases where technology is reshaping how trials are planned and executed. The discussion will examine how data-driven modelling and simulation tools are optimizing trial design and reducing risk, how real-time analytics enable dynamic decision-making during execution, and how artificial intelligence is fundamentally transforming trial delivery, from planning and workflows to the roles sponsors and partners play. Using practical examples, attendees will gain insight into how these technologies can be applied to improve quality, timelines, and decision confidence while positioning clinical operations for the next era of development.

Ben Dudley – Chief Commercial Officer – **MMS**

14:55 **KEYNOTE**

Streamlining Clinical Trial Set-Up: Health Research Authority

Clinical trial initiation in the UK has historically faced challenges related to complex, variable and unpredictable set-up pathways creating administrative burdens that can delay study start-up at site and impact sponsor decisions on site selection. Streamlining these processes is critical to maintaining the UK's competitiveness as a clinical research destination.

In this presentation, Kate will provide an update on the HRA's collaborative work to improve study set-up for clinical trials in the UK as part of the broader UK Clinical Research Delivery Programme, which is led by the Department of Health and Social Care. From an operational perspective, the presentation will demonstrate how these improvements translate into tangible benefits for trial sponsors, including simplified procedures, greater predictability in set-up timelines, clearer guidance and reduced administrative burden

Kate Greenwood - Senior Improvement Delivery Manager - **HRA**

15:20 **Afternoon Coffee & Networking Break**

International & Partnership Strategy

15:50 **KEYNOTE**

Difficult Indications, Predictable Pitfalls: Designing Clinical Trials to Avoid Historical Failures in HR-MDS

Clinical development in challenging indications like High-Risk Myelodysplastic Syndromes frequently repeats historical mistakes, with trial designs failing to account for well-documented pitfalls that have derailed previous programmes. Understanding how to systematically analyse past failures and translate those insights into robust trial designs and delivery strategies is essential for improving success rates in complex haematological malignancies.

In this session, Joab will present a practical case study on learning from historical HR-MDS clinical development failures, exploring how structured retrospective analysis informs contemporary trial design. Drawing on an upcoming collaborative review with Yale, discussing recurring failure modes including population heterogeneity, endpoint variability, statistical design flaws, and data completeness challenges to help clinical operations teams implement proactive "pre-mortem" approaches that systematically identify and mitigate predictable risks before study initiation, creating repeatable methodologies applicable across difficult indications where historical analysis transforms past failures into future competitive advantage.

Joab Williamson – VP Clinical Operations – **Faron Pharmaceuticals**

16:20 **KEYNOTE**

The Australian Clinical Trial Reality Check: A UK Sponsor's Unfiltered Perspective

Common narratives around Australian clinical trials emphasise R&D tax incentives and streamlined ethics approvals, creating expectations of straightforward international expansion for UK biopharma sponsors. However, the operational reality involves complex structural challenges and permanent organisational changes that extend far beyond simple trial execution.

In this session Hans-Jürgen will provide an unvarnished examination of conducting Australian trials from UK headquarters, exploring practical challenges including establishing effective governance

frameworks across incompatible time zones, navigating Australian-specific compliance requirements, and addressing intellectual property allocation complexities that necessitate Australian entity creation.

Hans-Jürgen Gruss – CMO – **Kadence Bio**

16:45 **KEYNOTE PANEL**
Generating Patient Data for UK Rare Disease Clinical Trials

Rare disease clinical research faces unique challenges stemming from small patient populations, geographic dispersion, diagnostic delays, and fragmented patient information across multiple NHS trusts and specialist centres. Successful trial execution depends on identifying eligible patients, capturing comprehensive clinical histories, and generating robust datasets that can support regulatory submissions while navigating complex data governance frameworks, patient consent requirements, and the practical realities of limited patient numbers.

In this discussion, the panel will explore strategies for generating high-quality patient data to support clinical trials in the UK. They will examine approaches to identifying and characterising patient populations through NHS records, specialist registries, and patient organisation networks, and discuss methods for collecting natural history data, biomarkers, and clinical outcomes that strengthen trial design and regulatory interactions.

Chair: **Emma Kinloch** – CEO – **Salivary Gland Cancer UK**
Rebecca Cosgriff – Scientific Director, Data Partnerships & Portfolio Strategy – **LifeArc**
Palak Trivedi - Professor of Cholestatic & Immune-Mediated Liver Disease - **University of Birmingham**
Andy Thurstan – Senior Director, Patient Services – **Wave Life Sciences**

17:15 **Chair's Day 1 Summary**
Sverre Bengtsson – CEO – **Digital Trial Solutions**

17:15 **Networking Drinks & Canapés Reception**
(complementary admission to all conference participants)

DAY 2 4th March 2026

08:00 **Registration & Morning Refreshments**

08:30 **Chair's Day 2 Welcome Address**
Sverre Bengtsson – CEO – **Digital Trial Solutions**

Financial & Clinical Strategy

08:35 **KEYNOTE C-SUITE PANEL**

Biopharma Investment and Operations in the UK: From Discovery to Clinic

The investment landscape for UK biotechnology has fundamentally shifted, with investors applying increasingly stringent criteria across all development stages, demanding clearer value propositions, and showing marked preferences for specific therapeutic areas and scientific approaches. Success requires sophisticated understanding of investor sentiment spanning preclinical validation through clinical development, strategic positioning of research portfolios, and adaptive financing strategies that account for therapeutic area dynamics, competitive landscapes, and evolving market conditions.

In this C-Suite panel discussion, industry leaders will share firsthand experiences navigating recent funding challenges across the UK biopharma sector, examining how investor sentiment varies between therapeutic areas, development stages, and the strategic implications for portfolio prioritisation from discovery through clinical trials. They will explore innovative financing structures including risk-sharing arrangements, milestone-driven funding, and strategic collaborations.

Chair: **Sverre Bengtsson** – CEO – **Digital Trial Solutions**
Neil Murray – CEO – **ReNewVax**
Nataly Hastings – CEO – **Cellestial Health**
Sam Windsor – CEO – **Ignota Labs**
David Brennan – CEO – **Aurum Biosciences**
Yvanne Enever – CEO – **PHARMExcel**
Ryan Geiser – CEO – **Axiom Therapeutics**
Ross Breckenridge – CEO – **Arjuna Therapeutics**

09:20 **KEYNOTE**

Advice on Advice: De Risking Clinical Development Through Scientific Advice

Clinical trials are often cited as accounting for 60-70% of R&D costs and are associated with a 90% attrition rate. How can regulatory scientific advice improve these outcomes? How does scientific advice influence market authorisation?

In this presentation Liam will discuss the types, benefits, opportunities, risks, and the future of scientific advice. By referring to personal cases and experience, Liam will outline when and how scientific advice can be utilised to de-risk clinical development and improve outcomes.

Liam Spencer – Senior Regulatory Project Manager – **Lumis International**

09:50 **KEYNOTE**

Navigating Alzheimer's Clinical Research: The Critical Role of Site Expertise and Collaboration

Conducting clinical trials in Alzheimer's disease presents unique methodological and operational challenges that extend far beyond standard trial execution, from complex diagnostic criteria and heterogeneous disease progression to protocol compliance difficulties and caregiver burden. The complexity of Alzheimer's research demands exceptional site capabilities, experienced principal investigators with deep therapeutic area knowledge, and collaborative partnerships that recognise the nuanced demands of working with cognitively impaired populations and their care networks.

In this session Joe will examine the specific challenges that distinguish Alzheimer's trials from other therapeutic areas, including patient identification and recruitment barriers, informed consent considerations, endpoint assessment complexities, and retention strategies for long-duration studies. Exploring how sponsors can identify and cultivate relationships with experienced sites and principal investigators who possess the specialised expertise required, while fostering collaborative approaches that leverage clinical insights to optimise protocol design, enhance patient and caregiver experience, and improve data quality in this demanding research landscape.

Joseph Milne – Director, Clinical Research – **Scottish Brain Sciences**

10:15 **KEYNOTE**

Optimizing Clinical Trial Site Budgeting and Payments: Lessons from Two Decades in Global Operations, in Collaboration with Medidata

Drawing on more than 20 years of hands-on experience in clinical trial site budgeting and payments at GlaxoSmithKline and TFS HealthScience, Jay Panchmatia explores the art and science of building efficient, transparent, and scalable financial frameworks for global studies. Examining the strategic design of country-specific budget templates, the real-world challenges of aligning internal cost structures with market expectations, and the critical role of data-driven planning in strengthening site relationships and improving financial predictability.

In this session Jay will share practical insights into how Medidata Grants Manager can act as a transformative platform for planning and managing global study budgets. Presenting expert perspectives on how he has addressed longstanding and emerging budgeting challenges, ensured alignment between sponsors and sites, and adapted approaches as industry practices have evolved over the decades.

Jay Panchmatia – Industry Consultant, Global Site Contracts, Budgets & Payments

10:45 **Morning Refreshments & Networking Break**

11:05 **KEYNOTE**

MHRA Initiatives: Strategic Enhancements to Accelerate UK Clinical Trial Delivery

The MHRA is implementing comprehensive strategic initiatives designed to strengthen the UK's position as a leading destination for international clinical research whilst maintaining rigorous safety and quality standards. Understanding how evolving regulatory processes, enhanced early-phase guidance, and evidence-based assessment frameworks are reducing timelines and improving sponsor experience is essential for organisations planning UK clinical development programmes.

In this session, Kingyin will share current and forthcoming regulatory enhancements, exploring how streamlined review processes, and strategies in clinical trials regulation may support innovation, and approval timelines. This will include artificial intelligence deployment to support assessment, new approach to supporting novel trial designs, and collaborative frameworks to help organisations understand how the MHRA's modernisation agenda creates advantages for UK clinical research whilst ensuring patient protection remains paramount.

Kingyin Lee – Head of Clinical Trials - **MHRA**

11:30 **KEYNOTE**

Strategic Clinical Trial Contracting: Risks, Realities & Smarter Negotiations

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, the Salvius Legal team 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. The presentation includes real case studies and also topics such as GDPR and AI.

Myrthe Trompert - CEO - **Salvius Legal**
Fiona Malaj - Legal Consultant - **Salvius Legal**

Mastering Bid Defence

12:00 **KEYNOTE**

Sponsor Perspective: Transforming Challenge into Competitive Advantage

Traditional bid defence strategies often focus solely on reactive damage control, creating adversarial dynamics that compromise stakeholder relationships and undermine long-term partnership value. Mastering effective bid defence requires proactive strategic frameworks that transform competitive challenges into opportunities for demonstrating enhanced value proposition, strengthening client relationships, and establishing market differentiation that positions sponsors as preferred partners for future collaborations.

In this session Diane will explore comprehensive methodologies for developing robust bid defence capabilities that go beyond price protection, including techniques for creating compelling value narratives that resonate with procurement decision-makers and establishing proactive communication frameworks that address concerns before they become competitive vulnerabilities.

Diane Chisholm – Head of Global Clinical Operations – **Owkin**

12:15 **KEYNOTE**

The Art of Bid Defence: Sponsor and CRO Perspectives on Protecting Strategic Partnerships

In this interactive panel session, we will continue to explore bid defence best practices from both client and vendor perspectives. Through real-world case studies and audience Q&A, panellists will examine why effective bid defence processes are critical for maintaining partnership quality, how to structure defence opportunities that drive value creation rather than cost erosion, and practical strategies for transforming competitive challenges into relationship-strengthening opportunities.

Diane Chisholm – Head of Global Clinical Operations – **Owkin**
Daizy Moumi – Associate Director, Clinical Operations – **Complement Therapeutics**

12:30 **KEYNOTE**

The Future of RBQM for Early Phase Studies Starts Here

RBQM is essential for protecting patient safety and driving quality by design principles across all phases of clinical research and is arguably more important in early phase studies than any other. Yet in practice, the application of RBQM to early phase is highly inconsistent, often relying on manual processes and individual judgement instead of structured processes, supported by compliant technology.

In this session Duncan will share where the gaps are in RBQM adoption and implementation, what's at stake when sponsors get this wrong, as well as how to move forward to implement a rigerous RBQM strategy for your trials. Attendees will leave with actionable insights on how flexible, structured monitoring can: Improve visibility into what's been reviewed, by whom and why, Drive efficiency and consistency without rigidity, and, Enable better decision-making and prioritization across diverse study designs. This session will provide you with a roadmap to bringing early phase studies into the RBQM fold.

Duncan Hall – CEO – **TRI**

13:00 **Lunch & Networking Break**

Technology & Regulatory Strategy

14:00 **KEYNOTE**

ICH E6(R3) Implementation: Sponsor Oversight and Risk Management for Emerging Biopharma

The implementation of ICH E6(R3) brings enhanced expectations for sponsor oversight and risk management that can present challenges for smaller biopharma companies with limited resources and regulatory experience. Successfully navigating these new requirements demands strategic planning, efficient resource allocation, and practical approaches to quality management that balance compliance rigor with operational feasibility.

In this session Mireille will provide step-by-step guidance for conducting comprehensive gap analyses against ICH E6(R3) requirements, helping smaller companies identify priority areas for immediate attention and longer-term development. Demonstrating practical approaches to updating standard operating procedures and quality management systems without overwhelming existing infrastructure, while exploring cost-effective strategies for implementing risk-based quality monitoring programs.

Mireille Lovejoy – Director, Clinical Risk Management & Process Excellence – **GE Healthcare**

14:30 **CLOSING KEYNOTE PANEL**

AI in Clinical Development: From Hype to Practice

Artificial intelligence in clinical research has reached a pivotal moment. Practical applications are now delivering measurable operational benefits, though adoption remains uneven and expectations often unrealistic.

This panel examines proven AI implementations in clinical trials, including automated data cleaning algorithms that reduce monitoring burden, predictive models for patient recruitment and site selection, and signal detection systems that enhance safety oversight. We'll explore the critical distinction between augmented intelligence (supporting human decisions) and artificial intelligence (operating independently), addressing practical considerations for implementation, validation, and regulatory acceptance.

Karthik Maddi – Global Associate Director & Lead, Clinical Development, Medical Affairs – **Pharmanovia**
Shikta Das – Scientific Lead Real World Evidence, Oncology – **AstraZeneca**

15:00 **Chair's Day 2 Summary & Closing Remarks**
Sverre Bengtsson – CEO – **Digital Trial Solutions**

End of Core Conference Agenda

15:00 – 17:00 **eCOA Innovations to Improve Data Quality and Increase Patient Engagement - a 'hands-on' workshop**

As protocols and data requirements become more complex and specialized trials target smaller populations, each patient is more valuable than ever. In this environment, the imperative for patient centricity and stronger patient-site relationships is more relevant and critical than ever before. Human-centric eCOA innovation is essential to achieving these objectives.

Workshop participants will learn what human-centric design looks like when applied to clinical trial patients and sites. Then, they'll see the real-world difference it can make—exploring how patient-centric design and uMotif's modern eCOA/ePRO platform helped to simplify the user experience, improve engagement, and increase data quality in a Phase III rare disease clinical trial. Participants will also gain insight into the latest developments and what's ahead, including recently published industry best practices, ways to streamline measurement instrument licensing, and the growing role of AI in eCOA evolution and use.

Topics	uMotif Presenters
Welcome and Introductions	Bruce Hellman, Chief Patient Officer
Human-centric design *What is it? What does patient-centric and site-centric really mean?*	Bruce Hellman, Chief Patient Officer and Ben James, Chief Design Officer

COG UK

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Case Study – Complex eCOA designs *Through case studies of a Phase III Rare Disease trial and a large-scale RWE study, learn how design innovation can simplify the user experience, improve patient engagement and retention, and increase data quality.*	Ben James, Chief Design Officer
Operational opportunities and challenges in eCOA • Licensing, copy review, UAT, translations • Role of AI • C-PATH industry best practices	Flo Mowlem, PhD, Chief Scientific Officer
Wrap-Up, followed by drinks etc…	Bruce Hellman, Chief Patient Officer

Pre workshop questions:

- In your last study, what was the biggest issue affecting delivery timeline?
- If you could change one thing about eCOA, what would it be?
- What do you believe is the biggest issue for sites when using eCOA systems?

Who Should Attend:
This workshop is ideal for clinical trial professionals, sponsors, researchers, and anyone involved in patient engagement, data capture strategy, or decentralized trial design.

Space is limited with separate registration required, reach out to Hannah at ht@thepbcgroup.com … Further details on session content and timing to follow.