COG: CRO Summit

Embassy Suites by Hilton, RTP

2nd & 3rd December 2025

Clinical Outsourcing Group

SPEAKERS

Gary Zammit – CEO – **Clinilabs**
Paul Johnson – Executive Director, Strategy Development – **PharPoint Research**
Sybil Wilson – Vice President, Global Commercial Operations – **Veristat**
Charlene Dark – COO – **Avania**
Earl Seltzer – Senior Director, Strategy & Innovation – **CTI Clinical Trial & Consulting Services**
Jasmina Jankicevic – CMO – **Indero**
Megan Liles – Vice President, Clinical Delivery – **HGI Clinical**
Tandy Tipps – CEO – **Winniedel Oncology**
John Mann – Senior Vice President, North American Operations – **Avance Clinical**
Trish Landry – Senior Vice President, Clinical Operations – **Beaufort CRO**
Claudia Christian – CCO – **FHI Clinical**
Sandy Robbins – Vice President, Commercial Operations – **MMS**
Chris Learn – Senior Vice President, Cell & Gene Therapy – **Parexel**
Mary Carson – Senior Director, Vendor Management – **Catalyst Clinical Research**
Lorraine Rusch – CEO – **Cardiovascular Clinical Sciences**
Jeanne Hecht – CEO & Chairwoman – **Lexitas Pharma Services**
Brad Doerschuk – President & CEO – **Infocus Clinical**
Karen Chu – Founder & CEO - **Harvest Integrated Research Organization (HiRO)**
Krystyna Kowalczyk – CEO – **Kapadi**
Dan Ballard – SVP, Digital – **Parexel**
David Pomfret – VP, US Clinical Operations – **Mobius Medical**
Brandon Harper - VP of Business Development & COO – **Cenetron**
Daneen Storc – Senior Product Marketing Manager – **M-Files**

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DAY 1 | 2nd December 2025

07:50 **Registration & Morning Refreshments**

08:50 **Organizer's Welcome Address**
Alexander O'Leary – Director – **PBC Group**

08:55 **Chair's Welcome Address**
Jasmina Jankicevic – CMO – **Indero**

Section A
Collaboration & Innovation

09:00 **KEYNOTE**
Strategic Alliances: Transforming CRO Collaboration into Competitive Advantage

Today's clinical research environment is shifting to favor alliances between small- to mid-size CROs with complementary strengths, opening doors to secure sophisticated trials that would be beyond any single organization's reach alone. Understanding how to structure effective inter-CRO collaborations while maintaining operational efficiency and quality is essential for sustainable growth in a specialized market.

In this session, Claudia will share practical insights into winning new business through strategic CRO-CRO partnerships, exploring how joint bid strategies, complementary capability presentations, and unified defense meetings can help get footholds and increase sponsor confidence. Further discussing operational integration frameworks, technology synchronization, communication protocols, and talent-sharing strategies to help CROs build seamless collaborative environments that preserve individual strengths while eliminating the handoff inefficiencies that typically challenge multi-vendor trial execution.

Claudia Christian – CCO – **FHI Clinical**

09:25 **KEYNOTE**
Leveraging Technology for Seamless Collaboration Across Distributed Teams

In today's globalized clinical research landscape, effective collaboration among teams across multiple locations, sponsors, sites, and vendors is paramount. Automating mission-critical trial workflows and processes are giving trial sponsor and CRO operational teams an advantage on reducing workflow friction, harnessing AI to enhance data quality through computer-assisted redaction of PHI, early identification of bottlenecks, and real-time study progress visibility.

In this session Catherine from Judi, will share how CROs, Trial Sponsors, and Sites harness these tools to streamline processes, enhance transparency, ensure stronger regulatory compliance, and improve data quality.

Catherine Tyner – Head of Clinical Strategy – **AG Mednet**

09:50 **KEYNOTE**

Site Collaboration Excellence: Mastering the Unique Dynamics of IVD Clinical Investigations

IVD studies present distinct site management challenges that differ fundamentally from traditional drug or device trials, requiring specialized approaches to ensure quality data generation and regulatory compliance. Understanding the laboratory-centric nature of these investigations and fostering true collaborative relationships with diagnostic facilities is essential for successful study execution.

In this session, Trish will share practical insights into building effective site relationships for IVD studies, exploring how laboratory workflow integration, technical staff engagement, and specialized training impact study timelines and data integrity. Discussing specimen management, laboratory-specific monitoring approaches, and collaborative quality systems to help sponsors navigate the unique intersection of clinical and laboratory environments while avoiding common pitfalls that can compromise IVD studies due to their distinct operational and regulatory requirements.

Trish Landry – Senior Vice President, Clinical Operations – **Beaufort CRO**

10:15 **PANEL**

Collaboration: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to collaboration & innovation.

10:35 **Morning Refreshments & Networking Break**

Section B
Vendor Integration

11:10 **KEYNOTE**

Partnership Excellence: Architecting a Collaborative Vendor Ecosystem

Effective vendor management extends far beyond procurement and contracts, requiring a comprehensive organizational approach to relationship development and governance. Understanding how to structure internal teams, establish clear ownership, and implement sustainable oversight mechanisms is essential for maximizing vendor value while minimizing risk.

In this session, Mary will share practical insights into building robust vendor management systems, exploring how Business Vendor Owner (BVO) roles, cross-functional vendor strategy committees, and purpose-built information platforms impact relationship quality and operational outcomes. Discussing stakeholder inclusion strategies, vendor performance measurement, internal training approaches, and collaborative oversight models to help organizations transform fragmented vendor interactions into partnership ecosystems.

Mary Carson – Senior Director, Vendor Management – **Catalyst Clinical Research**

11:35 **KEYNOTE**

Transforming Clinical Trials: The Impact of Patient Engagement Tools

Tools such as electronic consent (eConsent) and electronic patient reported outcomes (ePRO) are revolutionizing how CROs engage with participants and streamline operations. Incorporating these tools require seamless implementation, and can face adoption challenges.

In this session Stacey will explore the transformative benefits of patient engagement tools, including, Faster Enrollment: how eConsent accelerates the consent process, enabling quicker study launches and patient onboarding. Cost Efficiency: how reducing paperwork and optimizing resources can significantly lower trial costs. Enhanced Engagement: strategies to support participant understanding and retention, ensuring they feel informed and valued.

Stacy Lasser – Senior Project Manager – **Mednet**

12:00 **KEYNOTE**

CRO Strategy for Clinical Development Acceleration

The race to market in today's pharmaceutical industry demands faster clinical development without quality compromises - a key differentiator for forward-thinking sponsors and CROs alike. Identifying strategic approaches that compress timelines while preserving scientific rigor and patient safety has become essential for organizations committed to accelerating patient access to breakthrough therapies.

In this session, Dr. Jankicevic will share practical insights from over 20 years of clinical research experience, exploring how innovative protocol designs, strategic technology deployment, and optimized collaboration models impact development velocity and regulatory success. Discussing strategies and streamlined decision pathways to help CROs transform traditional sequential development paradigms into agile, quality-focused execution frameworks that significantly reduce time-to-market for critical therapies while strengthening rather than compromising the evidence base that supports their approval.

Jasmina Jankicevic – CMO – **Indero**

12:25 **PANEL**

Vendor Integration: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to vendor integration.

12:45 **Lunch & Networking Break**

Section C
Optimizing Resources

2:00 **KEYNOTE**

Financial Horizons: Strategic Resource Planning for CROs in a Challenging Market

CROs face unprecedented financial and operational planning challenges, understanding how to allocate resources effectively while maintaining operational flexibility is essential for sustainable growth. This session examines critical financial indicators and resource allocation strategies that CROs must consider when navigating current market conditions and preparing for future opportunities.

In this session, Paul will share practical insights into short, medium, and long-term financial projections for CROs, exploring how shifting sponsor demands, workforce dynamics, and technology investments impact profitability and operational efficiency. Discussing resource planning, capital expenditure prioritization, and financial risk mitigation to help CROs build resilience while positioning for strategic advantage in an increasingly competitive landscape.

Paul Johnson – Executive Director, Strategy Development – **PharPoint Research**

2:25 **KEYNOTE**

Advancing Clinical Trials: The Critical Role of Biostatistics Expertise in an Evolving Industry

In the rapidly evolving landscape of clinical trials, biostatistics expertise has become an indispensable component for success. This presentation explores how the integration of advanced statistical methodologies, consultative approaches, risk based and innovative technologies is reshaping the clinical development process across pharmaceutical, biotech, and medical device sectors.

Adam will examine the pivotal role that expert biostatisticians play in optimizing clinical trials and clinical programs, from protocol design through regulatory submission and defense. The discussion will highlight how early and often strategic statistical consulting can add significant value to clinical programs by enhancing trial design efficiency and effectiveness. Also discussing the necessity of expert biostatisticians to lead and support the latest innovations, innovative methodologies, and regulatory guidance.

Adam Hamm – SVP, Biostatistics & Strategic Consulting - **SDC**

2:50 **KEYNOTE**

Reimagining CRO Compensation Models for Industry Advancement

The industry has drifted toward procurement-driven contracting models that focus on hourly rates and transactional metrics, fundamentally misaligning incentives between sponsors and CROs. Understanding the psychology of effective compensation structures is essential for creating partnerships that drive innovation and efficiency rather than commoditized service delivery.

In this session, Sandy will share practical insights into alternative CRO compensation frameworks, exploring how value-based pricing, shared risk models, and outcome-linked incentives impact operational excellence and true cost efficiency beyond the illusory savings of procurement-focused negotiations. Discussing the psychological barriers within large CROs that perpetuate inefficient practices, sponsor approaches that inadvertently reward inefficiency, and revolutionary contracting strategies to help forward-thinking organizations create economic structures that properly incentivize the innovation and efficiency improvements needed to advance the entire clinical research ecosystem.

Sandy Robbins – Vice President, Commercial Operations – **MMS**

3:15 **PANEL**

Resourcing: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to optimizing resources.

3:35 **Afternoon Coffee & Networking Break**

Section D

People Development

4:00 **KEYNOTE**

Beyond the Science: How People, Process, and Systems Transform the Business of Life Sciences

In the current competitive talent landscape, building and maintaining high-performing clinical development teams requires innovative approaches to both attraction and retention, with CROs needing to evolve beyond traditional training models to develop and preserve their top performers.

In this presentation Gary will reveal proven strategies for building elite sponsor/CRO partnerships, including talent selection, goal alignment, communication frameworks, and collaborative approaches that consistently drive exceptional clinical development performance.

Gary Zammit – CEO – **Clinilabs**

4:25 **KEYNOTE**

People-Powered Precision: How Talent Structure Drives Operational Execution

Execution lives at the intersection of people, process, and accountability. Building a central lab, clinical supply, and logistics operations around deep subject-matter expertise, intentional role design, and a "don't cheat time" mindset that empowers teams to lead with clarity and precision.

In this session Brandon explores how to structure functional teams to ensure ownership, technical depth, and flexibility without sacrificing compliance or timelines. Learn how aligning team development to service delivery drives consistency, trust, and operational excellence — especially in outsourced models where success depends on reliable, high-accountability execution across roles.

Brandon Harper - VP of Business Development & COO - **Cenetron**

4:50 **KEYNOTE**

People First: Building & Nurturing Talent for CROs

CROs are fundamentally people businesses, and establishing effective talent development strategies is critical for maintaining smooth operations in a competitive market. Examining essential approaches

to training, retaining, and promoting staff that CROs must implement to thrive in current conditions while preparing for future growth opportunities.

In this session, Charlene will share practical insights into short, medium, and long-term talent development strategies for CROs, exploring how evolving sponsor expectations, workforce trends, and career advancement pathways impact operational excellence and employee satisfaction. Discussing talent acquisition, professional development investments, and retention risk mitigation to help CROs build a resilient workforce while creating strategic advantages in an increasingly competitive talent landscape.

Charlene Dark – COO – **Avania**

5:15 **PANEL**
People Development: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to people development.

5:30 **Chair's Day 1 Summary & Closing Remarks**

Jasmina Jankicevic – CMO – **Indero**

5:30 **Networking Drinks & Canapés Reception**

(complementary admission to all participants)

DAY 2 3rd December 2025

08:15 **Registration & Morning Refreshments**

Section E
Industry Advancement & Trends

09:00 **KEYNOTE C-SUITE PANEL**
Industry Predictions for 2026: Navigating the Future of Global Clinical Research

The global clinical research landscape continues to evolve, creating new opportunities and challenges for CROs and their biopharma partners. While emerging technologies and regulatory shifts promise

increased efficiency, geopolitical factors and resource constraints may reshape traditional operational models across regions.

This panel brings together leading CRO executives to discuss their predictions for the clinical research landscape in 2026. Examining how market dynamics, technological innovation, and regulatory developments will impact trial designs, operational strategies, and competitive positioning. The discussion will cover anticipated shifts in site selection preferences, patient engagement approaches, data management requirements, and investment priorities.

Panel Chair: **Sybil Wilson** – Vice President, Global Commercial Operations – **Veristat**
Lorraine Rusch – CEO – **Cardiovascular Clinical Sciences**
Jeanne Hecht – CEO & Chairwoman – **Lexitas Pharma Services**
Brad Doerschuk – President & CEO – **Infocus Clinical**
Karen Chu – Founder & CEO - **Harvest Integrated Research Organization (HiRO)**
Krystyna Kowalczyk – CEO – **Kapadi**

09:45 **Chair's Welcome Address**
Chris Learn – Senior Vice President, Cell & Gene Therapy – **Parexel**

09:50 **KEYNOTE**
Driving Diversity, Equity & Inclusion in Clinical Trials: A Data-Driven Approach

The lack of diversity among principal investigators and patient populations in clinical trials significantly impacts the efficacy of new therapies in real-world settings. This underrepresentation not only undermines global health equity but also introduces unacceptable risks of adverse reactions in different patient cohorts. Moreover, it can jeopardize billions of dollars in research investment.

In this session, the presenter will showcase how leveraging comprehensive data and advanced analytics can revolutionize the approach to diversity, equity, and inclusion (DEI) in clinical trials. Sharing strategies for selecting trial sites to improve diversity and health equity, leveraging AI-powered analytics to enhance trial design, and the role of social determinants of health data in building more inclusive trials.

Reserved for H1

10:15 **KEYNOTE**
Australia Advantage: Unlocking the Pacific Research Powerhouse

Australia offers distinct operational benefits for clinical research that extend well beyond its regulatory incentives, presenting unique advantages when compared to Asian and other emerging markets. Understanding Australia's sophisticated investigator networks, streamlined regulatory framework, patient engagement culture, and available tax incentives is essential for sponsors seeking efficient early-phase execution and high-quality data.

In this session, John will share practical insights into maximizing Australia's research potential, exploring how rapid study start-up timelines, strong therapeutic expertise, and Western standard of care combined with diverse patient populations impact development strategies and global program integration. The discussion will cover the "Global Ready" approach - an expedited pathway that enables rapid Phase I work without IND, concurrent IND preparation, and initiation of Phase II in Australia before

transitioning to US sites upon approval. The operational realities of Australian trial conduct, comparative advantages over Asian markets, patient recruitment capabilities across key therapeutic areas, and integration approaches.

John Mann – Senior Vice President, North American Operations – **Avance Clinical**

10:40 **PANEL**
Industry Advancement: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to industry advancement.

10:55 **Morning Refreshments & Networking Break**

Section F
Technology Disruption

11:30 **KEYNOTE**
Transformation to a Digital First CRO: From Automation to Intelligent Insights

The digitalization of clinical research assets represents a fundamental shift that extends far beyond simple efficiency gains, creating the foundation for advanced analytics and AI-powered innovation. Understanding how to navigate this transition while addressing complex regulatory, data governance, and implementation challenges is essential for organizations seeking sustainable competitive advantage.

In this session, Dan will share practical insights from implementing 'digital workers' across diverse business functions, exploring how robotic process automation, natural language processing, and machine learning capabilities impact operational excellence from routine administrative tasks to complex data analysis. Discussing the progression from basic automation to hyper-automation, regulatory considerations, and strategic frameworks for technology selection to help organizations build comprehensive digital strategies that deliver measurable improvements in quality, speed, and risk management while unlocking the full value of data assets.

Dan Ballard – SVP, Digital - **Parexel**

11:55 **KEYNOTE**
Leveraging Enablement Technology for Optimal Site Performance

Clinical study sites are the backbone of successful trials, but often face challenges related to limited resources and process inefficiencies. Discover how innovative tools can reduce bottlenecks during study start-up, improve data quality, and enable sites to focus on what matters most – delivering high-quality patient care and reliable study results.

In this session Catherine will discuss how site enablement technology can be a game-changer in streamlining processes, enhancing reporting, and helping sites achieve more with their available resources. Providing practical insight into implementing site enablement technologies and strategies to maximize site performance and efficiency.

Catherine Gregor – Chief Clinical Trial Officer - **Florence Healthcare**

12:20 **KEYNOTE**

The AI Frontier: Balancing Innovation and Pragmatism in Clinical Research

The rapid evolution of artificial intelligence in healthcare applications presents both significant opportunities and substantial implementation challenges for stakeholders. Understanding the practical realities of AI adoption, including organizational readiness and regulatory considerations, is essential for developing balanced implementation strategies.

In this session, David will share practical insights from his experience with clients implementing AI in medical and treatment applications, exploring how organizational technology appetite, change management, and human-AI collaboration models impact successful implementation and value realization. Discussing AI applications in clinical decision making, resource optimization, and patient monitoring through personalized health technologies, before examining product development perspectives, and real-world case studies highlighting both implementation successes and critical cautions that emerge across these healthcare AI deployments.

David Pomfret – VP, US Clinical Operations – **Mobius Medical**

12:45 **PANEL**

Technology Disruption: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to the adoption of technology.

1:00 **Lunch & Networking Break**

2:00 **Delegate Prize Draws**

Section G
Effective Operations

2:10 **KEYNOTE**

Beyond Technology: Cultivating Human Connections for Oncology Site Excellence

The world is becoming digitalized however the fundamental importance of genuine site relationships in oncology trials is often overlooked. Understanding how to build and maintain meaningful connections with oncology investigators and site staff across diverse global environments is essential for successful study execution.

In this session, Tandy will share practical insights into developing authentic site partnerships in key oncology markets, exploring how personalized engagement, cultural awareness, and consistent communication impact recruitment success and data quality beyond what any technology platform can achieve. Discussing region-specific relationship-building approaches, investigator motivation factors, and high-touch site management models to help sponsors and CROs create lasting site

networks built on trust rather than transactional interactions that fail to address the true needs of today's strained oncology research ecosystem.

Tandy Tipps – CEO – **Winniedel Oncology**

2:35 **KEYNOTE**

Transforming Clinical Operations Today, Building the AI Foundation for Tomorrow

Clinical research organizations face mounting pressure to accelerate trials, ensure compliance, and reduce operational costs. Yet, much of the industry remains weighed down by outdated, document-centric manual processes and rigid legacy systems. These solutions were not built with today's complex regulatory landscape or the growing demand for collaboration in mind. The result is slow, error-prone processes, increased risk and a lack of true innovation in trial operations.

In this session, Daneen will explore how an AI-native document management system helps transform clinical operations for greater efficiency today, while also laying the essential groundwork for AI-driven innovation tomorrow. By unifying content and data across silos, ensuring compliance, and automating workflows, this approach streamlines trial operations and reduces risk. Just as importantly, it establishes a structured, metadata-driven information foundation that enables advanced analytics, predictive insights, and intelligent automation—positioning CROs and sponsors to move beyond operational efficiency and into the next era of clinical research powered by AI.

Daneen Storc – Senior Product Marketing Manager - **M-Files**

3:00 **KEYNOTE**

Navigating the Biotech Frontier: Tailoring CRO Support for Emerging Innovators

Emerging biotechs represent both significant opportunity and unique challenges for CROs, with their distinct operational realities requiring specialized partnership approaches. Understanding the resource constraints, funding milestones, and knowledge gaps of these sponsors is essential for creating successful collaborations that advance novel therapies.

In this session, Megan will share practical insights into building effective relationships with emerging biotech sponsors, exploring how flexible payment structures, enhanced guidance on vendor oversight, and streamlined site feasibility processes impact both sponsor success and CRO differentiation in this competitive landscape. Discussing milestone-aligned invoicing approaches, grant-compatible budgeting, strategic resource allocation, and educational partnership models to help CROs create tailored solutions for biotech innovators while avoiding the common pitfalls of applying traditional sponsor engagement frameworks to these uniquely structured organizations with their distinct regulatory and financial pressures.

Megan Liles – Vice President, Clinical Delivery – **HGI Clinical**

3:25 **PANEL**

Effective Operations: Q&A Panel Discussion

This interactive Q&A session provides a unique opportunity to engage directly with this section's presenters, gain further perspectives, and explore challenges facing CROs and trial sponsors with regards to effective operations.

3:40 **Chair's Summary & Closing Remarks**

Chris Learn – Senior Vice President, Cell & Gene Therapy – **Parexel**

End of Conference