Clinical Outsourcing Group: CRO Summit

Raleigh Marriott City Centre, North Carolina

3rd & 4th December 2024

Sarah Ruiz – Senior Director, Product Management Operations – **Vial**
Krystyna Kowalczyk – Chief Executive Officer – **Kapadi**
Jeanne Hecht – Chief Executive Officer - **Lexitas**
Adam Hamm – SVP, Biostatistics & Strategic Consulting - **SDC**
Colin Hayward – Head of Medical Science – **ERGOMED**
Catherine Gregor – Chief Clinical Trial Officer - **Florence Healthcare**
Chris Learn – Vice President, Cell & Gene Therapy – **Parexel**
Hiroki Matsushima – Branch Manager, US – **A2 Healthcare**
Jasmina Jankicevic – Chief Medical Officer – **Innovaderm Research**
Steve Chriscoe – Vice President, Oncology Project Management – **Worldwide Clinical Trials**
Tomasz Bartlomiejski - CRA Resourcing Manager, Clinical Operations - **Stiris Research**
Vatche Bartekian – President – **Vantage Biotrials**
Kirk Wroblewski – Chief Information Officer - **Propharma**
Catherine Tyner – Head of Clinical Strategy – **AG Mednet**
Becky Knockemus – Senior Vice President - **Biorasi**
Jin Dai – Chief Operating Officer – **Everest Clinical Research**
Sybil Wilson – Senior Director, Global Strategic Partnerships – **Veristat**
Paul Johnson – Executive Director, Strategy Development – **PharPoint Research**
Cassandra Erato – Chief Executive Officer – **Spaulding Clinical**
Thomas DeSena – Director, RWE Project Management – **CTI Clinical Trial & Consulting**
Stacy Lasser – Senior Project Manager – **Mednet**
Keaton Fonvielle - Executive Director, Program Management – **Endpoint Clinical**
Shae Wilkins – Chief Executive Officer – **TRYAL**
François Moisson – Chief Executive Officer & Co-Founder – **Excelya**
Ryan Brown – Regional Vice President, Trial Landscape Sales – **H1**
Beatrice Setnik – Chief Scientific Officer – **Altasciences**
Gary Zammit - Chief Executive Officer & President - **Clinilabs**

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

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Day 1: 3rd December 2024

08:00 – 08:40 **Registration & Morning Refreshments**

08:40 **Welcome Address**
Jasmina Jankicevic – Chief Medical Officer – **Innovaderm Research**

SECTION A
Collaboration

08:45 Opening Keynote
Fostering Effective Collaboration Between Sponsor and CRO

Exploring strategies to optimize collaboration between a sponsor and CROs. Discussing how to establish well-defined delivery plans, streamline communication methods, build cohesive teams, and set clear deliverables.

In this session Steve will share real-world examples of challenges faced from his Biopharma & CRO experiences and provide practical solutions to overcome them. Providing insights to enhance working relationships and drive successful trial outcomes.

Steve Chriscoe – Vice President, Oncology Project Management – **Worldwide Clinical Trials**

09:10 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**

09:35 Keynote
Harnessing CRO's Therapeutic Expertise to Accelerate Trial Delivery

CROs possess invaluable internal therapeutic area expertise that can significantly accelerate trial delivery when effectively utilized. Exploring how sponsors can leverage their CRO's therapeutic lead to identify key opinion leaders, select the most suitable clinical trial sites, and determine the optimal geography for trial launch.

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In this session, Jasmina will discuss strategies for maximizing the impact of therapeutic expertise, enhancing decision-making processes, and ultimately accelerating the delivery of clinical trials. Bridging the gap between CRO knowledge and execution to achieve optimal results.

Jasmina Jankicevic – Chief Medical Officer – **Innovaderm Research**

10:00 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.

10:20 **Coffee Break**

SECTION B

Technology Integration

10:50 Keynote

The Digital Revolution: Your Guide to Digitalizing Clinical Trials

Digitalization is playing a pivotal role in transforming the way we approach endpoint measurement, study design, and patient engagement. Navigating regulatory requirements while prioritizing the needs of patients and sites.

In this session Sarah will explore how to effectively leverage technology to bring clinical trials into the digital world, focusing on the vast opportunities presented by digital and decentralized clinical trials (DCTs). Emphasizing the importance of streamlining and optimizing processes for patients, sites, and CROs to support the use of technology, ensuring it serves as an enabler rather than a hindrance.

Sarah Ruiz – Senior Director, Product Management Operations - **Vial**

11:15 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**

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11:40 Keynote

Winning Together Case Study: CRO and Vendor Partnerships

In an increasingly competitive landscape, CROs must explore innovative strategies to differentiate themselves and secure clinical trial contracts. One powerful approach is to forge strategic alliances with industry partners providing complementary services.

In this session, Jin will discuss how effective partnerships can be forged to deliver cutting edge capabilities, operational efficiency, and business development for the benefit of the CRO and to advance delivery of a client's clinical programs. A case study of a successful CRO-vendor alliance in data management will highlight the key factors that contribute to a win-win partnership.

Jin Dai – Chief Operating Officer – **Everest Clinical Research**

12:05 Panel

Technology 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 technology integration.

12:25 **Lunch**

SECTION C

Vendor Alliances

1:25 Keynote

Mastering Audit Readiness: Preventing Common Issues in Clinical Trials

Effective audit preparation is crucial for CROs to maintain compliance and ensure the integrity of clinical trials. Identifying common audit findings and implementing preventive measures are key to successful trial management.

In this session, Vatche we will explore proven strategies for identifying potential audit issues, implementing robust quality management systems, and fostering a culture of continuous improvement within CROs. Navigate common audit challenges, optimize quality assurance processes, and establish clear protocols to keep all aspects of clinical trials audit-ready.

Vatche Bartekian – President – **Vantage Biotrials**

1:50 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**

2:15 Keynote

Seats at the Table: Collaborative Strategies for Competitors in Large-Scale Clinical Trial Outsourcing

In today's complex landscape of clinical trial operations, sponsors often engage multiple competing CROs to support large-scale development projects. This approach, while leveraging diverse expertise, presents unique challenges in aligning competitors towards shared client goals.

In this session, Thomas will explore innovative strategies for fostering productive collaboration among CROs within projects and across multiple opportunities. Drawing from real-world experiences, presenting methods for establishing a cooperative framework that maintains competitive integrity while prioritizing client objectives. Key topics will include creating transparent communication channels, defining clear roles and responsibilities, and ensuring all parties have a meaningful "seat at the table" in driving successful clinical trial outcomes.

Thomas DeSena – Director, RWE Project Management – **CTI Clinical Trial & Consulting**

2:40 Panel

Vendor Alliances: 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 overall CRO market.

3:00 **Coffee Break**

SECTION D
Budgeting, Governance & Forecasting

3:30 Keynote

Mastering Budget Management for Clinical Trial Profitability & Transparency

Effective budget management is essential for CROs to maintain profitability and ensure the financial viability of trials. Detailing best practices for risk assessment, financial forecasting, and proactive budget adjustments

In this session Paul will explore proven strategies for building contingencies into trial budgets, predicting future costs, tracking spending, and fostering transparent communication between CRO, sites, and

sponsor. Navigating common budgetary challenges, optimize resource allocation, and establish clear lines of communication to keep all stakeholders informed.

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

3:55 Keynote

Governance in Clinical Trials: A Strategic Look at KPIs from an RTSM Perspective

In clinical trials, measuring KPIs is essential for ensuring effective governance and maintaining strong relationships between CROs, RTSM vendors, and sponsors. However, the challenge with traditional KPIs is that they often focus narrowly on compliance and operational metrics, missing the broader, strategic indicators that reflect the quality and depth of these partnerships.

In this presentation, Keaton will draw on real-world scenarios and explore how CROs can better leverage KPIs to monitor and strengthen vendor relationships, ensuring that both parties are aligned on expectations and performance. Attendees will learn how to create and implement KPIs that offer meaningful, actionable insights for sponsors and leadership teams. This session is designed to inspire CRO leaders to rethink their approach to governance and build metrics that foster stronger, more transparent partnerships in clinical trials.

Keaton Fonvielle - Executive Director, Program Management – **Endpoint Clinical**

4:20 Keynote

Radiopharmaceutical Clinical Trials: Scientific, Strategic, and Operational Considerations for Trial Optimization

Trials involving Radiopharmaceuticals face several unique challenges, including radiation exposure risk, often short half-lives, and limited patient populations. Investigation into radiopharmaceutical drugs is booming with the market expected to be worth $13 billion by 2032.

In this session Colin will share his experience when conducting clinical research with radiopharmaceuticals. Providing insight into the unique challenges faced requiring enhanced vendor engagement, as well as specialised IMP supply & site selection.

Colin Hayward – Head of Medical Science - **ERGOMED**

4:45 Panel

Budgeting, Contracting & Forecasting: 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 overall CRO market.

5:05 **Networking Drinks & Canapes Reception**

(complementary admission to all conference participants)

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Day 2: 4th December 2024

08:00 **Registration & Morning Refreshments**

SECTION E
Site Relationships

08:30 Keynote C-Suite Panel Discussion

Navigating the Future: Strategic Outlook for the CRO Industry

The biopharma landscape is experiencing unprecedented changes, driven by technological advancements, evolving funding models, and shifting healthcare dynamics. CROs are challenged to adapt their strategies to these transformative forces while continuing to deliver innovative therapies and value to patients.

In this session, the panel of CRO executives will examine the impact of AI, discuss emerging funding and payment models, consider the expanding role of pharmacies in trial delivery, and analyze industry-wide consolidation trends. The panel will also explore how these impactful changes are reshaping the landscape for trial delivery.

Chair: **Sybil Wilson** – Senior Director, Global Strategic Partnerships – **Veristat**
Jin Dai – Chief Operating Officer – **Everest Clinical Research**
Cassandra Erato – Chief Executive Officer – **Spaulding Clinical**
Jeanne Hecht – Chief Executive Officer – **Lexitas**
Beatrice Setnik – Chief Scientific Officer – **Altasciences**
François Moisson – Chief Executive Officer – **Excelya**
Becky Knockemus – Senior Vice President - **Biorasi**
Gary Zammit - Chief Executive Officer & President - **Clinilabs**

09:15 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**

09:40 Keynote

Cell & Gene Therapy Trials: A Site Collaboration Success Story

As cell and gene therapies continue to push the boundaries of medical innovation, clinical study sites face unique challenges in conducting these specialized trials. Exploring the best practice for site identification in both the US and Europe, ensuring the selection of the most qualified and experienced sites for these cutting-edge studies.

In this session Chris will focus on effective strategies for upskilling clinical study site staff to handle the complexities of cell and gene therapy trials confidently and competently. Expanding into training approaches, site selection criteria, and collaboration techniques to optimize site engagement and performance in the realm of cell and gene therapies.

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

10:05 Panel
Site Relationships: 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 site relationships.

10:30 **Coffee Break**

SECTION F
Artificial Intelligence

11:00 Keynote
Harnessing AI and LLMs within Internal CRO Operations

Artificial Intelligence (AI) and Large Language Models (LLMs) have the ability to streamline internal processes within CROs. While off-the-shelf solutions exist, many CROs are choosing to build in-house to maintain control over their data and processes.

In this session Kirk will explore the potential of these technologies to streamline internal processes, drive efficiency, and create value across operations. Sharing the experience in building AI-powered tools in-house, discussing the potential challenge of data, and the opportunity for a de-risked approach to AI implementation.

Kirk Wroblewski – Chief Information Officer - **Propharma**

11:25 Keynote
The Reality of AI: Beyond the Hype

Artificial Intelligence has emerged as a transformative force in healthcare, promising revolutionary advancements in patient care, drug discovery, and operational efficiency. The journey from potential to practical implementation is often more complex than headlines suggest, with both successes and challenges that deserve equal attention.

In this session, Tomasz will explore AI in healthcare, balancing hype with practical applications. He'll compare Machine Learning and Generative AI, discussing their potential and risks. Using case studies

Tomasz will highlight AI implementation realities, including key success factors such as clear objectives, collaboration, data preparation, and ongoing evaluation.

Tomasz Bartlomiejski - CRA Resourcing Manager, Clinical Operations - **Stiris Research**

11:50 Keynote
Accelerating Clinical Research with AI-Powered Technologies

CROs are facing increased pressure to accelerate study timelines, reduce costs, and deliver high-quality data in an increasingly competitive and complex clinical trial landscape. The search for technical solutions that help clinical trial professionals do more, with less, faster and without sacrificing quality is in overdrive.

In this session, Shae will provide a framework for assessing the impact of AI solutions in clinical trials to avoid rework, privacy concerns, and potential safety issues. With specific examples, Shae will discuss where AI has already provided value for CRO's and biopharmaceutical companies.

Shae Wilkins – CEO – TRYAL

12:15 Panel
Artificial Intelligence: 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 Artificial Intelligence.

12:45 **Lunch**

SECTION G
Patient Enrolment & Engagement

1:45 Keynote
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 infrastructure, as well as high-quality data generation.

Hiroki Matsushima – Branch Manager, US – **A2 Healthcare**

2:10 Keynote
Driving Diversity, Equity & Inclusion in Clinical Trials: A Data-Driven Approach

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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, Ryan 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.

Ryan Brown – Regional Vice President, Trial Landscape Sales – **H1**

2:35 Keynote

Revolutionizing Patient Access: Broadening the US Clinical Research Landscape

Despite common misconceptions, the US market for clinical research is far from saturated. Researchers often rely on familiar sites, limiting geographical reach and patient diversity. It's time for a paradigm shift in our approach to site selection and patient recruitment. By adopting a more proactive strategy we can dramatically reduce trial recruitment timelines, improve patient access to research, and achieve true diversity in clinical trials and create opportunity.

In this session, Krystyna will challenge traditional site selection and start-up methods, presenting an innovative approach to expanding the clinical research footprint across the United States and potentially globally. Exploring how changing attitudes and embracing a more flexible, patient-centric model can transform the industry.

Krystyna Kowalczyk – Chief Executive Officer - **Kapadi**

3:00 Closing Panel

Patient Enrolment & Engagement: 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 budgeting and contracts.

End of Conference