Clinical Outsourcing Group DMV Area

Bethesda, Maryland, USA

May 13th - 14th 2025

Confirmed Speakers;

Anya Derbij – VP, Clinical Operations – **Cellphire Therapeutics**

Christina Hochul – Head of Strategic Alliance Development **– Alexion, AstraZeneca Rare Disease**

Jeffrey Hausfeld – Chairman of the Board and Chief Medical Officer **– BioFactura**

Ricki Fairley – Chief Executive Officer and Co-Founder – **Touch, The Black Breast Cancer Alliance**

Christine Cornwell – Head of Clinical Operations US – **AbelZeta**

Beata K. Glogowska – Founder and CEO – **Indigo SEA Biotech Solutions**

Samantha Chen – Head of Clinical Operation, EMEA and APAC

Sanghita Bhattacharya – Director Data Science & Digital Health, Global Functions – **Johnson & Johnson**

Monika Sharma – VP, Product Development **– Diagonal Therapeutics**

Sumaira Ahmed, Founder/Executive Director**, The Sumaira Foundation**

Christian Walker – CEO **– Solaxa**

Vaidehi Agrawal – Director - Vaccine Product Portfolio (Health Program Director) **– Center for Vaccine Development & Global Health**

William Stilley – CEO **– Adovate**

Fatima Karzai – Deputy Clinical Director **– National Cancer Institute (NCI)**

Kristi Jones – CEO **– NexImmune**

Shazia Ahmad – Head of Site & Patient Engagement **– argenx**

Bonnie Koo – Fuel Accelerator Strategic Advisor, MPH/MBA Candidate at Johns Hopkins University **– Bloomberg Public Health School & Carey Business School**

Jenna Brager – Executive Vice President of Drug Development

Paula Fischthal – Director, Clinical Operations – **Takeda**

Deb Kientop – Vice President Clinical Operations – **Deka Biosciences**

Jennifer Fetterolf – Clinical Operations Director **– Gilead Sciences**

Elna Narula – US Site Relations and Patient Recruitment Lead **– Diamyd Medical**

Irina Fish – Group Medical Director, Immunology, Medical Safety Evaluation – **AbbVie**

Yasmine Hassan – Global Patient Affairs Director **– AstraZeneca**

Anna Osinski – Associate Director, Patient Centricity and Engagement Development Unit Lead – **Biogen**

Bruce Smith – Senior Director, Strategic Sourcing and Vendor Management **– ADC Therapeutics**

Azhar Bisle – Senior Manager, Clinical Compliance – **Moderna**

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Day 1: May 13th 2025

7:30 – 8:25 **Registration & Morning Refreshments**

8:25 **Welcome Address**
Chair: **Jeffrey Hausfeld –** Chairman of the Board and Chief Medical Officer **– BioFactura**

8:30 Opening Keynote
Vendor Oversight Spotlight: Stop Treating it Like a One-Way Street; Focus on Maintaining and Measuring Effective Communication

For small-mid sized sponsors with no other option but to outsource, vendor oversight is a vital part of day to day life. Inefficient communication is one of the biggest obstacles with the sponsor-vendor relationship.

In this presentation X speaker will address best practices for vendor oversight including monitoring vendors against KPIs; laying out roles and expectations early on; governance structures and how technology can aide oversight. Sharing advice based on their experience of implementing effective oversight strategies and vendor management.

Christine Cornwell – Head of Clinical Operations US **– AbelZeta**

9:00 *Session Reserved for Mednet*

9:30 On-Stage Interview
How to Position Yourself as a Top Priority for the CRO and Maintain the A-Team Throughout the Study

Due to insufficient resources and training, sponsors often find themselves working with different CRO teams than those initially selected during the bid defence. This inconsistency is negatively affecting a huge number of trials across the US and causing costly delays.

In this on-stage interview, our host will ask X to examine the problem from the beginning, assessing what should be put into the RPF, what you should discuss with your CRO initially and how to set boundaries and expectations. X will also address how to handle situations when a member of your study team not pulling their weight. How can you encourage a more proactive work environment?

Bruce Smith – Senior Director, Strategic Sourcing and Vendor Management **– ADC Therapeutics**

10:00 Panel Discussion
The Critical Role of Effective Communication Strategies in Clinical Trials to Ensure Success, Compliance, and Patient Safety

Understanding the importance of communication between CROs and sponsors, and how regular meetings can foster a proactive work environment and align expectations on both sides. Teamwork (regardless of side), trust, communication and respect must be a priority.

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In this interactive discussion, our expert panellists will explore the significance of open communication, proactive engagement, voicing expectations, and strategies for building trust during clinical trials. They will draw on their individual experiences, giving the audience practical takeaways.

Moderator: **Jeffrey Hausfeld –** Chairman of the Board and Chief Medical Officer **– BioFactura**
Panellists: **Beata K. Glogowska –** Founder and CEO **– Indigo SEA Biotech Solutions**
Jenna Brager – Executive Vice President of Drug Development
Azhar Bisle – Senior Manager, Clinical Compliance – **Moderna**
Shazia Ahmad – Head of Site & Patient Engagement – **argenx**

10:45 **Coffee Break**

11:15 **Panel Discussion: Unlocking the Full Potential of RWD in Patient Referral by Developing Effective Partnerships and Overcoming Existing Barriers**

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

This panel discussion will explore the complexities of patient referral using RWD, identify critical barriers, and proposes strategic solutions to enhance its efficacy. Our goal is to acknowledge past use cases, as well as come up with proposed strategies, to transform patient referral into a reliable and efficient mechanism for clinical trial recruitment.

Panellists: **Sanghita Bhattacharya –** Director Data Science & Digital Health, Global Functions **– Johnson & Johnson;**

Tentatively Confirmed: **Adeniyi Togun** – Associate Research Director Global Big Data RWE – **Jazz Pharmaceuticals**

11:45 **How to Manage Increasingly Complex Trial Designs**

With changes to the industry such as regulations, competitive pressure and new innovative trial formats, protocol complexity is rising. This puts even more pressure on ClinOps and other study teams. Given the patient is already burdened with the disease, it is crucial to design and implement well-structured protocols with the patient in mind.

This session will explore how to handle more complex trial designs and X will pinpoint key strategies they implemented to manage complexities effectively.

Samantha Chen – Head of Clinical Operation, EMEA and APAC

12:15 Panel Discussion
The (Multi) Million Dollar Question: Should You Choose a Large CRO or Small, Specialised One?

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Particularly with smaller biotech, the big question is whether to go for a larger CRO and get multi-faceted support or identify a niche, smaller CROs for your trial. Working with the wrong partner for your trial it could cause costly delays, while also negatively impacting patients.

This interactive panel will tackle CRO selection pain points from a small company perspective. Is this large CRO nimble enough for our trial? How can we ensure they put us first? How can we work towards getting the A team from start to finish? Should we or shouldn't we pick large CRO- how to make the decision?

Moderator: **Jeffrey Hausfeld –** Chairman of the Board and Chief Medical Officer **– BioFactura**
Panellists: **Anya Derbij –** VP, Clinical Operations **– Cellphire Therapeutics**
Monika Sharma – VP, Product Development **– Diagonal Therapeutics**
Tentatively Confirmed: **Scott Currence –** VP Clinical Development Operations **– Kelonia Therapeutics**

1:00 **Lunch**

2:00 **Managing Patient Recruitment/Retention and Battling Staff Turnover to Ensure Continuation of Efficient, High Quality Clinical Trials**

With industry burnout reaching crisis levels, sponsors must navigate staff turnover challenges and work with the study team to come up with creative solutions, focussing on the bigger picture.

Vaidehi will share advice on handling staff turnover, the importance of sharing expectations and timelines early on and incentive ideas for CRO performance. She will also give advice and practical takeaways for patient recruitment and retention strategies.

Vaidehi Agrawal – Director - Vaccine Product Portfolio (Health Program Director) **– Center for Vaccine Development & Global Health**

Tech & Innovation Hour

2:30 **Digital Health Innovations in Clinical Trials: What's New?**

Discover the latest trend in digital health for clinical trials, from digital biomarkers and remote monitoring to AI-driven insights and decentralized models. This session highlights how these innovations are paving the way for the future of clinical research.

Bonnie Koo – Fuel Accelerator Strategic Advisor, MPH/MBA Candidate at Johns Hopkins University **– Bloomberg Public Health School & Carey Business School**

2:50 **Fireside Chat: Enhancing Sponsor-CRO Collaboration Through Technology**

Strengthening Sponsor-CRO partnerships with technology can streamline clinical trials, improve data accuracy, and foster real-time communication. Both sponsors and CROs can achieve better alignment on study goals, timelines and quality standards by utilizing project management and monitoring platforms.

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Where delays and inefficiencies occurred, technology can step in and enable a more seamless integration of systems.

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

Moderator:

Jenna Brager – Executive Vice President of Drug Development

3:10 **Trial Innovation - Can Smaller Companies Afford to Think This Way?**

When studies encounter problems, we often revert to familiar methods. However, with so many new options available, it's essential to explore innovative approaches to get trials back on track.

This session will examine whether smaller companies can afford the latest advancements in clinical trial innovation or if these remain out of reach. What can small companies realistically look at with regards to clinical innovation?

Deb Kientop – Vice President Clinical Operations – **Deka Biosciences**

3:30 **Coffee Break**

4:00 **Achieving Diverse Clinical Studies: Partnering with Patient Advocacy Groups**

Building trust and understanding amongst under-represented patient groups is essential to ensure that trials recruit and represent a diverse population of patients. Often under-represented groups may have a limited understanding of the standard of clinical care, a fear for their safety, as well as inconsistent or unrelatable recruitment or marketing information.

This presentation shares the benefits found when organisations have worked with TOUCH The Black Breast Cancer Alliance to redesign and create targeted trial recruitment campaigns to reach under-represented minority patients.

Ricki Fairley – CEO & Co-Founder – **TOUCH, The Black Breast Cancer Alliance**

4:30 **Building a Foundation of Excellence: Fostering a Culture of Quality in Clinical Operations**

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

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

Beata K. Glogowska – Founder and CEO **– Indigo SEA Biotech Solutions**

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5:00 Closing Panel Discussion

Putting Patients at the Heart of Clinical Trials: Strategies for Enhancing Patient-Centricity, Diversity, and Stakeholder Collaboration

In the rapidly evolving landscape of clinical trials, patient-centricity has emerged as a critical priority for biopharma companies. This session will explore strategies for putting patients at the heart of clinical trial design and execution.

In this panel attendees will gain valuable insights aiming to drive patient-centricity, diversity, and stakeholder collaboration. Practical strategies and real-world examples will be discussed, to inspire and inform clinical development leaders.

Moderator:
Panellists: **Irina Fish** – Group Medical Director, Immunology, Medical Safety Evaluation – **AbbVie**
Yasmine Hassan – Global Patient Affairs Director – **AstraZeneca**
Anna Osinski – Associate Director, Patient Centricity and Engagement Development Unit Lead – **Biogen**

5:45 **Networking Drinks Reception *(complementary admission to all conference participants)***

Day 2: May 14th 2025

8:15 – 9:00 **Registration & Morning Refreshments**

9:00 Interactive Panel
Fuelling the Future: CEO Perspectives on Funding Clinical-Stage Biotechs

Securing sufficient investment remains challenging for biotech companies, whether they are seeking to enter clinical trials, or seeking investment to move to later stages. Clear communication of drug/device candidate potential, as well as possible creative funding/ equity models.

This CEO panel will bring together biotech leaders in the DMV region to discuss strategies for financing clinical pipelines. Topics will include international trends in venture capital, public markets, licensing deals, local government funding, and cross-border partnerships.

Moderator: **Jeffrey Hausfeld –** Chairman of the Board and Chief Medical Officer **– BioFactura**
Panellists: **Christian Walker** – CEO – **Solaxa**
William Stilley – CEO **– Adovate**
Kristi Jones – CEO **– NexImmune**

9:45 **The Sumaira Foundation Case Study: The Poster Child for Rare Disease Clinical Trials**

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Rare disease clinical trials face significant challenges, including the need for complex and innovative trial designs, advanced strategies for patient recruitment, and greater efforts to engage minority and underrepresented patient populations.

The Sumaira Foundation was set up to raise awareness of NMOSD and MOGAD; raise investment in R&D; support patient communities; and encourage patients to join suitable trials. Sumaira will discuss her personal experience with a rare disease condition (NMOSD) and explore how Patient Advocacy Groups can be involved in co-leadership of clinical trials, bringing the patient voice to the study design.

Sumaira Ahmed – Founder/Executive Director – **The Sumaira Foundation**

10:15 **Vendor Relationships: How to Fix an Unhealthy Relationship? What Should You Do When It's Not Working? How Can You Create One Study Team?**

Paula, using her broad experience in improving sponsor-CRO relationships, will explore the root causes of misalignments and collaboration challenges often encountered between these two key players in clinical research. She'll address how factors such as unclear expectations, miscommunication, and playing the blame game can create friction, leading to setbacks in trial progress.

Drawing from real-life case studies, Paula will examine both the sponsor and CRO perspectives, offering valuable lessons learned and essential takeaways.

Paula Fischthal – Director, Clinical Operations – **Takeda**

10:45 **Coffee Break**

11:15 **In Conversation: Navigating the CRO Landscape for Oncology Trials**

Selecting the right CRO is crucial when planning clinical trials, especially in complex areas such as Oncology. Working with multiple vendors may allow for scalability and flexibility as the pipeline develops.

In this onstage interview Jennifer will share their preferred provider vendor selection process, as well as examine the day-to-day operations working with vendors, and the opportunities, and challenges this presents.

Jennifer Fetterolf – Clinical Operations Director **– Gilead Sciences**

12:00 **A Deep Dive into the Structure of Investigator Initiated Clinical Trials at The Center for Cancer Research (CCR), National Cancer Institute (NCI) and National Institutes of Health (NIH)**

Fatima will introduce the CCR, NCI and NIH, and delve into what kind of clinical cancer research is conducted here. This session will look at the most important aspects of investigator initiated clinical research and how clinical research should be conducted to address barriers to clinical trial participation.

Fatima Karzai, M.D. – Deputy Clinical Director **– National Cancer Institute (NCI)**

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12:30 **Rare Disease Trial Focus: Delving into Transportation Obstacles and the Value of PAGs**

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

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

Christina Hochul – Head of Strategic Alliance Development **– Alexion, AstraZeneca Rare Disease**

1:00 **Lunch**

2:00 Panel Discussion

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

Patient recruitment has always been a challenge in clinical research, but with study saturation and study criteria becoming increasingly specific, identifying patients is a harder task.

This panel will bring together experts to pinpoint best practice for a more targeted patient recruitment process. Covering patient-centric trial designs, recruitment for global sites, achieving diversity targets, and the use of tools and social media.

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Panellists: **Sanghita Bhattacharya –** Director Data Science & Digital Health, Global Functions **– Johnson & Johnson**
Shazia Ahmad – Head of Site & Patient Engagement **– argenx**
Elna Narula – US Site Relations and Patient Recruitment Lead **– Diamyd Medical**
Tentatively Confirmed: **Holly Patterson –** Associate Director, Patient Recruitment & Retention **– Takeda**

2:45 **Regulator Keynote: FDA Shining the Spotlight on Vaccine Clinical Trials and Diversity**

Our FDA speaker will give a general overview of vaccine clinical trial regulations as well as delving into his role. Sudhakar will explore how trials are conducted, asking are trials safe and are they answering the right questions? He will also be discussing patient populations included in trials, with a focus on diversity.

3:15 Closing Keynote

Diversity Conversation: Delving into Protocols to Identify the Most Appropriate Inclusion/Exclusion Criteria with Diversity Front of Mind

LaShell Robinson – Senior Director of Diversity Equity & Inclusion in Clinical Research **– Takeda**

3:45 **End of Conference**

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Extra Available Sessions:

Health Inequity in Clinical Trials: Improving Diversity and Inclusion in Order to Promote Health Equality

Health inequities in clinical trials can lead to skewed data that often don't accurately reflect the health needs of diverse populations. Addressing health inequity involves ensuring inclusive recruitment practices, tailoring study designs to diverse populations, and actively working to remove barriers that prevent underrepresented groups from participating.

X will explore the disparities in access to, and representation in, clinical studies in different demographic groups – in order to improve health outcomes for all.

Diversity Conversation: How Can the DMV Region Enhance Diversity in Clinical Trials?

Clinical trials in the US have historically been underrepresented in terms of diversity, with some groups being significantly underrepresented. The FDA are currently shining a spotlight on this topic, encouraging trial sponsors to examine their current patient recruitment strategies and identify areas to improve.

Our speaker will address the diversity questions and patient recruitment as a whole.

RFP Focus Session: Comparing Apples to Apples

RFPs are critical for finding the best CRO for your study. However, in the complicated world of outsourcing clinical trials, using RFPs to compare CROs can be incredibly challenging.

In this session, groups will work together to identify key elements to include in an RFP and develop a basic template. Each group should list 5-10 criteria that are essential for assessing vendor qualifications to ensure we are comparing apples to apples.

'Not asking for feedback is what less capable people do' – discuss the importance of RFP feedback!

Workshop

RFP Focus Session: Comparing Apples to Apples

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'Not asking for feedback is what less capable people do' – discuss the importance of RFP feedback!

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

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

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

Advantages and Obstacles with Exploring Unchartered Territories for Your Clinical Trial

As the number of studies in the US increases, leading to study saturation and a shrinking pool of untapped patients, sponsors are expanding their search to new regions. This approach helps to achieve target patient demographics, enhance diversity, and ensure that the data collected is more representative. But with its own unique challenges, venturing into different locations for trials requires thorough preparation and local expertise to ensure compliance and quality standards are maintained.

In this session X will explore how embracing these new locations for your study can enhance patient recruitment, diversity and result accuracy.

Supply Case Study
Cell & Gene Therapy Trial Set Up and Execution

Cell and gene therapy clinical trials face several unique challenges. In this session our speaker will discuss the obstacles faced when setting up a gene therapy trial, and draw on their wealth of experience to share how to plan and collaborate to successfully implement the trial.

Site Selection Spotlight: Using Data-Driven Site Lists to Pinpoint Your Exact Requirements

Site selection is a critical, but increasingly challenging, aspect of clinical research. We see trial sponsors continuing to be risk-adverse and stick to the sites they have always worked with, even if they don't yield the results required.

In this session, X will address the benefits of a risk-taking attitude by developing a data-driven site list and working with new sites. Both small and big Biopharmaceutical companies seem to be sticking with what they know, we need to push boundaries to find more relevant sites and therefore more patients. What role can CROs do in helping us make good site decision?

Protocol Amendments – Causes, Impacts and Strategies from a Small Company Perspective

Due to the increasing complexity of studies (as discussed in the previous session), we are seeing more protocol amendments. This is particularly challenging for those in small-mid sized sponsor companies due to timeline delays, reduced patient retention rates, site burdens and overall costs.

In this presentation, X will share their experiences with protocol amendments, offering expert insights and practical suggestions for small companies to apply to their own trials.

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