Clinical Outsourcing Group West Coast

Hyatt Regency San Francisco Airport

October 8th & 9th 2024

Caro Unger – Director, Head of Clinical Operations – **Asher Biotherapeutics**
Jasmine Washington – Associate Director, Clinical Outsourcing & Contract Management – **Cytokinetics**
Qian Zhang – Senior Director, Head of Clinical Data Management – **Enliven Therapeutics**
Thomas Tredennick – Associate Director, Supply Chain – **Arsenal Bio**
Yuyi Shen – Head of Development, Manufacturing & Supply Chain – **Abcuro**
Eduardo Bruno Martins – CMO – **Sagimet Biosciences**
Ndidi Rickert – Director, Quality Culture Excellence – **Ultragenyx**
Tassos Nicolaou – President & CEO – **Delpor**
Johnston Erwin – CEO - **TRexbio**
Pamela Contag – CEO – **Bioeclipse Therapeutics**
Aroba Hafeez – Director, Clinical Data Management – **Asher Biotherapeutics**
Dave Borbas – VP, Head of Data Management - **Abcuro**
Kalyan Obalampalli (KO) – Founder & CEO – **ClinAI**
Zelanna Goldberg – CMO – **Replicate Bioscience**
Scott McClellan – CMO – **Orca Bio**
Daniel Dornbusch – CEO – **Excision BioTherapeutics**
Stephen Maricich – CMO – **Ashvattha Therapeutics**
Ardania Johnson – Director, Clinical Quality Assurance – **Cullinan Therapeutics**
Debby Holmes-Higgin – VP, Clinical – **BioCardia**
Julie Moore – Portfolio Operations Lead – **Astellas Gene Therapies**
Malinda Longphire – Executive Director, Clinical Sciences – **Alexza**
Kim Du – Senior Director, Clinical Operations - **Avisi Technology**
Ernest Odame – Director, Global Evidence & Outcomes, Oncology – **Takeda**
Dorothy Kwok – Head of Clinical Operations – **Bodyport**
Swaminathan Murugappan – Consultant CMO – **Trident Bio Consulting**
Elaine Chien – CMO – **Antiva Biosciences**
Susan Schneider – Principal – **Susan Schneider Consulting**
Mylea Charvat – CMO – **Altoida**
Jenelle Lin – Associate Director, Clinical Operations – **Vir Technology**

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Day 1: October 8th 2024

08:10 – 08:40 **Registration & Morning Refreshments**

08:40 **Organizer's Welcome Address**

Alexander O'Leary – Director – **PBC Group**

08:45 **Chair's Welcome Address**

Kalyan Obalampalli (KO) – Founder - **ClinAI**

08:50 CMO Keynote Interactive Panel

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 biopharmaceutical companies. This panel brings together a group of distinguished bay-area Chief Medical Officers to discuss strategies for putting patients at the heart of clinical trial design and execution.

Through this interactive panel discussion, attendees will gain valuable insights into the evolving role of the CMO in driving patient-centricity, diversity, and stakeholder collaboration in clinical trials. The panel will discuss practical strategies and real-world examples to inspire and inform clinical development leaders as they work to bring innovative therapies to patients in need.

Eduardo Bruno Martins – CMO – **Sagimet Biosciences**
Zelanna Goldberg – CMO – **Replicate Bioscience**
Scott McClellan – CMO – **Orca Bio**
Stephen Maricich – CMO – **Ashvattha Therapeutics**
Swaminathan Murugappan – Consultant CMO – **Trident Bio Consulting**
Elaine Chien – CMO – **Antiva Biosciences**
Mylea Charvat – CMO - **Altoida**

09:30 Keynote

Clinical Outsourcing Trends in 2024

RESERVED for August Research

09:50 Keynote

Leveraging RWD & Digital Technology to Accelerate Clinical Development

Digital innovation presents tremendous opportunities to transform clinical trials through the adoption of Big Data, AI, Blockchain, Wearables to drive patient engagement.

In this presentation Ernest, will present strategies to pilot and implement new tech and data to drive patient engagement, efficiency, and data quality. Case studies of successful deployments will highlight what went right, and lessons learned.

Ernest Odame – Director, Global Evidence & Outcomes, Oncology – **Takeda**

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10:20 Keynote

AI & ML Tech to Improve Quality

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10:50 **Coffee Break**

	Stream A **Clinical Outsourcing Confusion**	Stream B **Sites, Patients, & Supply**
11:20	Interactive Panel **Outsourcing Clinical Trials: Navigating the Complexities and Confusion** *Outsourcing aspects of clinical trials to CROs and functional vendors has become standard practice but also introduces challenges in choosing the right vendor, oversight, and communication – to name a few.* This panel will bring together experts to demystify best practice for outsourcing. Covering vendor selection, establishing transparency, data protection, personalised service models, strategies for small biotechs, and what to avoid! **Jasmine Washington** – Associate Director, Clinical Outsourcing & Contract Management – **Cytokinetics** **Caro Unger** – Director, Clinical Operations – **Asher Biotherapeutics**	Interactive Panel **Accelerating Trial Start-up & Improving Patient Engagement Through Effective Patient Advocacy** *Patient recruitment, and engagement are challenging aspects of all clinical trials. Through adopting a patient centric approach sponsors can see improved results.* This panel will bring together leaders from San Francisco's patient advocacy community to determine strategies to better engage patients. Covering topics around non-profit partnerships, diversity, and site collaboration. **Kim Du** – Senior Director, Clinical Operations - **Avisi Technology**
11:55	Insight **Accelerating your drug development through efficient regulatory documents** **RESERVED for Aixial Group**	Insight **The Role of RWE in the Clinical Development Journey** **RESERVED for PSI CRO**
12:25	Insight **Oversight Strategies to Effectively Manage Clinical Studies** *Effective oversight is crucial for successful management of clinical studies. Failure to do so can result in lack of planning, improvement and collaboration.* In this presentation Caro will draw on her experience designing and executing early-phase clinical studies. Sharing advice based on her experience of implementing effective oversight strategies, plans, data capture, and vendor management.	Insight **Personal Development: Navigating the Path to Becoming a CMO in a Clinical-Stage Biopharma** *Becoming a Chief Medical Officer for a biopharma company can be a challenging yet rewarding career goal. Often to path to this career can be unclear.* In this session Susan will delve into the complexities of advancing to a CMO role, the areas needed to upskill from clinical operations/development roles, and take you on the journey of her career, including mistakes made along the way.

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Caro Unger – Director, Clinical Operations – **Asher Biotherapeutics**

Susan Schneider – Principal – **Susan Schneider Consulting**

12:55 **Lunch**

	Stream A **Trial Design & Contracts**	Stream B **Technology & Innovation**
01:55	Insight **Innovative Design & Logistical Considerations for Autologous Cell Therapy Studies** *Autologous cell therapy studies present unique challenges in the field of regenerative medicine. Logistical considerations are key due to use of patient's own cells.* In this session Debby will introduce the design and operational challenges faced for BioCardia's two CardiAMP trials to understand how oversight, strong partnerships and patient engagement help drive trial success. **Debby Holmes-Higgin** – VP, Clinical – **BioCardia**	Interactive Panel **Integrating Technology in Clinical Trials** *Innovation is at the heart of emerging biopharma. The increase in availability of digital technologies mean more trial sponsors are adopting these to streamline trials.* In this session the panel will discuss the future role technology will play in clinical trials, with areas of discussion around advanced analytics, AI, wearables, and remote trial management. **Julie Moore** – Portfolio Operations Lead – **Astellas Gene Therapies** **Ernest Odame** – Director, Global Evidence & Outcomes, Oncology – **Takeda**
02:25	Insight **Embracing Quality as a Culture: A Roadmap for Maintaining CRO Oversight** **RESERVED for Delve Health**	Insight **Drug Supply Management: Ensuring Supply Safety While Generating Huge Savings** **RESERVED for Mednet**
02:55	Panel **Strategic Contracting/ FP&A for Clinical Trial Dominance** *Correctly drafted clinical trial agreements are essential to ensure research quality, ethical standards, and legal protections.* In this session, the panel will share tips and tricks for ensuing clinical trial dominance when contracting vendors and sites for your clinical trial. Sharing, key contracting priorities, compliance considerations and key sections of clinical trial agreements.	Onstage Interview **Supply Chain Challenges & Considerations in Cell Therapy Clinical Trials** *Cell therapy treatments hold huge promise in revolutionizing patient care, and treatment. However they also present unique and complex supply chain challenges.* In this session Thomas, will share the key challenges faced by trial sponsors when starting trials for cell therapies, delving into the planning and oversight strategies to adopt, as well as safety, and vendor relationships.

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Malinda Longphire – Executive Director, Clinical Sciences – **Alexza**

Thomas Tredennick – Associate Director, Supply Chain – **Arsenal Bio**

03:25 **Coffee Break**

03:55 **Building Effective Partnerships Between Trial Sponsors and Investigators**

Strong partnerships between trial sponsors and investigators are crucial to facilitating efficient, high-quality clinical research. Aligning priorities and effective collaboration enables successful trial execution, recruitment, and data collection.

In this panel, we will examine best practices for building robust partnerships between clinical trial sponsors and investigator sites. It will outline strategies to align priorities, incentives, and expectations to conduct high quality, efficient trials.

Dorothy Kwok – Head of Clinical Operations – **Bodyport**

04:30 Keynote
Empowering Patient-Centric Outcomes: The Synergy of ePRO, Wearables, and Patient Engagement in Clinical Trials

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05:00 **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, the panel will discuss practical ways you can promote quality behaviours and mindsets among clinical development and operational teams. Key areas of discussion will include leadership engagement, communication approaches, quality infrastructure, continuous improvement processes, and methods for recognizing and rewarding quality outcomes.

Ndidi Rickert – Director, Quality Culture Excellence – **Ultragenyx**
Ardania Johnson – Director, Clinical Quality Assurance – **Cullinan Therapeutics**

05:30 **Chair's Day 1 Summary**
Kalyan Obalampalli (KO) – Founder - **ClinAI**

05:35 **Networking Drinks & Canapés Reception**
(complementary admission to all conference participants)

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Day 2: October 9th 2024

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

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

Kalyan Obalampalli (KO) – Founder - **ClinAI**

09:00 CEO Keynote 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 leaders of biotechs 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.

Tassos Nicolaou – President & CEO – **Delpor**
Johnston Erwin – CEO - **TRexBio**
Pamela Contag – CEO – **Bioeclipse Therapeutics**
Daniel Dornbusch – CEO – **Excision BioTherapeutics**

09:45 Keynote

Next-Generation Clinical Supply Planning: Strategies for Identifying & Mitigating Supply Chain Risk

When developing your clinical supply strategy, it is important to plan for potential supply chain challenges that may arise. The study's protocol requirements, drug characteristics, packaging specifications, as well as identifying any patient compliance concerns are all key factors of which to obtain a strong understanding.

In this session XXX will focus in on strategies to build understanding and delve into ways to help avoid common pitfalls within your clinical supply plan.

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10:15 Keynote Interactive Panel

Optimizing Data Collection: New Trends for Maximizing Value

Optimizing data collection in clinical research by only capturing meaningful, high-value data points allows researchers to reduce costs, minimize patient burden, accelerate study timelines, and ultimately enhance the likelihood of uncovering insights that will benefit treatment indications.

This panel will discuss emerging approaches to optimizing clinical trial data collection. Panellists will share insights on determining high-value data points, reducing unnecessary data capture, and easing patient burden - all while

maintaining scientific and regulatory standards. Key topics of discussion: Determining Essential Data, Avoiding Data Waste, Regulatory Guidance and Requirements, and Impacts on Patients and Trial Efficiency.

Aroba Hafeez – Director, Clinical Data Management – **Asher Biotherapeutics**
Dave Borbas – VP, Head of Data Management – **Abcuro**
Qian Zhang – Senior Director, Head of Clinical Data Management – **Enliven Therapeutics**

11:00 Keynote
Trial Considerations for Radiopharmaceutical: Piecing Together Industry Prospectives

Trials involving Radiopharmaceuticals face several unique challenges, including radiation exposure risk, often short half-lives, and limited patient populations.

In this session XXX will review the key operational considerations with conducting clinical trials in Radiopharmaceuticals. Incorporating the prospectives of key industry partners from sites, sponsors, as well as CROs.

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11:30 **Coffee Break**

12:00 Onstage Interview
Navigating the Complexities of Clinical Manufacturing Scale-Up: Strategies for Success

The transition from small-scale laboratory processes to large-scale production for clinical trials is a complex journey filled with numerous challenges that can significantly impact the success of these trials. This panel will delve into the intricacies of scaling up clinical manufacturing, exploring the key hurdles and discussing effective strategies to overcome them.

In this onstage interview Yuyi will share best practices for regulatory compliance, process characterization, optimization, and validation, as well as strategies for technology transfer, vendor qualification, and risk mitigation in raw material sourcing and supply chain management. They will also discuss cost-effective strategies, resource allocation, and process optimization opportunities in clinical manufacturing.

Yuyi Shen – Head of Development, Manufacturing & Supply Chain – **Abcuro**

12:40 Keynote

RESERVED

01:10 Keynote
Enhancing Clinical Trial Engagement Through Technology Adoption

Technology has emerged as a powerful enabler for improving patient engagement, optimising trial operations, and accelerating the development. Technology is increasingly being used to engage patients to reduce trial drop-out rates.

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In this session XXX will explore the latest trends, best practices, and success stories in technology adoption for clinical trial engagement, providing attendees with practical insights and actionable strategies to harness the power of digital innovation in their studies.

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01:40 **Lunch**

02:40 Closing Keynote Panel

Revolutionizing Clinical Trials: Innovations in Trial Design for Faster, Smarter, and More Efficient Drug Development

The landscape of clinical trials is evolving rapidly, driven by the need for faster, more efficient, and patient-centric drug development. This panel discussion will explore the latest innovations in clinical trial design, focusing on strategies that can accelerate timelines, improve data quality, and enhance patient engagement.

The panellists will explore adaptive trial designs, the integration of advanced technologies such as AI and machine learning, and the growing trend of decentralized and virtual trials. Sharing insights on the application of real-world evidence, innovative statistical approaches, and patient-reported outcomes to complement traditional randomized controlled trials. Discussing the regulatory landscape, and collaborative efforts to facilitate the adoption of innovative designs.

Jenelle Lin – Associate Director, Clinical Operations – **Vir Technology**

02:55 **Chair's Day 2 Summary & Closing Remarks**

Kalyan Obalampalli (KO) – Founder - **ClinAI**

End of Conference