Clinical Outsourcing Group West Coast

San Francisco Airport Marriott Waterfront, Burlingame, CA

November 7th & 8th, 2023

Day 1: November 7th

07:45 **Registration & Welcome Refreshments**

08:30 **Welcome Address**

Alexander O'Leary, Director, PBC Group

08:35 Opening Keynote Panel

Driving Diversity, Equality & Inclusion in Clinical Trials

The need to attract a diverse group of patients is no longer a nice to have but a need to have since the FDA published guidelines on this in 2022. Since then trial sponsors have seeked collaborations to drive trust, and reach a wide range of patient groups.

In this panel, we will discuss the measures taken at both trial sponsor and site level to attract diverse patient groups to clinical studies. With the panel sharing best practice and case studies of past projects, as well as idealising how to increase diversity in the future.

Chair: Nicole Powell – VP, Business Development – SDC (Statistics & Data Corporation)
Rajbir Singh - Executive Director, Precision Medicine and Health Equity Trials Design - Meharry Medical College
Arla Yost – Clinical Research Operations Director – Helen Diller Family Comprehensive Cancer Center (UCSF)
Meghan McKenzie – Principal, Patient Inclusion & Health Equity, Chief Diversity Office - Genentech

09:15 **Introduction to Conference Chair**

Kalyan Obalampalli - CEO - ClinAI

09:20 Keynote

Clinical Outsourcing Trends in 2023

Understanding what is key for successful outsourcing for small sponsors, and how sponsors make the 'right 'choice of vendors is essential for study success. The clinical outsourcing market is constantly evolving, impacted by the economic environment, regulatory considerations and personnel challenges.

Dana will draw on her experience working for both small and large CROs over the past two decades to share case studies of what has worked well and, not so well, for small biotechs outsourcing their clinical trial activities. Sharing recent trends to be impacting outsourcing models in 2023.

Dana Leff Niedzielska - CEO - August Research

09:50 Keynote

Building the Foundations of Patient Advocacy in Clinical Research

The role of patient advocacy in clinical planning, development and execution is constantly changing. With more and more trial sponsors choosing to build teams in-house to help the clinical research function.

In this session Mary will share her experience building and developing the patient advocacy function at Cytokinetics, as well as providing insight into recent successes when incorporating patient input for protocol development and designing innovative endpoints.

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Mary Pomerantz – Senior Director, Patient Advocacy & Engagement - Cytokinetics

10:20 **Morning Refreshments & Networking Break**

	Stream A **Patients** Chair: Sarah Mullen – VP, Clinical, Quality, Regulatory - HeartFlow	Stream B **Clinical Trial Supply & Technology** Chair: *Kalyan Obalampalli - CEO - ClinAI*
10:50	Insight **Applying the Principals of Patient Finding to Non-Rare Disease Studies** *When recruiting for rare disease studies, due to the very nature of the population it is challenging to find and recruit patients, the principals adopted can be translated into mainstream studies.* This session will share how these principals can be translated into non-rare disease trials. Sharing principles of population mapping, process scheduling and collaboration. *Mari Maurer – Independent Rare Disease Consultant*	Interactive Panel **Impact of Technology on Trials Since the Pandemic** *In 2022 there were over 1,300 clinical trials which were either fully decentralised or incorporated a virtual component. Most trials adopt a hybrid structure which would have previously not been possible if it were not for the plethora of technologies available to trials sponsors.* This panel explores the technologies available today (from Biometrics, to Wearables) to incorporate into study design & execution, and the key considerations when implementing a DCT or hybrid trial design. *Allyson Gunsallus – Associate Director, Clinical Outsourcing – BridgeBio* *Mamta Thakker – Director, Clinical Operations – Pliant Therapeutics* *Shae Wilkins – CEO - TRYAL*
11:20	Insight **Is the hype real? Real-life user experience of an AI tool for Clinical Study Report (CSR) production** What a year it's been for artificial intelligence (AI)! The pace at which the conversation around AI has accelerated in 2023 is unprecedented. AI is beginning to affect almost every industry, and medical writing is no different. Looking back on almost 1 year of using an AI tool in day-to-day CSR production at a medical writing company, this session will report on how using the tool changes the process of planning and writing regulatory documents and will give some ideas about new ways of thinking that medical writers and authoring teams need to be open to as these technologies become common place.	Insight **Drug Supply Management: Ensuring Supply Safety While Generating Huge Savings** Managing drug inventory is crucial for sponsors and sites to meet the requirements of trials while controlling costs. However, drug supply management comes with risks of shortages, expirations, and waste. In this session Yves will share the key challenges faced when supplying investigational and comparator drugs to international clinical trials. Sharing tactics as to how to reduce waste, and reduce costs. *Yves Dethier - Founder - BOOSTCODE*

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Lisa Chamberlain James - Senior Partner - Trilogy Writing & Consulting

11:50

Insight

Oncology: How to (& how not to) Engage Patients

One report states that the minimum cost of a phase 1 oncology trial to be $2.5m, sharply rising for later stages. Oncology trials often struggle with patient recruitment and retention, and heterogeneity of patient population.

In this session Caro will share initiatives adopted to attract, identify and engage patients in early-stage oncology trials. Providing insight into her experience partnering with vendors for patient identification, genomics & concierge travel services. As well as enforcing the importance of results sharing post-trial.

Caro Unger – Senior Director, Clinical Operations– Kinnate Biopharma

Interactive Panel

Meeting Complex Clinical Supply Chain Requirements

Clinical trials are becoming more complex with the rise of DCT, multi-site international studies, cell & gene therapies, & temperature sensitive drugs.

This panel discussion is designed to review the current landscape for clinical drug supply, highlighting challenges faced in 2023 and measures suggested to meet requirements.

Yuyi Shen – VP, Technical Operations – Abcuro
Thomas Tredennick – Association Director, Supply Chain - ArsenalBio

12:20 **Lunch & Networking Break**

	Stream A **Patients** Chair: *Kalyan Obalampalli - CEO - ClinAI*	Stream B **Clinical Trial Supply & Technology** Chair: *David Jones – Head of Content – COG Series*
1:20	Insight **Partnering with Patients: Embedding the Patient Voice into Clinical Development Pathways** *Involving the patient's voice at study design stage can help achieve patient enrolment goals, as well as ensure that patients remain engaged throughout the trial.* This presentation will share how insights from patients can be obtained across the drug development lifecycle through partnering with patients and patient advocacy groups. Ranging from developing patient panels, to patient interaction throughout the clinical development process. *Lisa Lea - Director, Patient Insights – Merck*	Insight **Utilising Real World Evidence to Adapt Study Design & Execution** *With availability of digital and analogue modes of data collection we need to ensure their appropriate use in real world studies, both within study design and the future execution.* The presentation will share models of RWE collection and how to influence study design to best enable patients and collect data to benefit future study phases, and commercial launch. *Ritu Verma – Head of Global Clinical Affairs – Natus Medical*
1:50	Insight	Insight

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Building Customization into Innovative Clinical Trial Solutions

Not all clinical trials are the same, so why use a solution that treats them the same? SDC has crafted applications that focuses on customization capabilities from the beginning, allowing for rapid deployment of the solutions that are flexible and fit nearly every need.

In this session Julian will focus on SDC's proprietary ePRO solution, SDC Capture as well as SDC Data Hub which allows for the centralization and mapping of disparate data sources using custom business logic. This will also show how a cost-effective solution provides greater patient compliance and participation. We are looking forward to an interactive demonstration with the audience!

Julian Philips - VP Data Insights & Automation - SDC

Empowering Patients and Sponsors: Revolutionizing Clinical Trials through Wearable Technology and Digital Integration

From tracking vital signs and activity levels in real-time, to capturing continuous patient data remotely, wearables provide researchers with data quality and accuracy—objective and unbiased—painting a comprehensive picture of a patient's health.

This presentation delves into the cutting-edge innovations in wearable device technology and the world of consumer-based wearables and what could be their seamless integration into clinical trials, powered by Delve Health's pioneering platform. Demonstrating the unparalleled advantages of wearable accessibility, as well as overall efficiency and accuracy of data collection. Empowering researchers, clinicians and patients alike—while also saving sites/sponsors time and money by automating workflows which reduce human errors.

Wessam Sonbol – CEO – Delve Health

2:20

Insight

Harnessing Patient Populations in Developing Countries

A recent study found that 85% of clinical trials were conducted in the 25 highest income countries. Trials need to be conducted on the patient populations where the disease is most prevalent.

This presentation will address the opportunities as well as challenges of executing trials in the developing word, including enrolment considerations, barriers and hurdles to patient access as well as regulatory considerations.

Eric Humphriss - VP, Global Program Team Leader, Portfolio Strategy & Operations – Annexon Biosciences

Insight

Fireside Chat: Global Trade Compliance's Role in the Clinical Supply Chain

When conducting international clinical trials, it is essential to adhere to local laws on trade compliance. Failure to do so will result in delays, and possible fines.

During this onstage interview Matt will share key insight into how to meet international regulations and avoid unnecessary delays. As well as overall best practice on how to approach trial supply from a customs perspective.

Matt Burns – Director, Global Trade Compliance– Gilead Sciences

2:50 **Afternoon Coffee & Networking Break**

3:20

Keynote

Strategic AI Adoption for Accelerated & Cost-effective Clinical Trials

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If you're not talking about AI, you're probably thinking about it! The benefits of AI adoption seem to be limitless with boardrooms across the globe looking at ways to integrate AI-based tech to save time, resources and money.... But how do you identify hype vs. results?

In this presentation Shae will explore how artificial intelligence and automation can be leveraged to rapidly set up and configure clinical trial systems, reducing costs and accelerating study timelines. When is AI suitable for adoption, and when will it cost you more time and resources?

Shae Wilkins – CEO - TRYAL

3:50 Keynote

Maximizing Success: Strategic Planning & Execution of Large Pivotal Double-Masked Phase III Trials in Ophthalmology

Phase III trials typically require substantial resources in terms of funding, personnel, infrastructure, and logistics. Smaller organizations often struggle executing large phase III trials due to limited budgets and resources.

Bruno will share insight into Opthea's program to develop an innovative treatment for Age-Related Macular Degeneration (wet AMD), which includes two large double-masked trials (200 sites per study with ~1,000patients each). Sharing best practice into the design, planning and execution of large pivotal phase 3 trials with limited resources.

Bruno Gagnon – Senior Vice President, Global Clinical Operations – Opthea

4:20 Keynote

The Essential Role of Adjudication Technology in Clinical Trials

In clinical trials, the Clinical Events Committee (CEC) plays a vital role in assessing the occurrence and severity of adverse events and determining their relationship to the investigational drug or device. Adjudication can help reduce bias, variability, and uncertainty in interpreting study results. The increasing regulatory pressure for independent adjudication, coupled with greater complexity in study designs and varied endpoints, makes managing the adjudication process critical.

This presentation explores the ways in which comprehensive EDC platforms can enhance and streamline the CEC Adjudication process in clinical trials. Additionally, Lasser highlights the essential tools to look for in technology solutions that support the evolving demands of today's clinical trials.

Stacey Lasser - Sr. Project Manager - Mednet

4:50 Keynote

Applying Theory to Practice

When executing new strategies within clinical research there is often a lack of resources for practical application. This lack of resources can negatively impact start up schedules, as well as execution of clinical trials.

In this session Jess will share insight into the formation of ACRPM, and its key mission to improve project management processes across clinical research. As well as sharing resources available via ACRPM to improve overall quality of clinical research, and up skill project managers in the space.

Jess Thompson – CEO & Founder – Association of Clinical Research Project Managers

5:20 **Networking Drinks Reception *(complementary admission to all conference participants)***

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Day 2: November 8th

08:15 **Registration & Welcome Refreshments**

08:50 Keynote Interactive Panel

Site Collaboration: Sharing Best Practise of How to Select, Manage and Retain Clinical Study Sites

Partnering with the right Clinical trial site(s) will impact the success of your trials. With many to choose from across North America, as well as Internationally, it is key to define your criteria for success, and thoroughly research the benefits of the sites based on the patient population you hope to attract.

This interactive panel discussion examines how the panellists chose and managed their clinical trial site, including insights on methods of management, data collection as well as addressing clinical needs to ensure success.

Chair: *Kalyan Obalampalli - CEO - ClinAI*
Jasmina Jankicevic – Independent Consultant (Pharma, Biotech, MedDevice & Cosmetic)
Anthony Maida – Chief Clinical Officer, Translational Medicine – Oncotelic Therapeutics
Ritu Verma – Head of Global Clinical Affairs – Natus Medical

09:30 Keynote

Best Practices for Optimizing Your Clinical Trial Execution Strategy for Biomarker and PK Samples

As precision medicine continues to grow across many therapeutic areas, researchers are zeroing in on specific genes, proteins, and other biomarker targets. Rigorous scientific evidence is needed in order to demonstrate a drug's ability to stimulate these mechanisms of action — but biomarkers and PK samples demand complex logistics, extensive vendor collaboration, and specialty assays that now support primary and secondary endpoints.

In this session, Mark will introduce the unique challenges associated with managing biomarker and PK samples before sharing important considerations for vendor management, data management, and operations when executing a clinical trial that relies on precision medicine.

Mark Melton – VP, Scientific Operations & Development - SLOPE

10:00 Keynote

How to Leverage Vendors/ CROs

Official figures list just over 450,000 active studies globally, with a vast majority being developed through commercial trial sponsors. In this highly competitive landscape, it is key to adopt strategies to best leverage development partners – no matter the size of your organization.

In this presentation Todd will delve into his experience working across small/ medium biotech, as well as most recently at Pfizer to share the methods of leverage over CROs/Vendors when conducting clinical trials.

Todd Reul – Director, Clinical Outsourcing - Pfizer

10:30 Keynote

Building a Robust, Flexible, and Sustainable Clinical Supply Chain

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Creating, maintaining, and managing a clinical supply chain can be incredibly complex due to regulatory compliance, demand variability, global considerations, and supplier management. Sponsors often seek to outsource supply chain management to ensure and maintain its integrity.

In this session Sascha will share current challenges facing clinical supply chains, as well as provide insights into predicted challenges ahead. Presenting innovations from SanaClis which support a durable supply chain.

Sascha Sonnenberg - Global Vice President, Business Development – SanaClis

11:00 **Morning Refreshments & Networking Break**

11:30 Insight

Top 10 Tips for CRO Selection

The CRO market is awash with consolidation, spinoffs, and strategic partnerships – making it hard to firstly identify the best partner for your clinical studies as well as compare them for their suitability.

Having sourced CROs over the last twenty years for companies in Europe and the US, biotech and pharma, and having recently selected a partner for a novel Small Biotech phase III program, Chris will share some new insights and implementable solutions for common challenges in CRO selection.

Christopher Saunders – Executive Director, Development Outsourcing – Alladapt Immunotherapeutics

12:00 Insight

Phase I Outsourcing: Small Biotech Perspective

The average cost for a Phase I trial is widely reported at $4 million but can vary dependant on therapeutic area and complexity. In the perspective of a small biotech this a huge investment and you want to work with the best vendors for your company to be best positioned for success.

This case study shares insights from Nonnie at Terns Pharmaceuticals when planning for a past Non-alcoholic steatohepatitis (NASH) study. Nonnie will provide insights into methods used to engage with suppliers, identify and engage the right sites, as well as enrol patients.

Nonnie Licona – Senior Director, R&D Outsourcing, Contracts & Vendor Management – Terns Pharmaceuticals

12:30 Insight

Outsourcing to Australia: The Essential Tips for Trial Success

A recent report states that clinical trials in Australia be 60% more cost-effective, after-tax incentives, when compared to the US. Coupled with high quality research facilities, efficient ethics and regulatory frameworks and fast regulatory approval timelines.

In this session Oranee shares insights from her experience when outsourcing clinical research to Australia, sharing her ‘dos’ and ‘don’ts’ to avoid common mistakes made.

Oranee Daniels – Chief Medical Officer – Antiva Biosciences

1:00 **Lunch & Networking Break**

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2:00

Keynote

Trauma-Informed Study Design & Facilitation in Psychedelic Research

This presentation proposes a trauma-informed approach to psychedelic research, addressing study design, facilitation, participant retention, and diversity/inclusion. By integrating trauma-informed psychotherapeutic practices, research studies can prevent re-traumatization of vulnerable populations. Attention to diversity and inclusion principles in psychedelic research ensures ethical practices and more comprehensive data.

Gisele Fernandes-Osterhold – Director, Psychedelic Facilitation – University of California San Francisco

2:30

Keynote

Cell & Gene Therapy: Considerations for Early Phase Study Design & Execution

Conducting trials in cell and gene therapy candidates often bring additional challenges such as logistical considerations for collecting, modifying and re-administering, safety, small patient populations, and strict regulatory compliance.

This session will discuss ASC Therapeutics' GVHD allogeneic cell therapy phase IIb and Hemophilia A gene therapy phase I trial design, and execution. With experience across both cell and gene therapy trials Oscar can provide insight into the importance of collaboration with both academic and commercial partners to drive trial success.

Oscar Sergurado – Chief Medical Officer – ASC Therapeutics

3:00

Closing Keynote

Can You Sleep at Night? CRO Oversight & Governance

Trial sponsors must actively oversee outsourced studies and ensure patient safety, the ultimate responsibility for the trial activities and quality sits with the sponsor. Failing to provide proper oversight can result in regulatory compliance issues causing delays and shutdowns.

This presentation will address the best practice adopted by trial sponsors when overseeing an outsourced clinical study, whilst weighing up the risks when working with a local vs international vendor to reduce overall outsourcing compliance risk.

Jasmina Jankicevic – Independent Consultant (Pharma, Biotech, MedDevice & Cosmetic)

Meeting Ends