# Clinical Outsourcing Group West Coast

## San Francisco Airport Marriott Waterfront, Burlingame, CA

## November 7th & 8th, 2023

Blake Morrison – Vice President, Head of Global Medical & Scientific Affairs - **Sumitomo Pharma Oncology**
Lisa Lea - Director, Patient Insights – **Merck**
Rajbir Singh - Executive Director, Precision Medicine and Health Equity Trials Design - **Meharry Medical College**
Anthony Maida – Chief Clinical Officer, Translational Medicine – **Oncotelic Therapeutics**
Allyson Gunsallus – Associate Director, Clinical Outsourcing - **BridgeBio**
Arla Yost – Clinical Research Operations Director – **Helen Diller Family Comprehensive Cancer Center (UCSF)**
Sarah Mullen – Vice President, Clinical, Quality & Regulatory – **HeartFlow**
Jasmina Jankicevic – Independent Consultant, Clinical Development & Operational Strategy
Eric Humphriss – Vice President, Global Clinical Operations – **Annexon Biosciences**
Yves Dethier - Founder - **BOOSTCODE**
Todd Reul – Director, Clinical Outsourcing - **Pfizer**
Tim Davies - Executive Director of Business Development - **Delve health**
Irene Szeto – Executive Director, Global Digital Quality Management Systems & Business Intelligence - **BeiGene**
Trisha Devlin – Associate Vice President, Neuroscience Advocacy & Partnerships - **Eli Lilly and Company**
Jess Thompson – CEO & Founder - **ACRPM**
Mari Maurer – Independent
Mary Pomerantz – Senior Director, Patient Advocacy & Engagement – **Cytokinetics**
Christopher Saunders – Executive Director, Development Outsourcing – **Alladapt Immunotherapeutics**
Nonnie Licona – Senior Director, R&D Outsourcing, Contracts & Vendor Management – **Terns Pharmaceuticals**
Lisa Butler – Executive Vice President, Mission Impact – **National Eczema Association**
Yuyi Shen – Vice President, Technical Operations – **Abcuro**
Dana Leff Niedzielska - CEO - **August Research**
Thomas Tredennick – Association Director, Supply Chain – **ArsenalBio**
Ritu Verma – Head of Global Clinical Affairs – **Natus Medical**
Lisa Chamberlain James - Senior Partner - **Trilogy Writing & Consulting**
Gisele Fernandes-Osterhold – Director, Psychedelic Facilitation – **University of California San Francisco**
Oranee Daniels – Chief Medical Officer – **Antiva Biosciences**
Sascha Sonnenberg - Global Vice President, Business Development - **SanaClis**
Matt Burns – Director, Global Trade Compliance – **Gilead Sciences**
Bruno Gagnon – Senior Vice President, Global Clinical Operations - **Opthea**
Craig Peterson – Vice President, Clinical Research - **Vivus**
Mamta Thakker – Director, Clinical Operations – **Pliant Therapeutics**
Oscar Sergurado – Chief Medical Officer – **ASC Therapeutics**
Meghan McKenzie – Principal, Patient Inclusion & Health Equity, Chief Diversity Office – **Genentech**
Caro Unger – Senior Director, Clinical Operations – **Kinnate Biopharma**

**Complimentary delegate attendance** passes are exclusively reserved for pharma, biotech, and medical device companies who are trial sponsors and not those who offer a service or solution of any kind.

Register for your pass here:
*https://www.thepbcgroup.com/registration-page*

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# November 7th - Day 1

08:00

Registration & Breakfast 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 driverse 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.

*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

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*

09:45

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.

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

10:15

Keynote

**Session Title To Be Confirmed**

**EarlyHealth Group**

10:45

Morning refreshments and networking break

| | Track A - Patients | Track B - Technology & Supply |
|---|---|---|
| 11:15 | Interactive Panel<br>**Driving Enrolment in Clinical Trials**<br><br>*Research has shown that up to 80% of studies are delayed by a month or more due to patient enrolment challenges.*<br><br>This panel will explore themes such as, but not limited to: Strategies adopted to attract and retain patients for studies, partnering with patient advocacy groups, reasons for trial termination and embedding clinical trials into the care environment to reach underrepresented populations.<br><br>*Blake Morrison, VP, Head of Global Medical & Scientific Affairs, Sumitomo Pharma Oncology*<br>*Sarah Mullen – VP, Clinical, Quality & Regulatory – HeartFlow* | Interactive Panel<br>**Impact of Technology on Trials Since the Pandemic**<br><br>*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.*<br><br>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.<br><br>*Irene Szeto – Executive Director, Global Digital Quality Management Systems & Business Intelligence – BeiGene*<br>*Allyson Gunsallus – Associate Director, Clinical Outsourcing – BridgeBio*<br>*Mamta Thakker – Director, Clinical Operations – Pliant Therapeutics* |
| 11:45 | Insight<br>**Session Title To Be Confirmed**<br><br>SDC | Insight<br>**Session Title To Be Confirmed**<br><br>*Yves Dethier - Founder - BOOSTCODE* |
| 12:15 | Insight<br>**Applying the Principals of Patient Finding to Non-Rare Disease Studies**<br><br>*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.*<br><br>This session will share how these principals can be translated into non-rare disease trials. Sharing principals of population mapping, process scheduling and collaboration.<br><br>*Mari Maurer – Independent Rare Disease Consultant* | Interactive Panel<br>**Meeting Complex Clinical Supply Chain Requirements**<br><br>*Clinical trials are becoming more complex with the rise of DCT, multi-site international studies, cell & gene therapies, & temperature sensitive drugs.*<br><br>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.<br><br>*Yuyi Shen – VP, Technical Operations – Abcuro*<br>*Thomas Tredennick – Association Director, Supply Chain - ArsenalBio* |
| 12:45 | Lunch and networking break | |

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| | Track A - Patients | Track B - Technology & Supply |
|---|---|---|
| 13:45 | Insight<br>**Partnering with Patients: Embedding the Patient Voice into Clinical Development Pathways**<br><br>*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.*<br><br>This presentation will share how insights from patients can be obtained across the drug development lifecycle through partnering with patients and patient advocacy groups.<br>Ranging from developing patient panels, to patient interaction throughout the clinical development process.<br><br>*Lisa Lea - Director, Patient Insights – Merck* | Insight<br>**AI & ML Tech to Improve Quality**<br><br>*Biopharma organizations are gradually adopting the AI and Big Data across all functions. The additional cost of this technology is easily recouped from streamlining processes and generating actionable insights to aid in strategic decisions.*<br><br>In this session Irene shares how BeiGene have adopted AI & ML technologies to provide predictive analysis and insights for upstream business operations – how this works, and the benefits felt.<br><br>*Irene Szeto – Executive Director, Global Digital Quality Management Systems & Business Intelligence - BeiGene* |
| 14:15 | Insight<br>**Is the hype real? Real-life user experience of an AI tool for Clinical Study Report (CSR) production**<br><br>*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.*<br><br>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.<br><br>*Lisa Chamberlain James - Senior Partner - Trilogy Writing & Consulting* | Insight<br>**Empowering Patients and Sponsors: Revolutionizing Clinical Trials through Wearable Technology and Digital Integration.**<br><br>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.<br><br>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.<br><br>*Tim Davies - Executive Director, Business Development - Delve Health* |
| 14:45 | Insight<br>**Harnessing Patient Populations in Developing Countries**<br><br>*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.*<br><br>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.<br><br>*Eric Humphriss - VP, Global Clinical Operations – Annexon Biosciences* | Insight<br>**Fireside Chat: Global Trade Compliance's Role in the Clinical Supply Chain**<br><br>*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.*<br><br>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.<br><br>*Matt Burns – Director, Global Trade Compliance – Gilead Sciences* |

15:15

Afternoon coffee and networking break

15:45

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 ~1,000 patients each). Sharing best practice into the design, planning and execution of large pivitol phase 3 trials with limited resources.

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

16:15

Keynote

**Session Title To Be Confirmed**

**Mednet**

16:45

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 - ACRPM*

17:15

Keynote Interactive Panel

**Harnessing Non-Profit Organisations: From Academic to Patient Advocacy How to Improve Trial Awareness & Improve Enrolment**

*North America is home to some of the world's leading institutions for research (13 of top 20 universities globally), many of which initiate trials and conduct globally recognised medical research. Patients are supported by an extensive network of patient advocacy groups which lead the discussion on developing new treatments. Connecting with these organisations provides access to patient populations as well as the opportunity to benefit from the wealth of knowledge held by industry and medical experts.*

This panel shares the opportunity and benefits for trial sponsors when collaborating with not-for-profit organisations – understanding and access to patient populations, driving trial recruitment as well as generation of RWE.

*Trisha Devlin – Associate Vice President, Neuroscience Advocacy & Partnerships - Eli Lilly and Company*
*Mary Pomerantz – Senior Director, Patient Advocacy & Engagement – Cytokinetics*
*Lisa Butler – Executive Vice President, Mission Impact – National Eczema Association*

17:50

Networking Drinks and Canapés Reception (complementary admission to all conference participants)

# November 8th - Day 2

08:20

Registration & Breakfast 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.

*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

**Session Title To Be Confirmed**

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**

*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 it's 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 and networking break

| | Track A - Outsourcing | Track B - Study Design |
|---|---|---|
| 11:30 | Insight<br>**Top 10 Tips for CRO Selection**<br><br>*The CRO market is awash with consolidation, spin-offs, and strategic partnerships – making it hard to firstly identify the best partner for your clinical studies as well as compare them for their suitability.*<br><br>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 phase III program Chris will share some new insights into internal stakeholder engagement, contract negotiations as well as CRO assessment.<br><br>*Christopher Saunders – Executive Director, Development Outsourcing – Alladapt Immunotherapeutics* | Insight<br>**Utilising Real World Evidence to Adapt Study Design & Execution**<br><br>*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.*<br><br>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.<br><br>*Ritu Verma – Head of Global Clinical Affairs – Natus Medical* |
| 12:00 | Insight<br>**Phase I Outsourcing: Small Biotech Perspective**<br><br>*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.*<br><br>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.<br><br>*Nonnie Licona – Senior Director, R&D Outsourcing, Contracts & Vendor Management – Terns Pharmaceuticals* | Insight<br>**Oncology: How to (& how not to) Engage Patients**<br><br>*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.*<br><br>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.<br><br>*Caro Unger – Senior Director, Clinical Operations – Kinnate Biopharma* |
| 12:30 | Insight<br>**Outsourcing to Australia: The Essential Tips for Trial Success**<br><br>*A recent report states that clinical trials in Australia can 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.*<br><br>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.<br><br>*Oranee Daniels – Chief Medical Officer – Antiva Biosciences* | Insight<br>**Trauma-Informed Study Design & Facilitation in Psychedelic Research**<br><br>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.<br><br>*Gisele Fernandes-Osterhold – Director, Psychedelic Facilitation – University of California San Francisco* |

13:00

Lunch and networking break

14:00

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***

14:30

Keynote

**Phase IV Trial Start-Up & Execution in Adolescents**

*Conducting trials with adolescent patients can bring a multitude of huddles to overcome; consent, recruitment and retention, and, adherence and compliance.*

This session will discuss the phase IV Qsymia trial of 200 adolescent patients. Craig will share the challenges faced in comparison to the adult trial, as well as complications faced due to the COVID pandemic. Including site selection & patient recruitment, telemedicine & remote monitoring, and vendor outsourcing.

***Craig Peterson – Vice President, Clinical Research - Vivus***

15:00

Closing Keynote

**Can You Sleep at Night? CRO Oversight & Governance**

*Proper oversight of any outsourced study is absolutely necessary. The risk-based approach to oversight and high-touch sponsor practices are crucial for ensuring continued patient safety, regulatory compliance, high quality of the dataset and completion within projected timelines and budget.*

This presentation will address the best study oversight and governance practices adopted by sponsors and CRO to predict and mitigate risks and challenges in the current global, regional, and project-specific clinical research environments.

***Jasmina Jankicevic – Independent Consultant, Clinical Development & Operational Strategy***

**End of Conference**