CLINICAL OPERATIONS IN ONCOLOGY TRIALS WEST COAST 2023

25th – 26th April

Burlingame, **California**

www.arena-international.com/event/oncologywestcoast/

2023 SPEAKERS

Ekatherina Goryachikov, VP and Head of Clinical Operations, **Adicet Bio**

Oscar Segurado, Chief Medical Officer, **ASC Therapeutics**

Arla Yost, Director, HDFCCC Clinical Research Operations**, University of California San Francisco**

Luis A. Aguilar, VP, Business and Clinical Operations, **Candel Therapeutics**

Joe Coffie, Director, Clinical Operations, **Imago Biosciences**

Joe Shan, Executive Director, Clinical Development Operations, **MEI Pharma**

Farah Anwar, Senior Vice President, Head of Development Operations and Inclusion, Diversity and Equity, **Sana Biotechnology**

Dorothy Nguyen, Vice President of Clinical Development, **AmMax Bio**

Gary Albert, Director, Clinical Operations, Patient Recruitment and Trial Management, **Formerly of Turning Point Therapeutics**

Lixia Wang, Senior Vice President, Data Science, **Vaxxinity**

Umar Hayat, Vice President, CMC and Supply Chain, **Union Therapeutics**

Prasun Mishra, Founding Partner, **World Investors and Entrepreneurs Society**

Joan Chambers, CEO, **Greater Gift**

Allyson Gunsallus, Associate Director, **BridgeBio**

Mary Syto, Senior Director, Clinical Science, **Bristol Myers Squibb**

Harit Nandani, Director, Clinical Data Management**, GRAIL, Inc**

Elise Brownell, Executive Vice President, Portfolio and Project Management, **Vivacitas Oncology**

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Catherine Caserza, Director, Clinical Operations, **Daichii Sankyo**

John Tomaro, Vice President, Clinical Operations, **Bolt Biotherapeutics**

Anthony Maida, Chief Clinical Officer, **Sapu BioScience**

Iris Sison, Senior Director Clinical Operations Oncology **,IGM Biosciences**

Clinical Operations in Oncology Trials 2023

DAY 1 – Tuesday 25th April 2023

7:45am	**Registration and refreshments**
8:20am	**Chairperson's opening remarks** **Iris Sison,** Senior Director Clinical Operations Oncology**, IGM Biosciences**
8:30am 	**Keynote Panel:** **Tackling the current industry trends in patient enrolment for oncology trials** • How we as an industry can work together to enhance enrolment • Analysing current trends in enrolment and sharing advice to increase trial uptake • Looking into the future and working together to build trust in the industry **PANELLISTS:** **Gary Albert,** Director, Clinical Operations, Patient Recruitment and Trial Management, **Formerly of Turning Point Therapeutics** **Arla Yost, Director,** HDFCCC Clinical Research Operations**, University of California San Francisco** **Luis A. Aguilar VP,** Business and Clinical Operations, **Candel Therapeutics**
9:00am 	**Oncology trial success: knowledge gained from 2020-2022** • Preparing for the unexpected – Lessons learned from 2Q20 • Thinking outside the box – Awareness of capabilities is the key to success • Strength within – Strategies for effectively leveraging the experience of your teams • It's a brave new world – The landscape of oncology trials going forward **Laura Currie,** Senior Clinical Research Associate, **ProTrials**
9:30am 	**Expanding early phase oncology trials outside of the US** • The pros and cons of internationalizing your trial at an early stage • Choosing which countries to expand your trials into, how to know which is best for you • Exploring the viability of other countries thanks to advances in data integrity • Site availability issues particularly following loss of sites due to geopolitical issues **Ekatherina Goryachikov,** VP and Head of Clinical Operations, **Adicet Bio**

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10:00am 	**Advancing Oncology Clinic Trials Option to Patients in the Local Community Setting** • Leveraging strategic site partnerships with local community hospitals • Expanding the advanced clinical trial offering and awareness • Easing the financial burden of local clinical trials vs travel to large hospitals for additional options • Patient and Care Family Story **Sarah Anderson**, Executive Director, Oncology Strategy Lead, **Worldwide Clinical Trials**	
10:30am	**Morning refreshments and networking**	
	Stream A: Clinical Operations in Oncology Trials **Chair: Iris Sison,** Senior Director Clinical Operations Oncology, **IGM Biosciences**	**Stream B: Technology & Innovation** **Sakis Paliouras,** Associate Director, Oncology and Hematology, US, **GlobalData**
11:00am 	**How are today's patients coping with modernized trials?** • A firsthand insight onto what it is like participating in a trial • Which key things helped make my time simpler on a trial • How even minor things from the protocol can have a huge impact on patients **Catherine Caserza,** Director, Clinical Operations, **Daichii Sankyo**	**Precision clinical trials in the era of big data, artificial intelligence, and precision medicine** • Exploring the innovations in modern clinical trials that have made a difference in precision medicine. • In the modernising world of AI how much impact can we expect that to have on clinical trials. • Identifying the future of Precision trials and highlighting the big players in the fie **Prasun Mishra,** Founding Partner, **World Investors and Entrepreneurs Society**
11:30am 	**Getting hard feasibility data: how to do it** • How do you access current, hard feasibility data? • Does your CRO have a stable, permanent clinical team with trial legacy capability and expertise in your domain? • Are your sites and vendors audit proof? • Does your CRO act like a SMO with a dedicated site network? • Are you confident your CRO has the capacity to achieve your study milestones on or before deadline? • Is your CRO independent, and well-rounded in regard to systems, with a collaborative vendor team of specialized expertise to support your program?	**Early phase oncology imaging endpoints: optimize the opportunity and avoid the risks** • Early phase imaging presents an opportunity to understand the nuances of your compound • Learn budget-friendly strategies to collect and assess radiology results in a phase 1 study • Know the risks of site-based imaging assessments **Kohkan Shamsi,** MD, PhD: Co-founder and Principal, **RadMD**

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	Julie Martin, CEO, **Scimega Research**	
12:00pm 	**Panel Discussion:** **Exploring modern innovation in oncology trials, have trials become over complicated with options?** • Highlighting the key changes in oncology in recent years • What do technological advancements actually offer for those running a trial • Discussing the uses of hybrid trials and what successes have been had **Dorothy Nguyen,** Vice President of Clinical Development, **AmMax Bio** **Prasun Mishra,** Founding Partner, **World Investors and Entrepreneurs Society** **Harit Nandani,** Director, Clinical Data Management, **GRAIL, Inc**	**Stream B Will Resume at 12:30**
12:30pm 	**LabCorp Presents** Case study in clinical trial management by LabCorp Our speaker from LabCorp will be joining us to share insights into cutting edge innovation in clinical trials and an update on LabCorp's latest technological developments	**Tech Spotlight** **Running up that hill: accelerate cycle times & reach patients faster with elluminate** *Learn how the elluminate Clinical Data Cloud and Biometrics Services deliver* • Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety • Improved study oversight with a holistic view of risk across all data sources • 50 out-of-the-box visualizations to support supports cross-study analysis for deeper insights with self-service access to clinical and operational analytics • Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles **Dan McGann,** Solutions Consultant, **eClinical Solutions**
1:00pm	**Lunch and networking**	

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2:00pm 	**Panel Discussion:** **Reducing the patient burden, what we as an industry can do to help** • Can we utilize parts of decentralized trials to help patients or do they actually make things worse • How to work with sites to ensure that we create patient friendly protocols • Sharing experiences from previous trials to learn together for the good of the patient **PANELLISTS:** **Joan Chambers**, CEO, **Greater Gift** **Mary Syto,** Senior Director, Clinical Science**, Bristol Myers Squibb**	**Best practices for safety and data review committees for early oncology studies** • Real ways of managing the essential committees that you need to work with • Tips and tricks of realizing which type of companies are essential to work with and how to work with them **Lixia Wang,** Senior Vice President, Data Science, **Vaxxinity**
2:30pm 	**Closing the divide, how to work with supply as clin ops when it comes to study design.** • The essentials of communication with your CMC team when designing a study to ensure its success • Highlighting the current issues in supply and what to expect in the near future • Tips and tricks for a strong overall clinical team **Umar Hayat,** Vice President, CMC and Supply Chain, **Union Therapeutics**	**Workshop: How to create an essential product target profile for drug development** • An interactive session designed to give a key skillset to those looking to enhance their skills in drug development **Elise Brownell**, Executive Vice President, Portfolio and Project Management, **Vivacitas Oncology**
3:00pm	**Tech Spotlight** **TRIAL DIVERSITY: Tech-enabled selection of clinical trial sites with diverse patient populations** • FDA now requires Phase 3 trials to submit a Diversity Plan; learn about what should be included • Learn about an effective, tech-enabled solution to identify clinical trial sites with the most diverse patient populations • Translate data into Diversity Plan enrollment targets for your clinical trial and an action plan for site selection and activation **Sandra Shpilberg,** Co-Founder & CEO, **Adnexi**	
3:15pm	**Afternoon refreshments and networking**	

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3:45pm 	**Panel Discussion:** **Working in partnership with clinical sites to improve the accuracy and efficiency of your trial** • Highlighting the common issues of an oncology trial from a site perspective • How to work with sites to reduce turnover and burnout • Best practices to support sites to reduce the overall burden on them • Designing protocols with sites to ensure ease of use **PANELLISTS:** **Joe Coffie,** Director, Clinical Operations, **Imago Biosciences** **Joan Chambers**, CEO, **Greater Gift** **Anthony Maida**, Chief Clinical Officer, **Sapu BioScience**
4:30pm 	**Drive oncology trial execution with the right tools, resources, and experience** • Over the last decade, novel oncology treatments across multiple therapeutic classes have driven better patient outcomes • A proliferation of oncology focused biotechs and therapies in development resulted in a highly competitive field focused on many of the same therapeutic targets • In addition, the number of ongoing and recruiting oncology clinical trials has slowed patient enrolment and made site identification more difficult • To avoid clinical trial delays it is critical to identify research experienced investigators and sites that treat protocol-specific patient populations **Andy Kinley,** Vice President, Innovation and Clinical Science, **Precision For Medicine**
5:00pm	**Chairperson's closing remarks**

END OF DAY 1 AND NETWORKING DRINKS

Clinical Operations in Oncology Trials 2023
DAY 2 – Wednesday 26th April 2023

8:15am	**Registration and refreshments**
8:50am	**Chairperson's opening remarks**

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9:00am 	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into four 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within clinical operations in oncology trials. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: **Addressing the latest budgeting challenges we are facing and sharing cost saving techniques.**
	ROUNDTABLE 2: Working alongside CROs, tips and strategies for relationship management.
	ROUNDTABLE 3: Working on protocol design for the long run, discussing best practices for modern trials **Joe Shan**, Executive Director, Clinical Development Operations , **MEI Pharma**
	ROUNDTABLE 4: How to work with sites to get them to prioritise your study **Iris Sison,** Senior Director Clinical Operations Oncology, **IGM Biosciences**
10:15am	**Morning refreshments and networking**
10:45am 	**Innovative approaches to oncology clinical study designs and operations after the pandemic disruptions** • Defining the key changes driven by the pandemic • Patient focus and decentralization in oncology trials: • Looking into the future, what to consider when planning early phase trials **Oscar Segurado,** Chief Medical Officer, **ASC Therapeutics**
11:15am 	**Designing and pperationalizing oncology trials that increase patient diversity across study phases** • Trial Design and Start-up Considerations • Enrolment and Retention Tactics • Patient Advocacy and Community Strategy **Laura Accettola,** Vice President, Hematology/Oncology, Therapeutic Unit Head, **PPD** **Jeffery Pettit-Williams,** Principal Project Manager, Patient Diversity, **PPD**
11:45am 	**Case Study:** **Handling an early phase trial that doesn't go to plan** • Discussing the key problem areas that can go wrong in early phases of clinical trials • Negotiations with CRO's when you have contradicting expectations of a trial • Diverting resources in the most efficient way when something unexpected happens

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	John Tomaro, Vice President, Clinical Operations, **Bolt Biotherapeutics**
12:00pm	**Lunch and networking**
1:30pm 	**A Survey of Colleagues:** **Identifying how have shifts in available tech have impacted clinical trial and work success in recent years** • Highlighting the key areas in which the industry is thriving and struggling with new tech • Comparing Oncology studies with alternative indications in a variety of factors • Discussing impacts on quality of work as a sponsor in the industry **Allyson Gunsallus**, Associate Director, **BridgeBio**
2:00pm	**The clinical development landscape of cell therapies in oncology** • Clinical trial landscape of pipeline drugs • Overview of currently marketed drugs and future projections • Analysis of hematological versus solid cancers • Overview of the most promising technologies by market size, including CAR-T and CAR-NK cells, TCRs, and others **Sakis Paliouras,** Associate Director, Oncology and Hematology, US, **GlobalData**
2:30pm	**Chairperson's closing remarks**

END OF CONFERENCE