17th Annual Outsourcing in Clinical Trials West Coast 2025

11th - 12th February Hyatt Regency San Francisco Airport, California USA

'This conference will bring industry professionals together to share knowledge, with a focus on collaboration, advancing clinical development and concentrating on clinical operations, innovation, and technology'

Event website

For the 17th Annual event, our flagship show will focus on providing delegates with practical take-aways and solutions to their most current operational and outsourcing challenges in clinical trials, this is an event not to be missed.

2025 Speakers

Leesa Gentry, Chief Clinical Officer**, RenovoRx**
Laurin Vincent, Executive Director, Vendor Quality Management**, Gilead**
Susan Edelstein, PhD, SVP, Clinical Research**, Ardelyx**
Joshua Cox, Vice President of Clinical Data & Analytics Capabilities**, Eli Lilly and Company**
Bao Dinh, Global Development Business Operations**, Takeda**
John Rootenberg, Principal Director, Digital Safety and Decision Support**, Genentech**
Matthew Albert, Vice President, Translation & Early Clinical Development**, Octant Bio**
Sandra Nino-Siddens, Vice President Global Regulatory Affairs**, Ultragenyx Pharmaceutical**
Ros Cheetham, Vice President, Clinical Operations**, MacroGenics**
Jad Adaimi, Executive Director - Global Regulatory Affairs**, Ultragenyx**
Anthony L Colenburg Sr, Senior Director & Site Head of Quality**, Sutro Biopharma**
Meir Pinco, Associate Director, IT Data & Analytics**, BeiGene**
Laura O'Donnell, Senior Director, Head, Global Site Engagement**, GSK**
Cathy Scharf, Patient Advocate**, Patient Advocates of the East Bay**
Abby Kennedy, Senior Vice President of Clinical Operations**, DermBiont**
Vineeta Gulati, Former Director of Clinical Operations**, CymaBay Therapeutics**
Yuyi Shen, Vice President, Technical Operations**, Abcuro**
Peter St.Wecker, Ph.D., Clinical Development Lead, Neurology**, UCB**
Sarah Hamirani, Portfolio Director**, AbbVie**
Thomas Tremblay, Vice President, Head of Clinical Operations**, Trefoil Therapeutics**
Jasmina Jankicevic, Clinical Development and Medical Affairs**, RAPT Therapeutics**
Gina Morton, Former Director of Contracts and Outsourcing**, Calico and Genentech**
Jenni Herber, Associate Director, Clinical Operations**, Kamau Therapeutics**
Janet Moga, Lead, DCT Operations**, Astellas Gene Therapies**
Shantheri Pai, Associate Director, Clinical Operations – Oncology, **Gilead**
Sage Callaway, Associate Director, Clinical Business Operations, Oncology**, Ascendis Pharma**
Christine Van Raesfeld, Patient Advocate

Join our new community on LinkedIn
#OCTWestCoast | @ArenaIntPharma

Jenelle Lin, Associate Director, Clinical Operations, **Aditum Bio**

Chris Chan, Vice President, Financial Planning & Analysis**, IGM Biosciences**

Bruce Morimoto, Head of Drug Development, **Fuku Biotech**

Meghan McKenzie, Director of Health Equity and Clinical Research, Chief Diversity Office, **Genentech**

Archana Sah, Oncology Board Member**, Society for Clinical Research Sites**

Amy Que-Xu, Health Technology, Clinical Science Team**, Meta**

Nisha Trivedi, Rare Disease Patient Advocate

Tatiana Eidus, Director Corporate Development North America, **ARENSIA Exploratory Medicine**

Bogdan Sandica, Senior Manager Trial Optimization**, ARENSIA Exploratory Medicine**

Amy Mou, Vendor Strategy Expert

David Larwood, CEO**, Valley Fever Solutions**

Rozanno Gonzales, Clinical Innovation & Technology Leader**, Genentech**

Hayley Lane, Vice President Clinical Operations**, Star Therapeutics**

Prasun Mishra, Founder and CEO, Agility Pharmaceuticals

Chitrang Dave, Global Head of Enterprise Data & Analytics**, Edwards Lifesciences**

Lian Cunningham, Vice President of Clinical Affairs**, Endogenex**

Charles Aunger, Managing Director**, Health2047**

Revati Tatake, Global Head of Pharma Research, Analysis and Competitive Intelligence**, GlobalData**

Tania Pearson, Regulatory Systems Director**, Medtronic**

Kathryn Wine, Vice President Clinical Affairs**, Novocuff**

Kade Shippy, Chief Diversity Office, Patient Inclusion and Health Equity, **Genentech**

Audrey Funwie, Chief Diversity Office, Patient Inclusion and Health Equity**, Genentech**

Eleanor Miller, Clinical Trial Liaison**, PSI CRO**

Steve Rosenberg, Chief Executive Officer**, uMotif**

Sandra Shpilberg, CEO & Co-founder**, Adnexi**

Lona Sheeran, Senior Vice President, Clinical Operations Early Phase**, Worldwide Clinical Trials**

Kenneth Park, MD, VP, R&D Strategy and Productivity, Consulting**, Fortrea**

Avnika Agarwal, Senior Director, Project Delivery**, ICON Biotech**

Marija Jovanovic, MD, Director, Project Delivery, **ICON Biotech**

Andrew Feigin, MD, Chief Medical Officer**, Rho**

Peter Schmidt, PhD, Chief Scientific Officer**, Rho**

Catherine Jervis, General Manager Integrated Solutions**, MRN**

Zahiah (Zee Zee) Gueddar, Senior Director, Commercial Lead, Financial Strategy & Corporate Development, **IQVIA Technologies**

Katsura Kasahara, Executive Professional**, EPS Corporation**

Kathleen Dowell, VP, Medical Imaging and Specialty Solutions**, Clario**

Aditya Kotta, Head of Business Development US & EU, **Novotech**

Stephanie Hitchcock, Director, Project Management – Global Clinical Trials**, PCM Trials**

Neil Berger, Vice President, FSP Commercial and Operational Strategy**, Parexel**

Sarah Cross, PhD, Vice President and Global Head of Medical Affairs**, Premier Research**

Jon Raven, Chief Commercial Officer**, Emsere**

Bryan Dunlap, Business Develop Manager, North America**, Emsere**

Sales Enquiry
Nick McCudden
Head of OCT Events
T: +61 280 978 126
E: nicholasmccudden@arena-international.com

Speaker Enquiry
Niki Khoshkbary
Senior Conference Producer
T: +44 (0)20 4540 7545
E: niki.khoshkbary@arena-international.com

OUTSOURCING IN CLINICAL TRIALS WEST COAST
DAY 1 - Tuesday 11th February 2025

7:30am	**Registration and refreshments**
8:20am	**Chair's opening remarks** **Chair: Susan Edelstein, PhD, SVP, Clinical Research, Ardelyx**
8:30am	**KEYNOTE: How to optimize efficiencies at clinical trial sites when they're underperforming** • Building a partnership reciprocity between sites and sponsors to reduce discord and ensure sites are confident enough to succeed • Is it fair to place the shortcomings of trial success on site performance? • Developing an integrated strategic global site engagement model to transform site experience • Enabling innovative approaches to drug development and delivering new treatments to patients faster • Equipping sites with a clear and well-defined protocols to be able to best respond to sponsor needs ***Leesa Gentry, Chief Clinical Officer, RenovoRx***
9:00am	**Why so slow? Insider insights from the clinic floor to speed up the conduct of proof-of-concept patient trials** • Feasibility figures true to delivery • Regulatory dynamics for strategic advantages • Collaborate with patients and physicians to enhance access to innovative therapies • New study designs that accelerate development programs ***Tatiana Eidus, Director Corporate Development North America, ARENSIA Exploratory Medicine***
9:30am	**Optimizing clinical trials: Sponsor/CRO cooperation; working together to enroll appropriate patients** • Choosing the "right" CRO for your study and ensuring you get the "A" team or the team you were promised: and building a positive relationship with them • Clearly identifying who is responsible for each action item; especially items that are part of study start up (site ID, feasibility, site qualification) and how to proceed efficiently • Establishing realistic timelines and practicing constant communication to avoid timelines slipping • Keeping patients in mind when designing the protocol • Utilizing updated technology: A look at a recently adopted eISF system and potentially adopting a RBQM system • Using sites with a diverse population and promising constant communication with them • Sending an initial budget template early on to help streamline the budget process and identify sites that may not fit within the study budget early on. ***Susan Edelstein, PhD, SVP, Clinical Research, Ardelyx***
10:00am	**Maximizing the consultative partnership between CRO and pharma/biotech partners** • How early engagement can improve outcomes • How do we speak the same language, no one size fits all approach • Simplifying the complex, in a world of overwhelming outsourcing options and models

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	Marija Jovanovic, MD, Director, Project Delivery, ICON Biotech		
10:30am	**Morning refreshments and networking break sponsored by Ergomed** 		
	Stream A: Outsourcing & Clinical Operations Chair: Susan Edelstein, PhD, SVP, Clinical Research, Ardelyx	**Stream B: Clinical Technology & Innovation** Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company	**Stream C: Patient Centricity and DEI** Chair: Cathy Scharf, Patient Advocate, Patient Advocates of the East Bay
11:00am	**Ensuring that vendor oversight is embedded from end-to-end** • Effectively implementing a risk-based approach to vendor oversight • How to right-size vendor oversight for our high-risk activities being outsourced • Why is vendor oversight important and what regulations drive this • Recognizing the importance of cross-functional collaboration to best manage vendor activity ***Laurin Vincent, Executive Director, Vendor Quality Management, Gilead***	**How Machine Learning (ML) and human genetics are accelerating drug discovery: Foreseeing the impact on clinical trials** • In such sensitive environments, can you really trust AI to ensure the total compliance of your clinical trial? • How can we overcome data shortages in smaller trials for the necessary algorithms • Tangible use cases for successful implementation of AI in clinical trial data management • Ascertaining an attractive ROI with AI investment • Redefining biostatistics reporting as we traditionally know it with AI tools • Unlocking new endpoints ***Matthew Albert, Vice President, Translation & Early Clinical Development, Octant Bio***	**Ethical requirements and rights for patient disclosure and consent when implementing AI tools** • How do we look at data transparency issues when scaling AI? • Case study on AI rights and a look at recently released survey discussing where things need to change • Without GDPR, what can be done to protect patients regarding data sovereignty? • Delving into the unique and amplified challenges for AI risk assessment • How can we effectively leverage AI in our heavily regulated environment? ***Christine Van Raesfeld, Patient Advocate***
11:30am	**The 2025 Biotech Landscape: Perspectives and Projections** • Trends observed during the JP Morgan Healthcare conference • The impact of the new administration on clinical trials ***Aditya Kotta, Head of Business Development US & EU, Novotech***	**End-to-End financial management: Challenges and opportunities** • Gain insights into the complete process of end-to-end financial management. • Identify the inefficiencies caused by manual steps and siloed technologies. • Explore how combining services and software can	**From guidance to action: Navigating inclusivity in clinical trials** • Understand the evolving regulatory landscape and its implications for inclusivity in clinical trials. • Review data on industry trends and the growing emphasis on diversity in sponsor submissions and filings.

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		optimize the financial management process. • Learn how IQVIA Technologies' expertise and global reach can support your financial management needs, whether insourced or outsourced. ***Zahiah (Zee Zee) Gueddar, Senior Director, Commercial Lead, Financial Strategy & Corporate Development, IQVIA Technologies***	• Discover practical methods to recruit, engage, and retain underrepresented populations in clinical research. • Examine how prioritizing inclusivity improves study validity, compliance, and applicability, supported by real-world data. ***Stephanie Hitchcock, Director, Project Management – Global Clinical Trials, PCM Trials***
12:00pm	**PANEL DISCUSSION: Battling insufficient resources to allow your trial to succeed in an increasingly competitive landscape** • Battling site competitiveness to reduce delays on study start-up: what can you do differently to tackle these operational challenges? • When there are immense pressures on the trial ecosystem, how can we build quality and ensure quantity in an innovative way • Developing an optimized strategy as a small to medium-sized biotech with limited resources to stay afloat • Discussing the importance of protocol optimization and specialized statistical support to reduce the pressure on sites and relieve bottlenecks ***Chair: Susan Edelstein, PhD, SVP, Clinical Research, Ardelyx*** ***Panelists: Sage Callaway, Associate Director, Clinical Business Operations, Oncology, Ascendis Pharma***	**PANEL DISCUSSION: Translating technology into tangible outcomes and what are the latest ways in which it's disrupting the clinical trial industry** • Are we playing technology catch-up: What can we learn and adapt from other industries, and how can we implement this on scale despite increased regulation? • Lots of clinical management systems are generic but do we have ones that are clinically focused: Are you reaching the right audience in the right way and how can CROs get recognized by biotechs? • Recognizing the impact of technology solutions on the patients journey and ways to progress this even further • How do smaller biotechs prepare their supply chains for IRT adoption and compliance? ***Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company*** ***Panelists: Meir Pinco, Associate Director, IT Data & Analytics, BeiGene***	**PANEL DISCUSSION: Is clinical trial exclusion criteria too stringent?** • How is the industry approaching diversity and what should the primary focus be? • Increasing accessibility to trials whilst simultaneously maintaining an appropriate level of patient safety • Assessing the link between restrictive eligibility criteria and rates of serious adverse events to make informed decisions on expanding exclusion conditions • Alternative solutions to improve patient numbers amidst pressures to hit recruitment milestones • How have increased pressures of patient recruitment lead to the questioning of traditional enrollment methods? ***Chair: Cathy Scharf, Patient Advocate, Patient Advocates of the East Bay*** ***Panelists: Jad Adaimi, Executive Director - Global Regulatory Affairs, Ultragenyx***

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	Jenni Herber, Associate Director, Clinical Operations, Kamau Therapeutics ***Laura O'Donnell, Senior Director, Head, Global Site Engagement GSK*** ***Avnika Agarwal, Senior Director, Project Delivery, ICON Biotech***	***John Rootenberg, Principal Director, Digital Safety and Decision Support, Genentech***	***Nisha Trivedi, Rare Disease Patient Advocate*** ***Meghan McKenzie, Director of Health Equity and Clinical Research, Chief Diversity Office, Genentech***
12:45pm	**Breaking through: Success in streamlining SAD/MAD and NDA-Enabling studies** • Breaking through the complexity of phase 1 studies • Prioritizing Phase 1 schedule • Optimizing efficiencies for NDA-Enabling studies ***Lona Sheeran, Senior Vice President, Clinical Operations Early Phase, Worldwide Clinical Trials***	**Unlocking trial success: How clinical adjudication drives sponsor and regulatory confidence in study results** • How independent adjudication improves endpoint accuracy and consistency in trials. • Ways adjudication improves data accuracy and regulatory compliance. • Strategies to reduce risk and streamline trial timelines. • How to reduce variability and disputes in clinical endpoint assessments. ***Kathleen Dowell, VP, Medical Imaging and Specialty Solutions, Clario***	**The benefits of building trials, focused on patients, delivered in their own community** • In-home trial delivery makes participation easier, more convenient and more accessible • Increasing trial access to more patients by empowering and supporting a variety of community research sites • How trial design can deliver increased recruitment and retention in a cost-effective way ***Catherine Jervis, General Manager Integrated Solutions, MRN***
1:15pm	**Lunch and networking sponsored by Thermo Fisher Scientific**		
	Stream A: Outsourcing & Clinical Operations Chair: Bruce Morimoto, Head of Drug Development, Fuku Biotech	**Stream B: Clinical Technology & Innovation** Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company	**Stream C: Patient Centricity and DEI** Chair: Cathy Scharf, Patient Advocate, Patient Advocates of the East Bay
2:15pm	**Bridging the silos between patients, providers, and the general public through all phases of clinical trials in the space of rare disease and curative cell and gene therapies** • Understanding and connecting with the community as it pertains	**The state of the biopharma industry 2025: Key trends and issues impacting pharma industry** • Overview of the most impactful emerging industry trends, key themes and technologies impacting	**Patient Engagement starts with the Informed Consent Form.** **This session will explore how the ICF can become a patient engagement tool.** • How do potential participants view consent forms?

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	to specific indications through the eyes of all stakeholders • Building and creating a patient-centric model from bench to boedside • Supporting unbiased initiatives designed to inform and educate • Thoughtful utilization of tools and vendors to support the mission of patient enrollment, patient engagement, regulatory compliance, data collection, and long-term follow-up participation ***Jenni Herber, Associate Director, Clinical Operations, Kamau Therapeutics***	advancements in biopharma • Spotlight on clinical trials – Challenges and use of emerging technologies for drug development • Outlook for 2025 clinical trial outsourcing ***Revati Tatake, Global Head of Pharma Research, Analysis and Competitive Intelligence, GlobalData***	• Changes to make the consent form to be more engaging. • Practical tips for changing your consent template. • Challenges that exist for implementing a different type of consent form. ***Ros Cheetham, Vice President, Clinical Operations, MacroGenics***
2:45pm	**Driving success: Strategies for optimal site support** • The evolving landscape of clinical trials and the need for more engaged sites: trial complexity, competition, and site staff turnover • How the CRO fits into addressing site support as a focal point • The sponsor's role in site support • The road forward: methods of addressing site support ***Eleanor Miller, Clinical Trial Liaison, PSI CRO***	**Maximizing asset valuation for biopharma** • Biopharma has historically focused on achieving regulatory approval for value creation • Asset valuations at the time of licensing or sale can be increased by expanding research plans to address non-regulatory stakeholders • At the same time, new innovations in R&D productivity can lower the cost of trials while better managing risks of trial success ***Kenneth Park, MD, VP, R&D Strategy and Productivity, Consulting, Fortrea***	**Patient advocacy groups: Bridging clinical trials and patient communities for meaningful DEI impact** • Understand the need for collaborative partnerships with patient advocacy groups • Discuss valuable insights these groups provide into the patient journey, clinical trial design, and study participation to reduce barriers faced by diverse patient populations • Share best practices for leveraging advocacy groups to enhance patient recruitment and retention • Explore how patient advocacy groups help align the objectives of clinical trials with broader diversity and inclusion goals ***Sarah Cross, PhD, Vice President and Global Head of Medical Affairs, Premier Research***

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3.15pm	**FIRESIDE CHAT: Successful strategies on CRO FSP management, scaling teams, and bridging low-cost offshore footprint while maintaining quality and efficiency** • Evolution of CRO FSP models • Balancing growth and quality in a hybrid model • The future of scaling and offshore integration ***Moderator: Revati Tatake, Global Head of Pharma Research, Analysis and Competitive Intelligence, GlobalData*** ***Bao Dinh, Global Development Business Operations, Takeda*** ***David Larwood, CEO, Valley Fever Solutions***	**Cross-functional team collaboration and alignment in meeting 'on time' clinical supply needs** • Aligning the clinical trial ecosystem to be operationally efficient and reduce delays in supply deliverables • Fine-tuning the clinical supply vendor partnership: How can sponsors and service providers start using guidance in totality instead of in silos? • Maintaining open communication with manufacturers to address precise trial needs and perfect demand planning • Working in tandem across the trial ecosystem to better manage demands for increasingly complex clinical supply needs ***Anthony L Colenburg Sr, Senior Director & Site Head of Quality, Sutro Biopharma***	**Patient perspective: My clinical trial journey** • Details of my two hybrid clinical trial participations • What worked well during the trials • Areas of improvement observed during/after the trials • Recommendations for ensuring patient-centric trial design ***Nisha Trivedi, Rare Disease Patient Advocate***
3:45pm	**Afternoon refreshments and networking**		
4:05pm	**PRIZE DRAW** **Visit our exhibitors' booths throughout the day and collect stamps in order to enter our Prize Draw and be in for a chance of winning Apple devices or Amazon vouchers. The Prize Draw will take place in the Exhibition Hall. Make sure you don't miss out!**		
4:15pm	**What do you mean you need equipment? Demystifying the complexities of the equipment supply chain** • Explore the critical role of equipment in enabling clinical trial success, from ensuring compliance to supporting protocol-specific needs. • Understand key challenges in the equipment supply chain, including global logistics, maintenance, and vendor management. • Discover practical solutions, such as	**Start expecting more from eCOA/ePRO** Patient data is the lifeblood of a clinical trial, but the eCOA/ePRO market has yet to live up to the promise of engaging more patients. Sponsors and CROs should expect more. We need an objective look at where the market is lagging, and concrete steps we can take to improve. • Describe why a legacy eCOA/ePRO system will not deliver the same results as a system developed with modern, digital technology	**From endpoints to impact: Designing trials that resonate with patients** • Redefining hope: navigating tough conversations about disease-modifying treatments • Genetic testing's unexpected role in driving patient enthusiasm for trials • When science outpaces understanding: bridging the gap with patients and clinicians

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	centralized planning, global harmonization, and leveraging technology for supply chain optimization. • Learn from real-world examples illustrating how proactive equipment management saves time, reduces costs, and ensures trial continuity. ***Jon Raven, Chief Commercial Officer, Emsere*** ***Bryan Dunlap, Business Develop Manager, North America, Emsere***	• Examine how eCOA/ePRO technologies should promote compliance by giving patients apps that are akin to apps they use in daily life, on their own devices • Discuss how eCOA/ePRO will not become a strategic component of sponsor and CROs technology portfolios unless vendors embrace continuous innovation ***Steve Rosenberg, Chief Executive Officer, uMotif***	• Lessons from case studies ***Andrew Feigin, MD, Chief Medical Officer, Rho*** ***Peter Schmidt, PhD, Chief Scientific Officer, Rho***
4:45pm	**CLOSING PANEL DISCUSSION: Macro perspective: Facilitating the harmonization and equivalence of working across regions** • How can sponsors and service providers start using guidance in totality instead of in silos? • Overcoming the lack in consistency of regulations between regions and countries • Collaborative ways to render it easier for regulators to accept multiregional trial data • Developing shared expectations for trial conduct, acceptability of endpoints and data transparency ***Chair: Revati Tatake, Global Head of Pharma Research, Analysis and Competitive Intelligence, GlobalData*** ***Panelists: Leesa Gentry, Chief Clinical Officer, RenovoRx*** ***Sandra Nino-Siddens, Vice President Global Regulatory Affairs, Ultragenyx Pharmaceutical***	**CLOSING PANEL DISCUSSION: How sustainable drug development will empower and optimize the way clinical trials are planned to improve productivity and minimize costs** • Future-proofing supply chains to endure greater long-term sustainability responsibilities • Adhering to sustainable practices without adding cost and risk to already tight budgets • Operational implications of striving for more sustainable trial design • Collaborating with supplier ecosystems to drive sustainability goals • Sharing best practice for circular supply chain strategies and creating win-win business opportunities ***Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company*** ***Panelists: Yuyi Shen, Vice President, Technical Operations, Abcuro*** ***Sarah Hamirani, Portfolio Director, AbbVie***	**CLOSING PANEL DISCUSSION: Innovative approaches to engage and retain patients in an era of recruitment struggles** • DEI considerations: How can we establish trust within less-represented groups? • How can patient advocacy groups remain at the forefront of the discussion on study design and tailored communication programs • Overcoming obstacles in recruiting pediatric patients and how to make it easier for them and their parents to participate • Ensuring optimal communication with sites to support their efforts • The need for clinical trials to be accessible to patients ***Chair: Ros Cheetham, Vice President, Clinical Operations, MacroGenics*** ***Panelists: Susan Edelstein, PhD, SVP, Clinical Research, Ardelyx*** ***Bruce Morimoto, Head of Drug Development, Fuku Biotech***

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5:30pm	**Chair's closing remarks**		

END OF DAY 1 AND NETWORKING DRINKS
SPONSORED BY Dr. Vince Clinical Research



OUTSOURCING IN CLINICAL TRIALS WEST COAST
DAY 2 – Wednesday 12th February 2025

8:30am	**Registration and refreshments**		
8:50am	**Chair's opening remarks** **Stream A: Outsourcing & Clinical Operations** Chair: Revati Tatake, Global Head of Pharma Research, Analysis and Competitive Intelligence, GlobalData	**Chair's opening remarks** **Stream B: Clinical Data Management** Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company	**Chair's opening remarks** **Stream C: Medical Devices** Chair: Chitrang Dave, Global Head of Enterprise Data & Analytics, Edwards Lifesciences
9:00am	**KEYNOTE: Designing trials to reduce patient and site burden** • How to create a patient-centric clinical protocol to obtain the necessary data and validate your primary objective • How biotechs are using tools internally and managing different stakeholders to pressure test themselves to have less complicated protocols • Looking at ways to ensure patients don't go through a burdensome process • Championing collaborative sites for a streamlined trial	**KEYNOTE: Automating manual processes to improve decision-making and patient care** • Automating Adverse Event Evaluations: Enhancing speed and accuracy using AI. • Streamlining Clinical Protocol Training: Efficiently generating consistent training materials with AI. • Improving Medical Coding: Utilizing AI for accurate adverse event classification and regulatory compliance. • Reducing cycle times and operational costs and	**KEYNOTE: Innovating with data in life sciences** Data plays an increasingly critical role in the age of AI in life sciences. Using data and AI effectively can help: • accelerate research & development by making new and larger data points easily accessible • optimize trial design and enrolment by analyzing population and patient characteristics • improve manufacturing efficiency and commercialization

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E: niki.khoshkbary@arena-international.com

	Shantheri Pai, Associate Director, Clinical Operations – Oncology, Gilead Sciences	enhancing data accuracy to better clinical trial results ***Meir Pinco, Associate Director, IT Data & Analytics, BeiGene***	***Chitrang Dave, Global Head of Enterprise Data & Analytics, Edwards Lifesciences***
9:30am	**Beyond traditional labels: Customized outsourcing strategies for biotech and pharma** • Prioritizing your organizational structure and goals • Key considerations for developing a bespoke outsourcing framework • Building resilient outsourcing strategies that align with future clinical development needs ***Neil Berger, Vice President, FSP Commercial and Operational Strategy, Parexel***	**Integrating Risk-Based Quality Monitoring (RBQM) into each phase of the trial to ensure maximum efficiency and robust data validation processes** • Designing and executing a successful RBQM framework to meet your specialized trial goals • Sharing best practice on implementing new modern EDC systems to provide built-in validation checks and automated information checks when some CROs are lacking • Focusing on critical data and processes by documenting risks, roles, and mitigation strategies • Meaningful key performance indicators for RSQM ***Thomas Tremblay, Vice President, Head of Clinical Operations, Trefoil Therapeutics***	**Building a robust medical device clinical development program: best practices and insights** • Key considerations for medical device clinical development program at different stages • Optimize protocol design using data-driven approaches • Leveraging policy advantages of Asia-Pacific to accelerate the program timeline • Important factors when selecting a contract research organization (CRO) or other partners to manage a successful medical device study ***Lian Cunningham, Vice President of Clinical Affairs, Endogenex***
10.00am	**Winning the "Clinical Operations Super Bowl": Regulatory inspections from a Clinical Operations perspective** • Showcasing and defending the clinical operations strategy and outcome for pivotal studies during Sponsor regulatory inspections as the culmination of years of intense and important work; or the "Super Bowl" of Clinical Operations • Sharing best practices based on real-life examples, for surviving and thriving during FDA and EMA Sponsor regulatory inspections	**INTERACTIVE PANEL DISCUSSION: Choosing an outsourcing model: FSO vs FSP vs inhouse** • Weighing up pros and cons of different outsourcing models: which is best for your trial? • When is mixing and matching better than fully outsourcing or keeping trials fully in house? • Developing an outsourcing strategy as a small to medium sized biotech with limited resources • Why is FSP becoming a popular choice among sponsor companies and how can this support meeting trial timelines?	**Remote study on a shoestring: lessons from an OTC clinical trial** • Milli Expanding Vaginal Dilator's Regulatory Arc: Wellness to Rx to OTC • Market told us robust clinical would support adoption—need to do fast and cheap • Developing the study protocol and clinical operations POMPOM - Milli • Recruitment strategies and metrics • Remote data collection and compensation • Baseline Data Abstract accepted by ISSWSH • What we learned • Future studies: lather-rinse-repeat

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	from the Clinical Operations viewpoint • Collaborating with QA and other cross-functional partners for success • Best practices in logistics and Clin Ops teamwork in advance of, during and after the inspections • Common, recent findings related to Clinical Operations during inspections ***Abby Kennedy, Senior Vice President of Clinical Operations, DermBiont*** ***Vineeta Gulati, Former Director of Clinical Operations, CymaBay Therapeutics***	• How do strategic alliances impact this decision? ***Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company*** ***Panelists: Hayley Lane, Vice President Clinical Operations, Star Therapeutics*** ***Ros Cheetham, Vice President, Clinical Operations, MacroGenics*** ***Thomas Tremblay, Vice President, Head of Clinical Operations, Trefoil Therapeutics*** ***Jenni Herber, Associate Director, Clinical Operations, Kamau Therapeutics***	***Debbie Donovan, Head of Commercial Operations, Materna Medical***
10.30am	**Breaking Borders: Mastering the art of global business expansion to Japan** Japan, as do other countries, has unique characteristics that are often difficult to understand from an outsider's perspective. These differences include not only pharmaceutical regulations and medical systems but also customs, culture, and language. Despite efforts toward global harmonization, the distinctiveness of each country, shaped over many years, still persists. This guide serves as your ultimate resource for navigating the complexities of conducting clinical trials on a global scale, including Japan. • Understanding key factors for conducting drug development in Japan • Analyzing the challenges of drug development in regions with less visible dynamics, using Japan as a case study. • Exploring solutions to maximize the probability of success in drug development.		**Recent FDA guidance on clinical research topics and what it means to you** • Find out when you can waive the need for Consent Forms • When needed, ensure that Informed Consent Forms include key information • Implement decentralized clinical trial elements to improve trial participant engagement, recruitment, enrollment, and retention ***Katie Bessette, Head of Regulatory Affairs, Abbott***

Sales Enquiry
Nick McCudden
Head of OCT Events
T: +61 280 978 126
E: nicholasmccudden@arena-international.com

Speaker Enquiry
Niki Khoshkbary
Senior Conference Producer
T: +44 (0)20 4540 7545
E: niki.khoshkbary@arena-international.com

	Katsura Kasahara, Executive Professional, EPS Corporation		
11.00am	**Morning refreshments and networking**		
11.45am	**Examination of the World Health Organization's (WHO) recently released guidance on best practices for clinical trials to enhance the efficiency and credibility of clinical research** • Looking at gathered contributions from clinical trial regulators, researchers, civic society and patient groups, pharmaceutical industry, ethicists, funders and many more • Exploring the key contributors to a successful clinical trial ecosystem to achieve clinical development operational excellence • Reinforcing global standards in the design, conduct and reporting of clinical trials ***Archana Sah, Oncology Board Member, Society for Clinical Research Sites***	**Realizing the value of data sharing and outlining the supported initiatives to enhance data transparency** • Recognizing and preserving patient trust: how and why should their data be shared? • How data sharing platforms can work for you and what are the pragmatic ways to achieving the benefits? • Ensuring an ROI on your data: Key financial considerations of data curation • Logistical and regulatory challenges hindering the progress of data sharing ***Bruce Morimoto, Head of Drug Development, Fuku Biotech***	**Global UDI Compliance: strategies for navigating unique device identification standards worldwide** • Understanding UDI requirements across regions • Implementing UDI systems for traceability and safety • Leveraging UDI data for operational efficiency ***Tania Pearson, Regulatory Systems Director, Medtronic***
12:15pm	**TECHNOLOGY SPOTLIGHT: Innovative Digital Opinion Leaders identification with Adnexi to improve trial awareness** • Understand the reliance of both patients and doctors alike on online resources for trial and disease awareness. • Learn about a new technology solution to search for Digital Opinion Leaders sharing content online about the therapeutic area • Discover how to identify and track Digital Opinion Leaders across all social and online platforms	**PANEL DISCUSSION: Embracing innovative technologies in clinical data management: Opportunities and challenges** • Overcoming regulatory hurdles: How are agencies responding to new technologies? • Ethical considerations: Ensuring patient data privacy and compliance. • Operational barriers: Integration with existing trial frameworks (or do we need to adapt?) • Future Outlook: What technologies will dominate in the next 5–10 years?	**PANEL DISCUSSION: Key considerations for evaluating clinical vendors in effective study execution** • Aligning vendor expertise with study needs • Exploring the differences in clinical evaluation requirements for vendors between pharma and medical device manufacturers • Assessing operational transparency and communication • Balancing innovation with compliance

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	• Plan how to engage Digital Opinion Leaders in trial awareness ***Sandra Shpilberg, CEO & Co-founder, Adnexi***	• Looking at the use and challenges of eDiaries ***Chair: Joshua Cox, Vice President of Clinical Data & Analytics Capabilities, Eli Lilly and Company*** ***Panelists: Janet Moga, Lead, DCT Operations, Astellas Gene Therapies*** ***Peter St. Wecker, Ph.D., Clinical Development Lead, Neurology, UCB*** ***Prasun Mishra, Founder and CEO, Agility Pharmaceuticals***	***Chair: Chitrang Dave, Global Head of Enterprise Data & Analytics, Edwards Lifesciences*** ***Panelists: Dorothy H. Kwok, Head of Clinical Operations, Bodyport*** ***Rozanno Gonzales, Clinical Innovation & Technology Leader, Genentech***

12:30pm	**Put on your "risk management goggles" when evaluating common areas of negotiations**
	• Uncover and understand stakeholder and vendor business requirements
	  ○ Who's bringing what to the party?
	  ○ Quality/Speed/Price
	• Various development phases and vendor types
	  ○ Business risks
	  ○ Legal considerations
	  ○ Vendor types
	  • Early research/ development
	  • CROs
	  • Clinical sites and collaborations/HCPs
	  • CMO/CDMOs
	• Escalations and governance as a safety net
	
	Gina Morton, Former Director of Contracts and Outsourcing, Calico and Genentech		

1:00pm	**Lunch and networking**		
2:00pm	**Clinical trials in rare disease populations: challenges and opportunities, a case study** Clinical operations in rare disease trials have unique challenges due to small patient populations, limited understanding of the disease, and lack of established clinical endpoints. In this case study, we will explore: • Adaptive trials designs to adjust clinical protocols based on interim results • Specialized approaches to managing sponsor and site relationship	**Closeout process of vendor strategy management beginning with a finish in mind** • Begin with the end in mind: Termination Clause • Identify and access file repositories • Understand PII and security requirements • Close out projects in the storage phase • Secure vendor-backed documents and files • Reconcile finances and finalize invoices • Issue termination letters • Complete contract close-out	**Strengthening partnerships and processes for clinical trial excellence in medical devices** • Learning criteria for identifying investigator aligned with study goals, device expertise and regulatory expectations • Building relationships at clinical sites • Effective training for investigators and site staff • Optimizing the informed consent process ***Kathryn Wine, Vice President Clinical Affairs, Novocuff***

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	• Decentralized trials and leveraging technology to perform remote assessments • Collaboration with patient communities and others We may also discuss approaches that we previously employed but concluded as not suitable or too premature for rare disease trials. ***Jenelle Lin, Associate Director, Clinical Operations, Aditum Bio***	***Amy Mou, Vendor Strategy Expert***	
2:30pm	**The 7 wondrous ways to immediately improve your R&D Financial Accruals process** • Discuss why financial accruals for clinical and R&D activities are still so challenging after all these years • Using real-life case studies, discuss common pain-points experienced by biopharma companies when it comes to financial accruals • Ponder easy implementations you can consider for your accruals processes that can significantly improve efficiency and decrease pain ***Chris Chan, Vice President, Financial Planning & Analysis, IGM Biosciences***	**AI transforming healthcare and life sciences: From discovery to delivery** • Delving into the transformative impact of AI across the healthcare and life sciences ecosystem • Exploring how AI technologies are revolutionizing drug discovery, enhancing clinical trial efficiency, and enabling more personalized patient care. • Streamlining early-stage research and optimizing real-world applications in patient monitoring and therapeutic delivery • How AI is paving the way for faster, more precise, and impactful healthcare solutions • Insights into the latest AI-driven innovations and how these advancements are shaping the future of healthcare from concept to patient outcomes ***Prasun Mishra, Founder and CEO, Agility Pharmaceuticals***	***Close of stream***
3:00pm	**Afternoon refreshments and networking**		
3:20pm	**PRIZE DRAW** **Visit our exhibitors' booths throughout the day and collect stamps in order to enter our Prize Draw and be in for a chance of winning Apple devices or Amazon vouchers. The Prize Draw will take place in the Exhibition Hall. Make sure you don't miss out!**		
3:30pm	**Speaker Hosted Round Tables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best		

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	practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable lasts for 30 minutes, delegates can select up to 2 roundtables.
RT 1	**Careful planning and effective communication to implement tailored patient recruitment strategies** *Hosted by Bruce Morimoto, Head of Drug Development, Fuku Biotech*
RT 2	**Opportunities for AI and Digital Health to improve clinical research** *Hosted by: Meghan McKenzie, Director of Health Equity and Clinical Research, Chief Diversity Office, Genentech* *Kade Shippy, Chief Diversity Office, Patient Inclusion and Health Equity, Genentech* *Audrey Funwie, Chief Diversity Office, Patient Inclusion and Health Equity, Genentech*
RT 3	**Navigating the regulation landscape and the different approaches trial stakeholders are taking to be compliant** *Hosted by Gina Morton, Former Director of Contracts and Outsourcing, Calico and Genentech*
RT4	**MEDICAL DEVICE ROUNDTABLE: Overcoming barriers to scaling: funding, regulatory hurdles, and market entry strategies for startups**
4:30pm	**Chair's closing remarks and end of conference**

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