Outsourcing in Clinical Trials New England

15th Annual Outsourcing in Clinical Trials New England 2023

John B. Hynes Veterans Memorial Convention Centre, Boston

1st-2nd November 2023

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The 15th Annual Outsourcing in Clinical Trials New England event will bring together clinical trial professionals from big and small biopharma to uncover new technologies and processes, to optimize their clinical and outsourcing operations.

2023 Speakers

- **Hollie Schmidt,** Vice President, Scientific Operations, **Accelerated Cure Project for MS**
- **Adrienne Gaggi,** Associate Director, Clinical Development, **Aldeyra Therapeutics**
- **Deborah Howe,** Director, Global Patient Recruitment and Engagement, **Alexion**
- **Rohita Sharma, PhD,** Global Senior Director, LEAP Lead, Patient Insights and Solutions, Medical Affairs, **Alexion**
- **Shelby Abel-Kilmartin,** Director, Data Management Strategic Outsourcing and Vendor Management, **Alexion, AstraZeneca Rare Disease**
- **Joyce Moore,** Global Head of Patient Engagement, **Allucent**
- **Marilyn Fontaine,** Director, Clinical Operations, **AnHeart Therapeutics**
- **Claudia Hesselmann, PhD,** Founder and Chief Executive Officer, **ARENSIA**
- **Tola Olorunnisola,** Senior Vice President, Clinical Services and Strategy, **Avantor**
- **Siddharth Parulkar,** Senior Director, Head of Clinical Operations, **Aprinoia Therapeutics**
- **Kevin Ahonen,** Former Head of Digital Engagement, **Biogen**
- **Behtash Bahador,** Director, Health Literacy, **CISCRP**
- **Sarah Tressel Gary,** Senior Scientific Advisor, eCOA Clinical Science and Consulting, **Clario**
- **Cathleen Platt,** Vice President, Clinical Operations, **Click Therapeutics**
- **Jodi Coughlin,** Director, Vendor Relationship Management, **Deciphera Pharmaceuticals**
- **Stacey Limauro,** Executive Director, Clinical Operations, **Deciphera Pharmaceuticals**
- **Holly Huang,** Vice President, Head of Biometrics, **Denovo Biopharma**
- **Ritu Mehta,** Director, Business Development, **DP Clinical**
- **Jason Konn,** Solution Consultant, **eClinical Solutions**
- **Jenny Bentsen Gordon,** Vice President, Head of Clinical Operations, **Editas Medicine**
- **Christine Slater,** Associate Director, Patient Recruitment, **Editas Medicine**
- **Colleen Graham,** Vice President, Head of Clinical Operations, **Mediar Therapeutics**
- **Ching Tian,** Chief Innovation Officer, **Emmes**
- **Neha Ghosh,** Associate Director, Clinical Research, **Fresenius Medical Care**
- **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**
- **Vikas Agarwal,** Vice President, Head of Program Development, **Greenfire Bio**

Join our new OCT community on LinkedIn

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- **Blake E Wilson,** Partner, **Hogan Lovells LLP**
- **Chris Cain,** Vice President, Clinical and Regulatory Affairs, **Hyalex Orthopaedics**
- **Missy Hansen,** Paediatric Strategy Liaison, **ICON Plc**
- **Kelsey Miller,** Director, Clinical Development, **Intrinsic Therapeutics**
- **Stuart Thiede,** Vice President and General Manager, Clinical Trial Payments, **IQVIA Technologies**
- **Leonella Seeley,** Associate Director of Vendor Management and Operations, **Karyopharm**
- **Judith Murphy,** Executive Director, Centralized Contracting and Outsourcing, **Kura Oncology**
- **David Sherris,** Board Member, **Kurve Therapeutics**
- **Harry Barnett,** Executive Chairman, **Lubris Biopharma**
- **Ken Hamill,** Senior Director, Clinical Operations Portfolio, **Medidata**
- **Kelly McKee,** Vice President, DCTs and Patient Registries, **Medidata**
- **Tom Gottschalk,** Senior Director, Business Development, **Mercalis**
- **Mackenzie Johnson,** Senior Manager, Patient Centricity, **Moderna**
- **Jessica Perry,** Director, Patient Centricity, Clinical Innovation, **Moderna**
- **Leticia Tarilonte,** Senior Director, Clinical Operations Consultant, **Nimbus Therapeutics**
- **Rana Said,** Biomarker Study Coordinator, **Novartis**
- **Kathryn Duschean,** Senior Scientist, Laboratory Excellence and Operations, **Novartis**
- **Alyce King,** Associate Director, Business Development, **Novotech**
- **Donna Fraser,** Director, Client Operations, **Novotech**
- **Nan Doyle,** Patient Advocate
- **Chris Weiss,** Vice President, Sales, **OpenClinica**
- **Prasanna Rao,** Senior Director, Global Head of AI and ML, **Pfizer**
- **Stacey Oppenheimer,** Imaging Vendor Oversight and Sourcing Strategy Lead, **Pfizer**
- **Douglas Henry,** President, **Phazemos**
- **Robert Loll,** Senior Vice President, Business Development and Strategic Planning, **Praxis**
- **Nicole Stansbury,** SVP and Head of Global Clinical Operations, **Premier Research**
- **David Hadden,** President, Founder and Chief Game Changer, **Pro-ficiency**
- **Christine Hurley,** VP, Clinical Business Operations and Innovation, **Relay Therapeutics**
- **Emily Matthews,** Senior Manager, Clinical Business Operations, **Relay Therapeutics**
- **John J Seman,** Chief Executive Officer, **Revitale Pharma**
- **Shari Coslett,** Vice President, Clinical Operations, **Rhythm Pharmaceuticals**
- **Steven Cummings,** Executive Director, **San Francisco Coordinating Center, California Pacific Medical Center Research Institute**
- **Rinaldo Dorman, MBA, CPSM,** Associate Director, R&D Global Procurement & Strategic Sourcing, **Sarepta Therapeutics**
- **Dima Hendricks,** Sickle Cell Patient Advocate
- **Ivor Clarke,** Chief Innovation Officer, **SubjectWell**
- **Jim Palma,** Executive Director, **TargetCancer Foundation**
- **Nissa Ashenbramer,** Senior Project Manager, Oncology and Hematology, **TFS Health Science**
- **Meredith Frank-Molnia,** Senior Director, Clinical Operations, **Third Pole Therapeutics**
- **Hope Weisser,** Senior Product Manager, **TransPerfect**
- **April Mattison-Wolfe,** Senior Solutions Architect, **TransPerfect**
- **Ken Getz,** Executive Director and Professor, **Tufts Center for the Study of Drug Development, Tufts University School of Medicine**
- **Mary Jo Lamberti,** Research Associate Professor and Director, Sponsored Research, **Tufts Center for the Study of Drug Development**
- **Sverre Bengtsson,** Co-Founder, Senior Vice President Strategic Relations, **Viedoc**

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

Speaker Enquiry
Louisa Manning
Conference Producer
E: Louisa.Manning@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

- **Mike Waters,** Global Vice President Biopharma Business Development, **Cerba Research**
- **Amy Raymond, PhD, PMP,** Therapeutic Strategy Lead, Gene Therapy Think Tank, **Worldwide Clinical Trials**
- **Lisa Kang,** Head, Clinical Development Operation, **Yoda Pharmaceuticals**
- **Evan Hahn,** Senior Vice President, IRT Solutions**, YPrime**

Outsourcing in Clinical Trials New England

DAY 1 – Wednesday 1st November

7:30am	**Registration and refreshments**
8:20am	**Chairperson's opening remarks** **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**
8:30am	**OPENING KEYNOTE: Innovation in the US pharma industry: uncovering challenges and opportunities** • Harnessing the power of language models such as GPT to revolutionize pharma innovation • The potential of advanced technology to drive advancements in drug discovery, optimize clinical trials and enable personalized medicine • Practical takeaways: how you can leverage AI and Generative AI to achieve transformative innovation in your clinical trial **Prasanna Rao,** Senior Director, Global Head of AI and ML, **Pfizer**
9:00am	**Solving the clinical data challenge** *Patient centricity requires data centricity to integrate and manage a growing variety of data sources. The challenge lies in integrating and managing those sources to deliver high-quality data. How do we overcome this?* • Moving from manual, reactive data review and cleaning to proactive, risk-based approaches based on integrated data • Providing clinical data management and monitoring teams with workflows and analytics that support their day-to-day functions • Leveraging technologies that incorporate AI to automate manual tasks and identify potential issues sooner **Ken Hamill,** Senior Director, Clinical Operations Portfolio, **Medidata**
9:30am	**PATIENT ADVOCACY KEYNOTE: Patient experience in oncology trials: lessons learned from a patient advocacy-driven, decentralized clinical trial** • How easy and accessible are oncology trials to patients, and where are the main hurdles? • What do pharma and biotech sponsors need to be doing in order to ensure a reduced burden on patients participating in clinical trials? • Decentralized clinical trials: and what are the benefits and challenges of incorporating elements of decentralization into your clinical trial from a patient perspective? **Jim Palma,** Executive Director, **TargetCancer Foundation**
10:00am	**Perspectives on the biotech/CRO investment landscape** • Perspective on investment landscape • Biotech workforce current trends and the implications for clinical trials • M&A activity in the CRO landscape and how that impacts sponsors **Alyce King,** Associate Director, Business Development, **Novotech**
10:30am	**Morning refreshments and networking break**

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E: Louisa.Manning@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

	Stream A: Clinical Outsourcing and Operations	Stream B: Clinical Technology and Innovation	Stream C: Patient Recruitment and Engagement
	Chair: **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**	*Chair:* **Meredith Frank-Molnia,** Senior Director, Clinical Operations, **Third Pole Therapeutics**	*Chair:* **Robert Loll,** Senior Vice President, Business Development and Strategic Planning, **Praxis**
11:00am	**Choosing a vendor as a small biotech: creating a hierarchy of considerations** • What are the most important factors when selecting vendors and CROs for your clinical trial? • Is it always crucial to have trial partners with expertise in your therapeutic area? • Should cost be the primary factor in vendor selection? **Jodi Coughlin,** Director, Vendor Relationship Management, **Deciphera Pharmaceuticals** **Stacey Limauro,** Executive Director, Clinical Operations, **Deciphera Pharmaceuticals**	**Incorporating real world evidence into clinical trials: what new opportunities are created?** • Tapping into the full potential of real world evidence and incorporating this into your trial • Barriers to adopting real world evidence: how to address and overcome these • Navigating regulations in the USA in relation to the use of real world evidence in clinical trials **Lisa Kang,** Head, Clinical Development Operation, **Yoda Pharmaceuticals**	**PANEL DISCUSSION: Navigating new regulations around diversity and inclusion** • The importance of ensuring your patient population is diverse • Strategies to improve diversity, equity and inclusion in your trial • Building trust and relationships with communities who may not traditionally participate in clinical trials • Innovative methods of engaging with the wider patient community • Best practice in working closely with patient advocacy groups **MODERATOR: Behtash Bahador,** Director, Health Literacy, **CISCRP** **PANELLISTS: Blake E Wilson,** Partner, **Hogan Lovells LLP** **Cathleen Platt,** Vice President, Clinical Operations, **Click Therapeutics** **Marilyn Fontaine,** Director, Clinical Operations, **AnHeart Therapeutics** **Missy Hansen,** Paediatric Strategy Liaison, **ICON Plc**
11:30am	**Simplifying protocols to enable home-base trial activities** • How simplification of a protocol for Parkinson's disease enabled a home-based trial • Lean Design approach to radical simplification: results for Merck protocols • Overcoming resistance to simplification: common issues	**TECHNOLOGY SPOTLIGHT: Running up that hill: accelerate cycle times and reach patients faster with elluminate** *Learn how elluminate and eClinical's Biometrics Services deliver:* • Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety	**Accelerated performance of complex exploratory patient studies: practical insights from investigational site** • Global challenges and industry trends • Research clinics dedicated to early patient trials • Key elements to consider when planning a Phase Ib/IIa patient trial

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	Steven Cummings, Executive Director, **San Francisco Coordinating Center, California Pacific Medical Center Research Institute**	• Improved study oversight with a holistic view of risk across all data sources • 50 out-of-the-box visualizations to support 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 **Jason Konn,** Solution Consultant, **eClinical Solutions**	• Case studies **Claudia Hesselmann, PhD,** Founder and Chief Executive Officer**, ARENSIA**
		TECHNOLOGY SPOTLIGHT: eSource: auto-populate eCRFs with source data on study Day 1 *Learn how eSource, EHR-to-EDC integration automatically populates eCRFs on study day one with source data. We'll discuss practicality, implementation and scalability so you can see how we're keeping patients at the center of clinical trials with proven solutions that lessen the burden for researchers, sponsors and patients alike. Join this session and learn how to:* • Get source data on study Day 1 • Ease the burden with smart, automated workflows • Simplify enrollment, data sharing and participation • Enhance decision support for site and sponsor stakeholders • Improve recruitment and retention with engaging digital solutions **Chris Weiss,** Vice President, Sales, **OpenClinica**	

12:00pm	**The state of the biopharmaceutical industry: mid-year update and 2024 outlook** • Reviewing results from our annual survey - were the 2023 predictions correct? • Key themes and technology advancements in the biopharma industry that are expected to have the largest (positive and negative) impacts on the industry • Spotlight on clinical trial technologies: trends of cell and gene therapies, virtual trials and ai used in drug development • Leveraging data to predict the outlook for 2024 clinical trial outsourcing • Trends, key players, opportunities and threat in biopharma, focusing on AI, DCTs, cell and gene therapy, etc. • What the latest investment trends show for small and medium biotechs **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**	**PANEL DISCUSSION: Is DCT old news?** • How we should be thinking about decentralization in the long term • Hybrid vs decentralized vs traditional clinical trial models: the pros and cons of each • Which indications and therapeutic areas does DCT have potential in? • FDA regulations and guidance around DCT • Incorporating elements of DCT into your clinical trial: is this now commonplace or are we moving away from this? • Working with vendors and CROs in order to deliver decentralized and hybrid clinical trial **MODERATOR: Christine Hurley,** VP, Clinical Business Operations and Innovation, **Relay Therapeutics** **PANELLISTS: Harry Barnett,** Executive Chairman, **Lubris Biopharma** **Mackenzie Johnson,** SM, Patient Centricity, **Moderna** **Kelly McKee,** Vice President, DCTs and Patient Registries, **Medidata**	**Benchmarking patient enrollment and use of recruitment tactics** • An overview of Tufts CSDD's study on study and site level metrics on patient enrollment effectiveness and site activation rates • Global recruitment and retention tactics • Benchmarking results for enrollment and site activation • Differences and similarities in cycle times and performance across therapeutic areas **Mary Jo Lamberti,** Research Associate Professor and Director, Sponsored Research, **Tufts Center for the Study of Drug Development**

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12:30pm	**Assessing risk in your clinical trial using the Pediatric Risk Assessment Map (PRAM):** • An interactive, reusable, and shareable tool that helps to identify common risks that may exist in a pediatric clinical trial • Populates with risk category and mitigation strategies for consideration when risk is identified • Tallies and populates key risks and categories identified **Missy Hansen,** Paediatric Strategy Liaison, **ICON Plc**	**Digitalization in clinical trials: a 360 view** • Presenting on how to digitalize clinical trials in e.g. endpoints, and study designs • Highlighting the possibilities that digital trials bring, whilst moving away from the common brick-and-mortar sites • Discussing the rigorous standards and scientific integrity required by regulators, whether a regular brick-and-mortar trial or a digital trial • How we tend to focus too much on technology when it's actually the processes for the patients and the sites that matter even more • Major points to consider in designing digital trials; building blocks and practical examples to best prepare you to meet the needs of regulators whilst keeping the patient and sites front of mind **Sverre Bengtsson,** Co-Founder, Senior Vice President Strategic Relations, **Viedoc**	**Bridging barriers: streamlining oncology study startup in today's clinical environment** • Utilizing tactics to attract enthusiastic sites and PIs • Mastering the art of streamlined contract and budget negotiations • Optimizing vendor selection and oversight • Implementing best practices for consistent and committed enrollment **Nissa Ashenbramer,** Senior Project Manager, Oncology and Hematology, **TFS Health Science**
1:00pm	**Lunch and networking break**		

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2:00pm	**CASE STUDY: Best practice in managing ongoing relationships with CROs, vendors and other partners** • Communicating and liaising effectively with CROs: overcoming common challenges • Creating and fostering a long term relationship with vendors • Balancing levels of vendor oversight in your clinical trial **Christine Hurley,** Vice President, Clinical Business Operations and Innovation, **Relay Therapeutics** **Emily Matthews,** Senior Manager, Clinical Business Operations, **Relay Therapeutics**	**PANEL DISCUSSION: The impact and potential of new AI tools in clinical trials** • An overview of how AI and ML are evolving in the pharma industry • ChatGPT and its potential in supporting clinical trials • What risks and potential pitfalls are there when using AI? • Does AI eliminate the need for a human, or is it simply a tool? • How FDA guidelines impact the use of AI and machine learning in clinical trials **MODERATOR: Vikas Agarwal,** VP, Head of Program Development, **Greenfire Bio** **PANELLISTS: Blake E Wilson,** Partner, **Hogan Lovells LLP** **Lisa Kang,** Head, Clinical Development Operation, **Yoda Pharmaceuticals**	**Working closely with advocacy groups around clinical trial design** • Key considerations in designing a patient-centric clinical trial • How to bring the patient voice into your clinical trial design • Engaging patient advocacy groups from the beginning of your design process and benefits of this **Adrienne Gaggi,** Associate Director, Clinical Development, **Aldeyra Therapeutics**
2:30pm	**Continued evolution of cell and gene therapy development programs** • Technology-based development trends • Driving success in either unexplored settings or in saturated market settings • Context-dependent stakeholder engagement **Amy Raymond, PhD, PMP,** Therapeutic Strategy Lead, Gene Therapy Think Tank, **Worldwide Clinical Trials**	**Re-imagining IRT for modern clinical development** • The majority of clinical studies are being run on technology that is over 10 years old, which limits the ability to innovate and optimally support modern trials • IRT as a driver of innovation and not a constraint when advances in the technology landscape are applied to allow for more flexible solutions • Deliver scalable, robust, and future-proof IRT solutions by applying lessons learned from other industries • Examples include: A.I.-enabled datasets, no-code study deployment, automated excursion reviews, rapid prototyping, reduced (or removed) need for change orders, and ability to adapt to unforeseen challenges **Evan Hahn,** Senior Vice President, IRT Solutions, **YPrime**	**How do we make participation in clinical research more patient-friendly** • Barriers to patient participation in clinical research • Pre- and post-pandemic patient expectations • Balancing the need for robust data collection and reduced patient burden • What does – a potential – future hold? **Joyce Moore,** Global Head of Patient Engagement, **Allucent**

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3:00pm	**Biomarker opportunities in FiH and clinical pharmacology studies run in an outsourcing model** • Introduction: history of "fully outsourced" studies at Novartis • Personalized medicine and the shift in clinical trial goals • CRO relationships with biomarkers • Lessons learned from biomarkers • Balancing risks vs benefits **Kathryn Duschean,** Senior Scientist, Laboratory Excellence and Operations, **Novartis**	**Finances and managing your clinical trial budget as a small or medium sized biotech company** • Cutting down your expenses without compromising on the quality of your trial • Forecasting and budgeting costs for your clinical trial • Solutions in order to ensure your trial budget stays on track **Marilyn Fontaine,** Director, Clinical Operations, **AnHeart Therapeutics**	**Designing patient engagement strategies to inform clinical trial recruitment** • An overview of frameworks developed around patient recruitment and engagement • How to best engage patients, caregivers and advocacy groups in your clinical trial design • Key considerations in ensuring your patient recruitment strategy is as patient-centric as possible **Deborah Howe,** Director, Global Patient Recruitment and Engagement, **Alexion Pharmaceuticals**
3:30pm	**Afternoon refreshments and networking break**		
3:50pm	**EXHIBITION APPLE 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!*		

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Haida Amirzadah
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4:00pm	**PANEL DISCUSSION: What degree of oversight should you have over your vendors and CRO partners?** • Establishing upfront communication on responsibilities and escalation processes • What do vendors expect from sponsors in terms of oversight? • Best practice in building a strong relationship with vendors • Regulatory guidance for sponsors around vendor communications and oversight: what do you need to be doing as a sponsor? **MODERATOR: John J Seman,** CEO, **Revitale Pharma** **PANELLISTS: Stacey Oppenheimer,** Imaging Vendor Oversight and Sourcing Strategy Lead, **Pfizer** **Shari Coslett,** VP, Clinical Operations, **Rhythm Pharmaceuticals** **Shelby Abel-Kilmartin,** Director, Data Management Strategic Outsourcing and Vendor Management, **Alexion, AstraZeneca Rare Disease** **Leonella Seeley,** Associate Director of Vendor Management and Operations, **Karyopharm Therapeutics**	**CASE STUDY: Implementing eClinical technology in a medical device setting** • Implementing EDC, CTMS and eTMF for a medical device trial and what benefits these can bring • Choosing between technology providers: what are the main factors in decision-making? • Common challenges and hurdles when introducing new systems to your medical device clinical trial • Considerations for medical device trials compared to drug trials in EDC, CTMS and eTMF **Meredith Frank-Molnia,** Senior Director, Clinical Operations, **Third Pole Therapeutics**	**FIRESIDE CHAT: Reducing the burden of clinical trials on patients: what tools are available?** • Culture shift from the inside out: opportunity to briefly immerse yourself in the clinical trial journey from a patient's perspective • What are the main barriers for patients participating in clinical trials and how can these be minimized? • Incorporating technology to support patients and increase engagement and retention **INTERVIEWER: Robert Loll,** Senior Vice President, Business Development and Strategic Planning, **Praxis** **INTERVIEWEES: Rohita Sharma, PhD,** Global Senior Director, LEAP Lead, Patient Insights and Solutions, Medical Affairs, **Alexion Pharmaceuticals** **Deborah Howe,** Global Patient Recruitment and Engagement, **Alexion Pharmaceuticals**
4:30pm	**Innovative processes to better address today's trial dynamics** • Supply chain efficiency: why do extra work and spend more money than necessary? • Payment process efficient: leverage an existing workflow process that sites use everyday • Understanding the total value a vendor can provide • Select a vendor that can demonstrate its total value (and	**Clarity in the complex: the untapped potential of simulation-based training in clinical research** • Explore the future state of performance-based training • Discuss how to interpret and apply learning results to optimize and de-risk your study • Discover how simulation-based training improves study performance	**Improving randomization rates with Machine Learning and AI** • Learn the key differences between Machine Learning and Artificial Intelligence for patient recruiting • Find out why study data is more impactful than patient data on predicting recruitment success • Discover how to combine your model's results with your business strategy to create reliable recruitment

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Marketing Enquiry
Haida Amirzadah
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E: Haida.Amirzadah@arena-international.com

	make you look good in the eyes of your company) **Tom Gottschalk,** Senior Director, Business Development, **Mercalis**	**David Hadden,** President, Founder and Chief Game Changer, **Proficiency**	**Ivor Clarke,** Chief Innovation Officer, **SubjectWell**
5:00pm	**Designing a vendor strategy that works for your clinical trial** • Choosing between one full service CRO and working with multiple vendors: what are the main advantages and disadvantages? • Ensuring sponsors, vendors and sites are aligned under one shared goal • Overcoming challenges around communication with vendors in order to create strong relationships **Siddharth Parulkar,** Senior Director, Head of Clinical Operations, **Aprinoia Therapeutics**	**Key considerations when choosing vendors and partners as a small biotech** • How specialized should your CRO be in your therapeutic area: is this the most important factor? • As a small biotech, what are the benefits of working with a large global CRO vs a small specialized organization? • Working with and collaborating with multiple vendors: considerations and best practice **Leonella Seeley,** Associate Director, Vendor Management and Operations, **Karyopharm Therapeutics**	**Working with diverse groups in order to meet achieve DEI in clinical trials** • How to recruit and engage populations who would not typically participate in clinical trials • Ensuring your clinical trial participants are representative of the general population • Overcoming common challenges around diversity and inclusion **Neha Ghosh,** Associate Director, Clinical Research, **Fresenius Medical Care**
5:30pm	**Chairperson's closing remarks** **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**		

END OF DAY 1 AND NETWORKING DRINKS SPONSORED BY KPS LIFE

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

Speaker Enquiry
Louisa Manning
Conference Producer
E: Louisa.Manning@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

Outsourcing in Clinical Trials New England

DAY 2 – Thursday 2nd November

8:00am	**Registration and refreshments**		
	Stream A: Clinical Outsourcing and Operations	**Stream B: Clinical Technology and Innovation**	**Stream C: Patient Recruitment and Engagement**
	Chair: **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**	*Chair:* **Jessica Perry,** Director, Patient Centricity, Clinical Innovation, **Moderna**	*Chair:* **Robert Loll,** Senior Vice President, Business Development and Strategic Planning, **Praxis**
9:00am	**Innovating and introducing new technology while ensuring patients remain at the heart of your clinical trial** • Ensuring any new technology is for the benefit of the patient: the importance of involving the patient voice and advocacy groups in innovation • Where are the main difficulties for patients when participating in a clinical trial? • Decentralized and remote elements of clinical trials to ease the burden on patients **Leticia Tarilonte,** Senior Director, Clinical Operations Consultant, **Nimbus Therapeutics**	**PANEL DISCUSSION: How to choose technology vendors for your study** • Key questions to ask when selecting clinical trial technology • Building relationships with vendors in order to deliver a seamless and efficient clinical trial • Working with patients and advocacy groups to ensure all new technology is for the ultimate benefit of the patient • Making technology and systems easy for sites to adopt • Balancing cost and opportunity when weighing up benefits of new technology **MODERATOR: Jessica Perry,** Director, Patient Centricity, Clinical Innovation, **Moderna** **PANELLISTS: Colleen Graham,** VP, Clinical Operations, **Mediar Therapeutics** **Christine Hurley,** VP, Clinical Business Operations and Innovation, **Relay Therapeutics**	**Patient centricity through health literacy** • Sponsor funded initiatives that incorporate Health Literacy into the clinical trial lifecycle • Beginning patient involvement before the study: building awareness of clinical research • The importance of partnership and co-development throughout the research lifecycle • Tools and resources available to assist research organizations in effective patient centricity planning **Behtash Bahador,** Director, Health Literacy, **CISCRP**
9:30am	**Modernizing site management and monitoring roles to meet the dynamic needs of clinical research** • The purpose of a Site Manager and how they interact with other monitors on the study to avoid duplicate efforts and contain costs	**Find a cure for your complex technology headaches** *Join Emmes' Chief Innovation Officer, Ching Tian as she addresses how the technology we are accustomed to in clinical trials are getting more complex while not meeting today's clinical research needs. Ching will provide a peek*	**The importance of scientific validation and data integrity when using accessibility features** • FDA recommendation for accessible features and designs to increase clinical trial inclusivity eg zoom in/zoom out functionality

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Marketing Manager
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	• When to use a Site Manager for optimal study conduct • The benefits a Site Manager can bring to studies with highly complex logistics, such as cell and gene therapies or rare disease trials • How technology drives efficiencies and streamlines communications across the various resources on a study **Nicole Stansbury,** Senior Vice President and Head of Global Clinical Operations, **Premier Research**	*into a new paradigm of the next-gen solutions with the goal to achieve an 'iphone' like experience. In this session, you will learn:* • How technology is negatively disrupting clinical research • What a new paradigm needs to look like to turn technology into an enabler for all users • An example of the next-gen that's already available for use today **Ching Tian,** Chief Innovation Officer, **Emmes**	• Importance for patients who may have visual impairments, hearing, motor and dexterity, or cognitive difficulties that may impact inclusivity into clinical trials • Significance of deploying these functionalities where the drug under study may cause visual impairment such as certain oncology treatments or population under study, eg older adults, may have one or more impairments • Results of an industry-first clinical study on the ePRO instrument equivalence across accessibility features and patient communication modality preferences **Sarah Tressel Gary, Ph.D.,** Senior Scientific Advisor, eCOA Clinical Science and Consulting, **Clario**
10:00am	**PANEL DISCUSSION: Assessing the potential of different geographical regions for running a clinical trial** • Benefits and opportunities of running clinical trials outside of the US including Latin America, Europe, Asia and Australia • Do the challenges and risks outweigh the benefits of running trials internationally? • Understanding and navigating clinical trial regulations in different geographical regions • What factors are most important when choosing a location for your clinical trial? **MODERATOR: Harry Barnett,** Executive Chairman, **Lubris Biopharma** **PANELLISTS: Chris Cain,** VP, Clinical and Regulatory Affairs, **Hyalex Orthopaedics**	**CASE STUDY: Revolutionizing drug delivery devices: paving the way for clinical success** • Overview: the potential from using nose-to-brain technology to treat complex CNS disorders • Learnings and outcomes from running a clinical trial on a drug delivery device • Advancing treatment for neurogenerative diseases: how Kurve is reshaping this **David Sherris,** Board Member, **Kurve Therapeutics**	**CASE STUDY: Recruiting for a rare disease trial** • Identifying eligible patients for an orphan drug trial: designing your recruitment campaign • Best practice in collaborating with patient advocacy groups for rare diseases • The role of social media and other online tools to drive patient recruitment for a rare disease trial **Christine Slater,** Associate Director, Patient Recruitment, **Editas Medicine** **Dima Hendricks,** Sickle Cell Patient Advocate

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

Speaker Enquiry
Louisa Manning
Conference Producer
E: Louisa.Manning@arena-international.com

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Haida Amirzadah
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	Kelsey Miller, Director, Clinical Development, **Intrinsic Therapeutics** **Judith Murphy,** ED, Centralized Contracting and Outsourcing, **Kura Oncology** **Donna Fraser,** Director, Client Operations, **Novotech**		
10:30am	**Morning refreshments and networking break**		
11:00am	**Strengthening the CRO/sponsor relationship: a deep dive into studies** • Maintaining and tracking the CRO/sponsor partnership • Exploring tools and metrics that can be put in place • How best to utilize these in order to strengthen partnerships with CROs to ensure trial success **Rana Said,** Biomarker Study Coordinator, **Novartis**	**Innovating your data management strategy: how to stay ahead of the curve** • Developing efficient infrastructures and processes for clinical data management • Navigating changing regulatory requirements around data in clinical trials • Key drivers for innovation: considerations for 2024 **Holly Huang,** Vice President, Head of Biometrics, **Denovo Biopharma**	**Engaging patients in a rare disease clinical trial** • How rare disease trials are unique when it comes to building and fostering relationships with patients • Reasons and tactics to engage longitudinally with rare disease patients • Working with patients, carers and advocacy groups for a successful patient engagement strategy **Nan Doyle,** Patient Advocate
11:30am	**An agile approach to PBMC collection in vaccine trials** • Critical aspects of PBMC processing in the context of clinical trials • Challenges of sample handling flows • Importance of consistent isolation protocols • Main quality control aspects of PBMC handling • Upscaling capacity planning for sample collection • Importance of accessibility to an established global network **Mike Waters,** Global Vice President Biopharma Business Development, **Cerba Research**	**The importance of real-time forecasting in biotech trials** • Review the challenges of forecasting clinical trial costs and its impact on cash flow • Understand how a data-driven and automated approach can produce more accurate forecasts quickly • Learn how a biotech company can apply these methodologies **Stuart Thiede,** Vice President and General Manager, Clinical Trial Payments, **IQVIA Technologies**	**The innovations of decentralized clinical trials** • Decentralized clinical trial numbers grow and are forecast to continue, even after the accelerated adoption driven by the Covid-19 global pandemic • A view on the next steps of innovations within decentralized clinical trials • Why “consumerisation of clinical trials” continues to be key when considering patient centricity • How multi-channel data collection is at the heart of clinical trials – and the need to integrate data sources to maximise the value of this powerful by-product of decentralised clinical trial methodologies **Tola Olorunnisola,** Senior Vice President, Clinical Services and Strategy, **Avantor**

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12:00pm	**CASE STUDY: Running a clinical trial when repurposing an existing drug** • An overview of benefits, challenges and key considerations in drug repurposing clinical trials • FDA regulations and guidance when it comes to drug repurposing • Utilizing existing safety studies to speed up your trial timeline **John J Seman,** Chief Executive Officer, **Revitale Pharma**	**Revolutionizing clinical trials with accelerating clinical evidence models** • Novel approaches for drug approvals with accelerated approval pathway to streamline processes • Enhancing collaboration between the FDA and CMS in developing new payment methods for drugs approved via accelerated approval • Improving patient access to post-market safety and efficacy data **Blake Edward Wilson,** Partner (FDA Regulatory), **Hogan Lovells**	**Utilizing technology to accelerate clinical trial enrolment** *Kevin will be sharing his experience of using tools such as a patient engagement website, a strategic partnership and social media to impact patient enrolment across the portfolio of Biogen clinical trials. Join him to hear more about how to optimize your patient enrolment, with Kevin's top tips and lessons learned.* **Kevin Ahonen,** Former Head of Digital Engagement, **Biogen**
12:30pm	**Lunch and networking break**		
	Chair: **Robert Loll,** Senior Vice President, Business Development and Strategic Planning, **Praxis**		
1:30pm	**Operating conditions and trends impacting global clinical trial performance** • Review macro-level drug development trends • Characterize the current operating environment for planning and executing clinical trials • Discuss underlying drivers of inefficiency and poor performance • Explore new strategies to address and counter the effect of underlying drivers **Ken Getz,** Executive Director and Professor**, Tufts Center for the Study of Drug Development, Tufts University School of Medicine**		
2:15pm	**Forging the future with CTMS** *Clinical trials play a crucial role in medical advancements. With increasing challenges, it is essential for our tools to adapt. CTMS represents a significant step forward in how we manage these trials, and by utilizing it effectively, we can improve the healthcare landscape for everyone.* **Hope Weisser,** Senior Product Manager, **TransPerfect** **April Mattison-Wolfe,** Senior Solutions Architect, **TransPerfect**		

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2:45pm	**KEYNOTE PANEL DISCUSSION: Where can we expect clinical trials to be in 2024?** • How will new and upcoming regulations affect clinical trials, and how can sponsor companies best navigate these? • The impact of emerging AI tools such as ChatGPT on clinical trials: are these a challenge or an opportunity? • Should we still be discussing decentralization as a long term clinical trial model? • Where are the primary opportunities to make clinical trial participation easier on patients and thus improve recruitment, engagement and retention? **MODERATOR:** **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData** **PANELLISTS:** **Hollie Schmidt,** Vice President, Scientific Operations, **Accelerated Cure Project for MS** **Prasanna Rao,** Senior Director, Global Head of AI and ML, **Pfizer** **Rinaldo Dorman, MBA, CPSM,** Associate Director, R&D Global Procurement & Strategic Sourcing, **Sarepta Therapeutics** **Behtash Bahador,** Director, Health Literacy, **CISCRP**
3:15pm	**Afternoon refreshments and networking break**
3:35pm	**EXHIBITION APPLE PRIZE DRAW** *Visit our exhibitors' booths throughout the conference 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!*
3:45pm	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into three '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. Roundtables will take place in the Stream B conference room.*
	ROUNDTABLE 1: US vs international CROs: which is best for your trial? **Vikas Agarwal,** Vice President, Head of Program Development, **Greenfire Bio**
	ROUNDTABLE 2: Managing clinical trial budgets effectively **Marilyn Fontaine,** Director, Clinical Operations, **AnHeart Therapeutics**
	ROUNDTABLE 3: Delivering large and complex clinical trials with cross functional teams **Jenny Bentsen Gordon,** Vice President, Head of Clinical Operations, **Editas Medicine**
	ROUNDTABLE 4: Maximizing your CRO relationship and building a solid partnership **Ritu Mehta,** Director, Business Development, **DP Clinical** **Douglas Henry,** President, **Phazemos**
5:00pm	**Chairperson's closing remarks**

END OF CONFERENCE

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