OUTSOURCING IN CLINICAL TRIALS
NEW ENGLAND 2023

1-2 November 2023

Boston, **Massachusetts**

SPEAKERS

Judyth Zahora, Senior Director, Global Quality Systems and Process Improvement, **Agenus**

Shelby Abel-Kilmartin, Director, Data Management Strategic Outsourcing and Vendor Management, **Alexion, AstraZeneca Rare Disease**

Behtash Bahador, Director, Health Literacy, **CISCRP**

Cathleen Platt, Vice President, Clinical Operations, **Click Therapeutics**

Marilyn Fontaine, Director, Clinical Operations, **Compass Therapeutics**

Jodi Coughlin, Director, Vendor Relationship Management, **Deciphera Pharmaceuticals**

Stacey Limauro, Executive Director, Clinical Operations, **Deciphera Pharmaceuticals**

Colleen Graham, Vice President, Head of Clinical Operations, **Eledon Pharma**

Amanda Murphy, Senior Director, Data Intelligence and Solutions, **GlobalData**

Bonnie Bain, Global Head of Pharma and Executive Vice President, Healthcare Operations and Strategy, **GlobalData**

Blake E Wilson, Partner, **Hogan Lovells LLP**

Chris Cain, Vice President, Clinical and Regulatory Affairs, **Hyalex Orthopaedics**

David Sherris, Board Member, **Kurve Therapeutics**

Harry Barnett, Executive Chairman, **Lubris Biopharma**

Stacey Oppenheimer, Imaging Vendor Oversight and Sourcing Strategy Lead, **Pfizer**

Christine Hurley, Vice President, Clinical Business Operations and Innovation, **Relay Therapeutics**

Shari Coslett, Vice President, Clinical Operations, **Rhythm Pharmaceuticals**

Meredith Frank-Molnia, Senior Director, Clinical Operations, **Third Pole Therapeutics**

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Mary Jo Lamberti, Research Associate Professor and Director, Sponsored Research, **Tufts Center for the Study of Drug Development**

Outsourcing in Clinical Trials New England DAY 1 – Wednesday 1st November			
7:30am	**Registration and refreshments**		
8:20am	**Chairperson's opening remarks** **Judyth Zahora,** Senior Director, Global Quality Systems and Process Improvement, **Agenus**		
8:30am	**OPENING KEYNOTE PANEL: What does new technology mean for clinical trials in the US?** • Managing additional data created by increased use of technology: is this a benefit or a challenge? • What does technology mean for the pharma industry and how clinical trials are run? • Can tools such as ChatGPT facilitate greater efficiency for clinical trials? • Mitigating risks created by increased reliance on technology: what are these, and how can we best manage them? • Training and supporting site staff to facilitate smooth transitions to new technology, systems and processes		
9:00am	**Session reserved for featured sponsor**		
9:30am	**PATIENT ADVOCACY KEYNOTE: Where are biopharma sponsor companies falling short when it comes to supporting patients participating in clinical trials?** • An overview of key hurdles for patients in clinical trials: where can the burden on patients be reduced? • Engaging patients throughout a clinical trial: why do patients drop out of trials, and what can be done to minimize this? • Balancing decentralization and physical site visits: what works best for patients?		
10:00am	**Session reserved for featured sponsor**		
10:30am	**Morning refreshments and networking break**		
	Stream A: Clinical Outsourcing and Operations	**Stream B: Clinical Technology and Innovation**	**Stream C: Patient Recruitment and Engagement**
	Chair: **Judyth Zahora,** Senior Director, Global Quality Systems and Process Improvement, **Agenus**	*Chair:*	*Chair:*

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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**	**2023 update: the state of the biopharmaceutical industry** *Bonnie Bain from GlobalData will join us to give an update and overview of trends and themes in the biopharmaceutical industry for 2023 and 2024. Find out about new technology and innovation in clinical trials, and how to stay ahead of the curve in order to ensure your trial is a success.* **Bonnie Bain,** Global Head of Pharma and Executive Vice President, Healthcare Operations and Strategy, **GlobalData**	**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**
11:30am	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**

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12:00pm	**SITE PERSPECTIVE: How can sponsors foster a strong relationship with sites in order to improve efficiency?** • An overview of challenges faced by sites during a clinical trial: where can sponsors help? • How can sponsors relieve the burden on understaffed and overworked sites? • Training and supporting site staff on new tools and technology	**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 trials **MODERATOR:** **Christine Hurley,** Vice President, Clinical Business Operations and Innovation, **Relay Therapeutics** **PANELLISTS:** **Harry Barnett,** Executive Chairman, **Lubris Biopharma**	**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**
12:30pm	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**
1:00pm	**Lunch and networking break**		

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2:00pm	**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	**PANEL DISCUSSION: The impact and potential of new AI tools in clinical trials** • 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 **PANELLISTS:** **Blake E Wilson,** Partner, **Hogan Lovells LLP**	**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
2:30pm	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**
3:00pm	**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**	**Leveraging remote monitoring and wearables to increase the effectiveness of your clinical study** • How incorporating remote monitoring can benefit patients, caregivers and your overall study • Building a robust data strategy to support insights from wearables • Opportunities to enhance trial efficiency by using wearables and digital tools in your study	**Why do patients drop out of clinical trials: increasing your retention rates** • How to engage patients in order to maximize retention • Listening to patients and advocates in order to fully understand burdens and hurdles for patients • An overview of the main reasons patients drop out of trials
3:30pm	**Afternoon refreshments and networking break**		

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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? **PANELLISTS:** **Stacey Oppenheimer,** Imaging Vendor Oversight and Sourcing Strategy Lead, **Pfizer** **Shari Coslett,** Vice President, Clinical Operations, **Rhythm Pharmaceuticals** **Shelby Abel-Kilmartin,** Director, Data Management Strategic Outsourcing and Vendor Management, **Alexion, AstraZeneca Rare Disease**	**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	**Reducing the burden of clinical trials on patients: what tools are available?** • How to lessen the financial impact of clinical trial participation in order to ease pressure on patients • 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
4:30pm	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**
5:00pm	**CASE STUDY: Practical challenges when running an oncology trial as a small biotech organization** • The regulatory landscape for oncology trials in the US: what do you need to be aware of? • Learnings and outcomes from running an oncology trial • Working with CROs and vendors in order to deliver a successful cancer clinical trial	**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 **Meredith Frank-Molnia,** Senior Director, Clinical Operations, **Third Pole Therapeutics**	**Designing a cutting-edge patient recruitment strategy** • What opportunities do tools such as AI present for patient recruitment in clinical trials? • An overview of technology, tools and devices available to enhance patient recruitment • How to use technology to reach a wider population when recruiting for your clinical study
5:30pm	**Chairperson's closing remarks** **Judyth Zahora,** Senior Director, Global Quality Systems and Process Improvement, **Agenus**		

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END OF DAY 1 AND NETWORKING DRINKS

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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: **Judyth Zahora,** Senior Director, Global Quality Systems and Process Improvement, **Agenus**	*Chair:*	*Chair:*
9:00am	**The impact of high turnover of site staff on data collection and what sponsor companies can do to help** • How to deal with high turnover of staff as a sponsor company: what issues are caused by this? • Assessing available technology and processes to alleviate pressure and workload on site staff • The importance of maintaining a strong relationship with sites when it comes to data entry and collection	**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 **PANELLISTS:** **Colleen Graham,** Vice President, Head of Clinical Operations, **Eledon Pharma** **Christine Hurley,** Vice President, Clinical Business Operations and Innovation, **Relay Therapeutics**	**Patient centricity through health literacy** *Easily understandable and accessible clinical trial information empowers and engages the patient community, HCPs and other non-specialist physicians. The value of integrating patient-centric practices extends to more efficient trials, including shorter IRB review and approval cycles, improved patient enrollment, retention, and satisfaction, and greater likelihood of product reaching market. This session will cover:* • 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	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**

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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,** Vice President, 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
10:30am	**Morning refreshments and networking break**		
11:00am	**CASE STUDY: Overcoming operational challenges for a CAR-T trial: learnings and best practice** • How are CAR-T trials unique from an operational standpoint: what do you need to consider? • Designing KPIs and other metrics to measure the efficiency of your CAR-T trial • Best practice in collaboration with CROs, vendors and other partners to make your CAR-T trial a success	**Best practice for engaging sites with new technology** • Benefits and challenges for site staff when introducing new technology and processes • Collaboration and training to ensure sites are confident with new systems • Reducing the burden on sites and ensuring processes are easy to follow and adapt to	***Reserved for*** **Amanda Murphy,** Senior Director, Data Intelligence and Solutions, **GlobalData**
11:30am	**Session reserved for event sponsor**	**Session reserved for event sponsor**	**Session reserved for event sponsor**

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12:00pm	**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, **Compass Therapeutics**	**Getting buy in from internal and external stakeholders for investment in new clinical trial technology** • Creating an internal culture of innovation to foster adoption of technology and ideas • Maximizing ROI when incorporating new processes • Staying ahead of the curve: why investment in technology remains important for clinical trial sponsors	**CASE STUDY: 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
12:30pm	**Lunch and networking break**		
1:30pm	***Reserved for keynote speaker***		
2:00pm	**Session reserved for event sponsor**		
2:30pm	**CLOSING 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?		
3:00pm	**Afternoon refreshments and networking break**		
	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.*		
	ROUNDTABLE 1: Identifying partners and vendors to improve the efficiency of your clinical trial		
	ROUNDTABLE 2: Managing clinical trial budgets effectively **Marilyn Fontaine,** Director of Clinical Operations, **Compass Therapeutics**		
	ROUNDTABLE 3: Are decentralized trials here to stay?		

4:00pm	**Chairperson's closing remarks** **Judyth Zahora,** Senior Director, Global Quality Systems and Process Improvement, **Agenus**

END OF CONFERENCE

Additional topic suggestions:

Adaptive study design: creating a trial that is flexible and responsive to change

- Assessing the advantages of adaptive design over traditional fixed designs and how this can improve your clinical trial efficiency
- Key considerations for adaptive design
- What additional flexibility is available when using adaptive design?

Choosing the right site for your study: key factors

- Selection criteria when identifying sites: what should you measure?
- Transparency around site costs: ensuring you are budgeting and forecasting efficiently
- Building a strong relationship with your site in order to maximize study success

CASE STUDY: eConsent and the benefits for patients, sites, investigators and sponsors

- Using eConsent as a tool to speed up recruitment and thus overall trial timelines
- The regulatory landscape surrounding eConsent: what challenges are there to this?
- Maintaining a relationship with patients in order to ensure consent is informed in remote settings

CASE STUDY: Overcoming hurdles in running a paediatric clinical trial

- Alleviating the burden on caregivers during clinical trial participation
- Additional considerations around patient centricity when running a paediatric study
- Understanding and navigating regulatory guidance for clinical trials involving under 18s

Risk based quality management systems: an overview of solutions available in the market

- Best practice in processes for risk based management
- Tools available to streamline risk based management and how to best leverage these
- How can risk based quality management be used effectively in order to maximize trial success