



# 10<sup>th</sup> Annual Outsourcing in Clinical Trials UK & Ireland 2023

Hilton Park Lane, London UK

5<sup>th</sup>- 6<sup>th</sup> September 2023

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*'Welcome to the 10<sup>th</sup> Annual Outsourcing in Clinical Trials UK & Ireland Conference 2023'*

This exclusive event brings together attendees from established pharma, large and small, alongside biopharmaceutical companies and gives opportunity to dive into the operational challenges and innovations in clinical development found within the UK & Ireland

## 2023 Speakers

Lord James O'Shaughnessy, Member of the House of Lords, former Health Minister, Senior Partner at Newmarket Strategy  
 Prof Lucy Chappell, Chief Scientific Adviser, Department of Health and Social Care  
 Dr Janet Messer, Director of Approvals Service, Health Research Authority (HRA)  
 Nigel Blackburn, Director of Drug Development, Cancer Research UK  
 Ian Bruce, Director, NIHR Manchester Biomedical Research Centre  
 Emma Challans-Rasool, Chair & Founder of Proud2bOps  
 Barbara Hepworth-Jones, Director Capability Building, Global Clinical Operations, GSK  
 Abi Hunter, Senior Director Head of Clinical Sampling, AstraZeneca  
 Prof Sandip Mitra, Deputy Director, NIHR Devices for Dignity MedTech Co-operative and Consultant Nephrologist & Professor of Renal Medicine, Manchester University NHS Foundation Trust  
 Sverre Bengtsson, Co-Founder, Senior Vice President Strategic Relations, Viedoc  
 James Rudge, Technical Director, Neoteryx  
 Oliver Buckley-Mellor, Innovation and Research Policy Manager (Clinical), The Association of the British Pharmaceutical Industry (ABPI)  
 Neelam Patel, CEO, MedCity  
 Erica White, Director of Innovation, Royal Free London NHS Foundation Trust  
 Roman Fishchuk, Head of Clinical Trials Department, Central City Clinical Hospital, Ukraine  
 Martin Edobor, Clinical Lead for Digital Transformation, NHS North East London  
 Romain Bejot, VP CMC & Supply, Blue Earth Diagnostics  
 Nina Skorytchenko, CEO, Avenna  
 Surbhi Gupta, Head of Regulatory Affairs, Thriva  
 Dr Suki Balendra PhD, Director of Strategic Partnerships, Paddington Life Sciences. Life sciences Lead for the NIHR CRN Northwest London, Board Advisor  
 Marisa Papaluca, Expert medicines regulatory adviser. Former Senior Scientific Adviser, European Medicines Agency, and, Visiting Professor, Imperial College London  
 Greig Duncan, Solution Sales Specialist - Clinical Operations, Medidata  
 Krzysztof Potempa, Founder and Chief Executive Officer, Braincures  
 Bob Stevens, Patient Advocate, Group CEO, MPS Society & Rare Disease Research Partners Vice Chair, LSD Collaborative Co-Chair, International MPS Network  
 Antoine Vigneau, Senior Director, Biosamples Head of Alliances and Technology, AstraZeneca  
 Becky Purvis, Director of Policy and Partnership, Health Research Authority (HRA)  
 Angela Ibal, Real World Evidence leader Emmes  
 Davy Yeung, COO, TCRS  
 Achilleas Zaras, Senior Manager, Solution Consulting, eClinical Solutions  
 Nicola Yallup, Head of Business Development and Marketing, NIHR Clinical Research Network  
 Dr. Claudia Hesselmann, Founder and CEO, Arensia  
 Jennifer Duff, General Manager, Zelta Clinical Trials Solutions, (Merative)  
 Rachel Haines, Director of Clinical Operations, Rinri Therapeutics  
 Shaun Cochrane, Deputy Director R&D, Guy's and St Thomas' NHS Foundation Trust  
 Ameeta Retzer, Equity, Diversity and Inclusion Lead, National Institute of Health and Care Research Applied Research Collaboration West Midlands  
 Siobhan McKenna-Power, Client Services Lead, 4G Clinical  
 Callum Leavers, Associate Portfolio Director, YPrime  
 Willie Muehlhausen, Co-Founder, Safira Clinical Research Limited

# Outsourcing in Clinical Trials UK and Ireland 2023

DAY 1 – 5<sup>th</sup> September 2023

8:00	<b>Registration and refreshments</b>
8:50	<b>Chairperson's opening remarks</b> <b>Quentin Horgan</b> , Associate Director of Drug Intelligence, <b>GlobalData</b>
9:00	<b>KEYNOTE with Q&amp;A</b>  <b>Future of UK Clinical Research: Achieving Our Vision</b> In this keynote presentation, Lucy Chappell, Chief Scientific Adviser to the Department of Health and Social Care and CEO of the National Institute of Health and Social Care Research, will discuss the achievements that have been accomplished to recover and improve the clinical trials ecosystem post-pandemic. The talk will be structured based on the five visions of The Future of UK Clinical Research Delivery's implementation plan, which includes, streamlined, efficient and innovative research; clinical research embedded in the NHS; patient-centred research; research enabled by data and digital tools; a sustainable and supported research workforce.  <b>Prof Lucy Chappell, Chief Scientific Adviser, Department of Health and Social Care</b>
9:30	<b>Leveraging local relationships for best in-country solutions to accelerate global drug development</b> <ul style="list-style-type: none"><li>Partnering with a CRO to access European infrastructure, in depth local knowledge, site relationships and diverse patient populations</li><li>Strategies to fast-track clinical trial start-up and patient recruitment timelines</li><li>Are you ready for EU CTR? Challenges and lessons learned</li></ul> <b>David Chia</b> , Senior Business Development Manager, <b>Novotech</b> <b>Diana Filipescu</b> , Business Development Manager, <b>EastHORN</b> , - A Novotech Company
10:00	<b>Busting RBQM Myths: Practical Tools for Proactive Data Quality Management in Clinical Trials</b>  It's time to bust the myths of managing data quality in today's complex clinical trials. The explosion of digital capabilities to collect and monitor data remotely is truly disrupting traditional paradigms and opening up opportunities to improve patient, sponsor, and site outcomes.  However, as companies embrace digitalization, patient safety oversight and data reliability are the top concerns. Risk-based quality management (RBQM) strategies are increasingly used for decentralized trials to ensure data integrity and quality when various data types are collected and integrated from disparate sources. The industry still needs clarification about how best to implement these strategies in repeatable and scalable ways.  Join us as we "bust" five myths about data quality oversight and provide practical guidance on establishing effective clinical operations strategies to support the complexity of today's clinical trials.  <b>Greig Duncan</b> , Solution Sales Specialist - Clinical Operations, <b>Medidata</b>
10:30	<b>Morning refreshments and networking sponsored by Aixial</b>
	<b>STREAM A: Clinical Operations and Outsourcing</b>   <b>STREAM B: Clinical Technology and Innovation</b>

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	<p><i>Chair: Emma Challans-Rasool, Chair &amp; Founder, Proud2bOps</i></p>	<p><i>Chair: Quentin Horgan, Associate Director of Drug Intelligence, GlobalData</i></p>
11:00	<p><b>Diversity in Finding New Medicines</b></p> <ul style="list-style-type: none"> <li>• Discussing how diversity affects medical research</li> <li>• Focusing on the importance of diversity in health research</li> <li>• Why is diversity needed in clinical trials for the advancement of medicine?</li> <li>• Strategies for achieving IDEA (Inclusion, Diversity, Equity, and Access) in UK Clinical Trials</li> <li>• Recognising steps the FDA have taken to address unrepresented minority groups in US clinical trials – can/should the UK expect to follow suit?</li> </ul> <p><b>Dr Suki Balendra PhD</b>, Director of Strategic Partnerships, Paddington Life Sciences. Life sciences Lead for the <b>NIHR CRN North West London, Board Advisor</b></p> <p><b>Neelam Patel</b>, Non-exec director <b>Health Research Authority</b>, former CEO <b>MedCity, Advisor</b></p>	<p><b>Data to Drive Sustainability</b> <i>Collecting and using data to make decisions that guide measurable and responsible clinical practices</i></p> <ul style="list-style-type: none"> <li>• What is sustainability data collection?</li> <li>• Discussing how data is useful for sustainable development</li> <li>• Focusing on how to manage sustainability data</li> </ul> <p><b>Antoine Vigneau</b>, Senior Director, Biosamples Head of Alliances and Technology, <b>AstraZeneca</b></p>
11:30	<p><b>Spare a thought for the hospitals as they are essential in delivering your clinical trial</b></p> <ul style="list-style-type: none"> <li>• Do you spend enough time understanding all your clinical sites?</li> <li>• Are you managing them correctly?</li> <li>• How are you motivating them to deliver on your clinical study?</li> </ul> <p><b>Davy Yeung</b>, COO, <b>TCRS</b></p>	<p><b>Quality eCOA: On Time and Within Budget. How Partnering with Specialists Achieves This for Any Sponsor Project</b></p> <p>Clinical research is a team sport. The combined YPrime and Safira teams will outline how we partner to ensure delivery of a quality eCOA solution that is built for your specific protocol needs. Our combined specialized experience supports on-time and high-quality delivery, whilst reducing the burden on Sponsor teams</p> <p><b>Callum Leavers</b>, Associate Portfolio Director, <b>YPrime</b></p> <p><b>Willie Muehlhausen</b>, Co-Founder, <b>Safira Clinical Research Limited</b></p>
12:00	<p><b>Operational Management and Clinicians: Leaders change culture-culture changes organisations</b></p> <p>In this session we will take the opportunity to reflect and learn from the lived experiences of our speaker, supported by tangible examples of culture transformation and organisational effectiveness. In exploring this, we will together consider the role of operational managers, and clinical leaders in influencing culture, leading by the shoulder of others and how through shared vision and values you can help improve the effectiveness of an organisation. Our aim is for you to learn, be curious and leave with energy and practical tips to help you lead well, approach change with confidence</p>	<p><b>How precision medicine technologies can be used as complementary diagnostics to optimise clinical trial efficiency</b></p> <ul style="list-style-type: none"> <li>• Improving success rates of clinical trials for anti-inflammatory drugs using prognostic and predictive biomarkers for chronic inflammatory diseases (cIDs)</li> <li>• Overview current and next generation biomarkers for Inflammatory Bowel Disease (IBD)</li> <li>• GlyHealth technology– Glycomics as a Sweet Spot in Precision Medicine diagnostics</li> <li>• Addressing challenges in anti-inflammatory drug development with</li> </ul>

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	<p>and recognise the value of collaborative leadership in challenging times.</p> <p><b>Emma Challans-Rasool</b>, Chair &amp; Founder of <i>Proud2bOps</i></p>	<p>GlyHealth biomarkers (stronger evidence, better selection, and higher approval rates for drugs)</p> <ul style="list-style-type: none"> <li>Optimising clinical trial efficiency with reliable, precision medicine biomarkers for Chronic Inflammatory Diseases (cIDs)</li> </ul> <p><b>Nina Skorytchenko</b>, CEO, <i>Avenna</i></p>
12:30	<p><b>Implementation Science in biomedical research:</b></p> <p><i>Implementation Science is a relatively new field of research to promote the systematic uptake of research findings and other evidence-based practices into routine practice. It aims to improve the quality and effectiveness of health services including the study of influences on healthcare professional and organisational behaviour. The session will provide insight to Evidence as a foundation for Implementation Science by:</i></p> <ul style="list-style-type: none"> <li>Outlining the different types of evidence</li> <li>Discussing evidence translation strategies for dissemination and Implementation including stakeholder and types of dissemination and implementation strategies</li> <li>Highlighting challenges in implementing evidence-based guidelines and policies into routine practice</li> </ul> <p><b>Angela Ibal</b>, Real World Evidence leader <i>Emmes</i></p>	<p><b>Hybrid trials using DCT technology and processes; focus on patients and the sites</b></p> <ul style="list-style-type: none"> <li>Highlighting the complexity that Hybrid/DCT brings whilst moving away from the common brick-and-mortar sites.</li> <li>Discussing the rise in regulator concerns in areas such as investigator oversight, and participant's safety when face to face contact is limited.</li> <li>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.</li> <li>Major points to consider in designing hybrid/DCT 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.</li> </ul> <p><b>Sverre Bengtsson</b>, Co-Founder, Senior Vice President Strategic Relations, <i>Viedoc</i></p>
13:00	<b>Lunch and networking</b>	
14:00	<p><b>Delivering trials through NHS Organisations</b></p> <p><i>As Research Lead for the NHS Trust Manchester Royal Infirmary at Manchester University Hospitals, one of the largest NHS hospital trusts in UK, Professor Sandip Mitra has been involved in delivering research trials for 15+ yrs working in partnership with industry and external stakeholders. He understands the growing need to interact with commercial organisations and research platforms and how to successfully engage with NHS systems and clinical teams to deliver research</i></p> <p>This session will cover the following: <b>Navigating through NHS systems and pathways for efficient delivery of R&amp;I trials</b></p> <p><b>Professor Sandip Mitra</b>, Deputy Director, <b>NIHR MedTech Co-operative D4D</b>, Consultant Nephrologist &amp; Professor of Medicine, <b>Manchester University Hospitals NHS Foundation Trust</b></p>	<p><b>INTERACTIVE SESSION</b></p> <p><b>This workshop will explore different approaches and strategies for putting patients at the centre when collecting samples for decentralised and hybrid clinical trials</b></p> <ul style="list-style-type: none"> <li>Primer on costs of centralised trials and how decentralisation helps to reduce costs and drive recruitment</li> <li>Discuss benefits of decentralised clinical trials</li> <li>Discuss challenges</li> <li>What does the future look like?</li> </ul> <p><b>James Rudge</b>, Technical Director, <i>Neoteryx</i></p>

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<p>14:30</p>	<p><b>The Landscape of Precision and Personalized Medicine (PM) Clinical Trials:</b>  <i>This presentation will highlight:</i></p> <ul style="list-style-type: none"> <li>• The competitive landscape of PM indicating the top industry sponsors, CROS, non-industry sponsors, regions and countries leading the way</li> <li>• The research landscape of PM included the top therapy areas, indications, drugs in PM clinical trials</li> <li>• Use of virtual components in PM studies</li> <li>• Leading causes of trial termination/suspension/withdrawal (Low accrual, financial, business/strategic decision)</li> </ul> <p><b>Sonnika Lamont</b>, GlobalData Analyst – Trials Intelligence, GlobalData</p>	<p><b>Running Up That Hill: Accelerate Cycle Times &amp; Reach Patients Faster with elluminate</b></p> <p><i>This presentation will highlight how the elluminate Clinical Data Cloud and Biometrics Services can reshape your data architecture by automating data flows to keep up with the pace of data evolution and speed time to insights.</i></p> <p>Learn how elluminate and eClinical's Biometrics Services deliver:</p> <ul style="list-style-type: none"> <li>• Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety</li> <li>• Improved study oversight with a holistic view of risk across all data sources</li> <li>• 50 out-of-the-box visualizations to support cross-study analysis for deeper insights with self-service access to clinical and operational analytics</li> <li>• Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles</li> </ul> <p><b>Achilleas Zaras</b>, Senior Manager, Solution Consulting, eClinical Solutions</p> <hr/> <p><b>Featured toolkit coverage: Capturing a representative and equitable sample in health research</b></p> <ul style="list-style-type: none"> <li>• Research participants often do not represent the target population for treatment, limiting generalisability of research findings and perpetuating health inequalities</li> <li>• The Toolkit addresses this by providing guidance to inform representative and equitable inclusion in research</li> <li>• Use of the Toolkit may promote trust between communities and research institutions, increase participation in, and improve generalisability of health research</li> </ul> <p><b>Ameeta Retzer</b>, Equity, Diversity and Inclusion Lead, National Institute of Health and Care Research Applied Research Collaboration West Midlands</p>
<p>15:00</p>	<p><b>PANEL DISCUSSION</b>  <b>What are the different outsourcing relationships and how do you manage them?</b></p> <ul style="list-style-type: none"> <li>• What are the categories and the driving needs for 2024?</li> <li>• How has this changed over the years?</li> <li>• Key strategies that sponsor companies have – how has this changed?</li> <li>• Did the pandemic effect these strategies?</li> </ul> <p>Moderator: <b>Emma Challans-Rasool</b>, Chair &amp; Founder, Proud2bOps</p>	<p><b>PANEL DISCUSSION</b>  <b>Focusing on today's Innovation &amp; Technological Advancements</b></p> <ul style="list-style-type: none"> <li>• Are we making the most of Technology &amp; Innovation in the UK &amp; Ireland Clinical Trial space?</li> <li>• How are these tools being utilised?</li> <li>• What's next?</li> <li>• Considering the use of AI in healthcare &amp; Clinical Trials</li> </ul> <p>Moderator: <b>Quentin Horgan</b>, Associate Director of Drug Intelligence, GlobalData</p> <p>Panelists:</p>



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	<p>Panelists:</p> <p><b>John McEvoy</b>, <i>General Counsel, Amryt Pharma</i></p> <p><b>Roman Fishchuk</b>, Head of Clinical Trials Department, <b>Central City Clinical Hospital, Ukraine</b></p> <p><b>Nina Skorytchenko</b>, <i>CEO, Avenna</i></p>	<p><b>Krzysztof Potempa</b>, Founder and Chief Executive Officer, <b>Braincures</b></p> <p><b>Martin Edobor</b>, Clinical Lead for Digital Transformation, <b>NHS North East London</b></p> <p><b>Marisa Papaluca</b>, Expert medicines regulatory adviser. Former Senior Scientific Adviser, <b>European Medicines Agency</b> and, Visiting Professor, <b>Imperial College London</b></p> <p><b>Greig Duncan</b>, Solution Sales Specialist - Clinical Operations, <b>Medidata</b></p>
15:30	<b>Afternoon refreshments and networking</b>	
16:00	<p><b>Charting a Course through Complexity: Leveraging Experience in Approaching Complex Clinical Trial Protocols</b></p> <p>The landscape of clinical trials has undergone a remarkable transformation with the introduction of eClinical solutions, fundamentally reshaping day-to-day processes from traditional approaches. Automation and the integration of cutting-edge technologies are now the standard for clinical trial teams. However, amidst these advancements, the core requirements and understanding essential for running successful clinical trials remain steadfast. Experience emerges as the primary predictor of success – experience with protocol designs, study team and site expectations, and best standard practices.</p> <p>Join Siobhan McKenna-Power, an industry veteran with 20 years of expertise in designing and delivering regulated systems, as she delves into the intricate distinctions involved in delivering these sophisticated solutions and why experience is critical. Discover how mastery of these crucial elements can be the key to achieving the successful implementation of technology solutions supporting modern clinical trials. Don't miss this opportunity to explore the perfect blend of cutting-edge technology and invaluable experience that can revolutionise the future of clinical trials.</p> <p><b>Siobhan McKenna-Power</b>, Client Services Lead, <b>4G Clinical</b></p>	
16:30	<p><b>Closing Keynote</b></p> <p><b>The Patients Perspective</b> Helping patients on their clinical trial journey</p> <ul style="list-style-type: none"> <li>• Living with a rare disease</li> <li>• Patient expectations &amp; considerations</li> <li>• Proven approaches to increase patient retention in clinical trials</li> <li>• Focusing on the future of patients in clinical trials</li> </ul> <p><b>Bob Stevens</b>, <i>Patient Advocate, Group CEO, MPS Society &amp; Rare Disease Research Partners Vice Chair, LSD Collaborative Co-Chair, International MPS Network</i></p>	
17:00	<p><b>Chairperson's closing remarks followed by Drinks Reception</b></p> <p><b>Emma Challans-Rasool</b>, <i>Chair &amp; Founder, Proud2bOps</i></p>	

**END OF DAY 1 AND NETWORKING DRINKS RECEPTION SPONSORED BY TFS HealthScience**

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# Outsourcing in Clinical Trials UK and Ireland 2023

DAY 2 – 6<sup>th</sup> September 2023

8:00	<b>Registration and refreshments</b>
8:50	<b>Chairperson's opening remarks</b> <b>Chair: Barbara Hepworth-Jones</b> , Director Capability Building, Global Clinical Operations, <b>GSK</b>
9:00	<b>OPENING KEYNOTE: CLINICAL TRIAL REVIEW</b>  In early 2023 Lord James O'Shaughnessy was commissioned by the Government to carry out an independent review of commercial clinical trials in the UK, which was published in May. The review offers recommendations on how commercial clinical trials can help the life sciences sector unlock UK growth and investment opportunities. It also advises on how to resolve key challenges in conducting commercial clinical trials in the UK.  <b>Lord James O'Shaughnessy</b> , Member of the House of Lords, former Health Minister, Senior Partner at Newmarket Strategy
9:30	<b>Accelerated performance of complex exploratory patient studies: practical insights from investigational site</b> <ul style="list-style-type: none"><li>• Unique model of dedicated research clinics in Eastern Europe</li><li>• Strategies for fast patient enrollment and retention</li><li>• Operational tips for flawless study conduct</li><li>• Takeaways after operating under unprecedented circumstances / case studies</li></ul> <b>Dr. Claudia Hesselmann</b> , Founder and CEO, <b>Arensia</b>
10:00	<b>How NIHR infrastructure can enhance industry and commercial collaboration in clinical trials: the Greater Manchester Example</b> <ul style="list-style-type: none"><li>• Outline of current NIHR Infrastructure</li><li>• How NIHR infrastructure can support industry collaborations</li><li>• Post Covid RESET and research recovery</li></ul> <b>Ian Bruce</b> , Director, <b>NIHR Manchester Biomedical Research Centre</b>
10:30	<b>Rethinking Sponsor Oversight in a Digital First World</b>  The transition from a manual, paper-based approach to a digital first approach in clinical trials opens new opportunities for sponsors to achieve enhanced oversight on study progress, quality, and patient safety. This session will address how data insights generated from digital first clinical trials: <ul style="list-style-type: none"><li>• Increase speed and transparency</li><li>• Redefine site engagement</li></ul>

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	<ul style="list-style-type: none"> <li>Identify areas for corrective action sooner</li> <li>Generate learning capital for other trials</li> </ul> <p><b>Dr. Brendan Buckley</b>, Chief Medical Officer, <b>Teckro</b></p>				
11:00	<b>Morning refreshments and networking</b>				
	<table border="1"> <tr> <th style="background-color: #002060; color: white;">STREAM A: Clinical Operations and Outsourcing Chair: <b>Barbara Hepworth-Jones</b>, Director Capability Building, Global Clinical Operations, <b>GSK</b></th> <th style="background-color: #002060; color: white;">STREAM B: Clinical Technology and Innovation Chair: <b>Quentin Horgan</b>, Associate Director of Drug Intelligence, <b>GlobalData</b></th> </tr> <tr> <td> <p><b>Protecting Our Planet: Minimising carbon impact in Human Biosample lifecycle in clinical trials</b></p> <ul style="list-style-type: none"> <li>Focusing on the minimization of our carbon footprint of Human samples in clinical trials</li> <li>Finding the balance between scientific impact &amp; the cost to our planet</li> <li>Small changes can have a large impact - cold chain</li> </ul> <p><b>Abi Hunter</b>, Senior Director Head of Clinical Sampling, <b>AstraZeneca</b></p> </td> <td> <p><b>Regulatory considerations for Remote Diagnostics in Decentralised clinical trials</b></p> <p><i>The session will discuss <b>Regulatory Considerations</b> to avoid pitfalls later down the line focussing on following key areas</i></p> <ul style="list-style-type: none"> <li><b>Regulatory Approval</b> including application submission to regulatory bodies such as the MHRA</li> <li><b>Informed Consent</b>: to ensure participants understand the nature of the remote testing procedures and the risks and benefits involved</li> <li><b>Data Security and Privacy</b>: remote diagnostic testing involves the transmission of sensitive health information over digital platforms. Appropriate measures to protect the privacy and security of participant data will be discussed.</li> <li><b>Quality Assurance</b>: to ensure that the data collected is accurate and reliable Remote diagnostic testing can offer several advantages in decentralized clinical trials, including increased convenience and reduced participant burden. However, it is essential to ensure that appropriate regulatory considerations are taken into account to ensure the safety and integrity of the study data.</li> </ul> <p><b>Surbhi Gupta</b>, Head of Regulatory Affairs, <b>Thriva</b></p> </td> </tr> </table>	STREAM A: Clinical Operations and Outsourcing Chair: <b>Barbara Hepworth-Jones</b> , Director Capability Building, Global Clinical Operations, <b>GSK</b>	STREAM B: Clinical Technology and Innovation Chair: <b>Quentin Horgan</b> , Associate Director of Drug Intelligence, <b>GlobalData</b>	<p><b>Protecting Our Planet: Minimising carbon impact in Human Biosample lifecycle in clinical trials</b></p> <ul style="list-style-type: none"> <li>Focusing on the minimization of our carbon footprint of Human samples in clinical trials</li> <li>Finding the balance between scientific impact &amp; the cost to our planet</li> <li>Small changes can have a large impact - cold chain</li> </ul> <p><b>Abi Hunter</b>, Senior Director Head of Clinical Sampling, <b>AstraZeneca</b></p>	<p><b>Regulatory considerations for Remote Diagnostics in Decentralised clinical trials</b></p> <p><i>The session will discuss <b>Regulatory Considerations</b> to avoid pitfalls later down the line focussing on following key areas</i></p> <ul style="list-style-type: none"> <li><b>Regulatory Approval</b> including application submission to regulatory bodies such as the MHRA</li> <li><b>Informed Consent</b>: to ensure participants understand the nature of the remote testing procedures and the risks and benefits involved</li> <li><b>Data Security and Privacy</b>: remote diagnostic testing involves the transmission of sensitive health information over digital platforms. Appropriate measures to protect the privacy and security of participant data will be discussed.</li> <li><b>Quality Assurance</b>: to ensure that the data collected is accurate and reliable Remote diagnostic testing can offer several advantages in decentralized clinical trials, including increased convenience and reduced participant burden. However, it is essential to ensure that appropriate regulatory considerations are taken into account to ensure the safety and integrity of the study data.</li> </ul> <p><b>Surbhi Gupta</b>, Head of Regulatory Affairs, <b>Thriva</b></p>
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11:30					

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12:00	<p><b>Think Ecosystem – how seamless technology integration is a win/win for everyone</b></p> <p>Nothing in clinical research happens in a vacuum and the more healthcare and clinical trials collide, and research moves closer to the more natural point of care, the more it requires an ecosystem of technology solutions and capabilities to access the right insights at the right time. We believe that “thinking ecosystem” is critical to solving key industry challenges.</p> <p>Join our session as we talk about the power of business partnerships and outsourcing to support data integration when it comes to successfully executing clinical research.</p> <p><b>Jennifer Duff</b>, General Manager, <b>Zelta Clinical Trials Solutions</b>, (Merative)</p>	<p><b>Commercial trials in the UK: How primary care can answer the call</b></p> <p>Reflecting on the recent independent report from Lord O’Shaughnessy, this session will explore the potential of primary care to transform commercial clinical trials in the UK, including:</p> <ul style="list-style-type: none"> <li>• Harnessing the trusted networks established in primary care settings</li> <li>• Unlocking the potential of healthcare data for targeted trial recruitment at pace and scale</li> <li>• Thinking differently to drive diversity, representation and innovation in trial delivery</li> </ul> <p><b>Dr. Ian Wood</b>, Clinical Director, <b>EMIS</b></p>
12:30	<b>Lunch and networking</b>	
13:30	<p><b>Fireside Chat</b></p> <p><b>Reviewing shifts in the UK clinical trial space and thoughts on where we go from here.</b></p> <p>This talk will include an overview on the huge decision for Cancer Research UK to consider taking their trials outside of the UK for the first time ever.</p> <p><b>Moderator: Barbara Hepworth-Jones</b>, Director Capability Building, Global Clinical Operations, <b>GSK</b></p> <p><b>Nigel Blackburn</b>, Director of Drug Development, <b>Cancer Research UK</b></p>	<p><b>Decentralised and people-centric trials; how and why this approach could make it easier to run trials in the UK - including sharing details of the national survey the HRA recently conducted with the public to understand the views of patient and the public about participating in research</b></p> <ul style="list-style-type: none"> <li>• Understand what builds public trust in research</li> <li>• Explore actions you can take to make research more people-centred</li> <li>• Learn how you can implement people-centric and decentralised research in the UK</li> </ul> <p><b>Dr Janet Messer</b>, Director of Approvals Service, <b>Health Research Authority (HRA)</b></p>
14:00	<p><b>Sponsor and NHS Site Collaboration to accelerate set-up timelines</b></p> <p><i>Sponsors of trials of novel therapeutics rely on the world-leading multidisciplinary clinical and research expertise found within NHS Trusts to deliver their complex trials. However, when faced with the current challenges of conducting commercial clinical trials within the NHS, it is tempting to more heavily weight timelines over expertise in site selection considerations. Another option is for Sponsors to choose to lean in and be part of the solution for UK clinical research. This talk will describe, from a Sponsor and NHS Trust perspective, how early Sponsor-initiated collaborative engagement on patient-pathway and protocol development can be undertaken in the shared aim of accelerating post-submission site feasibility and approval timelines, bringing these much-needed treatments to patients faster.</i></p>	<p><b>Challenges of just in-time manufacturing and supply of investigational products (perspectives from experience with short-lived radiopharmaceuticals)</b></p> <ul style="list-style-type: none"> <li>• Overview of the supply chain: e.g., manufacture, release, importation</li> <li>• Specificities of local vs. centralised production, incl. redundancy/performance aspects and management of multiple CDMOs/vendors</li> <li>• IRT and IMP order/accountability</li> <li>• practical experience with US/Europe clinical trials</li> <li>• specific challenges with clinical trials in the UK (manufacture, Northern Ireland status, importation, release)</li> </ul>

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	<p><b>Rachel Haines</b>, Director of Clinical Operations, <b>Rinri Therapeutics</b></p> <p><b>Shaun Cochrane</b>, Deputy Director R&amp;D, <b>Guy's and St Thomas' NHS Foundation Trust</b></p>	<p><b>Romain Bejot</b>, VP CMC &amp; Supply, <b>Blue Earth Diagnostics</b></p>
<p>14:30</p>	<p><b>PANEL DISCUSSION</b></p> <p><b>Building back a thriving, competitive life science sector in the UK &amp; Ireland:</b> <i>the UK has fallen behind other countries in the number of studies initiated, with a drop of 44% in commercial clinical trials in the last five years taking us from 4th to 10th in the global standings.</i></p> <ul style="list-style-type: none"> <li>• Exploring maintenance and growth of research delivery in NHS sites</li> <li>• Appreciating global life science industry timelines; highlighting regulatory approval, ethics reviews, and the time it takes to set-up at a site, and recruit the first participants</li> <li>• Unlocking costing for commercial contract research</li> <li>• Addressing clinical capacity within the NHS in order to increase revenue and increase trials based in the UK</li> <li>• Discussing MHRA Introductory measures to streamline the process of running trials making the UK a 'more attractive' place to conduct clinical trials</li> </ul> <p>Moderator: <b>Barbara Hepworth-Jones</b>, Director Capability Building, Global Clinical Operations, <b>GSK</b></p> <p>Panellists:</p> <p><b>Ian Bruce</b>, Director, <b>NIHR Manchester Biomedical Research Centre</b></p> <p><b>Dr Janet Messer</b>, Director of Approvals Service, <b>Health Research Authority (HRA)</b></p> <p><b>Oliver Buckley-Mellor</b>, Innovation and Research Policy Manager (Clinical), <b>The Association of the British Pharmaceutical Industry (ABPI)</b></p> <p><b>Alison McMorn</b>, VP, Clinical Development, <b>AMO Pharma</b></p>	
<p>15:15</p>	<p><b>Afternoon refreshments, networking, and Apple Prize Draw</b></p>	
<p>15:45</p>	<p><b>ROUNDTABLE SESSIONS</b></p> <p><i>During the roundtable discussion session, the conference hall will be divided into zones. Delegates can choose which zone they would like to join. Each zone will be led by a table lead/host and will focus on a different challenge within the industry. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.</i></p> <p><b>RT 1- Disaster Preparedness: How can the clinical trial industry prepare for the unexpected? Using the Ukrainian crisis as central to the conversation</b>  <b>Roman Fishchuk</b>, Head of Clinical Trials Department, Central City Clinical Hospital, Ukraine</p> <p><b>RT 2- How do you successfully adopt and scale proven research &amp; innovation across the health and care sector.</b>  <b>Erica White</b>, Director of Innovation, <b>Royal Free London NHS Foundation Trust</b></p>	

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**RT 3- Responsible AI in Healthcare & Clinical Trials – how industry and the NHS can work together**  
*Katie Tucker, Senior Innovation Consultant, Royal Free London NHS Foundation Trust*

**RT 4- Strategies for achieving IDEA (Inclusion, Diversity, Equity, and Access) in UK Clinical Trials – where do we go from here? Recommendations on how to move forward.**

*Dr Suki Balendra PhD, Director of Strategic Partnerships, Paddington Life Sciences. Life sciences Lead for the NIHR CRN North West London, Board Advisor*

**RT 5 Paradigm shift: The power of partnership working**  
*Nicola Yallup, Head of Business Development and Marketing, NIHR Clinical Research Network*

**RT 6 Making it easier to do clinical trials that everyone can trust: making research more transparent and increasing public involvement in a proportionate and agile way. Supporting best practice for all studies.**  
*Becky Purvis, Director of Policy and Partnership, Health Research Authority (HRA)*

16:45

**Chairperson's closing remarks**  
**Barbara Hepworth-Jones, Director Capability Building, Global Clinical Operations, GSK**

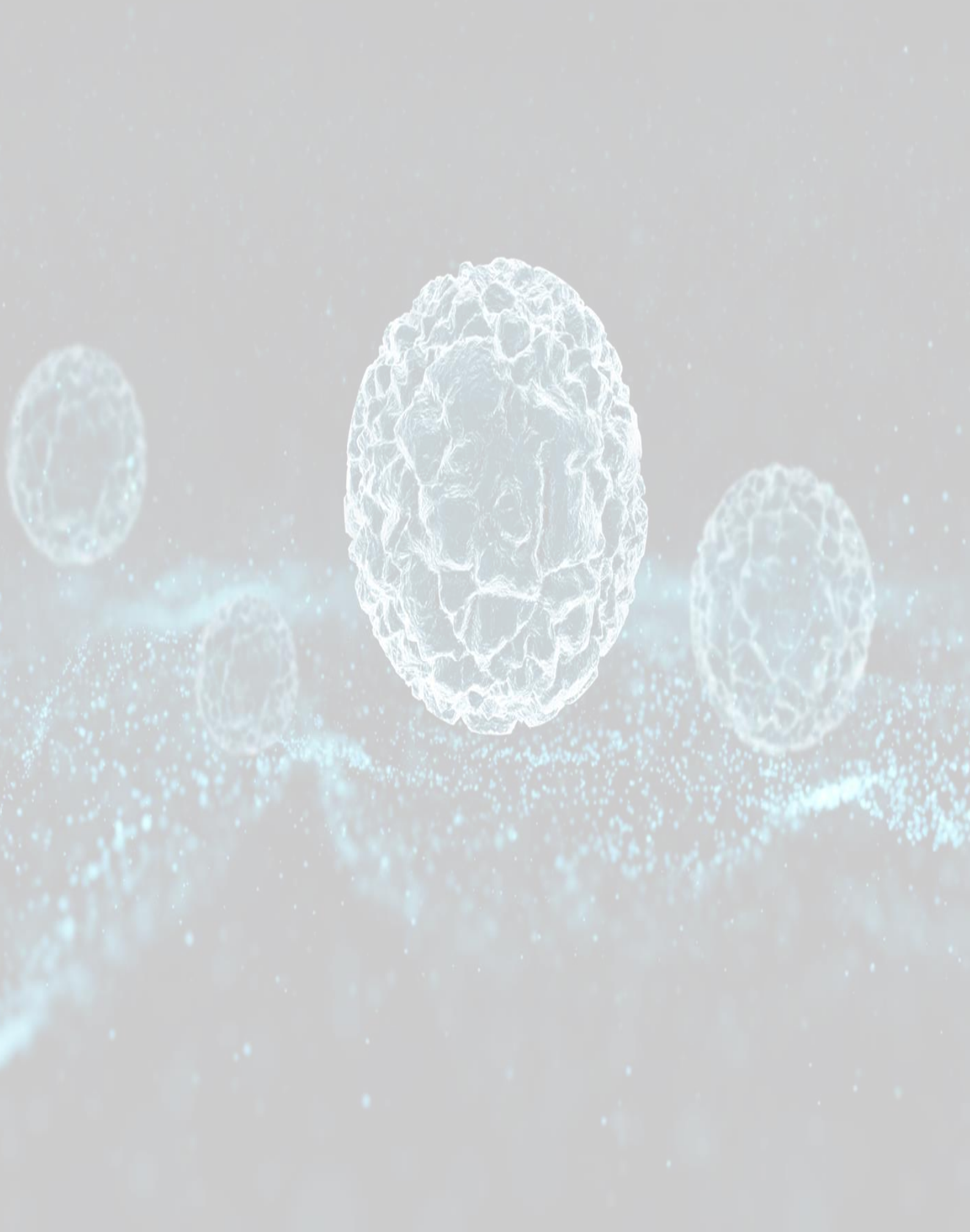
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