OUTSOURCING IN CLINICAL TRIALS UK & IRELAND 2023

5th & 6th September, London

Confirmed 2023 Speakers

Lord James O'Shaughnessy, Member of the House of Lords, former Health Minister, Senior Partner at Newmarket Strategy

Nigel Hughes, Scientific Director, Observational Health Data Analytics/Epidemiology, **Johnson & Johnson, Office of the Chief Medical Officer**

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, Chair & Founder of **PRroud2bOps** and Director of Organisational Development, Culture and Talent **NHS Nottingham**

Catherine Mela, Executive Director, Head of Biosamples, **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**

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**

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

Marisa Papaluca, Expert medicines regulatory adviser. Former Senior Scientific Adviser, **European Medicines Agency,** and, Visiting Professor, **Imperial College London**

Oliver Buckley-Mellor, Research Policy Manager, **The Association of the British Pharmaceutical Industry (ABPI)**

Neelam Patel, CEO, **MedCity**

Erica White, Director of Innovation, **Royal Free London NHS Foundation Trust**

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5TH-6TH SEPTEMBER | LONDON

Greig Duncan, Solution Sales Specialist - Clinical Operations, **Medidata**

Brian MacNamara, Senior Product Manager, **Teckro**

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)**

Outsourcing in Clinical Trials UK and Ireland 2023

DAY 1 – 5th September 2023

8:00	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Emma Challans**, Chair & Founder of **Proud2bOps and** Director of Organisational Development, Culture and Talent **NHS Nottingham**
9:00	**PANEL DISCUSSION** **Building back a thriving, competitive life science sector in the UK & Ireland:** *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.* • Exploring maintenance and growth of research delivery in NHS sites • 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 • Unlocking costing for commercial contract research • Addressing clinical capacity within the NHS in order to increase revenue and increase trials based in the UK • Discussing MHRA Introductory measures to streamline the process of running trials making the UK a 'more attractive' place to conduct clinical trials Moderator: GlobalData Panellists: **Ian Bruce,** Director, **NIHR Manchester Biomedical Research Centre** **Oliver Buckley-Mellor,** Research Policy Manager, **The Association of the British Pharmaceutical Industry (ABPI)** **Dr Janet Messer**, Director of Approvals Service**, Health Research Authority (HRA)**

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9:30	*Session Reserved for **Novotech***	
10:00	**Busting RBQM Myths: Practical Tools for Proactive Data Quality Management in Clinical Trials** 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. **Greig Duncan,** Solution Sales Specialist - Clinical Operations, **Medidata**	
10:30	**Morning refreshments and networking**	
	STREAM A: Clinical Operations and Outsourcing	**STREAM B: Clinical Technology and Innovation**
	Chair: **Emma Challans**, *Chair & Founder, **Proud2bOps***	*Chair: **GlobalData***

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11:00	**Diversity in Finding New Medicines** • Discussing how diversity affects medical research • Focusing on the importance of diversity in health research • Why is diversity needed in clinical trials for the advancement of medicine? • Strategies for achieving IDEA (Inclusion, Diversity, Equity, and Access) in UK Clinical Trials • Recognising steps the FDA have taken to address unrepresented minority groups in US clinical trials – can/should the UK expect to follow suit? **Suki Balendra PhD**, Director of Strategic Partnerships, Paddington Life Sciences. Life sciences Lead for the **NIHR CRN North West London, Board Advisor** **Neelam Patel,** CEO, **MedCity**	**The real-world data/experience paradigm shift & new architectures** • The emergence of federated data networks (FDNs) and trusted research environments (TREs) as a main architecture for evidence generation • The regulatory transition to FDNs in EU and UK - the role of EMA DARWIN EU(R) and MHRA strategy • Applications, e.g., pharmacovigilance and challenges e.g., governance **Nigel Hughes,** *Scientific Director, Observational Health Data Analytics/Epidemiology,* ***Johnson & Johnson, Office of the Chief Medical Officer***
11:30	**'Spare a thought for the hospitals'** ***Davy Yeung,*** *COO,* ***TCRS***	*Session Reserved for* ***YPrime***

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12:00	**Operational Management and Clinicians: Leaders change culture-culture changes organisations** 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 and recognise the value of collaborative leadership in challenging times. **Emma Challans,** *Chair & Founder of* ***PRroud2bOps*** *and Director of Organisational Development, Culture and Talent* ***NHS Nottingham***	**How precision medicine technologies can be used as complementary diagnostics to optimise clinical trial efficiency** • Improving success rates of clinical trials for anti-inflammatory drugs using prognostic and predictive biomarkers for chronic inflammatory diseases (cIDs) • Overview current and next generation biomarkers for Inflammatory Bowel Disease (IBD) • GlyHealth technology– Glycomics as a Sweet Spot in Precision Medicine diagnostics • Addressing challenges in anti-Inflammatory drug development with GlyHealth biomarkers (stronger evidence, better selection and higher approval rates for drugs) • Optimising clinical trial efficiency with reliable, precision medicine biomarkers for Chronic Inflammatory Diseases (cIDs) **Nina Skorytchenko**, *CEO,* ***Avenna***
12:30	**Implementation Science in biomedical research** **Angela Ibald,** *Real World Evidence leader* ***Emmes***	**Hybrid trials using DCT technology and processes; focus on patients and the sites** • Highlighting the complexity that Hybrid/DCT brings whilst moving away from the common brick-and-mortar sites. • Discussing the rise in regulator concerns in areas such as investigator oversight, and participant's safety when face to face contact is limited. • 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 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. **Sverre Bengtsson**, *Co-Founder, Senior Vice President Strategic Relations,* ***Viedoc***
13:00	**Lunch and networking**	

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<table>
<tr>
<td>14:00</td>
<td>Delivering trials through NHS Organisations

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

This session will cover the following: Navigating through NHS systems and pathways for efficient delivery of R&I trials

Professor Sandip Mitra, Deputy Director, NIHR MedTech Co-operative D4D, Consultant Nephrologist & Professor of Medicine, Manchester University Hospitals NHS Foundation Trust</td>
<td>INTERACTIVE SESSION
This workshop will explore different approaches and strategies for putting patients at the centre when collecting samples for decentralised and hybrid clinical trials

• Primer on costs of centralised trials and how decentralisation helps to reduce costs and drive recruitment
• Discuss benefits of decentralised clinical trials
• Discuss challenges
• What does the future look like?

James Rudge, Technical Director, Neoteryx</td>
</tr>
<tr>
<td>14:30</td>
<td>Session Reserved for Calyx</td>
<td>Running Up That Hill: Accelerate Cycle Times & Reach Patients Faster with elluminate

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.

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
• 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

eClinical Solutions</td>
</tr>
<tr>
<td></td>
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<td>Featured toolkit coverage: Capturing a representative and equitable sample in health research

• Research participants often do not represent the target population for treatment, limiting generalisability of research findings and perpetuating health inequalities</td>
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</table>

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		• The Toolkit addresses this by providing guidance to inform representative and equitable inclusion in research • Use of the Toolkit may promote trust between communities and research institutions, increase participation in, and improve generalisability of health research **Ameeta Retzer,** Equity, Diversity and Inclusion Lead, National Institute of Health and Care Research Applied Research Collaboration West Midlands
15:00	**PANEL DISCUSSION** **What are the different outsourcing relationships and how do you manage them?** • What are the categories and the driving needs for 2023? • How has this changed over the years? • Key strategies that sponsor companies have – how has this changed? • Did the pandemic effect these strategies? Moderator: **Emma Challans**, *Chair & Founder,* ***Proud2bOps*** Panelists: **John McEvoy,** *General Counsel,* ***Amryt Pharma*** **Diane Driver,** Head Program Delivery, PV Development Solutions, **UCB BioPharma UK** **Nicola Yallup,** Head of Business Development and Marketing, **NIHR Clinical Research Network**	**PANEL DISCUSSION** **Focusing on today's Innovation & Technological Advancements** • Are we making the most of Technology & Innovation in the UK Clinical Trial space? • How are these tools being utilised? • What's next? • Considering the use of AI in healthcare & Clinical Trials Moderator: **Erica White,** Director of Innovation, **Royal Free London NHS Foundation Trust** Panelists: **Krzysztof Potempa,** Founder and Chief Executive Officer, **Braincures** **Martin Edobor,** Clinical Lead for Digital Transformation, **NHS North East London** **Marisa Papaluca,** Expert medicines regulatory adviser. Former Senior Scientific Adviser, **European Medicines Agency** and, Visiting Professor, **Imperial College London**
15:30	**Afternoon refreshments and networking**	

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16:00	*Session Reserved for Event Sponsor*
16:30	**Closing Keynote** **The Patients Perspective** Helping patients on their clinical trial journey • Living with a rare disease • Patient expectations & considerations • Proven approaches to increase patient retention in clinical trials • Focusing on the future of patients in clinical trials **Bob Stevens,** *Patient Advocate, Group CEO, MPS Society & Rare Disease Research Partners Vice Chair, LSD Collaborative Co-Chair, International MPS Network*
17:00	**Chairperson's closing remarks followed by Drinks Reception** **Emma Challans**, *Chair & Founder,* ***Proud2bOps***

END OF DAY 1 AND NETWORKING DRINKS RECEPTION SPONSORED BY TFS

Outsourcing in Clinical Trials UK and Ireland 2023

DAY 2 – 6th September 2023

8:00	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Chair: Barbara Hepworth-Jones,** Director Capability Building, Global Clinical Operations, **GSK**

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9:00	**OPENING KEYNOTE: CLINICAL TRIAL REVIEW** The government have appointed Lord James O'Shaughnessy to conduct an independent review into the UK commercial clinical trials landscape. This review will offer recommendations on how commercial clinical trials can help the life sciences sector unlock UK growth and investment opportunities. It will also advise on how to resolve key challenges in conducting commercial clinical trials in the UK. **Lord James O'Shaughnessy,** Member of the House of Lords, former Health Minister, Senior Partner at Newmarket Strategy
9:30	**Accelerated performance of complex exploratory patient studies: practical insights from investigational site** • Unique model of dedicated research clinics in Eastern Europe • Strategies for fast patient enrollment and retention • Operational tips for flawless study conduct • Takeaways after operating under unprecedented circumstances / case studies **Dr. Claudia Hesselmann,** Founder and CEO, ***Arensia***
10:00	**How NIHR infrastructure can enhance industry and commercial collaboration in clinical trials: the Greater Manchester Example** • Outline of current NIHR Infrastructure • How NIHR infrastructure can support industry collaborations • Post Covid RESET and research recovery **Ian Bruce,** Director, **NIHR Manchester Biomedical Research Centre**
10:30	**Rethinking Sponsor Oversight in a Digital First World** 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: • Increase speed and transparency • Redefine site engagement • Identify areas for corrective action sooner • Generate learning capital for other trials **Brian MacNamara,** Senior Product Manager, **Teckro**
11:00	**Morning refreshments and networking**

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	STREAM A: Clinical Operations and Outsourcing **Chair: Barbara Hepworth-Jones,** Director Capability Building, Global Clinical Operations, **GSK**	STREAM B: Clinical Technology and Innovation
11:30	**Protecting Our Planet: Minimising carbon impact in Human Biosample lifecycle in clinical trials** • Focusing on the minimization of our carbon footprint of Human samples in clinical trials • Finding the balance between scientific impact & the cost to our planet • Small changes can have a large impact - cold chain **Catherine Mela,** Executive Director, Head of Biosamples, **AstraZeneca**	**Regulatory considerations for Remote Diagnostics in Decentralised clinical trials** *The session will discuss **Regulatory Considerations** to avoid pitfalls later down the line focussing on following key areas* • ***Regulatory Approval** including application submission to regulatory bodies such as the MHRA* • *Informed Consent: to ensure participants understand the nature of the remote testing procedures and the risks and benefits involved* • ***Data Security and Privacy:** 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.* • ***Quality Assurance:** 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.* **Surbhi Gupta,** Head of Regulatory Affairs**, Thriva**
12:00	*Session Reserved for **Merative***	*Session Reserved for **EMIS***

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<tr><td>13:30</td><td>Fireside Chat

Reviewing shifts in the UK clinical trial space and thoughts on where we go from here.

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.

Moderator: Barbara Hepworth-Jones, Director Capability Building, Global Clinical Operations, GSK

Nigel Blackburn, Director of Drug Development, Cancer Research UK</td><td>Data to Drive Sustainability

Collecting and using data to make decisions that guide measurable and responsible clinical practices

• What is sustainability data collection?
• Discussing how data is useful for sustainable development
• Focusing on how to manage sustainability data

Antoine Vigneau, Senior Director, Biosamples Head of Alliances and Technology, AstraZeneca</td></tr>
<tr><td>14:00</td><td>Challenges of just in-time manufacturing and supply of investigational products (perspectives from experience with short-lived radiopharmaceuticals)

• Overview of the supply chain: e.g., manufacture, release, importation
• Specificities of local vs. centralised production, incl. redundancy/performance aspects and management of multiple CDMOs/vendors
• IRT and IMP order/accountability
• practical experience with US/Europe clinical trials
• specific challenges with clinical trials in the UK (manufacture, Northern Ireland status, importation, release)

Romain Bejot, VP CMC & Supply, Blue Earth Diagnostics</td><td>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

• Understand what builds public trust in research
• Explore actions you can take to make research more people-centred
• Learn how you can implement people-centric and decentralised research in the UK

Dr Janet Messer, Director of Approvals Service, Health Research Authority (HRA)</td></tr>
<tr><td>14:30</td><td colspan="2">KEYNOTE FROM THE MHRA: An overview of the MHRA’s consultation on new clinical trial legislation

• An overview of proposals for the UK’s clinical trial legislation designed to make the UK the best place to research and develop safe and innovative medicines
• Results from the MHRA’s consultation: feedback on proposals
• What the new clinical trial legislation will mean for the future of clinical trials in the UK

Tentative confirmation – MHRA Senior representative</td></tr>
<tr><td>15:15</td><td colspan="2">Afternoon refreshments, networking, and Apple Prize Draw</td></tr>
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	PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS *During the roundtable discussion session, the conference hall will be divided into two 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within clinical operations in oncology trials. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	RT 1- Disaster Preparedness: How can the clinical trial industry prepare for the unexpected? Using the Ukrainian crisis as central to the conversation **Roman Fishchuk, Head of Clinical Trials Department, Central City Clinical Hospital, Ukraine**
15:45	**RT 2- How do you successfully adopt and scale proven research & innovation across the health and care sector.** ***Erica White,*** *Director of Innovation,* ***Royal Free London NHS Foundation Trust***
	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. ***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**
END OF CONFERENCE	

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