# Clinical Outsourcing Group UK

## Leonardo Royal Hotel London, Tower Bridge

## 20th & 21st February 2024

### Clinical Outsourcing Strategy

- Maximising the Value of Clinical Outsourcing
- Contract & Legal Considerations
- UK Partnerships

### Technology & Supply Chain

- Gene Therapy Trials
- AI & Advanced Analytics
- Decentralised & Hybrid Clinical Trials

### UK Research

- Our Future Health Programme
- Hackathon: Enabling Clinical Trials in the UK
- Trials in Northern Ireland

### Patient-Driven Innovation

- Biostatistics to Drive Patient-Centric Trials
- Age Diversity
- FDA & EMA Designations

**Janette Rawlinson - Patient Representative**
**Chi Onwurah MP** - Shadow Minister for Business, Energy, & Industrial Strategy – **Labour, UK Government**
**Andre Valente** – Partner – **L.E.K. Consulting**
**Suki Malhi** – VP Clinical Operations, Supply & Data Management – **Wave Life Sciences**
**Rachael McTegart** – Outsourcing & Contracts Director – **Vaccitech**
**Richard Knight** – Supply Chain Director – **Summit Therapeutics**
**Karan Turnbull** – Operational Strategy Lead, Clinical Supplies - **Pfizer**
**Krzysztof Potempa** – Founder & CEO – **Braincures**
**John McEvoy** – Global General Counsel – **Amryt Pharma**
**Ilan Chaitowitz** – Founder & CEO – **BioZen**
**Valeria Nicoli-Carr** – Senior Director, Patient Solutions – **AstraZeneca**
**Zara Ghodsi** – Associate Director, Biostatistics Lead, Early Clinical Development **– Pfizer**
**Esther McNamara** – Senior Health Policy Lead – **ILC UK**
**Barry Henderson** – Senior Industry Manager – **HSC Northern Ireland**
**Lucy Clossick Thomson** – Director, Clinical Development – **Artios**
**Tim Sprosen** – Executive Director, Recruitment – **Our Future Health**
**Joab Williamson** – Director, Program Management – **Faron Pharmaceuticals**
**Peter MacLennan** – CEO – **Tailored Clinical Research Solutions (TCRS)**
**Charlotte Smerdon** – Senior Director, Clinical Operations – **Purespring Therapeutics**
**Nina Skorytchenko** – CEO – **Avenna**
**Gabriel Lambert** – Head of Clinical Operations – **TidalSense**
**Kate Alcock** – Head of Research – **Muscular Dystrophy UK**
**Robert Burley** – Head of Engagement – **Muscular Dystrophy UK**
**Yvanne Enever** – CEO – **PHARMExcel**
**Liz Perraudin** - Clinical Policy Manager - **Association of Medical Research Charities**
**Caroline Jacobs** – Lead Outsourcing Manager – **Reckitt**
**Brian Sheridan** – VP Global Adherence & Clinicals - **Westrock**

PBC GROUP

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20th & 21st February 2024

## Day 1: 20th February 2024

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|---|---|
| 08:00 – 08:55 | **Registration & Morning Refreshments** |
| 08:55 | **Welcome Address** |
| 09:00 | Opening Keynote<br>**Nothing About Patients Without Patients: Top 10 Innovative Ways to Engage Patients**<br><br>Before you've got a trial, you've got patients. Maintaining partnerships with patients, and patient groups is essential to drive patient-centric trial design, recruitment, engagement, and overall trial compliance.<br><br>In this session Janette, patient representative will share their top 10 innovative ways to engage patients throughout the development cycle. Presenting case studies based on previous – successful – partnerships where a patient-centric approach has driven trial engagement and adherence.<br><br>**Janette Rawlinson - Patient Representative** |
| 09:30 | Keynote<br>**Driving Clinical Trials in the UK**<br><br>**Reserved for Tailored Clinical Research Solutions (TCRS)** |
| 10:00 | Keynote<br>**Adapting to the Winds of Change: Key Trends Reshaping the Clinical Outsourcing Landscape**<br><br>The past 12 months have been awash with consolidations and acquisitions across the CRO, Clinical Vendor and Study Site landscape. The global CRO market is forecast to reach $188 billion by year 2030, with a few multi-nations dominating the market, is there still space for growth from small and medium sized suppliers?<br><br>In this session Andre will share trends impacting the global CRO market from the past 12 months, highlighting significant areas of consolidation, as well as cross-industry acquisitions which may impact CRO and Clinical Vendor choice. Questioning where this stands in terms of competitivity.<br><br>**Andre Valente – Partner – L.E.K. Consulting** |
| 10:30 | **Reserved for MyData-TRUST** |
| 11:00 | **Coffee Break** |

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| | Stream A<br>**Outsourcing & Oversight** | Stream B<br>**Clinical Trial Supply & Technology** |
|---|---|---|
| 11:30 | Interactive Panel<br>**Getting Less for More: Maximising the Value of Clinical Outsourcing in a Challenging Macroeconomic Environment**<br><br>Following a decade of low inflation, low interest rates, we now find ourselves with high inflation, with high interest rates. Meaning that many trial sponsors are faced with soaring costs, whilst having reduced access to financial support.<br><br>This panel will explore the measures trial sponsors can take to manage and reduce outsourcing costs, whilst maintaining quality. Exploring themes such as building in-house teams, contract negotiation, and international study locations.<br><br>**Suki Malhi – VP Clinical Operations, Supply & Data Management – Wave Life Sciences**<br>**Rachael McTegart – Outsourcing & Contracts Director – Vaccitech**<br>**Nina Skorytchenko – CEO – Avenna**<br>**Yvanne Enever – CEO – PHARMExcel**<br>**Caroline Jacobs – Lead Outsourcing Manager - Reckitt** | Interactive Panel<br>**Obstacles and Solutions in Modern Clinical Trial Supply: An Industry-Wide Panel Discussion**<br><br>The supply of investigational drugs is ever-evolving; impacted by patient-centric trial design, hybrid and decentralized models, geopolitical challenges, and the increase of cell and gene therapy studies.<br><br>This panel is designed to discuss the broad challenges facing the clinical trial supply landscape today. Exploring themes around direct-to-patient, growing pains in scaling up, and methods to ensure reliable supply.<br><br>**Richard Knight – Supply Chain Director – Summit Therapeutics**<br>**Karan Turnbull – Operational Strategy Lead, Clinical Supplies - Pfizer** |
| 12:00 | **Reserved for VCTC** | **Reserved for Boostcode** |
| 12:30 | Insight<br>**Onstage Interview: Clinical Research Contracts with Sites & Vendors**<br><br>When engaging vendors & sites, successful planning and contract management can vastly improve your negotiation position and benefit your study timelines, which will drive positive management throughout the duration of clinical studies. Studies are often carried across a vast network of sites, which adds to their complexities.<br><br>In this onstage interview, John will share key insights into how trial sponsors can position | Insight<br>**Navigating the Logistical Challenges of Gene Therapy Trials: Ensuring Adequate Patient and Specimen Supply**<br><br>Gene therapy clinical trials face unique logistical challenges due to the limited number of rare disease patients, high burden of clinical specimen collection and specialist bioanalytical assays. Sponsors must work closely with patients throughout enrolment, and trial duration, and maintain a strong patient pipeline to avoid delays. |

| | | |
|---|---|---|
| | themselves through planning, negotiation, and contract execution to reduce costs, gain leverage, and protection against overruns.<br><br>**John McEvoy – Global General Counsel – Amryt Pharma** | In this two-part session, Charlotte will examine strategies for establishing efficient specimen collection protocols, specimen shipments, and working closely with gene therapy manufacturers to ensure adequate production capacity. Coupled with patient supply and engagement considerations for typical rare disease studies.<br><br>**Charlotte Smerdon – Senior Director, Clinical Operations – Purespring Therapeutics** |
| 13:00 | **Lunch** | |
| 14:00 | Insight<br>**Harnessing Precision Medicine for Smarter Clinical Trials: Complementary Diagnostics to Drive Cost Efficiency and Success**<br><br>Clinical trials face challenges of high costs and lengthy timelines, with high failure and low engagement rates. Precision medicine offers solutions through complementary diagnostics that can optimise patient selection, improve cohort stratification, provide predictive biomarkers, and enable adaptive designs.<br><br>In this presentation Nina will explain how omics based complementary diagnostics can significantly improve trial efficiency, reduce costs, and boost success rates. She will also exemplify it with case studies such as GlyHealth- IBD and Avenna Lifebook.<br><br>**Nina Skorytchenko – CEO – Avenna** | Insight<br>**AI and Advanced Analytics for Clinical Trials**<br><br>The rise of new technology is hard to avoid. AI and Machine Learning (ML) is now becoming mainstream, with biotech now looking to this to solve challenges in clinical trials.<br><br>This session will discuss, demonstrate, and challenge how technologies like AI and ML can optimise trial design, improve efficiency, and enhance safety monitoring. Demonstrating case studies of successful AI and ML deployment.<br><br>**Krzysztof Potempa – Founder & CEO – Braincures** |
| 14:30 | **Reserved for Premier Research** | **Reserved** |
| 15:00 | Insight<br>**First-in-Human Trials: Investment & Partnerships for Early-Stage Outsourcing** | Insight<br>**Leveraging Biostatistics to Put Patients at the Centre of Clinical Trials**<br><br>Clinical trials have not always focused on outcomes that are most meaningful to |

When preparing for a first-in-human trial it is key to forge the right industry partnerships, and obtain sufficient investment.

This session Ilan will share BioZen's journey to form and develop treatment for hormone-related disorders, including early partnership with Syneos and investor outreach.

**Ilan Chaitowitz – CEO & Founder - BioZen**

patients. Biostatistics techniques can help design and analyse trials that keep patient perspectives at the forefront; greater patient engagement, reduced patient burden, capturing real-world insights, evaluating ethics, and enhancing data accessibility.

This presentation will explore how patient input can inform better trial outcomes, how innovative trial designs can accommodate patient needs, and how patient-reported outcomes, risk/benefit assessments, and data transparency can make trials more patient-centric.

**Zara Ghodsi – Associate Director, Biostatistics Lead, Early Clinical Development – Pfizer**

15:30 **Coffee Break**

16:00 Keynote Panel

**Making Patient-Centric Research a Reality: Practical Steps and Innovations for Decentralised Trials**

Implementing a DCT, or Hybrid aspects to trial design can result in seamless data capture, minimised reliance on trial sites, and reduced trial costs, when executed correctly. The bulging market of wearables, telemedicine, mobile applications, and direct-to-patient supply has now made the DCT dream a reality.

This industry-wide panel examines the products and services available to trial sponsors, and CROs when designing a DCT or hybrid study. Discussing the benefits of implementing technology for remote patient consent, engagement, and monitoring.

**Richard Knight – Supply Chain Director – Summit Therapeutics**
**Valeria Nicoli-Carr – Senior Director, Patient Solutions – AstraZeneca**
**Brian Sheridan – VP Global Adherence & Clinicals - Westrock**

16:30 **Reserved for TRI**

17:00 Keynote

**Medicine 3.0: Improving Health and Lifespan through the UK's Our Future Health Programme**

Medicine 3.0 is a holistic, personalized, and participatory approach to healthcare that leverages new technologies and data, to engage individuals in their own health and

wellbeing. Our Future Health is the largest health research programme which is accelerating the UK to Medicine 3.0 status.

In this session Tim will share insights into the Medicine 3.0 theory, what technology and data is needed to meet the needs of personalised health and wellbeing programmes. Also futuristically looking at what can be done to leverage data collected through Our Future Health to create new 'blue zones' of longevity in the UK.

**Tim Sprosen – Executive Director, Recruitment – Our Future Health**

17:30 **Networking Drinks Reception *(complementary admission to all conference participants)***

## Day 2: 21st February 2024

08:15 – 09:00 **Registration & Morning Refreshments**

09:00 **COG UK Annual Hackathon: Enabling Clinical Trials in the UK**

You are invited to join one of the below 4 roundtables. The audience are to imagine they are either part of the sitting UK Government, Regulators, Public Health, or Academia.

Each group is tasked to come up with 10 initiatives in answer to the below question. Followed by 30 minutes where the host from each roundtable will take to the stage to present their 10 initiatives.

**What can you do to further enable clinical trials in the UK, streamline processes, and make clinical research in the UK more appealing on the Global stage?**

| Group 1: Government | Group 2: Regulation | Group 3: Public Health | Group 4: Academia |
|---|---|---|---|

09:45 **Presentation of Hackathon Findings**

10:15 Keynote
**Accelerating UK Clinical Research and Life Sciences: Labour's Vision for the Future**

**Reserved for Chi Onwurah MP - Shadow Minister for Business, Energy, & Industrial Strategy**

10:45 **Coffee Break**

| Stream A | Stream B |
|---|---|
| **Clinical Trials in the UK** | **Site & Patient Collaboration** |

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11:15

Insight

### Muscular Dystrophy UK: The Patient-Voice Role in Influencing NICE Treatment Assessment and NHS Access

Patient advocacy groups play a critical role in ensuring the patient voice is heard in the NICE drug approval process. Exploring how to effectively engage with NICE consultations and, highlighting patient needs, and preferences based on experience from clinical trials and early access programmes.

In this session Muscular Dystrophy UK will examine how to influence the National Institute for Health and Care Excellence's (NICE) assessments of new treatments. Highlighting best practice for patient groups and trial sponsors seeking to positively impact NICE guidance and NHS commissioning policies.

**Kate Alcock – Head of Research – Muscular Dystrophy UK**
**Robert Burley – Head of Engagement – Muscular Dystrophy UK**

Insight

### Trial & Error: Supporting Age Diversity in Clinical Trials

ILC UK recently conducted a project looking at methods and strategies for enhance age diversity in clinical trials. Due to an aging population in the developed world, involving older patients is now becoming the norm.

In this session Esther will share the insights and objectives from the Trial and Error project and share recommendations made to enhance age diversity in clinical trials.

**Esther McNamara – Senior Health Policy Lead – ILC UK**

11:45

**Reserved**

**Reserved**

12:15

Insight

### Unleashing Potential: Clinical Trials in Northern Ireland

Northern Ireland provides a unique – maybe overlooked - opportunity in the United Kingdom for conducting clinical research. This is an attractive destination for clinical trials due to patient population, established infrastructure, research expertise, regulation, and geographic position.

In this session Barry Henderson will provide insight into the unique challenges and opportunities faced by biotechs who choose to conduct clinical trials in Northern Ireland, including patient demographics (1.8m), access to NIECRs, and the strong network of

Interactive Workshop

### Effective Virtual Site Initiation: Strategies for Remote Study Startup

While in-person site initiation visits have traditionally been viewed as an essential first step in study startup, most of these activities can be effectively conducted online.

This interactive workshop, hosted by Lucy Clossick Thomson, will see attendees brainstorm effective and innovative ways of conducting Site Initiation Visits remotely, sharing past experiences to design a remote-ready approach to remote study startup.

**Lucy Clossick Thomson – Director, Clinical Development - Artios**

industry, academia, and health organisations available.

**Barry Henderson – Senior Industry Manager – HSC Northern Ireland**

12:45 **Reserved** **Reserved**

13:15 **Lunch**

14:15 Keynote

**Advancing Science & Awareness: The Value of Strategic Charity Partnerships in Clinical Research**

Charities act as the catalysts for patient engagement, leading on patient insights and community engagement for specific therapeutic areas.

This session Liz explores the benefits of partnering with the network of UK charities for clinical trials in the UK. Sharing the models for charity involvement across the trial lifecycle.

**Liz Perraudin - Clinical Policy Manager - Association of Medical Research Charities**

14:45 Keynote

**Navigating the Rare Disease Landscape: Innovative Approaches to Patient Finding and Recruitment**

Traditional trial recruitment methods rarely work for rare disease trials. Patients are hard to come by, often resulting in time and resource being spent, with little results.

This session explores the methods use to 'patient find' in rare diseases, looking at strategies which can be adopted across non-rare disease trials to aid recruitment.

**Suki Malhi – VP Clinical Operations, Supply & Data Management – Wave Life Sciences**

15:15 Keynote

**Leveraging FDA & EMA Designations for Faster Approvals and Commercial Success**

FDA & EMA drug designations can provide incentives for the development both directly and indirectly. These include Orphan Drug Designation, Fast Track Designation, Breakthrough Therapy, Regenerative Medicine Advanced Therapy.

In this session Joab will share insight into key FDA designations, delving into their developmental and economic impact. Based on published article(s), Joab will share new

research on the direct and indirect effects that these designations have on small pharma and biotech.

**Joab Williamson – Director, Program Management – Faron Pharmaceuticals**

15:45 Closing Keynote

**Achieving Together: How UK Collaboration Enabled a 740-Patient Clinical Trial**

In 2022 TidalSense partnered with Innovate UK, National Institute for Health Research, Modality Partnership, and uMED, to recruit and execute a large scale trial for the N-Tidal Device. With the trial requiring 2 breath records per day per participant the trial took a DCT/Hybrid approach to data collection.

In this presentation Gabriel will share insight into the recruitment strategy and execution of the CARES study, detailing methods used to attract and engage patients, and ensure adherence to trial requirements. Providing an overview of the N-Tidal device, and clinical trial outcomes.

**Gabriel Lambert – Head of Clinical Operations – TidalSense**

**End of Conference**