
# Streamline & Innovate Clinical Trials Operations Against A Backdrop of Shifting Priorities and Political Change

This 4th edition of Arena International's Outsourcing Clinical Trials global series tackles the critical issues currently challenging the UK and Ireland Pharmaceuticals sector in this diverse and evolving commercial area.

From addressing the **evolving political forces** impacting at a macroeconomic level, to exploring the **potential of disruptive technologies** such as wearables and automated dosing to improve **data quality, trial oversight and patient centricity**, this year's events core theme is ***'Managing Trials Effectively In Uncertain Times'*.**

**Tackling your operational issues**, as well as your specific outsourcing concerns, this year's programme delivers comprehensive insight into **how to ensure that your trials emerge unscathed from the year's inevitable disruption and change.**

Tailored specifically to prioritise the issues at the top of your agenda, this year's OCTUK forum will address the below key areas of opportunity and concern for the coming year:

- **Patient centricity & effective recruitment**
- **Trial strategy** ; cost, location, quality
- **Data Management and Analytics**; for performance measurement, as well as clinical data management
- **Technological Innovation;** to streamline Operations/Outsourcing – automation, digitisation, wearable technology, automated dosing, non-invasive diagnostics
- **Insourcing vs. Collaboration**; what is the best model to ensure optimal delivery
- **Brexit**; the impact to the UK pharma market
- **Complex supplier networks;** Niche/specialist providers and how to secure the best expertise
- **Regulatory inspections;** MHRA, ICH, oversight, RSI and TMFs
- **Value of strategic partnering with CROs**; do they really benefit pharma?
- **Maintaining quality of outsourced work**; – what is adequate sponsor oversight?
- **Real impact of risk based monitoring**; in terms of cost and data quality

Delivering leading conferences to the Clinical Trials sector, globally, has been the stalwart of Arena International's focus for the past 15 years. Continuing on the success of this global series, we present this Clinical Trials Operations and Outsourcing Summit to the global pharmaceutical market, based in the UK and Ireland.

We very much look forward to welcoming you to the Summit in London, this coming June.

Kind regards,

Clinical Trials Team
Arena International


# Outsourcing in Clinical Trials, UK & Ireland

**Programme Day One: Streamlining Clinical Trials Operations, Oversight & Data**
**Wednesday 28th June, 2017**

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| **08:30** | **Registration and refreshments** |
| **08:50** | **Chairman's opening remarks- Chair for Day 1: Dr Simon Roitt, Head of Clinical Development, Karus Therapeutics** |
| | **Tackling the Evolving Political and Regulatory Landscape in the UK: Brexit, EMA, ICH Guidelines & More** |
| **09:00** | **Keynote Panel: What Will The Impact of Brexit Be On UK Pharma's Reputation And Critical Operating Models?**<br><br>With prevailing uncertainty as to the impact of Brexit, this year's annual conference will explore the key themes dominating the UK and Irish Pharmaceuticals sectors, to offer a sounding board for your concerns in the run up to Britain's departure from the EU.<br><br>Panellists from across the industry will share their expert insights into the potential short and long term impacts of Brexit on your ability to:<br><br>- Effectively manage talent and resource across a shifting political backdrop to support your current trials programmes<br>- Will certain roles and functions be lost from the UK Pharmaceuticals and Biotech sector? How could this impact Ireland?<br>- Scenario plan operational cost and risk to improve your ability to smoothly manage Brexit<br>- Consider the regulatory impact of leaving the UK, including re-location of the EMA, approvals in country, site selection strategies and access to new drugs<br><br>Plus, explore the impact of a foundering NHS on UK centric trials and the ability to recruit patients in the UK, in light of Brexit and broader political uncertainty.<br><br>**Panellists:**<br>Dr Simon Roitt, *Head of Clinical Development*, **Karus Therapeutics**<br>John Shillingford, *Clinical Operations Director*, **Orsus Medical**<br>Paul Steckler, *Chief Commercial Officer*, **Shield Therapeutics**<br>Steven Twait, *VP, Alliance and Integration Management (AIM)* , **AstraZeneca** |
| **09:45** | **Managing Trials In Uncertain Times: The Risk-Mitigation Benefits of Rescue Trial Expertise**<br><br>As the regulatory landscape evolves, and additional risks present themselves, the potential for derailment of current trials has increased significantly.<br><br>Learn from this leading CRO about the value of working collaboratively with partners to mitigate these universal risks, and understand the opportunity to rescue trials if the worst does present itself, mid-trial:<br><br>***Reserved for SynteractHCR*** |


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| **10:15** | **Regulatory Update: ICH GCP E6 (R2) Addendum**<br>**What is Oversight and How Can You Ensure You Are Managing Your Partners Effectively, Without Hampering Trial Efficacy?**<br>This exclusive update session from a new start-up will provide you with the *need-to-know* perspectives on the most recent ICH addendum, relating to improved oversight and management of clinical trials, while continuing to ensure protection of human subjects participating in trials and clinical trial data integrity.<br><br>Join this expert speaker to understand how to improve your trial operations in:<br><br>- Clearly defining 'oversight' and what this means in day-to-day operations<br>- Decoding the various routes to ensure patient centricity is upheld, in line with investigator expectations<br>- Data integrity, including personal patient data from new data sources, is captured, shared and analysed in a compliant way<br><br>Dr. Yuri Martina, *VP Clinical Operations*, **Shionogi** |
| **10:45** | **Morning Break and Refreshments** |
| **11:15** | **Key Principles of Third Party Supplier Relationship Management as part of sponsor oversight in the management of clinical trials.**<br><br>This exclusive joint session from AZ-GSK will provide an overview of key principles Third Party Supplier Relationship Management as part of sponsor oversight in the management of clinical trials, while continuing to ensure protection of human subjects participating in trials and clinical trial data integrity. In particular;<br>- Clearly defining 'oversight' and what this means in day-to-day operations<br>- Key principle of establishing robust governance structures in particular for Sponsor-CRO strategic relationships<br>- Key principles of performance management across Sponsor-CRO strategic relationships<br><br>Join this interactive discussion to define your strategy for 2017.<br><br>**Co-presenters:**<br>Panni Patel, *Strategic Relationship Director*, **GSK**<br>Stephen Walker, *Outsourcing Programme Director*, **AstraZeneca** |
| **11:45** | **Fast Through First-in-Human: Taking a Programmatic Approach**<br><br>Emerging biopharma plays a critical role in drug innovation. In fact, approximately 70% of industry's new sales today originated in small companies, up from 30% in 1990, according to the Boston Consulting Group and Wall Street Journal. Top pharma companies are requiring more efficacy data to acquire or license in new assets and the increased complexity of early drug development is shifting focus to earlier de-risking of assets.<br><br>Now there is a programmatic model to drug development that bridges both nonclinical and clinical, including regulatory and commercial, which can reduce timelines as much as 30% while adding tangible value to your asset. It's a fully architected plan that can be shared with investors and other stakeholders.<br><br>- FIH protocols designed and submitted with your IND/CTA – delivered at the right time – early enough for use in regulatory meeting, leveraging the data and experts familiar with your compound and program<br>- Prospective, strategic journey mapping helps eliminate white space for tangible economic savings |


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| | on your program<br>- Increased confidence in your compound or reach an early NO GO decision based on Target Product Profile (TPP) criteria<br><br>**Co-presenters**:<br>Raymond Donninger, MB ChB, *Senior Clinic Director*, **Covance**<br>Hazel Clay, PhD, *Drug Development Leader,* **Covance** |
| **12:15** | **Lunch and Networking** |
| **13:45** | **Quality vs. Quantity: How to Derive Meaningful Data Insights to Support Decision-Making and Monitor Trials Effectively**<br><br>New technologies and increasingly complex and niche clinical practices bring with them a proliferation of data. The industry is fast relying on tetra and zeta-bytes of information to power scientific and commercial decision-making.<br><br>In this arena however, there are limiting factors that must be acknowledged in gathering too much data, and challenges continue to present themselves within current CRO-sponsor relationships as to what data is required, and most importantly, what data is useful to ensure the trial can be approved.<br><br>Join this industry leader to examine the true value of data, and:<br><br>- Define Risk-Based Monitoring and how to execute this in practice<br>- Explore the potential of streamlining your data capture and analytics strategies to improve data integrity at trial submission<br>- Consolidate your understanding of what will deliver unique business intelligence, not a mass of potentially relevant statistics<br>- Consider how to maximise the use of EDC systems to ensure you are capturing the right data, at the right quality, in the right quantity<br>- Evaluate your approach to preparing for audit; what are the risks of penalties with too much data vs. minimal data<br><br>Jeff Pilot, *Head of Clinical Project Management,* **Norgine** |
| **14:15** | **A transformative approach to IRT systems built: Rapid-Deployment IRT Using Iterative UAT-Design process**<br>Advances in software technology combined with years of experience have allowed for numerous improvements to clinical IRT solutions. This talk will describe how a configurable tool allows sponsors and end-users design and deploy an IRT system in less than 2 weeks without relying on the burdensome requirements documentation process. Steve will explain how a user can conduct iterative UAT to achieve the desired IRT design using an agile methodology.<br><br>Steve Rawbone, *Associate Director, Regional Operations & Client Onboarding*, Client Services**, Bracket Technologies** |
| **14:45** | **Afternoon Refreshments and Networking** |
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| | **Patient Centricity, Recruitment & Retention:<br>Evolve Your Patient Strategy To Meet Shifting Patient Requirements** |
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| **15:15** | **Trials Through Your Patient's Eyes: Improve Patient Recruitment & Retention Using Insights Direct From Patients To Develop Your Trial Design**<br><br>Whilst scientific accuracy is core to Trial success, the key vehicle for approval lies in the hands of your patients, making recruitment, engagement and retention critical to the overall outcome at each stage of your trial programme.<br><br>To ensure that you are developing the best possible strategies to ensure patient centricity, this session delves into the perception of trials, from the patient perspective, to keep you up to speed with shifting expectations, and to ensure that you are:<br><br>- Considering ease of access and convenience at trial design phase to ensure that patients are willing and able to participate<br>- Ensuring that not just consent, but other relevant information regarding the impact of the trial is communicated up front to patients through a range of media to ensure they are on-boarded effectively<br>- Walking patients through the protocol – step by step to give a practical angle as regards to the burden on the patient to be part of that trial<br>- Designing trial questionnaires in line with patient focused-outcomes i.e. what they want to achieve or alleviate through the trial, not just the assumed scientific outcome<br><br>Co-Presenters:<br>Dr. Julie Hapeshi, *Associate Director R&D*, **NH Research Design Service**<br>Joanne Welshman, *Patient – Engaged Research Fellow, Centre for Biomedical Modelling & Analysis*, **University of Exeter**<br>Dr. Andy Gibson, *Associate Professor, Patient & Public Involvement*, **University of West England** |
| **15:45** | **Patient Recruitment Through Internet & Social Media – Opportunity or Risk?**<br><br>Many large or healthy volunteer programmes are starting to use Internet and Social Media as a recruitment and engagement tool. The availability of key data, as well as real time updates, interactive photo and data sharing technology and a personal approach certainly stand out as benefits of this route to recruit, however there are also challenges and barriers to success to consider.<br><br>This session will afford you the opportunity to explore how to:<br>- Effectively design a recruitment strategy appropriate to the age and demographic of patients you aim to recruit<br>- Consider the privacy and intimacy of sharing trial participation information on a social media platform<br>- Evaluate the benefits of appearing personal, cool and millennial, given the context<br><br>Tanja Ouimet, *PhD, Head of Clinical Operations*, **Pharma Leads** |
| **16:15** | **Chairman's Summary** |
| **16:25** | **Close of Day 1** |
| **16:30<br>17:30** | **OCT Global Series: London Drinks Reception** |


# Outsourcing in Clinical Trials, UK & Ireland

**Programme Day Two: Clinical Outsourcing Strategy, Governance & Contracting, Site/Location Sourcing**
**Thursday 29th June, 2017**

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| **08:30** | **Registration and Refreshments** |
| **08:55** | **Chairmans Opening Remarks, Day 2- Chair for Day 2: Paul Quinn** |
| | **Sourcing Models: Horizon Setting & Latest Trends** |
| **09:00** | **Managing Your CRO for Competitive Advantage**<br>To most, Vendor Management features low on the list of exciting, commercially dynamic and productive areas of their time. Negotiating contracts? Possibly. New technology? Certainly. But the actual day to day relationship management? Not so much.<br><br>However, within this heavily legal-focused area, lies the opportunity for you to manage dynamically and competitively, to gain significant advantage by applying some core principles:<br><br>- Identify which elements of your relationshp can offer you true competitive advantage: resource, access to data, speed of delivery<br>- Calculate the areas of greatest expenditure laid out within contracts to ascertain the areas in which there is potential for renegotiation<br>- Develop a scalable approach to demonstrate effective responses in line with regulatory requirements for oversight<br><br>John Shillingford, *Clinical Operations Director*, **Orsus Medical** |
| **9:30** | **Driving A Dynamic Sourcing Strategy to Effectively Meet Your Specific CRO Requirements: What are the Key Selection Criteria for Success?**<br><br>Shifting regulations demand a review of selection criteria when it comes to CROs. Are your current providers able to offer you regulatory compliance, clinical best practice, and competitive advantage?<br><br>Address the latest in key selection criteria in order to ensure that your next selection process seamlessly evaluates each potential partner against your key drivers:<br><br>- Consider selection criteria to improve Risk Management: What key risk factors does your CRO bring to the table, and are you set up to manage them?<br>- Develop an internal set of parameters to ascertain data quality and compatibility to guarantee speed and efficiency in data analysis in-trial<br>- What patient centricity factors does your potential partner bring to the table and will they deliver against your protocol as regards to recruitment timelines?<br><br>**Co-presenters:**<br>Paul Quinn, *Head of Clinical Operations,* **Vectura Group**<br>Emma Webby-Mears, *Senior Clinical Document Manager*, **Vectura Group** |
| **10:00** | **Morning Refreshments and Networking** |


| | Contracting & Governance: Setting Up For Success |
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| **10:30** | **Recognise The Benefits In Using Technology To Enhance Patient Engagement and Accelerate Drug Development**<br><br>Demonstrating technology innovation in practice, this interactive case study session will showcase how the latest technology innovations are currently being applied within live Clinical Trials.<br><br>Discover how AstraZeneca are embracing innovation to stand at the forefront of a new era of technology driven Clinical Trials in order to:<br><br>- Enhance patient centricity to deliver more competitive and attractive trials to market<br>- Drive efficiency in data-capture, monitoring and quality within trial settings<br>- Gain real time insights into drug performance and abnormalities in trial, using technology<br><br>Anthony G. Johnson, *Vice President, Early Clinical Development*, **AstraZeneca** |
| **11:00** | **Practical Insights on How To Effectively Manage a Complex Network of Partners and Sub-Contractors**<br>The increasingly dynamic sourcing market has resulted in the emergence of more niche vendors and single issue contractors. Even if partnerships are in place with large CROs, they are increasingly likely to be working with smaller technology or research partners to support your trial. The benefits are self-explanatory from the scientific perspective, however the increased risk of complex supplier networks needs to be efficiently managed to ensure timely and compliant delivery of your trial.<br><br>This session delves into the contracting and operational implications of these emerging supplier networks to help you unravel the exact responsibilities of trial sponsors, and how to manage the risk of this new supplier backdrop effectively across these key areas:<br><br>- Evaluate the potential for liability when contracting to avoid additional risk and responsibility. Are your contracts robust enough to protect you from sub-contractors?<br>- Ascertain where change requests apply across a complex network to ensure chain of command consistently resides with you at sponsor level<br>- Review communications plans to guarantee that your changes, protocols and relevant performance information can be driven effectively across all parties<br>- Consider tactics to streamline budgeting, forecasting and reconciliation when managing multiple contracts<br><br>Dr Simon Roitt, *Head of Clinical Development*, **Karus Therapeutics** |
| **11:30** | **Master Service Agreements: What Are The Practical Implications?**<br>Seemingly straightforward and all encompassing, Master Service Agreements (MSAs) are one option when considering how to streamline vendor management.<br><br>Alongside this obvious benefits however, are a series of considerations that also need consideration prior to taking the plunge for 5, 10, 15 year agreements. Or additional tactics must be deployed to effectively manage MSAs in line with current regulation and shifting internal priorities.<br><br>This interactive presentation will take you through each key benefit and offer consideration and support against the below points: |


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| | - Determine whether heading straight through to Statements of Work can increase the risk of non-compliance with evolving regulation, in particular with regards to patient consent, data integrity and data security<br>- Evaluate if time saved on RFP process, budgeting and payments set-up delivers true value in the long term<br>- Could removing the bottlenecks of complex negotiations open you up to a weaker deal?<br>- Share practical insights on how to ensure your incumbent CRO can deliver to the specifics of individual trials effectively within Master Service agreements<br>- Evaluate the appropriateness of this approach were you to require scalability and flexibility given the increasingly complex landscape of the UK in 2017?<br><br>Ian Hodgson, *Head of Clinical Operations*, **MereoBioPharma** |
| **12:00** | **Networking Lunch** |
| **13:30** | **Speaker Hosted Roundtables: Reviewing the Building Blocks for Clinical Trials Success**<br>Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Each roundtable session lasts for 45 minutes.<br>Delegates may select the most relevant roundtable discussion to their area of interest.<br>All roundtable findings will be collated by your host, and shared post-event.<br><br>*Afternoon refreshments and networking after round 1 of roundtables* |
| **Roundtable 1** | **Exploring patient recruitment strategies using a successful case study**<br>Tanja Ouimet, *PhD, Head of Clinical Operations*, **Pharma Leads** |
| **Roundtable 2** | **What Does Effective Communication Look Like When Managing Established CRO Partners**<br>Liz Coxon, *Head of Clinical Operations*, **Diurnal** |
| **Roundtable 3** | **Get your best out of your CRO**<br>John Shillingford, *Clinical Operations Director*, **Orsus Medical** |
| **15:00** | **Chairman's Summary** |
| **15:05** | **Close of Conference** |