Outsourcing in Clinical Trials Europe

Barcelona, Spain

3rd & 4th May 2023

www.arena-international.com/octeurope

'This event will focus on optimizing strategies to create an operationally efficient, specifically targeted clinical trial'

For the 13th Annual event, our flagship European clinical show will focus on providing delegates with practical take-aways and solutions to their most current operational and outsourcing challenges in clinical trials, this is an event not to be missed.

2023 Confirmed Speakers

- *Roman Fishchuk, Head of Clinical Trials Department,* ***Central City Clinical Hospital, Ukraine***
- *Mariusz Olejniczak, CEO,* ***WPD Pharmaceuticals***
- *Sonja Weiser, Senior Director Clinical Operations,* ***Insmed***
- *Marco Salami, Head of Clinical & RWE Outsourcing Management,* ***Chiesi Farmaceutici***
- *Werner Gladdines, VP, Clinical Development Operations,* ***Immunic Therapeutics***
- *Ivanna Rosendal, Senior Director, IT Business Partner,* ***Ascendis Pharma***
- *Ivan Vyshnivetskyy, President,* ***Ukrainian Association for Clinical Research***
- *Estrella Garcia,* ***Senior Director Global Clinical Operations, Almirall***
- *Silvia Perez Torres, Director, Clinical Quality Compliance,* ***AstraZeneca***
- *Roel van der Heijde, Facilitator & Trainer,* ***Patient Experience Association***
- *Daniel McVeigh, Director, Clinical Project Lead ,* ***Alexion***
- *Benoît Marchal, Chief Digital Trust Officer,* ***Partners for Patients, PicAps (NFP)***
- *Laia Casas, Clinical Project Leader,* ***Noucor Health SA***
- *Priya Nair, Senior Analyst,* ***GlobalData***
- *Robert S. Greene, President,* ***Hunger and Thirst Foundation***
- *Michael Zörer, Head of Clinical Operations,* ***VarmX***
- *Domenico Merante, Therapeutic Area Clinical Lead Nephrology, Rare and Orphan Diseases,* ***CSL Vifor***
- *Xavi Jofre, Digital Transformation Director,* ***Barcelona Health Hub***
- *Henrik Schou, VP, Global Head Evidence Generation,* ***Vifor Pharma Group***
- *Begoña Nafria Escalera, Patient Engagement & Research Coordinator,* ***Sant Joan de Deu Barcelona Hospital***
- *James Rudge, Technical Director,* ***Trajan Scientific and Medical***
- *Balint Feher, Senior Clinical Research Manager,* ***Geistlich Pharma AG***
- *Stephen Lutsch, Former Director - Revolutionize Clinical Trials (ReCT),* ***LEO Pharma***
- *Joana Claverol, Clinical Research Unit Manager,* ***Sant Joan de Deu Barcelona Hospital***
- *Jelena Mihajlović, Clinical Operations Program Lead,* ***Immunic Therapeutics***
- *Laura Jiménez Robledo, Clinical Project and Innovation Manager,* ***Novo Nordisk***
- *Smruthi Panyam, Director, Clinical Data Informatics,* ***BeiGene***
- *Elena Carzana, Vendors Alliance Manager DM&Stat,* ***Chiesi Farmaceutici***
- *Anna Pugnetti, Global Clinical and RWE Outsourcing Manager,* ***Chiesi Farmaceutici***
- *John Zibert, Chief Medical Officer,* ***Coegin Pharma AB***
- *Stefania Alvino, Digital Orchestrator & Omnichannel Marketing Manager,* ***Daiichi Sankyo***

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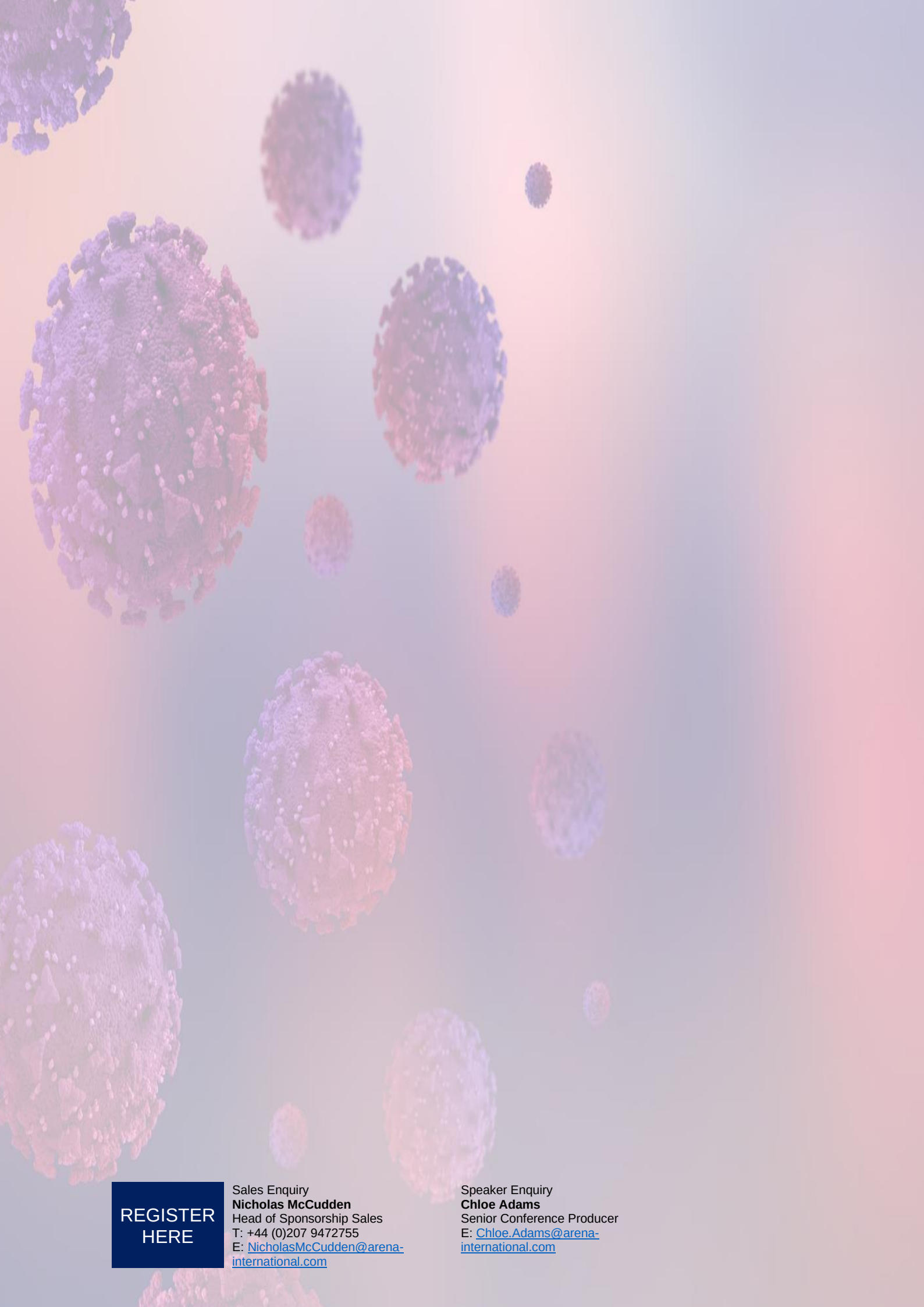

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Outsourcing in Clinical Trials Europe

Barcelona, Spain 3rd-4th May 2023

DAY ONE – WEDNESDAY 3RD MAY 2023

07:45	Conference registration and refreshments
08:20	Chair's opening remarks *Chair:* ***Robert S. Greene, President, Hunger and Thirst Foundation***
08:30	**KEYNOTE** **Disaster Preparedness: How can the clinical trial industry prepare for the unexpected? Using the Ukrainian crisis as a case study** • Briefly explaining the impact of the war on Ukraine's/Europe's clinical trial industry • Involving sites with sponsor decisions when developing Decentralized models – what tech and solutions can sites offer? • Identifying what protocol changes help sites vs what makes their job harder • A message to Ukrainian Pharma offices: Importance of backup plans to ensure data integrity and keep trials moving • Mitigation risk plans: Making plans for the future and involving all clinical trial stakeholders • New solutions – bringing in a reliable Ukrainian CRO with local knowledge to work directly with trial sponsors ***Roman Fishchuk****, Head of Clinical trials department,* ***Central City Clinical Hospital, Ukraine***
09:00	*Session Reserved for Medidata*
09:30	**INTERACTIVE SESSION** **The Diversity Conversation – follow up from the 2022 discussion and what we should do for 2023 and beyond** *This session will cover diversity and race inequalities in clinical trials; why we have underrepresentation and why it's vital we improve. Robert & Roel will give an overview and then open up the discussion to the audience;* • Exploring what diversity means in clinical trials – what have we done to improve this since the 2022 event? • How can we improve engagement by paying more of a focus on race and socioeconomic disparities? • Exploring the role of patient advocacy groups in tackling underrepresentation • Highlighting the impact on your trial if all groups aren't adequately represented – ask ourselves why not • Brainstorming solutions: What actions can we take now to get groups interested in participating in trials? • Audience stories, feedback and strategies moving forward ***Robert S. Greene,*** *President****, Hunger and Thirst Foundation &*** ***Roel van der Heijde****, Facilitator & Trainer,* ***Roel Rotterdam & Patient Experience Association***
10:00	*Session Reserved for Featured Sponsor*
10:30	

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	Morning refreshments and networking		
	Stream A: Outsourcing & Clinical Operations *Chair:* ***Robert S. Greene, President, Hunger and Thirst Foundation***	**Stream B: Clinical Technology & Innovation** *Chair:* ***Priya Nair, Senior Analyst, GlobalData***	**Stream C: Clinical Data; Strategy & Planning** *Chair:* ***Roel van der Heijde, Facilitator & Trainer, Roel Rotterdam & Patient Experience Association***
11:00	**PANEL DISCUSSION** **Handling prolonged site start-up times and the worldwide site staff shortages crisis** • Pinpointing the challenges of getting all vendors/systems in place for study start-up –is this beyond the site's capacity? • Encouraging all stakeholders to take time and get involved in budget negotiation to reduce site activation delays • With complexity of trials increasing, what affect will this have on site staff training? • Importance of easy access to training particularly when site staff is low – can vendors help? • Sharing ideas for retaining site staff/physician talent in the industry • Could flying study nurses help in the short term? *Moderator:* ***Robert S. Greene****, President,* ***Hunger and Thirst Foundation*** *Panellists:* ***Sonja Weiser****, Senior Director Clinical Operations,* ***Insmed;*** ***Roman Fishchuk,*** *Head of Clinical trials department,* ***Central City Clinical Hospital, Ukraine;*** ***Ivan Vyshnivetskyy,*** *President,* ***Ukrainian Association for Clinical Research***	**PANEL DISCUSSION** **Key considerations for designing and implementing DCTs; exploring the protocol design** • Exploring the idea that DCT is not a one-size-fits-all approach • Looking to outsource if you lack internal capabilities to operationalize DCT • Designing a proactive strategy with patient groups to maximize efficiency and the patient experience • Considering a hybrid trial as a more agile design • Importance of engaging with regulatory agencies early • Using the knowledge of traditional sites – how to work with a combination of physical and remote sites for protocol design • Explore user testing and involvement when going digital *Moderator:* ***Priya Nair****, Senior Analyst,* ***GlobalData*** *Panellists:* ***John Zibert****, Chief Medical Officer,* ***Coegin Pharma AB****;* ***Stephen Lutsch,*** *Former Director - Revolutionize Clinical Trials (ReCT),* ***LEO Pharma***	**CASE STUDY** **Data Access vs Data Privacy. Would the simplest not be to ask the patients themselves?** *In this talk Benoît will introduce PicAps (Patient in Control, Anonymity Privacy Secured) and explore the benefits of a direct anonymous communication with the patients.* • For what? Clinical trials use cases: Lay summaries, Recruitment, Clinical trial data sharing, long time follow-up, home delivery, continuous monitoring ... • How it works: decentralized network of trusted neutral organizations to ensure privacy • Regulatory aspect • The big picture: access to EHR data ***Benoît Marchal,*** *Chief Digital Trust Officer,* ***Partners for Patients, PicAps***
11:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*

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12:15	**CASE STUDY** **Stop taking the easy route! Delving into recent societal changes and how Clinical Trials can adapt** • Appreciating the need to be more inclusive with race but what about other underrepresented groups? • Discussing the use of male vs female in ICFs and inclusion/exclusion criteria – impact of not including LGBTQ+ • Exploring the benefits of updating your ICF to adapt to societal changes and linguistic challenges • Best practices for engaging with ethics committees and coming to an agreement on terms • Examples of getting wording approved by ethics committee – get hands on today! ***Laia Casas,*** *Clinical Project Leader****, Noucor Health SA***	**Explore how Barcelona Health Hub is pushing forward digital tools in clinical trials** *How does digital transformation happen?* • Discover how the health ecosystem looks like in 10 years from now • Barcelona Health Hub and digital health as a solution • How to choose a relevant partner for your clinical validation ***Xavi Jofre****, Digital Transformation Director,* ***Barcelona Health Hub***	**Exploring how to use data collected through consumer-wearables and integrate them into a clinical trial** • How to integrate data collected through consumer-wearables into a clinical trial • Why consumer-wearables can provide wider access to clinical trials • Consumer wearables and data that they can reliably collect • Getting data from the wearables to contribute to the clinical trial ***Ivanna Rosendal****, Senior Director, IT Business Partner,* ***Ascendis Pharma***
12:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
13:15	Lunch and networking		
14:15	**Call for research in creative climate in organization in clinical development** *Mariusz will explore his research and discovery on how to help CRO and pharma to be more productive* ***Mariusz Olejniczak****, CEO,* ***WPD Pharmaceuticlas***	**2023 UPDATE: Sharing practical experiences with Decentralized & Hybrid Trials – is there a future for DCT?** • Advantages of DCT; from taking the trial to the patient boosting recruitment • The benefits and constraints of DCT based on practical experience from running DCT • Learnings from an inspection of an interventional DCT - what is the role of the patient? • Strategy/Planning: How do you make the decision to run a DCT; what are the considerations? • Is the future hybrid trials as they are more realistic and	**Utilizing Data Mesh technologies for data analysis in clinical trials** *Bullets to come* ***Mateusz Zabolski****, Head of Technology – Biosamples,* ***AstraZeneca*** *& colleague*

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		practical compared to full DCT? ***John Zibert**, Chief Medical Officer, **Coegin Pharma AB***	
14:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
15:15		**Communication & Innovation: Defining innovation in clinical trials** • What is innovation in clinical trials? • Why communication is key in our innovation strategy? • How do we communicate innovation? ***Laura Jiménez Robledo,** Clinical Project and Innovation Manager**, Novo Nordisk***	**The rise of RWE/RWD: Unlocking how to properly utilize real world evidence to improve study design and execution** • Sharing positive experiences of supplementing clinical trial data with RWD/RWE • Navigating RWE to gain metrics on how many patients sites bring in to improve site selection • Utilizing RWE in a non-international study to look into desired factors • RWE allowing a better understanding of unmet need and unrepresentativeness- how can this benefit physician and patient? • Regulatory landscape isn't giving many clues – what are regulators saying and how should we approach it? ***Smruthi Panyam,** Director, Clinical Data Informatics, **BeiGene***
15:45	Afternoon refreshments and networking		
16:15	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*	
16:45	**Pro et contra of working with Professional Site Networks for sponsors and CROs** • Does the industry needs professionalization of clinical research sites?	**Paediatric-centric clinical trials: A right for children and young people** • Children's rights in their involvement in clinical research • Why? Who? Where? Involve children and young people • Return on the investment and return on the engagement • eYPAGnet: European Network of Young Person's Advisory Groups Network • Case study: DCT in paediatric clinical trials	

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	• The general perception of site networks and site management organizations • What benefits can professional site networks provide to sponsors and CROs • Risks and drawbacks of working with Professional Site Networks ***Ivan Vyshnivetskyy**, President, **Ukrainian Association for Clinical Research***	***Begoña Nafria Escalera**, Patient Engagement & Research Coordinator, **Sant Joan de Deu Barcelona Hospital*** ***Joana Claverol,** Clinical Research Unit Manager**, Sant Joan de Deu Barcelona Hospital***
17:15	**CLOSING KEYNOTE** **Can the new EU Clinical Trial Regulation revolutionize clinical trial processes across Europe, creating a more streamlined application?** *Gain a comprehensive overview of the EU Clinical Trial Regulation and changes for trials in the EU* • Benefits of submitting through same portal for all ethics committees/authorities • The advantages for biopharma companies of standardized timelines • Understanding the new trial authorisation process for regulatory and ethical approval • Overview of major new requirements, such as risk-based evaluations and informed consent • Update since January 2023 *Reserved for **Sermes CRO & biopharma***	**CLOSING KEYNOTE** **Decentralized Clinical Trials/Hybrid Trials: Lessons learned and what you need to know to run them successfully** • Delving into the promise of DCT • Laying the innovation and technical foundation for DCT • My key learnings from running DCT/hybrid trials • Tangible takeaways ***Stephen Lutsch,** Former Director - Revolutionize Clinical Trials (ReCT)**, LEO Pharma***
17:45	Chair's Summary & Drinks Reception	

DAY TWO – THURSDAY 4TH MAY 2023

08:10	Registration and refreshments
08:45	

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	Chair's opening remarks	
	Stream A: **Outsourcing & Clinical Operations** *Chair:* ***Werner Gladdines, VP, Clinical Development Operations, Immunic Therapeutics***	**Stream B:** **Clinical Technology & Innovation** *Chair:* ***Priya Nair, Senior Analyst, GlobalData***
09:00	**PANEL DISCUSSION** **Reversing the Conversation: What the clinical trial industry really wants from its service providers** *We've all had to sit through pitches from vendor companies telling us what they can do for us, but now it's time to reverse the conversation! Hear from the trial industry as they discuss the services they would like to see from their solution providers, including:* • What they like to see in an outsourced partner organization • What they would like a partner to know about them / how they work • What things do they need a partner to do and what they don't need! • What things can be best done in house? *Moderator:* ***Werner Gladdines****, VP, Clinical Development Operations,* ***Immunic Therapeutics*** *Panellists:* ***Sonja Weiser****, Senior Director Clinical Operations,* ***Insmed;*** ***Daniel McVeigh,*** *Director, Clinical Project Lead,* ***Alexion;*** ***Michael Zörer,*** *Head of Clinical Operations,* ***VarmX***	**WORKSHOP** **Introducing The Patient Centric Sample Interest Group** *This workshop will explore different approaches and strategies for putting patients at the centre when collecting samples for clinical trials* ***James Rudge****, Technical Director,* ***Trajan Scientific and Medical***
09:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
10:15	**FIRESIDE CHAT** **Establishing strong CRO/sponsor relationships and building trust in a more virtual landscape- What 5 things does our expert speaker say to focus on right now?** • Oversight with less presence– designing an oversight plan based on KPIs, fewer monitoring visits and more virtual meetings, how to make this work • Lessons learned on how to effectively build working relationships remotely • Strategies to deliver training and upskill your clinical trial team • Handling hard discussions with the site remotely if can't get there in person	**Case study: Clinical digitalization roadmap for medical device companies** • Outlining the specific digital transformation goals and requirements • Overcoming operational challenges associated with medium-sized medical device companies • Journey to successful clinical digitalization ***Balint Feher,*** *Senior Clinical Research Manager,* ***Geistlich Pharma AG***

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	• Guidance on improving CRO communication channels– keep CROs in the loop and draw on their experience • We are all human, we all fail: Ensuring positivity in initial stages and taking responsibility *Moderator:* ***Werner Gladdines,*** *VP, Clinical Development Operations,* ***Immunic Therapeutics*** ***Marco Salami****, Head of Clinical & RWE Outsourcing Management,* ***Chiesi Farmaceutici***	
10:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
11:15	Morning refreshments and networking	
11:45	**Optimizing oversight & governance: What does oversight mean to you?** • Best practices and tools for managing supplier governance and ascertaining who is accountable • Identifying the criteria to determine level of oversight needed for a vendor • Local vendor oversight vs global provider oversight – how would you manage this differently? • Strategies for managing CRO governance for small/start-up companies with limited resources or large companies with competing priorities ***Daniel McVeigh,*** *Director, Clinical Project Lead****, Alexion***	**Bridging the gap from RCTs through Real World Evidence into clinical practice; exploring how to improve patient focussed disease management** • Relevance of generating Real World Evidence data in rare ad orphan kidney diseases • The urgent need to access main clinical data, including those from still unpublished clinical studies • Bridging an existing gap between randomized clinical trials results and clinical practice evidence for people affected by rare and orphan kidney diseases • Development of 'personalized' treatment algorithms to improve patient-focused outcomes in patients suffering from these diseases ***Domenico Merante****, Therapeutic Area Clinical Lead Nephrology, Rare and Orphan Diseases,* ***CSL Vifor*** ***Henrik Schou,*** *VP, Global Head Evidence Generation,* ***Vifor Pharma Group***
12:15	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
12:45	**Exploring the role of Quality in vendor oversight and vendor quality agreements** • How can Quality provide more support to the study team, particularly with vendor oversight? • Exploring the importance of quality agreements and vendor communications – how can we add more value with monitoring/safety aspects? • Best practices in reporting to ensure patience safety and preventative action	**Innovation topic TBC** ***Stefania Alvino,*** *Digital Orchestrator & Omnichannel Marketing Manager****, Daiichi Sankyo***

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<table>
<tr><td></td><td>How can Quality work more closely with regulatory bodies on reporting issues to ensure GCP?
Exploring risk-based quality management strategies
Silvia Perez Torres, Director, Clinical Quality Compliance, Astrazeneca</td><td></td></tr>
<tr><td>13:15</td><td colspan="2">Lunch and networking and Apple Prize draw</td></tr>
<tr><td>14:15</td><td>Session Reserved for Event Sponsor</td><td>Session Reserved for Event Sponsor</td></tr>
<tr><td rowspan="3">14:45

15:15</td><td rowspan="2">The current impact and future of Decentralized Clinical Trials
The impact of COVID-19 on the future of clinical trials and the main concern for primary sponsors and CRO's during the COVID-19 pandemic
The movement towards DCT's and why sponsors are incorporating digital elements into clinical trials and the challenges around this
How AI can aid decentralized trials and real-life case studies
Priya Nair, Senior Analyst, GlobalData</td><td>INTERACTIVE THINK TANKS

Interactive think tank sessions offer a unique opportunity to come together to share best practice and develop solutions to challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, think tanks are an interactive way to build your personal network and learn from the experience of others.
Each think tank session lasts for 30 minutes, and delegates may attend up to 2</td></tr>
<tr><td>Think Tank 1: What does the clinical trial industry really want from its service providers?
Host: Estrella Garcia, Senior Director Global Clinical Operations, Almirall</td></tr>
<tr><td>TBC TOPIC
Choosing a CRO as a small to mid-sized biotech company: factors to consider
Balancing the benefits of working with a small CRO vs a large global CRO: which is better equipped to handle the needs of a smaller biotech?
How important is it to choose a CRO with experience in your therapeutic area?
Working with multiple vendors: is this the best option for smaller sponsor companies?
Jelena Mihajlović, Clinical Operations Program Lead, Immunic Therapeutics</td><td>Think Tank 2: Building strategic partnerships with CROs
Host: Elena Carzana, Vendors Alliance Manager DM&Stat, Chiesi Farmaceutici
& Anna Pugnetti, Global Clinical and RWE Outsourcing Manager, Chiesi Farmaceutici

Think Tank 3: Working with Patient Advocacy Groups & overcoming barriers with patient engagement
Host:</td></tr>
<tr><td>15:45</td><td colspan="2">End of Event</td></tr>
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