Outsourcing in Clinical Trials Europe

Barcelona, Spain

3rd & 4th May 2023

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'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***
- *Werner Gladdines, VP, Clinical Development Operations,* ***Immunic Therapeutics***
- *Ivanna Rosendal, Senior Director, IT Business Partner,* ***Ascendis Pharma***
- *Ivan Vyshnyvetskyy, - President of the* ***Ukrainian Association for Clinical Research,*** *Managing Director Ukraine at FutureMeds*
- *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***
- *Mateusz Zabolski, Head of Technology – Biosamples,* ***AstraZeneca***
- *Domenico Merante, Therapeutic Area Clinical Lead Nephrology, Rare and Orphan Diseases,* ***CSL Vifor***
- *Henrik Schou, Global Head Evidence Generation****, CSL Vifor***
- *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, Senior Director Clinical Trial Digital Innovation,* ***Genmab***
- *Joana Claverol, Clinical Research Unit Manager,* ***Sant Joan de Deu Barcelona Hospital***
- *Laura Jiménez Robledo****,*** *Clinical Project and Innovation Manager****, Novo Nordisk***
- *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, HEAD of Digital Innovation,* ***Daiichi Sankyo***
- *Orlando Vergara, Barcelona Health Hub Ambassador, former Novartis Neuroscience Head*
- *Caoimhe Vallely-Gilroy, Independent Advisor – HIRANI, former Global Head of Digital Health & Therapeutics at Healthcare Business*
- *Neil Vivian, Senior Director of Business Solutions and Product Manager,* ***Anju Software***

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- *Kateryna Orlovska, Country Clinical Quality Management Lead Ukraine, Georgia and CIS,* ***MSD***
- *Sverre Bengtsson, Co-Founder, Senior Vice President Strategic Relations,* ***Viedoc***
- ***Ana Moreno,*** *Director Global Clinical Operations,* ***APICES***
- ***Gilyana Borlikova,*** *Data Science Manager,* ***ICON plc***
- **Raquel Reviejo,** EU Regional Submission Lead, MSD
- *Kevin Landells, Vice President, Business Head of IRT,* ***IQVIA Technologies***
- *Karen Maduschke, Senior Director and GM, Patient Consent,* ***IQVIA Technologies***

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Sales Enquiry
Nicholas McCudden
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: NicholasMcCudden@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: maya.hudson@arena-international.com

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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	**Remote Strategies Around the World: DCT Regulations & Clinical Trials Optimization** Accelerating advancements in medicine, device, and diagnostic development wouldn't be possible without significant innovations in remote and decentralized technologies. In order to keep pace with technological capabilities, as well as offer flexibility to reduce burden for clinical trial stakeholders, regulatory adaptation and reform should help propel optimization in the industry. Join this session to learn about the end-to-end clinical trial process and discover how innovations in clinical trials, namely remote operations and management strategies, are shaping necessary adaptations in regulatory frameworks. ***Joseph Lovett,*** *Solution Specialist, Patient Cloud,* ***Medidata, Dassault Systemes*** ***Fiona Maini BSc MSc,*** *Principal - Global Compliance and Strategy,* ***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?

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Sales Enquiry
Nicholas McCudden
Head of Sponsorship Sales
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E: NicholasMcCudden@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: maya.hudson@arena-international.com

	• 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	**Advancements in AI: turning big data into actionable intel for optimal site identification** Despite advancing technologies, trials still struggle to meet patient enrolment goals. Slow enrolment directly impacts schedule and budget, with each day of delay carrying cripplingly high costs. Successful, timely patient recruitment is directly linked to effective site selection. Conversely, selecting the wrong site can negatively impact recruitment or result in total failure to enroll patients. Join us to learn how advancements in AI can help the pharma industry identify the best sites for their clinical trials through the harnessing of big data. Topics include: • Transitioning from data overload to data driven decision-making • The role of Artificial Intelligence in optimizing site identification and selection • Expected and unexpected downstream benefits of an AI-enabled site selection strategy **Gilyana Borlikova, Data Science Manager, ICON plc**		
10:30	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	**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	**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 ...

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	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 Vyshnyvetskyy,*** *President,* ***Ukrainian Association for Clinical Research***	• 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,*** *Senior Director Clinical Trial Digital Innovation,* ***Genmab***	• 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	**Optimizing Cell-based Gene Therapy Programs Through the Continued Evolution**
	
	• Lessons across therapeutic areas
	• Driving success in either unexplored settings or in saturated market settings
	• Context-dependent stakeholder engagement
	
	Amy Raymond, PhD, PMP
	Worldwide Clinical Trials Therapeutic Strategy Lead, Gene Therapy Think Tank
		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***
			Patient Engagement and eConsent – a historical look at Decentralized Trials and their future with a focus on eConsent
			Patients will be more empowered
			• Trials will become decentralized
			• Technology will support this decentralization:
			  • Wearables
			  • Telemedicine
			  • eConsent
			
			Neil Vivian, Senior Director of Business Solutions and Product Manager, Anju Software

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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***	**Clinical Validation Center for Digital Health Solutions: generating evidence on the impact of digital tools through clinical trials** • Generating evidence of the impact on health of digital tools • Improving patients' experience and medication adherence after heart transplant using a multilevel mHealth intervention: The mHeart randomized clinical trial **Alicia Borràs**, Study Coordinator, Digital Health Unit, Strategy Office Més Sant Pau, **Hospital de Santa Creu i Sant Pau**	**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	**Leveraging local relationships for best in-country solutions to accelerate global drug development** • Partnering with a CRO to access European infrastructure, in depth local knowledge, site relationships and diverse patient populations • Strategies to fast-track clinical trial start-up and patient recruitment timelines • Are you ready for EU CTR? Challenges and lessons learned	**Simplifying site & patient engagement technology strategies through integration & automation** *Technology strategies that reduce effort, cost & support sustainability goals* • ***Sites just want to get the job done*** *Reduce the barrier to eClinical technology adoption at sites by offloading burden* • ***Not all technology, integration and automation strategies are the same*** *Understand how best-in-class technologies, established integrations and seemless automation comes together to make*	**The Opportunities and Challenges of Moving to Electronic Capture of Informed Consent** Technology has revolutionized the process of obtaining a patient's informed consent to participate in a clinical trial. Benefits of electronic informed consent (eConsent) include increased security, speed of roll-out, and detailed reporting in real time. However, concerns remain about the patient's experience with the informed consent process while they are being asked to make a serious decision about their own health. In this presentation, we will explore • The advantages with eConsent for both

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	David Chia, Senior Business Development Manager, **Novotech** **Diana Filipescu,** Business Development Manager, **EastHORN (A Novotech Company)**	*a difference for sites, patients and sponsors* • ***How to evaluate technologies partners to maximize impact towards sustainability goals*** *How the right technology investments and automations can reduce carbon footprint and optimize the clinical supply chain* **Kevin Landells,** *Vice President, Business Head of IRT,* ***IQVIA Technologies*** **Karen Maduschke,** *Senior Director and GM, Patient Consent,* ***IQVIA Technologies***	patients and clinical site staff • Potential user experience challenges of consenting on a digital device • The design-led approach that YPrime has taken to its new eConsent app ***Karl McEvoy****, Product Director, Decentralised Trial Technology,* ***YPrime*** **Paul Margerison,** *Director, User Experience & Design YPrime*
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***	**Delving into Digital Health in Oncology clinical trials** • How can Digital health solutions benefit oncology clinical trials • What digital health solution inclusion means for sponsors, investigators, solution providers and trial participants • What do we need to do to make this inclusion, standard of practice ***Caoimhe Vallely-Gilroy,*** *Independent Advisor – HIRANI, former Global Head of Digital Health & Therapeutics at Healthcare Business*	**The Ecosystems Leaders Mindset in Healthcare** • Discussing how companies will not compete against companies anymore. Ecosystems will compete against Ecosystems. You have to build ecosystems to win. • Discovering the power of ecosystems to create disruptive and innovative value proposition • Uncovering the leadership mindset needed to work in ecosystems: Moving from EGO to ECOsystems ***Orlando Vergara****, Barcelona Health Hub Ambassador, former Novartis Neuroscience Head*
14:45	**Controlling Drug Supply Risk by Enabling Complex Protocols Through Modern RTSM Support**	**Accelerated performance of complex exploratory patient studies: practical insights from investigational site**	**Running Up That Hill: Accelerate Cycle Times & Reach Patients Faster with elluminate**

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	In today's clinical trial landscape, oversight and risk management are essential for ensuring patient safety and regulatory compliance. However, controlling these risks is not without its challenges. From demand/supply planning issues to forecasting inaccuracies, drug supply management can be a daunting task, especially with rising complexity in the protocol development process. So, how can we best enable this rising protocol complexity while controlling end-to-end drug supply risk for your studies? *Join this session to explore how these challenges can be addressed through modern Randomization and Trial Supply Management (RTSM) software. We will examine how advanced RTSM systems can be implemented for complex protocols without the need for lengthy implementation timelines. We will also discuss how modern RTSM forecasting/resupply algorithms can work to control drug supply risks in complex protocols. Finally, we'll consider how modern RTSM systems can combine the features highlighted above with providing flexible and prompt post go-live support through extensive self-service trial management capabilities* **Benjamin Etschmann,** *Senior Forecasting Services Lead,* ***4G Clinical***	• 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 Exploratory Medicine***	**Operational oversight within outsourced models has become increasingly complex for teams who are tasked with managing trials amid a rapidly changing landscape of partners, technologies, and global regulations. Data proliferation along with dwindling resources has made it a top priority for clinical development teams to look to technology to improve cycle times and the overall experiences of data managers, medical monitors, and clinical operations leaders.** *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 supports 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

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			programming and statistical analysis roles ***Jason Konn,*** *Solution Consultant,* ***eClinical Solutions***
15:15	**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***	**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 practical compared to full DCT? ***John Zibert****, Chief Medical Officer,* ***Coegin Pharma AB***	**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***
15:45	Afternoon refreshments and networking		
16:15	**Pro et contra of working with Professional Site Networks for sponsors and CROs** • Does the industry need professionalization of clinical research sites? • 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	**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 ***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***	

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	Ivan Vyshnyvetskyy**, President, **Ukrainian Association for Clinical Research	
16:45	**IND Versus CTA Submissions: Is Your Drug Development Program Ready to Take on Both?** Submitting an Investigational New Drug Application (IND) in the US and a Clinical Trial Application (CTA) in the EU are important milestones in new drug development, marking the transition from bench research to clinical studies in human participants. Successful IND and CTA submissions require careful planning and strict compliance with regulatory requirements, which can be especially challenging for first-time applicants. This presentation will cover: • An introduction to the IND, including the document structure, optimal data to include, and timeline considerations • Key differences in the IND and CTA submission process, and how to leverage similarities in your drug development program • The impact of the new, centralized EU trial regulation in global drug regulations ***Federica Martini,** Ph. D. Associate Director, Regulatory Affairs, **Premier Consulting***	**Innovation to Strengthen Patient Accessibility to High Impact Medicines** ***Utilizing Patient Experience Data to Maximize Value in a Time of Narrowing Margins*** *Obtaining Marketing Authorisation through Regulatory Approval and specific defined pathways in key geographies is a necessary step in the lifecycle of drug development and patient access to new medicines. However, convincing regulators of a product's safety and efficacy to obtain Marketing Authorisation is only one part of the value chain.* *As biopharma looks to plan for the needs of complex healthcare ecosystems, there is increasing demand for evidence generation to demonstrate the required value, harmonise needs of multiple stakeholders, and continue listening to the patient voice from early on in drug development, through authorisation and beyond. A robust demonstration of clinical differentiation is required, as well as the importance to leverage real world data for evidence generation.* *In this session, we will discuss the intrinsic need to understand and capture Patient Experience Data through Patient Centered Outcomes Research (PCOR) and innovative technology, from the beginning of the lifecycle of drug development all the way through to prospective data collection in a real-world setting.* **Adam Levy**, *Senior Director, Business Development, **THREAD***

17:15	**CLOSING KEYNOTE** **Gain a comprehensive overview of the EU Clinical Trial Regulation and changes for trials in the EU** • Intro to EuCTR and CTIS • Experience in CTIS and KPIs: Organization model Sponsor-CRO: Challenges and Success cases • Benefits of submitting through the same portal for all sponsors/CROs and the advantages for biopharma companies of standardized timelines • Overview of major new requirements, such as transparency rules and regulatory submission packages • Understanding the new trial authorization process for regulatory and ethical approval ***Lidya Domínguez**, Clinical Research Director, **Sermes CRO*** **Raquel Reviejo,** EU Regional Submission Lead, **MSD**	**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,** Senior Director Clinical Trial Digital Innovation, **Genmab***
17:55	Chair's Summary & Drinks Reception	

DAY TWO – THURSDAY 4TH MAY 2023

08:10	Registration and refreshments	
08:45	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***
9:00	**PANEL DISCUSSION** **Reversing the Conversation: What the clinical trial industry really wants from its service providers**	**WORKSHOP** **Introducing The Patient Centric Sample Interest Group**

PANEL DISCUSSION

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Sales Enquiry
Nicholas McCudden
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: NicholasMcCudden@arena-international.com

Speaker Enquiry
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	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***	*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	**EU MDR: how attractive is Europe for innovation?** *Talking Points: "The aim of the presentation is to highlight MDR positive and negative consequences on the development of new medical devices by answering to the following questions:* • What are the main regulatory challenges for new medical devices after EU MDR? • How MedTech companies are reacting? • Is CE-mark still "first choice" by start-ups and SMEs? ***Enrico Perfler,*** *CEO,* ***1Med***	**Practical innovation: Powering IRT for improved patient management and drug logistics in a clinical trials platform** • Clinical trials today are becoming increasingly complex, and the technology landscape to manage them can be complicated and overwhelming. • Seamlessly connecting IRT with eConsent and eCOA in a single platform enhances the user experience, reduces workloads, and drives rapid deployment through centrally shared data and streamlined workflows. • Explore examples of how interoperable systems increase visibility to patient data, more accurately project supply and resupply needs, and support timely outcomes data collection, all through your IRT. ***Marcel Besier,*** *Senior Director, Services Delivery,* ***Suvoda*** ***Daniela Duffett,*** *Solutions Consultant,* ***Suvoda***
10:15	**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 metaverse in Pharma it could be a possible solution?** • Explore what's the metaverse • If the pharma industry is ready for the tech • What could be an add value for the Customer

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	• 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***	***Stefania Alvino,*** *HEAD of Digital Innovation****, Daiichi Sankyo***
10:45	**How to succeed in your Oncology clinical trial from regional-medium CRO's point of view?** • What is the added value of the small and medium CROs? • Can these CROs successfully manage current changes in technology paradigm? • Can we help to optimize enrollment challenge to reduce costs and get results within timelines? ***Ana Moreno,*** *Director Global Clinical Operations,* ***APICES***	**Advancing Towards Patient-Centered Measurement Methods by Integrating ePRO in Oncology Trials;** **Lessons Learned from a Recent Study** • Reviewing the strategy for the provision of the user-friendly platforms • Identifying the potential barriers in day-to-day utilization and how they can be overcome • Discussing the expectations of PRO in oncology research moving forward **Edyta Korzuch,** Senior Director, Project Management, Oncology, **TFS HealthScience**
11:15	Morning refreshments and networking	
11:45	**Being a Process Manager, when all processes collapse – War in Ukraine, one sponsor's perspective** • What is business continuity during the war in Ukraine and how are we ensuring it? • Leading people, process, projects • Processes adaptation, flexible decisions: remote SDR and SDV implementation • Experience in patients transfers within and outside of Ukraine ***Kateryna Orlovska,*** *Country Clinical Quality Management Lead Ukraine, Georgia and CIS****, MSD***	**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,*** *Global Head Evidence Generation,* ***CSL Vifor***
12:15	**Why Patient Participation Isn't Recovering and Tactics to Drive Change**	**Embedding patient recruitment into healthcare systems** As the UK's leading health tech supplier, we're connecting study sponsors and clinical research

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Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: maya.hudson@arena-international.com

	• Covid-19 pandemic has changed the paradigm of clinical research, with a rapid uptick in adoption of new technologies and integrated ecosystems, to enable and support decentralized trials, patient recruitment and retention, or data transference form electronic health records (EHC) into electronic data capture (EDC), among others • This new technologically-driven environment requires additional collaboration between Sponsors, Clinical Research Organizations (CRO), investigators and other vendors and providers. • In parallel, global analysis shows a trend on decreasing number of subjects participating in clinical trials, as well as recruitment rates • Is it time to look into clinical trials from a different angle? ***Esther Mahillo PhD, Vice President, Operational Strategy, Precision Medicine***	organisations with our vast network of healthcare professionals and patients to source quality clinical trial candidates at speed. Join this session to learn more about our Recruit solution, including: • How we're enabling primary care organisations to get involved in patient recruitment for clinical trials • How we're empowering participants to take part in clinical research by contacting them through trusted sources • How we're making it easier for study sites to review and contact potentially eligible participants **Mihad Mohamed,** *Head of Product Management – Research and Life Sciences,* ***EMIS***
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 • 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***	**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***
13:15	Lunch and networking and Apple Prize draw	
14:15	**Is a clinical trial a customer experience? Insights from consumer research** • Consumer brands thrive on a sophisticated understanding of the needs and motivations of their customers, and the role the brand plays in their lives.	**Practical use cases to improve clinical site efficiency with technology** • Using technology to work with sites • Using machine learning to increase efficiency

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Sales Enquiry
Nicholas McCudden
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: NicholasMcCudden@arena-international.com

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	• Clinical trials don't typically prioritise such a deep understanding of their end user, but trials don't happen in a vacuum. • As people increasingly expect consumer-like personalisation and choice from their healthcare, what can clinical trials learn from thinking of participants as customers? ***Harry Yeates**, Strategy Director, **Langland Advertising & Marketing Ltd***	• Leveraging interoperability to streamline operations ***Jay Smith**, Head of Product, Trial Interactive, **TransPerfect***
14:45	**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*	
	Think Tank 1: What does the clinical trial industry really want from its service providers? *Host: **Estrella Garcia**, Senior Director Global Clinical Operations, **Almirall***	
	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: **Communication & Innovation: Defining innovation in clinical trials** ***Laura Jiménez Robledo,** Clinical Project and Innovation Manager**, Novo Nordisk***	
	Think Tank 4: **Fighting the System: A Provocative Discussion on Challenging the Flaws and Injustices of the Clinical Trials Industry for Better Results** **Ivan Vyshnyvetskyy,** - President of the Ukrainian Association for Clinical Research, Managing Director Ukraine at FutureMeds	
15:45	End of Event	

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