

PROGRAMME

PRE-CONFERENCE: SUNDAY FEBRUARY 2ND

19:00 - 22:00 **Sunday Evening Networking**

DAY ONE: MONDAY FEBRUARY 3RD

08:00 - 09:00 **Registration, Coffee & Exhibition**

09:15 - 09:25 **Welcome**

Presented by Martine Dehlinger Kremer | EUCROF President & ICON Plc

Modernising Clinical Research in the EU

Presented by Emer Cooke | The European Medicines Agency

The future of the EU CTR

10:45 - 11:30 **Break & Exhibition**

11:30 - 12:45 **MedEthicsEU - the 5 Ws**

Presented by Monique Al | CCMO

Improving the Clinical Trial Landscape in EU/EEA

Presented by Marianne Lunzer | AGES MEA

12:45 - 14:00 **Lunch & Exhibition**

Breakout Stream 1	Artificial Intelligence & Technology Chair: Alexandre Malouvier	European Regulatory Considerations Chair: Martin O'Kane	DCT's Chair: Nicole Bohrmann	Operational Excellence Chair: Benedikt Van Nieuwenhovem & Vivienne van de Wall	Special interests: Paediatrics Chair: Vivienne van de Wall
14:00 - 15:15	<p>EU AI Act on Focus Maria Veleva Velev Consulting Ltd</p> <p>Leveraging Traditional AI Techniques to Enhance Generative AI and Mitigate Hallucinations Lionel Guérin ScienceOne</p>	<p>From EU CTR Regulation to Global CTA Efficiency: A Cross-Functional Approach Charlene Muscat & Manan Trivedi UCB Pharma</p> <p>How Belgian Medical Research Ethics Committees evaluate clinical trials since the implementation of the Clinical Trial Regulation Audrey Van Scharen Belgian Association of Research Ethics Committees</p>	<p>4 years after pandemic - where are we in Europe with the decentralization of the clinical trials and why do we still need it? Iwona Tongbhoyai Futuremeds LTD</p> <p>Clinical trial home visits, do's and don't's Geert Briers Deltaclinical</p>	<p>Optimizing regulatory relationships in clinical trials: strategic approaches for success Cécile van der Heijden Axon Lawyers</p> <p>Code of Conduct in Clinical Trials Oncology Sweden - A work of collaboration Annika Baan CTU oncology Sahlgrenska Comprehensive Cancer Center Sweden & Christina Stenberg Akademiska University Hospital</p>	<p>Language discrimination in the access to paediatric clinical trials in Europe Begonya Nafria Escalera Sant Joan de Déu Research Foundation</p> <p>Using historical control data in nutritional clinical trials in preterm infants: Challenges and considerations Atiye Nazari Nestle Research</p>

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14:00 - 15:15	Dynamic Benefit-Risk Predictions: Transforming Patient Outcomes with Real-Time AI Insights Romain Clément & Charbel Alhelou ArcaScience	How can the regulatory framework support the competitiveness of the EU Lene Grejs Petersen Danish Medicines Agency		Preference and feasibility analysis of DCT in paediatric clinical trials: Barcelona Children's Hospital case study Joana Claverol Torres Sant Joan de Déu Research Foundation
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15:15 - 15:45 **Break & Exhibition**

15:45 - 17:00 **Why Diversity Matters in Clinical Research**

My Perspective as a Woman Living with Parkinson's & an Innovator

Presented by Richelle Flanagan | My Moves Matter

Advancing Equity: Inclusive SOGI Data Collection and Gender-Neutral Protocols in Clinical Research

Presented by Garo Kiledjian | SGM Alliance

Panel

Presented by Garo Kiledjian | SGM Alliance, Richelle Flanagan | My Moves Matter & Viviënne van de Walle | PT&R

19:30 - 22:30 **Networking Reception & Conference Dinner** Sponsored by  **MEDIDATA**

DAY TWO: TUESDAY FEBRUARY 4TH

08:00 - 09:00 **Registration, Coffee & Exhibition**

09:00 - 10:30 **Harnessing the Power of AI in Clinical Research**

AI Agents at Work at Sanofi

Presented by Lionel Bascles | Sanofi & Bianca Anghelina | Aily Labs

How the deployment of AI is critical to a CRO growth and execution strategy

Presented by Gerard Quinn | ICON plc

10:30 - 11:00 **Break & Exhibition**

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Breakout Stream 2	Artificial Intelligence & Technology Chair: Sverre Bengtsson	European Regulatory Considerations Chair: Martin O'Kane	DCT's Chair: Nicole Bohrmann	Operational Excellence Chair: Benedikt Van Nieuwenhovem & Vivienne van de Wall	Special interests: Devices Chair: Martin O'Kane
11:00 - 12:15	Empowering Patient-Centric Research: The Role of AI in The Synergist Clinical Trial Distribution Network (CTDN) Project Nicholas Brooke Synergist	The changing legal landscape and its impact on clinical research Cécile van der Heijden Axon Lawyers	Home Trials Services, "diversity" in stakeholders expectations, good practice implementation Gabriele Schwarz BfAr, Nicolas Thevenet Euraxi Pharma, Joachim Lövin Novo Nordisk, Dominique Hamerlijnck European Lung Foundation & Vivienne van de Walle PT&R	Back to Basics: Connecting with people to drive recruiting and retention Matt Feldman InTheDistance Media	Overcoming Challenges and Maximizing Opportunities in Medical Device Clinical Studies under the Medical Device Regulation (MDR) Karen Gabriels Archer Research
	At the Crossroads of Data: eCOA and Sensors Converging for Novel Insights Kevin Macho Gamboa & Paul O'Donohoe Medidata	Regulatory landscape and opportunities for using digital health technologies in clinical trials Cathelijne de Gram J&J & Melissa Pauline Herman Lundbeck		Protocol design considerations for more efficient recruitment and retention Graham Wylie MRN	EU MDR and EU IVDR - Act 2 - getting back into innovation, pediatrics and orphan devices and supporting SMEs Erik Vollebregt Axon, Gert Bos Qserve Group & Sabina Hoekstra van den Bosch TUV SUD
		The approach to clinical data transparency and disclosure is changing and EMA's Policy 0070 is a large contributor to this Honz Slipka Certara		A Retrospective Study on Patient Referral Patterns of Family Physicians to different specialties in a Tertiary Hospital Novilyn Villanueva & Valerie Tumaliuan Region 1 Medical Center	

12:15 - 13:15 **Lunch & Exhibition**

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Breakout Stream 3	Artificial Intelligence & Technology Chair: Sverre Bengtsson	European Regulatory Considerations Chair: Martin O'Kane	DCT's Chair: Nicole Bohrmann	Operational Excellence Chair: Benedikt Van Nieuwenhovem & Vivienne van de Wall
13:15 - 14:30	Beyond EDC - Facilitating Comprehensive Integration of Clinical Data Across Platforms Majd Mirza Viedoc	Current status and future opportunities for Patient Involvement in Clinical Trial Applications Cathelijne de Gram J&J	Management of Medical Waste During Off-Site Visits in Decentralized Clinical Trials: Compliance with International Standards and European Union (EU) Guidelines Szilvia Harsányi Research Professionals Ltd.	Strategic Risk Management in TMF: Elevating Quality and Compliance in Clinical Trials Donatella Ballerini Montrium
	Leveraging Advanced Analytics to Optimize Enrollment in a Dynamic Trial Landscape Eleanor McLaurin Medidata	Enhancing Accessibility of Clinical Trials in Europe: Lessons Learned and Future Directions after 1 Year of operation ClinicalTrials.eu Lukasz Wiech & Lukasz Izbicki ClinicalTrials.eu	Creating an efficient, integrated ecosystem for clinical trials in-home and at-site Catherine Jervis MRN	CRO & Biotech: Bridging the Communication Gap Tanja A.M. Hoffman TNJ Life Sciences Consultancy Site sustainability in the fast-growing clinical research environment Anna Titkova Pratia
14:30 - 15:00 Break & Exhibition				
15:00 - 16:30 Showcasing Success in Clinical Trials				
16:30 - 16:45 Closing Remarks with Martine Dehlinger Kremer EUCROF President & ICON Plc				