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 | Icon Plc & President of EUCROF

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
	EU AI Act on Focus Maria Veleva | Velev Consulting Ltd	**From EU CTR Regulation to Global CTA Efficiency: A Cross-Functional Approach** Charlene Muscat & Manan Trivedi UCB Pharma	**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	**Optimizing regulatory relationships in clinical trials: strategic approaches for success** Cécile van der Heijden | Axon Lawyers	**Language discrimination in the access to paediatric clinical trials in Europe** Begonya Nafria Escalera | Sant Joan de Déu Research Foundation
14:00 - 15:15	**Leveraging Traditional AI Techniques to Enhance Generative AI and Mitigate Hallucinations** Lionel Guérin ScienceOne	**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	**Clinical trial home visits, do's and dont's** Geert Briers Deltaclinical	**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	**Using historical control data in nutritional clinical trials in preterm infants: Challenges and considerations** Atiye Nazari Nestle Research

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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

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

Embracing Diversity in European Clinical Reseach: How and Why?
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 it 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
	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 & Viviënne 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
11:00 - 12:15	**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, pedriatrics 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
	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
13:15 - 14:30	**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 | Icon Plc & President of EUCROF			