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 - 10:45	**Welcome & Plenary 1** Presented & chaired by Martine Dehlinger-Kremer | President of EUCROF & Icon Plc
	Modernising Clinical Research in the EU Presented by Peter Artlett | The European Medicines Agency
	Looking to the future for EU Clinical Research Presented by Rainer Becker | European Commission
10:45 - 11:30	**Break & Exhibition**
11:00 - 11:20	**Live Lounge** MEDIDATA
11:30 - 12:45	**Plenary 2** Chaired by Martin O'Kane
Room: Sweden	**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**
13:10 - 13:30	**Live Lounge** HERAX Life Science

Room	Norway	Sweden	Iceland	Finland	Denmark
Breakout Sessions	**Artificial Intelligence & Technology** **Chair: Alexandre Malouvier**	**European Regulatory Considerations** **Chair: Martin O'Kane**	**DCT's** **Chair: Nicole Bohrmann**	**Operational Excellence** **Chair: Benedikt Van Nieuwenhovem**	**Special interests: Paediatrics** **Chair: Viviënne van de Walle**
	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?** Rebeca González Vicedo | Futuremeds	**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	**Dynamic Benefit-Risk Predictions: Transforming Patient Outcomes with Real-Time AI Insights** Romain Clément & Charbel Alhelou ArcaScience	**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, Helena Lüning | ASCRO & Eva Adås | Johnson & Johnson Innovative Medicine	**Using historical control data in nutritional clinical trials in preterm infants: Challenges and considerations** Atiye Nazari Nestle Research

PROGRAMME

14:00 - 15:15	**Leveraging Traditional AI Techniques to Enhance Generative AI and Mitigate Hallucinations** Lionel Guérin ScienceOne	**Panel Discussion: How can the regulatory framework support the competitiveness of the EU** Lene Grejs Petersen | Danish Medicines Agency, Charlene Muscat & Manan Trivedi | UCB Pharma, Audrey Van Scharen | Belgian Association of Research Ethics Committees - Vrije Universiteit Brussel			**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**
15:25 - 15:45	**Live Lounge** Curewiki
15:45 - 17:00	**Plenary 3: Why Diversity Matters in Clinical Research** Led by Viviënne van de Walle | PT&R, Moderator: Doug Peddicord, ACRO
Room: Sweden	**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 Terttu Haring | SGM Alliance **Panel** Terttu Haring | SGM Alliance, Richelle Flanagan | My Moves Matter & Viviënne van de Walle | PT&R
19:30 - 20:00	**Networking Drinks Reception** Sponsored by MEDIDATA
20:00 - 23:30	**Conference Dinner** Sponsored by MEDIDATA

DAY TWO: TUESDAY FEBRUARY 4TH

08:00 - 09:00	**Registration, Coffee & Exhibition**
09:00 - 10:30	**Plenary 4: Harnessing the Power of AI in Clinical Research** Chaired by Alexandre Malouvier
Room: Sweden	**Risk proportional Validation of Artificial Intelligence** Presented by Torsten Stemmler | Federal Institute for Drugs and Medical Devices **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**
10:40 - 11:00	**Live Lounge** nubilaria

PROGRAMME

Room	Norway	Sweden	Iceland	Finland	Denmark
Breakout Sessions	**Artificial Intelligence & Technology** **Chair:** Alan Yeomans	**European Regulatory Considerations** **Chair:** Martin O'Kane	**DCT's** **Chair:** Nicole Bohrmann	**Operational Excellence** **Chair:** Benedikt Van Nieuwenhovem	**Special interests: Devices** **Chair:** Sverre Bengtsson
	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	**Panel Discussion: 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 & Mieke Tempels Archer Research
11:00 - 12:15	**At the Crossroads of Data: eCOA and Sensors Converging for Novel Insights** Kevin Machado Gamboa & Paul O'Donohoe | Medidata	**Regulatory landscape and opportunities for using digital health technologies in clinical trials** Cathelijne de Gram J&J & Stewart Polley Novo Nordisk		**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
		CTIS evolutions (past and future): insider's view Pierre-Frederic Omnes TransPerfect Life Sciences		**A Retrospective Study on Patient Referral Patterns of Family Physicians to different specialties in a Tertiary Hospital** Novilyn Villanueva Municipal Health Office Agoo	
12:15 - 13:15	**Lunch & Exhibition**				
12:30 - 12:50	**Live Lounge** Agilent				
12:55 - 13:15	**Live Lounge** GOETHE UNIVERSITÄT FRANKFURT AM MAIN				

PROGRAMME

Room	Norway	Sweden	Iceland	Finland	Denmark
Breakout Sessions	**Artificial Intelligence & Technology** Chair: Alan Yeomans	**European Regulatory Considerations** Chair: Martin O'Kane	**DCT's** Chair: Nicole Bohrmann	**Operational Excellence** Chair: Benedikt Van Nieuwenhovem	**Special interests: The rise of the European Patient Data Ecosystem** Chair: Alexandre Malouvier
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 & Melissa Herman H. Lundbeck	**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	**The impact of the EHDS for clinical research** Dipak Kalra The European Institute for Innovation through Health Data **Unveiling the European Health Data Space: Transforming Clinical Research through Secondary Use of Health Data** Mélodie Bernaux EC SANTE C1
	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	**xShare and Data Portability Solutions in Europe: Implications for Clinical Research** Vincent Keunen Andaman7 **Federated analyses & mastering heterogenous data** Nora Sagel | Honic
14:30 - 15:00	**Break & Exhibition**				
15:00 - 16:30	**Plenary 5: Showcasing Success in Clinical Trials** Chaired by Sverre Bengtsson | Digital Trial Consultants				
Room: Sweden	**New report on clinical trials places Spain as a leader and success story in Europe** Presented by Amelia Martín Uranga | Farmaindustria **Public-Private Collaboration builds a Strong Clinical Trial Ecosystem** Presented by Marianne Pilgaard | TrialNation **Successful outsourcing underpins successful Clinical Trials** Presented by Dorte Pederson | PCMG				
16:30 - 16:45	**Closing Remarks** with Martine Dehlinger-Kremer | President of EUCROF & Icon Plc				

Programme subject to change - please check event app for up to date content and session details.