EUCROF24

19-20 FEBRUARY | PRAGUE

7TH EUROPEAN CONFERENCE ON CLINICAL RESEARCH: PUSHING BOUNDARIES AND ACCELERATING INNOVATION

EUCROF24 will bring together pharma, biotech, medical device companies, CROs and other service providers, technology providers, regulators, patients, and academia, to discuss the current challenges, and future direction of Clinical Research across Europe. EUCROF24 is the 7th running of the EUCROF Clinical Research Conference that attracts a diverse range of speakers and attendees from functions including clinical operations, regulatory, data management, statistics, medical and safety, digital health technology, quality assurance, as well as patient groups and regulators.

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PRE-CONFERENCE: SUNDAY FEBRUARY 18TH

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

DAY ONE: MONDAY FEBRUARY 19TH

08:00 - 09:30	**Welcome Coffee & Exhibition**
09:30 - 09:40	**Conference Opening with Martine Dehlinger-Kremer | ICON PLC & EUCROF**
09:40 - 09:45	**Welcome from the Deputy Minister of Health, Czech Republic - Jakub Dvořáček**
09:45 - 10:15	**Key Note: Changing Regulatory Landscape affecting Clinical Research** Presented by Laura Pioppo | EMA
10:15 - 10:45	**Key Note: AI Powered Technology – Game Changer for Clinical Research** Presented by Lisa Moneymaker | Saama
10:45 - 11:15	**Break & Exhibition**
11:15 - 13:00	**EU Clinical Trials Regulation 536/2014 and Clinical Trials Information System – Two Years into the Transition Period** Chairs: Dagmar Chase | Clinrex Munich & Martin O'Kane | Novartis Speakers: Eva Hrušková Reinová | SUKL, Georg Schmidt | AKEK, Pierre Omnes | Transperfect, Stéphanie Kromar | EORTC
13:00 - 14:00	**Lunch & Exhibition**

Breakout Stream 1	Clinical Trials Regulation/Clinical Trials Information System Chair: Martin O'Kane	Decentralised Clinical Trials Chair: Benedikt van Nieuwenhove	Artificial Intelligence Chair: Alan Yeomans	Insights Chair: Viviënne van de Walle
14:00 - 15:00	**The Challenge with Transition Trials: Theory and Reality** Martin O'Kane | Novartis	**EU Recommendation Paper - US Guidance for Industry - A Comparison from a regulatory perspective** Gabriele Schwarz | BfArM	**AI state-of-play around clinical research** Lina Gaggi | Viedoc	**Clinical use case – why you need a data-driven approach for site selection and feasibility** Elke Ydens | Anju Software
	Experience in the management of an Advanced Therapy Medicinal Product submission to Clinical Trials Information System Arianna Bertolani | CVBF	**Do Decentralised Clinical Trials improve representativeness?** Bart Lagerwaard | Trials at Home	**Using Technology and AI to deliver compliance, data integrity and operational efficiency with next generation RBQM** Rich Davies | CluePoints	**Best Practices and Standardisation of Contracts between Sponsors and Investigational Sites** Michaela Vančová | RetInsight & Roman Fishchuk | University Hospital UA

15:00 - 15:30	**Break & Exhibition**

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15:30 - 17:00	**Empowering patients in clinical research** Chairs: Darina Hrdlickova | ACRO-CZ & Alexandre Malouvier | ICON PLC
15:30 - 16:00	**Nothing about us without us! - The added value of involving patients/ patient representatives in clinical research** Presented by Sally Hofmeister | World Duchenne Organization
16:00 - 16:30	**Cross-border access for patients to clinical trials – the EU-X-CT initiative** Presented by Susan Bhatti | Merck BV
16:30 - 17:00	**Patient Mediated Research - This Is Really Different** Presented by Vincent Keunen | Andaman7
19:30 - 23:30	**Drinks Reception & Conference Dinner**

DAY TWO: TUESDAY FEBRUARY 20TH

08:00 - 09:00	**Coffee & Exhibition**
09:00 - 10:30	**ICH News: Good Clinical Practice and Clinical Trial Protocol** Chairs: Dagmar Chase | Clinrex Munich & Goran Vesov | CResT Consulting
09:00 - 09:30	**ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)** Presented by Mumtaz Sultani | EMA
09:30 - 10:30	**ICH E6 (R3) Principles and Annexes** Presented by Gabriele Schwarz | BfArM & Rebecca Stanbrook | Novartis
10:30 - 11:00	**Break & Exhibition**

Breakout Stream 2	Clinical Trials Regulation/Clinical Trials Information System Chair: Dagmar Chase	Decentralised Clinical Trials Chair: Fiona Maini	Artificial Intelligence Chair: Antonio Torres	Insights Chair: Yoanni Matsakis
11:00 - 12:00	**Protection of personal data and commercially confidential data when using Clinical Trials Information System** Laura Pioppo | EMA	**The successful implementation of an e-consent process in a decentralised trial** Kees van Ooik | Your Research **The role of patient reported outcomes in hybrid trials and/or DCTs** David Renzelmann & Manuel Neukum | EvidentIQ	**AI based Data Management and Pharmacovigilance Safety Monitoring** Paul Wallbott | Alcedis **The Future of Medical Writing with Generative AI** Emmanuel Walckenaer | Yseop	**GDPR: First Code of Conduct for Clinical Research** Victoria Watts | Premier Research **(DP)2 – Data processing and - protection in the age of A.I.** Gero zur Hellen | GCP Service International
12:00 - 13:00	**Lunch & Exhibition**			

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Breakout Stream 3	Clinical Trials Regulation/Clinical Trials Information System Chair: Bendikt van Nieuwenhove	Decentralised Clinical Trials Chair: Fiona Maini	Artificial Intelligence Chair: Alexandre Malouvier	Insights Chair: Alan Yeomans
13:00 - 14:00	**Burning Questions & Reliable Answers** Pierre Omnes | Transperfect & Laura Pioppo | EMA	**Home visits in Decentralized Trials – Challenges and Opportunities** Sofie Sibia | IDTM **Delivery and Administration of IMP at Home - Issues and Best Practices** Oksana Nedostup | ULC	**AI Powered Patient Enrollment Prediction & Forecasting in Clinical Trial Design** Eleanor Mclaurin | Medidata **The AI Journey at Roche So Far** Joanne Donald | Roche	**Nature of a Distributed Trial Master File – Practical Aspects** Aurélie Delaunay | Merck, KGaA **Computer Systems: End of Life Considerations and Challenges** Neil Konopka | Oracle
14:00 - 14:30	**Break & Exhibition**			
14:30 - 15:00	**Preclinical development: in silico models for investigating metabolism and toxicity of candidate drugs** Presented by Jana Brajdih Cendak | Billev Pharma East **European Health Data Space** Presented by Lenka Kaska | Pfizer **The X-Share Project** Presented by Roxana Albu | EUCROF			
15:00 - 16:00	**Panel Discussion: Game Changers in the Product Life Cycle** Chair: Doug Peddicord | ACRO Panelists: Gabriele Schwarz | BfArM, Jana Brajdih Cendak | Billev Pharma East, Lisa Moneymaker | Saama, Lenka Kaska | Pfizer, Roxana Albu | ECCRT, Martin O'Kane | Novartis, Viviënne van de Walle | SCRS & Sally Hofmeister | World Duchenne Organisation			
16:00 - 16:15	**Closing Remarks** with Martine Dehlinger-Kremer | ICON PLC & EUCROF			

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

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