

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.

www.conference.eucrof.eu





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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**

EU Clinical Trials Regulation 536/2014 and Clinical Trials Information System – Two Years into the Transition Period

11:15 - 13:00 **Chairs: Dagmar Chase | Clinrex Munich & Martin O’Kane | Novartis**

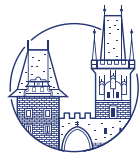
Speakers: Eva Hrušková Reinová | SUKL, Georg Schmidt | AKEK, Pierre Omnes | Transperfect, Stéphanie Kromar | EORTC

13:00 - 14:00 **Lunch & Exhibition**

Breakout Stream 1	Clinical Trials Regulation/Clinical Trials Information System	Decentralised Clinical Trials	Artificial Intelligence	Insights
	Chair: Martin O’Kane	Chair: Benedikt van Nieuwenhove	Chair: Alan Yeomans	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

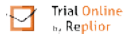
15:00 - 15:30 **Break & Exhibition**

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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	Decentralised Clinical Trials	Artificial Intelligence	Insights
	Chair: Bendikt van Nieuwenhove	Chair: Fiona Maini	Chair: Alexandre Malouvier	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	AI Powered Patient Enrollment Prediction & Forecasting in Clinical Trial Design Eleanor Mclaurin Medidata	Nature of a Distributed Trial Master File – Practical Aspects Aurélie Delaunay Merck, KGaA
		Delivery and Administration of IMP at Home - Issues and Best Practices Oksana Nedostup ULC	The AI Journey at Roche So Far Joanne Donald Roche	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			
15:00 - 16:00	European Health Data Space Presented by Lenka Kaska Pfizer The X-Share Project Presented by Roxana Albu EUCROF 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, Vivienne 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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