

EUCROF24

19-20 FEBRUARY | PRAGUE



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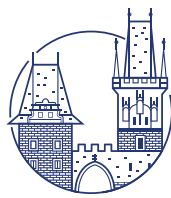
EUCROF24 will bring together pharma, biotech, medical device companies, CROs and other service providers, technology providers, regulators, patients, and academia, to discuss the current challenges, and future direction of Clinical Research across Europe. EUCROF24 is the 7th running of the EUCROF Clinical 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.

Benefits to our member organisations:

- €500 discount on exhibition stand
- Discounted delegate fees

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PRE-CONFERENCE: FEBRUARY 18TH

Sunday Evening Networking 19:00 - 22:00

DAY ONE: FEBRUARY 19TH

Welcome Coffee 08:00 - 09:30

Conference Opening 09:30 - 09:45

Key Note: Changing Regulatory Landscape affecting Clinical Research 09:45 - 10:15

Key Note: AI powered Technology – Game Changer for Clinical Research 10:15 - 10:45

Break 10:45 - 11:15

EU Clinical Trials Regulation 536/2014 and CTIS – Two Years into the Transition Period - Experiences from different Stakeholders 11:15 - 13:00

Lunch 13:00 - 14:00

Breakout Stream 1 14:00 - 15:00

CTR/CTIS

The Challenge with Transition Trials: Theory and Reality

Experience in the management of an Advanced Therapy Medicinal Product submission to CTIS

Decentralised Clinical Trials

EU Recommendation Paper - US Guidance for Industry - A Comparison from a regulatory perspective

Do Decentralised clinical trials improve representativeness?

Artificial Intelligence

The use of Artificial Intelligence (AI) in the medicinal product lifecycle (EMA Reflection Paper)

Using Technology and AI to deliver compliance, data integrity and operational efficiency with next generation RBQM

Insights

Clinical use case – why you need a data-driven approach for site selection and feasibility

Standard Contracts between Sponsors and Investigator Sites

Break 15:00 - 15:30

Empowering patients in clinical research 15:30 - 17:00

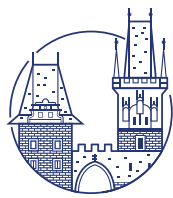
Nothing about us without us! - The added value of involving patients/patient representatives in clinical research 15:30 - 16:00

Cross-border access for patients to clinical trials – the EU-X-CT initiative 16:00 - 16:30

Patient Mediated Research - This Is Really Different 16:30 - 17:30

Drinks Reception & Conference Dinner 19:30 - 23:30

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DAY TWO: FEBRUARY 20TH

Welcome Coffee	08:00 - 09:00
ICH News: Good Clinical Practice and Clinical Trial Protocol	09:00 - 10:30
ICH E6 (R3) - Principles and Annexes	09:00 - 09:45
ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)	09:45 - 10:30
Break	10:30 - 11:00
Breakout Stream 2	11:00 - 12:00
CTR/CTIS	
Protection of personal data and commercially confidential data when using CTIS	
Decentralised Clinical Trials	
The successful implementation of an e-consent process in a decentralised trial	
The role of patient reported outcomes in hybrid trial and/or DCTs	
Artificial Intelligence	
AI based Data Management and Pharmacovigilance Safety Monitoring	
AI in Medical Writing - does Chat GPT play a role?	
Insights	
GDPR: First Code of Conduct for Clinical Research	
(DP)² – Data processing and -protection in the age of A.I.	
Lunch	12:00 - 13:00
Breakout Stream 3	13:00 - 14:00
CTR/CTIS	
Burning Questions & Reliable Answers	
Decentralised Clinical Trials	
Home visits in Decentralized Trials – Challenges and Opportunities	
Delivery and Administration of IMP at Home - Issues and Best Practices	
Artificial Intelligence	
AI Powered Patient Enrollment Prediction & Forecasting in Clinical Trial Design	
Insights Breakout Session	
Nature of a Distributed Trial Master File – Practical Aspects	
Computer Systems: End of Life Considerations and Challenges	
Break	14:00 - 14:30
Panel Discussion: Game Changers in the Product Life Cycle	14:30 - 16:00
Closing Remarks	16:00 - 16:15

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