7th Nordic Conference on Pediatric and Orphan Medicines 26-27May, 2026 Helsinki, Finland

Rare Needs, Big Impact: Paediatric & Orphan Medicines in the New EU Framework

Venue and Lecture Room: The University of Helsinki, Athena Building, Athena Hall and Lobby (exhibition area), Siltavuorenpenger 3 A, 00170 Helsinki, Finland.

Day 1: The impact on the EU Pharma Legislation on Pediatric and Orphan medicines

12:00 **Registration**

13:00 Welcome and practicalities, Mia Bengtström, Åbo Akademi University, University of Helsinki

Session 1: Reflections of the new EU Pharma legislation – possibilities and potential impact
Chair: Kaisa Sunela, Head of section, Clinical Assessor, Finnish Medicines Agency – Fimea, Finland

13:10 Nordic University Hospital Alliance (NUHA) views – Malene Fischer, Deputy Chief Executive, Research Director, Research, Innovation & Education, Rigshospitalet, Denmark
13:35 Enpr-EMA and academic networks views – Ricardo Fernandes, Chair, Enpr-EMA, Portugal
14:00 Pharmaceutical industry view – Martine Dehlinger-Kremer, UCB Pharma, Belgium
14:25 PIP Mode of Action (MoA) in oncology– Angeliki Siapkara, Astra Zeneca, Cambridge, U.K.

14.50-15:45 **Coffee, Exhibition & Networking**

Session 2: How can the new legislation enhance clinical trial implementation in practice?
Chair: (TBC)

15.45 EC views – Outi Konttinen, General Secretary, National Committee on Medical Research Ethics, Finland
16:00 Clinical perspective, CTU Research Nurse – Pernille Skovby, Rigshospitalet, Denmark
16.25 Patient & Family view – Rafif Makboul, mother of a son living with Duchenne muscular dystrophy, founder and chair of the Duchenne and Becker Muscular Dystrophy patient organization, Sweden
16:50 Clinician view – Matti Hero, Head Physician, HUS Pediatric CTU, New Children´s Hospital, Finland
17:15 End of the Day 1, Conclusions Day 1, guidance to City Hall, Chair

17:25-17:55 - ***Walking to Old City Hall***

Networking Event
18:00 – 19:00 Networking Event – Reception Hosted by the City of Helsinki
Venue and Address: Old Court House, Aleksanterinkatu 20, 00100 Helsinki

Day 2: The impact of EU Life Science Strategy, Biotech Act and ICH GCP (R3)

Session 3: New Life Science Strategy, ACT EU and ICH GCP (R3) supporting clinical trials in Europe
Chair: (TBC)

09:00 Welcome to Day 2, Chair
09:05 EU Life Science Strategy – Carlos Gómez Muñoz, Policy Officer - DG RTD, EU Commission
09:30 ACT EU Initiative and Workshop with Enpr-EMA – Anette Solli-Karlsen, PDCO, NOMA, Norway
09:55 Cross-Border Access to trials – Tarja Nylund, Lead Clinical Study Manager, Bayer Finland
10:20 Decentralized Clinical Trials – Hanna Sund, Head of Medical Affairs & Patient Access, Oriola, Sweden
10:45 ICH GCP (R3) – Tiina Holmberg, Seconded National Expert at EMA, Inspections Office

11:10-12:10 Lunch, Exhibition and Networking

Session 4: New EU Biotech Act supporting pediatric and orphan medical unmet needs in practice
Chair: (TBC)

12:10 EU Biotech Act – Fabio D'Atri, Policy Officer, EU Commission
12:35 Advancing Personalized Medicine / ATMP products – Company view (TBC)
13:00 Fingenious® - Finnish Biobanks advancing research in rare diseases – Meri Lähteenmäki, FINBB
13:25 Manufacturing ATMPs in academic hospitals: challenges and opportunities – Anna Pasetto, Director, Centre for Advanced Cell Therapy, Section for Cell Therapy, Oslo University Hospital, Norway

13.50 - 14.30 Coffee, Exhibition & Networking

Session 5: Why do we not have more CTs in Nordic countries? Round table discussion about solutions
Moderator: (TBC)

14:30 Introduction of the Round Table discussion - Moderator
- Representatives from industry, hospital clinics, regulatory authority, ethics committee, patients

15:20 Conference conclusions and conference feedback (QR Code) by attendees – Mia Bengtström
15:30 End of the conference - Thank you and goodbye!

This event is supported by (will be updated according to new sponsor agreements):