

# 7th Nordic Conference on Pediatric and Orphan Medicines

26-27 May, 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** Turning the New EU Pharmaceutical Legislation into Reality: Implications for Paediatric and Orphan Medicines – Martine Dehlinger-Kremer, UCB Biosciences, 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: Martine Dehlinger-Kremer, Snr Development Strategy Lead Pediatrics – UCB Biosciences, Belgium

**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: Taneli Raivio, Director of Research and Research Innovation - HUS Helsinki University Hospital, Finland

**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: Samppa Ryhänen, Chief Physician, HUS New Children's Hospital, Finland

**12:10** EU Biotech Act – Fabio D'Atri, Policy Officer, EU Commission

**12:35** Beyond Phase 1–3: Pediatric ATMP Development Across CAR T and HSC Gene Therapy – Jennifer Whangbo, Snr. Global Development Medical Director - Astra Zeneca, USA

**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: How to have more CTs in Nordic countries? Round table discussion about solutions

Moderator: Risto Lapatto, Pediatrician, Chair, FINPEDMED - HUS New Children's Hospital, Finland

**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):



**FINPEDMED**  
Finnish Investigators Network for Pediatric Medicines  
Det nationella nätverket för forskning av barnläkemedel  
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