4th Nordic Conference on Paediatric Medicines – Shaping the environment to facilitate research and access of paediatric and orphan medicines in EU

EU Paediatric Regulation (EC 1901/2006) came into force in 2007 with the aim to improve the health of the children in Europe by increasing the research and authorization of medicines for children and improving the information on medicines designed for children. Since 2013, Finnish Investigators network for Paediatric Medicines – FINPEDMED - have been facilitating academic and Pharma Industry collaboration with the Pharma Industry Finland to support medicine development and clinical trials in the Nordic area. This collaborative conference is fourth in order following the 2017, 2018 and 2019 events.

The 4th Nordic conference is organized by NordForsk Nordic Trial Alliance, FINPEDMED and Åbo Akademi University. In this event we will discuss the new clinical research environment facing the legal reform of the EU Pharmaceutical Strategy, including EU Paediatric Regulation and Orphan Regulation. The reform will benefit paediatric clinical trial processes in Europe. Large collaborative networks and research infrastructures support these changes and new processes by proving unique services and innovative solutions.

Venue: The Business Finland building, Porkkalankatu 1, 00180 Helsinki, Finland.

Hotel, Holiday Inn Helsinki - West Ruoholahti: Sulhasenkuja 3, Helsinki, 00180 Finland

Day 1: Activities along the EU legislation reform in the new research environment

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

EU pharma strategy, paediatric medicine development and access, data, and digital tools
Chair: Pirkko Lepola, FINPEDMED, Enpr-EMA

13:10 The landscape of Paediatric and Orphan medicines - Kalle Hoppu, Helsinki
13:25 Findings from the review of Paediatric Regulation and Orphan Regulation – Fabio D'Atri, European Commission, Belgium
13:50 Towards successful paediatric medicines development and access – Solange Corriol-Rohou, Efpia Clinical Research Expert Group, Astra Zeneca, France
14:15 Towards successful paediatric orphan medicines development – Gesine Bejeuhr, Pediatric Regulatory Leader, Bayer AG, Germany
14:40 How to make treatments for rare diseases less rare? -Tina Taube, Efpia, Belgium
15:05-15:35 Coffee break
15:40 Access to new paediatric medicines in the Nordic countries - Siri Wang, NOMA, Norway
16:05 Data and digital tools in Paediatric clinical trials – Rhian Thomas-Turner, Noah's Ark Children's Hospital for Wales, Cardiff & Vale University, U.K.
16:30 **Panel discussion:** Competent Authority, Patients, EFPIA, PDCO, EC, Ethics Committee
17:20 Thank you for the day and Instructions for the reception
18:00-19:00 Reception - Helsinki Town Hall, Helsinki City

Day 2: How to facilitate paediatric clinical research and collaboration?

European research networks, infrastructures and trial sites, Young Person´s Advisory Groups
Chair: Kalle Hoppu, Helsinki

9:00 Update of c4c -Conect4Children - Katharine Cheng, Johnson and Johnson, U.K.

9:25 Supporting Pediatric Trials through c4c National Hubs and National Networks - Ricardo Fernandes, c4c Network Infrastructure Office and NH Forum, Lead STAND4Kids, Portugal

9:50 Young Person´s Advisory Groups enhancing clinical trials - Begonya Nafria, Sant Joan de Déu Children´s Hospital, Barcelona, Spain

10:05 How Helsinki University Hospital can support Clinical Trials? - Taneli Raivio, HUS, Helsinki

10:35 Nordic Pediatric Clinical Trial Unit development process - Tina Kjellén and Jenny Kindblom, Queen Silvia Children´s Hospital, Gothenburg, Sweden

11:00 ITCC in the Nordic Countries, the Finnish perspective – Virve Pentikäinen, HUS New Children´s Hospital, Helsinki

11:25-12:20 Lunch

Adolescent inclusion to paediatric trials, clinical development centres and Clinical Trial Units, paediatric cancer, and rare disease research
Chair: Pia Annunen, BMS Finland

12:25 Integration of Paediatric Development into Drug Development – 2 examples of how to do it? – Martine Dehlinger-Kremer, ICON Plc., EFGCP and EUCROF, Germany

- The role and benefit of a Centre for Paediatric Clinical Development
- How and when to include adolescents in adult research?

13:00 The NORDICPEDMED Paediatric Research Network´s development progress - René Mathiasen, DanPedMed, Denmark

13:30 How to organize a paediatric Clinical Trials Unit - Sauli Palmu, PeeTu / TAYS, Tampere

13:50 How to enhance the rare disease research? – Mikko Seppänen, HUS, Helsinki

14:20-14:30 Conclusions, Thank you and Goodbye!