



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European network of paediatric research at EMA (Enpr-EMA)

Introduction/Update

Presented by:

Gunter Egger, Paediatric Medicines Office, Scientific Evidence Generation (H-EG)

Jose Drabwell, patient representative in Enpr-EMA's coordinating group

Joint PCWP and HCPWP meeting on 28 February 2024

An agency of the European Union





Legal basis

- **European Paediatric Regulation:** 'The EMA shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.'
- **Launch:** 2011
- Umbrella network (>50 members)
- **Co-chairs:**
 - Pirkko Lepola (Finnish network)
 - Gunter Egger (EMA)





Members of Enpr-EMA

- Paediatric clinical trial networks: National networks; paediatric 'sub-specialty' networks; age-related networks (e.g. neonates)
- Members perform research with children (newborns to adolescents), in multiple therapeutic areas, ranging from pharmacokinetics to pharmacovigilance.
- Other stakeholders of Enpr-EMA: Patients and consumers; healthcare professionals, learned societies; young peoples' advisory groups; PDCO; industry associations
- Europe and beyond (US, Canada, Japan)
- Recognition criteria for membership






Mission

- Facilitate trials to **increase availability of paediatric medicines**
- Provide efficient inter-network and stakeholder **collaboration**
- Build up **competences** at European level
- Raise **awareness** among HCPs, parents, carers, children on need for clinical research
- Enter into dialogue with **ethics committees**
- Facilitate **development of PIPs**
- **Contact point** for industry to facilitate conduct of clinical trials
 - Enpr-EMA does NOT fund studies or act as CRO/manage studies



Searchable database of Enpr-EMA members

Search | Contact



Welcome to the EnprEMA Network Database

This database includes research networks and centres with recognised expertise in performing clinical studies in children. It is part of the European network of paediatric research at the European Medicines Agency (Enpr-EMA).

About the database:

This database provides easy access to data about each individual Enpr-EMA network. The information includes sources of expertise and research experience across Europe. This is the central resource for researchers and study sponsors seeking to identify research networks for paediatric clinical trials in Europe. Centres can be identified through networks. The available data reflect the information received by the EMA every two years in the networks' self-assessment forms, including:

- Network identification and contact details
- Network description (including size of the network)
- Research experience and ability
- Scientific competencies and capacity to provide expert advice
- Quality management
- Training and educational capacity to build competences
- Public involvement

The database is fully searchable and allows the identification of Enpr-EMA registered networks in several ways (please see search page):

1. A global search (this will search on the entire information provided in the network self-assessment forms)
2. A detailed search (this will search on specific and relevant parts of the network self-assessment forms)

<http://enprema.ema.europa.eu/enprema/>



What does Enpr-EMA do to fulfil its mission?

- Provides neutral platform for **communication** between various groups
- Shares **best practices, guidance, expertise** on paediatric research
- Provides network opinions to **PDCO**
- Updates members on **regulatory news, research advances**
- Provides/collates responses to **public consultations**
- Provides access information on **EC framework programmes**
- Organises **annual meeting/workshop** for all stakeholders (and regular coordinating group meetings)
- Forms ad-hoc **working groups**
- **Publishes information on networks/sites** on website (→ identification of centres with capability to conduct trials)



Recent output of Enpr-EMA working groups

Some recent achievements of Enpr-EMA & its working groups :

- Guidance for **collaboration between networks and industry**
- Information on **informed consent/assent** requirements in Europe
- Guidance on **clinical trial preparedness**
- Publication on **repurposing of products** used off-label in paediatrics

A summary of Enpr-EMA's recent activities can be found here:

https://www.ema.europa.eu/en/documents/report/report-2023-annual-workshop-european-network-paediatric-research-ema-enpr-ema_en.pdf



Current priority activities of Enpr-EMA working groups

- Defining **quality criteria for paediatric clinical trial sites**
- Strengthening role of **paediatric research nurse** across Member States
- **Inclusion of paediatric patients across borders**
- **Guidance on CTA process** and ethics approval across jurisdictions (EU, US, UK, Can, Jap, Aus)
- Linking up with **ACT-EU** (e.g. methodology workshop, guideline review)



The EU Paediatric Regulation is a success; the EC's proposal for a new pharmaceutical legislation provides an opportunity to further improve the regulatory environment.



Extended remit of Enpr-EMA in proposed legislation

Proposed Regulation, Art 95:

*The Agency shall develop a European network of **patient representatives, academics, medicines developers**, investigators and centres with expertise in the performance of studies in the paediatric population.*

*The objectives of the European network shall be, inter alia, **to discuss priorities in the clinical development of medicines for children, in particular in areas of unmet medical need**, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.*



Annual open Enpr-EMA workshop/meeting

Who: All stakeholders involved in paediatric clinical research

*When: planned **2nd October 2024***

I am Jose Drabwell and represent IPOPI at the PCWP

Many years ago I was asked to represent PCWP at the Enpr-EMA coordinating group and the general meetings/workshops.

Over time I have informed paediatricians about Enpr-EMA, shared the contacts of some European clinical research nurses. Also made the members aware of DCT's especially important for kids. Did some networking about the use of AI in hospitals.

Although I am more of an observer due to the fact that I am neither a paediatrician nor represent industry, I feel that I have made valuable contributions to this and ensured that the patients voice was heard



Thank you

Further information:

<https://www.ema.europa.eu/en/partners-networks/networks/european-network-paediatric-research-european-medicines-agency-enpr-ema>

Contact:

enprema@ema.europa.eu