

Report from the coordinating group (CG)

Update on Enpr-EMA activities, achievements and challenges

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European network of paediatric research
at the European Medicines Agency



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Topics

- Background
- Activities
- Achievements
- Challenges



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Mission statement of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)

Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.

This will be achieved by:

- ☐ Fostering high quality ethical research on the safety and effectiveness of medicines for children.
- ☐ Establishing a European paediatric research network of national and European specialty networks, investigators and centres with expertise in performing trials in the paediatric population.



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Mission statement of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)

- ☐ Efficient inter-network and stakeholder collaboration in order to build up the necessary competences at Community level and to avoid unnecessary duplication of studies.
- ☐ To inform parents, carers, children and young people about clinical trials and encourage their participation.
- ☐ Raising awareness among health care professionals of the need for clinical trials in all ages of children and supporting their involvement in such studies.
- ☐ Assisting and entering into discussions with ethics committees on issues relevant to research and clinical trials in children.



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Activities

- Working Groups
- Meetings
 - Coordinating Group 27th January
 - Chairs and Secretariat, 6 weekly
- Chairs' Activities
 - Advocacy, e.g. Transcelerate, FDA.
- Industry involvement (IE)
- Drafting paper about children's roles in networks (BP)



Activities

- Dialogue with new networks



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Achievements

- Information about networks on EMA website
 - Question 31
- Searchable database
- Dialogue between networks
 - Working Groups
- Abstract accepted by European Academy of Paediatric Societies (Barcelona, October 2014)



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Questions and answers: Paediatric-investigation-plan guidance

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This page lists questions that applicants for [paediatric investigation plans](#) (PIPs) may have before submitting an application. The information is available as questions and answers, which the Agency revises as necessary.

Q31. Why should I consider involving paediatric networks when preparing the PIP? New January 2014

A30. The European Network for Paediatric Research at the European Medicines Agency ([EnprEMA](#)) provides a point of contact for a number of specialty and multi-specialty networks. Early involvement of clinical research networks may help to develop a PIP in a number of ways, and should be considered when preparing the application. Areas of expertise that can be offered by Enpr-EMA members are reported in the [Enpr-EMA database](#).

Networks may provide assistance in the following areas: identification of existing databases, location of study sites and investigators to conduct natural history studies, access to clinicians who can provide data about patient throughput or develop bespoke feasibility assessments, definition of important paediatric needs, priorities and relevant outcomes, identification of acceptable trial procedures / visit schedules, and clarification of other scientific questions.



Searchable database

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



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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).



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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



Searchable database

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

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)

e.g.:

- Country
- Paediatric age ranges of study participants covered by the network
- Preterm and/or term newborn
- Infants from 1 month to less than 24 months of age
- Children from 2 years to less than 12 years of age
- Adolescents from 12 years to less than 18 years
- Specialties/conditions covered
- Speciality or disease specific
- Number of collaborating countries
- Number of collaborating centres
- Type of activities / studies



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Characteristics of good networks

- “Meaningful nearness”
- Constructively shared interests
- Bridges



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Single contact point for all European networks

Single point of contact for all European paediatric clinical research networks

enprema@ema.europa.eu



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