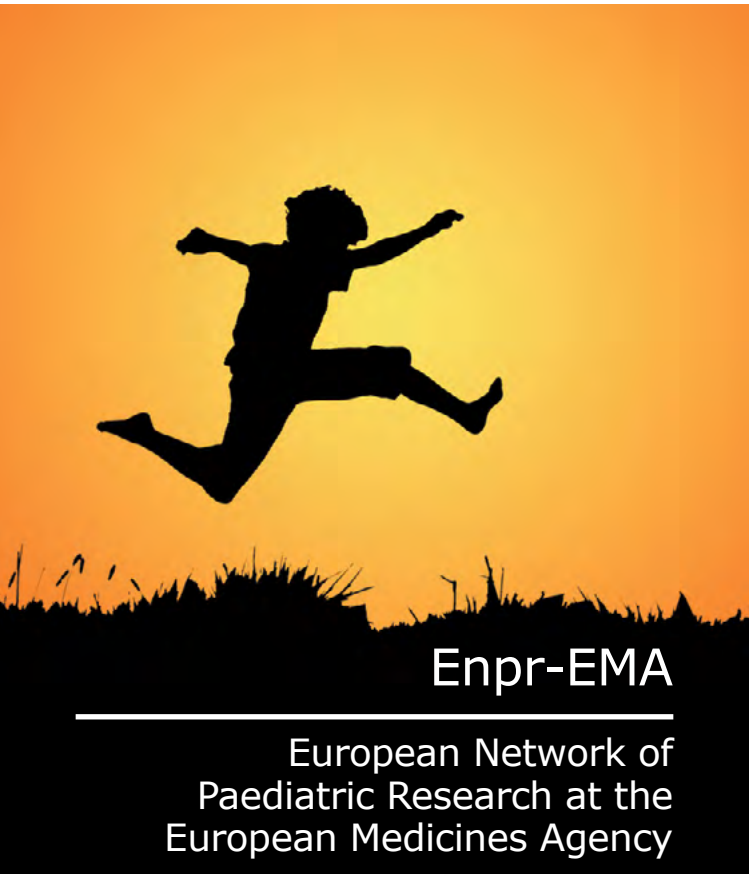
European Network of Paediatric Research at the European Medicines Agency



Enpr-EMA

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

An agency of the European Union

European Network of Paediatric Research at the European Medicines Agency

Mission statement

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

Aims of the network

Enpr-EMA aims to fulfil its mission by:

- establishing a European paediatric research network of national and European specialist networks, investigators and centres with expertise in performing paediatric clinical trials to foster high-quality, ethical research on the safety and effectiveness of medicines for children;
- efficient inter-network and stakeholder collaboration, to build up the necessary competences at European Union level, and to avoid unnecessary duplication of studies;
- raising awareness among healthcare professionals, parents, carers, children and young people of the need and support for paediatric clinical trials;
- assisting and entering into dialogue with ethics committees on issues relevant to research and clinical trials in children.

Legal background

One of the objectives of the Paediatric Regulation (Regulation (EC) No 1901/2006) is to foster high-quality ethical research on medicinal products to be used in children. This should be achieved through efficient inter-network and stakeholder collaboration.

To meet this objective, the European Medicines Agency established Enpr-EMA, officially launched and presented to stakeholders in March 2011.

Early consultation of Enpr-EMA members is encouraged in the new Commission guideline on paediatric investigation plans (PIPs) to facilitate the development of a PIP.

Recognition criteria

Enpr-EMA's members are required to fulfil a list of criteria in six categories, namely:

- research experience and ability;
- network organisation and processes;
- scientific competencies and ability to provide expert advice;
- quality-management;
- training and educational capacity to build competences;
- public involvement.

Operational structure

The operational centre of Enpr-EMA is the Coordinating Group (CG), which is responsible for the network's long- and short-term strategy.

The European Medicines Agency provides the

secretariat support, and organises and hosts Enpr-EMA meetings. A workshop open to all stakeholders is held at the Agency once a year.

Main tasks of the Coordinating Group

- Facilitate the pharmaceutical industry's access to paediatric clinical-study centres and experts.
- Identify new and emerging networks, and invite them to apply for Enpr-EMA membership.
- Act as a forum for communication.
- Discuss and resolve operational and scientific issues.
- Develop common educational tools for children and parents, and encourage their participation in clinical trials.
- Liaise with the European Medicines Agency's Paediatric Committee (PDCO), which is the scientific committee of the network.

Enpr-EMA overview

The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population.

Members

Enpr-EMA members perform research in children (from newborns to adolescents) in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance. A fully searchable database provides easy access to each individual Enpr-EMA network:

http://enprema.ema.europa.eu

Would you like to join Enpr-EMA?

Networks, centres or investigators interested in becoming members of Enpr-EMA are invited to complete a self-assessment form (available on the European Medicines Agency's website) and send it to:

enprema@ema.europa.eu

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Further information

Visit **www.ema.europa.eu** and click on this banner:

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