



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

Patients' and Consumers' Working Party Meeting
13th September 2011



Aim of this presentation

- **To introduce Enpr-EMA:**
background, stakeholders, milestones, patients' role
- **To discuss how possible ways to collaborate and cooperate could be initiated and established.**
- **Most importantly to get your feedback** 😊

Introduction and background of Enpr-EMA

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.”

Introduction and background of Enpr-EMA

Mission Statement:

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

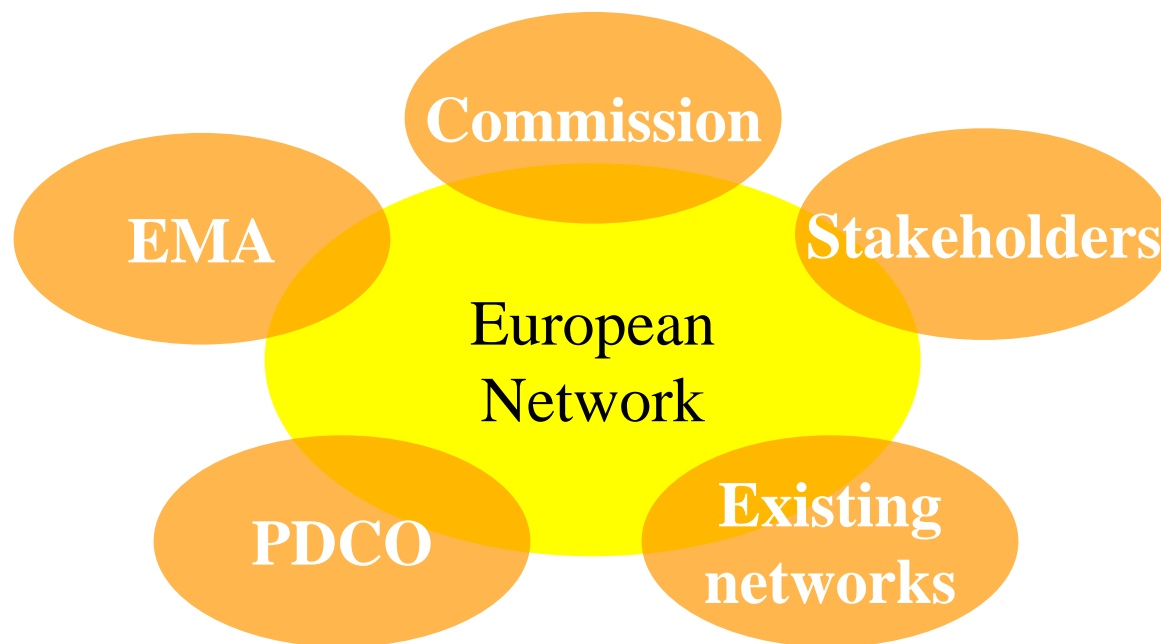
Introduction and background of Enpr-EMA

This will be achieved by:

- Fostering high quality ethical research on the safety and effectiveness of medicines for children.
 - 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 collaborating with ethics committees on issues relevant to
- 5 research and clinical trials in children.

Introduction and background of Enpr-EMA

Organisation and structure



Introduction and background of Enpr-EMA

Stakeholders

- Pharmaceutical Industry
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics Committees
- Medical devices industry
- CRO's
- Hospital pharmacists
- Laboratories and imaging centres

What has been achieved so far?

- Identification of existing networks
- Implementation strategy adopted by EMA Management Board (01/2008)
- 1st workshop with existing networks (02/2009)
- 2 working groups:
 - WG 1:** structure and operational model (06/2009)
 - WG 2:** definition of recognition criteria (Public consultation 02/2010)
- 2nd workshop with existing networks (03/2010)
- Publication of finalised recognition criteria for self-assessment (05/2010)

What has been achieved so far?

- 3-month period for networks to do self-assessment and publish results
- Self-assessment reports screening and clarifications requested
- Publication of list of Networks members of Enpr-EMA (01/2011)
- 3rd workshop with existing networks and industry representatives (03/2011)
- 1st Coordinating Group face to face meeting (06/2011)
 - Mission statement, Mandate, and Conflict of Interest policy agreed
 - Communication strategy: visibility and website (adopted)
- Currently 33 networks:
 - Category 1: 18
 - Category 2: 1
 - Category 3: 14

Enpr-EMA information: <http://www.ema.europa.eu>



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About Us

The European Medicines Agency is a decentralised body of the European Union located in London

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on medicines

A report written by an independent expert has highlighted a number of recommendations to help improve the European Medicines Agency's communication on the benefits and risks of medicines. ... [Read more](#)

30/05/2011 **European Medicines Agency website updated with new pages**

The European Medicines Agency's website, ema.europa.eu, has been updated with three new types of content. ... [Read more](#)

27/05/2011 **Report and videos available from Enpr-EMA launch**

The European Medicines Agency has published the report from the third workshop on the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA). ... [Read more](#)

27/05/2011 **European Medicines Agency recommends revaccination for some travellers in need of protection with Ixiaro**

The European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) was informed that a specific batch of the Japanese encephalitis vaccine Ixiaro (batch JEV09L37), manufactured by Intercell AG, may be less potent than expected and may not induce a full

Counterfeit medicines



Enpr-EMA

ENEPP Network

EU Telematics

EudraCT EudraGMP eSubmission EudraPharm EudraVigilance

Enpr-EMA information: <http://www.ema.europa.eu>

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European Network of Paediatric Research at the European Medicines Agency

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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 studies in children.

Enpr-EMA aims to foster **high-quality ethical research** on quality, safety and efficacy of medicines to be used in children. It does this through networking and stakeholder collaboration with members from within and outside the European Union (EU).

Enpr-EMA's main objectives are to:

- foster high-quality, ethical research on medicines for use in children;
- enable collaboration between networks and stakeholders;
- co-ordinate studies relating to paediatric medicines and avoid unnecessary testing in children;
- build up scientific and administrative competence at a European level;
- help with the recruitment of patients for clinical trials;
- promote European Commission framework programme applications.

Enpr-EMA does not perform clinical trials or fund studies or research or decide on areas for paediatric research, as this is the responsibility of Member States, the European Commission or each individual network.

Related information

- [Medicines for children](#)
- [Paediatric Committee](#)
- [Paediatric medicine development](#)
- [The network of Paediatric Networks at the EMA implementing strategy \(15/01/2008\)](#)

Contact point:

enprema@ema.europa.eu

Enpr-EMA information: <http://www.ema.europa.eu>

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Following a call for expressions of interest in 2010, the [European Network of Paediatric Research at the European Medicines Agency](#) (Enpr-EMA) published a full list of applicants for Enpr-EMA membership in January 2011.

To date, a total of **33 networks and centres** have submitted self-assessment reports. These documents are published below and are categorised according to ability to fulfil the criteria for membership:

- **Category 1** includes the 18 networks and centres that are now **members of Enpr-EMA**;
- **Category 2** includes the networks and centres currently undergoing **clarification** before membership of Enpr-EMA;
- **Category 3** includes the networks and centres that **do not currently qualify** for membership.

Networks which currently do not yet fulfil all minimum criteria are still informed of all news and relevant information concerning Enpr-EMA. The Agency will also invite them to take part in the annual Enpr-EMA workshops.

The Agency encourages all networks to **update their self-assessment** at least once a year or to inform the Agency when they meet the criteria and submit revised reports.

Networks, centres, or investigators interested in **becoming members** of Enpr-EMA can also complete the [self-assessment form](#) and send it to merja.heikkurinen@ema.europa.eu.

In addition, see the complete [list of network members of Enpr-EMA](#) and other networks not yet fulfilling all criteria, with links to the networks websites.

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- ✚ **Category 1: Networks fulfilling all minimum criteria for membership of Enpr-EMA**
- ✚ **Category 2: Networks currently undergoing clarification before membership of Enpr-EMA**
- ✚ **Category 3: Networks currently not qualifying for Enpr-EMA membership**

Self-assessment report

Networks should be recognised by quality of paediatric research
Recognition criteria and quality standards for self-assessment elaborated
6 Criterion:

- **Research experience and ability**
- **Efficiency requirements**
- **Scientific competencies and capacity to provide expert advice**
- **Quality management**
- **Training and educational capacity to build competences**
- **Public involvement**

To become member of Enpr-EMA a set of minimum recognition criteria had to be fulfilled

Criterion 6: Public involvement

- 6.1. Involvement of patients, parents or their organisations in the protocol design.
- 6.2. Involvement of patients, parents or their organisations in creating the protocol information package.
- 6.3. Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children.

To become member of Enpr-EMA involvement in at least one of the above items.

Suggestions for collaboration between Enpr-EMA and PCWP

- Our Aim is to increase awareness of the need to participate in paediatric trials, AND increase patient participation in protocol design, protocol information package and prioritisation of needs for clinical trials in children.
- We have a few high level suggestions BUT we need your feedback.
- To link available webpages
 - On Enpr-EMA webpage to create a section for Patients organisations & link to their own pages?
 - On patients organisations websites to create a link to Enpr-EMA pages?
- Active collaboration with a PCWP representative? Would you consider nominating a contact person?? Participation in Annual workshop? CG meetings?

Collaboration between Enpr-EMA and PCWP

**Thank you for your attention,
Any feed back will be greatly appreciated**