



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

## Background of Enpr-EMA

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## Introduction and background

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### 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

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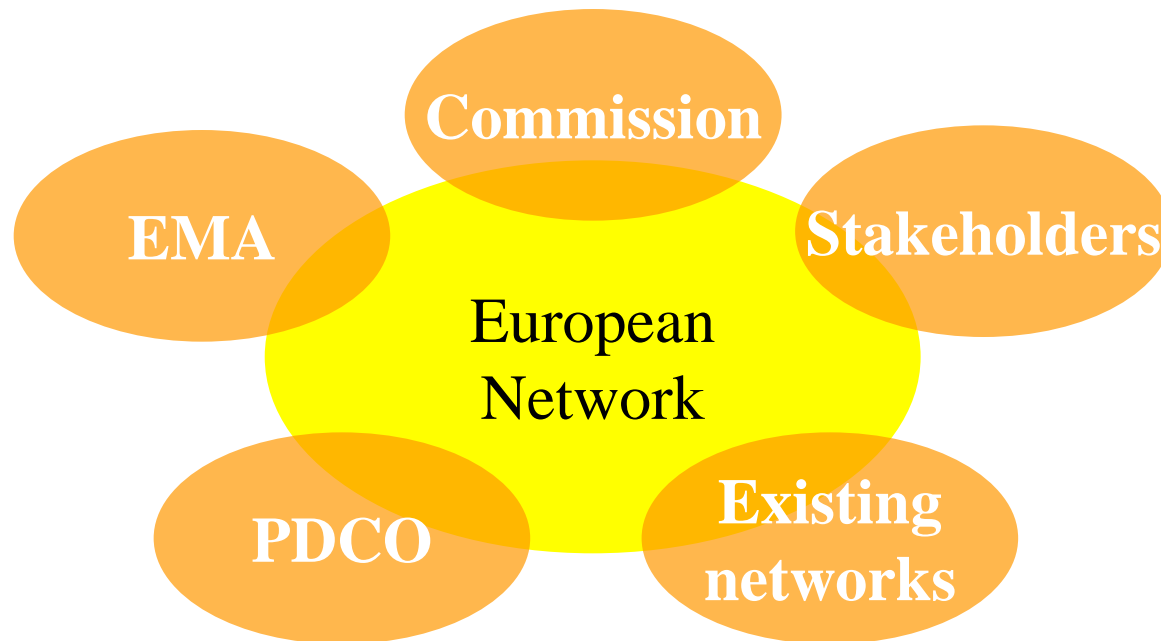
### Objectives/Operational goals of Enpr-EMA

- Collaboration and communication (between existing networks and stakeholders)
- Facilitation of recruitment in clinical trials (providing expertise and access to infrastructure for industry to conduct studies in children)
- Building competences (defining strategies for resolving major challenges)
- Avoiding unnecessary studies
- Stimulating high quality research (defining consistent and transparent quality standards; harmonising clinical trial procedures)
- Strengthening the foundations of the European Research Area

## Introduction and background

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### Organisation and structure



## Introduction and background

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### 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?

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- Identification of existing networks
- Implementation strategy adopted by EMA Management Board (Jan 2008)
- 1<sup>st</sup> workshop with existing networks (Feb 2009)
- 2 working groups:
  - WG 1:** structure and operational model (June 2009)
  - WG 2:** definition of recognition criteria (Public consultation Feb 2010)
- 2<sup>nd</sup> workshop with existing networks (March 2010)
- Publication of finalised recognition criteria for self-assessment (May 2010)
- 3-month period for networks to do self-assessment and publish results.
- Self-assessment reports screening and clarifications requested (Dec 2010)
- Publication of list of Networks members of Enpr-EMA (Jan 2011)
- 6 ➤ 3<sup>rd</sup> workshop with existing networks and industry representatives (March 2011)

## Coordinating Group (background info)

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### **Role of the Coordinating Group:**

- to contribute to the short and long-term strategy of the network
- to discuss and solve operational and scientific issues for the network
- to discuss and agree scientific quality standards
- to act as a forum for communication

## Self-assessment report

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**Networks should be recognised by quality of paediatric research**

**To elaborate and agree on recognition criteria and quality standards for self-assessment in the following areas:**

➤ **Capacity**

- to involve patients (for study design and for recruitment)
- to manage trial and to perform trials according to GCP
- to build up competence and to involve further centres
- to innovate in trials (methodology, techniques, e.g. microassays)

➤ **Expertise in the therapeutic area**

➤ **Established quality assurance systems of the network**

➤ **Potential conflicts of interest**

➤ **Ability and content to share in relation to competencies and experience**

*(the elaboration of the self-assessment report was performed using the Delphi and Nominal Group consensus techniques)*



## Breakdown of networks by type and category

- Table of the current networks and their status:

National	Oncology/ Haematologic Malignancies	Diabetes/ Endocrinology/ metabolic disorders/ Gynaecology	Gastroenterology/ Hepatology	Allergology/ Immunology/ Rheumatology	Stem Cell and Organ Transplantation/ Haematology(non malignant) /Haemostaseology	Respiratory diseases /Cystic Fibrosis
NIHR-MCRN	Newcastle-CLLG	AMIKI	ESPGHAN	PRINTO	EBMT	ECFS-CTN
FinPedMed	ITCC			JSWG of PRES	IPTA	
MCRN-NL	IBFMSG					
MICYRN	EPOC					
Scotmcn	CLG- of EORTC					
CICPed						
IPCRN						
NCCHD						
BLF						
RIPPS						
Futurenest CR						
BPDN						

**Category 1:** Networks fulfilling all minimum criteria for membership of Enpr-EMA.

**Category 2:** Networks potentially fulfilling all minimum criteria – but needing to clarify some issues before becoming a member of Enpr-EMA.

**Category 3:** Networks currently not yet fulfilling minimum criteria.

Cardiovascular diseases/ Nephrology	Psychiatry/ Neurology	Infectious diseases/ Vaccinology	Intensive Care/Pain/ Anaesthesiology/ Surgery	Special Activities / Age Groups	European neonatal network	European paediatric pharmacists	special activities (Phv, long term follow up, community paediatricians)	Unable to fill self- assessment report
	EUNETHYDIS	PENTA UKPVG			GNN		FIMP-MCRN	Expertise in clinical trial methodology
		PENTI			EuroNeoNet Neo-circulation			TEDDY PRIOMEDCHILD ECRIN GRIP
					INN			

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

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30/05/2011 **European Medicines Agency website updated with new pages**  
The European Medicines Agency's website, [ema.europa.eu](http://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

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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](mailto:enprema@ema.europa.eu)





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### Enpr-EMA membership

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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](mailto: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**