EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Introduction

Contact: enprema@ema.europa.eu
Web: https://www.ema.europa.eu/en/partners-networks/networks/european-network-paediatric-research-european-medicines-agency-enpr-ema

Last updated: October 2020

Objectives of the EU Paediatric Regulation

(Regulation (EC) No 1901/2006, in force since Jan 2007)

- Improve the health of children:
  - Increase high quality, ethical **research** into medicines for children
  - Increase **availability** of authorised medicines for children
  - Increase **information** on medicines
- A system of OBLIGATIONS and REWARDS
- Main pillars
  - Paediatric Committee (PDCO)
  - Paediatric Investigation Plan (PIP)

Paediatric Committee (PDCO) and Paediatric Investigation Plans (PIP)

Paediatric Committee (PDCO)

- Main role:
  - Assessing content of PIPs, waiver applications
  - Providing advice on questions on paediatric medicines, at request of Eur Commission
  - Advising Member States (MS) on surveys on uses of medicines in children
  - Establishing inventory of paediatric medicine needs
  - Advising & supporting Enpr-EMA
- Plenary meeting each month
- 36 Members (+36 alternates), including 3 (+3) patient representatives and 3 (+3) health care professional representatives

Paediatric Investigation Plan (PIP)

- Basis for development and authorisation of a medicinal product for all paediatric population subsets
- Includes details of the timing and the measures/studies proposed, to demonstrate:
  - Quality
  - Safety
  - Efficacy

Marketing Authorisation Criteria → Benefit/risk

- To be agreed upon and/or amended by the PDCO
- Binding on company → compliance check
  (but modifications possible, at the company's request)

Enpr-EMA

Enpr-EMA
European network of paediatric research at EMA

An umbrella network of research networks, investigators and centres with recognised expertise in performing paediatric clinical trials

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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.'
- Launch: 2009
- 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 included in Enpr-EMA: Learned societies; patient organisations; young peoples' advisory groups; PDCO members; healthcare professional organisations, industry associations as observers
- Europe and **beyond** (US, Canada, Japan)

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

Recognition criteria for member networks

- 6 recognition criteria and quality standards for self-assessment
    1. Research experience and ability
    2. Efficiency requirements
    3. Scientific competencies and capacity to provide expert advice
    4. Quality management
    5. Training and educational capacity to build competences
    6. Involvement of patients, parents or their organisations
- Each criterion composed of several sub-items
- Set of minimum criteria to be fulfilled
- Self-assessment to be updated every 2 years

Member networks by type & category

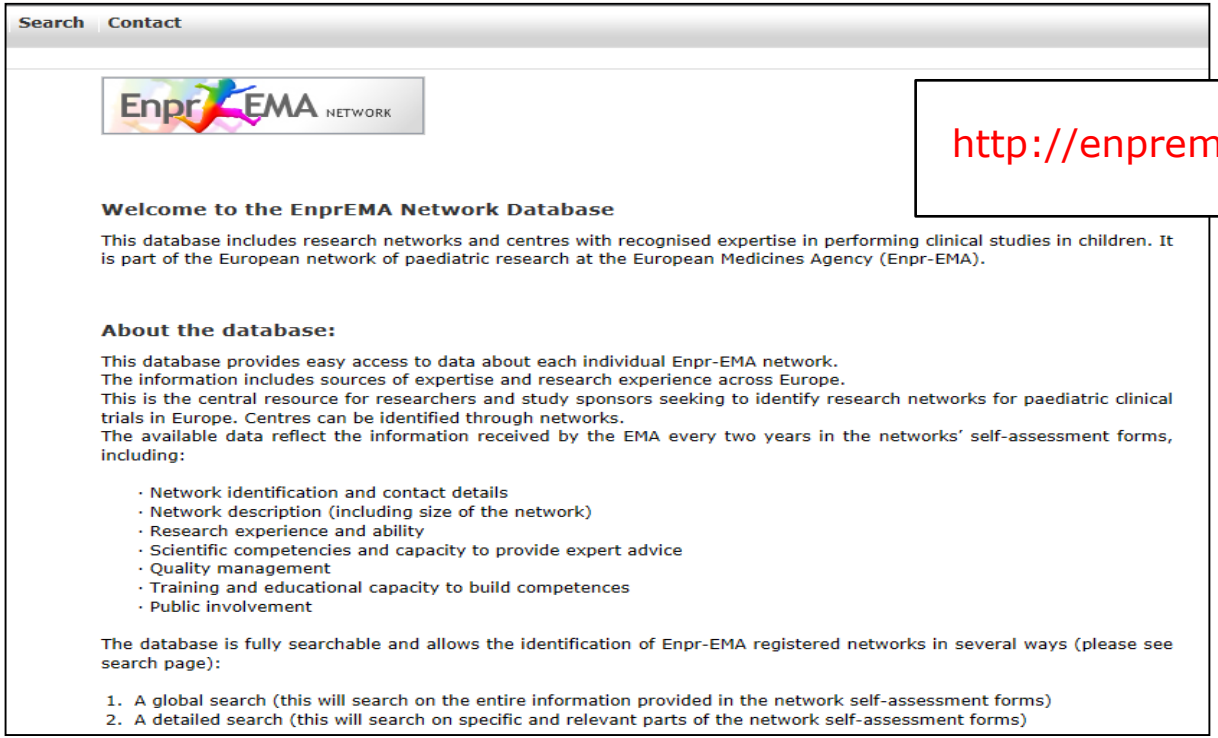
National	Oncology/ Haematologic Malignancies	Diabetes/ Endocrinology/ metabolic disorders/ Gynaecology	Gastroenterology/ Hepatology	Allergology/ Immunology/ Rheumatology	Stem Cell /Organ Transplantation/ Haematology/Haemostaseology	Respiratory diseases /Cystic Fibrosis
DCRI	ITCC		EPLTN	PRINTO	EBMT PDWP	ECFS-CTN
NIHR-CRN	Newclastle-CLLG		PEDDCReN	JSWG of PRES		SPACE
ScotCRN	I-BFM-SG		PIBD-Net	JIA uveitis WG		
FinPedMed						
Pedmed-NL	EORTC CLG					
MICYRN	CEPOETA					
RECLIP						
RIPPS						
OKIDS						
NorPedMed						
MCRN-Hungary						
IPCRN						
PEDSTART						
SwissPedNet						
STAND4Kids						
NCCHD-Japan						
c4c						
HunPedNet						
NETSTAP						
PCIC-Belgium						

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.
Category 4: Networks not performing clinical trials; e.g. methodology, infrastructure, etc.

SPECIAL ACTIVITIES / AGE GROUPS

Psychiatry/ Neurology	Infectious diseases/ Vaccinology	Intensive Care/Pain/ Anaesthesiology/ Surgery	European neonatal network	European paediatric pharmacists	special activities (Phv, long term follow up, community paediatricians)	Expertise in clinical trial methodology
EUNETHYDIS	PENTA-ID	ESPNIC	GNN		FP-MCRN	TEDDY
ECAPN	UKPVG		INFANT			eYPAGnet
	ReSViNet		Neo-circulation			EAPRASnet
	RITIP		ESDPPP			TREAT-NMD
			Red SAMID			

Searchable database of Enpr-EMA members



Search Contact

Enpr EMA NETWORK

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/

Enpr-EMA's main stakeholders

- Research networks and learned societies
- Pharmaceutical industry
- CROs
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics committees
- Hospital pharmacists
- Research nurses

What does Enpr-EMA do to fulfil its mission?

- Shares **best practices** and expertise with centres/networks on paediatric research
- Provides **guidance** and **connection** between stakeholders
- Facilitates communication between various groups
- Facilitates **communication with PDCO**
- Updates members on **regulatory news** & collates responses to **public consultations**
- Facilitates access to **SMEs** for collaboration
- Supports ad hoc **working groups**
- Provides access information on **EC framework programmes**
- Organises **annual workshop** for all stakeholders
- Organises regular coordinating group meetings (3/year)
- Provides regular **newsletter** to stakeholders
- Provides secretariat and support for meetings

What does Enpr-EMA NOT do?

- Fund studies
- Act as CRO or manage studies
- Decide on research priorities

Because these are the responsibility of:

- the Member States
- the European Commission through Community programmes
- each individual network

Networks: Why should you join Enpr-EMA?

To increase visibility as potential site(s) for industry-sponsored studies

- to gain access to SMEs for collaboration
- to present your centre/network at European level
- to save resources by sharing work, avoiding duplication
- to share skills and expertise with other centres/networks
- to shape the future development in paediatric research
- to access information on EC framework programmes

Industry: What can Enpr-EMA offer to industry

- Contacts to pool of patients for inclusion in trials
- Speeding up of trial recruitment
- Expert advice
  - treatment options (standard of care)
  - paediatric needs
  - feasibility of paediatric clinical trials
- Access to academic partners through collaboration with the EMA's SME office

Enpr-EMA - Coordinating Group

Role of the Coordinating Group

1. to contribute to the short and long-term strategy of the network
2. to address operational and scientific issues for the network
3. to agree scientific quality standards
4. to act as a forum for communication

Priority activities / working groups

Some outputs of Enpr-EMA working groups :

- Guidance for collaboration between networks and industry
- Information on informed consent/assent requirements in Europe
- Guidance on clinical trial preparedness

More information on current priority activities can be found here:

https://www.ema.europa.eu/en/partners-networks/networks/enpr-ema/enpr-ema-priority-activities

What can Enpr-EMA offer?

- Neutral platform for dialogue between academia, industry, patients, regulators
- Exchange of best practices
- Parent/patient input and feedback (e.g. feasibility, use of diaries, trial duration)
- Update on research advances, e.g. novel biomarkers, ongoing EU funded research projects, paediatric needs, patient/disease registries
- For industry / researchers: Identification of centres with capability to conduct (global) trials, with large pool of patients for inclusion
- For PDCO: Network opinion (e.g. feasibility, paediatric needs, standard of care)

Thank you

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