EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA

European Network of Paediatric Research at the European Medicines Agency

Exploring commonalities between the networks

An agency of the European Union

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Introduction and background

- Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population
- Members perform research with children (newborns to adolescents), in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance

Introduction and background

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."

Mission statement

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

Mission statement

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 necessary competences at EU level and to avoid unnecessary duplication of studies.
- Informing 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 discussion with ethics committees on issues relevant to research and clinical trials in children.

Main Stakeholders

- Pharmaceutical Industry
- CRO's
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics Committees

Recognition criteria

- Networks to be recognised by quality of paediatric research
- 6 recognition criteria and quality standards for self-assessment
  - ➢ **Research experience and ability**
  - ➢ **Efficiency requirements**
  - ➢ **Scientific competencies and capacity to provide expert advice**
  - ➢ **Quality management**
  - ➢ **Training and educational capacity to build competences**
  - ➢ **Involvement of patients, parents or their organisations**
- Each criterion composed of several sub items
- Set of minimum criteria to be fulfilled
- Self-assessment to updated annually

Arch Dis Child 2012;97:185-188

Recognition criteria for self-assessment

Criteria for the recognition of an investigator*, site* or network as a member of the EnprEMA

* only when the investigator or the site is not part of a network

Identification M

Name		Include legal address, define acronyms
Type		Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street		
Postal code		
Town		
Country		
Telephone 1		
Telephone 2		
Mobile phone		
Fax		
Web site		If available (see criterion 4)
Email for general enquiries		If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available

www.
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EnprEMA NETWORK

ENEPD Network

Scroll down to

Breakdown of networks by type and 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
NIHR-MCRN	Newclastle-CLLG	AMIKI	ESPGHAN	PRINTO	EBMT	ECFS-CTN
ScotCRN	EPOC					
FinPedMed	ITCC			JSWG of PRES	IPTA	
MCRN-NL	IBFMSG					
MICYRN	CLG- of EORTC					
CICPed						
IPCRN						
NCCHD						
BLF						
RIPPS						
Futurenest CR						
SwissPedNet						
Red SAMID						
NCCHD-Japan						

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.

Unable to fill self-assessment report

SPECIAL ACTIVITIES / AGE GROUPS

Cardiovascular diseases / Nephrology	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	Pediatric Critical Care	GNN		FIMP-MCRN	TEDDY
		UKPVG		EuroNeoNet			PRIOMEDCHILD
				Neo-circulation			ECRIN
				INN			GRIP
				ESDPPP			

What Enpr-EMA can offer to industry

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

What Enpr-EMA does not do

- **fund** studies
- act as a **CRO** and **manage** studies
- **decide** on research priorities which

remain the responsibility of

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

Potential Cooperation Enpr-EMA - ENCePP

Scientific:

- Encourage Enpr-EMA members with expertise in PhE and PhV to become partner of ENCePP
- To contribute to paediatric aspects for methodological standards

Organisational:

- To circulate paediatric related industry queries to Enpr-EMA
- How to increase visibility to industry
- How to acknowledge and raise visibility of active members
- How to motivate members to actively contribute

Where to find information - contact details

- www.ema.europa.eu - Enpr-EMA
- enprema@ema.europa.eu

Brochure

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.

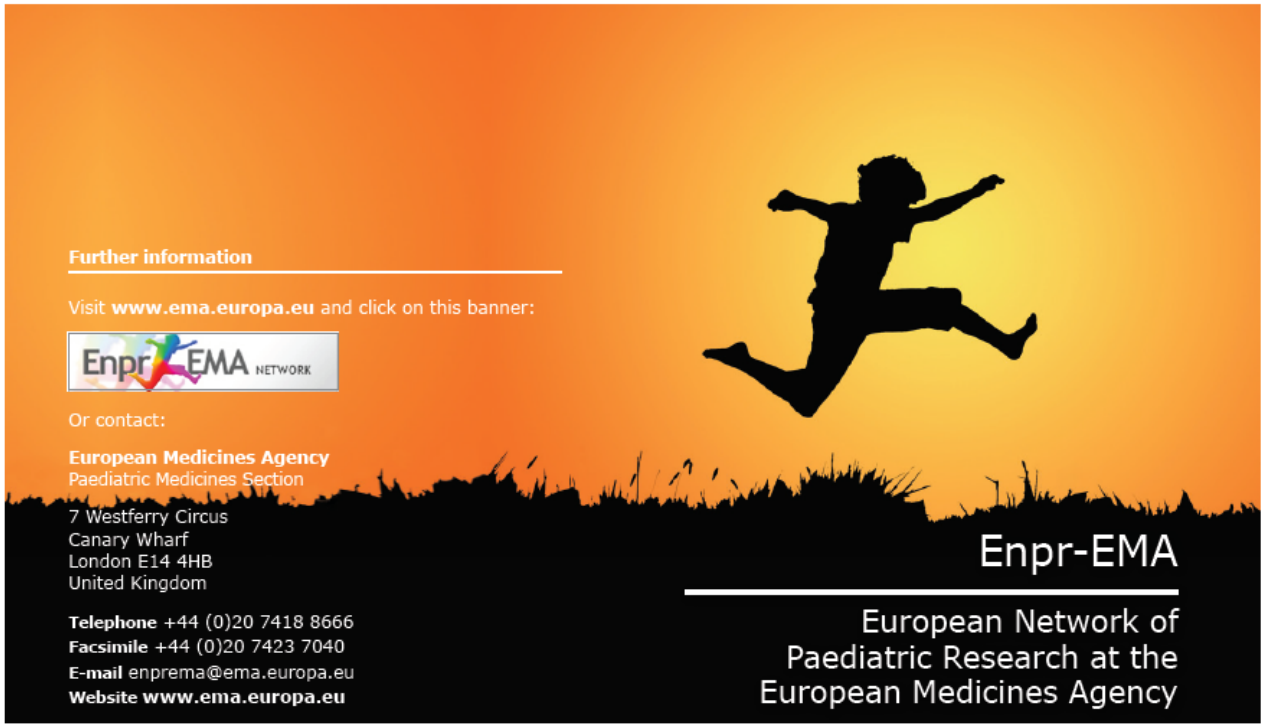
Members

Enpr-EMA members perform research in children (from newborns to adolescents) in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance.

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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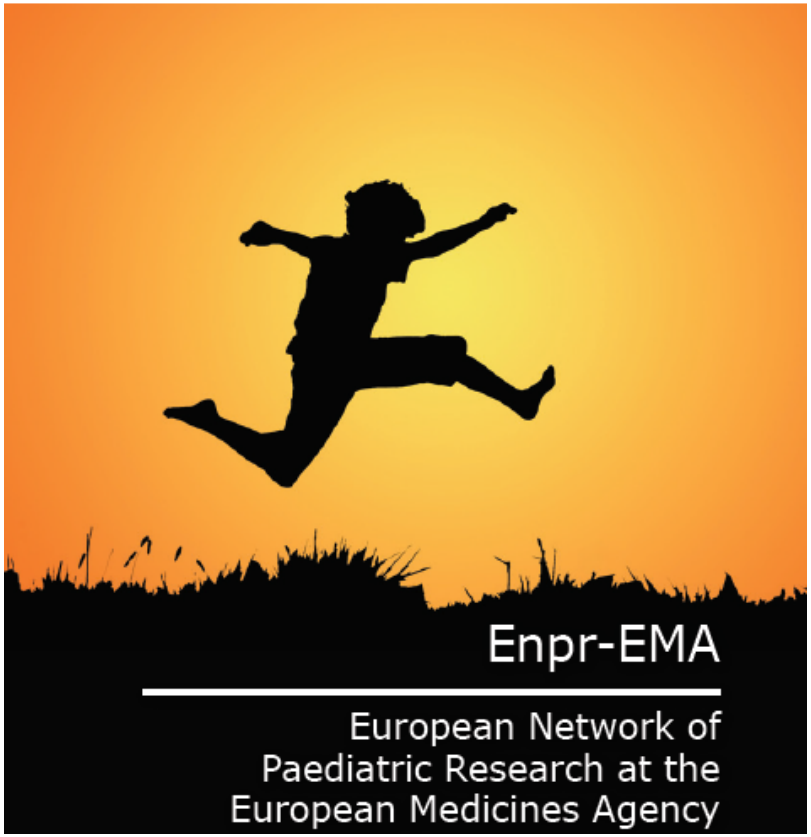
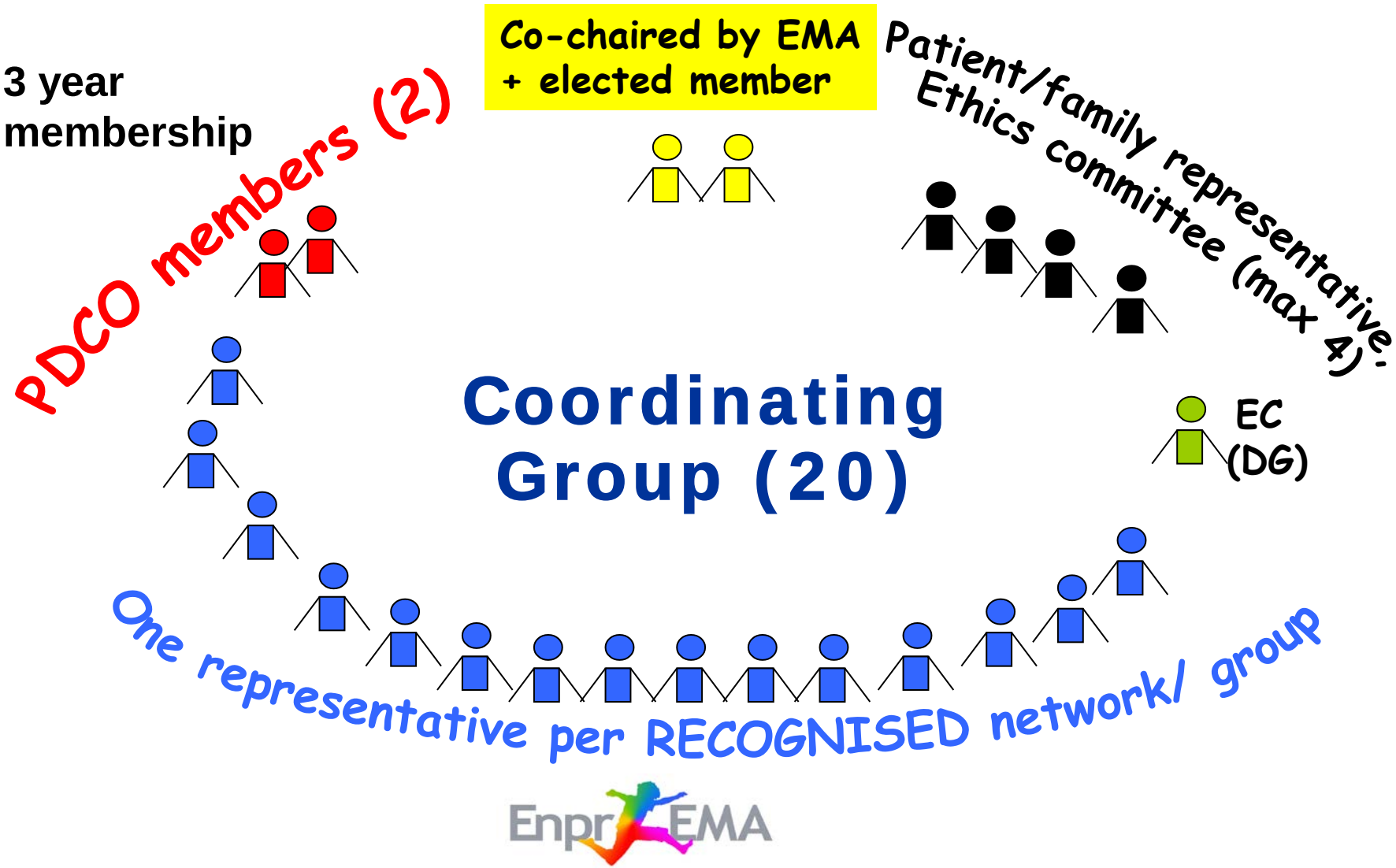
Thank you - Questions ??



EnprEMA

Back-up slides

Structure - Coordinating Group



Coordinating Group - Composition

- Max 20 members (for a maximum of 3 years): 2 PDCO + 18 Networks
- Aim to be as diverse as possible (various types of network, different therapeutic areas, special activities, age subsets)
- Only category 1 networks eligible
- Need for networks to group themselves to be jointly represented in CG, when number of category 1 networks exceed 18

Coordinating Group

Role of the Coordinating Group:

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

Interaction with stakeholders

- Annual workshop – open to all stakeholders
- Virtual meetings
- Mail exchange
- Scientific/regulatory conferences

Key operational goals

- To link existing networks
- To provide expert advice and clinical access to industry
- To define consistent and transparent quality standards
- To harmonise clinical trial procedures
- To develop strategies for resolving major challenges
- To communicate with external stakeholders