



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from the EnprEMA workshop (European Network of Paediatric Research)

Background information



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 in children (newborns to adolescents), in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance

Recognition criteria

Networks should 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**
- **Public involvement** (Involvement of patients, parents or their organisations)

Each criterion is composed of several subitems

To become member of Enpr-EMA a set of minimum recognition criteria has 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.

Minimum criterion to become member of Enpr-EMA:
involvement in at least one of the above items

Breakdown of networks by type and category

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.

Special Activities /Age Groups							Unable to fill self-assessment report
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	Network for	GNN		FIMP-MCRN	TEDDY
		UKPVG	Research in	EuroNeoNet			PRIMEDCHILD
		PENTI	Pediatric Critical	Neo-circulation			ECRIN
			Care	INN			GRIP



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



Further information

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



Or contact:

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Enpr-EMA

European Network of
Paediatric Research at the
European Medicines Agency





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World Veterinary Day

28 April 2012

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30/04/2012 **Reflection paper on classification of advanced therapy medicinal products released for public consultation**

The European Medicines Agency released a reflection paper on the classification of advanced-therapy medicinal products for public consultation today. ... [Read more](#)

27/04/2012 **World Veterinary Day: 28 April 2012**

The European Medicines Agency supports World Veterinary Day, taking place on Saturday 28 April 2012. ... [Read more](#)

27/04/2012 **European Medicines Agency closed 1 May 2012**

The European Medicines Agency is closed from 6.30pm on Monday 30 April until 7.30am on Wednesday 2 May 2012. ... [Read more](#)

27/04/2012 **European Medicines Agency publishes new versions of controlled vocabularies used to comply with Article 57 (2) requirements on submission of information on medicines**

The European Medicines Agency has published a set of updated versions of Extended EudraVigilance product report message (XEVMPD) controlled vocabularies. ... [Read more](#)

27/04/2012 **European Medicines Agency approves 100th herbal Community monograph**

The Committee on Herbal Medicinal Products (HMPC) at the European Medicines Agency has approved its 100th herbal Community monograph since the Committee began work in 2004. ... [Read more](#)

25/04/2012 **European Medicines Agency's Scientific Coordination Board starts reflection on best cooperation between scientific committees**

The European Medicines Agency has formally launched its new Scientific Coordination Board. ... [Read more](#)

25/04/2012 **Electronic application form pilot to be extended to initial veterinary applications**

On 2 May 2012, the European Medicines Agency is extending its pilot of electronic application forms to include initial applications for marketing authorisations of veterinary medicines. ... [Read more](#)

23/04/2012 **eSubmission Gateway now live for all applications for human medicines to the European Medicines Agency**

Following a successful pilot, the European Medicines Agency's eSubmission Gateway is now live for all applications for centralised marketing authorisations for human medicines. ... [Read more](#)

20/04/2012 **European Medicines Agency maintains recommendation not to grant a marketing authorisation for Glybera**

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) at its April 2012 meeting maintained its recommendation not to grant a marketing authorisation

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Thank you - Questions ??

