



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					
OT OD . I		•	•	•		

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 Activitie	assessment report				
			Intensive			special activities			
Cardiovascular		Infectious	Care/Pain/	European	European	(Phv, long term follow	Expertise in		
diseases/	Psychiatry/	diseases/	Anaesthesiology/	neonatal	paediatric	up, community	clinical trial		
Nephrology	Neurology	Vaccinology	Surgery	network	pharmacists	paediatritians)	methodology		
	EUNETHYDIS	PENTA	Network for	GNN		FIMP-MCRN	TEDDY		
		UKPVG	Research in	EuroNeoNet			PRIOMEDCHILD		
		PENTI	Pediatric Critical	Neo-circulation			FCRIN		
			Care	INN			GRIP		



Unable to fill self-

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.



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

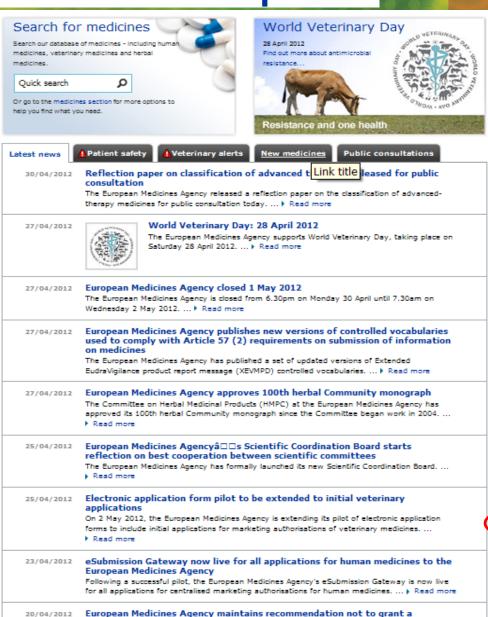








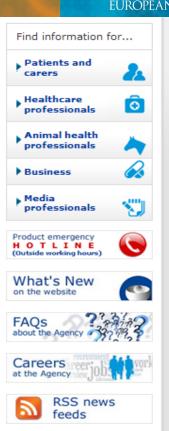
http://www.ema.europa.eu



The European Medicines Agencyâ□□s Committee for Medicinal Products for Human Use (CHMP)

at its Ancil 2012 meeting maintained its recommendation not to great a marketing authorization

marketing authorisation for Glybera

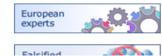




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Thank you - Questions ??



