



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Report from the coordinating group (CG)

Update on Enpr-EMA activities,  
achievements and challenges

Workshop June 7<sup>th</sup> 2018



# Introduction and background

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## **Enpr-EMA** - umbrella network of existing networks

- provides access to networks/sites with expertise in performing clinical trials in the paediatric population
- enables collaboration/learning of individual networks from each other
- versus different role of the clinical trial networks which actually conduct and perform the clinical trials
- Members perform research with children (newborns to adolescents), in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance

## Membership

- To ensure certain quality standards, Enpr-EMA introduced set of minimum **recognition criteria** which have to be fulfilled
  - to become category 1 member of Enpr-EMA
  - to be eligible as coordinating group member
- Recognition criteria were developed by networks themselves by consensus formation techniques and focus on:
  - ✓ 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
- Self-assessment to be updated every second year

# Key operational goals

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Platform for close interactions of all stakeholders necessary to facilitate the conduct of (large) studies in children

- To link together existing networks EU and extra-EU
- To share best practices
- To offer single point of contact for (European) networks  
[enprema@ema.europa.eu](mailto:enprema@ema.europa.eu)
- To define strategies for resolving major challenges
- Enpr-EMA does NOT
  - fund / conduct clinical trials
  - act as a CRO and manage studies

# 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/Ha emostaseology	Respiratory diseases /Cystic Fibrosis	
DCRI	ITCC			PRINTO	EBMT	ECFS-CTN	
NIHR-MCRN							
ScotCRN	Newcastle-CLLG		PEDDCReN				
FinPedMed	IBFMSG		EPLTN	JSWG of PRES			
PEDMED-NL							
MICYRN	CLG- of EORTC						
CICPed	CEPOETA						
RIPPS	<p><b>Category 1:</b> Networks fulfilling all minimum criteria for membership of Enpr-EMA.</p> <p><b>Category 2:</b> Networks potentially fulfilling all minimum criteria – but needing to clarify some issues before becoming a member of Enpr-EMA.</p> <p><b>Category 3:</b> Networks currently not yet fulfilling minimum criteria.</p> <p><b>Category 4:</b> Networks not performing clinical trials; e.g. methodology, infrastructure,</p>						
OKids							
RECLIP							
NETSTAP							
IPCRN	<p>Unable to fill self-assessment report</p>						
MCRN-Hungary							
	<b>SPECIAL ACTIVITIES / AGE GROUPS</b>						
SwissPedNet	Psychiatry/ Neurology	Infectious diseases/ Vaccinolog y	Intensive Care/Pain/ Anaesthesiolog y/ Surgery	European neonatal network	European paediatric pharmacists	special activities (Phv, long term follow up, community paediatricians)	Expertise in clinical trial methodology
Red SAMID							
NCCHD-Japan	EUNETHYDIS	PENTA-ID		GNN		FIMP-MCRN	TEDDY
NorPedMed	ECAPN	UKPVG	ESPNIC	INFANT		Futurenest CR	EAPRASnet
		RITIP		Neo-circulation			PedCRIN
		ReSVINet		ESDPPP			EYPAG net
							TREAT-NMD

# Coordinating Group

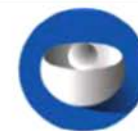
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## **Role of the Coordinating Group:**

- 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



European network of paediatric research  
at the European Medicines Agency

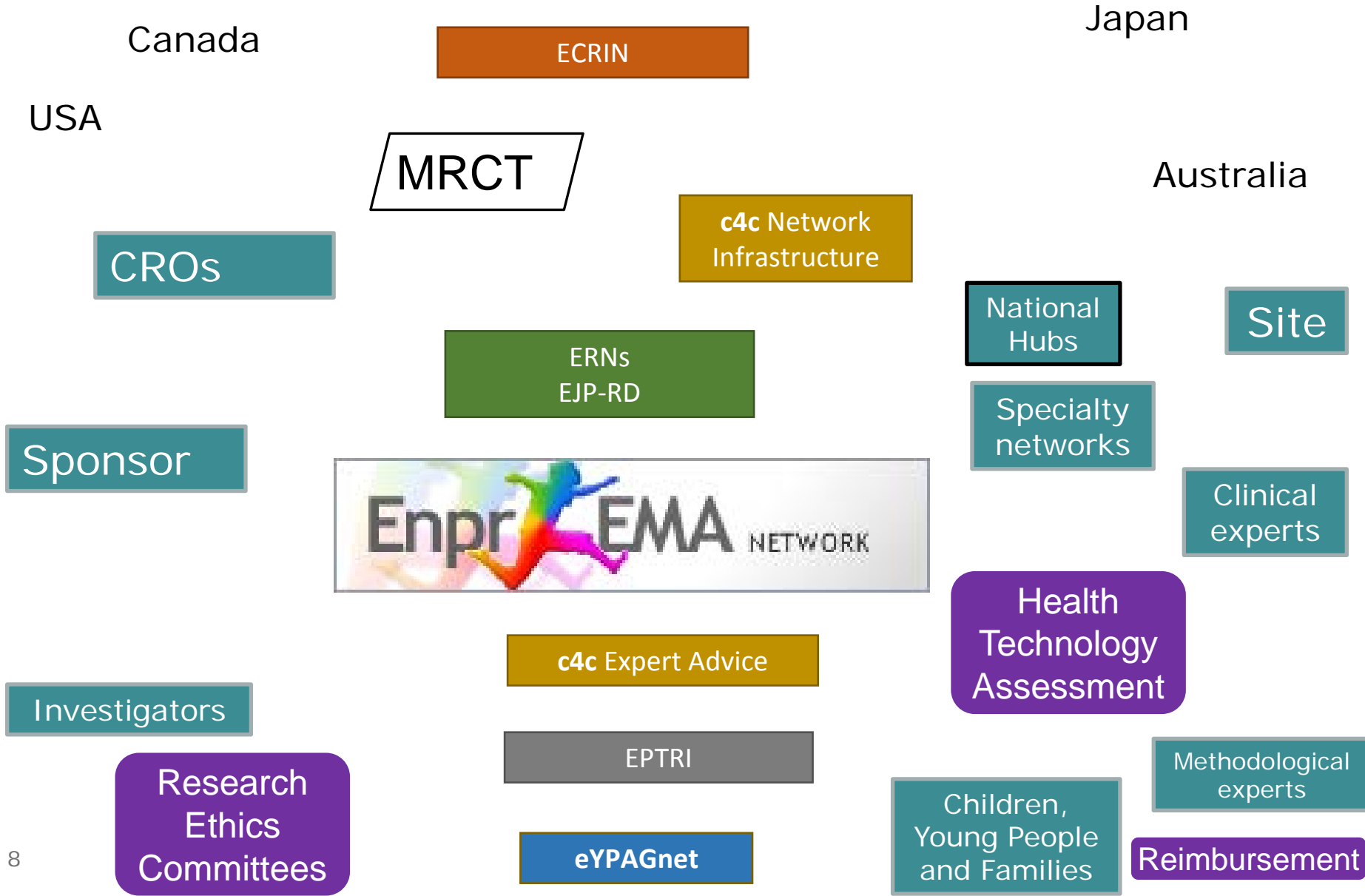


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28 February 2018  
EMA/493016/2013 Rev. 6  
Product Development and Scientific Support Department

**Mandate of Enpr-EMA working groups**

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2014/03/WC500163382.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/03/WC500163382.pdf)





# Biggest Achievement

To develop and maintain a platform that can:

- Identify needs
  - Address needs
  - Host ongoing discussion
  - Engage multiple stakeholders
  - Integrate perspectives
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- Minimise use of resources

# Summary

## **Activities**

Driven by needs and contributions of multiple stakeholders

## **Achievements**

1. Clear, concrete outcomes
2. Progression with time

## **Challenges**

Unity in diversity

Specifying and delivering tasks