EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

Background of Enpr-EMA

An agency of the European Union

Emma Sala Soriano, Ph.D

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."

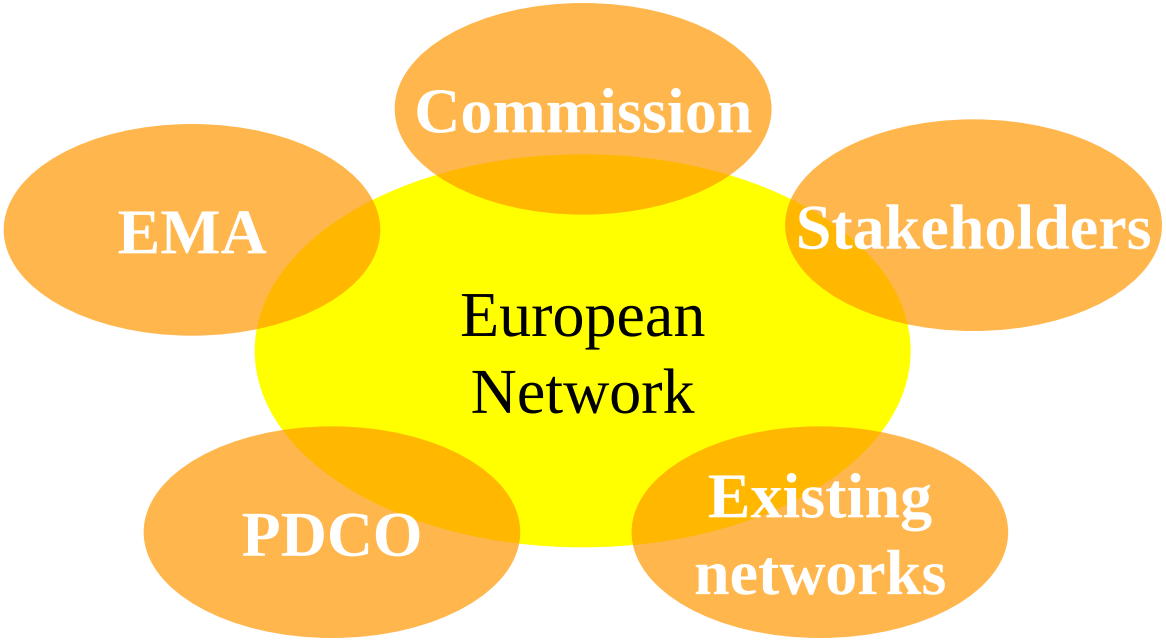
Introduction and background

Objectives/Operational goals of Enpr-EMA

- Collaboration and communication (between existing networks and stakeholders)
- Facilitation of recruitment in clinical trials (providing expertise and access to infrastructure for industry to conduct studies in children)
- Building competences (defining strategies for resolving major challenges)
- Avoiding unnecessary studies
- Stimulating high quality research (defining consistent and transparent quality standards; harmonising clinical trial procedures)
- Strengthening the foundations of the European Research Area

Introduction and background

Organisation and structure



Introduction and background

Stakeholders

- Pharmaceutical Industry
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics Committees
- Medical devices industry
- CRO’s
- Hospital pharmacists
- Laboratories and imaging centres

What has been achieved so far?

- Identification of existing networks
- Implementation strategy adopted by EMA Management Board (Jan 2008)
- 1st workshop with existing networks (Feb 2009)
- 2 working groups:

  WG 1: structure and operational model (June 2009)

  WG 2: definition of recognition criteria (Public consultation Feb 2010)
- 2nd workshop with existing networks (March 2010)
- Publication of finalised recognition criteria for self-assessment (May 2010)
- 3-month period for networks to do self-assessment and publish results.
- Self-assessment reports screening and clarifications requested (Dec 2010)
- Publication of list of Networks members of Enpr-EMA (Jan 2011)
- 3rd workshop with existing networks and industry representatives (March 2011)

Coordinating Group (background info)

Role of the Coordinating Group:

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

Self-assessment report

Networks should be recognised by quality of paediatric research

To elaborate and agree on recognition criteria and quality standards for self-assessment in the following areas:

- **Capacity**
  - to involve patients (for study design and for recruitment)
  - to manage trial and to perform trials according to GCP
  - to build up competence and to involve further centres
  - to innovate in trials (methodology, techniques, e.g. microassays)
- **Expertise in the therapeutic area**
- **Established quality assurance systems of the network**
- **Potential conflicts of interest**
- **Ability and content to share in relation to competencies and experience**

(the elaboration of the self-assessment report was performed using the Delphi and Nominal Group consensus techniques)

Breakdown of networks by type and category

- Table of the current networks and their status:

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.

Cardiovascular diseases/ Nephrology	Psychiatry/ Neurology	Infectious diseases/ Vaccinology	Intensive Care/Pain/ Anaesthesiology/ Surgery	Special Activities /Age Groups: European neonatal network	Special Activities /Age Groups: European paediatric pharmacists	Special Activities /Age Groups: special activities (Phv, long term follow up, community paediatritians)	Unable to fill self-assessment report: Expertise in clinical trial methodology
	EUNETHYDIS	PENTA		GNN		FIMP-MCRN	TEDDY
		UKPVG		EuroNeoNet			PRIOMEDCHILD
		PENTI		Neo-circulation			ECRIN
				INN			GRIP

Enpr-EMA

Enpr-EMA information: http://www.ema.europa.eu

Enpr-EMA

Enpr-EMA information: http://www.ema.europa.eu

Enpr-EMA

Enpr-EMA information: http://www.ema.europa.eu