The Organisational and Functional Structure of Enpr-EMA

Christina Peters on behalf of WG1

Enpr-EMA: **Legal basis**

"The objectives of the European network shall be

- **to coordinate studies relating to paediatric** medicinal products
- **to build up competence at a European level**
- **to avoid unnecessary duplication of studies and testing in the paediatric population."**

Enpr-EMA: Key operational goals

- To link together existing networks
- To provide expertise and access to infrastructure for industry to conduct studies in children
- To define consistent and transparent quality standards
- To harmonise clinical trial procedures
- To define strategies for resolving major challenges
- To communicate with external stakeholders

Coordinating Group Enpr-EMA

Being as diverse as possible, representing various types of networks:

Networks focusing on specific therapeutic areas,

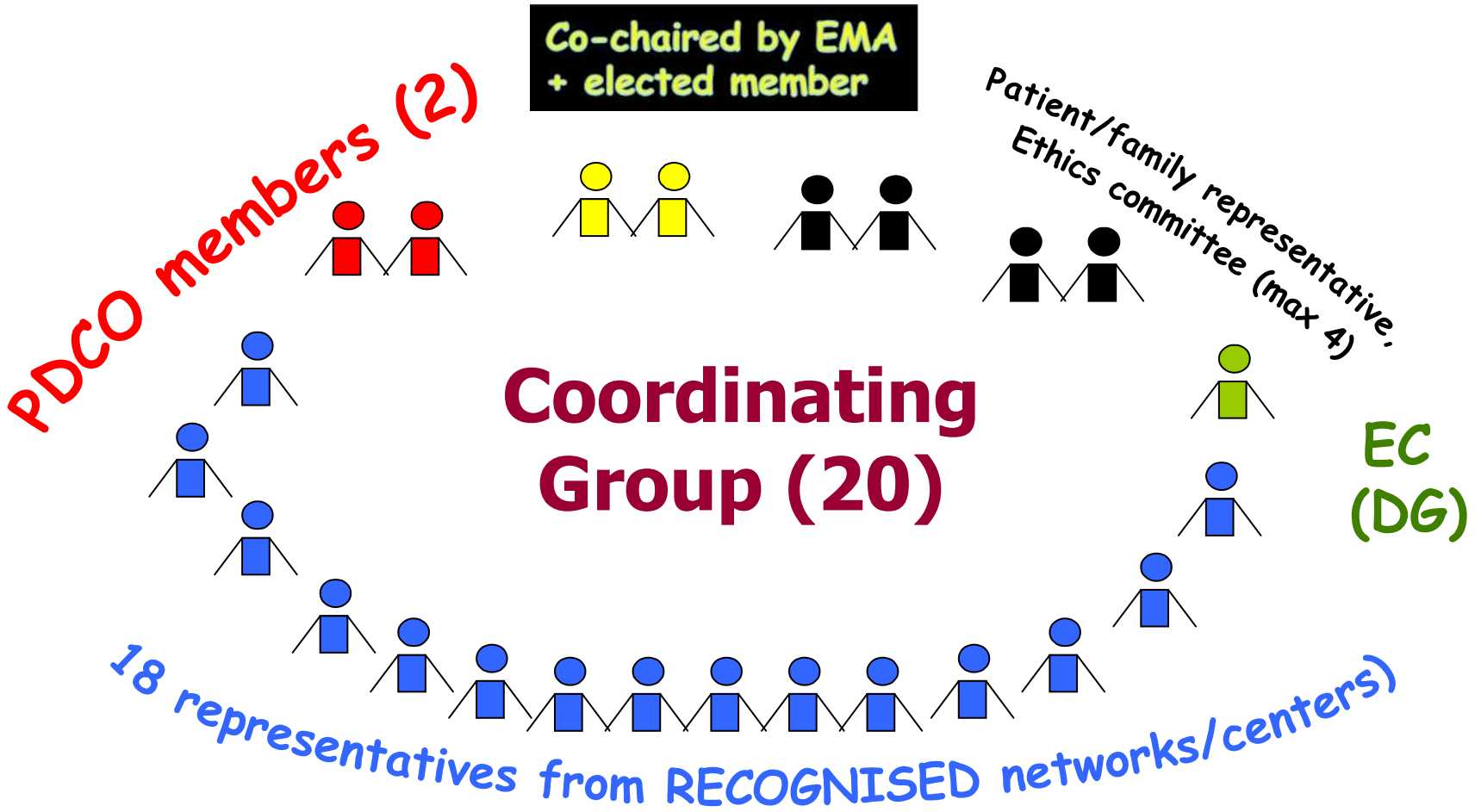
Networks covering

- **specific needs/age subsets (e.g. neonatal /adolescent networks) or**
- **specific activities (e.g. pharmacovigilance),**

Organisational networks (e.g. national networks linking together either several clinical trial centres or community paediatricians):

Accommodating for regional differences throughout Europe with regards to how the medical care of children is organised

Structure Coordinating Group



Composition of the recognized NWs:

- 4 networks representing national networks
- 10 members representing diverse therapeutic areas
- 3 members representing special activities/ age groups:
  - 1 member from European neonatal network
  - 1 member representing European paediatric pharmacists
  - 1 member representing special activities, eg pharmacovigilance, long-term follow up, Phase 4 studies eg via network of community paediatricians
  - 1 member of methodology networks

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Self-assessment reports received- first screening

➢ **Number of self-assessment reports received: 32.**

➢ ➢ **Just to clarify: EMA did not check whether claims are actually true**

➢ **Following a preliminary assessment 3 categories were identified:**

- **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**
- **Category 3: Networks currently not yet fulfilling minimum criteria.**

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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						

Cardiovascular diseases/ Nephrology	Psychiatry/ Neurology	Infectious diseases/ Vaccinology	Intensive Care/Pain/ Anaesthesiology/ Surgery	Special Activities /Age Groups: European neonatal network	European paediatric pharmacists	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
							GRIP

Tasks for Secretariat of the Coordination Group - European Medicines Agency

- to provide secretarial support to the activities of the network
- to organize and host meetings of the network
- to coordinate exchange of information between network partners
- to coordinate exchange of and provide information to external partners and stakeholders

Enpr-EMA CG: First Steps

- **Main Goal: Communication (between Industry, Regulators, Patient Organisations)**
- **1st Action point:**

  webpage, resource database
- **Determine 3 major topics to identify and establish time limited working groups:**

  "Model PIP"

Next Steps - Timelines

- Meeting report and presentations put on EMA webpage within approx. 4 weeks
- 20 June face to face meeting Coordinating group
- 2012: next Enpr-EMA workshop with all networks, industry and patient/parent organisations

European Paediatric Research Network EMA

National Networks Enpr-EMA

- FINPedNet (Finnish Investigators Network for Pediatric Medicines)
- MCRN-NL(Medicines for Children Research Network - The Nederland)
- MCRN-UK [National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN) United Kingdom]
- Scotmcn (Scottish medicines for children network)

Age/Activity specific Networks

- **Neonatal network:**

  GNN (German Neonatal Network)

- **Paediatric pharmacists:**

  Newcastle-CLLG (Newcastle CCLG Pharmacology Studies Group)

- **Long term follow up, translation, adolescents:**
  - FIMP-MCRN (Family Paediatricians - Medicines for Children Research Network)
  - MICYRN (Mother Infant Child Youth Research Network)

Disease Specific Networks Enpr-EMA

- **Oncology/Haematologic Malignancies:**
  - ITCC (Innovative Therapies for Children with Cancer)
  - IBFM-SG (Network of National Study Groups for the treatment of hematological malignancies)
  - EPOC (A European Paediatric Oncology off patent medicines Consortium)
- **Allergology/Immunology/ Rheumatology:**
  - PRINTO (Pediatric Rheumatology International Trials Organisation)
- **Stem Cell and Organ Transplantation/Haematology:**
  - EBMT (European Group for Blood and Marrow Transplantation)
- **Infection/Vaccinology:**
  - UKPVG (United Kingdom Paediatric Vaccines Group)
  - PENTA (Paediatric European Network for the Treatment of AIDS)
- **Respiratory diseases /Cystic Fibrosis:**
  - ECFS - CTN (European Cystic Fibrosis Society-Clinical Trials Network)
- **Psychiatry/Neurology:**
  - EUNETHYDIS (the European Network for Hyperkinetic Disorders)

Disease specific Networks Enpr-EMA

- Diabetes/Endocrinology/Metabolic disorders/Gynaecology
- Gastroenterology/Hepatology
- Cardiovascular diseases/Nephrology
- Intensive Care/ Pain/ Anaesthesiology/Surgery
- Haemostaseology

Role of EMA at Enpr-EMA

- to provide secretarial support to the activities of the network
- to organize and host meetings of the network
- to coordinate exchange of information between network partners
- to provide information to external partners and stakeholders
- The EMEA does not decide on recognition

Category 2 & 3:

Networks still having to clarify some issues before fulfilling criteria:

- CLG (Children Leukemia Group)
- CICPed (Paediatric Network of Clinical Investigation Centers)

Networks currently not fulfilling minimum criteria:

- BPDN (Belgian Pediatric Drug Network)
- AMIKI (The Paediatric Trial Network)
- EuroNeoNet (European Neonatal Network)
- JSWG of PRES (Juvenile Scleroderma Working Group Pediatric Rheumatology European Society)
- Neo-circulation (Network in Neonatology)
- PENTI (Paediatric European Network for the Treatment of Infection)
- RIPPS (Réseau d'Investigations Pédiatriques des Produits de Santé)
- IPCRN (Irish Paediatric Clinical Research Network)
- BLF (Swedish Peadiatric Society)
- NCCHD (National Center for Child Health and Development)
- IPTA (International Pediatric Transplant Association)
- FUTURENEST CLINICAL RESEARCH ESPGHAN (European society of Gastroenterology, Hepatology and Nutrition)

Tasks for Coordinating group

- to facilitate access for industry to paediatric clinical study sites (i.e. coordinate industry requests / enquiries / feasibilities to the Networks / Centers of Excellence / experts / societies needed in the particular case)
- to identify networks which are not yet on the list
- to act as platform to communicate and negotiate with industry
- to define common agreement/contracts with industry across Europe
- to develop common educational tools for patients/parents to increase willingness to participate in paediatric trials
- to help ensure feasibility of studies and monitor trial recruitment so that feasibility can be maintained
- to help with financing strategies for clinical studies for clinical research groups or small pharmaceutical industries in cooperation with the EMA office for small and medium-sized enterprises

Tools for communication within members of the European network

- Newsletter
  - **to spread information**
  - **to provide networks opportunity to present themselves**
  - **to support communication between EMEA-Coordination Group, clinics and pharmaceutical industries**
  - **to support public view for clinical studies in childhood**
- Regular meetings:
  - **Coordinating Group 3 meetings per a year**
  - **one workshop yearly, open to all network participants. Representatives of networks under construction or still in the recognition process may attend as observers.**
  - **one meeting yearly for "subcommittees" the afternoon before the workshop**
- Meeting reports
- e-mails
- tele- or video-conferences
- Communication with other stakeholders:
  - **Industry**
  - **Patient's organisations**
  - **Eurodis (European Organisation for Rare Diseases)**
  - **Ethic committees**

Tasks for Secretary of the Coordination Group

- organisation of the meetings etc.
- realisation of the decisions made by the Coordination Group
- contact office/support for the local networks
- coordination with other existing important institutions/groups
- Duration of membership:
  - The Implementation strategy states that membership of the Coordinating Group will be for 3 years only to ensure sufficient renewal and involvement of various members.
  - The WG proposes that not all members of the coordinating group should be automatically replaced after three years. Some members should have the opportunity to stay to ensure continuity.

Next Steps

- Once networks will have provided proof (e.g. publishing the annual report, the organisation's program, etc) that they fulfil the recognition criteria, the final composition of the CG should be chosen to meet the above criteria.
- Discussion:
  - to define so called "subcommittees", i.e. representatives of networks which have grouped themselves to be represented within the coordinating group.

Potential incentives to attract best people/best existing networks/study centres to become member of ENPRema

- Access to clinical trials requested in PIPs and financial compensation for the conduct of those trials (not considered to be sufficient as the sole incentive)
- increased visibility on a European level as potential site(s) for industry-sponsored studies
- to present the network at a European level
- to save resources by sharing work and link activities
- to share skills and expertise of other networks
- to shape and influence future development in paediatric research
- access to information and procedure of application for EC framework program
- to have a European forum to feed back to any difficulties/problems/hurdles encountered
- to have a forum to address encountered common problems/hurdles on an European level