



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Paediatric Research at the European Medicines Agency EnprEMA

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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.”

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

What has been achieved so far ?

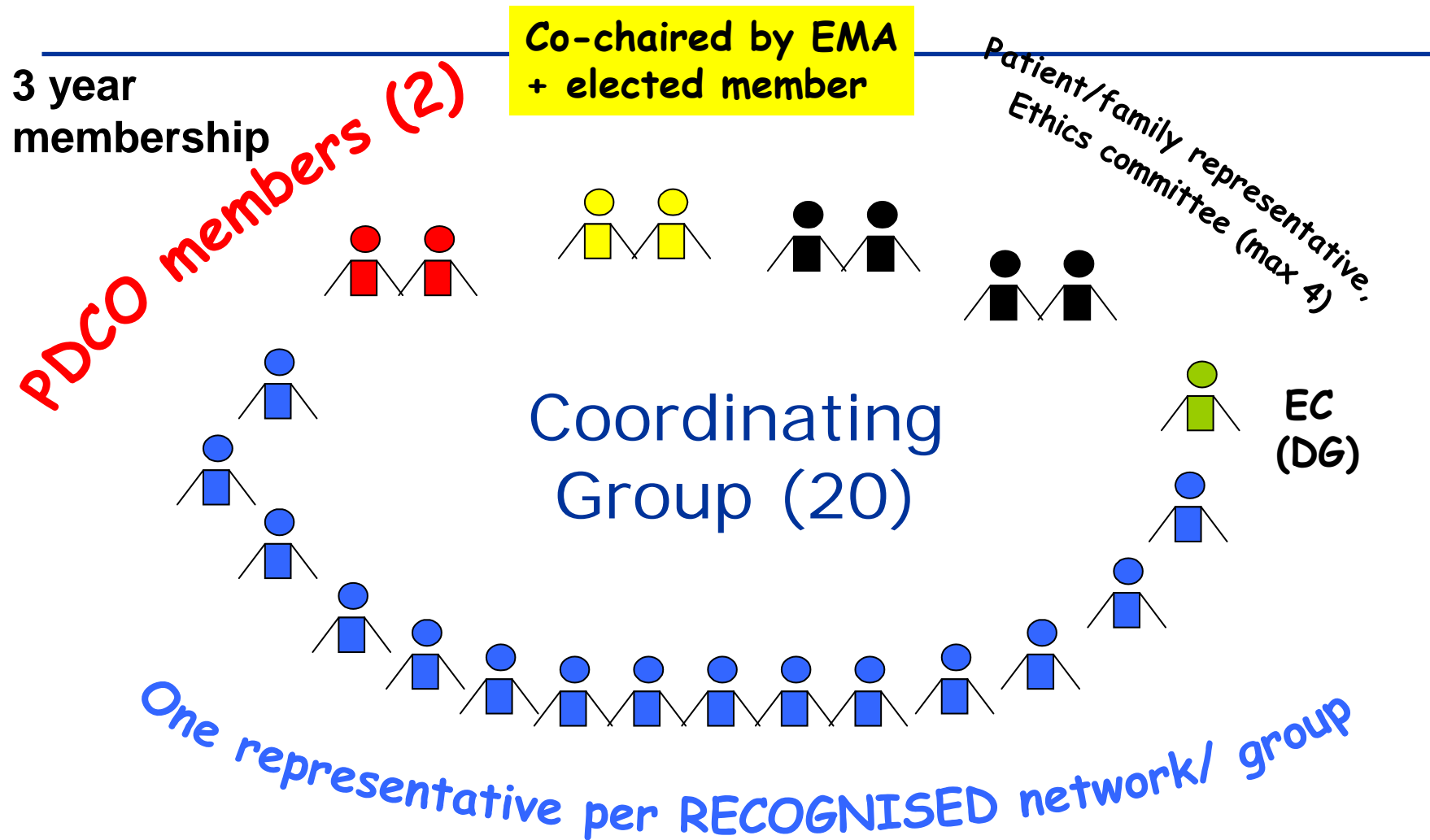
- Identification of existing networks
 - List published on EMA webpage (2009)
- Implementation strategy adopted by EMA Management Board (Jan 2008)

Implementation strategy

Coordinating Group:

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

Proposed Structure - Coordinating Group



Coordinating Group

- Max 20 members, for a maximum of 3 years
- 2 Members of the Paediatric Committee
- 1 Member of the European Commission
- 17 representatives of networks / groups of networks
- No industry in the group but obvious stakeholder

Role of EMEA

- 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

8 The EMEA does not decide on recognition

What has been achieved so far ?

- Identification of existing networks
- Implementation strategy adopted by EMA Management Board (Jan 2008)
- First workshop with existing networks (Feb 2009)
- 2 working groups:
 - WG 1:** structure and operational model
 - June 2009
 - WG 2:** definition of recognition criteria
 - Criteria published on the EMA web-page for public consultation (Feb 2010)

Meeting June 2009

Structure and operational model

Chair:

- Christina Peters (EBMT)

Members:

- Stephen Tomlin (Neonatal+Paed. Pharmacist Group)
- Klaus Hartman (PTN)
- Deborrah Alfarez (PRIOMEDCHILD)
- Pirkko Lepola (FINPEDMED)
- Dr. Vanessa Poustie (MCRN UK)

Recognition criteria

Chair:

- Nicola Ruperto (PRINTO)

Members:

- Giles Vassal (ITCC)
- Mike Sharland (PENTA)
- Monika Seibert-Grafe (Paed-Net)
- Lars Hjorth (PanCare)
- Adolf Valls-i-Soler (Europ.Neonatal Network)

Criteria published on the EMA web-page for public consultation
(Feb 2010)

Objective of today's workshop

- To inform you about outcome of the working groups (presented by chairs)
- To discuss and adopt structure and operational model for the European network
- To discuss and finalise recognition criteria
- To discuss minimum requirements

Proposed composition of coordinating group

Chair:

- Christina Peters (EBMT)



Next Steps

- Publication of finalised recognition criteria for self-assessment
- 3-month period for networks to do self-assessment and publish results
- All networks fulfilling recognition criteria automatically member of EnprEMA
- Implementation of coordinating group by August 2010
- First meeting Coordinating group: Oct 2010
- Election of Chair