



Proposal for the organisation and structure of the EMEA network

Elin Haf Davies

Introduction

The EU Paediatric Regulation

Paediatric Committee

Guidance for applicants

[Scientific advice](#)

[Paediatric investigation plans \(PIPs\), waivers and modifications](#)

[Paediatric-use marketing authorisations \(PUMAs\)](#)

[Compliance](#)

[Submission of paediatric studies](#)

Opinions and decisions on PIP applications

[Background](#)

[Class waivers](#)

[Product-specific decisions](#)

Paediatric-related information

[Paediatric needs](#)

[Paediatric clinical trials](#)

[Priority list of off-patent medicines](#)

[Scientific guidance](#)

[Paediatric formulations](#)

[Presentations](#)

[EU paediatric network](#)

Global cooperation

[Member States](#)

[International](#)

[Workforce](#)

Medicines for children



A brighter future
for child health

Paediatric-related information

EU paediatric network

The Paediatric Regulation provides for the EMEA to 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. An implementing strategy for the network has been adopted by the EMEA Management Board on 15 January 2008.

The Implementing Strategy for the launching and operation of the EU paediatric network can be found [here](#).

The first step is to identify all existing networks, centres and investigators with specific paediatric expertise. Any information can be sent to the following email: enpremea@emea.europa.eu.



European Medicines Agency

London, 15 January 2008
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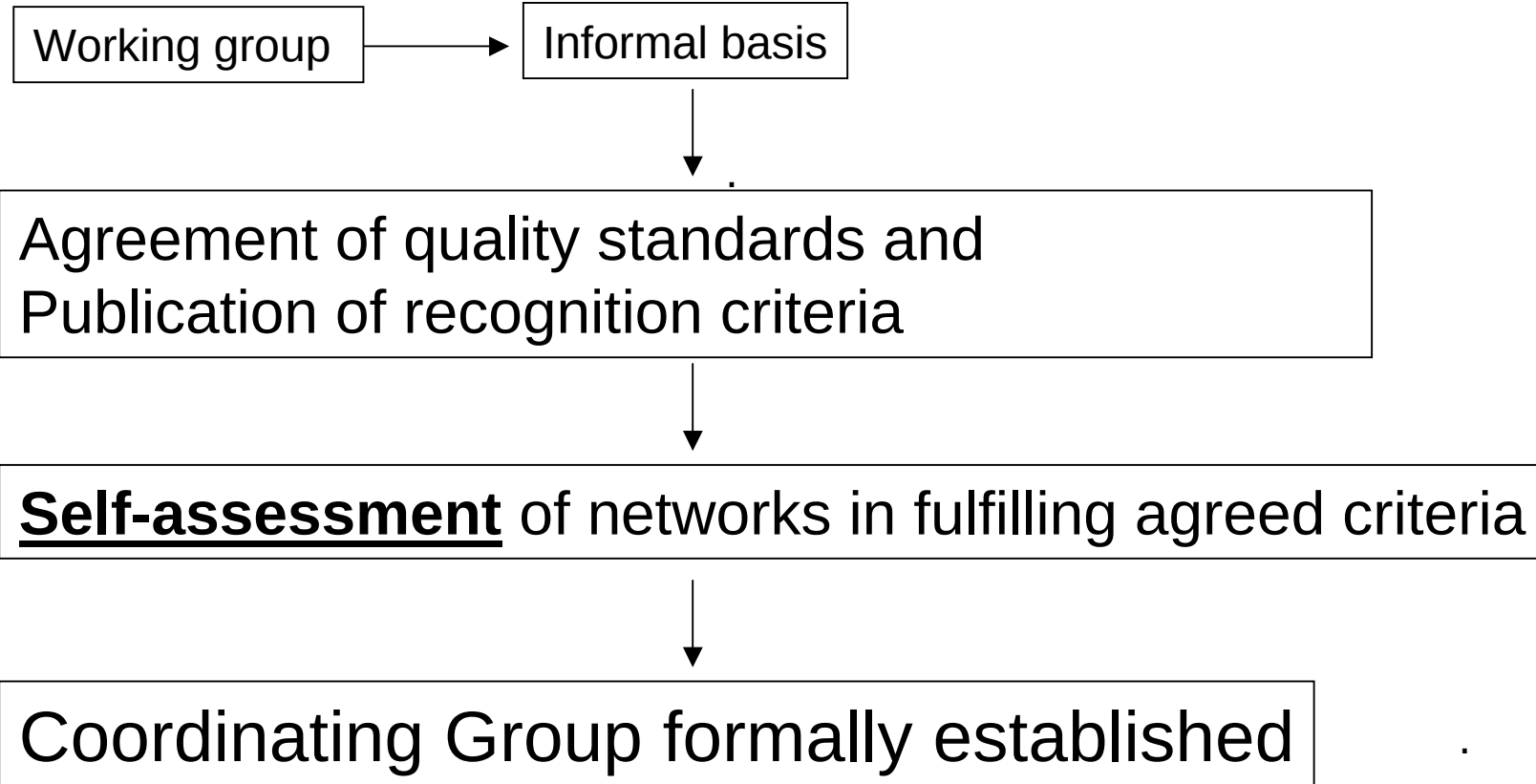
The Network of Paediatric Networks at the EMEA Implementing Strategy

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Process to establish group





3 year
membership

Co-chaired by EMEA
+ elected member

Observers

Industry

Patient/family representative,
Ethics committee (max 4)

European
Commission
(DG)

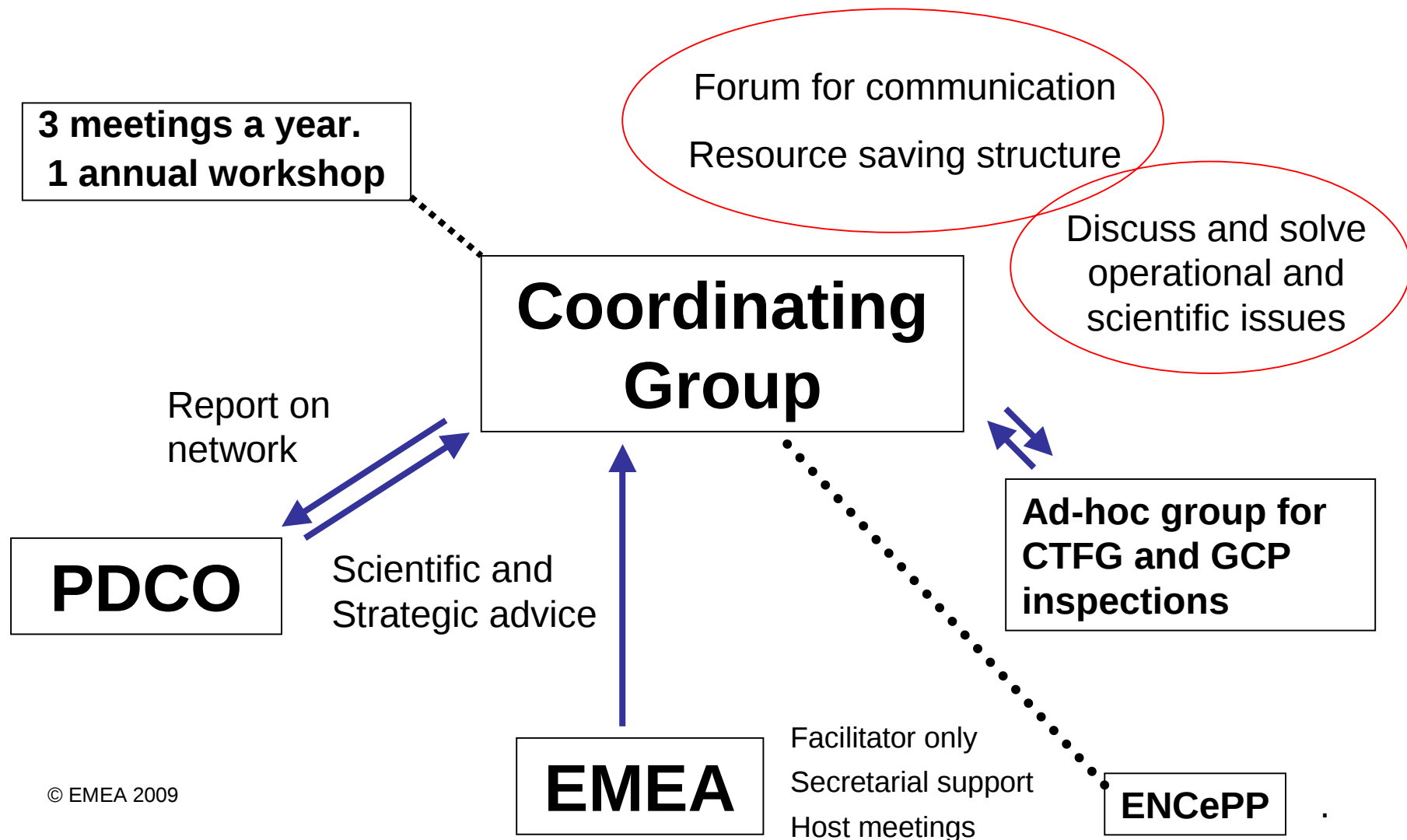
Coordinating Group (20)

PDCO members (2)

One representative per RECOGNISED network/ group



Coordinating Group – proposed organisation





Aims

- Contribute to the short and long-term strategy of the network
- Discuss and solve operational and scientific issues for the network (including scientific quality standards for clinical trials)
- Report to the Paediatric Committee
- Act as a forum for communication
- Adoption of Conflict of Interest policy (supported by EMA)



- Avoid creating a resource-intensive structure
- Avoid replicating existing bodies
- Avoid overlap of activities and responsibilities