European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Proposed structure for the operation of the network

One-year informal "construction phase"
- to elaborate operational infrastructure
- to elaborate and agree on recognition criteria for self-assessment of networks

After agreement of quality standards and recognition according to the criteria agreed by the participating networks, a **Coordinating Group** to be established with members from recognised networks.

Role of the Coordinating group:

- to adopt a conflict of interest policy
- to discuss and agree scientific quality standards
- to contribute to the short and long-term strategy of the network
- to discuss and solve operational and scientific issues for the network
- to report to the Paediatric Committee
- to act as a forum for communication.

Coordinating Group not to exceed 20 members in total and to consist of the following members:
- 1 representative per recognised network or group of centers (networks or centers may have to group themselves to be represented once the maximum number has been reached)
- 2 members of the Paediatric Committee
- 1 representative of the European Commission (DG Research)
- A maximum of 4 additional members following a decision of the Coordinating Group to bring additional expertise needed for its operation (e.g. patients' representatives, Ethics Committee representative)

Membership of the Coordinating Group is for 3 years only, to ensure sufficient renewal and involvement of various members.

The Coordinating Group is co-chaired by the EMEA and a chair chosen among the members. The EMEA only plays a role of facilitator and does not decide on recognition of networks.

Industry not represented in the Coordinating Group through membership, but expected to be a major stakeholder in the discussions.

Meetings of the Coordinating Group to take place usually 3 times a year. In addition, a workshop should be held on a yearly basis, open to all network participants.
Representatives of networks under construction or still in the recognition process may attend as observers.

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Role of PDCO:

- to act as the Scientific Committee of the network.
- Members of the Paediatric Committee to be involved in the Coordinating Group to advise on scientific issues and on the future strategy of the network.

Role of the EMEA:

- to provide secretarial support to the activities of the network
- to organize and host the meetings of the Coordinating Group.
- to cover travel and accommodation expenses for the Coordinating Group meetings (3 per year)

Support is focused

- on the coordination of exchange of information between the network partners,
- providing information to external partners and stakeholders,
- facilitating the work of the Coordinating Group

Stakeholders or interested parties include:

- Patients, parents and families, organisations representing children, patients' organisations.
- Paediatric and other relevant learned societies.
- Academia (EU and international), including cooperative research groups, methodologists and other relevant groups.
- Government-funded research institutions (including outside EU).
- Research funding bodies (e.g. European Commission DG Research, Technology and Development).
- National Competent Authorities (for authorisation of trials or medicines authorisation, GCP and GMP compliance evaluation).
- Paediatric health care providers.
- Government-funded health services and National Health Systems.
- Ethics Committees (and Investigational Review Boards).
- Pharmaceutical industry.
- Medical devices industry.
- Clinical Research Organisations.
- Hospital pharmacists.
- Laboratories and imaging centres.