Suggestions for the composition and aims of ENPRema

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Coordinating Group

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

The working group could not agree that initially all networks meeting the recognition criteria would automatically become member of the coordinating group with all other networks having to group themselves to be represented once the maximum number has been reached.

Composition of the coordinating group

- 4 networks representing national networks
- 10 members representing diverse therapeutic areas (either existing and recognised European networks or learned societies, which have access to clinical trial centres, which then must meet predefined quality standards
- The following therapeutic areas were discussed as being “essential”: (The grouping of therapeutic areas may be re-discussed)
  - **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**
  - **Cardiovascular diseases / Nephrology**
  - **Psychiatry / Neurology**
  - **Infectious diseases / Vaccinology**
  - **Intensive Care / Pain / Anaesthesiology / Surgery**
- 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**

Role of the Coordinating group

- To discuss and confirm 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

Objectives European Network

- To harmonise clinical trial procedures (SOP's, documents, data management, monitoring, training curricula, etc.) - at European level
- To define strategies for resolving major challenges of paediatric clinical trials (insurance, divergent Ethic Committee positions, lack of paediatric expertise, etc.) - at European level
- To ensure effective coordination and communication between individual networks, investigators and paediatric clinical trial centres
- To stimulate and facilitate the development and integration of new national networks and trial centres

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

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.

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

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**

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.