EUROPEAN MEDICINES AGENCY
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Human Medicines Development and Evaluation

Mandate of the Coordinating Group of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)

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1. General considerations

One of the objectives of the Paediatric Regulation (EC) No 1901/2006, as amended, is to foster high quality ethical research on medicinal products for use in children by efficient inter-network and stakeholder collaboration. To meet this objective, a European paediatric network of existing networks, investigators and centres with specific expertise in performing medicines trials in the paediatric population has been established at the European Medicines Agency. The aim of the European network of paediatric research at the EMA (Enpr-EMA) is to coordinate[1] interventional clinical trials and other studies relating to paediatric medicinal products, to build the necessary scientific, methodological, ethical and administrative competences at European level, to avoid duplication of studies and testing in children, to strengthen the foundations of the European Research Area and promote European Commission framework programme applications.

The benefits of Enpr-EMA include, but are not limited to strengthening complementary scientific, ethical, methodological and/or administrative competences in the performance of paediatric clinical trials and medicinal product related studies through effective collaboration. They also include – by providing a platform for communication - the avoidance of duplication of work and effort, making the best use of existing research infrastructure, developing common methods of working with special attention to quality assurance and recruitment of patients.

Enpr-EMA should act as contact point between regulators, Pharma Industry, SMEs, Contract Research Organisations (CROs) and individual networks/centres designing and performing paediatric clinical trials and other relevant paediatric research related to medicinal products. Enpr-EMA should lobby with policy makers and funders to help guarantee that paediatric research meets the needs of the children and the medical priorities identified by the scientific community.

The network itself is not intended to initiate and fund trials, or to decide on priority areas of paediatric research, which will remain the responsibilities of individual networks, Member States, and the European Commission and the Community (Member States) through its research and funding programmes and priorities.

2. Role and specification of the CG members

The 'Enpr-EMA Coordinating Group' has been established in order to act as a forum for communication, contribute to the short and long-term strategy of the network, discuss and solve operational and scientific issues for the network, and report to the Paediatric Committee, which acts as the scientific committee of Enpr-EMA.

As per Article 44 of the Paediatric Regulation, Enpr-EMA should consist of networks, investigators and centres with specific expertise in the performance of studies in the paediatric population. The membership criteria, as stipulated in Enpr-EMA's implementing strategy, include four categories of membership. The Enpr-EMA Coordinating Group (CG) consists of active participants from category 1 networks. The full list of all networks (categories 1-4) can be found in the *Enpr-EMA database*. Only European Union/European Economic Area (EU/EEA) networks shall become full members with speaking and voting rights. (see: 3.2)

[1] "Coordinating studies" is interpreted as facilitation of studies defined as: acting as contact point between regulators, industry, CROs and individual networks/centres actually performing trials.

3. Coordinating group definition

3.1. Composition

The CG shall consist of a maximum of 20 members as follows:

- 2 members representing the Paediatric Committee (members or alternate members of the Paediatric Committee)
- A total of 18 members representing category 1 networks (see 3.2 for the selection of these representatives), ensuring that the distribution of network representatives shall ensure as extensive as possible representation of all paediatric sub-specialties and all paediatric age groups. The representation of paediatric sub-specialties and age-groups should be proportional as much as feasible and should reflect the distribution of Enpr-EMA member networks and special expertise groups. The following breakdown shall act as a guidance:
  - members representing national and multinational multispecialty networks
  - members representing specific therapeutic areas, including for example any of the following:
    - Oncology
    - Diabetes/Endocrinology/metabolic disorders/Gynaecology
    - Gastroenterology/Hepatology
    - Allergology/Immunology/Transplantation/Rheumatology
    - Haematology /Haemostaseology
    - Respiratory diseases /Cystic Fibrosis
    - Cardiovascular diseases/Nephrology
    - Psychiatry/Neurology
    - Infectious diseases/Vaccinology
    - Intensive Care/Pain/Anaesthesiology/Surgery
    - Rare diseases
    - Neonatology
  - members with other special expertise, including for example any of the following:
      - Paediatric hospital pharmacists
      - Paediatric research nurses
      - Pharmacovigilance activities / long-term follow-up and Phase 4 studies
      - Paediatric clinical study methodology

Additional ad hoc Expertise (max. 4)

Following a decision of the CG to bring additional expertise required for its operation (e.g. patients' representatives, ethics committee representative) a maximum of 4 additional places is available.

3.2. Selection of CG members

Once networks have provided proof that they fulfil the membership criteria, the final composition of the CG will be established to meet the above criteria. Networks or centres may have to group themselves to be represented ("special interest groups") once the maximum number as per composition criteria of the CG has been reached.

Special interest groups should identify a representative best able to represent their views as a member of the CG and should meet at least once yearly at the EMA, on the occasion of the annual workshop, to ensure inter-network exchange and information.

If there are more than the agreed numbers per composition criteria and no proposal for grouping can be obtained, appointment to the CG will be made by the Chair and two EMA staff representatives using the following criteria:

- Balance of skills and expertise within the respective category
- Level of participation in the Network over the past year
- National and/or Regional balance of the Committee

Applications for CG membership should be submitted in writing to the Enpr-EMA Secretariat no later than two weeks before the date of the Enpr-EMA annual plenary meeting. At the time of application, candidates shall submit a brief résumé, including a brief statement of no more than 400 words in support of their candidature. The Enpr-EMA Secretariat will circulate the list of candidates and their résumés in advance of the Enpr-EMA annual plenary meeting at which the selection is to take place. In case a CG member needs to be replaced during the year and it is deemed beneficial not to wait until the next annual plenary meeting, the Enpr-EMA Secretariat will circulate the candidates' résumés and selection will take place in writing (e.g. via e-mail) or at the following CG teleconference.

Enpr-EMA members shall be informed about the selection together with a description of the role and functions of the CG and the rules of the selection procedure no later than 4 weeks in advance of the annual plenary meeting

3.3 CG observer members

In addition of the listed in 3.1., representatives of the European Commission may attend as observers.

According to the Enpr-EMA Implementing Strategy industry is classified as a major stakeholder. While not represented directly in the CG, industry can be invited as observer to attend CG meetings on ad-hoc basis to discuss selected topics, warranting its involvement in the activities of Enpr-EMA. The CG will ensure that there is representation from both, big pharma and SMEs.

In addition to CG members and to ensure close cooperation with international networks, non-EU/EEA network members fulfilling the recognition criteria are eligible to become observers. Appointments of observers shall be considered by the CG on a case by case basis.

3.4. Duration of CG membership

CG membership is for individuals and for a 3-year term. However, this membership can be renewed for more than one term if replacement cannot be nominated and it is not objected by the CG.

After 2 full terms, a new network representative should be proactively proposed to ensure sufficient renewal and involvement of various individuals.

3.5. Chairs of the Coordinating Group

The CG is co-chaired by the Chair elected from among the members and the EMA.

3.5.1. Election process

The Chair of the CG shall be elected by and from amongst its members.

Nominations for Chair of the CG should be submitted in writing to the Enpr-EMA Secretariat no later than two weeks before the date of the Enpr-EMA plenary meeting at which the election is to take place. At the time of application, candidates shall submit a brief statement of no more than 400 words in support of their candidature. The Enpr-EMA Secretariat will circulate the list of candidates and their résumés in advance of the Enpr-EMA plenary meeting at which the selection is to take place.

At the Enpr-EMA plenary meeting each of the candidates will be given the opportunity to give a short (three minutes) presentation before proceeding to the election. For reasons of force majeure candidates may stand for election in absentia. In this case, a presentation may be possible via teleconference.

Enpr-EMA members shall be informed about the election no later than 4 weeks before the meeting at which the Chair will be elected. A description of the role and functions of the Chair of the CG and the rules of the election procedure shall be provided no later than 4 weeks prior to the election.

The election of the Chair of the CG shall be based on a simple majority vote and shall be performed by secret ballot. Participation of the quorum (see 4.1) is necessary for the conduct of the vote. The candidate receiving most votes will be chosen. In case of a tie another round of voting may be necessary. Members of the CG who are unable to attend the election may appoint a proxy to vote on their behalf.

The Co-chair shall be appointed by the European Medicines Agency for the duration of the term of service of the CG (three years).

3.5.2. Term of service

The Chair of the CG shall be elected for one term of three years, renewable for one additional 3-year term only, to ensure sufficient renewal and involvement of various members.

Terms shall begin at the close of the meeting at which the Chair is elected.

In the event of the Chair resigning during the tenure, a call for nominations for election for the vacated position will be held.

In the event of resignation of the Chair, the Co-Chair shall take the chair until a new election is convened.

3.5.3. Role and tasks of the CG members and chairs

1. The responsibilities of the CG Co-Chairs include: agreeing dates of meetings, preparing the agenda with the secretariat, ensuring that meetings are properly conducted, and regular reporting to the Paediatric Committee (PDCO), which acts as the scientific committee of Enpr-EMA. The Chairs should strive to obtain consensus for all decisions of the CG.
2. The tasks of the CG will include, but are not limited to the following:

2.1. Identification of Enpr-EMA's priority actions to achieve its main task, i.e. to facilitate the conduct of paediatric research in order to increase the availability of safe and effective medicines for children. This will include participation in and facilitation of dialogue between regulators (PDCO and other relevant EU and EMA Bodies and Committees), industry, CROs and investigators to promote trials for marketing authorisation.

2.2. Approval and oversight of Enpr-EMA's work and activities.

2.3. Adjudicator in case of discrepancies or complaints in the context of Enpr-EMA.

2.4. Ongoing review of Enpr-EMA's working model and working group structure, and assistance to the EMA in making any necessary revisions

2.5. Champion and promote Enpr-EMA

3. The secretariat co-ordinates and records all CG-related activities including invitations and the organisation of meetings (virtual and face-to-face), distribution of the agenda, preparing minutes of the CG meetings and managing the members' declarations of interests.

3.6. Stakeholders

Collaboration should be established with ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) to avoid duplication of tasks and harness synergies.

The CG will establish strong links with the Clinical Trial Facilitation Group (CTFG) and the GCP Inspectors Working Group to develop a common understanding and improvement of processes.

Industry and CROs are not represented directly within the Coordinating Group but are expected to be a major stakeholder in discussions about future developments and their impact on paediatric research and clinical trials. Industry/CRO representatives will be invited to the annual workshops of Enpr-EMA and to attend CG meetings as observers[2] on ad-hoc basis, to discuss selected topics.

4. Rules of procedure

4.1. Methods of work

- Membership of the CG implies a commitment to attend its meetings regularly and to participate actively in its work. In cases where a member is unable to attend a meeting, he or she may nominate a replacement.
- The CG shall meet three times per year. The Chairs are responsible for convening meetings. The Chairs may propose additional meetings if considered necessary. This should be considered in the context of the Agency's work programme and available resources.
- A minimum attendance (quorum) of two thirds of the members (not including observer members) is mandatory for any decision on membership or direction of the network.
- Meetings will be face-to-face, virtual or by tele/web conference.
- The Enpr-EMA Secretariat is responsible for ensuring that the agenda of the meeting and supporting documentation is made available to the members in good time before meetings.

[2] See footnote 2 above

- Business will be conducted by careful and considered deliberation leading to consensus where possible. Where consensus is not achieved recommendations shall be decided by majority vote. In the case of a tie vote the person acting as Chair shall be entitled to a casting vote.
- The CG may decide to ask parties who are not members of the CG to participate in a meeting so that they can provide relevant information, material or knowledge to the Coordinating Group. These co-opted experts may be representatives from e.g. non-EU regulators, learned societies, or experts with a relevant background (e.g. legal, scientific, ethical, etc).
- The CG may establish working groups within the CG's mandate. Each working group shall include at least one CG member and any number of co-opted Enpr-EMA members.
- The Co-chair together with the two PDCO representatives will regularly report to the Paediatric Committee, which acts as the scientific committee of Enpr-EMA.

4.2. Speaking and voting rights

CG members have speaking and voting rights. In cases where a member is unable to attend a meeting, he or she may nominate a replacement, who would have speaking and voting rights on their behalf for the duration of that meeting. Appointments of replacements should be communicated to the Enpr-EMA Secretariat prior to the meeting.

Observers and co-opted experts have speaking but no voting rights.

4.3. Channels of Communication

The Enpr-EMA Secretariat reports the outcome of each CG meeting to all networks /centres referred to as the Enpr-EMA plenary.

Minutes of Enpr-EMA meetings will be published on the website.

The Chairs of the CG report to the annual Enpr-EMA workshop and to PDCO.

4.4. Consultation Process

The CG is encouraged to consult the Enpr-EMA plenary on particular issues; if it decides to consult, it will determine the form and method of consultation. Consultation might involve, but is not restricted to, the annual workshop of Enpr-EMA, questionnaires and surveys, or web-based consultation.

The CG must consider any proposals submitted by Enpr-EMA members.

4.5. Review of terms of reference and mandate

The Enpr-EMA plenary in collaboration with the PDCO shall review the mandate of the CG at least every 3 years, taking into account any recommendation(s) from the CG for modifications. The CG may at any time ask the Enpr-EMA plenary and the PDCO to consider a recommendation for changes to its terms of reference and mandate. These changes are subject to formal agreement by the European Medicines Agency.

4.6. Conflicts of interest and code of conduct

Individual CG members should commit to follow the Policy on transparency and the handling of potential conflicts of interests of members of the European Network of Paediatric Research at the European Medicines Agency(Enpr-EMA) Coordinating Group and working groups.

Any external communication should be in line with standard EMA procedures and Code of Conduct. When participating in international or other fora, CG members shall make clear that the views expressed are their own views and use an appropriate disclaimer, unless they are formally mandated to represent the views of Enpr-EMA. They cannot commit or engage Enpr-EMA without the mandate of Enpr-EMA.

4.7. Travel and accommodation

Face-to-face meetings of the CG take place at the EMA premises in Amsterdam, and travel and accommodation for the meetings will be reimbursed according to the EMA Rules for reimbursement of expenses for delegates and experts attending meetings.

No remuneration is available for activities relating to Enpr-EMA.