Minutes - Enpr-EMA Coordinating Group meeting

Date: 06 March 2025; 14:00-16:00 CET; online; and 29 April 2025; 15:00-16:00 CET; online (induction of newly appointed members and observers)

Chairpersons: Pirkko Lepola / Gunter Egger

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Adoption of agenda: The agenda was adopted without changes.
Introduction of all the members of the renewed Coordinating Group (CG): Pirkko Lepola welcomed the new CG of Enpr-EMA and gave the opportunity to each member to introduce themselves and their network, providing a brief overview of their activities and goals.
Structure of Enpr-EMA: Pirkko Lepola provided an overview of the structure and objectives of Enpr-EMA, explaining its foundation based on the Paediatric Regulation and its continuity based on the upcoming new pharmaceutical legislation, as an organisation that facilitates paediatric clinical studies, building competences, with the ultimate goal to increase the availability of medicines for children. Enpr-EMA is linked to the European Medicines Agency (EMA) and the Paediatric Committee (PDCO), along with other multistakeholder groups and partners which support the development of the network. It is composed of networks and other stakeholders involved in the development of medicines for the paediatric population, currently counting with 57 networks among its members. The CG serves as the operational centre of Enpr-EMA, responsible for defining the network's strategy and activities. Having been renewed for a three-year term mandate, the new CG is now composed of 12 networks, 2 PDCO members and observers including an additional PDCO representative, with the possibility to invite additional members to provide specific expertise.
Priority activities of Enpr-EMA

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Isabel Sanchez presented the activities which the network is currently working on. The priority tasks and needs are identified during the annual workshop and dealt with by Enpr-EMA working groups that are formed ad-hoc to work on these identified activities.

The following working groups (WG) are currently active:

1) **WG on paediatric clinical trial site quality criteria**

The group was formed to address the additional complexities involved in conducting paediatric clinical trials with the main objective to establish a set of standardised minimum quality requirements and a development pathway for clinical sites to conduct paediatric clinical trials. A recommendation paper has been developed and following a public consultation period it will be published on the Enpr-EMA website. Moreover, a scientific publication is in preparation.

2) **WG on cross-border access to paediatric clinical trials**

The group was established to address discrimination based on language, culture, and other factors affecting paediatric clinical trials. The group's main goal is to enable paediatric patients to participate in clinical trials conducted in different languages and countries. To achieve this, the group is analysing data to identify instances of discrimination, reporting their findings in a publication, and creating guidance to ensure paediatric patients can be included in cross-border clinical trials in Europe.

3) **WG on international collaboration**

The group aimed to promote international collaboration to facilitate the conduct of global paediatric clinical trials. It included members from regulatory authorities and networks in Europe, the US, Canada, Japan, Australia, and the UK. The group's projects focused on defining site requirements and outlining the approval and ethics review processes for paediatric clinical trials in these six jurisdictions.

As a result of these efforts, a working group on site quality criteria was created, and two manuscripts detailing clinical trial authorisation and ethics review processes have been published in Frontiers in Medicine.

- Requirements and special considerations for drug trials with children across six jurisdictions: 1. Clinical trial application review in the regulatory approval process
- Requirements and special considerations for drug trials with children across six jurisdictions: 2. Ethics review in the regulatory approval process

With these projects completed, the working group is currently on hold until new topics are identified.

4) **WG on paediatric research nurses**

The group was established to enhance the role of paediatric research nurses in clinical trials, with the goal of creating a network of paediatric research nurses and a European peer support forum. To achieve this, the group is investigating employment conditions, career and development opportunities, training needs, and recruitment and staff retention issues affecting paediatric research nurses in Europe. A report is being prepared for publication on the Enpr-EMA website.

5) **WG on patient and public involvement (PPI) and young person's advisory groups (YPAG)**

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The group was established to enhance patient and public involvement (PPI) capabilities in paediatrics across Europe, ensuring meaningful participation of paediatric patients and parents. They have set three primary objectives: mapping existing PPI capabilities, assessing the training and resource needs of identified groups, and developing a framework to involve children, young people, and parents. The main outcomes will be the creation of a guidance document, training materials, and the publication and dissemination of key findings.

6) **WG on clinical trials in emergency settings**

New WG to be formed to deal with the specific requirements of paediatric clinical trials conducted in emergency situations.

Role and responsibilities of the CG:

Gunter Egger outlined the role and responsibilities of the CG, which acts as the governance body, responsible for addressing operational and scientific issues, contributing to both short-term and long-term strategies of Enpr-EMA.

The group consists of up to 18 members from category one networks, two PDCO representatives, and up to four additional experts, with membership for a three-year term, renewable for up to two terms. Currently, it is chaired by Pirkko Lepola (elected by the members) and co-chaired by Gunter Egger (appointed by EMA). In autumn the group will elect a new chair by and from among its members.

The primary responsibilities of the CG include identifying and overseeing priority activities to improve paediatric research, promoting events, facilitating access to centres and experts and supporting the evolution of the networks. The CG convenes three times annually, with the addition of an annual face-to-face workshop open to all stakeholders and the public.

Discussion and decision on inviting additional expertise to CG

In the meeting on 6 March 2025, the structure and competence of the CG was discussed. According to the mandate of the CG, additional expertise can be brought into the group on a permanent or ad-hoc basis, as additional members, observers and co-opted experts.

The group discussed the need to invite additional members to the CG, noting that four places are currently available for permanent members. It was generally agreed that adding additional expertise would be beneficial. Suggestions included inviting patient representatives, healthcare professionals, regulatory experts, and academic experts.

It was decided to issue a call for expression of interest to patient representatives, healthcare professionals and Med Ethics EU, while leaving the possibility open to include other experts in the future, depending on the strategic objectives of Enpr-EMA and the CG. Furthermore, it was agreed to invite industry representatives and category 1 networks from outside the EU as observers.

Following the responses to the invitations for the additional members and observers, an induction meeting with the newly joined members (patient and healthcare professional representatives) and observers (industry and non-EU network representatives) was held on 29 April 2025, with

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the same agenda as the March meeting (except for the discussion on inviting additional expertise).
Enpr-EMA meetings 2025 The following upcoming meetings are planned: - June (CG and Enpr-EMA networks meeting): date tbd. - Annual face to face meeting on **19-20 November 2025**: including the election of a new chair and an open workshop for all stakeholders.

A list of all members of the CG can be found here:
Members of the Coordinating Group of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)