Minutes - Enpr-EMA Coordinating Group meeting

Date: 30 June 2022; 14:00-15:30 CEST; By Webex

Chairpersons: Pirkko Lepola / Gunter Egger

Invitees: Coordinating Group members and observers

Agenda	Minutes
OPEN SESSION (coordinating group members and industry observers)	
Adoption of agenda	The agenda was adopted without changes.
Overview of Enpr-EMA working groups (WG): • WG on international collaboration • WG on research staff • WG on off-label evidence • WG on inclusion of paediatric patients in trials across countries.	Enpr-EMA chairs provided an overview of the different activities currently ongoing within the working groups. <u>WG on international collaboration:</u> The working group on international collaboration covers the topics of clinical trial authorisation across jurisdictions and site requirements and preparedness. For the first topic, two manuscripts are being prepared to separately cover the Clinical Trial Authorisation process in relation to Regulatory Authorities, and the Ethics Review process, in 6 different regions: Europe, UK, US, Canada, Australia and Japan. The site preparedness and requirement work has the aim of defining the criteria that sponsors require for a potential trial site to be considered appropriate for conducting paediatric clinical trials. A global paediatric site standard survey among pharmaceutical industry and contract research organisations (CROs) has been conducted, obtaining 24 completed responses and identifying

Agenda	Minutes
	several participants who have confirmed willingness to participate in a follow-up interview. The results obtained from this project along with the complementary work that is being carried out by conect4children (c4c), will be the main topic for a workshop planned as part of the Enpr-EMA Annual Meeting in October 2022. WG on research staff: The working group has resumed its activities to strengthen the role of paediatric research nurses in clinical trials across Europe. With this aim, a survey has been launched to identify training needs, development opportunities and to standardise and define the clinical research nurse role. Additionally, peer support activities have been implemented with the establishment of forums and other collaborative activities with different networks, such as with c4c for training opportunities. WG on off-label evidence: The objective of this working group is to raise awareness of the data and information that is already available regarding the use of different medicines that are prescribed off label for the treatment of paediatric patients. A manuscript is being prepared exploring the possibilities of having these data assessed, possibly resulting in new approved indications. WG on inclusion of paediatric patients in trials across countries: A new working group has been created to assess the patients' rights in regards of cross-border access to clinical trials in Europe, and to identify the main challenges and problems faced at the time of participation in these trials. The planned activities include a survey, multi-stakeholder discussions and the publication of guidance with recommendations and best practices.
Overview of other activities: • Linking up with "Accelerating Clinical Trials in the EU" (ACT EU): for better clinical trials that address patients' needs • Collaboration with Multi-Regional	Linking up with "Accelerating Clinical Trials in the EU" (ACT EU): The ACT EU initiative aims to promote and optimise the environment for clinical trials in Europe. In this context Enpr-EMA has been identified as an important source of paediatric expertise to

Agenda	Minutes
Clinical Trials Center (MRCT) of Brigham and Women's Hospital and Harvard (e.g. trial information brochures, webinars)	participate in two ongoing initiatives: • Decentralised clinical trials: A paper is being prepared with recommendations for sponsors to guide the conduct of decentralised clinical trials. Feedback from a paediatric perspective of these recommendations was sought. Two members of the coordinating group expressed their interest in being involved and will be put in contact with the Clinical Trials Coordination Group (CTCG), who coordinate this work. • Complex clinical trials: A Questions & Answers document to supplement the guidance on complex clinical trials has been published on the website of the European Commission. Enpr-EMA members were encouraged to review the document and inform Enpr-EMA secretariat of any comments they may have from a paediatric perspective. These would be taken into account for an update of the document (probably to be published in early 2023). Collaboration with Multi-Regional Clinical Trials Center (MRCT) of Brigham and Women's Hospital and Harvard: Enpr-EMA members are actively collaborating with MRCT on their activities of advancing clinical research in paediatric medicines. These activities include the creation of educational brochures directed to paediatric patients participating in clinical trials. The brochures cover the topics of starting and ending participation in clinical research, defining for example the assent and informed consent process. Enpr-EMA members (eYPAGnet) are participating in the adaptation of these brochures to the European Legislation in order to co-brand these materials and make them available in Europe. Additionally, in line with the objective of promoting global clinical research in children, a series of 5 webinars (three have already taken place and two more are planned) are being organised with the participation of members of Enpr-EMA, to advance the design, review, conduct and oversight of global

Agenda	Minutes
	paediatric research.
Topic proposals for next annual meeting and beyond: • Trial site standards • Call for topic proposals for network specific slot at the annual meeting • Call for topic proposals for industry slot at the annual meeting	Members were asked to discuss and propose topics for the next Enpr-EMA annual meeting that will take place on 4 October 2022, preceded by a workshop on site standards and preparedness scheduled on 3 October 2022. The workshop will present the results of the international working group's global paediatric site standard survey in combination with c4c work on site standardisation. Agenda and further details will follow. Topics proposed for the annual meeting included complex and decentralised clinical trials, and Health Technology Assessments (HTA) for paediatric medicines. Members expressed great interest in the latter topic as it has (among other things) an important impact on the patients' access to approved medicines and their availability, highlighting the importance of involving HTA bodies from the initial steps of the medicine development. It was suggested to invite speakers from EUnetHTA to the meeting, in order to have a clear view of their requirements, to implement discussions and to elucidate steps in order to plan clinical trials that could lead to increasing the availability of paediatric medicines.
CLOSED SESSION (without industry observers)	
Endorsement of newly received or updated applications for Enpr-EMA membership	The members were informed of the following membership updates: - NETSTAP: already existing Enpr-EMA member, a multi-specialty network, that has been upgraded to category 1 according to the updated self-assessment form. - PolPedNet: a new application for a multi-specialty Polish national paediatric network. Still some outstanding issues in the self-assessment to be resolved. - Neocirculation: specialty network in neonatology that has been closed and will thus be removed from the Enpr-EMA member network database.
Enpr-EMA membership and coordinating group composition:	The CG discussed the evolving paediatric landscape, which has seen the creation of new

Agenda	Minutes
• How to manage "double-membership" of networks like currently those part of conect4children (c4c) • How to ensure equal voice / influence / representation of networks -> future structure and memberships • Call for feedback on Enpr-EMA self-assessment form for membership application	initiatives, technologies, funding opportunities and networks since the inception of Enpr-EMA. The co-chairs initiated this brainstorming about an "Enpr-EMA 2.0" in terms of adjusting the strategy of the network, its objectives, composition and role within the current environment. Based on a presentation by the chair, Enpr-EMA membership criteria, the categories, the application procedure and the self-assessment form were discussed. It was pointed out by the chair that the characteristics of the membership definition as agreed at the inception of Enpr-EMA, corresponded to the original circumstances and needs, but that currently there is a need to adapt to the new environment both in terms of network structure and in terms of activities. A member suggested expanding the focus to cover not only the clinical development but also pre-clinical and all the steps of drug discovery, promoting the participation of academia. Although these important parts of the drug development are out of the legal scope of Enpr-EMA, an opportunity could be sought in relation to the ongoing revision of the Paediatric Regulation. It was agreed that the membership criteria along with the application procedure and the self-assessment form could be revised, simplifying the procedure and reducing bureaucracy. Moreover, it was stated that the benefits of each of the membership categories could be more clearly defined, along with the structure and role of the coordinating group. The adequateness of the representation of all EU member states and of all therapeutic areas in the coordinating group, as well as the collaboration with other stakeholders and observer members were some of the topics suggested for further discussions and "re-thinking". The position of Enpr-EMA among the co-existing networks, the issue of "double and triple memberships" between them, and the main benefits of being a member of Enpr-EMA (values, benefits, mission) were briefly discussed. Participants stated that Enpr-EMA membership was considered important in order for networks to be presented at a European level, above all for countries with fewer opportunities for development

Agenda	Minutes
	and for the area of rare diseases, as Enpr-EMA represents an opportunity for training, development and spreading of knowledge and expertise. Furthermore, the close collaboration between Enpr-EMA and the PDCO was highlighted as a differentiative characteristic of Enpr-EMA over other networks and initiatives. This collaboration should be bidirectional, where on the one hand, the PDCO seeks advice related to the experience and expertise of the networks, related to specific PIP applications (feasibility issues, clinical landscape, special needs, etc), and on the other hand, the networks bring topics about specific conditions or therapeutic areas for discussion to the PDCO. Participants acknowledged that further discussions on these topics would be warranted.
Election of chairperson of coordinating group at the annual meeting in October 2022	Members were reminded that at the next Enpr-EMA annual meeting the election of the chair will take place and members of the coordinating group were encouraged to submit their candidatures. Further information will be sent to the members in due course.
AOB End of meeting	The members were informed of the planned TEDDY Hearing within the Council of Europe (COE) regarding children's participation in the decision making in the biomedical field. More detailed information was provided in a follow-up email.