Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 21 February 2020; 14:00-15:30 CET; By Adobe Connect

Invitees: Coordinating Group members, Enpr-EMA member networks, working group chairs

Apologies: Dimitrios Athanasiou, Saul Faust, Thierry Lacaze, Tim Lee, Vincent O'Mahony, Christina Peters

EMA participants: Irmgard Eichler, Lise Flaunoe

Chairpersons: Pirkko Lepola / Gunter Egger

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Adoption of agenda	The agenda was adopted without changes.
Updates from the working groups (WG): • WG on ethics • WG on parents and patients • WG on research staff • WG on clinical trial preparedness • WG on international collaboration → Cross WG collaboration & integration - discussion	Members of the working groups gave brief updates on progress since the face-to-face meeting in October 2019. • WG on ethics (Pirkko Lepola) A guidance document related to consent / assent information was finalised and awaiting publication on the Enpr-EMA website. In addition, a manuscript for submission to a scientific journal was close to finalisation. It was agreed to close the working group until the need for further work on ethics arises. Pirkko thanked all members of the WG for their excellent collaboration. • WG on parents and patients (Dimitrios Athanasiou) The update was deferred due to Dimitrios' absence. • WG on research staff (Vincent O'Mahony) Due to Vincent's absence Gunter presented on his behalf (C: The group plans to implement some recommendations from the survey among paediatric research nurses: 1) Determine feasibility of online training portal, webinars, face-to-face training and workshops, as well as peer-to-peer

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	communication and support 2) Standardisation of role of paediatric research nurse and promotion of role across countries, including determination of feasibility of standardised job descriptions, contact pharmaceutical industry to determine expectation of nurses/coordinators at site to aid standardisation. 3) Enpr-EMA members were encouraged to spread the word of this European group of paediatric research nurses when attending scientific conferences, within their networks / hospitals /organisations. Interested paediatric research nurses can get in touch via enprema@ema.europa.eu. The WG was advised to contact recently emerged Enpr-EMA networks, such as PEDDCReN, OKIDS, SwissPedNet, ECFS-CTN, for information on funding possibilities and advice on how to establish a new group/network. • WG on clinical trial preparedness The group was informed that due to the withdrawal agreement following the UK's departure from the EU Angeliki Siapkara, former PDCO member appointed by the MHRA (UK), can no longer be involved in Enpr-EMA's activities after 31 January 2020. Pirkko and Gunter thanked Angeliki for her excellent contributions to Enpr-EMA's activities and for her work as WG chair. It was agreed that the appointment of a new WG chair would be discussed with the members of the WG in the near future. The document on recommendations on trial preparedness was being finalised incorporating the comments received during public consultation and is expected to be published on the Enpr-EMA website. Another delivery of this working group, the outcome of a survey among stakeholders, is planned to become a separate publication. • WG on international collaboration (Thierry Lacaze) Due to Thierry's absence Gunter presented on his behalf: The environmental scan on requirements for clinical trial applications in 5 different regions (Europe, US, Canada, Australia, Japan) was progressing, but information from one region (US) was still missing. The comprehensive overview summarised in a user-friendly table is planned to be published in a scientific journal to serve as guidance for sponsors of multiregional trials. The CG was informed that Thierry would also collaborate

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	with MRCT (Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard) to ensure that synergies between the Enpr-EMA WG on international collaboration and MRCT's initiative on promoting global clinical research in children are fostered and to avoid duplication of work. → It was highlighted that WGs should cross-reference work of other WG where applicable (e.g. trial preparedness & network consultation model, ATMPs & labelling).
Updates on other initiatives: • Advanced Therapy Medicinal Products (ATMPs) • Clinical practice evidence in the labelling • Opportunities for European patients in global programmes	• Advanced Therapy Medicinal Products (ATMPs) (Christina Peters) At the CG meeting in October 2019, it was suggested that a brief scientific article from academia and clinical investigators (e.g. European Society for Blood and Bone Marrow Transplantation (EBMT)), would be an important first step to raise awareness about the need for clearer guidance on several issues regarding cell-based products (e.g. ownership of cells, responsibilities regarding long-term preservation). After the annual congress of EBMT at the end of March Christina will inform the CG about the final decision of EBMT's paediatric diseases working party on how to proceed. • Clinical practice evidence in the labelling (Saskia De Wildt) A first teleconference has taken place to discuss the problem statement on "Off-label is not always off-evidence: Proposal to add existing evidence in the paediatric drug label". It was agreed that a draft manuscript would be prepared by the currently established small group before disseminating the draft among Enpr-EMA members for their comments. In preparation of this first draft, all Enpr-EMA members were kindly asked to send examples (of one or two drugs) which are frequently used (high therapeutical need) in children but do not have a paediatric label or drugs which have a paediatric label but are frequently used in another paediatric indication (high therapeutical need) off-label to enprema@ema.europa.eu. • Opportunities for European patients in global programmes Only 6 networks had replied to the initial survey to explore the views of Enpr-EMA network members whether European patients had equivalent access to clinical trial opportunities compared to other patients globally. Therefore, as agreed at the last CG meeting, the survey was resent. However, only 3 more networks replied, and it was indicated that the problem observed in the field of cystic fibrosis, where trials might be run first in the US and only later in the EU, was not seen as a general problem but disease specific. Consequently, it was agreed to not proceed with this topic any further.

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Enpr-EMA's links to other paediatric research initiatives: current status - how to optimise?	A current list of all initiatives which Enpr-EMA is linked to via its networks, individual experts or expert groups, was presented. The list was discussed, and it was further mentioned that a link to the European Children's Hospitals Organisation (ECHO) should be added to this list, as it is also represented in Enpr-EMA by Marek Migdal (PDCO representative). All connections to other organisations and initiatives may be beneficial in order to increase Enpr-EMA's reach among health care professionals and facilitate sharing of public information. It was mentioned that there was a plan to organise a "paediatric research-landscape" -meeting, where the European Commission (EC) will be invited as well as all relevant organisations, networks, infrastructures and initiatives, to discuss the paediatric research landscape and its various roles with a focus on investigators' needs. The meeting is planned to take place in Q3 2020, possibly in Brussels. Planning of the event, costs and funding will be discussed separately. Mark Turner agreed to keep Enpr-EMA Secretariat informed about the progress of planning for this meeting with a view of ensuring Enpr-EMA involvement.
AOB • *Note on EC report on Paediatric and Orphan Regulation* • *F2F meeting on 28/29 September 2020* • *Next CG teleconference*	• The EC report on the Paediatric and Orphan Regulation is expected in the summer of 2020. • The annual Enpr-EMA meeting 2020 is scheduled to take place on 28/29 September 2020. • Members were informed that the next CG teleconference was planned for June 2020. Members will be consulted through Doodle poll regarding possible dates.
End of meeting	