27 June 2017
EMA/329838/2017
Human Medicines Research & Development Support Division

Minutes of the 2017 annual face to face meeting of the Enpr-EMA Coordinating Group (CG)

Wednesday 17 May 2017

Chairpersons: Mark Turner / Irmgard Eichler

Item	Summary of discussion
Adoption of the minutes of the Coordinating Group meeting by TC on 20 January 2016 Adoption of the Agenda	The minutes of the last CG teleconference were adopted as well as the agenda of this meeting.
Outcomes of 9th annual workshop 2017	The CG reviewed and confirmed the following outcomes / action points reached at the annual workshop: ***Working group on GCP training across multiple specialties and countries*** 1. Submission for publication of the manuscript on training needs of research nurses. 2. By October 2017. 3. Development of a core training curriculum for research nurses: The group will investigate different arrangements that are available and gather examples of good practices for building up a pool of research nurses, and propose a priority list of actions. Enpr-EMA members will reach out to nurses in order to involve them in the working group By October 2017.

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	Working group on ethics 4. To allow Enpr-EMA secretariat regular updating of the ethics toolkit all stakeholders are requested to check and inform the secretariat about changes or mistakes. 5. Collaboration with EUREC and establishing a joint Enpr-EMA/EUREC group in order to develop an agenda for transnational harmonisation of paediatric expertise in ethics committees. The group will collaborate with EUREC in order to develop an agenda for transnational harmonisation of paediatric expertise in ethics committees for national implementation. As a first step a teleconference with EUREC will be organise. By July 2017. 6. Collaboration with young people's advisory groups (YPAG) The group will collaborate with eYPAGnet in order to create a model for e-consent forms and to review the assent template created by the ethics working group. YPAG will be asked for advice as to how the text in the form should be presented and a template should be agreed. By October 2017. ***Working group on young patient advisory groups*** 7. Creation of a business model for eYPAGnet At a meeting scheduled in June 2017 the group is expected to propose different models. Then a dialogue with industry regarding funding should ensue and an update provided to the Coordinating Group. By October 2017. 8. Interface creation between eYPAGnet and disease specific patient support groups By October 2017. ***Working group on public-private partnership*** 9. Pilot of consultation process The group will publish the consultation recommendation document and ask for volunteers to test it during a pilot phase. The pan-European paediatric research network (IMI2 project) may be a helpful collaborator for this project. By October 2017. 10. Survey among companies who took part in the pilot No timeline specified.

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	Working group on paediatric clinical trials for antibiotics 11. Publication of summary document on trial design No timeline specified. Other action points: ***European Reference Networks (ERNs)*** 12. It will be crucial to establish a close dialogue with the ERN Coordinating Group. Ruth Ladenstein will act as EMA's contact to ERNs and will promote close collaboration between ERNs and Enpr-EMA at the next meeting of the ERN Coordinating Group. Mark Turner may take part in one of those meetings, either in person or remotely. ***International collaboration*** 13. There is a need for establishing one single network/group per jurisdiction in order to enable communication and discussions between global networks (Enpr-EMA, Institute for Advanced Clinical Trials for Children (iACT), China, Paediatric Trials Network Australia (PTNA), etc.). Kalle Hoppu will provide contact points for certain initiatives.
Industry perspective & proposals	The support Enpr-EMA can provide is considered very useful for industry, but Enpr-EMA is still not well known among industry. It was discussed that there is a need to raise awareness about the existence of Enpr-EMA and its work. It is crucial to reach the paediatric research centres in pharmaceutical companies who design paediatric trials. Regulatory staff may not be the appropriate target group. Paediatric centres within companies may have meetings where they bring in external experts. This could be an opportunity to promote Enpr-EMA. It was suggested that EFPIA could assist Enpr-EMA in this effort. The following actions were discussed to help to raise awareness about Enpr-EMA: • Enquire with EFPIA about the possibility to attend (remotely) meetings with paediatric research centres in pharmaceutical companies. • Awareness webinars, like the first one which took place in December 2016, should be repeated in order to publicise Enpr-EMA's work. The webinar will be published on Enpr-EMA's website. • The role of Enpr-EMA should be included and highlighted in the EU Network Training Centre for regulators. • Enpr-EMA brochures could be distributed to all industry delegates who come to meetings at the EMA. • The report of the annual workshop and the annual newsletters should be disseminated to all trading associations. • The EMA website should be improved in order to give more visibility to Enpr-EMA. • The working group on public-private partnership could consider organising a meeting with companies to inform them about Enpr-EMA.

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	• Enpr-EMA representatives should at least include the Enpr-EMA logo in all their presentations, and perhaps also a statement along the lines of 'this network is a member of Enpr-EMA'. Members should be actively invited to use the logo. • A short video could be produced (pending resources) in order to be used in conference settings. • An Enpr-EMA Twitter account may be useful (to be discussed with the EMA's Communication team).
PDCO perspective & proposals	Paediatric Committee (PDCO) members expressed their appreciation of the collaboration with Enpr-EMA, which is considered crucial for the successful conduct of paediatric investigation plans (PIPs). The committee members would like to strengthen the following aspects in order to better reach the common goals of improving clinical trial methodology, and designs in order to increase the availability of high quality licensed paediatric medicines: • Collaboration on guideline development and on development of paediatric inventories on therapeutic needs • Contribution to PIP process for therapeutically meaningful drug developments • Creation of networks' contact points to facilitate experts' identification and procedural participation within the strict timelines of the PIP process • Creation of regulatory/disease-specific training sessions for networks / EMA / PDCO members Presentation - PDCO perspective and proposals (Angelika Siapkara)
Organisation of CG meetings	It was proposed to have two virtual meetings for working group updates, of 1-hour duration each. In addition there should be a 1-hour teleconference for the actual CG meeting. These meetings will be scheduled for autumn 2017. Following the meetings it will be re-evaluated if this schedule is more convenient that the previous practice of one 3-hour CG meeting.
Communication of difficulties with paediatric studies to PDCO	If a paediatric trial included in an agreed PIP becomes unfeasible or if the therapeutic environment changes it becomes necessary to modify the agreed PIP, for example in order to change the trial design. In such cases it may be helpful for the PDCO to have a direct dialogue with the network involved with the trial. From EMA perspective, a direct communication with PDCO can only be possible through the sponsor/PIP applicant. Therefore, in order for the network to get in touch with the PDCO the sponsor/PIP applicant could request an oral explanation meeting during a PIP modification procedure. Representatives of the network could then be invited by the sponsor to present at the oral explanation meeting. To this end it would be important to clarify the scope of the discussion beforehand in order to avoid confidentiality issues. In addition, the network representative(s) would need a confirmation from the network that they are indeed authorised to speak on behalf of the network.

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	A summary of the proposed approach for this kind of interaction will be drafted in order to be discussed with industry associations.
Update on status of emerging networks	Severe Paediatric Asthma Collaborative Europe (SPACE) SPACE is an emerging network which aims to enhance participation of asthmatic children in therapeutic trials of new biologics and receptor blockers. Two meetings have been held at the EMA (May 2016, March 2017), bringing together paediatricians specialised in the area of respiratory diseases. Among other things a core dataset has been worked on to allow identification of eligible children with severe asthma across Europe.
Endorsement of newly received applications for Enpr-EMA membership	The following networks were endorsed as Enpr-EMA members: • Spanish Paediatric Clinical Trials Network (RECLIP) (Category 1) • Spanish Translational Research Network in Paediatric Infections (RITIP) (Category 3) • Respiratory Syncytial Virus Network (ReSViNET) (Category 3) • Central European Paediatric Oncology Early Trials Alliance (CEPOETA) (Category 3) • Medicines for Children Network Norway (NorPedMed) (Category 3) • European Young Person's Advisory Group Network (eYPAGnet) (Category 4)
Notification of need for renewal of network representation in CG in 2018	The members were reminded that soon there will be the need for re-nomination of network representation in the CG. Enpr-EMA secretariat will send out a reminder.
Next Enpr-EMA CG teleconference to be scheduled	The date of the next CG teleconference will be scheduled for autumn 2017. A Doodle poll will be sent out. The next annual face to face meeting of the Enpr-EMA Coordinating Group (CG) is scheduled for 8 June 2018.