20 June 2016
EMA/520986/2016
Human Medicines Research & Development Support Division

Minutes of the 2016 annual meeting of Enpr-EMA members

Friday 03 June 2016

Chairpersons: Mark Turner / Irmgard Eichler

Item	Summary of discussion
Introduction and welcome: • Outcomes of the annual workshop. • Network wish list for next year working plan.	The annual meeting of Enpr-EMA members started with an overview presented by the Chair of Enpr-EMA, Mark Turner, of the outcomes of the Workshop held the previous day in order to summarize the agreed action points: **Action point 1**: to contribute to Public consultation on the revision of Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors. A small group will prepare a comments document to be distributed to the networks for additional comments and endorsement. Deadline: First draft to be prepared by end of June for distribution to the networks for comments. Involvement of the ethical committee network was suggested and agreed. Integration of paediatric specific issues in trainings for ethic committees: Pirkko Lepola to present Enpr-EMA at EUREC meeting (European Network of Research Ethics Committees); she will raise this issue and report back to Coordinating Group in October 2016 for further discussion. **Action point 2**: **Young people advisory groups**. **Proposal**: to develop a European-oriented network of young advisory groups. The aim is to establish a platform to promote common practices in the different EU countries, to harmonise and standardise training and educational material, and to give support in case specific expertise is needed. The need to develop database of YPAGs was identified. Financial contribution from networks should be considered. Further discussion planned at the upcoming iCAN Summit in Barcelona in June. **Action point 3: Network and industry interaction**. Finalisation of the guidance draft; comments will be asked from industry. Deadline for the questionnaire: maybe ready for CG meeting in October.

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	Action point 4: **Generic/ non product-specific issues related to paediatric clinical trials**. Industry identified urgent need for multi-stakeholder meetings to discuss non-product specific, generic issues and difficulties encountered with the conduct of paediatric clinical trials as well as for discussions on clinical trial preparedness. A draft SOP how to organise such multi-stakeholder meetings has been prepared by Enpr-EMA working group and is currently under review to align it with the relevant EMA policies. "Trial preparedness" will be discussed in a dedicated session at the EFGCP/DIA/EMA meeting on 10/11 October 2016 where it should be agreed how to proceed; consider a follow-up meeting hosted by Enpr-EMA early 2017. **Action point 5**: **How could EMA and PDCO work better with Enpr-EMA?** There is lack of awareness of existing pathways for interaction with the Agency, e.g. public consultation, becoming experts in scientific advice procedures. Raising awareness and making them more available to the networks should be first step. Additional proposals: To develop a list of networks with available specific expertise to enable PDCO to identify experts in advance (panel of experts). Networks are encouraged to publish as much as possible (topics such as outcome measures, how networks work…) These publications can be used by the PDCO for their assessment. Organise PDCO-network meetings on therapeutic areas selected by the PDCO 2-3 times per year for training /education. **Action 6: how can Enpr-EMA work with learned society?** All networks already linked with learned societies should inform Enpr-EMA secretariat to identify what areas are not represented at all; Enpr-EMA secretariat to create a list of learned societies represented among the networks for next Coordinating Group meeting in Oct.
Welcome to new networks	Two new networks joint Enpr-EMA: • DCRI (Duke Clinical Research Institute) - USA • MCRN-Hungary
How to access the European Clinical trial registry	Networks received short training on "**How to obtain personalised updates from EU Clinical Trials Register:"** Word document: https://rawgit.com/rfhb/euctrnotifications/master/howto.docx Web page: https://github.com/rfhb/euctrnotifications
Break-out sessions: Opportunity to share experiences, discuss (new), common approaches,	Interaction between networks to benefit from common and shared interests The opportunity to share experiences and discuss different approaches and modes of operation among networks was highly appreciated, in particular by the multispecialty national networks. One hour was considered too short; it was proposed to have an additional separate meeting among national networks, potentially the evening before the annual Enpr-EA meeting. Networks want to learn and know more about the other networks, how they

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exchange of work plan and establish action learning sets • National Networks (including Family networks) • Specialty Networks (including emerging networks)	work, operate, differ, how to find partners,… The information currently provided in the self-assessment report considered insufficient; amending the assessment forms was proposed. Topics of discussion among specialty networks included - transparency: it was suggested that networks should publish on their own website how they are funded. This is in line with the Enpr-EMA's policy on transparency and recommendation. - interaction between PDCO/Enpr-EMA: to plan regular TCs between networks and PDCO members within therapeutic-specific areas.
Feedback from FDA workshop on long-term paediatric safety studies	The group was provided with an outline of the FDA Public Workshop- Advancing the Development of Pediatric Therapeutics (ADEPT): Successes and Challenges of Performing Long-Term Pediatric Safety Studies 13-14 April 2016. The Chair of the PDCO presented the perspective of the EMA who is evaluating an increased number of post-authorisation safety study protocols for medicines that are newly authorised for paediatric patients. This would be particularly relevant for the work of the joint EnprEMA-ENCePP working group. Presentations and transcript of the work-shop are available on the FDA website. http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm
Feedback from EMA workshop on extrapolation	The networks welcomed the Update from EMA Workshop on extrapolation of efficacy in children
Update on recent activities by ITCC	The network followed with interest this update
Publication of networks' updates on Enpr-EMA website	The networks agreed to the publication of the annual updates they send to the Enpr-EMA Secretariat ahead of the annual workshop.
Networks financial disclosure to collect data on source of network funding	The networks were reminded to fill in and publish on their websites the adopted financial disclosure form
Conclusions and next steps	All suggestions made will be presented to and discussed by the Coordinating Group. The minutes of the meeting will be circulated to all networks for comments. The data of next year face-to-face network meeting is scheduled for Wednesday, 17th May 2017, the day after the annual open Enpr-EMA workshop.