



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2018
EMA/752866/2018

Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 22 October 2018; 14-16.00 UK time

Location: via Adobe Connect

Attendees: Alessandro Zudas, Angeliki Siapkara, Begonya Nafria, Cristina Calvo, Cristina Peters, Cristina Seren, Denise Sturdy, Donato Bonifaci, Edit Muhari-Stark, Gilles Vassal, Heike Rabe, Jean Conwa, Luca Sangiorgi, Marek Migdal, Mark Turner, Martine Dehlinger-Kremer, Mary Costello, Pascale Wenger, Pirkko Lepola, Rebecca Leary, Regina Demlova, Ruth Ladenstein, Saskia de Wild, Segolene Galliard, Susan Tansey, Thierry Lacaze, Tim Lee, Wolfgang Goepel

Present: Gunter Egger, Irmgard Eichler, Isabel Perez

Apologies: Pamela Dicks

Chairpersons: Mark Turner / Irmgard Eichler

Agenda	Minutes
Adoption of agenda	The agenda was adopted without changes
Update on work plans and feedback on progress from each Enpr-EMA working group:	Members of the working groups gave brief updates on progress since the last face to face meeting in June.
- WG on public-private partnership - WG on ethics & collaboration with EUREC - WG on young patient advisory groups - WG on educational training for research staff on paediatric clinical trials - WG on clinical trial	It was agreed that a separate working group for standard of care would not be established for the moment, but that it should be considered to include this topic in the work of the WG on international cooperation. Updates on training for research staff and on parent/patient involvement were deferred due to absence of WG speakers



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preparedness • WG on parent/patient involvement • WG on international cooperation • WG on standard of care	
Update on c4c	Mark Turner gave an update on the progress made by Conect4Children (c4c). The national hubs have started work. A call for applications to fund non-industry sponsored trials to test the viability of the c4c network has been opened: 57 expressions of interest have been received. Industry will also select some studies to evaluate the viability of the c4c network. Expert groups to support strategic feasibility work by Sponsors are under development.
Update on Paediatric Action Plan	Gunter Egger updated Enpr-EMA about the publication of the EMA/EC action plan to boost the development of paediatric medicines. It was highlighted that the outcome of several work streams of Enpr-EMA would feed into these actions (as had previously been communicated and agreed) and that these outcomes would be included in the progress reporting for the action plan, also to highlight Enpr-EMA's achievements.
Proposed data protection action	It was reported that a new data protection statement for the Enpr-EMA network database had been published on the Enpr-EMA website. Members were informed about EMA's plan to include in the future a respective statement directly in the self-assessment template for Enpr-EMA membership. Moreover, members whose personal e-mail addresses were listed in the Enpr-EMA network database were asked to either confirm by e-mail that they still agreed with this or to send a new self-assessment form with an updated general contact e-mail address.
Reminder on need for update of self-assessment forms	Members were reminded to submit an updated self-assessment form every two years.
Change in Co-chairmanship in 2019	The group was informed that from January 2019 Gunter Egger would succeed Irmgard Eichler as co-chair of Enpr-EMA.
AOB	• Paediatric Ethics-EUREC training boot camps The WG on ethics will reach out to EUREC to follow up on training "boot camps" • Annual Workshop 2019 Members were informed that due to the EMA's Business

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	Continuity Planning in relation to its relocation to Amsterdam it would not be possible to organise the usual annual open workshop. However, it was mentioned that a face to face meeting of the coordinating group and the networks was planned for Q4 2019. As a tentative date for this meeting the 14th of October 2019 was mentioned. Enpr-EMA members would be informed of a definitive date as soon as possible. - Brainstorming: Enpr-EMA working practices until next f2f meeting Due to the long period before the next face 2 face meeting members were asked to provide any suggestions for improvement of communication and collaboration in between those meetings. - Next CG teleconference Members were informed that the next CG teleconference was planned for February 2019. Members will be consulted through Doodle poll regarding possible dates.