



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Minutes - Enpr-EMA Coordinating Group & networks meeting

19 February 2019; 14-15.30 UK time;

Location: via Adobe Connect

Attendees: Donato Bonifazi, Martine Dehlinger-Kremer, Jose Drabwell, Irmgard Eichler, Segolene Gaillard, Wolfgang Goepel, Regis Hankard, Ettore Napoleone, Angeliki Siapkara, Thierry Lacaze, Tim Lee, Pirkko Lepola, Isabel Perez, Denise Sturdy, Susan Tansey, Tessa van der Geest
Apologies: Dimitrios Athanasiou, Christoph Hornik, Andy Pearson, Christina Peters, Jurgen Schwarze, Mathew Snape, Gilles Vassal, Gareth Veal, Ian Wong

Chairpersons: Mark Turner / Gunter Egger

Agenda	Minutes
Open Session	
Adoption of agenda	The agenda was adopted without changes.
Introduction of new Co-Chair	Gunter Egger introduced himself as new Co-Chair of Enpr-EMA
Update on work plans and on progress made since last CG meeting from Enpr-EMA working groups:	<u>1. WG on public-private partnership</u> Guidance document was published on Enpr-EMA website in Dec 2018. Since then: Setting up of the pilot, 7 interested networks responded to survey what services they provide and whether or not they charge a fee for services. 2 companies expressed interest to participate in pilot: NovoNordisk and GSK.
1. WG on public-private partnership	
2. WG on ethics & collaboration with EUREC	To allow additional networks to still join, Isabel to resend survey to all Enpr-EMA members. Reach out again to industry using EFPIA, EUCOPE and EUCROF contacts with deadline extended until end February (no responses from EUCOPE and EUCROF received so far).
3. WG on young patient advisory groups	
4. WG on educational training for research staff on paediatric clinical trials	A survey and potentially also case studies with companies participating in the pilot are planned in order to get feedback what companies would be most interested in very early in the development phase of paediatric medicines.
5. WG on clinical trial	While it was agreed to link the responses of the sponsor companies

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preparedness 6. WG on parent/patient involvement 7. WG on international cooperation	directly to most suitable networks (and not through Enpr-EMA), Enpr-EMA should be put in copy (cc) in all communication for tracking purposes. <u>2. WG on ethics & collaboration with EUREC</u> Guidance document on informed consent/assent: It took more than a year to develop document on what should be included in consent/assent and how different parts should be addressed as per various age groups; final draft currently under review by European Academy of Paediatrics (EAP) WG on ethics. Final document will be published on Enpr-EMA webpage; a scientific paper is also planned. Collaboration with European Network of Research Ethics Committees (EUREC): European Network of Research Integrity Offices (ENRIO) and EUREC mutually initiated the European Network of Research Ethics and Research Integrity (ENERI) to establish an operable platform of actors in the fields of research ethics and research integrity. A Boot Camp for Research Ethics Committees focusing on research with minors will be held in connection to a EUREC meeting in Prague, March 26/27 2019. Pirkko to attend and present Enpr-EMA and also inform participants about ethic initiatives going on in C4C. Book: Ethics of Research Involving Minors. A European Perspective (Dirk Lanzenrath, Marcella Rietschel (eds). Link to order book: http://www.lit-verlag.de/isbn/3-643-90975-6 Reihe: Medizin-Ethik. Medical Ethics Schriftenreihe des Arbeitskreises Medizinischer Ethik-Kommissionen in Deutschland <u>3. WG on young patient advisory groups</u> Online application for new YPAGs is now possible on EYPAGnet webpage. Several groups are already asking to become members of EYPAGnet. General assembly will take place in May It was suggested to add information on governance and on membership criteria for EYPAGnet on the webpage. Training curriculum: work in progress for 2019 <u>4. WG on educational training for research staff on paediatric clinical trials</u> A teleconference with interested research nurses from across Europe identified a need for networking and communication between the various nurse groups; Enpr-EMA could provide a platform for such dialogue; group now awaited to organise

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	themselves, nominate spokespersons and report back to Enpr-EMA to discuss future membership in Enpr-EMA as category 4 network of research nurses. <u>5. WG on clinical trial preparedness</u> Final version of draft outcome will be presented to PDCO to give them opportunity to comment before it will be put on Enpr-EMA webpage for wider consultation. Actual data of survey not included in the draft document, will be included as an Annex in a future paper. <u>6. WG on parent/patient involvement</u> As the chair was unable to attend T-conference, an update was provided in writing: A core group including patient representatives of EMA committees and working parties, which have experience in regulatory activities and medicines development in the paediatric population, has been established. Areas of interest are (1) structuring of expertise that can be gathered from the parent/patient community, (2) mapping of interaction with clinical research networks, and (3) data usage and sharing optimization. A teleconference was planned for March 2019 with EMA's patient engagement office to propose objectives and deliverables. <u>7. WG on international cooperation:</u> WG was established in September 2018, with representation of regulators and networks from 5 regions/jurisdictions: Japan/Australia/US/Canada/Europe Two teleconferences so far; agreed to describe the processes (differences/ similarities) for Clinical Trial Applications within each of the 5 regions as first step; it is planned to include some questions regarding interaction/relationship between ethics committees and regulators into this environmental scan. The outcome should be summarised in a document for publication. At a later stage the group plans to continue with Paediatric Regulation processes and Drug Approval Processes. Next teleconference: 2 April 2019
Update on F2F meeting in 4Q 2019	Preliminary agreement for a smaller meeting (only networks, and CG including the representatives of trade associations, but not industry) on 14 October 2019. Due to the imminent relocation of EMA to Amsterdam, budget for 2H 2019 not yet agreed; consequently, at present not known what kind of reimbursement will be available. Further update will be provided in due course.

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AOB <i>Update on paediatric action plan</i> <i>Update on C4C</i> <i>Data protection action: Remove personal contact details from EnprEMA database, need for general enquiry contact details</i> <i>Next CG teleconference</i>	<u>Update on paediatric action plan</u> Action plan items have been prioritised according to public health need and taking into account the Agency's Business Continuity Plan (BCP) due to its relocation. It is planned to publish outcomes of action plan on EMA and EC's websites. Enpr-EMA WG outcomes in scope of the action plan will also be linked there. <u>C4C</u> 27 applications for non-industry proof of viability studies currently under review: 4 or 5 will be selected to run in 2020-2023. Industry and non-industry will run in parallel. 18 national hubs established Processes how to work internationally under development During discussion the need and importance for close collaboration with specialty networks, similar as with national hubs, was stressed <u>Data protection:</u> Revised Enpr-EMA data protection disclaimer will be published soon, followed by amendment of the self-assessment form. Networks will be requested to submit a new self-assessment form. Networks are encouraged to provide general e-mail addresses and no longer private e-mail addresses for publication on Enpr-EMA database. For any questions please send e-mail to Isabel. <u>Next CG teleconference</u> in June, Isabel to send out Doodle poll. (Last week of June was mentioned not to be a good option due to concurrent meetings.)

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Closed Session	
Preparation for election of new Chair at F2F meeting	A call for interest will be sent to all CG members. CG members are asked to express their interest to become new chair by end of May before next CG teleconference. TEDDY representative reminded the chairs of their request to become member of the CG.
Endorsement of new or updated applications for Enpr-EMA membership: Pediatric Inflammatory Bowel Disease Network (PIBD-NET) French Pediatric Clinical Research Network (PEDSTART)	The two networks PIBD-NET and PEDSTART were endorsed as category 3 members.
End of meeting	