22 February 2017
EMA/45320/2017

Enpr-EMA Coordinating Group meeting with Chairs of the working groups

Friday, 20 January 2017, 13.30 – 16.30 UK time, EMA room 03-K and via Adobe Connect;

Role	Name
Chair/Co-chair	Chairpersons: Mark Turner / Irmgard Eichler
Present:	Denise Sturdy, Ettore Napoleone, Ian Wong, Kale Hoppu, Pamela Dicks, Mark Turner, Pirkko Leppola, Tim Lee, Wolfgang Goepel, Ruth Ladenstein, Adamos Hadjipanayis, Salma Behrouz, Mike Sharland, Segolene Gaillard, Gareth Veal John Watson, William Treem. Angeliki Siapkara, Marek Migdal, Irmgard Eichler, Gunter Egger, Isabel Perez, Ingrid Vilimelis Piulats
Apologies:	Jose Drabwell, Saul N. Faust, Brian Smith, Christina Peters.
Copy to:	
Minutes:	Ingrid Vilimelis Piulats

Topic	Agenda item	Topic leader	Minutes
Open Agenda			
1	Apologies Adoption of agenda	Mark Turner	The agenda was adopted
2	Feedback on updated work plans and work progress from each Enpr-EMA WG • WG on GCP Training • WG on Ethics • WG Young People advisory groups • WG on antibiotics	Irmgard Eichler / Mark Turner / Chairs of the Working Groups	**2.1 WG on GCP Training** The group is focusing on training of research nurses who conduct clinical trials, gathering information on various models, needs and trying to identify current gaps across different specialties and countries. A questionnaire was circulated to 75 organisations from 15 countries

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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	• WG interaction network-industry-regulators		focusing on the following questions: - types and frequency of training / training needs in different countries; - satisfaction at level of training by country / specialty; - any identified gaps in training / additional training received; - research nurse roles / differences between countries A total of 343 responses have been received. The analysis of the data is currently ongoing; it is planned to publish the results in a scientific journal with data summary and link to publication through Enpr-EMA website. **2.2 WG on Ethics** As a follow-up task on the already completed "Tool Kit - Informed Consent and Assent for Paediatric Clinical Trials in Europe", published on the Enpr-EMA website and in Arch Dis Childh 2016, the group is now working on a partly harmonized informed consent / assent template by reviewing existing templates, compiling standard sections and using similar key elements across assents and from the WHO template and to verify those also with the "Tool Kit" data in order to draft partly harmonized (as much as possible) core templates with standard language (English) and to make recommendations, what type of visual aid could be used, and what is publicly available. The first draft template is currently under review by the working group members before it will be disseminated for comments among Enpr-EMA network members by end of February. **2.3 WG Young People advisory groups** The purpose of this WG is to review the current Young Person Advisory Groups (YPAGs) that have been established within the Enpr-EMA members and to develop a database of YPAG's that can be used as a resource for EMA/PDCO and Pharma and develop operational issues. (US and Canada will be involved through ICAN). On 24th of January 2017 a European network of young people advisory groups, eYPAGnet, will be constituted as well as their steering committee: legal aspects, trial design, participation in

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			projects will be discussed. eYPAGnet has been invited and encouraged to send the self-assessment form to become a new Enpr-EMA member. **2.4 WG on antibiotics** This working group has been established in view of the planned EMA/CHMP paediatric addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections, and because of the concerns in global bacterial resistances as well as the low number of trials in children compared to adults. The role of the WG is advisory, to elicit and summarise views from a range of key stakeholders, i.e. regulators, industry and relevant academic groups/networks. The group is preparing a summary document of the core components of PK design across all age groups, the key components of design for efficacy in paediatric antibiotic trials, the specific aspects of modelling and extrapolation relevant to paediatric clinical trials (CTs) and key components of safety in paediatric AB CTs. The draft document is planned to be circulated in February to Enpr-EMA members. **2.5 WG interaction network-industry-regulators** As a follow-up task to the publication on the results of a survey among industry and networks, “Pharmaceutical Industry and Pediatric Clinical Trials networks in Europe- how do they communicate?” published in Applied Clinical Trials, 2016, the group is now preparing a recommendation document and diagram to assist companies in taking advantage of scientific and logistic expertise available from paediatric research networks. The document and draft diagram will be distributed among Enpr-EMA networks for their review and comments. The diagram will also be presented to PDCO in March.
3	Review agenda for annual Enpr-EMA workshop and face to face members meetings	All	The draft agendas were presented to and agreed by the Coordinating Group.

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4	Industry chosen topic: IMI 2 project:	William Treem	The Coordinating group was informed about the recent launch of an IMI2 call on the Creation of a pan-European Paediatric Clinical Trials Network. Applicant consortia can submit proposals by 28 March 2017.
5	Enpr-EMA awareness webinar	John Watson / Mark Turner	The awareness webinar was held in December 2016, focusing on promoting Enpr-EMA to the industry, both big pharma and SMEs: how to get access to Enpr-EMA and what benefits to expect. The recording of the webinar has been published on the EMA website. To further increase visibility of Enpr-EMA, the Coordinating Group suggested broadcasting or recording the face to face meetings on the website.
6	Plan to establish Enpr-EMA WG on "Trial preparedness"	Mark Turner	Establishing such an Enpr-EMA WG was suggested at last year's EFGCP/DIA/EMA meeting on paediatric medicines. The focus of such WG should be on challenges, hurdles and feasibility issues related to paediatric drug trials. The suggestion was strongly supported by several industry representatives who expressed their interest to get involved. The CG discussed that ideally, this WG should be co-chaired by a network representative and a PDCO member. A first step would be to formally propose the scope, the terms of reference and then make a call to all stakeholders to become a member. Segolene Gillard and Ruth Ladenstein accepted to participate in this WG.
7	Collaboration with EUREC	Mark Turner / Pirkko Lepola / Irmgard Eichler	Enpr-EMA's activities include, as outlined in Enpr-EMA's mission statement, to assist and enter into discussions with ethics committees on issues relevant to research and clinical trials in children. To this end, a first contact with EUREC, the European Network of Research Ethics Committees has been established. A teleconference with EUREC's Secretary General, the chair of Enpr-EMA and the chair of Enpr-EMA's working group on ethics, has been set up to explore ways of collaboration between Enpr-EMA and EUREC. It was clarified that EUREC is an association of national ethics committees' associations; as such its sphere of influence is limited as it cannot reach out to and/or communicate with individual ethics committees who are not united within one national ethic committee, as is the case in several

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			European countries that do not have one national ethics committee. It was agreed to brainstorm and collect ideas for collaboration from among both, EUREC and Enpr-EMA members, discuss them in a follow-up T-conference and to add the topic to this year's annual Enpr-EMA workshop with the aim to design a roadshow.
8	Update on PEDCRIN	Mark Turner	The Paediatric Clinical Research Infrastructure Network (PedCRIN), funded by a Horizon 2020 grant, had its kick-off meeting in early January 2017. PedCRIN brings together ECRIN and the European Paediatric Clinical Trial Research Infrastructure (EPCTRI) to develop capacity for multinational paediatric clinical trials. 11 Enpr-EMA member networks are part of PEDCRIN. Congratulations to Salma who has been appointed as coordinator of PEDCRIN.
9	Self-assessment form	Gunter Egger	The updated self-assessment form was presented: it now includes the request to provide information of source of funding. The new form was adopted without objections and will soon be published on the Enpr-EMA website.
10	Template for annual updates	Ingrid Vilimelis	A structured template for submitting annual updates on individual network's activities was developed and presented in order to harmonize information from annual updates. As no comments were received, it will be distributed prior to this year's annual workshop among all Enpr-EMA members. All updates received will be published on the Enpr-EMA website.
Closed Agenda			
11	Public consultation of 10 year report on Paediatric Regulation	Mark Turner	A first draft will be prepared by Mark and circulated for comments. However timelines are tight, as the public consultation period will close on February 20th.
12	Interaction of networks with PDCO	Mark Turner	In 2016 a new initiative to increase direct dialogue between networks and PDCO was started: Every 2 months network representatives are invited to the PDCO meetings to present their network and its activities to the committee and to discuss together relevant topics and/or issues related to paediatric research.

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			Mark, Pirkko and Salma reported back on their experience, when they met with PDCO in November 2016. The Coordinating Group welcomed this initiative and proposed the following wish-list to make the dialogue more agile: Networks to have an opportunity • to report to PDCO on the progress or lack of progress, difficulties and challenges encountered in the setting up/conduct of clinical trials, after consent by sponsor to do so has been obtained; • to discuss general issues, such as overlap between trials or on therapeutic area level, in face to face meetings; • to share intelligence between sites and to evaluate the success of trials; • in case a study faces major problems to find a mechanism where network-PDCO-company can discuss together; It was agreed to add this topic to this year's annual workshop: selected networks will present their experience with interaction between networks, sponsors and regulators.
13	Organisation of CG meeting: Proposal to split agenda into a section with topics for discussion and information to which all networks are invited and then one closed section for category 1 networks as per mandate of the CG to vote or consent.	Irmgard Eichler / Mark Turner	The proposal to open the CG meetings to all network members to increase transparency and knowledge transfer was not supported by all CG members; concerns were mainly: • the CG meetings via teleconference in the current format already last for 3hours which is considered too long • Enpr-EMA is enlarging; participation of all Enpr-EMA members in CG-teleconferences would make such meetings even lengthier and most likely inefficient. It was proposed • to not only publish the minutes of the CG meetings on the Enpr-EMA website but to disseminate among all Enpr-EMA members for information • to have more frequent, but shorter (max 2 hours) T-conferences

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			• to consider a network session open to all Enpr-EMA members for sharing information, followed by a closed coordinating group meeting for discussion. The topic was postponed and will be re-discussed with all Enpr-EMA members at the annual face to face meeting in May.
	End of meeting		