9 November 2017
EMA/743801/2017

Minutes - Enpr-EMA Coordinating Group & networks meeting

Wednesday 25 October 2017, EMA room 03-H and via Adobe Connect; 15.00 to 17:00 UK time

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Minutes
15:00	Adoption of agenda	Mark Turner	The agenda was adopted.
15:05	Update on work plans and feedback on progress from each Enpr-EMA working group	Irmgard Eichler / Mark Turner Chairs of working groups	• **WG on ethics & collaboration with EUREC:** This WG was reorganised to only include members who actively contribute to the work in order to increase efficiency; on a general principle, the total number of members was restricted (10) and it was agreed to have only 1 member of each organisation; However, additional persons interested to contribute are welcome to e.g. review documents prepared by the core member group. The WG is already working on the 3rd task, i.e. a partly harmonized informed consent / assent template. Next steps include: comparison of different comments and identify conflicting elements in order to prepare a template that Enpr-EMA could place publicly for all stakeholders. An additional task is the already initiated collaboration with the European network of research ethics committees (EUREC): on 13th November 2017 a f2f kick-off meeting with representatives of EUREC and the clinical trial facilitation group was hosted by

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			EMA. The following action points and timelines were agreed: 1. Compilation and reference to available “ethics” training programmes and summary of identified gaps in paediatric specific aspects; Timeline: By 31 January 2018. 2. Compilation and reference to available guidance documents and draft template for ethical considerations in paediatric research; Timeline: By 31 January 2018. 3. Share UK experience with documentation of patient/young people involvement; propose scope of and framework for how to organize systematic involvement of YPAGs to do ethics assessment about new CTs (non-official opinion); Timeline: By 31 January 2018. 4. Propose paediatric specific training modules for the EUREC training boot camp planned in April 2018 in Helsinki and ensure contribution/involvement of PPGs/YPAGs; Timeline: By 31 January 2018. • **WG on young patient advisory groups:** The next focus of the group is – the elaboration of a new EU curriculum to train young patients/persons; – to establish a single contact point; – the development of a sustainability business model. • **WG on educational training for research staff on paediatric clinical trials** The first task is successfully completed with publication of the manuscript “Investigating the roles and training of paediatric research nurses working across Europe: a questionnaire-based survey” in BMJ Paediatrics Open. The link to the publication is also available on the Enpr-EMA webpage. A teleconference will be set up to discuss next actions.

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			• **WG on paediatric clinical trials on antibiotics** A systematic review of safety signals in paediatric and adult antibiotic trials has been accepted in Drugs. Another broad manuscript about aspects and design of paediatric antibiotics trials is nearing finalisation. Once this is also published, the working group has completed their tasks and will be closed. • **WG on clinical trial preparedness** This new working group had its 1st face to face meeting on 18 October 2017.The following action points and timelines have been agreed: 1. Review the current regulatory guidance and academic publications in relation to the conduct of trials in the paediatric population to identify discussion on preparedness. ➢ Deliverable: Short summary and links to guidance documents. ➢ Timeline: By 31 January 2018. 2. Summarise previous initiatives on paediatric clinical trials (e.g. DIA/EFGCP, ACCELERATE, IMI2, ERN, Enpr-EMA and EPAC community) to identify existing valuable guidance on overcoming challenges. ➢ Deliverable: List of initiatives on trial conduct. ➢ Timeline: By 31 January 2018. 3. Utilise deliverables from other Enpr-EMA WGs which have an impact on paediatric clinical trial conduct. ➢ Deliverable: Summarise output from previous Enpr-EMA working groups. ➢ Timeline: By 31 January 2018. 4. Development of a prompt guide/questionnaire to be used in interviews and brainstorming sessions on trial preparedness with stakeholder groups. ➢ Deliverable: Define the action point further (target groups, high-level plan including deliverables and timelines. ➢ Timeline: By 30 November 2017

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			5. Development of preparedness-orientated guidance document including (a) narrative, (b) Q&A, (c) decision tree, (d) risk management strategy ➢ Deliverable: First draft of preparedness guidance document. ➢ Timeline: By 31 January 2018. ➢ Further deliverables with involvement of all working group members, and timelines: Draft ready for public consultation by June 2018, finalisation by December 2018. • **WG on public-private partnership** (pilot of guidance to industry) The group has prepared a recommendation document and diagram to guide companies in taking advantage of scientific and logistic expertise available from paediatric research networks. The diagram has been presented to PDCO in March 2017. In order to prepare to a pilot period and invite industry to use the service from networks, for which networks will charge a fee, the WG would like to send a survey to selected networks so that they can specify for which services they would be available. Networks are requested to send their feedback regarding this survey to the Enpr-EMA mailbox. After the pilot phase certain elements of the survey should also be included in the self-assessment forms and be made available via the Enpr-EMA database.
16:15	Proposal for pan-European IMI2 paediatric network	Mark Turner	The final decision is expected by the end of 2017.
16:25	Update on emerging networks outside EU	Mark Turner	The overall goal is to ensure that global clinical trial networks/groups are working together so that companies can have the same expectations in EU, USA, Canada and Japan. Experiences and data created from initiatives in the various countries/regions should be shareable around the world; cooperation between EU and US trial conduction should be ensured. Duke Clinical Research Institute and the Institute for clinical trials for children (iACT for children) received a grant of the US FDA for a 5 year cooperative agreement to foster establishment of a “Global

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			Pediatric Clinical Trials Network". The grant will be used to create a coordinating centre comprising three cores for network operations, patient engagement, and scientific oversight and five clinical study groups devoted to study design, dosing, regulatory/pharmacy, network partnerships, and rare diseases.
16:35	Enpr-EMA contribution to public consultation on the reflection paper on the use of extrapolation in the development of medicines for paediatrics	Mark Turner (Saskia de Wildt)	Propose to establish a small core group to prepare a first draft. Consultation will be held during next 2 months.
16:40	AOB *10-year report on Paediatric Regulation* *Ethics-EUREC WG kick-off meeting* Data Anonymisation meeting November 30th *Annual Workshop 2018* *ERANET in Personalised Medicine to open in December 2017* *Next CG teleconference*	Irmgard Eichler / Mark Turner	• 10-year report on Paediatric Regulation Will be released by EC the 26th October 2017 and the document linked at the EMA webpage. • Ethics-EUREC WG kick-off meeting: see above • Data Anonymization meeting November 30th Members were asked to share any experience with anonymised data platforms, because the organisers of the meeting would be interested in the view of paediatric networks. It was discussed that the involvement of a young patient representative should be considered. • Annual Workshop 2018 Members were asked to send proposals for topics for the next annual workshop which is going to be held on the 7th and 8th of June 2018. The umbrella theme will be a holistic approach to paediatric research involving academia, patients, networks and also health technology bodies. As another topic it was suggested to discuss national differences in the evaluation of clinical trial applications by ethics committees. Members were asked to send case examples. • Mark Turner informed the group about ERANET in personalised medicine. This project will provide an opportunity to participate within a network for personalised medicines which will involve 32

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			countries and is going to be open in December 2017. • Next CG teleconference 22nd November 2017 for CG members February 2018 (a doodle poll to be sent in January).
17:00	End of meeting		