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Human Medicines Research & Development Support Division

Minutes of the 2017 annual meeting of Enpr-EMA members

Wednesday 17 May 2017

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 and a summary of agreed action points: Action points for working groups: ***Working group on GCP training across multiple specialties and countries*** 1. Submission for publication of the manuscript on training needs of research nurses by October 2017. 2. Development of a core training curriculum for research nurses: The group will investigate different arrangements that are available and gather examples of good practices for building up a pool of research nurses, and propose a priority list of actions. Enpr-EMA members will reach out to nurses in order to involve them in the working group by October 2017. ***Working group on ethics*** 3. To allow Enpr-EMA secretariat regular updating of the ethics toolkit all stakeholders are requested to check and inform the secretariat about changes or mistakes. 4. Collaboration with the European Network of Research Ethics Committees (EUREC): The group will collaborate with EUREC in order to develop an agenda for transnational harmonisation of paediatric expertise in ethics committees for national implementation. As a first step a teleconference with members of

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	EUREC who have paediatric expertise and/or interest will be organised, by July 2017, with the aim to establish a joint Enpr-EMA/EUREC working group. 5. Collaboration with young people's advisory groups (YPAG): The group will collaborate with eYPAGnet in order to create a model for e-consent forms and to review the assent template created by the ethics working group. YPAG will be asked for advice as to how the text in the form should be presented and a template should be agreed by October 2017. ***Working group on young patient advisory groups*** 6. Creation of a business model for eYPAGnet: At a meeting scheduled in June 2017 the group is expected to propose different models. Then a dialogue with industry regarding funding should ensue and an update provided to the Coordinating Group by October 2017. 7. Interface creation between eYPAGnet and disease specific patient support groups by October 2017. ***Working group on public-private partnership*** 8. Pilot of consultation process: The group will publish the consultation recommendation document and ask for volunteers to test it during a pilot phase. The pan-European paediatric research network (IMI2 project) may be a helpful collaborator for this project. Volunteers for the pilot should send their interest by sending an e-mail to the Enpr-EMA secretariat (enprema@ema.europa.eu) by October 2017. 9. Survey among companies who took part in the pilot. No timeline specified. ***Working group on paediatric clinical trials for antibiotics*** 10. Publication of summary document on trial design. No timeline specified. Other action points: ***European Reference Networks (ERNs)*** 11. It will be crucial to establish a close dialogue with the ERN Coordinating Group. Ruth Ladenstein will act as EMA's contact to ERNs and will promote close collaboration between ERNs and Enpr-EMA at the next meeting of the ERN Coordinating Group. Mark Turner may take part in one of those meetings, either in person or remotely. ***International collaboration*** 12. There is a need for establishing one single network/group per jurisdiction in order to enable communication and discussions between global networks (Enpr-EMA, Institute for Advanced Clinical Trials for Children (iACT), China, India, Paediatric Trials Network Australia (PTNA) etc.). Kalle Hoppu will provide contact points for certain initiatives. Presentation - Outcomes of the annual Enpr-EMA workshop (Mark Turner)

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Welcome to new networks	Six new networks joined Enpr-EMA: • Spanish Paediatric Clinical Trials Network (RECLIP) (Category 1). • Spanish Translational Research Network in Paediatric Infections (RITIP) (Category 3). • Respiratory Syncytial Virus Network (ReSViNET) (Category 3). • Central European Paediatric Oncology Early Trials Alliance (CEPOETA) (Category 3). • Medicines for Children Network Norway (NorPedMed) (Category 3). • European Young Person's Advisory Group Network (eYPAGnet) (Category 4). Furthermore, the following network is in the process of applying to become a member of Enpr-EMA: • Severe Paediatric Asthma Collaborative Europe (SPACE).
Break-out sessions: Opportunity to share experiences, discuss new, common approaches, to exchange work plans and establish action learning sets • National networks (including family networks) • Specialty networks (including emerging networks)	National networks: The biggest threat that networks face is a lack of funding which leads to non-sustainability. The national networks shared experiences regarding funding issues and discussed potential solutions. Only 15 out of 27 (56%) national networks who participated in a survey receive funds to maintain their work. Networks would be able to provide more and better services if funding were increased. Continuity of funding is considered crucial. Industry fees are not sufficient to cover costs. In order to be able to apply for public funding it is important to be recognised as a legal entity. Examples of successful models included: • Contracts with Contract Research Organisations (CROs) for remunerated feasibility assessments (e.g. Austria); • Pooling of research nurses within hospitals; • Hospitals pay annual fee to network to compensate them for their work because CROs make contracts with hospitals directly (e.g. Finland); • Federal funding for research nurses (e.g. Switzerland). It was mentioned that perhaps through the IMI2 call for a pan-European paediatric research network it may be easier to negotiate on a European level contracts with pharmaceutical industry associations in order to guarantee some core funding. Specialty networks: Specialty networks discussed the experience with international collaboration. Better collaboration beyond national borders was identified as an important area to improve on in order to be able to provide more consolidated network responses to industry and regulators. Neonatology was identified as an area of high need for closer and more standardised international collaboration between neonatology sites and networks; the activities of the International Neonatal Consortium (INC) are an important

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	step into this direction. Ethics approval particularly for rare diseases was deemed to still be a challenge.
Enpr-EMA/PDCO interaction: First experience with regular meetings with PDCO	Since January 2017 a regular slot at the Paediatric Committee (PDCO) plenary meetings has been reserved for networks to enter into direct dialogue with the PDCO. The experience so far has been very positive. The regular meetings are a good platform to build a common understanding. It was mentioned that basic research and basic science methodology is also an important area to foster, in addition to the conduct of clinical trials. If problems with development programmes arise the involved network should initiate a dialogue with the PDCO via the sponsor in order to find a solution or to modify the programme. The PDCO may also seek advice from networks regarding general questions/issues. Disease-specific meetings between the PDCO and networks in order to discuss priorities and clinical trial issues may also be beneficial. Presentation - PDCO perspective and proposals (Angelika Siapkara)
Update on revision of the document on ethical considerations for clinical trials on medicinal products conducted with the paediatric population.	The revised guideline is expected to be adopted in May 2017. Among other things the revised guideline stresses the fact that involvement of parents and children in design, conduct and evaluation of clinical trials is important. Assent/agreement should be sought from an early age, putting maturity before age. Burden affecting the participant is subjective and can only be self-assessed. Presentation - Ethics Guideline – Review of Ethical Considerations (Agnes Saint-Raymond)
Collaboration with the European Network of Research Ethics Committees (EUREC) – Proposal to establish joint EUREC/Enpr-EMA working group on ethics in paediatric research	It was agreed that there will be a small group within the working group on ethics, to collaborate with EUREC members with paediatric interest and expertise in order to develop an agenda for transnational harmonisation of paediatric expertise in ethics committees.
Recording and publishing the annual workshop	The network members deemed it inappropriate to broadcast or record such a long meeting (1 day). It was considered more useful to publish a summary.
The revised self-assessment form for Enpr-EMA member networks	The self-assessment form has been updated to improve the user's guidance. Furthermore, the new form will require networks to disclose the source of funding in order to increase transparency. It was agreed that non-disclosure of funding should be flagged in the database. In the future it may even result in a downgrading of the network category. Any

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	such consequences would need to be decided by the Coordinating Group. It was suggested to re-discuss this issue in one year's time. The revised self-assessment form is expected to be published in the next month.
Conclusions and next steps	It is crucial that networks work in standardised ways, have a clear business proposition and are predictable, in order to show the networks' value and make them sustainable. The next annual meeting of Enpr-EMA members is scheduled for 8 June 2018.