



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Research & Development Support Division

Minutes of the 2016 annual face to face meeting of the Enpr-EMA Coordinating Group (CG) members

Friday 03 June 2016

Chairpersons: Mark Turner / Irmgard Eichler

Item	Summary of discussion	Action
Adoption of the minutes of last Coordinating Group teleconference on 12 January 2016 Adoption of the Agenda	Minutes of the last CG teleconference were adopted as well as the agenda of this meeting.	N/A
Election of Enpr-EMA (Co)Chair	The Group congratulated Mark Turner for his dedication and achievement during the last 3 years and unanimously renewed his mandate as (Co)Chair for a new term of 3 years.	N/A
Outcomes of 8 th annual workshop 2016	<p>The Group reviewed and confirmed the following outcomes reached at the annual workshop:</p> <p>Working Group on Ethics</p> <p>The Working Group will take part in the public consultation of the revision of the Ethical considerations for clinical trials on medicinal products conducted with the paediatric population (2008) that will be opened from June to 31st August 2016.</p> <p>The guidance how to work with Ethics Committee is being put on hold until implementation of the new Clinical Trial Regulation takes place. EUREC (Research Ethics Committees (RECs) associations) will be involved.</p> <p>How to move forward in training for Ethic Committees on paediatric</p>	Enpr-EMA / EMA



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	<p>specific issues to be further discussed at the next CG TC in October 2016 upon feedback from a planned meeting with EUREC.</p> <ul style="list-style-type: none"> • Working group to address issues with EU multi-languages of Young patient advisory groups (YPAG) <p>A plan for education and training of young people advisory groups working in specific areas will be pursued in the next year.</p> <p>The Group is supportive of the creation of an EU young person advisory group network for harmonisation. The aim will be to establish a platform to promote common practices in the different EU countries. The working group identified the need to develop a database of YPAGs. The details of setting up such network and database should be discussed with and implemented together with EMA patient and consumer working party to avoid duplication and ensure synergies.</p> <ul style="list-style-type: none"> • WG How to establish communication between Enpr-EMA networks and industry & Sharing Good Practice within EnprEMA and with Industry Partners <p>The Working Group worked toward a model showing how industry can engage with Enpr-EMA/networks to be available on the EnprEMA website. An annotated diagram, the final deliverable of this group, will be finalized by October 2016 for publication on the Enpr-EMA microsite. The exact timing will be agreed at the next CG after endorsement.</p>	
Industry perspective & proposals	<p>The presentation focused on feasibility of conducting paediatric clinical trials and on the role that networks can have in assessing such aspect.</p> <p>Industry representatives emphasized that a discussion on clinical trial preparedness is important and a multi-stakeholder meeting on this subject would be welcome by industry. Involving healthcare professionals was considered essential.</p> <p>The group agreed to take the discussion forward and noted that a first platform for discussion will be provided by Joint DIA/EFGCP/EMA better medicines for children conference 2016 on optimisation of drug development for the benefit of children on 10-11 October 2016.</p> <p>The Group proposed to include a link to the Enpr-EMA pages, including a link to the Networks database in the relevant EMA - Paediatric templates and in other EMA webpages as a suggestion to industry to use Enpr-EMA as a resource tool.</p>	
PDCO perspective & proposals	<p>On the topic on how EMA / PDCO can work better with Enpr-EMA the PDCO representative presented a few points that would facilitate and promote a fruitful interaction and cooperation:</p> <ul style="list-style-type: none"> • Commenting to concept paper/guidelines (in preparatory stage and during public consultation). • Providing expert support to general topics for which PDCO is seeking consultation; regular generic discussions with PDCO for 	

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	<p>specific therapeutic areas was suggested.</p> <p>To this end networks will need to nominate a “PDCO” contact within their network for such interactions. Said representatives acting as contact person of the network should be truly representative of the full network. To ensure this proper training and a mandate need to be provided by the network.</p> <p>The proposal was endorsed by the group and will be presented to the PDCO at their July 2016 meeting.</p> <p>Presentation: PDCO perspectives & proposals - Enpr-EMA coordinating group</p>	
Update on status of emerging networks:	<ul style="list-style-type: none"> • Cardiology (Task Force of AEPC) – EMA will try to make final contact with the representative of this network which otherwise will be considered non active. • Endocrinology/Diabetes (EUCADET) – an updated was provided at the face to face meeting. <p>Other updates:</p> <ul style="list-style-type: none"> • Severe Paediatric Asthma Collaborative in Europe (SPACE) –The Group received an update on the first meeting of this Clinical Research Collaboration (CRC), including their objectives and planned deliverables. The information will be spread to all Enpr-EMA networks. <p>Presentation: Severe Paediatric Asthma Collaborative in Europe (SPACE)</p>	EMA
Update on new Enpr-EMA working group on clinical trial design for paediatric antibiotic studies	<p>An outline on the working group activities and planned deliverables was presented to the Group.</p> <p>Deliverables will be a summary document of key components of design for paediatric clinical trials with antimicrobials and identified challenges with the conduct of paediatric antibiotic trials. This document is thought to provide available evidence for use in the planned EMA Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.</p> <p>Presentation: Update on new Enpr-EMA Paediatric Antibiotic Clinical Trial Working Group</p>	N/A
Application for creating a new Enpr-EMA working group on oncology	<p>A proposal for an Enpr-EMA working group on paediatric oncology was presented.</p> <p>The initiative was triggered by SIOPE in 2015 inviting PDCO to discuss improving research and care in this area.</p> <p>The WG aims at gathering experience from paediatric oncology medicine developments and to discuss good practices. There will be a kick-off meeting on 24 June 2016. An outline of the proposed objectives and the work plan was presented to the Group.</p> <p>The initiative was endorsed.</p>	

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	Further discussion on deliverable will take place at the next Coordinating Group meeting by TC on 6 October 2016.	
Endorsement of newly received applications for Enpr-EMA membership: <ul style="list-style-type: none"> • Medicines for Children Research Network MCRN-Hungary 	The CG endorsed the application of MCRN-Hungary and recommended contacting the responsible contact persons to clarify the networks relation with CRO(s).	EMA
Date Next Enpr-EMA CG teleconference	The next Coordinating Group teleconference will take place on 6 October 2016, 13 – 15.00 UK time.	EMA