



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2014
EMA/664345/2014

Minutes – Enpr-EMA Coordinating Group (CG) teleconference

24 October 2014, 15:00 – 16:30 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

Coordinating Group Members: Saskia de Wildt, Gareth Veal, Tim Lee, Anne Junker, Pirkko Lepola, Jose Drabwell, Kale Hoppu, Andrea Biondi, Anne Junker, Carlo Giaquinto, and David Coghill

Industry observer: William Treem

Apologies:

Nicola Rupperto, Christina Peters, Dirk Mentzer, Pamela Dicks, Stephen Greene, Wolfgang Goepel, Veerle Bulteel, and Geneviève Michaux

Item	Summary of discussion	Action
1	Adoption of the minutes of last Coordinating Group face to face meeting on 27 June 2014 Adoption of agenda	N/A
2	Dates for 7 th annual Workshop of Enpr-EMA, 2015 The 7 th annual workshop of Enpr-EMA is scheduled on 28 th May 2015 morning until mid-afternoon. The workshop will be followed by the Enpr-EMA members meeting in the mid to late afternoon. The CG face to face meeting is scheduled on the day after the workshop, i.e. 29 th May 2015.	N/A



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3	<p>EU Pharmaceutical Industry attitude towards Paediatric Clinical Trial Networks</p> <p>Will T has a meeting with EFPIA on 29th Oct. Possible discussions to include</p> <ul style="list-style-type: none"> - Industry collaboration to support paediatric research as an IMI project. A WG should be arranged around this topic. - EFPIA considering similar approach as Transcelerate for accrediting existing GCP courses ? (see agenda topics 4, 5) - EMA's submitted proposal in neonatology for a future IMI project ((see agenda topic 6) <p>Will T to report on this at next CG teleconference.</p>	Industry observer
4	<p>Report on Working Groups:</p> <ul style="list-style-type: none"> • Updated work plans • New deliverables for year 2015 <p><u>WG on Priority Setting:</u></p> <p>To report on work progress on 3 identified areas of prioritisation at next WG TC:</p> <ul style="list-style-type: none"> • Pre-clinical and early phase where drug development and clinical use is being decided by pharma companies; • Methods of prioritisation for study design and collaboration when different pharma companies have developed similar drugs for a rare or common condition; • Prioritisation of older off patent medicines and need to improve process evidence base. <p><u>WG on Public-Private Partnership:</u></p> <ul style="list-style-type: none"> • To circulate finalised reports to Enpr-EMA ,WG members and SME office at EMA for distribution; • To publish on Enpr-EMA website and potentially on EFPIA and EUCOPe websites. It is recommended to publish in a scientific journal first before publishing on Enpr-EMA webpage. WG to carry out a search on potentially appropriate scientific journals for publication (e.g. to search for journals related to drug development as opposed to paediatrics only); • To develop recommendations for new networks to present at next WG TC. <p><u>WG on Ethics:</u></p> <ul style="list-style-type: none"> • To check accuracy of table date, add country-specific additional information and write report by end 2014; • To draft abstract from report on selected partial issues (high level summary); • To publish table on Enpr-EMA webpage after article is published in scientific journal. <p><u>WG on interactions network-industry-regulators when issues with conducting PIP:</u></p> <ul style="list-style-type: none"> • One main challenge: Conflict of interest (CoI) when 	<p>WGs</p> <p>Enpr-EMA chair</p> <p>Enpr-EMA co-chair</p> <p>Industry observer</p>

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	<p>only a few experts available in certain rare diseases, who are important for both regulators and industry. Unified repository of publicly available CoI declarations would be long-term goal. In meantime use of available tools (e.g. EMA expert database). In addition to CoI of individual experts, need for more transparency of academic networks identified. EMA DoI for organisations a way forward to collect data on source of network funding (this info will need to be publically available on each network website)?</p> <ul style="list-style-type: none"> • IE to circulate document on organisation of CoI to all networks; • To report on detailed work progress at next WG TC. <p><u>WG on Neonatology:</u></p> <ul style="list-style-type: none"> • Critical Path Institute, meeting in Washington (28/11): to propose EU response to FDA initiative; • To bring together neonatologists, PDCO WG on Neonatology and learned societies at EMA Dec meeting (15/12); • To feedback on USA and EMA neonatology meetings and work progress at next WG TC. <p><u>WG on Paediatric Pharmacovigilance:</u></p> <ul style="list-style-type: none"> • Drafting on the revision of the paediatric pharmacovigilance guideline: first draft is dated 16/10/14. A 3 month public consultation is foreseen beginning of next year after draft is agreed by PDCO and PRAC; • In the new year, a survey on capacity of Enpr-EMA and ENCePP networks to conduct PASS in children should be prepared. <p><u>WG on Networks Funding, Sustainability and FP7 Projects:</u></p> <ul style="list-style-type: none"> • MT to circulate to networks paper summarising issues with funding and to publish in scientific journal; • EFPIA/EC meeting with PDCO to discuss hurdles/issues with funding of paediatric medicine clinical trials on 12/11; • Following this meeting, to issue recommendations to be included in H2020 stream work. <p><u>WG on Issues with EU-Multi Languages of YPAGs:</u></p> <ul style="list-style-type: none"> • ICAN (International children's advisory network) network currently being established linking existing young person advisory groups in USA, Canada and 	

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	<p>UK; (http://www.icanresearch.org/)</p> <ul style="list-style-type: none"> To report on detailed work progress at next WG TC. <p><u>WG on GCP Training:</u></p> <ul style="list-style-type: none"> TransCelerate has accredited some GCP trainings. Networks to check if their national GCP course, if not already accredited by TransCelerate, can be submitted for accreditation. Will T and MT to find out contact point at TransCelerate for accreditation and disseminate to all networks; To report on detailed work progress at next WG TC. 	
5	<p>Update on international initiatives:</p> <ul style="list-style-type: none"> Global Paediatric Clinical Trial Network TransCelerate <p><u>Global Paediatric Clinical Trial Network:</u></p> <ul style="list-style-type: none"> Current model foresees to identify approx. 50 large paediatric clinical research centres with capacity to conduct paediatric drug trials (PhI –IV), starting in the US and Canada and later to phase out to Europe. At present NIHR CRN: children already included. It was pointed out that in Europe not only large centers but already existing national/specialty networks should be considered. Business case to be created after AAP meeting; Networks from CG who wish to be part of the Global Network to reach out to Will T/MT so they are included. <p><u>TransCelerate:</u></p> <ul style="list-style-type: none"> Initial plans to get involved in development of global paediatric network no longer pursued; at present to increase transparency high level/strategic information on pharma companies pipelines in preparation; Accreditation for GCP courses (see item 4); MT to report on regular basis. 	<p>Networks from CG</p> <p>Enpr-EMA chair</p>
6	<p>Initiative on neonatology, feedback from EAPS meeting in Barcelona</p> <ul style="list-style-type: none"> Successful meeting on industry studies in neonatology, at the EAPS 2014. Around 60 neonatologists attended; EMA to announce neonatology meeting to be held on 15 Dec to discuss on the way forward to collaborate with FP7 networks/learned societies and PDCO WG on neonatology to offer a strong neonatology delivery network; Will T to report back to EMA on EMA's submitted proposal on topic of interest in neonatology for a future IMI project. 	<p>N/A</p> <p>EMA</p> <p>Industry observer</p>
7	<p>Funding paediatric clinical trials and European Commission</p> <ul style="list-style-type: none"> This topic will be discussed between a few investigators who had received EU funding for FP7 project on research into off-label medicines, the PDCO, EFPIA and the European Commission on 12/11 PDCO meeting at 	<p>Enpr-EMA chair and co-chair</p>

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	<p>the EMA;</p> <ul style="list-style-type: none"> • MT/IE to report back to all Enpr-EMA networks further to the meeting 	
8	<p>Endorsement of newly received applications for Enpr-EMA membership:</p> <ul style="list-style-type: none"> • <i>PEDDCReN</i> • <i>ESPNIC Medicine Research Network</i> 	N/A
9	<p>Expiry of the mandate term for the CG members</p> <ul style="list-style-type: none"> • CG members are requested to discuss with their board/institution the expiry of the term of their mandate within the CG and the possibility for them for a 3 year term renewal or appointment of another representative from their institution or their withdrawal from the CG; • Saskia de W and Carlo G. confirmed that following discussions among their boards, it was decided for them to continue their role within the Enpr-EMA CG; • All other CG members are requested to inform Enpr-EMA secretariat enprema@ema.europa.eu with the decision taken by 15/12/14. 	CG members
10	<p>Proposal for networks which still haven't submitted their updated electronic self-assessment</p> <ul style="list-style-type: none"> • A further reminder for those Enpr-EMA networks who still have not submitted their updated self-assessment forms should be sent asking them if they require help and assistance in completing these; • Enpr-EMA networks who have not submitted their updated self-assessment forms are not registered in the Enpr-EMA network database (therefore not visible to external stakeholders) but are still kept up-to-date as they remain in the Enpr-EMA network distribution list. 	Enpr-EMA co-chair
11	<p>Next Enpr-EMA CG/WG teleconference to be scheduled (Q1 2015)</p> <ul style="list-style-type: none"> • Next CG and WG teleconference to be scheduled between 19 and 22/01/2015; • A doodle poll will be sent to CG members to identify best convenient date and time. 	Enpr-EMA secretariat
12	A.O.B	None