25 February 2015
EMA/52509/2015

Minutes of the Enpr-EMA working group chairs teleconference meeting

21 January 2015, 14:00 – 16:00 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

Coordinating Group Members: Christina Peters, Wolfgang Goepel Anne Junker, Pirkko Lepola, Jose Drabwell, Kalle Hoppu and Dirk Mentzer

Working Groups Chairs: Saul Faust, Susan Tansey, (Dirk Mentzer), (Mark Turner), (Pirkko Lepola) and Ron Portman

Industry observer: William Treem

Apologies:

Mike Sharland, Susan MacFarlane, Pamela Dicks, Saskia de Wildt, Gareth Veal, Ettore Napoleone, Stephen Greene, Joachim Boos, David Coghill, Tim Lee, Andrea Biondi, and Carlo Giaquinto

	Item	Summary of discussion	Action
1	Adoption of agenda	The agenda of the teleconference with the Enpr-EMA Working Group Chairs was adopted.	N/A
2	Joint Working Group on priority setting	• No update; • The WG chair is requested to provide an update at the 7th annual Enpr-EMA workshop on 28/05/15	WG
3	Joint working group on public-private partnership	• Final report on outcomes of survey gathering examples of good practice from both networks and industry working with Enpr-EMA networks, has been drafted • Next steps: – Submission for publication in a scientific journal	WG

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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		e.g. “Applied Clinical Trials” before it can be published on Enpr-EMA, SME Office webpages; distributed to EFPIA, and EUCOPe; – Utilise results to develop guidelines for new networks and make recommendations to current networks; – Develop a dissemination strategy to distribute and share good practice. Some ideas would include distributing via newsletters, EnprEMA website, meeting presentations, Webinars.	
4	Working group on Ethics	• Preliminary abstract on the requirements by EC with regards to the data including legislative surroundings of the informed consent for paediatric clinical trials, listed by country, has been suggested to one editor from Arch Dis Childh; • Final abstract to be drafted and submitted for second evaluation; • A paper/report will follow if the final abstract is accepted; • Tool kit to be published on the Enpr-EMA webpages once it has been accepted for publication in a scientific journal.	WG
5	Working group on interactions network-industry-regulators when implementation / conduct of clinical trials agreed in PIPs is no longer possible	• There is a clear need for a formal process when PIPs are threatened by recruitment issues and when the clinical space is limited compared to the number of agents that need to be evaluated. • Enpr-EMA is well-placed to broker discussions between Sponsors, Networks and Regulators. • DoI and source of funding issue: in addition to individual DoIs, DoI are needed for the institutions / networks that will participate in discussions. EMA to send specific DoI template for institutions which will be published on the Enpr-EMA website; • WG will start drafting report on scope/high level SOP on the arrangement for PIPs that encounter difficulties / crowded clinical trials areas / competitive studies in therapeutic areas; • The draft will be discussed at the Enpr-EMA workshop.	WG & EMA
6	Working group on Neonatology	• USA initiative: Critical Path/FDA meeting in Autumn 2014; • EMA is hosting on 17/03/15 a meeting on neonatology	WG

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		with the objective of bringing closer Academia and Regulators: EU KOLs in neonatology, PDCO working group on neonatology, Enpr-EMA specialised networks and Enpr-EMA WG on neonatology are invited; • Outcomes of the March meeting will be reported during the Enpr-EMA workshop on 28/05/15;	
7	Joint Enpr-EMA/ENCePP Working group on paediatric Pharmacovigilance	• Active contribution of the WG on the drafting of the revised paediatric pharmacovigilance guideline. First presentation to the PDCO and PRAC is aimed in spring 2015. A release for a 3 month public consultation will follow once the draft has been adopted by the Committees; • Preliminary discussion with ENCePP colleagues on the types of post-authorisation safety studies (PASS); • Next step: to define criteria to conduct PASS studies in children and create a short questionnaire to ENCePP/Enpr-EMA networks to identify which networks would be able to conduct such studies.	WG
8	Joint working group on network funding, sustainability and FP7 Projects	• Business case is being developed; • A paper on 5 successful networks (case studies) has been drafted. It outlines the needs for funding a successful networks and how the resources and time are managed; • Next steps: gather comments from networks on the paper and publish it in a scientific journal.	WG
9	Working group on strategic approaches to raise awareness of Enpr-EMA and the need to conduct paediatric clinical trials among learned societies	• The work of the WG has been postponed; • Perhaps it would be helpful to use the NCAs/HMAs to raise awareness about Enpr-EMA in the national EU countries. EMA to explore this and liaise with CMDh colleagues; • EMA to send to Ron Portman the set of published Enpr-EMA slides so that they can be presented at the American Paediatric Society.	EMA
10	Working group to address issues with EU multi-languages of Young person advisory groups (YPAG)	• GRiP has worked on writing best practices to set up a YPAG. Some recommendations should come from these best practices; • Other interested EU individual groups should be encouraged to join the virtual group which is set up at iCAN Research ; • However, it is important for Enpr-EMA to have an EU overall oversight of who is acting in the global virtual	WG and networks

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		group, and what is achieved in order to disseminate knowledge among networks across Europe.	
11	Working group on GCP training across multispecialty and countries	• There is a lack of GCP modules with specificities related to clinical trials in children; If a network is aware of any, these should be sent to Enpr-EMA secretariat for dissemination among all networks; • The details of the recognised GCP trainings by TransCelerate can be found at: http://www.transceleratebiopharmainc.com/site-qualification-and-training-resources/	WG and networks
12	Next update on WGs	All WG chairs are requested to present an update on their work progress and deliverables during the 7th annual Enpr-EMA workshop held at EMA on 28/05/15.	All WGs
13	AOB	The chair of Enpr-EMA thanked all working group chairs and members for their important work.	