

16 October 2014
EMA/410668/2014

Minutes of the sixth Enpr-EMA Coordinating Group (CG) face to face meeting

27 June 2014, 09:00 – 12:00 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

EMA: Franca Ligas

Coordinating Group Members: Saskia de Wildt, Paolo Rossi, Gareth Veal, Dirk Mentzer, Pamela Dicks, Tim Lee, Anne Junker, Pirkko Lepola, Leire Solis Garate

Observers: Kazuyuki Saito, Hidefumi Nakamura

Apologies:

Nicola Rupperto, Evelyne Jacqz-Aigrain, Jose Drabwell, Christina Peters, Kaarlo Magnus Hoppu

Item		Summary of discussion	Action
1	Adoption of the minutes of last Coordinating Group teleconference on 23 January 2014 Adoption of agenda	Minutes of the last CG teleconference were adopted as well as the agenda of this meeting.	N/A
2	Outcomes of 6 th annual workshop 2014: Reflections on Working Group (WG) activities – how to make the most of Enpr-EMA activity What support do	General reflection on previous day open workshop: - Industry feedback very positive; general agreement that the work of the various WGs much appreciated as it has helped to increase inter-network collaboration as well as with industry and to increase awareness of Enpr-EMA among industry. - Concern that with establishment of a global paediatric network with funding through industry smaller hospitals and countries may be left out. Need for Enpr-EMA to	N/A

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	individual networks need? Involvement of children	remain in close dialogue to explore how existing networks can collaborate and get involved with planned global paediatric network; potential need for Enpr-EMA to develop a strategy, e.g. Enpr-EMA “clearing house” to bridge and connect with European networks. • Reflections on WG activities: please see under item 3 • WG on best practices to address issues with EU multi-languages of a Young Patient Advisory Group: Volunteers for this WG: Pamela Dicks (chair), Anne Junker, Winnie Chan (GRiP), Charlie Thompson (Pfizer). Jenny Preston also to be involved. Anne Junker to share with the newly appointed WG members the work done by the Ethics WG. Links to be implemented with the Dutch Oncology network, Diabetes International Group, EURORDIS as they have experience with patients' communication in multi-languages.	
3	Implementation of the WG actions plans and definition of future steps	WG 1 and 2 to be merged into a joint WG 1-2 on priority setting. Need to involve public in priority discussion. Involvement of EMA patient and consumer working party? WG 3-5: ongoing work to be continued. Martine Dehlinger-Kremer (EUCROF) to join the WG. WG 4: Adriana Ceci to join the WG. Pirkko to write and abstract and get abstract with Ethics table published in a scientific journal before the same table is published on the Enpr-EMA webpage. WG 6: Draft document to be circulated to networks. With regards to stakeholder meetings, PENTA ID to offer support in the organisation of an EMA workshop on hepatitis C in Q4 2014/Q1 2015; Andrea Biondi to join this group. WG 7: members to work closely with FDA on neonatal issues. WG 8: requirements to conduct PASS studies in children to be established. WG 9 and 10 to be merged into a joint WG 9-10, funding/network sustainability. Adriana Ceci to join this joint WG.	WG members
4	Endorsement of newly received applications for Enpr-EMA membership	Presentation - Endorsement of new or updated applications for Enpr-EMA membership • Application from the European Paediatric Liver Transplantation Network (EPLTN) was endorsed by the CG members as an Enpr-EMA registered Category 3 member. • The updated application from RIPPS requesting an upgrade of category was not endorsed because this network does not fulfil one of the minimum criteria for being a category 1 member, i.e. involvement of	EMA

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	children or families. The CG members indicated that RIPPS should remain Category 3 member until changes with regards to public engagement in the network occur. - It was suggested to establish a new Paediatric ICU clinical trial network: - To schedule a discussion meeting at the Barcelona EAPS 2014 in October. - Anne Junker to circulate details of the existing paediatric network in Canada.	EMA and CG members
5	Promotion of the GRiP road-show about paediatric clinical pharmacology GRiP consortium (master/distance learning platform) to be launched in Nov: - Topics will cover paediatric pharmacology and research, methodology, regulatory and biomarkers: Paolo Rossi to circulate master programme to CG members - A module should be dedicated to global GCP training for physicians, site coordinators and clinical research nurses; - A WG should be set up to discuss how the training could be addressed across multispecialty, countries. Volunteers for the WG: A research nurse from ScotCRN (name TBA) and Pirkko Lepola, Paolo Rossi. This new WG should closely work together with WG 3 and 5 to avoid duplication. - Kalle Hoppu to circulate GRiP road show to Enpr-EMA members. - Proposal to develop a "forum of coordinators and research nurses as community of good practice. Maybe to liaise and involve EMA healthcare working party?	CG members
6	Amendment of the policy on transparency and handling of potential conflicts of interests of CG members and WG members Presentation - Proposed amendment to the policy on transparency and handling of potential conflicts of interests Further to the presentation of WG 6 on the importance of having declared CoI, the following was agreed: - CG members: requirement for up-to-date DoI, no need for additional information on research interests (addendum to research). - WG members: requirement for up-to-date DoI.	EMA
7	Industry representation within coordinating group Presentation - Industry representation within the Enpr-EMA Coordinating Group The CG members endorsed the proposal to invite one representing person from EFPIA or EUCOPE to be an observer and attend the CG meeting only for a selected topic for discussion. CG members to think about topics for discussion with EFPIA or EUCOPE observer and inform EMA It was also highlighted to explore possibility of an Enpr-EMA CG member to be an appointed observer at EFPIA or	CG members

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		EUCOPE meetings.	
8	Next Enpr-EMA CG teleconference to be scheduled	EMA to send doodle pool to CG members for dates of next TC (few days after EAPS Conference in Barcelona, i.e. from 22/10/14 onwards). One topic among others should focus on the review of WG plans and deliverables for next year (the detailed presentation of the work progress of the WGs will be discussed at a subsequent TC in January 2015).	EMA
9	A.O.B	None.	N/A