

20 July 2015
EMA/367915/2015

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

29 May 2015, 13:30 – 15:30 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

Coordinating Group Members: Christina Peters, Tim Lee, Kalle Hoppu, Anne Junker, Wolfgang Göpel, Pamela Dicks, Jose Drabwell, Pirkko Lepola and Ettore Napoleone

Industry Observer representing EFPIA: William Treem

Apologies:

Angelika Siapkara, Nicola Rupperto, Evelyne Jacqz-Aigrain, Saskia de Wildt, David Coghill, Gilles Vassal, Christoph Male, Carlo Giaquinto, and Geneviève Michaux

Item	Summary of discussion		Action
1	Adoption of the minutes of last Coordinating Group teleconference on 21 January 2015 Adoption of agenda	Minutes of the last CG teleconference were adopted as well as the agenda of this meeting.	N/A
2	Action plan for 2015/2016	As a main objective, it was agreed to reduce the list of active Enpr-EMA WGs and to really focus on defined tasks which could be delivered within each WG. Further details are available in the report of the 7 th annual open workshop of Enpr-EMA.	EMA
3	Industry perspective & proposals	Views from observer representing EFPIA for consideration: there is a need for a transnational focus/collaboration with one entry level for industry (i.e. centrally managed approach): Enpr-EMA to be the	N/A

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	coordinating centre/communicating platform which will pass on to a group of specialised networks or geographical networks when e.g. industry raises issues on study feasibility, standard of care, study acceptability by families. Enpr-EMA or a group working with Enpr-EMA would also bring online support and timely observation of the trial progress. It was agreed that networks should be surveyed and a gap analysis should be carried out on single EC approval within each Member State, single costing template, single site contract template and single site approval. Additional discussion is required with regards to the preparation of this survey.	Networks
4	PDCO perspective & proposals - It is important to involve networks as a whole (as opposed to individual experts or KOLs) in PDCO discussions. - It was agreed to start with <u>generic</u> discussions (not related to specific PIPs) between networks and PDCO members during the PDCO ORGAM TCs. Discussions would occur once every 3 months, depending on the identified need for such discussions. CF issues were agreed to be the first topic to be discussed with PDCO: ECFS-CTN will participate to one of the next PDCO ORGAM TCs. EMA to arrange and liaise with ECFS-CTN. - Next candidates for discussions at PDCO ORGAM TCs would be HSCT/Oncology (EBMT), Rheumatology (PRINTO) and ID (PENTA-ID). - In future, a 2 way communication is foreseen. If PDCO or networks raise issues, CG will need to decide <i>ad hoc</i> on participation of specific networks at PDCO ORGAM TCs and feed that back to either PDCO or networks. Presentation - PDCO perspectives & proposals Enpr-EMA coordinating group (A. Siapkara, C. Male)	EMA, CG and networks
5	Review on Enpr-EMA Working Groups This was discussed during the 7th annual open workshop of Enpr-EMA. Please refer to the report of the 7th annual open workshop of Enpr-EMA for further details.	N/A
6	Endorsement of newly received applications for Enpr-EMA membership: - OKIDS GmbH - INFANT - The CG endorsed membership and category numbers for the following networks: ➤ OKIDS GmbH as category 1, new representation within the Enpr-EMA CG; ➤ INFANT as category 3; ➤ NEO-CIRC, following updated SA, remains category 3. - The need was noted for amendment of the Enpr-EMA self-assessment form to add experience with actual conduct of studies requested in PIPs, as an additional visible quality marker, without requesting it as a	Networks EMA

Item	Summary of discussion	Action
	minimum requirement for full Enpr-EMA membership NewPresentation - Endorsement of new or updated applications for Enpr-EMA membership (Benjamin Pelle)	
7	Next Enpr-EMA CG teleconference to be scheduled The next TC will be scheduled during the week of 19 to 23 October 2015. A doodle poll with dates and times will be sent shortly to identify the most convenient date/time for a TC during that October's week.	EMA
8	A.O.B - EPOC is no longer an Enpr-EMA registered network (category 1) as the network has become inactive. - There are now 19 members in the CG. The members' representation within CG face to face meetings should not exceed 18 members (as per Enpr-EMA implementing strategy). Participation of same country for national networks or same specialty for specialty networks should be avoided: there is a need for re-discussion/agreement on this principle during the next face to face meeting of the Enpr-EMA members. Meanwhile, OKIDS GmbH could be represented by a single member: i.e. the Austrian PDCO alternate member who is acting for both PDCO and OKIDS GmbH within the Enpr-EMA CG. - It was noted that only a few CG members participate at the CG meetings, sometimes less than half of the group. The CG needs to have 18 active networks to ensure that input from all types of networks is taken into account when decisions of future activities and/or strategies are made. Networks that are not active in CG meetings, face-to-face meetings and workshops and Working Groups may need to retire from the CG in order to make space for more active networks.	N/A EMA & Networks