EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 September 2013
EMA/543361/2013

Minutes – Enpr-EMA Coordinating Group (CG) meeting

28 June 2013, 09:00 – 12:00 UK time

Attendees:

- Newly elected Enpr-EMA chair: Mark Turner
- Outgoing Enpr-EMA chair: Peter Helms
- Enpr-EMA co-chair: Irmgard Eichler (EMA)
- Enpr-EMA support: Benjamin Pelle, Isabel Perez
- EMA: Alessandro Jenkner, Richard Vesely, Xavier Kurz
- PDCO Chair: Daniel Brasseur
- Coordinating Group Members: Pamela Dicks, Gilles Vassal, Edwin Spaans, Dirk Mentzer, , Gareth Veal, Tim Lee, Anne Junker, Wolfgang Goepel, Pirkko Lepola, Christina Peters, Kaarlo Magnus Hoppu
- Observers: Nao Tsuchida, Hidefumi Nakamura

Apologies:

- Nicola Rupperto, Evelyne Jacqz-Aigrain, Jose Drabwell

	Item	Summary of discussion	Action
1	Apologies, adoption of minutes of last CG teleconference and CG meeting agenda	Attendance was noted, minutes and agenda were adopted without amendments. It was agreed to publish agenda and meeting summary (not detailed discussion minutes) on Enpr-EMA webpage.	N/A
2	Endorsement of Mark Turner's election as Enpr-EMA new chair	CG members endorsed Mark Turner's election as Enpr-EMA new chair (mandate is for 3 years)	N/A
3	Outcomes of 2013 annual workshop and implications on work programme 2013/2014	• It was noted that there is a significant amount of good practice already available. The needs now are to disseminate good practice, to share it with other networks in order to bring all networks to best practice and to communicate with industry • It was agreed to set up 6 Working Groups to develop pragmatic approaches to the dissemination of good practice on: – Approaches to priority setting: – Broad engagement in priority setting: – How to establish communication between Enpr-EMA, networks and industry – Dialogue and interaction with Ethics Committees – Sharing good practices within EnprEMA and with industry partners	Networks EMA and networks

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		– A framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible • Improve network visibility to Industry: an overview of each network's self-assessment from CG should be displayed on the first page of the Enpr-EMA website for quick access from Industry (see following item) • Many, but not all networks, felt that a standard approach is useful for first contact with Industry for top-level feasibility queries. There should be no charge and max 1 page introduction from network should be sent back to Industry. If Industry is seeking more detailed information and/or scientific advice, then funding will be requested by networks according to each network's policy. REDCap Survey https://octri.ohsu.edu/redcap/ was suggested as a tool that could be used by networks. This tool would allow to compile consolidated responses within networks. Alternatively, Enpr-EMA could develop a high-level feasibility template for first queries.	CG members
4	Enpr-EMA website reorganisation	• EMA discussion on improvement of current Enpr-EMA webpages: 1st page with info on networks (overview and links to self-assessment (SA) reports), updates on activities, what's new and Enpr-EMA information • Use of "Enpr-EMA List of Network Participants and the Disease Areas of Interest" drafted by Alios BioPharma (ahead of 5th annual workshop) to get an overview of each network	EMA EMA and networks
5	Endorsement of new applications for Enpr-EMA membership	• Hospital Sant Joan de Deu (single institution, initial SA) confirmed as Category 3 member but to be represented in larger group (through RED SAMID) at Enpr-EMA meetings • RED SAMID (updated SA) confirmed as Category 2 member Their self-assessment reports (SA) will be published on Enpr-EMA website	 EMA
6	Network representation in CG when total number exceeds 18, frequency of CG meetings and responsibilities to remain CG members	• Network skills and expertise should be balanced. It is not possible to have 2 national networks from the same country or same specialty networks represented in the CG • CG membership should be extended to global region (e.g. Japan, USA) to address international cooperation, potentially as observing or affiliate members • Need to create affiliate networks to 18 Category 1 networks • Reminder to update SA, CoI declaration and addendum on research interests. If not done by a certain timeline, Category 1 networks will be taken off the website and taken off the category 1 membership list.	EMA
7	Collaboration with PDCO: Therapeutic areas (JIA, Pneumology, Oncology), with large number of PIPs and where PDCO is confronted with several challenges, be it feasibility, lack of endpoints, several different products but limited number of patients To explore how individual networks	• Focus on prioritisation, and trial feasibility • PDCO encouraged to more frequently involve expertise of networks: if questions arise, they should be circulated among Enpr-EMA members to ensure to obtain current best evidence • Networks could be consulted when exploring the options for recruiting patients who have exhausted most, or all, of the existing therapeutic options to trials of innovative therapies • Discussion on approach to trials in neonatology: the currently accepted stepwise approach with initiation of studies in neonates at very late stage should be revised: Working Group set up • Asthma guideline is now going for public consultation: CG members are invited to comment on the guideline	CG members All

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	could be more actively involved and contribute to the PDCO discussion		
8	Could paediatric networks have a role in implementing the new PV legislation? (Disseminating information about the legislation, supporting the new broader spontaneous reports, doing registry based, targeted safety studies that are based on emerging safety concerns, etc.)	• ENCePP is used as a source of collecting evidence on drug safety issues • CG to identify available safety data/data evidence from paediatric clinical trials and report to ENCePP • Networks to consider registering with ENCePP when starting Pharmacoepidemiological or Pharmacovigilance studies • ENCePP update of the Guide on Methodological Standards in Pharmacoepidemiology - paediatric chapter planned. CG to contribute to the paediatric chapter • Briefing document on how to move forward with Pharmacovigilance to be prepared for the Networks (interaction with PRAC, registry design optimisation etc…) • A working group to mediate between ENCePP and Enpr-EMA was proposed	N/A CG members CG members CG members CG members
9	Next Enpr-EMA teleconference	• Next teleconference scheduled on first week on September (week starting 02 September). A doddle poll will be sent to all CG members to confirm date and time • Aim of this teleconference: to monitor progress of each Working Group set up during the annual workshop	EMA
10	Next steps	• To generalise good practice • To organise, monitor Working Group work, and finalise actions	All