



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2013
EMA/150389/2013

Agenda of the Enpr-EMA Coordinating Group meeting

Friday 28 June 2013, 09.00 to 12.00 UK time, 2D

Chair: Peter Helms (PH)

Co-chair: Irmgard Eichler (IE)

Chair Elect: Mark Turner (MT)

Invited: Benjamin Pelle (BP), Isabel Perez (IP) and Coordinating Group Members

Daniel Brasseur (Chair PDCO)

Richard Vesely (RV), Alessandro Jenkner (AJ), Xavier Kurz (XK), Paolo Tomasi, Agnes Saint

Raymond (all EMA)

Item	Preliminary draft agenda	Initials		Time
09.00	Apologies Adoption of the minutes of last Coordinating Group face to face meeting on 26 February 2012 Adoption of agenda	Peter Helms	For adoption	5'
09:05	Coordinating Group members endorsement of Mark Turner's election as Enpr-EMA new chair	Peter Helms / Mark Turner	For adoption	5'
09:10	Outcomes of the 2013 annual workshop and implications on work programme 2013/2014	Mark Turner	For discussion	25'
09:35	Enpr-EMA website reorganisation	Irmgard Eichler	For information	5'
09:40	Endorsement of new received applications	Benjamin Pelle	For information	5'
09:45	Representation of category 1 national networks in CG when the total number of 18 is exceeded and grouping in therapeutic areas Frequency of Enpr-EMA CG teleconferences Reminder on mandate and responsibilities in order to remain member of CG group	Irmgard Eichler / Mark Turner	For discussion	10'
09:55	Coffee break			15'



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10:10	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 could be more actively involved and contribute to the PDCO discussion	Daniel Brasseur / Dirk Mentzer/ Mark Turner / Richard Vesely / Irmgard Eichler / Alessandro Jenkner	For discussion	75'
11:25	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.)	Xavier Kurz Mark Turner	For discussion	20'
11:45	Next Enpr-EMA CG teleconference to be scheduled	Irmgard Eichler	For discussion	
	A.O.B	Peter Helms	For discussion	10'
	Conclusion and next steps	Mark Turner		5'
12:00	End of meeting			