

13 January 2015
EMA/706157/2014

Agenda – Enpr-EMA Coordinating Group (CG) meeting and Enpr-EMA Working Group (WG) meeting

Wednesday 21 January, via Adobe Connect; 14.00 to 17.00 UK time

Chair: Mark Turner (MT)

Co-chair: Irmgard Eichler (IE)

Enpr-EMA Secretariat: Benjamin Pelle (BP), Isabel Perez (IP)

Invited: Enpr-EMA Coordinating Group Members, Enpr-EMA Working Group Chairs (WGC), Enpr-EMA Industry Observers (Geneviève Michaux, GM and William Treem, WT), David Dunger (DD, EUCADET emerging network) and Ralf Herold (RH, EMA)

Part 1: Working Group Chairs and Coordinating Group Agenda

Item	Preliminary agenda	Initials		Time
1.	- Apologies - Minutes of last CG (teleconference 26/10/14) - Adoption of agenda	MT	For adoption	14.00
2.	Update from each individual WG on their work progress	WG Chairs	For discussion	14:05

Part 2: Coordinating Group Agenda

Item	Preliminary agenda	Initials		Time
Open session (for Enpr-EMA CG Members and Industry Observers)				
1.	Update following meeting with EFPIA in Dec 2014	WT/GM	For discussion	16:00
2.	Update on the Global Paediatric Clinical Trial Network	MT	For discussion	16:10
3.	Status update on new emerging networks:		For information	16:20
	Cardiology	IE		
	Diabetes	DD		

Item	Preliminary agenda	Initials		Time
4.	Topics to be discussed during the Enpr-EMA Workshop (28 May 2015):e.g. • <i>Updates on WGs</i> • <i>Update on iKAN (Worldwide Involvement of Children in Clinical Research)</i> • <i>Ways to fund involvement of children, young people and families in research</i> • <i>Collaboration with HCP organisations and need for GCP Training for network staff</i> • <i>Update on GRIP deliverables (and opportunities to incorporate new education, knowledge and products in research)</i> • <i>Business case and funding opportunities for clinical research networks</i> • <i>Update on Paediatric Regulation and its implementations (role of EMA, Ethics and implications for networks)</i>	MT/IE	For discussion	16:25
Closed session (for Enpr-EMA CG Members only)				
5.	Endorsement of new or updated applications for Enpr-EMA membership: • ECAPN • RIPPS	BP	For adoption	16:35
6.	Important items to be reported in clinical study protocols of paediatric clinical trials; issues to be discussed for publication – SPIRIT C, CONSORT C	IE	For discussion	16:40
7.	PDCO class waiver list review	IE/RH	For discussion	16:50
8.	A.O.B.			17:00