



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 August 2015
EMA/554410/2015
Human Medicines Research & Development Support Division

Agenda - Enpr-EMA Coordinating Group members meeting

Wednesday 21 October, EMA room 09-C and via Adobe Connect; 13.00 to 15.00 UK time

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader		Time
13:00	Apologies Adoption of agenda	Mark Turner	For adoption	5'
13:05	Update on status of emerging networks: <ul style="list-style-type: none"> Cardiology (Task Force of AEPC) Endocrinology/Diabetes (EUCADET) 	Sylvie Di Filippo David Dunger	For information	5'
13:10	Feedback on updated work plans and work progress from each Enpr-EMA WG	Irmgard Eichler / Mark Turner	For information	15'
13:25	Industry chosen topic - TBD	William Treem / John Watson	For discussion	7'
13:32	Introduction of new EUCOPE (European Confederation of Pharmaceutical Entrepreneurs) representative	John Watson	For information	3'
13:35	Topic approval process	Mark Turner/Irmgard Eichler	For discussion	10'
13:45	Updated networks' financial disclosure to collect data on source of networks' funding: tool to be used for specific meetings and need for transparency	Irmgard Eichler	For discussion	10'
13:55	Update on international initiatives: <ul style="list-style-type: none"> Global Paediatric Clinical Trial Network 	Mark Turner	For information	10'



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	<ul style="list-style-type: none"> EU Paediatric Clinical Trial Network 			
14:05	Neonatology initiatives: update from the established topic groups (neonatal seizures, BPD, data management and neonatal clinical pharmacology)	Mark Turner	For information	5'
14:10	Update on the ESFRI 2016 Road Map, following the September hearing meeting <i>(ESFRI: European Strategy Forum for Research Infrastructure)</i>	Mark Turner	For information	5'
14:15	Future of the Paediatric Regulation: proposal for a corporate message from Enpr-EMA on the future and improvements on the Paediatric Regulation	Irmgard Eichler / Mark Turner	For discussion	15'
14:30	Use and dissemination of the work of the Nuffield Council on Bioethics	Irmgard Eichler	For discussion	5'
14:35	March 2016 FDA workshop on Long-Term Pediatric Safety	Mark Turner	For information	5'
14:40	Endorsement of newly received or updated applications for Enpr-EMA membership: <ul style="list-style-type: none"> DCRI (new, category 1) INFANT (updated, category 2) 	Irmgard Eichler	For adoption	5'
14:45	Representation of category 1 networks within CG	Irmgard Eichler	For discussion	5'
14:50	Next Enpr-EMA CG and WG teleconferences to be scheduled in January 2016 and possible change of dates of the annual face to face workshop and members meeting	Irmgard Eichler	For discussion	5'
14:55	A.O.B Collaboration with: EFGCP paediatric working group EURORDIS-YES (youth empowerment school)	All	For discussion	5'
15:00	End of meeting			

List of Category 1 Enpr-EMA registered networks (20 networks):

Type of network and therapeutic area of the network	Name of category 1 network
National and multispecialty	NIHR-MCRN FinPedMed MCRN-NL MICYRN ScotCRN CICPed RIPPS OKIDS <i>DCRI (pending endorsement by CG at the 21/10/15 meeting)</i>
Oncology (solid / haematologic malignancies)	Newcastle-CLLG ITCC IBFMSG
Allergology / Immunology/ Rheumatology	PRINTO
Stem Cell and Organ Transplantation / Haematology (non-malignant) / Haemostaseology	EBMT
Respiratory diseases / Cystic Fibrosis	ECFS-CTN
Psychiatry / Neurology	EUNETHYDIS
Infectious diseases / Vaccinology	PENTA-ID UKPVG
Neonatology	GNN
Special Activities (pharmacovigilance, long-term follow up, community paediatricians)	FIMP-MCRN