

6 October 2016
EMA/456581/2016
Human Medicines Research & Development Support Division

Agenda - Enpr-EMA Coordinating Group members meeting

Thursday 06 October 2016, EMA room 03-K and via Adobe Connect;
13.00 to 15.20 UK time

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader		Time
Open part with participation of industry representatives as observer				
13:00	Apologies Adoption of agenda	Mark Turner	For adoption	5'
13:05	Feedback on updated work plans and work progress from each Enpr-EMA WG	Irmgard Eichler / Mark Turner	For information	35'
13:40	Industry chosen topic: IMI 2 project	William Treem	For discussion	10'
13:50	Webinar on Enpr-EMA	John Watson	For information	5'
13:55	Update on - EMA guidance for organisation of multi-stakeholder meetings - networks' financial disclosure to collect data on source of networks' funding: Current status	Irmgard Eichler	For information	10'
14:05	Plan to establish Enpr-EMA WG on "Trial preparedness"	Mark Turner	For information	3'
14:08	Update on: - PDCO: how to work /communicate with networks - Update from networks to provide PDCO contact points	Mark Turner /Irmgard Eichler		5'

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	Update from networks re contact with learned societies			
14:13	Update on PEDCRIN	Mark Turner	For information	7'
14:20	How to prepare for the corporate response to public consultation of 10 year report on Paediatric Regulation	Gunter Egger/Mark Turner	For discussion	5'
14:25	Suggestions for 3 Enpr-EMA working group meetings 2017	Irmgard Eichler / Mark Turner	For discussion	10'
14:35	Feedback on meeting with EUREC: how to train ECs on paediatric specific issues?	Pirkko Lepola	For information	10'
14:45	Next Enpr-EMA CG and WG teleconferences to be scheduled in January 2017	Irmgard Eichler	For discussion	2'
Closed part without participation of industry representatives as observer				
14:47	Propose topics for network specific slot in the annual f2f meeting without industry	Irmgard Eichler / Mark Turner	For discussion	5'
14:52	Project: analysis of factors influencing successfully completed paediatric clinical studies (as per attached document)	Irmgard Eichler	For discussion	5'
14:57	Endorsement of newly received or updated applications for Enpr-EMA membership: - EAPRASnet (category 4) - NorPedNet (Finland, Sweden, Denmark and Iceland) (category 3)	Irmgard Eichler	For adoption	3'
15:00	Revised self-assessment forms	Irmgard Eichler	For discussion	10'
15:10	- Grouping of networks for joint representation within CG: RIPPS/ CICPed - Proposal: only have one annual f2f CG meeting and invite all networks as observers to the other 2 CG T-conferences ?	Mark Turner / Irmgard Eichler	For discussion	5'
15:15	Publishing updates on networks	Idabel Perez	For information	3'
15:20	End of meeting			