



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2016
EMA/795122/2015

Agenda of the 2016 annual workshop of the European network of paediatric research at the EMA (Enpr-EMA)

Thursday 02 June 2016, Room 3A

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Action	Time
10:00	Arrival and registration			30'
10:30	Welcome address	Isabelle Moulon		5'
10:35	Session 1 Update on Enpr-EMA activities	Mark Turner Irmgard Eichler		
10:35	Report from the coordinating group (CG) Update on Enpr-EMA activities, achievements and challenges	Mark Turner	For information	20'
	Session 2 Update on the Enpr-EMA Working Groups	Mark Turner		
10.55	Feedback from each Working Group on their completed actions, deliverables and identification of follow-on action plans	Working Group Chair Persons	For discussion	125'
13.00	Lunch			60'
	Session 3 Selected topic discussions	Mark Turner		
14.00	Feedback on activities of International Neonatal Consortium	Mark Turner		10'
14:10	Update on networks:		For discussion	65'



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	<u>European networks:</u> <ul style="list-style-type: none"> OKids The European Paediatric Clinical trial network an IMI2 project 	Ruth Ladenstein Mark Turner / William Treem		
	<u>International networks:</u> <ul style="list-style-type: none"> The Duke Clinical Research Institute (DCRI) Global Paediatric Clinical Trial Network 	Brian Smith William Treem		
	<ul style="list-style-type: none"> Successful IMI project: INNODIA 	David Dunger		
	<ul style="list-style-type: none"> EPCTRI: Paediatrics in 2016. Roadmap of European Strategy Forum for Research Infrastructure (ESFRI) 	Mark Turner		
15:15	Update from Industry Representatives	John Watson (EUCOPE) William Treem (EFPIA)	For discussion	30'
15:45	Coffee break			15'
16.00	Paediatric specific and ethics issues related to implementation of Clinical Trial Regulation	Hugh Davies, Dirk Lanzerath, Maja León Grzymkowska (EC)	For discussion	85'
	Revision of Document on Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population	Agnes Saint Raymond, Ralf Herold, Pirkko Lepola,		
	Panel discussion			
17.25	Involvement of children in research: <ul style="list-style-type: none"> Feedback from the International Children's Advisory Network (ICAN) Research 1 year after establishment; 	Joana Claverol	For discussion	20'
17.45	Action points and conclusions	Mark Turner	For discussion	15'
18.00	End of workshop			

Close session:

Item	Agenda	Topic leader	Action	Time
18.00	Session 4 Network Business Meeting	Mark Turner		
18:00	Business meeting for the European Paediatric Clinical Trial Research Infrastructure (EPCTRI)	Mark Turner	For discussion	30'