



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

Agenda - Launch of the European network of paediatric research at EMA (Enpr-EMA)

11 March 2011: European Medicines Agency, 7 Westferry Circus, Canary Wharf, London, UK. Meeting room 2A.

Co-Chairs: Irmgard Eichler, Sophie Olivier and Peter Helms (Chair of Enpr-EMA CG)

Time	Item/ presentation title	Presenter, affiliation
8:30	Arrival and registration / coffee	
9:00	Welcome address	Hans-Georg Eichler, EMA Senior Medical Officer Paolo Biffignandi, TOPRA immediate past President



	Session 1: Introducing Enpr-EMA	Chair: Irmgard Eichler, EMA
9:10	The Paediatric Regulation as an instrument for European paediatric research	Paolo Tomasi, EMA
9:20	The organisational and functional structure of Enpr-EMA	Christina Peters, EBMT, chair of working group 1
9:30	The role of EnprEMA Scientific Committee: the paediatric committee (PDCO)	Daniel Brasseur, Chair PDCO
9:40	Paediatric networks for clinical trials in children: regulatory authorities perspectives	Chantal Belorgey, Chair CTFG
9:50	Discussion on the objectives	
10:15	COFFEE BREAK	
	Session 2: Expectations for Enpr-EMA from various stakeholders	Chair: Chair of Enpr-EMA coordinating group
	Industry perspective	
10:30	Expectations from a big Pharma perspective	Ramesh Padavala, Novartis Pharma AG
10:40	Expectations from Orphan perspective:	Tim Higenbottam, Chiesi Farmaceutici S.p.A.
10:50	Expectations from a SME perspective	Susan Conroy, Therakind Ltd
	Networks' perspectives	
11:00	Lessons learned - a large national network's perspective	Mark Turner, MCRN-UK
11:10	An oncology networks' perspective	Bruce Morland, Innovative Therapies for Children with Cancer Network
11:20	The role of Enpr-EMA - a neonatal network's perspective	Wolfgang Göpel, German Neonatal Network

	The patient perspective:	
11:30	2 representatives from patient/parent organisations	Tsveta Schyns, PDCO member representing patients' organisations
11:40		Cor Oosterwijk, European Genetic Alliances' Network (EGAN)
11:50	Discussion	
12:15	LUNCH	
	Session 3 The way forward	Chair: Sophie Olivier, EMA
13:15	Break out in 3 groups for discussion on 3 proposals: 1. The role of EMA staff, PDCO and PIPs (room 2D) 2. How industry can refer and use networks (room 2A) 3. How patients can be involved in networks (trial design etc) and in trials (room 4C)	Chairs: Paolo Tomasi Sophie Olivier Tsveta Schyns and Juan Garcia Burgos (EMA)
	Feedback from the 3 discussion groups (room 2A)	
14:15	1. Proposals on the role of EMA staff, PDCO and PIPs	
14:25	2. Proposals on how industry can refer and use networks	
14:35	3. Proposals on how patients can be involved in networks (trial design etc) and in trials	
14:45	COFFEE BREAK	

15:00	Panel discussion	
	Representatives from Industry	Ramesh Padavala; Tim Higenbottam; Robert Iannone (Merck Research Laboratories)
	Enpr-EMA	Chair of Enpr-EMA CG; Mark Turner; Bruce Morland; Wolfgang Göpel
	Patients	Tsveta Schyns; Cor Oosterwijk
	PDCO	Paolo Rossi; Dirk Mentzer
	EMA	Irmgard Eichler; Juan Garcia Burgos
16:25	Conclusions	Paolo Rossi, PDCO Member
16:30	Close of meeting	