



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 March 2012
EMA/39173/2012
Human Medicines Development and Evaluation

Agenda – Annual workshop on the European network of paediatric research at the EMA (Enpr-EMA)

Thursday, 22 March 2012, meeting room 2A

Chairpersons: **Peter Helms / Irmgard Eichler / Daniel Brasseur**

Item	Agenda	Topic leader	Time
10:00	Arrival and registration / coffee		30'
10:30	Welcome address	EMA (name TBC) and David Jefferys (President, TOPRA)	5'
10:35	SESSION 1: Update on Enpr-EMA	Chair: Daniel Brasseur (Chair of PDCO)	
	Report from the coordinating group (CG): Update on Enpr-EMA activities, achievements and challenges Interaction between industry and Enpr-EMA	Peter Helms, (Chair of Enpr- EMA CG)	15'
10:50	Emerging networks: Learn from successful networks: European Cystic Fibrosis Society - Clinical Trials Network (ECFS-CTN) The Paediatric Rheumatology International Trials Organisation (PRINTO)	Tim Lee (ECFS) Nicola Ruperto (PRINTO)	10' 10'
11:10	New initiatives: Gastroenterology Cardiology Diabetes/Endocrinology	Nick Croft (Barts and The London) Michael Burch (GOSH) Mehul Dattani (GOSH)	5' 5' 5'
11:25	The interface: industry – CRO - Clinical trials networks	Mark Turner,	10'

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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	Defining the roles	(NIHR-MCRN) Martine Dehlinger-Kremer (EUCROF)	10'
11:45	Interaction PDCO networks	Dirk Mentzer (PDCO)	10'
11:55	Discussion		30'
12:25	LUNCH		
13:25	SESSION 2: How to use Enpr-EMA - Perspectives from various stakeholders	Chair: Peter Helms, (Chair of Enpr-EMA CG)	
	The patient perspective: The International Patient Organization for Primary Immunodeficiencies (IPOPI) expectations	Jose Drabwell, (IPOPI)	5'
	How to set up a young adviser group within clinical networks:	Jenny Newman (NIHR- MCRN UK)	10'
13:40	Networks' perspective: What networks can offer	Kalle Hoppu (FinPedMed) David Coghill (Eunethydis) Adolf Valls-i-Soler (EuroNeoNet)	5' 5' 5'
13:55	Industry perspective: Proposals on how to interact and use Enpr-EMA	Helen Shaw (Proveca Ltd) Ali Harrison (Astra Zeneca)	10' 10'
14:15	Report on ethics meeting November 2011: Analysis of barriers and possible solutions. How can collaboration between Enpr-EMA and ethics committees be envisaged	Ralf Herold, (EMA)	10'
14:25	Discussion		30'
14:55	COFFEE BREAK		15'
15:10	SESSION 3: Break into 3 groups for discussion on :	Chair: Irmgard Eichler, (EMA)	45'
	Group 1: Proposals on how to develop and foster new networks	Chair: Mark Turner (NIHR-MCRN)	
	Group 2: Proposals on how to encourage clinicians to participate in	Chair: Saskia de Wildt (MCRN-NL)	

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	Clinical Trials Proposals on how industry can refer and use networks		
	Group 3: Proposals on how patients can be involved in networks (trial design etc) and in trials	Chairs: Elizabeth Vroom (Duchenne Parent Project) / Juan Garcia Burgos (EMA)	
15:55	BREAK FOR RETURNING TO MAIN ROOM (2A)		10'
16:05	Report to Plenary from the three groups		30'
16:35	Panel discussion with representatives from industry, Enpr-EMA, patient/parent organisations		50'
17:25	Conclusions and next steps	Peter Helms (Chair of Enpr-EMA CG) and Ali Harrison (Astra Zeneca)	5'
17:30	Open informal get-together session over coffee and tea with members of the Enpr-EMA		60'
18:30	Close of meeting		

List of speaker affiliations

Surname	Name	Affiliation
Brasseur	Daniel	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (Chair of Paediatric Committee at the European Medicines Agency)
Burch	Michael	Great Ormond Street Hospital for Children
Coghill	David	European Network for Hyperkinetic Disorder
Croft	Nicholas	Barts and the London NHS Trust
Dattani	Mehul	Great Ormond Street Hospital for Children
De Wildt	Saskia	Medicines for Children Research Network, NL
Dehlinger-Kremer	Martine	European CRO Federation
Drabwell	Jose	PCWP representative of Enpr-EMA coordinating group; International Patient Organisation for Patients with Primary Immunodeficiencies
Eichler	Irmgard	Vice-chair of Enpr-EMA coordinating group (European Medicines Agency)
Garcia Burgos	Juan	European Medicines Agency
Harrison	Ali	Astra Zeneca
Helms	Peter	Chair of Enpr-EMA coordinating group
Herold	Ralf	European Medicines Agency
Hoppu	Kalle	Finnish Investigators Network for Paediatric Medicines
Jefferys	David	The Organisation for Professionals in Regulatory Affairs
Lee	Tim	European Cystic Fibrosis Society
Mentzer	Dirk	PDCO representative of Enpr-EMA coordinating group; Paul-Ehrlich-Institut
Newman	Jenny	National Institute for Health Research/ Medicines for Children Research Network, UK
Ruperto	Nicola	Paediatric Rheumatology International Trials Organisation
Shaw	Helen	Proveca Limited
Turner	Mark	National Institute for Health Research/ Medicines for Children Research Network, UK
Valls-i-Soler	Adolf	European Neonatal Network
Vroom	Elizabeth	Duchenne Parent Project