



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Agenda - Enpr-EMA Coordinating Group & networks meeting

Date: 22 June 2020; 15:00-16:45 CEST; By Adobe Connect

Chairpersons: Pirkko Lepola / Gunter Egger

Agenda	Topic leader		Time
OPEN SESSION (all networks and observers)			
Adoption of agenda	Pirkko Lepola	For adoption	5'
Welcome to new members of coordinating group (CG): Alessandra Nardone: PENTA Cecile Ollivier – EUCOPE Sabine Scherer – PDCO Anette Solli Karlsen – PDCO (observer)	Gunter Egger	For information	5'
Brief Updates from the working groups (WG): - WG on ethics (Pirkko Lepola) - WG on parents and patients (Dimitrios Athanasiou) - WG on research staff (Vincent O'Mahony) - WG on clinical trial preparedness (Mark Turner & Sabine Scherer) - WG on international collaboration (Thierry Lacaze) - Clinical practice evidence in the labelling (Saskia De Wildt)	Pirkko Lepola / Gunter Egger / topic leads	For information and discussion	15'
Feedback from networks on impact of pandemic on regular clinical trial activities, business continuity planning, and feedback	Collin Hovinga / Thierry Lacaze / Mark Turner	For information and discussion	30'

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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	on activities related to COVID-19 Discussion on - Impact of pandemic on operational issues of paediatric trials, lessons learnt – plans for the future - Enabling collaborative studies for COVID-19 (and otherwise), what is going on in the networks, how can Enpr-EMA help, what information should be shared	Pirkko Lepola / Gunter Egger / all		
	Site accreditation by industry (survey by i-ACT)	Pirkko Lepola / Collin Hovinga	For information	10'
	FDA request for information on establishing a rare disease clinical trial network	Pirkko Lepola / Gunter Egger / all	For discussion	15'
	Planning for workshop/meeting in autumn - Logistical remarks - Topic suggestions	Pirkko Lepola / Gunter Egger / all	For discussion	10'
	CLOSED SESSION without industry observers			
	Review of mandate of CG	Pirkko Lepola / Gunter Egger / all	For discussion	10'
	AOB <i>Next CG teleconference</i>	Gunter Egger / Pirkko Lepola	For information	5'
	End of meeting			