



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Agenda - Enpr-EMA Coordinating Group & networks meeting

Date: 12 June 2024; 15:30-17:00 CEST; via Webex

Chairpersons: Pirkko Lepola / Gunter Egger

Agenda	Topic leader	Time
Welcome and adoption of agenda	Pirkko Lepola	2'
Update on legislative progress for new pharmaceutical legislation	Pirkko Lepola, Gunter Egger	5'
Working group update: Paediatric clinical trial site quality criteria	Ricardo Fernandes, Solange Rohou Pernille Skovby, Kirsten Sherman Cervati	20'
Working group update: Cross-border clinical trials	Begonya Nafria	15'
Working group update: International collaboration Clinical Trial authorisation and ethics review across jurisdictions	Thierry Lacaze	5'
Working group update: Research staff, nurses	Pamela Dicks	5'
New working group: Patient and Public Involvement (PPI) and Young Person's Advisory Groups (YPAG)	Segolene Gaillard	5'
Review/prioritisation of topics for annual meeting on 1 st /2 nd October 2024:	Pirkko Lepola	30'

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Agenda		Topic leader		Time
	- Legislative changes concerning paediatrics (pharmaceutical legislation, clinical trial legislation) - Health Technology Assessment (HTA) - Real World Data (RWD) - New research infrastructures and networks - Enpr-EMA working group deliverables and work plan - Ethics - New medicinal products			
	Organisational & AOB	Pirkko Lepola, Gunter Egger	For information	3'
	End of meeting			