

Agenda - Enpr-EMA Coordinating Group & networks meeting

Date: 29 June 2021; 15:00-16:30 CEST; By Webex

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 observer members of coordinating group (CG): <ul style="list-style-type: none"> Kanecia Zimmerman to replace Christoph Hornik for Duke Clinical Research Institute Welcome to new Enpr-EMA member networks: <ul style="list-style-type: none"> AEPC Task Force on Clinical (Drug) Trials [Association for European paediatric and congenital cardiology] 	Gunter Egger	For information	5'
Update from WG on international collaboration <ul style="list-style-type: none"> Clinical Trial authorisation across jurisdictions - manuscript Survey on requirements for paediatric trial sites 	Thierry Lacaze Collin Hovinga	For information and discussion	20'
Update from WG on research staff	Pamela Dicks	For information	5'
Update from WG on clinical practice evidence in the labelling	Saskia de Wildt	For information	5'
Academia collaboration matrix action plan Funding, training, and when	Lifang Liu		15'

Agenda	Topic leader		Time
Preparation of annual meeting (28 September 2021) <ul style="list-style-type: none"> • Revision of Paediatric Regulation (EC update) • Clinical Trial Regulation • COVID-19 developments • WG updates • Enpr-EMA membership 	All	For discussion	10'
Update on paediatric developments regarding COVID-19 vaccines and therapeutics	Laura Fregonese	For information and discussion	20'
CLOSED SESSION (without industry observers)			
N/A	N/A	N/A	
AOB End of meeting	Pirkko Lepola		5'