



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/439238/2021

Agenda of the 2021 annual meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (Enpr-EMA)

Date: Tuesday 28 September 2021

Time: 10:30 – 17:30 Central European Summer Time

Virtual meeting via Webex

Chairpersons: Pirkko Lepola, Gunter Egger

Time	Topic	Topic leader	Action
10:30	Welcome address	Pirkko Lepola / Gunter Egger	
10:35	Adoption of meeting agenda	Pirkko Lepola	
10:40	Report from the Coordinating Group (CG): Enpr-EMA activities, achievements and challenges	Pirkko Lepola	For information
10:50	Organisational aspects: - Self-assessment form & membership categories - Conflict of interest declaration	Gunter Egger / Liliya Dimitrova	For information
11:00	Report from the European Commission: - Update on EU evaluation of Paediatric & Orphan Regulation - Update on EU pharmaceutical strategy	Fabio D'Atri	For discussion
12:00 -	Lunch		

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Time	Topic	Topic leader	Action
13:00			
13:00	Update from EU initiative: Conect4children (c4c)	Mark Turner	For discussion
13:20	Update from global initiative: Multi-Regional Clinical Trials (MRCT) Center and its initiative on promoting global clinical research in children	Dominik Karres	For discussion
13:40	Real World Evidence to advance clinical development: - Observational studies projects (DARWIN EU & Rapid Analytics) - Real World Evidence to contribute to drug development and access	Francois Domergue Ralf Herold	For discussion
14:25	Report from the Working Groups (WG): - WG on international collaboration - Other updates (tbc)	Thierry Lacaze WG chairs (tbc)	For discussion
14:45 – 15:15	Coffee break		
15:15	EU Clinical Trial Regulation (CTR): Introduction to the Clinical Trial Information System (CTIS)	Ana Rodriguez	For discussion
16:15	COVID-19 affecting children: Update on development of therapeutics and vaccines for paediatric use	Laura Fregonese	For discussion
17:00	Update from EMA	Gunter Egger	For information
17:05	A.O.B.	All	For information
17:10	Conclusions	Pirkko Lepola	For information
17:30	End of meeting		

Speakers:

- Fabio D’Atri, European Commission (DG SANTE)

- Liliya Dimitrova, European Medicines Agency (EMA)
- Francois Domergue, European Medicines Agency (EMA)
- Gunter Egger, co-chair of Enpr-EMA, European Medicines Agency (EMA)
- Laura Fregonese, European Medicines Agency (EMA)
- Ralf Herold, European Medicines Agency (EMA)
- Dominik Karres, European Medicines Agency (EMA)
- Thierry Lacaze, Maternal Infant Child Youth Research Network (MICYRN)
- Pirkko Lepola, chair of Enpr-EMA, Finnish Investigators Network for Paediatric Medicines (FinPedMed)
- Ana Rodriguez, European Medicines Agency (EMA)
- Mark Turner, conect4children (c4c)