



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/440708/2020

Agenda of the 2020 annual meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (Enpr-EMA)

Date: Monday 28 September 2020

Virtual meeting via Adobe Connect

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	Adoption of update to CG mandate	Pirkko Lepola	
10:55	<ul style="list-style-type: none">Update on EU evaluation of Paediatric & Orphan Regulation (20 min)Update on EU pharmaceutical strategy (20 min)Discussion on role of paediatric networks to contribute to pharmaceutical strategy, and interactions between Enpr-EMA and the EC (25 min)	Fabio D'Atri Antonios Rodiadis	For discussion
12:00-13:00	Lunch		

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Time	Topic	Topic leader	Action
13:00	<p>EU-Initiatives progress update:</p> <ul style="list-style-type: none"> • Conect4children (c4c) (15 min) • European Paediatric Translational Research Infrastructure (EPTRI) (15 min) • European Reference Networks (ERN) (15 min) 	<p>Mark Turner</p> <p>Donato Bonifazi</p> <p>Luca Sangiorgi</p>	For discussion
14:00	<p>Global initiatives progress update:</p> <ul style="list-style-type: none"> • Multi-Regional Clinical Trials (MRCT) Center and its initiative on promoting global clinical research in children 	Dominik Karres	For discussion
14:20	<p>Report from the Working Groups (WG):</p> <p>Completed actions, deliverables and identification of follow-on actions by WG</p> <ul style="list-style-type: none"> • WG on research staff (10 min) • WG on clinical practice evidence in the labelling (10 min) • WG on international collaboration (10 min) 	<p>Pamela Dicks / Vincent O'Mahony</p> <p>Irmgard Eichler (o.b.o Saskia de Wildt)</p> <p>Thierry Lacaze</p>	For discussion
15:00-15:30	Coffee break		
15:30	<p>Clinical trial authorisation during a pandemic:</p> <ul style="list-style-type: none"> • Perspective of the Clinical Trials Facilitation Group (CTFG) 	Ann Marie Janson Lang	For discussion
15:45	<p>COVID-19 impact on paediatric clinical trials, and how to overcome the challenges. Can some new approaches be taken forward for future paediatric trials?</p> <ul style="list-style-type: none"> • Update from Europe: <ul style="list-style-type: none"> ○ European Reference Networks (ERN) – questionnaire on impact of COVID-19 (10 min) ○ C4c – business continuity survey (10 min) ○ Experiences and lessons learnt of other European networks (discussion – 10 min) 	<p>Luca Sangiorgi</p> <p>Mark Turner</p> <p>Collin Hovinga</p> <p>Thierry Lacaze</p> <p>Martine Dehlinger-Kremer / Cécile Ollivier</p>	For discussion

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	<ul style="list-style-type: none"> • Update from North America: <ul style="list-style-type: none"> ○ Institute for Advanced Clinical Trials for Children (i-ACT) (10 min) ○ Maternal Infant Child and Youth Research Network (MICYRN) (10 min) • Update from Industry/CROs (10 min) 		
16:45	COVID-19 affecting children: <ul style="list-style-type: none"> • Multi-system inflammatory syndrome in children • Preparedness for paediatric COVID vaccine trial(s) 	Laura Fregonese	For discussion
17:30	Update from EMA	Gunter Egger	For information
17:35	A.O.B	All	For information
17:40	Conclusions and next steps	Pirkko Lepola	For information
17:45	End of meeting		

Speakers:

- Donato Bonifazi, European Network of Excellence for Paediatric Clinical Research (TEDDY)
- Fabio D’Atri, European Commission (DG SANTE)
- Martine Dehlinger-Kremer, European Contract Research Organisations Federation (EUCROF)
- Saskia de Wildt, Medicines for Children Research Network Netherlands (PEDMED-NL)
- Pamela Dicks, Scottish Medicines for Children Network (scotcrn)
- Gunter Egger, co-chair of Enpr-EMA, European Medicines Agency (EMA)
- Irmgard Eichler, European Medicines Agency (EMA)
- Laura Fregonese, European Medicines Agency (EMA)
- Ann Marie Janson Lang, Clinical Trials Facilitation and Coordination Group (CTFG)
- 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 Pediatric Medicines (FinPedMed)

- Cécile Ollivier, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- Vincent O'Mahony, Irish Paediatric Clinical Research Network (IPCRN)
- Antonios Rodiadis, European Commission (DG SANTE)
- Luca Sangiorgi, European Reference Networks (ERN)
- Mark Turner, conect4children (c4c)