



European network of paediatric research  
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/564166/2022

## Agenda of the 2022 annual meeting of the members and Coordinating Group of Enpr-EMA

Date: Tuesday, 4 October 2022, online via Webex

Chairpersons: Pirkko Lepola / Gunter Egger

Time	Agenda	Topic leader	Duration
10:15	Virtual meeting room open		
<b>10:30</b>	<b>Welcome address</b>	Pirkko Lepola / Gunter Egger	5'
10:35	Adoption of meeting agenda	Pirkko Lepola	5'
10:40	Report from the Coordinating Group (CG): <ul style="list-style-type: none"> <li>Enpr-EMA activities, achievements and challenges</li> </ul>	Pirkko Lepola	10'
10:50	Report from Enpr-EMA/c4c workshop on paediatric trial site suitability criteria	Gunter Egger	10'
11:00	Report from the working groups (WG): <ul style="list-style-type: none"> <li>WG on international collaboration</li> <li>WG on paediatric research nurses</li> <li>WG on cross-border access to paediatric trials</li> <li>WG on off-label evidence</li> </ul>	Thierry Lacaze Pamela Dicks Begonya Nafria Saskia de Wildt	60'
12:00	Role of academic clinical trials in paediatric (cancer) drug approvals	Dominik Karres	15'
12:15	Lunch		60'
13:15	Health technology assessment (HTA) in		90'

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

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	childhood: <ul style="list-style-type: none"> <li>• Introduction to European HTA work and how HTAs and regulators cooperate under the HTA Regulation</li> <li>• Evidentiary challenges and novel approaches in paediatric HTA: Perspectives from Canada</li> <li>• The current paediatric challenges in the EU and perspectives</li> <li>• Panel discussion</li> </ul>	Niklas Hedberg / Michael Berntgen  Avram Denburg  Gilles Vassal Pirkko Lepola / all	
14:45	Coffee break		
15:00	Clinical Trials Regulation: Addressing pitfalls of the Clinical Trials Regulation	Anette Solli Karlsen	45'
15:45	A.O.B.	All	5'
15:50	Conclusions and action points	Pirkko Lepola	10'
<b>16:00</b>	<b>End of meeting</b>		

Time	Agenda	Topic leader	Duration
<b>16:00</b>	<b>Closed meeting for members and observer members of the Coordinating Group</b>	Pirkko Lepola / Gunter Egger	
16:00	Adoption of the minutes of last Coordinating Group teleconference on 30 June 2022.	All	5'
16:05	Introduction of candidates for position of chair of the Coordinating Group	Candidates	10'
16:15	Election of chair of the Coordinating Group	All	15'
16:30	Endorsement of new/updated applications for Enpr-EMA membership	All	5'
16:35	Reflections on outcomes of annual meeting and A.O.B.	All	10'
16:45	Conclusions and next steps	Pirkko Lepola	15'
<b>17:00</b>	<b>End of closed meeting</b>		

## List of speakers / chairpersons

Surname	Name	Affiliation
<i>Berntgen</i>	<i>Michael</i>	<i>European Medicines Agency</i>
<i>Denburg</i>	<i>Avram</i>	<i>SickKids Research Institute and University of Toronto, Canada</i>
<i>Dicks</i>	<i>Pamela</i>	<i>ScotCRN - Scottish Children's Research Network</i>
<i>Egger</i>	<i>Gunter</i>	<i>Co-chair of Enpr-EMA, European Medicines Agency</i>
<i>Hedberg</i>	<i>Niklas</i>	<i>Dental and Pharmaceuticals Benefits Agency Sweden; EUnetHTA21</i>
<i>Karres</i>	<i>Dominik</i>	<i>European Medicines Agency</i>
<i>Lacaze</i>	<i>Thierry</i>	<i>MICYRN (Maternal Infant Child and Youth Research Network, Canada)</i>
<i>Lepola</i>	<i>Pirkko</i>	<i>Chair of Enpr-EMA, Finpedmed (Finnish paediatric research network)</i>
<i>Nafria</i>	<i>Begonya</i>	<i>eYPAGnet - European Young Persons Advisory Groups Network</i>
<i>Solli Karlsen</i>	<i>Anette</i>	<i>Norwegian Medicines Agency; Paediatric Committee</i>
<i>Vassal</i>	<i>Gilles</i>	<i>ITCC - Innovative Therapies for Children with Cancer</i>
<i>Wildt</i>	<i>Saskia de</i>	<i>Pedmed-NL - Medicines for Children Research Network Netherlands</i>