



European network of paediatric research  
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/345059/2023

## Programme of the 2023 annual workshop of the European network of paediatric research at the EMA (Enpr-EMA)

Date: Tuesday, 10 October 2023

European Medicines Agency (room 1D), and online via Webex



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## Background:

The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in children. Enpr-EMA's main objective is to facilitate clinical trials in order to increase the availability of authorised medicines for children.

Enpr-EMA's annual workshop is a unique opportunity for networks as well as other stakeholders of paediatric clinical trials, such as health care professionals, parents, carers, patient representatives as well as medicine developers and regulators, to learn about the network's priority activities. The workshop aims to facilitate inter-network and stakeholder collaboration and to build competences at European level. This year's event will give Enpr-EMA stakeholders the opportunity to come together in person for the first time in several years.

## Objectives of the workshop:

Participants will have the opportunity to learn about the achievements and latest activities of Enpr-EMA and to discuss recent developments relevant to the conduct of paediatric clinical trials.

This includes among other things the strengthening of the role of the paediatric research nurse, quality criteria for paediatric clinical trial sites, as well as improving the access of paediatric patients to clinical trials across borders. The meeting will see discussions on decentralised elements in clinical trials and on the renovation of the ICH E6 guideline on Good Clinical Practice (GCP).

The EMA will inform participants and seek their feedback regarding planned actions to support academic sponsors as part of the ACT EU (Accelerate Clinical Trials in the EU) initiative. Moreover, the European Commission will present the main aspects of the proposed new EU pharmaceutical legislation relevant for paediatrics, which will provide first-hand insights and an opportunity for dialogue and discussion.

The final session of the day will focus on best practices for patient recruitment as well as involvement of patients and young people in clinical trial planning.

## Programme:

Chairpersons: Pirkko Lepola / Gunter Egger

Time	Topic	Topic lead	Duration
09:00	<i>Arrival and registration</i> <i>(Virtual meeting room open for remote participants)</i>		
09:30	<b>Opening remarks by Enpr-EMA co-chairs</b>	Pirkko Lepola Gunter Egger	5'
09:35	<b>Welcome address by EMA Executive Director</b>	Emer Cooke	10'
	<b><u>SESSION I – Enpr-EMA activities 2022-2023</u></b>		
09:45	<b>Annual report from the coordinating group:</b> Enpr-EMA activities, achievements and challenges	Pirkko Lepola	10'
09:55	<b>Update from Enpr-EMA working groups:</b>		50'

Time	Topic	Topic lead	Duration
	<ul style="list-style-type: none"> <li>Off-label evidence</li> <li>International collaboration</li> <li>Paediatric research nurses</li> <li>Paediatric clinical trial site standards</li> <li>Cross-border access to paediatric clinical trials</li> </ul>	Saskia de Wildt Thierry Lacaze Pamela Dicks Ricardo Fernandes Pernille Skovby Begonya Nafria	
10:45	<b>Decentralised elements in clinical trials – Paediatric perspective</b>	Monique Al Thierry Lacaze	25'
11:10-11:40	Coffee break		30'
	<b><u>SESSION II – Regulatory activities &amp; Pharmaceutical legislation</u></b>		
11:40	<b>Good Clinical Practice:</b> ICH E6 (R3) update from ACT EU (PA4)	Dong Ho Kim Pietsch	20'
12:00	<b>Support for academic sponsors:</b> Update from ACT EU (PA2)	Giacomo Capone	20'
12:20	<b>Reform of the EU pharmaceutical legislation and its impact on paediatric &amp; orphan medicine development</b>	Fabio D'Atri	40'
13:00-14:00	Lunch		60'
	<b><u>SESSION III – Highlights from Enpr-EMA networks and work plan 2023/2024</u></b>		
14:00	<b>Highlights in 2022-2023 of Enpr-EMA and its member networks:</b> Paediatric clinical trials need paediatric clinical trial budgets The conect4children (c4c) journey	Stavros Koulizakos Jenny Kindblom Mark Turner	45'
14:45	<b>Draft Enpr-EMA work plan 2023/2024</b>	Pirkko Lepola	10'
14:55-15:25	Coffee break		30'
	<b><u>SESSION IV – Patient recruitment &amp; involvement</u></b>		
15:25	<b>Patient recruitment and retention:</b>	Marek Migdal	20'

Time	Topic	Topic lead	Duration
	Practices to improve patient recruitment from a network's perspective		
15:45	<b>Involvement of patients &amp; young people in the planning of clinical trials:</b> Benefits of involving patients and young people in paediatric clinical research Improve paediatric health, medicine research, and innovation by sharing children's voices with iCAN	Begonya Nafria Donato Bonifazi	30'
16:15	AOB	All	5'
16:20	Conclusions	Pirkko Lepola	10'
16:30	End of meeting		

#### List of speakers / chairpersons:

Surname	Name	Affiliation
Al	Monique	Clinical Trials Coordination Group (CTCG), Central Committee on Research Involving Human Subjects (CCMO), Netherlands
Bonifazi	Donato	TEDDY European Network of Excellence for Paediatric Research
Capone	Giacomo	European Medicines Agency (EMA)
Cooke	Emer	Executive director of European Medicines Agency (EMA)
D'Atri	Fabio	European Commission (EC), DG SANTE
Dicks	Pamela	ScotCRN (Scottish Children's Research Network)
Egger	Gunter	Co-chair of Enrpr-EMA, European Medicines Agency
Fernandes	Ricardo	conect4children National HUB lead and STAND4kids (Portuguese paediatric research network)
Gaillard	Segolene	RIPPS (Paediatric Investigation into Health Products Network, France)
Koulizakos	Stavros	Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Gothenburg, Sweden
Kindblom	Jenny	Dept. of Clinical Pharmacology, Sahlgrenska University Hospital, Gothenburg, Sweden
Lacaze	Thierry	MICYRN (Maternal Infant Child and Youth Research Network, Canada)

Surname	Name	Affiliation
Lepola	Pirkko	Chair of Enpr-EMA, Finpedmed (Finnish paediatric research network)
Migdal	Marek	PDCO (Paediatric Committee) at EMA, conect4children National HUB, Poland
Nafria	Begonya	eYPAGnet (European Young Persons Advisory Groups Network)
Pietsch	Dong Ho Kim	European Medicines Agency (EMA)
Skovby	Pernille	conect4children National HUB, Denmark
Turner	Mark	conect4children co-coordinator, University of Liverpool, United Kingdom
Wildt	Saskia de	Pedmed-NL (Medicines for Children Research Network, Netherlands)