EMA/156670/2025

Draft Programme of the 2025 annual open meeting of the European network of paediatric research at EMA (Enpr-EMA)

Version 1.0

Thursday,
20 November 2025

European Medicines Agency (room 1C) and online

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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 meeting 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 meeting aims to facilitate inter-network and stakeholder collaboration and to build competences at European level.

Objectives of the event

The 2025 Enpr-EMA annual meeting aims to share regulatory updates, showcase network activities, and explore innovations in paediatric clinical trials. Key topics include the modernisation of Good Clinical Practice (GCP), implementation of the EU Clinical Trial Regulation, and updates from Enpr-EMA activities and its working groups. The meeting will also highlight advances in trial design, translational research, and the use of real-world data and artificial intelligence.

Programme

Chairpersons: Pirkko Lepola and Gunter Egger

Time	Topic	Topic lead	Duration
09:00	*Arrival and registration* *(Virtual meeting room open for remote participants)*		
09:30	**Welcome address**	*Ralph Bax*	*5′*
09:35	**Opening remarks by Enpr-EMA Co-chairs**	*Pirkko Lepola* *Gunter Egger*	*5′*
	SESSION I - Accelerating data use		
09:40	*European Health Data Space (EHDS)* *Introduction to EHDS*	EMA speaker (tbc)	*15´*
09:55	*Discussion – Q&A*		*5′*
10:00	*EMA Reflection Paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle* *Leveraging data and artificial intelligence (AI) in regulating human medicines in practice*	EMA speaker (tbc)	*15´*
10:15	*Discussion – Q&A*		*5′*
10:20	*Artificial Intelligence in paediatric research* *Data protection and ethics and use of data from minors for further research*	*Julian Isla*	*15´*
10:35	*Discussion – Q&A*		*5′*

Time	Topic	Topic lead	Duration
10:40 – 11:10	**Coffee break**		*30'*
	SESSION II – Enhancing trial design and conduct		
11:10	*Translational research from lab to patients* *Latest innovations by EPTRI (European Paediatric Translational Research Infrastructure)*	*Donato Bonifazi*	*15´*
11:25	*Discussion – Q&A*		*5'*
11:30	*Innovative trial designs in practice* • *Case 1* • *Case 2*	*Industry speaker(s) (tbc)*	*30´*
12:00	*Discussion – Q&A*		*5'*
	SESSION III - Enpr-EMA activities 2024/25 and new initiatives		
12:05	*Annual report from the coordinating group* • *Enpr-EMA activities, achievements and challenges* • *New CG structure* • *Newly elected Chair*	*Pirkko Lepola* *Isabel Sanchez* *Newly elected Chair*	*15'*
12:20	*Update from selected Enpr-EMA working groups* • *(tbd)*	*Working group chairs (tbc)*	*15'*
12:35	*New initiative – introductions* • *European Rare Disease Research Alliance (ERDERA)*	*Daria Julkowska*	*15'*
12:50	*Discussion – Q&A*		*5'*
12:55-13:55	**Lunch**		*60'*
	SESSION IV – Impact of ethics principles and public involvement		
13:55	*Declaration of Helsinki (DoH) 2024 in paediatrics*	*Dominique Sprumont*	*15´*
14:10	*Discussion – Q&A*		*5'*
14:15	*Patient & parent experience of advocacy and involvement*	*Sebastian Honor*	*15´*
14:30	*Discussion – Q&A*		*5'*
	SESSION V – Regulatory updates 1 – GCP		
14:35	*Good Clinical Practice (GCP): Implementation in clinical trials* *ICH E6 (R3) - Annex I - history, reasons, overview*	*Peter Twomey*	*15´*
14:50	*ACT EU and GCP modernisation*	*EMA speakers (tbc)*	*15´*

Time	Topic	Topic lead	Duration
	ICH E6 (R3) - Annex II – pragmatic trials, decentralised trials, use of real-world data sources		
15:05	*Discussion* **–** *Q&A*		*5′*
15:10 – 15:40	**Coffee break**		*30′*
	SESSION VI – Regulatory updates 2 – EU Regulatory Network		
15:40	*Clinical Trial Assessment (CTA) update* • *Paediatric clinical trial assessments under the new EU Clinical Trial Regulation – from PIP to CTA* • *Feedback from ACT EU workshop on assessment on paediatric clinical trials/interpretation of CTR article 32*	*Laura Frankhauser* *Anette Solli Karlsen*	*30′*
16:10	*Implementation of ICH E11A guideline on paediatric extrapolation in Paediatric Investigation Plans (PIPs)*	*EMA speakers (tbc)*	*15´*
16:25	*Discussion – Q&A*		*5´*
16:30	AOB	All	*5′*
16:35	Conclusions	*Pirkko Lepola* *Gunter Egger*	*10′*
16:45	End of the meeting		

List of speakers / chairpersons (tbc)