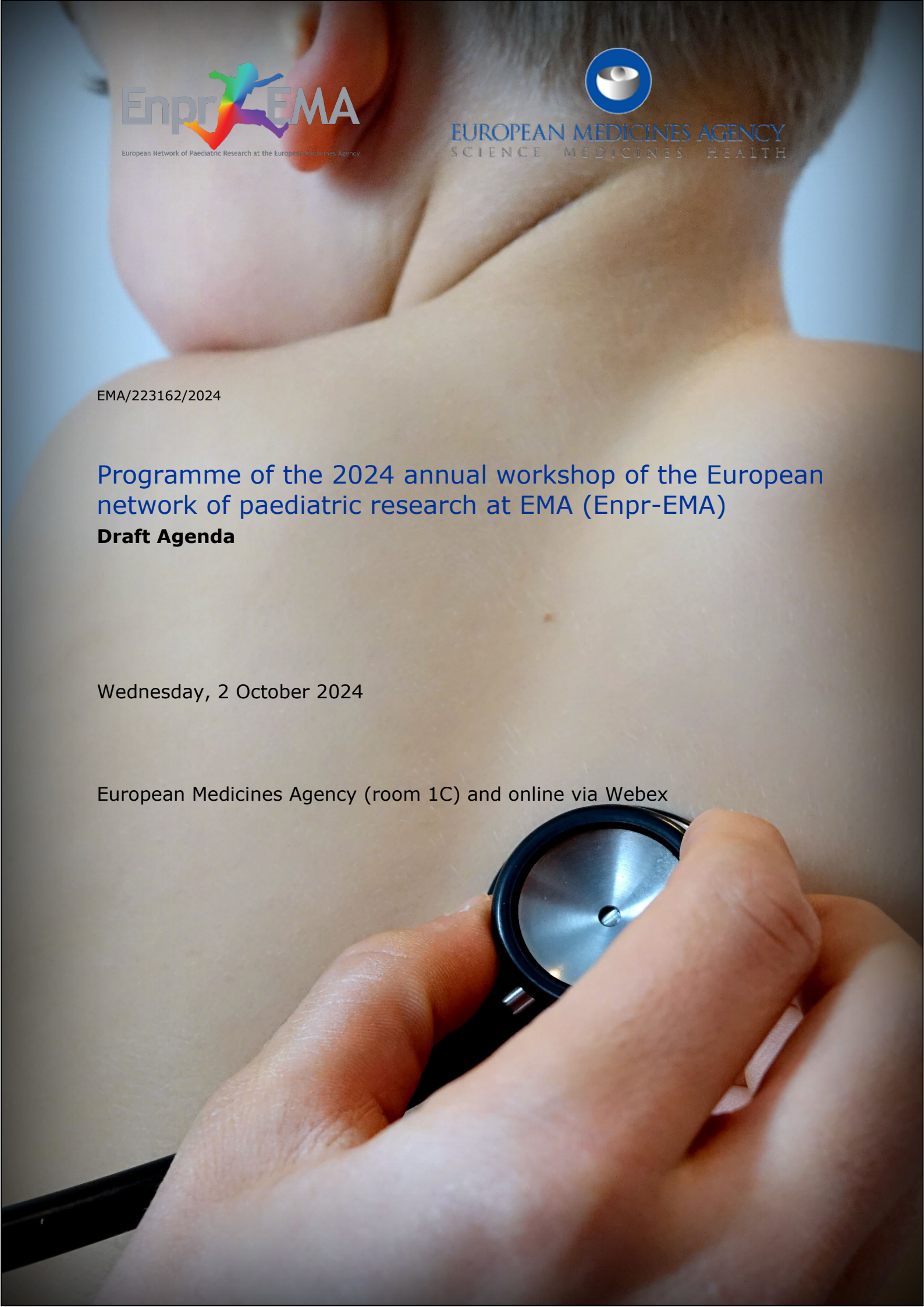

EMA/223162/2024

Programme of the 2024 annual workshop of the European network of paediatric research at EMA (Enpr-EMA)

Draft Agenda

Wednesday, 2 October 2024

European Medicines Agency (room 1C) and online via Webex

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.

Objectives of the event:

This workshop will provide an update on recent activities, regulatory changes, and new infrastructure developments in paediatric research.

Key topics will include advancements in clinical trial regulation, new transparency rules, and the establishment of sustainable research infrastructures. Participants will discuss the implementation and impact of new EU pharmaceutical legislation on paediatric medicines, share experiences with the Clinical Trial Regulation and Information System, and address emerging ethical challenges in paediatric clinical trials. The event will also highlight the significance of Health Technology Assessment (HTA) in paediatrics, focusing on upcoming regulatory changes and the role of real-world data.

Overall, the event aims to foster collaboration and knowledge sharing among researchers, regulators, and industry stakeholders to improve paediatric medicine research.

Programme:

Chairpersons: Pirkko Lepola / Gunter Egger

Time	Topic	Topic lead	Duration
09:00	*Arrival and registration* *(Virtual meeting room open for remote participants)*		
09:30	**Welcome address**	Steffen Thirstrup	10'
	<u>SESSION I – Enpr-EMA activities 2023/24 and new research network infrastructure</u>		
09:40	**Annual report from the coordinating group:** Enpr-EMA activities, achievements and challenges	Pirkko Lepola	15'
09:55	**Update from selected Enpr-EMA working groups:** • Paediatric clinical trial site quality criteria • Cross-border access to paediatric clinical trials	Ricardo Fernandes Pernille Skovby Begonya Nafria	50'

Time	Topic	Topic lead	Duration
10:45	**New research infrastructure** • Conect4children (c4c) stichting From IHI initiative to sustainable paediatric research infrastructure	Mark Turner	15
11:00-11:30	Coffee break		30’
	SESSION II – Clinical Trial Regulation (CTR), Clinical Trial Information System (CTIS) and ethical aspects		
11:30	**Networks’ experience with Clinical Trial Regulation (CTR) & Clinical Trial Information System (CTIS)** Experience from first 2,5 years since CTR implementation, including the concept of low-intervention clinical trials	*Speaker tbc*	20’
11:50	**Progress report on CTR implementation and new CTIS transparency rules (from 18th July 2024)**	Laura Pioppo Francesca Scotti	20’
12:10	**Discussion on CTR and CTIS for paediatrics – Q&A**		20´
12:30	**Emerging ethics assessment challenges in paediatric clinical trials and revision of Declaration of Helsinki - what will change?**	*Speaker tbc*	30’
13:00-14:00	Lunch		60’
	SESSION III – Pharmaceutical legislation & regulatory update		
14:00	**Reform of the EU pharmaceutical legislation and its impact on paediatric medicine development – brief update**	Fabio D’Atri	15’
14:15	**Paediatric investigation plans based on mechanism of action – regulator and academia reflections**	Sabine Scherer Gilles Vassal	30’
14:45	**Update from the Paediatric Committee (PDCO) on recent developments**	*Speaker tbc*	20’
15:05	**The COMBINE project – interface between medicines and medicinal products – pediatric clinical trials perspective**	*Speaker tbc*	20’

Time	Topic	Topic lead	Duration
15:25- 15:55	Coffee break		30’
	SESSION IV – Health Technology Assessment, Real World Data		
15:55	**How can academia build capacity to optimise RWD collection in order to support health technology assessment in paediatrics** Discussion on data requirements for HTA in paediatrics, the role of Real World Data, and how academia can build capacity to support this effort	Kelly Plueschke *Second speaker tbc*	40’
16:35	AOB	All	5’
16:40	Conclusions	Pirkko Lepola	10’
16:50	End of meeting		

List of speakers / chairpersons:

Plaese note that this is only draft list of speakers, and it is not complete.

Surname	Name	Affiliation
D’Atri	*Fabio*	*European Commission (EC), DG SANTE*
Egger	*Gunter*	*Co-chair of Enrpr-EMA, European Medicines Agency*
Fernandes	*Ricardo*	*conect4children National HUB lead and STAND4kids (Portuguese paediatric research network)*
Lepola	*Pirkko*	*Chair of Enpr-EMA, Finpedmed (Finnish paediatric research network)*
Nafria	*Begonya*	*eYPAGnet (European Young Persons Advisory Groups Network)*
Pioppo	*Laura*	*European Medicines Agency*
Plueschke	*Kelly*	*European Medicines Agency*
Scherer	*Sabine*	*Paediatric Committee (PDCO), Federal Institute for Drugs and Medical Devices, Germany (BfArM)*
Scotti	*Francesca*	*European Medicines Agency*
Skovby	*Pernille*	*conect4children National HUB, Denmark*

Surname	Name	Affiliation
Thirstrup	*Steffen*	*Chief Medical Officer, European Medicines Agency*
Turner	*Mark*	*conect4children co-coordinator, University of Liverpool, United Kingdom*
Vassal	*Gilles*	*ITCC (Innovative Therapies for Children with Cancer)*