



EnprEMA & ACT EU workshop on paediatric clinical trials

12 May 2026, 10:00- 17:00 (CET)

Hybrid meeting (Room 2A at the EMA and online)

The objective of the EnprEMA & ACT EU workshop on paediatric clinical trials is to define concrete actions to support the dialogue between regulators, sponsors, academia representatives, and patients' representatives on clinical trials in the paediatric population and to identify practical outputs that facilitate the design, approval, and conduct of paediatric clinical trials.

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Chaired by Ricardo Fernandes (*EnprEMA co-chair and STAND4Kids*) and Gunter Egger (*EnprEMA co-chair and EMA*)

09:45	Joining and technical checks	
10:00	Opening remarks	15 min
	Welcome and introduction Presenters: Ricardo Fernandes (<i>EnprEMA co-chair and STAND4Kids</i>) Gunter Egger (<i>EnprEMA co-chair and EMA</i>) Peter Arlett (<i>EMA</i>)	
10:15	Session 1: Addressing key considerations	60 min
	Understanding challenges in designing fit for purpose paediatric clinical trials – stakeholders’ perspectives Concrete use cases (protocols/applications) exemplifying design challenges in relation to Art 32 of the CTR and the revised Declaration of Helsinki leading to assessment variability across regulatory decision makers – from an academic, investigators, patient and industry perspective. The session will build and expand on the discussions held at the Workshop for assessors from NCAs and MRECs on paediatric clinical trials (July 2025), including scientific and ethical considerations (engagement of investigators and patients in trial planning, justice and equitable access to research and benefit-risk, and alignment between PIPs and CTAs). Moderators: Anette Solli Karlsen (<i>NOMA</i>) and Monique AI (<i>CCMO and MedEthicsEU</i>) Presenters: Jasper van der Lugt (<i>Princess Maxima Centrum</i>), Tim de Smedt (<i>UCB</i>), Maria Sheean (<i>EMA</i>)	
11:15	Coffee break	15 min
11:30	Panel discussion + Q&A	60 min
	Panel and audience discussion Learnings, feedback, and potential solutions to further support development of an assessors’ guidance on interpretation of Art 32, to contribute to an update of the recommendation paper on ethical considerations in clinical trials with minors. Moderators: Anette Solli Karlsen (<i>NOMA</i>) and Monique AI (<i>CCMO and MedEthicsEU</i>) Panellists: Industry view: Angeliki Siapkara (<i>AstraZeneca</i>) Regulatory view (NCA): Domenica Sorletti (<i>AIFA</i>)	

Academic/network view: Pirkko Lepola (*Helsinki University Hospital*)
Academic view: Marek Migdal (*Children's Memorial Health Institute*)
Ethics view: Michel Zwaan (*Princess Maxima Centrum*)
Patient view: Tomasz Grybek (*EURORDIS*)

12:30 **Lunch** **60 min**

13:30 **Session 2: Building the path forward** **90 min**

Enablers for delivering better paediatric clinical trials. Breakout sessions:

1. Paediatric platform trials and academia-industry collaboration

Rapporteur: Pamela Kearns (*University of Birmingham*)
Speakers: Julia Bielecki (*University Children's Hospital Basel*) and Pamela Kearns
Other supporters: Beate Wulff (*Roche*), Angeliki Siapkara, Pirkko Lepola, Leona Knox (*Solving Kids Cancer*)

2. Accelerating patient recruitment and retention, including strengthening patient engagement

Rapporteur: Marek Migdal
Speakers: Cristina de Juan (*UCB*), Franz Schaefer (*Heidelberg University*), Marek Migdal

3. Methodological approaches tailored to paediatric medicine development

Rapporteur: Dominik Karres (*EMA*)
Speakers: Dominik Karres, Juan José Abellán Andrés (*EMA*)

15:00 **Coffee break** **30 min**

15:30 **Feedback from breakout sessions + Q&A** **60 min**

Feedback and main recommendations from each breakout group.
Discussion and Q&A

Moderators: Ricardo Fernandes, Juan José Abellán Andrés
Rapporteurs: Pamela Kearns, Marek Migdal, Dominik Karres

16:30 **Summary of key outcomes and follow-up actions** **15 min**

Identification of priorities and actionable next steps for ACT EU, EnprEMA and other stakeholders.

Moderators: Ricardo Fernandes, Gunter Egger, Laura Pioppo (*EMA*)

16:45 **Closing remarks** **15 min**

Presenters: Ricardo Fernandes and Gunter Egger