EnprEMA & ACT EU workshop on paediatric clinical trials

12 May 2026, 10:00- 17:00 (CET)
Hybrid meeting (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, commercial and non-commercial sponsors, including academia, network 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 *(EnprEMA co-chair and STAND4Kids),* Gunter Egger *(EnprEMA co-chair and EMA) and* Peter Arlett *(EMA)*

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 *(NOMA)* and Monique Al *(CCMO)*

Presenters: TBC

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, and to inform sponsor guidance

Moderators: Anette Solli Karlsen *(NOMA)* and Monique Al *(CCMO)*

Panellists: TBC

12:30	**Lunch**	**60 min**
13:30	**Session 2: Building the path forward**	**60 min**

Enablers for delivering better paediatric clinical trials

Breakout sessions:

1. Paediatric platform trials and academia-industry collaboration
2. Accelerating patient recruitment and retention, including strengthening patient engagement
3. Methodological approaches tailored to paediatric medicine development

Rapporteurs: TBC

14:00	**Coffee break and debrief of the breakout sessions**	**30 min**
15:00	**Feedback from breakout sessions + Q&A**	**60 min**

Feedback and main recommendations from each breakout group

Discussions and Q&A

Moderators: TBC

16:00	**Summary of key outcomes and follow-up actions**	**45 min**

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

Moderators: TBC

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

Presenters: Ricardo Fernandes *(EnprEMA co-chair and STAND4Kids)* Gunter Egger *(EnprEMA co-chair and EMA)*