



# 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.

# EnprEMA & ACT EU workshop on paediatric clinical trials

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

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

09:45	Joining and technical checks	
<b>10:00</b>	<b>Opening remarks</b>	<b>15 min</b>
	<b>Welcome and introduction</b> Presenters: Ricardo Fernandes ( <i>EnprEMA co-chair and STAND4Kids</i> ), Gunter Egger ( <i>EnprEMA co-chair and EMA</i> ) and Peter Arlett ( <i>EMA</i> )	
<b>10:15</b>	<b>Session 1: Addressing key considerations</b>	<b>60 min</b>
	<b>Understanding challenges in designing fit for purpose paediatric clinical trials – stakeholders’ perspectives</b>  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).  <i>Moderators:</i> Anette Solli Karlsen ( <i>NOMA</i> ) and Monique AI ( <i>CCMO and MedEthicsEU</i> )  <i>Presenters:</i> Jasper van der Lugt ( <i>Princess Maxima Centrum</i> ), Tim de Smedt ( <i>UCB</i> ), Maria Sheean ( <i>EMA</i> )	
<b>11:15</b>	<b>Coffee break</b>	<b>15 min</b>
<b>11:30</b>	<b>Panel discussion + Q&amp;A</b>	<b>60 min</b>
	<b>Panel and audience discussion</b> 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.  <i>Moderators:</i> Anette Solli Karlsen ( <i>NOMA</i> ) and Monique AI ( <i>CCMO and MedEthicsEU</i> )	

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**Panellists:** Tomasz Grybek (*EURORDIS*), Angeliki Siapkara (*AstraZeneca*), Pirkko Lepola (*Helsinki University Hospital*), Marek Migdal (*Children's Memorial Health Institute*), Michel Zwaan (*Princess Maxima Centrum*), Domenica Sorleti (*AIFA*)

**12:30 Lunch 60 min**

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

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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**

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

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Feedback and main recommendations from each breakout group.

Discussion and Q&A

**Moderators:** Ricardo Fernandes, Juan José Abellán Andrés

**Rapporteurs:** Pamela Kearns, Mark Turner, Dominik Karres

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

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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**

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Presenters: Ricardo Fernandes and Gunter Egger