



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Minutes - Enpr-EMA Coordinating Group meeting

Date: 17 June 2026; 15:30-16:30 CEST; online

Chairpersons: Ricardo Fernandes / Gunter Egger

Welcome and adoption of agenda

Feedback from EnprEMA & ACT EU workshop on paediatric trials and main outcomes (12 May 2026)

A summary of the [EnprEMA & ACT EU workshop on paediatric trials](#) was provided, outlining the main sessions, breakout discussions, and key outcomes. Appreciation was expressed to members of the Coordinating Group and the Programme Committee for their contributions to the workshop agenda and for their support in various roles, including moderators and speakers.

Workshop overview and participation: The hybrid workshop held on 12 May attracted around 400 participants, including 70 in-person attendees in Amsterdam.

- **Morning plenary session:** The morning focused on Article 32 of the Clinical Trials Regulation, including use cases on the inclusion of adolescents in adult trials and the use of placebo controls, with input from a broad panel of stakeholders.
- **Breakout sessions and key themes:** Afternoon breakout discussions covered platform trials, accelerating recruitment and patient engagement, and innovative methodologies. Key themes included capacity building, decentralised trial elements, and the importance of patient-centred approaches.
- **Outcomes and follow-up actions:** Workshop outcomes are informing the drafting of guidance for clinical trial assessors. A report is being prepared with recommendations for follow-up actions - such as capacity building and training opportunities - and proposals for continued collaboration with ACT EU and other stakeholders on future initiatives.

Patient panels and engagement in clinical trials: Discussions explored how existing paediatric-focused patient panels within EnprEMA networks could be integrated into ACT EU's planned patient-engagement activities. Emphasis was placed on leveraging established structures, ongoing capability-mapping surveys, and avoiding duplication by building on current patient-advocate panels rather than creating new ones.

Coordination with ACT EU initiatives: EnprEMA continues to coordinate closely with ACT EU and the Agency to ensure integration of existing networks and to share relevant updates.

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Discussion of topic proposals for annual meeting (4 & 5 November 2026)

- **Draft agenda and topic collection:** A list of potential topics for the internal and open meetings was presented, outlining topics such as network organisation, platform trials, patient engagement, regulatory updates, and innovative methodologies, with an invitation for feedback on prioritisation.
- **Feedback on agenda scope:** Coordinating group members recommended a focused programme with fewer, more in-depth sessions. Suggestions included consolidating related topics - such as patient engagement and regulatory updates - into combined sessions.
- **Suggestions for additional topics:** Additional proposals included discussions on patient experience data, medical devices, joint clinical assessments, funding models, sharing best practices across networks, and developing training curricula to support young patient engagement.
- **Criteria for topic selection:** Members proposed using criteria such as balancing established and emerging themes and determining which subjects are best suited for in-meeting discussion versus post-meeting follow-up to guide final agenda selection.

Working group updates

Working groups: Cross-border clinical trials, Patient and Public Involvement (PPI) and Young Person's Advisory Groups (YPAG), Paediatric research nurses

Brief updates were provided on the activities of the cross-border access and patient and public involvement working groups, summarising recent publications, ongoing analyses, and timelines for upcoming deliverables.

- **Cross-Border access:** The group has published several papers on the expertise of European clinical trial units and on language as an eligibility criterion. Recommendations to prevent language-based exclusion in paediatric trials are currently being prepared. A public consultation is planned to begin in July, with communication to follow.
- **Patient and Public involvement (PPI):** A questionnaire to map PPI capabilities will be launched by July and remain open until September. Analysis is planned for October, with results to be presented at the EMA patient-engagement meeting and at the November EnprEMA meeting.

Public consultation on clinical trials in public health emergencies:

The group was informed that input from several EnprEMA members for the public consultation on ACT EU [guidance for clinical trials conducted during public health emergencies](#) was collected, consolidated, and submitted as EnprEMA feedback. Review of all consultation responses by ACT EU is currently ongoing.

Enpr-EMA meetings 2026

The following upcoming meeting is planned:

- EnprEMA annual meeting: 4 – 5 November 2026 (hybrid)