Minutes - Enpr-EMA Coordinating Group meeting

Date: 8 April 2026; 15:30-17:00 CEST; online

Chairpersons: Ricardo Fernandes / Gunter Egger

Welcome and adoption of agenda

Update on ACT EU & EnprEMA workshop on paediatric trials (12 May 2026)

Ricardo Fernandes provided a brief update on the upcoming multi-stakeholder EnprEMA & ACT EU workshop on paediatric clinical trials.

Key sessions will be moderated by Monique Al and Annette Solli Karlsen, with Pamela Kearns, Marek Migdal, and Dominik Karres leading breakout sessions on **platform trials, patient recruitment and engagement**, and **innovative trial methodologies**.

From EnprEMA's perspective, this workshop represents an important opportunity to **contribute to ACT EU activities** and to help influence related ongoing and **future initiatives**, while recognising that it is one of several forums addressing these topics.

Enhancing EnprEMA Foundations: Updates and futureproofing

Gunter Egger provided an update on EnprEMA's preparations for the upcoming EU pharmaceutical legislation, with a focus on future-proofing activities. The revised legislation is expected to expand EnprEMA's remit, including a stronger role in discussions on **unmet medical needs** and **development prioritisation**.

This anticipated change will serve as an opportunity to review and update EnprEMA's **governance documentation**, including the mandate of the Coordinating Group and related materials. Most of this work is expected to progress in the second half of the year, after which members will be invited to provide input and feedback.

Work is also underway to strengthen EnprEMA's **web presence**. Subject to approval, a full website redevelopment is planned for next year.

An update was provided on the EnprEMA **member networks database**. A new version was launched earlier this year, and several technical issues - such as search-order functionality - have been identified and are currently being addressed. Networks were reminded to update their self-assessments, as several entries remain outstanding.

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Practical steps for raising awareness of EnprEMA and disseminating outputs

Ricardo Fernandes led a discussion on practical steps to strengthen EnprEMA's visibility and the dissemination of its outputs. Several members shared network practices and suggestions, including audience-adapted communication, newsletters, webinars, and the use of social-media hashtags.

Some members described how they filter and distribute EnprEMA and EMA information within their networks, often through monthly or quarterly **newsletters**. They noted the challenge of **information overload** and duplication across channels.

A **two-tiered communication model** was proposed:

- real-time alerts for time-critical items
- a periodic newsletter for broader updates

Participants agreed this approach could improve impact while reducing email fatigue.

The importance of **audience-specific materials** was emphasised, noting that sponsors, trial sites, networks, children, and parents each have distinct information needs. It was suggested to offer open webinars and workshops to help trial teams better understand regulatory aspects.

It was also proposed that a dedicated **EnprEMA hashtag** be introduced to boost visibility and make related content easier to locate on social media. The hashtag **#EnprEMA** has now been adopted, and its use in social media communications is actively encouraged.

Working group (WG) updates

Isabel Sanchez presented updates from the EnprEMA working groups, highlighting progress on cross-border access to paediatric trials, the role of research nurses, and patient and public involvement (PPI). Ongoing work includes publications, recommendation papers, and stakeholder surveys.

a) ***Cross-border clinical trials***

The Cross-border trials group reviewed available information sources and has already published two papers on cross-border paediatric research, with additional manuscripts currently under review.

- Cross-border access to clinical trials: participation of pediatric patients and language inclusion
- Parents' Perspective on Access to Pediatric Rare Disease Cross-border Clinical Trials in Europe: Experiences of Language Inclusion and Preferences

Analysis of CTIS data is ongoing. EnprEMA recommendations aimed at preventing language-related exclusion in paediatric trials are expected to be published soon.

b) ***Paediatric research nurses***

The Paediatric research nurse group conducted a survey of research nurses and managers to better understand their responsibilities within clinical trials. The findings have been consolidated into a report, which will be submitted for publication on the EnprEMA website.

c) ***Patient and Public Involvement (PPI) and Young Person's Advisory Groups (YPAG)***

The PPI and YPAG working group is mapping current PPI capacity in paediatric research through a stakeholder questionnaire to be launched in June 2026. Results will be analysed over the summer, with follow-up actions planned for October.

ACT EU Guidance on the conduct of clinical trials during public health emergencies - Paediatric input and next steps

Ricardo Fernandes presented the **ACT EU guidance** on the conduct of clinical trials during public health emergencies, which is currently open for public consultation. Network members were encouraged to contribute paediatric-specific comments for inclusion in EnprEMA's consolidated response.

The guidance applies to trials conducted during public health emergencies, including studies not directly related to the emergency itself. It incorporates updates to the legislative framework and reflects lessons learned from the COVID-19 pandemic.

EnprEMA is actively engaging with ACT EU colleagues involved in drafting the guidance and related initiatives to ensure that paediatric considerations are fully represented in ongoing discussions and future revisions.

Template for Network Contributions to PIP Advice: ITCC Proposal

Pamela Kearns presented the **ITCC template for PIP input**, outlining the advisory process, contractual arrangements, and transparency measures. Pirkko Lepola and Fiona Dunlevy provided feedback on current network practices and the potential for wider adoption.

ITCC, an early-phase paediatric oncology network, described its structured approach to industry engagement, centred on a formal advisory service supporting development planning and trial delivery.

Pamela Kearns summarised the advisory workflow: preparatory discussions, contract negotiation, expert selection, confidentiality agreements, and delivery of a structured advisory report.

ITCC operates a fee-for-service model that funds network infrastructure rather than individual expert payments, differing from networks that compensate experts directly.

The advisory report—co-owned by ITCC and the company—includes background, questions addressed, and recommendations. Reports are shared with the ITCC Executive Committee, and a transparency declaration is published on the ITCC website.

The process is governed by a streamlined SOP and focuses on scientific validity, regulatory considerations (PIPs/IPSPs, waivers), and evidence gaps, drawing on preclinical partnerships such as ITCC-P4 and the PedCan Portal.

Input on short- and long-term priorities informing future work and meetings

A discussion was held on EnprEMA's upcoming priorities, focusing on relevant topics for future work, mapping stakeholder activities, and assessing the implications of new legislation. A preliminary list of potential priority areas—developed with input from the programme committee and workshop preparation—was presented, noting that several topics are not yet addressed by current activities.

Participants recommended mapping ongoing work across stakeholders and aligning EnprEMA's priorities with external initiatives, including ACT EU, methodological working groups, and areas linked to new pharmaceutical legislation.

It was noted that academic researchers and industry sponsors may have different needs and priorities, suggesting that future planning should incorporate both perspectives.

The discussion also highlighted the evolving regulatory landscape—particularly the **Biotech Act** and joint clinical assessment—and the importance of planning paediatric trials with future authorisation and reimbursement pathways in mind, especially for small patient populations.

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Update on annual meeting (04/05 November 2026)

An update was provided on preparations for the **2026 annual meeting**, scheduled for 4–5 November. The meeting will take place in a hybrid format, with in-person sessions in Amsterdam and online participation available.

A draft agenda will be shared ahead of the next coordinating group meeting on 17 June. The event will be promoted by the end of summer, and the final programme will be shaped by outcomes from the EnprEMA & ACT EU workshop.

Enpr-EMA meetings 2026

The following upcoming meetings are planned:

- EnprEMA & ACT EU workshop on paediatric clinical trials: 12 May (hybrid)
- CG and Enpr-EMA networks meeting: 17 June 2026 (online)
- EnprEMA annual meeting: 4 – 5 November 2026 (hybrid)