Quality criteria for paediatric clinical trial sites – an Enpr-EMA initiative

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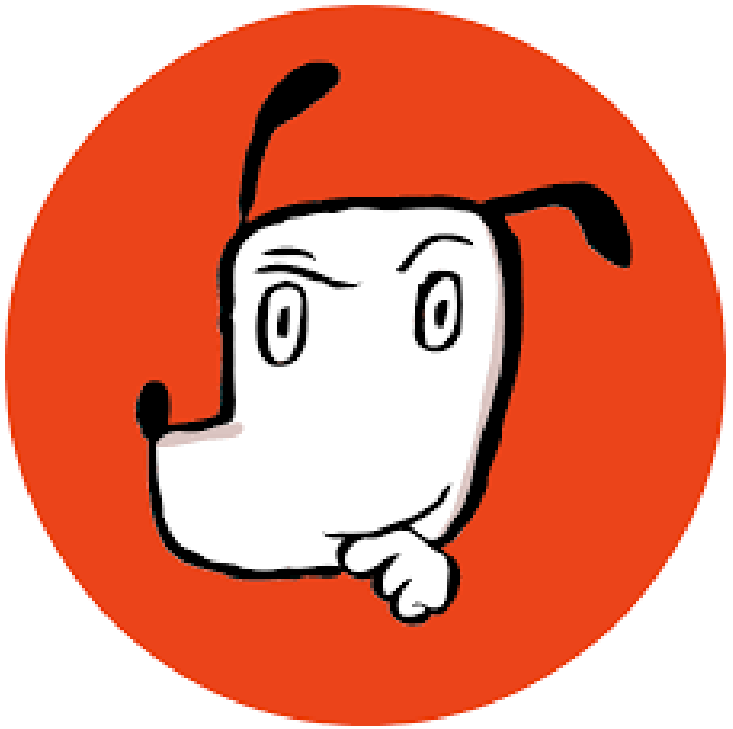
Agenda for today

Status update on Quality criteria document

Next steps



Results of the WG

- A document focusing on 4 questions:
  - What is a paediatric site?
  - Why do we need paediatric site standards?
  - What do we mean by quality of a paediatric site?
  - How to identify a fit-for-purpose paediatric site?

23/07/2024
EMA:

Quality criteria for paediatric clinical trial sites – an Enpr-EMA initiative

Recommendations by the Enpr-EMA working group on criteria for paediatric clinical trial site standards.

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Milestones

- Draft report presented at the 2024 annual meeting of Enpr-EMA (Oct 2024)
- Collection of additional WG feedback and EMA review (Oct/Dec 2024)
- Circulated for comments by Enpr-EMA networks (Jan/Feb 2025)
- Review of collated feedback (Apr/Jun 2025)
- Internal review considering relevant regulatory developments (Jul/Sep 2025)
- Final report ready to publish (Oct 2025)
- Adapted paper ready to submit for publication (Nov 2025)

Collected feedback and review

- Over 100 comments
  - Minor language edits
  - Substantial conceptual suggestions or open-ended questions
  - Illustrations or examples
- Structured documented review and rationale for inclusion
- Extensive review to ensure alignment in terminology and conceptual approach with the revised ICH E6(R3)
- Final version aims to maintain integrity of the text agreed on by the WG

Next (final) steps

- Guidance document on Enpr-EMA website
- Paper submission
- Continued dissemination and awareness
- Alignment with relevant initiatives and other stakeholders