



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA activities, proposals for 2024-2025

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Enpr-EMA workplan for 2023/24 (*revisited for 2024/25*)

Working Groups	Timelines
WG International	Articles submitted Q4 / 2023 -> Publications Q1 / 2024 → <i>articles to be submitted Q4 2024</i>
WG Research Nurses	Survey data analyzed Q4 / 2023 - Q1 / 2024 Publication Q1-Q3 / 2024 → <i>Survey analysis ongoing</i>
WG Cross-border CTs	Data collection Q4 / 2023 Survey data analyzed Q1/ 2024 Guidance to facilitate cross-border clinical trials Q1-Q3 / 2024 → <i>Data collection and analysis ongoing</i>
WG Clinical Trial Site Quality Criteria / Site Standards	Data analyzed Q4 / 2023 – Q1 / 2024 (2 separate -> 1 common) Recommendation paper Q2 / 2024 Publications Q1-Q3 / 2024 → <i>recommendation paper ready for consultation Q3 / 2024</i>
WG on patient and public involvement (PPI)	WG to be created, to raise awareness and foster PPI → <i>WG creation endorsed by CG in June 2024, first meeting in Sept 2024</i>



Potential new activities

Topics proposed by members

Real World Evidence, registries

Trial design challenges in rare diseases and the use of single arm studies with 'RWD' and/or registry data as controls

Note:

There is a 2023 EMA [Reflection paper on establishing efficacy based on single-arm trials submitted in a marketing authorisation application](#)

Decentralised elements in clinical trials, e-consent

How can we implement decentralisation of trials without losing trial quality?

Note:

There is a 2022 ACT EU [Recommendation paper on decentralised elements in clinical trials](#)

Platform trials

Logistical and regulatory challenges regarding these trials

Note:

There is a 2022 ACT EU document on [Complex clinical trials – questions and answers](#)

Clinical trials in emergency settings



Potential new activities (continued)

How can (an) Enpr-EMA working group(s) make an impact regarding these topics?

- Educate and advocate,
- Build on/supplement published guidance,
- Provide recommendations for practical application,
- Consider specificities of paediatric setting,
- Other?