



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA Workplan 2023-2024

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Enpr-EMA workplan for 2023 and 2024 – Working Group activities (continuation)

Working Group	Timelines
WG International	Articles to be submitted Q4 / 2023 -> Publications Q1 / 2024
WG Research Nurses	Survey data analyzed Q4 / 2023 - Q1 / 2024 Publication Q1-Q3 / 2024
WG Patient's Rights	Data collection Q4 / 2023 Survey data analyzed Q1/ 2024 Guidance to facilitate cross-border clinical trials Q1-Q3 / 2024
WG Labelling – Evidence for Off-label products	<i>WG work completed – publication June 2023</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

New topics of interest to members – ideas from meetings

Proposed new topics

Evaluation of Enpr-EMA in changing environment ("Enpr-EMA 2.0")

Decentralized Clinical Trials (DCT) Recommendation - Pediatric elements- *can be combined with Digital Health Technologies (DHT) used in DCT*

Clinical trials in Emergency Settings and Clinical Trials in Acute Diseases

Patient involvement / general awareness -> mapping the existing PPI & YPAG groups

RWE / RWD as a reference data for new product applications (new prospective data / existing patient data) and support EU Darwin project

Form of activity which can be supported by Enpr-EMA

1. "Share & Learn" – short sessions – amongst members – can include external speakers – results updated information sharing based on requested topic - *virtual*
2. Workshop – or Mini-Workshop - more formal event – can include all stakeholders – results common activity or public deliverable – *virtual OR F-2-F*
3. Collaboration with other EU-level initiatives and programs – providing input and contribution from pediatric perspective, via joining various events (organized by other organizations, such as ACT EU or Rare disease programs etc.) - *virtual OR F-2-F*
4. Annual Workshop & Regular meetings – predefined topics and agenda – highlights lectures / presentations – can include all stakeholders – results meeting minutes - *virtual OR F-2-F*
5. Focused information letters via e-mail – can include very specific topic / collected information – short format – collated by Enpr-EMA secretariat or member network
6. Other type of activity (?) – Brochure, News Flash,