



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 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	<i>WG work completed</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 WG (?) Topic...	Activity Q4 / 2023 ->

# New topics of interest to members – ideas from meetings (I)

## Proposed Topics

Digital Health Technologies (DHT) – *can be combined\**

Decentralized Clinical Trials (DCT) - *can be combined\**

Clinical trials in Emergency Settings (CTES)

RWE / RWD as a reference data for new product applications

Patient involvement / general awareness

Other new topics?

Need to select a few  
– no time for all topics!

## 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, .....

## New topics of interest to members – ideas from meetings (II)

Proposed Topics	Addressed by other routes and options / Out of Enpr-EMA remit
CTA & CTIS – more information	<ul style="list-style-type: none"> <li>• Session at 2022 Enpr-EMA Annual Meeting</li> <li>• WG on international collaboration upcoming publications on CTA and EC/IRB</li> <li>• EMA provides continuous training sessions and information sources</li> </ul>
Academic trial protocol design & regulatory steps	<ul style="list-style-type: none"> <li>• ACT EU support for academic sponsors to set up multi-national clinical trials</li> <li>• Enpr-EMA meeting June 2023</li> <li>• More suitable for “hands-on” and practical training / education events</li> </ul>
Health Technology Assessment (HTA)	<ul style="list-style-type: none"> <li>• Raise awareness and promote interactions among stakeholders</li> <li>• Health technology assessment in childhood session and panel discussion, Annual meeting of Enpr-EMA 2022.</li> </ul>
Clinical endpoints and biomarkers	<ul style="list-style-type: none"> <li>• Sharing information and promote discussions</li> <li>• More suitable topic for disease/condition specific forums and societies</li> </ul>
Repurposing a medicinal product for new indications	<ul style="list-style-type: none"> <li>• Out of Enpr-EMA remit</li> </ul>
Training courses or training programs	<ul style="list-style-type: none"> <li>• Not possible for Enpr-EMA to organize due to limitations of agency/staff</li> <li>• Various courses available via networks (e.g. c4c), companies, organizations (e.g. EFGCP)</li> </ul>