Enpr-EMA Annual Report 2023-2024

Pirkko Lepola, Chair, Enpr-EMA

2October2024

Governance & Queries

EUROPEAN MEDICINES AGENCY

Meetings	• **3 meetings**: 4-March 24 (CG), 12-June 24 (CG+Networks), 1, 2-October 24 (Annual Meeting and Workshop)
CG Members	**New members of the Coordinating Group:** ▪ **Thomasz Grybek**, representative of EURODIS and a patient representative in PDCO [observer]
Member Networks	**New networks:** - **POLPEDNET** (Polish Paediatric Clinical Trials Network), new category 2 network member of Enpr-EMA. - **BPCRN** (Belgian Pediatric Clinical Research Network), new category 1 network member of Enpr-EMA. - **EPTRI** (European Paediatric translational research Infrastructure), application received in revision process to become an Enpr-EMA member
Queries from Industry & PDCO & Networks	**Queries from Industry:** 1. Development of ***personalized vaccines for paediatric cancer patients***. – February 2024 **Queries from PDCO**: ***1.*** ***Severe paediatric asthma*** – February 2024. ***2.*** ***Homocysturia*** – June 2024 **Queries from Networks:** 1. Advice on how to seek support for a ***qualification request of a new biomarker***. – February 2024 2. Query on ***recording informed consent and children assent*** for a paediatric clinical trial conducted though the EU region. – November 2023

Enpr-EMA Secretariat information sharing

EUROPEAN MEDICINES AGENCY

Regulatory News

Conferences

Workshops

Initiatives

Webinars

Hearings

Trainings

Reports

Plans

1. Published Guidance on clinical evaluation of orphan medical devices (MDCG 2024-10)
2. Announcement of the establishment of the ACT EU Multistakeholder Platform Advisory Group and its first meeting in July 2024
3. ACT EU multi-stakeholder workshop on Clinical Trial Data Analytics – January 2024.
4. 5th Nordic Conference on Paediatric Medicines (Towards the future of paediatric and orphan clinical trials). – May 2024
5. I-ACT webinar on transforming clinical trials using artificial intelligence – September 2024
6. Annual EFGCP 'Better Medicines for Children' Paediatric Conference 2024 – October 2024
7. FDA funding opportunity to explore the role of digital health technologies in the evaluation of new drugs. – March 2024
8. Call for expressions of interest: representative of the ACT EU multi-stakeholder platform Advisory Group (MSP AG) - October 2023
9. Call for expression of interest to join the Patient and Public Involvement (PPI) and Young Person's Advisory Groups (YPAG) WG – July 2024.
10. Information: ACT EU training event for non-commercial clinical trial sponsors on transitioning trials to the CTR (CTIS) – February 2024
11. Information: outcome report of the ACT EU multistakeholder workshop on methodology guidance – March 2024
12. Information: launch of two new ACT EU Advice pilots to improve clinical trials in Europe – June 2024
13. Information: new ACT EU resources; an interactive map of support initiatives in each member state for non-commercial sponsors and a list of stakeholder and groups within the European medicines regulatory network involved in the clinical trial lifecycle. – July 2024
14. Enpr-EMA promotional slide to the members to be used at any applicable conference to publicize Enpr-EMA across all stakeholders.
15. **Conference: Annual EFGCP Better Medicines for Children 2024 - 22 & 23 October 2024 in Brussels. INFO: https://efgcp.eu** !

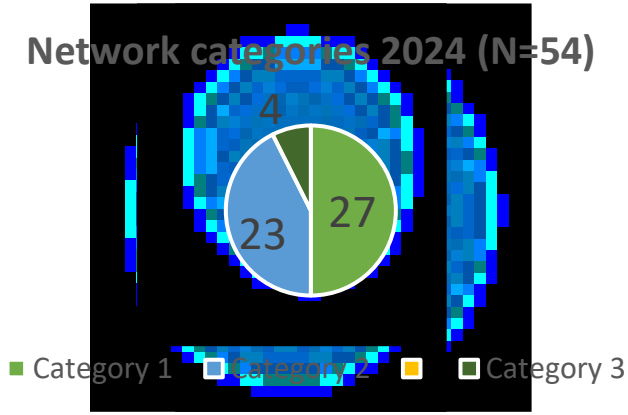
02.10.2024

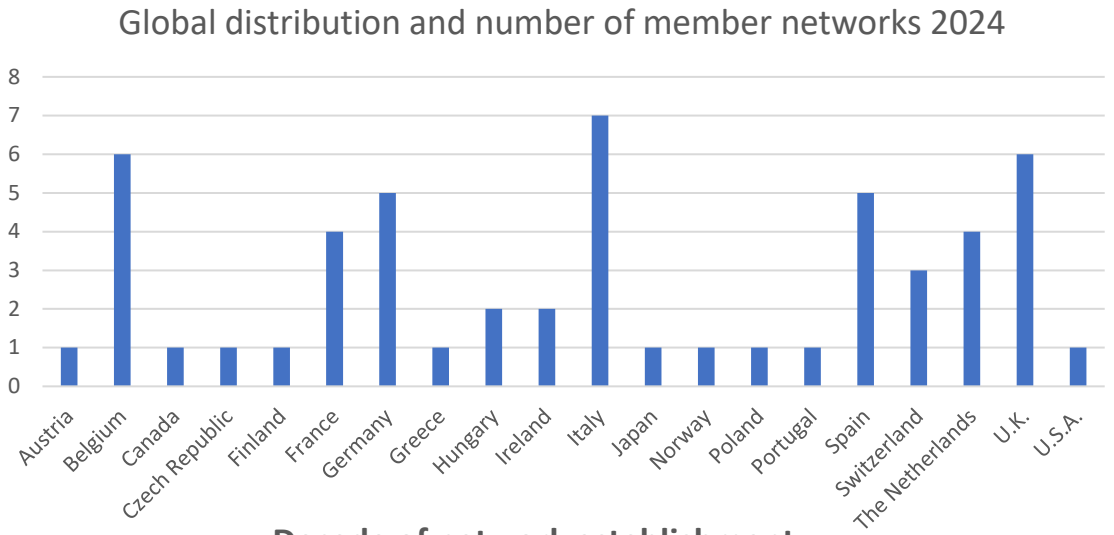
Achievements & Activities

EUROPEAN MEDICINES AGENCY

Activities	1. Enpr-EMA Annual Meeting and Workshop on 9&10 October 2023
Public Consultations & Surveys	1. Public consultation on the revision of the declaration of Helsinki on medical research involving human subjects – June 2024 2. Enpr-EMA recommendations on quality criteria for paediatric clinical trial sites shared for comments before submission for public consultation – September 2024 3. Survey on general knowledge and clinical practice patterns in neonatal kidney injury. – October 2023 4. Survey on cross-border access to paediatric clinical trials. – December 2023 5. Survey of the Employment, Qualifications and Training of Research Nurses working on Paediatric Studies in European Countries – December 2023. 6. Interview request to clinical trial units, principal investigators or trial coordinators on cross-border access to paediatric clinical trials – April 2024 7. European Commission survey on the availability of medical devices and in-vitro diagnostics – September 2024.
WG International	*2 Publications for regulatory (CTA) + Ethical (EC) requirements of 6 jurisdictions (EU, UK, USA, Canada, Japan, Australia) to be submitted for publication for the collection "Paediatric Drug Development" as part of the Regulatory Science Section of the Journal "Frontiers in Medicine" by 6th November 2024.*
WG Research Nurses	*e-Survey for Research Nurses and Research Nurse Managers.*
WG Patient´s Rights	*e-Survey for Clinical Research Units and Parents and interviews to clinical trial units, principal investigators or trial coordinators on cross-border access to paediatric clinical trials.*
WG Clinical Trial Site Quality Criteria	*Enpr-EMA recommendations on quality criteria for paediatric clinical trial sites shared for comments before submission for public consultation*
WG on Patient and Public Involvement	*New working group formed with identified objectives and initiatives.*

Enpr-EMA member networks 2024



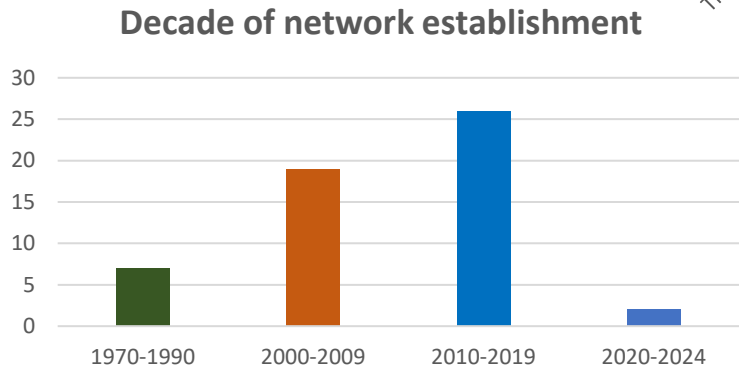


Category 1: Fulfilling all minimum requirements

Category 1 networks are part of the operational centre of Enpr-EMA ***– Coordinating Group,*** *sharing responsibility for the network's long- and short-term strategy.*

Category 2: Not currently fulfilling all minimum requirements

Category 3: Do not run pediatric clinical trials but have other expertise (i.e. methodology, trial design, PPI etc.)



Further development towards future

EUROPEAN MEDICINES AGENCY

1. Renewal of the Coordinating Group to term 2025-2028 (old CG expired)

- (2 PDCO)+18+4 representatives; prioritizing of new members
- Election of new Chair (for networks) in Annual meeting 2025 (current 2 full terms completed)
- After 2026 -> new legislation will formulate the renewal of next term CG composition and possibly the renewal of the CG mandate

2. Selection of new priority activities for Working Groups – 3-4 main topics

- Emphasizing the importance of global collaboration across jurisdictions

3. Increasing awareness of Enpr-EMA and member networks amongst stakeholders

- Enpr-EMA and many individual networks and PPI groups have remained still as unknown resource to larger academic communities, regulators, SMEs and many other industry partners