



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

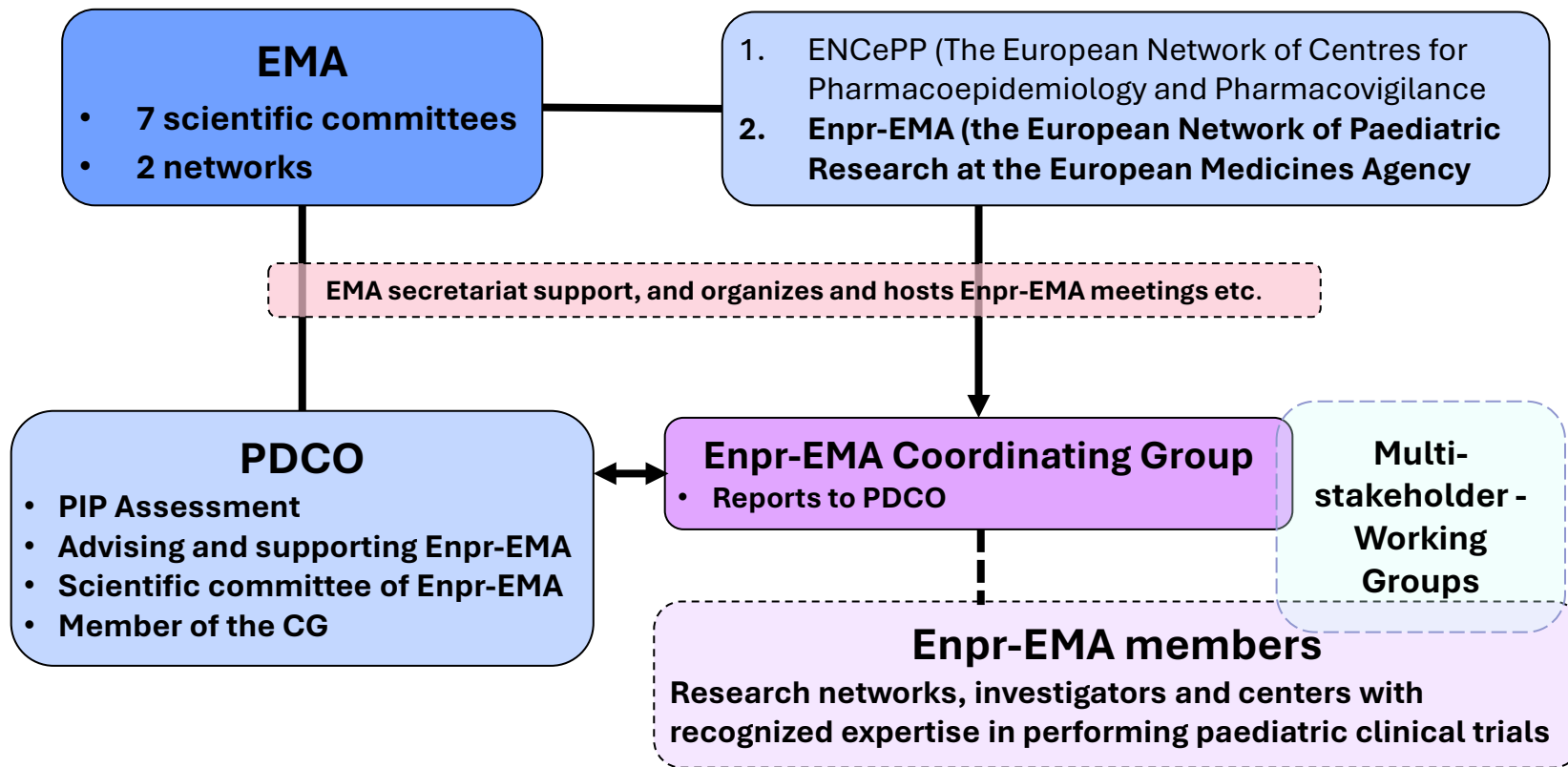
Enpr-EMA Annual Report 2024-2025

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20 November 2025

An agency of the European Union





1. Enpr-EMA Coordinating Group (CG)

- Governing body of Enpr-EMA
- Number of seats 20+4, including networks and key stakeholders
- Contributes to short and long-term strategy of Enpr-EMA
- Discusses and solves operational and scientific issues for the network
- Selects of priority activities – also for Working Groups
- After new EU pharma legislation -> renewal of CG mandate and next CG composition

2. Renewal of the Coordinating Group in March-April 2025

- 11 National and Specialty Networks, 4 Special Activity organizations, 2 PDCO reps., 7 observers (PDCO alternate, industry reps., non-EU networks)
- Election of new Chair (for networks) in Annual meeting 2025

PPI & YPAGs collaboration and consultation

Scientific activities

Reg.Authority collaboration
– Pediatric Cluster / EMA

Scientific advice
– by PDCO and EMA
committees for protocol
development

WHO, ICH etc. collaboration

Pre-clinical design and
collaboration

Medical Devices – EMA
Advice & opinions from
Expert Panels

Administrative level activities

Prepare for new EU legislation application

Collaborate with ACT EU & MedEthics EU

Respond to EU initiatives and consultations

Review of Enpr-EMA Governance documents

Share best practices & knowledge –
methodological, scientific, clinical...

Providing publications, guidance &
recommendations
-> produced by Working Groups

Enhancing International collaboration

Increasing Enpr-EMA visibility

Clinical trial activities

Medicine CTs

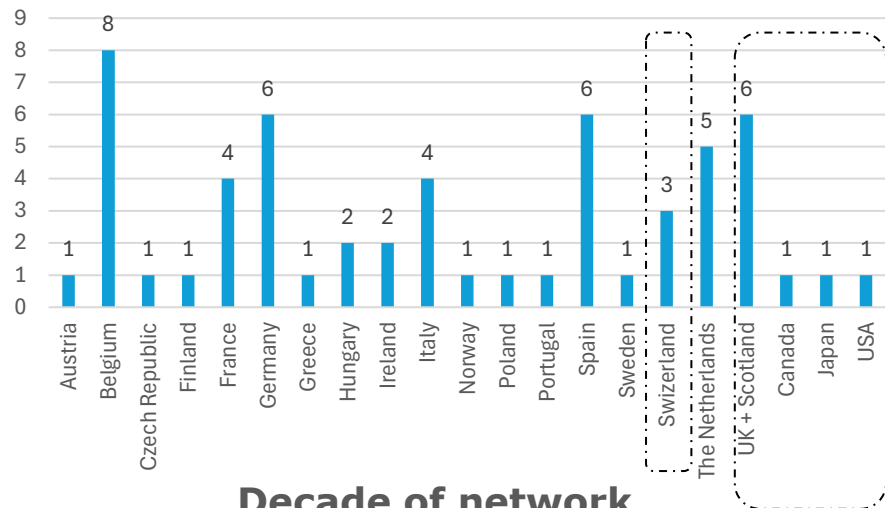
ATMP CTs

Combination
product CTs

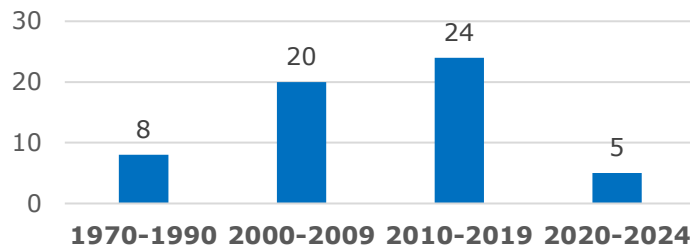
Enpr-EMA members - Individual networks & Experts

Member networks 11-2025 – Total of 57

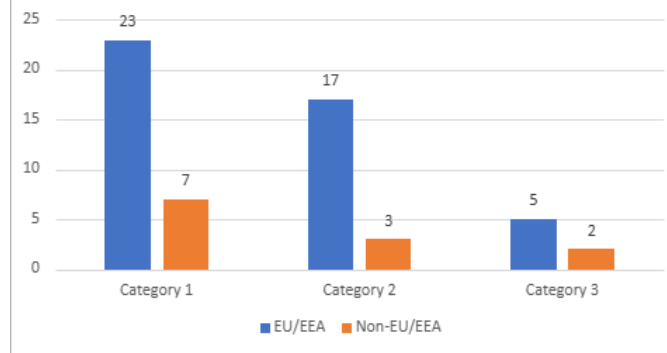
Enpr-EMA member networks 2025



Decade of network establishment



Category 1-3 networks

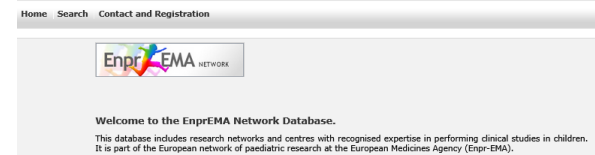


Category 1: Fulfilling all minimum requirements

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.)

<https://enprema.ema.europa.eu/enprema/search.php>



Networks by type 11-2025



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	22	1	6	4	4	3	3	3	2	1	1	7
	multispecialty national clinical	multi-specialty multi-national clinical	Hematology-Oncology/Bonemarrow	Neonatology	Infectious diseases / Vaccinology	Respiratory / Cystic Fibrosis	Gastro-enterology/Hepatology	Rheumatology	Psychiatry	Neurology	Cardiology	Special Expertise
1	BPCRN	c4c	ITCC	GNN	PENTA-ID	ECFS-CTN	PEDDCreN	PRINTO	EUNETHYDIS	TREAT-NMD	AEPC Task Force	TEDDY
2	DCRI		Newcastle-CLLG	INFANT	UKPVG	SPACE	EPLTN	MIWGUC-JIA	ECAPN			ESPD
3	FINPEDMED		I-BFM-SG	REDSAMID	RITIP	RESVinet	PIBDnet	JSWG of PRES				eYPAGnet
4	MICYRN		EORCT-CLG	ESPNIC	APCTN							NETSTAP e.V.
5	NIHR CRN		CEPOETA									FP-MCRN
6	OKIDS		EBMT-PDWP									EAPASnet
7	PEDMED-NL											EPTRI (AISBL)
8	PEDSTART											
9	RECLIP											
10	RIPPS											
11	SCOT-CRN											
12	HELPNET											
13	HUNPEDNET											
14	IPCRN											
15	MCRN-Hung.											
16	NORPEDMED											
17	PCIC Belg.											
18	POLPEDNET											
19	STAND4KIDS											
20	SWISSPEDNET											
21	SwedPedmed											
22	JPEDNET											

Classified as internal/staff & contractors by the European Medicines Agency



Meetings

- **4 meetings:** 6-March-25 (CG), 29-April-2025 (CG new members), 11-June-2025 (CG+Networks), 19, 20-November-25 (Annual Internal Meeting and Annual Open Meeting)



Queries from Industry & PDCO & General Public

- **7 Queries** from Industry, PDCO and General Public



Information sharing

- **Regulatory news, Initiatives, Trainings, Reports, Plans**

- World Children's Day
- Health Technology Assessment
- Good Clinical Practice E6(R3)
- Clinical trial map

- **Conferences, Workshops, Webinars, Hearings**

- WHO webinar "Global Briefing on New Clinical Trials Guidance"
- Workshop on use of external controls for evidence generation
- Webinar on Shaping the future of clinical trials

- **Surveys and Call for interest**

- Use of patient experience data (PED) in medicines regulation
- Use of Artificial Intelligence in the development and evaluation of medicines
- Call for experts regarding a Patient Involvement, paediatrics and rare diseases

- **Public Consultations**

Data strategy, Regulatory Science Research, EMA's horizon scanning, adaptive designs for clinical trials



11 (32%)

Regulatory News

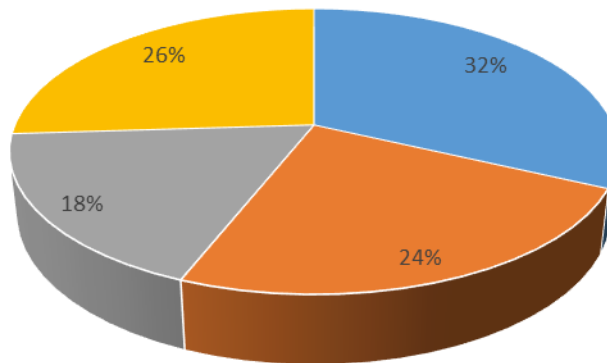
Initiatives

Trainings

Reports

Plans

Information sharing



■ News, reports, initiatives ■ conferences, webinars ■ surveys ■ public consultations

8 (24%)

Conferences

Workshops

Webinars

Hearings

6 (18%)

**Surveys & Call
for interest**

9 (26%)

**Public
Consultations**

Achievements of Working Groups



EUROPEAN MEDICINES AGENCY



WG Research Nurses

Analysis of the role of research nurse managers and research nurses across EU:

- *e-Survey for Research Nurses and Research Nurse Managers on career pathway, development opportunities and employment conditions. Report to be published in 2025.*



WG Patient's Rights

Analysis of potential discrimination on trial participation based on language and country of residence:

- *4 manuscripts submitted to scientific journals*
- *2 manuscripts in working progress (protocol analysis, sponsor's questionnaire)*
- *Guidance on paediatric cross-border clinical trials avoiding language discrimination to undergo public consultation from February to June 2026. Final version September 2026.*



WG Clinical Trial Site Quality Criteria

Define and map site standards for paediatric clinical trials:

- *Enpr-EMA recommendations on quality criteria for paediatric clinical trial sites . Final report to be published on Enpr-EMA website and a paper for publication on a scientific journal by November 2025.*



WG on Patient and Public Involvement

Map and evaluate the capabilities and the needs of PPI groups in paediatric development:

- *Questionnaire on PPI activities across EU. To be launched by November 2025, open until March 2026.*



Thank you!
