



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Further development of Enpr-EMA

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Pirkko Lepola, Chair of Enpr-EMA's Coordinating Group



## **Enpr-EMA Coordinating Group (CG)**

- Governing body of Enpr-EMA
- Discussing and solving operational and scientific issues for the network
- Contributing to short and long-term strategy of Enpr-EMA

## **CG membership**

- Number of seats limited (20 (+4), including networks and key stakeholders)
- Many new networks eligible for CG membership (i.e. Cat. 1)

→ [We are launching a call for expression of interest/application to join \(or to renew membership in\) CG to ensure sufficient renewal and involvement of various individuals](#)

# Enpr-EMA networks 09-2024 by database



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	21	1	6	4	3	3	3	3	2	1	1	6
	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	MIWG-JIA	ECAPN			ESPDDD
3	FINPEDMED		I-BFM-SG	REDSAMID	RITIP	RESVinet	PIBDnet	JSWG of PRES				eYPAGnet
4	MICYRN		EORCT-CLG	ESPNIC								NETSTAP e.V.
5	NIHR CRN		CEPOETA									FP-MCRN
6	OKIDS		EBMT- PDWP									EAPRASnet
7	PEDMED-NL											
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	JPEDNET											

# Current network categories in Enpr-EMA database



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EU / EEA National or Multinational Clinical Network	Category	Country	Previous term(s) in CG 2018-2021, 2021-2024	CG Chair (Cat. 1. network)
OKIDS - Medicines for Children Research Organization Austria	1	Austria	YES	NO
<b>BPCRN - Belgian Pediatric Clinical Research Network</b>	1	Belgium	<b>NO</b>	NO
FINPEDMED - Finnish Investigators Network for Pediatric Medicines	1	Finland	YES	YES
RIPPS - Réseau d'Investigation Pédiatrique des Produits de Santé Service de Pharmacologie Clinique	1	France (1.)	YES	NO
<b>PEDSTART - French national paediatric research network</b>	1	France (2.)	<b>NO</b>	NO
Pedmed-NL - Medicines for Children Research Network Netherlands	1	Netherlands	YES	NO
RECLIP - Spanish Pediatric Clinical Trials Network	1	Spain	YES	NO
HELPNET - Greek national network for pediatric clinical trials	2	Greece		
HunPedNet - Hungarian Primary Care Pediatricians' Clinical Research Network	2	Hungary		
Irish Paediatric Clinical Research Network (IPCRN) National Children's Research Centre (NCRC)	2	Ireland		
Medicines for Children Research Network (MCRN) -Hungary	2	Hungary		
NorPedMed - Medicines for Children Network Norway (Department of Pediatrics, Haukeland University Hospital) Norway	2	Norway		
Pediatric Clinical Investigation Center, PCIC-Belgium	2	Belgium		
POLPEDNET - Polish Network of Clinical Trials in Paediatrics	2	Poland		
STAND4Kids – Supporting Pediatrics Trials in Portugal	2	Portugal		
conect4children - Collaborative Network for European Clinical Trials for Children (c4c)	2	Italy		
<b>Outside EU /EEA (non-eligible for CG)</b>				
NIHR CRN-Children - National Institute for Health Research Clinical Research Network-Children	1	United Kingdom		
ScotCRN - Scottish Children's Research Network	1	United Kingdom, Scotland		
Duke Clinical Research Institute (DCRI)	1	USA		
MICYRN - Maternal Infant Child & Youth Research Network	1	Canada		
SwissPedNet - Swiss Research Network of Clinical Pediatric Hubs	2	Switzerland		
JPedNet - Japan Pediatric Society Drug Development Network	3	Japan		

**CG Composition by CG Mandate (2020) - Current network / membership structure:** National / multinational multispecialty clinical networks: 22 and other specialty networks and expert groups: 32.

Representative category	Seats for representative	Current division (Previous term(s) in CG 2018-2021, 2021-2024*)	
<b>PDCO members</b>	2	<b>2</b>	
<b>Category I networks:</b> <ul style="list-style-type: none"> <li>clinical networks</li> <li>national and multinational, and multispecialty networks</li> <li>all paediatric therapeutic areas and sub-specialties</li> <li>all paediatric age groups</li> <li>special expertise groups</li> </ul>	18	<b>5 National networks*:</b> <ol style="list-style-type: none"> <li>1. FINPEDMED (Chair), Finland</li> <li>2. OKIDS, Austria</li> <li>3. RIPPS, France</li> <li>4. PEDMED-NL, Netherlands</li> <li>5. RECLIP, Spain</li> </ol> <b>7 Sub-specialty / therapeutic area networks*:</b> <ol style="list-style-type: none"> <li>1. ECFS-CTN, Cystic fibrosis</li> <li>2. PENTA, Infectious diseases</li> <li>3. EBMT-PDWP, Oncology</li> <li>4. ITCC, Oncology</li> <li>5. I-BFM-SG, Oncology</li> <li>6. EUNETHYDIS, Psychiatry</li> <li>7. PRINTO, Rheumatology</li> </ol>	<b>6 Special activity / age group networks and organisations with additional expertise*</b> <ol style="list-style-type: none"> <li>1. GNN, Neonatology</li> <li>2. FP-MCRN, Primary care physicians</li> <li>3. NETSTAP, Primary care physicians</li> <li>4. TEDDY, Clinical trial methodology</li> <li>5. PO, Patients, (Primary Immunodeficiency) -&gt; EMA</li> <li>6. EAP, Healthcare professionals</li> </ol> <b>9 Observers*:</b> <ol style="list-style-type: none"> <li>1. MICYRN, Canada</li> <li>2. DCRI, U.S.A.</li> <li>3. EFPIA</li> <li>4. EUCOPE</li> <li>5. EUCROF</li> <li>6. ERNs</li> <li>7. C-Path, U.S.A.</li> <li>8. EURORDIS, Patient representative</li> <li>9. PDCO Extra</li> </ol>
Additional ad hoc Expertise (max. 4)	4	<b>14</b>	<b>6</b>
<b>Total number of seats available</b>	<b>20 (+4)</b>		
<b>Total number of seats with representatives</b>	<b>20</b>		
<b>In addition of the listed representatives, also observers – case-by-case basis</b> (observers have the right to speak but not to vote): <ul style="list-style-type: none"> <li>the European Commission</li> <li>Pharma Industry representatives – can be invited ad hoc basis</li> <li>non-EU/EEA network members fulfilling the recognition criteria</li> </ul>			

## Category I networks per specialty - excluding national /multinational clinical (EU /EEA):

Network	Country	Specialty	CG representation
ECFS-CTN - European Cystic Fibrosis Society - Clinical Trials Network	(Belgium)	Respiratory	YES
PENTA - Paediatric European Network for the Treatment of AIDS and Infectious Diseases	(Italy (1.))	Infections	YES
<b>RITIP - Translational Research Network in Pediatric Infectious Diseases</b>	Spain (1.)	Infections	<b>NO</b>
FP-MCRN - Family Pediatricians Medicines for Children Research Network	Italy (2.)	expert	YES
NETSTAP e.V. - Network of National Paediatricians in Germany	Germany (1.)	expert	YES
TEDDY - European Network of Excellence for Paediatric Research	Italy (3.)	expert	YES
<b>INFANT - Irish Centre for Fetal and Neonatal Translational Research</b>	Ireland	neonatal	<b>NO</b>
GNN - German Neonatal Network	Germany (2.)	neonatal	YES
ITCC - Innovative Therapies for Children with Cancer	France	Hema-Onko	YES
I-BFM-SG - International BFM Study Group	Italy (4.)	Hema-Onko	YES
EBMT PDWP - European Blood and Marrow Transplantation Paediatric Diseases Working Party	Spain (2.)	Hema-Onko	YES
EUNETHYDIS - European Network for Hyperkinetic Disorders	Netherlands	Psychiatry	YES
<b>ECAPN - European Child &amp; Adolescent Psychopharmacology Network</b>	Spain (3.)	Psychiatry	<b>NO</b>
PRINTO - Pediatric Rheumatology International Trials Organisation	(Italy (5.))	Reumatology	YES

Grouping?

Grouping?

- CG membership is **for individuals and for a 3-year term**
- **Last CG renewal in 2018 – 1 term has been bypassed** (2021-2024) without proactive renewal
- Membership can be renewed for more than one term if replacement cannot be nominated and it is not objected by the CG.
- After 2 full terms, a new network representative should be proposed **to ensure sufficient renewal and involvement of various individuals.**
- **Some GC members not involved in the GC meetings**

# What has happened since 2018?

10-2019: New CG Chair + Co-Chair

01-2020: COVID-19 Pandemic -> only virtual CG and networks meetings

02-2020: UK Brexit -> effects on WGs and CG composition -> UK networks excluded

01-2021: **Membership Category simplification -> from 4 to 3 categories**

06-2021: The CTIS + CTR development -> applied 01-2022 -> **IT fixing ongoing**

02-2023: **The Enpr-EMA Membership Application Form discussion and consultation by members ->**

03-2024: **Revision of Enpr-EMA Membership Application Form -> publication delay on Enpr-EMA website by EMA due to other more critical IT-activities**



- **Current Category 1 networks** – any Cat 1. network can apply
- **Current Category 2 networks -> can apply to be Category 1 network (updated self-assessment)**-> eligible to apply for CG membership
- **Networks may have to group themselves** to be represented (“special interest groups”) once the maximum number as per composition criteria of the CG has been reached.
- **Special interest groups should identify a representative** best able to represent their views

1. **Category 1 network**
2. **Located in EU or EEA**
3. **Prioritisation of applicants who have never been in CG / new Cat. 1 networks** (Sufficient renewal and involvement of various individuals while ensuring continuity)

And,

**If there are more than the agreed numbers per composition criteria and no proposal for grouping can be obtained**, appointment to the CG will be made by the Chair and two EMA staff representatives using the following criteria:

4. **Balance of skills and expertise within the respective category**
5. **Level of participation in Enpr-EMA over the past year**
6. **National and/or regional balance of the CG**

## Role and tasks of CG members

- Identification of priority actions and tasks of Enpr-EMA
- Approval and oversight of Enpr-EMA's work and activities
- Adjudicator in case of complaints in the context of Enpr-EMA
- Review of Enpr-EMA's working model and working group structure
- Championing and promoting Enpr-EMA

## Of note:

- 3 CG meetings per year
- Enpr-EMA CG chair to be elected by and from amongst its members (at annual meeting 2025)

→ [We are relaunching a call for expression of interest/application to join CG](#)

## Expression of interest/application for CG membership

- Representatives of Category 1 member networks
- Send expression of interest/application to Enpr-EMA secretariat (enprema@ema.europa.eu) **by 30th November 2024**
  - Brief resumé (cv), including outline of your motivation ( $\leq 400$  words)
  - Updated self-assessment form, if latest one was submitted in 2022 or before
- Enpr-EMA Sec will assess applications in December/January
- Announcement of new CG in Feb 2025 in writing, first meeting in Mar 2025
- 3-year term (2025-2028, unless earlier renewal due to new legislation)

Note: A separate call for patient and healthcare professionals and industry representatives, as well as PDCO representatives, as CG members & observers, will be launched by EMA's stakeholder department and committee secretariat.



## **Thank you in advance for your applications!**

- Enpr-EMA Secretariat will send out e-mail with detailed instructions.
- We look forward to continuing the great collaboration with a renewed CG.