

BECOMING A EUROPEAN REFERENCE NETWORK MEMBER

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EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



Preamble

Medical teams (Health Care Providers – HCPs) can be attributed the status of ERN member exclusively **following Calls launched by the European Commission**. The decision is taken by a Board of Members States following assessment of the HCP by an independent Executive Agency. The Coordinators of the ERNs do not have authority to nominate an HCP as member of an ERN.

Contribution to ERN missions and activities labelled by medical teams are done on a **voluntary basis**, the HCPs becoming members of an ERN are **not** funded by the Commission.

The European Reference Network for Rare and Complex epilepsies **ERN EpiCARE** is an established network composed of 38 full member HCPs (medical teams and/or consortia) in 16 EU countries and 12 affiliated members in 8 EU countries.

Full members: 7 in Italy; 6 in France; 4 in Germany; 3 in Spain and Portugal; 2 in Austria; Belgium; Czech Republic; Finland; 1 in Hungary; The Netherlands; Poland; Romania; Slovenia and Sweden.

*Affiliated members*¹: 2 in Croatia; Denmark; Estonia; Lithuania; 1 in Cyprus; Latvia; Luxembourg; and Malta.

ERNs Full membership implies:

- A recognized level of expertise in a large spectrum of rare and complex diseases requiring highly specialized healthcare;
- Availability of medical staff to regularly provide, *on a voluntary basis*, expertise to other centers at EU level (cross-border advice on the most appropriate diagnosis and the best treatment);
- Contribution to advances in the field of rare diseases; Collaborative research; Generation and sharing of knowledge; Publication in peer reviewed scientific journals;
- Regular contribution to patient association activities;
- Regular contribution to centralized Registries for rare diseases

The HCPs, members, or affiliated partners of an ERN, are regularly, and without previous notification, **subject to audits from independent agencies** missioned by the European Commission.

Reported indicators of activity are evaluated for accuracy and compliance. Responsibility for non-compliance lies with each HCP.

An audit may conclude that the label of ERN should be withdrawn.

ERN EpiCARE membership terms of reference

Full members of the ERN EpiCARE must fulfil several pre-established general criteria and specific requirements, summarized below.

General ERN criteria also applied by the ERN EpiCARE

1. HCPs applying for full membership are expected to actively contribute to the missions of the ERN EpiCARE. These include:
 - Availability of the medical staff to regularly provide expertise at CPMS Case discussions
 - Leadership and/or contribution to research projects and/or peer reviewed publications
 - Active contribution to the ERN EpiCARE Working Packages
 - Contribution to educational activities of the ERN EpiCARE network (production of educational webinars; organization of or lecturing at scientific meetings on rare & complex epilepsies; etc.)
 - Regular completing the EpiCARE Registry (see set of ERN indicators)
 - A structured transition children-adult program

¹ According to current EU legislation a country cannot have both full and affiliated members. When in one country an affiliated member is labelled full member, other affiliated centres lose the status of ERN affiliation.

2. **National endorsement**, with HCP recognition as a centre of expertise for rare/complex epilepsies, being able to **cover the full range of complex/rare epilepsies** (integrated diagnostic approach).

Before being diagnosed as suffering from a rare or complex epilepsy, all patients present with epileptic seizures. Patient chances for early diagnosis and optimal treatment increase when Level 3 and 4 National Reference centres can offer state-of-the-art expertise and access **to all available diagnostic tools and therapeutic options**. However, medical teams' members of EpiCARE, do not necessarily have to offer in one site the full spectrum of diagnostic and treatment facilities for all domains of clinical epileptology. ERN EpiCARE supports the **development of Consortia** (regional or national), involving proximity centres of competence covering missing areas of expertise.

The prerequisites for supporting Consortium memberships are established regular meetings between members of the different medical teams; collaborative research projects; collaborative publications and a signed agreement between HCP administrations.

3. Establishing national networks of care is strongly recommended. Consequently, the ERN EpiCARE complies with the principle for a **maximum nr. of full member HCPs per country** on a population basis: $\leq 10 \times 10^6 = 1$ centre, ≥ 10 and $\leq 20 \times 10^6 = 2$ centres etc. However, geographical (distance between cities/centres) and language issues are also taken under consideration.
4. For each HCP and/or Consortium are assessed:
 - the **minimum number of patients** (see below) regularly followed and/or new, in each domain of care offered.
 - the **availability of and expertise of medical and nursing staff, screening tests, diagnostic tools, therapies, facilities** (see below) is required.
5. In case of paediatric epilepsy surgery: **HCP complies with ILAE recommendations** for Level I or II epilepsy surgery centres (Gaillard et al. 2020). For very rare and complex surgical procedures, such as hemispherotomy, hypothalamic hamartomas, tuberous sclerosis with multiple tubers, indications for callosotomy etc. a long-term experience needs to be demonstrated.
6. HCP activities have had **demonstrable societal and/or scientific impact** (e.g.: publications, guidelines, dissertations, teaching, societal recognition [media coverage, prizes], editorial boards, scientific committees, policymaking committees etc.)

Specific requirements applied by the ERN EpiCARE

Experience - within one centre or an already established consortium of centres - in ALL main thematic groups of epilepsies: genetic, structural, infectious, immune, surgically treatable, syndromic, metabolic, neonatal seizures, status epilepticus

Key diagnostic tests available:

- **For all epilepsies:** regular access to 24h VEEG (3-4 days or more if needed) monitoring, 3T MRI (+anaesthesia), neuropsychology and/or neurodevelopment clinic; genetic counselling.
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- **For surgical epilepsies:** high-resolution MRI, high-field (at least 3T) MRI, MRI postprocessing, PET, SPECT, MEG/CSI, neuropathology, invasive monitoring, resective surgery (see criteria for level I or II centres in children).
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- **For other epilepsies:** microbiology, NGS, specialist neurobiochemistry and immunology lab, neonatal cVEEG

Minimum thresholds that HCPs/Consortia meet to contain competence and expertise:

Main thematic groups	Patients followed / year	Approximate N° of new patients/ year	Procedures/year
Genetic epilepsies	150	40	
Structural epilepsies	150	40	
Infectious epilepsies	25	5	
Immune epilepsies	25	5	
Surgically treatable epilepsies	50	45	<ul style="list-style-type: none"> • Minimum 20 resections (excluding VNS); • Minimum 10 invasive monitoring procedures
Syndromic epilepsies other	50	25	
Metabolic epilepsies	25	5	
Neonatal seizures	10	10	
Status epilepticus	10	10	
Annual activity General			200 prolonged monitoring VEEGs; 200 MRIs

Key treatments: registries; personalized treatment; experience and facilities to contribute to clinical trials; epilepsy surgery program; ketogenic diet program; minimum 2x/month multidisciplinary surgical discussions, dietary intervention, immunomodulatory treatment, chemotherapy, plasma exchange, clinical neonatal expertise, novel agents in refractory status

Staff: adult and/or paediatric epileptologist/neurophysiologists, neonatologist, geneticist, neuroradiologist with expertise in epilepsy, neuropsychologist, nuclear med physician, epilepsy neurosurgeon, neuropsychiatrist, ophthalmologist, biochemist, dietician, metabolic clinician. Established transition programs for adolescents.

EpiCARE HCP performance / monitoring indicators

Each HCP, full member, or affiliated partner of the ERN EpiCARE, regularly reports to the Executive Committee all what is requested for yearly reporting to HaDEA and DG SANTE

Generic indicators (for each ERN EpiCARE member)

1. Number of new patients (within EpiCARE scope) referred to HCP
2. Number of formal educational activities (i.e. those accruing higher educational credits) organized by HC
3. Number of clinical trials or observational prospective studies in which the HCP participates or leads
4. Number of accepted peer-reviewed publications in scientific journals (within EpiCARE scope)
5. Number of guidelines the HCP has produced/participated in
6. Number of congresses/meetings at which EpiCARE activities/results were presented
7. Level of patient satisfaction: standardized score forms; provide number and average score
8. HCP compliance to clinical guidelines

Additional EpiCARE-specific indicators

1. Number of patients diagnosed/treated per domain
2. Proportion of patients with rare/complex epilepsy receiving a specific aetiological diagnosis (not only in terms of ILAE aetiology category)
3. Average time between multidisciplinary team decision to perform epilepsy surgery and the actual procedure (surgical waiting-list)
4. Report on annual collaborations with patient associations (participation at patient meetings; contribution to Medical Boards; etc.)

The full version of the ERN EpiCARE Terms of Reference (ToR) and Terms of Engagement (ToE) can be found [here](#)

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