



European
Reference
Network



EpiCARE

ERN EpiCARE TERMS OF ENGAGEMENT V2

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EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

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GLOSSARY & DEFINITIONS

- *European Reference Network (ERN)*: a network for rare or low prevalence and complex disease(s), condition(s) or highly specialised intervention(s) as regulated by article 12 of the Directive 2011/24/EU on patients' rights in cross-border healthcare.
- *EpiCARE Network*: The European Reference Network on Rare and Complex Epilepsies, ERN EpiCARE
- *Member States*: countries in which the relevant legislation of the European Union applies (EU Member States and EEA countries).
- *Board of Member States (BoMS)*: the formal body in charge of the approval and termination of the ERNs and memberships as provided in the Commission Implementing Decision 2014/287/EU.
- *Health Care Provider (HCP)*: While legally speaking HCP refers to any institution or professional that provides healthcare services, in the present document the term is used to indicate institutions (hospitals in most of the cases).
- *Clinical Centre (CC)*. An entity that corresponds to the association of one or more multidisciplinary medical units/departments/services of one HCP, accredited membership to EpiCARE for their expertise in rare and complex epilepsies.
- *Consortium Clinical Centre (CCC)*. A virtual entity that corresponds to the association of units/departments/services of more than one HCP (Hospitals) awarded with a membership as a consortium to EpiCARE for their collaborative expertise in rare and complex epilepsies.
- *Full Member*: HCP complying with the criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) that has been awarded, following an EU call, with the **full membership** of a multidisciplinary team of health professionals (CC or CCC), specialized in rare and complex epilepsies and that undersigned the Network Application Form.
- *Affiliated Partner (AP)*: HCP that has been awarded, following an EU call, with affiliated partnership of a multidisciplinary team of health professionals (CC or CCC), specialized in rare and complex epilepsies. The Board of Member States endorsed a statement on the definitions and types of Affiliated Partners.
- *Supporting Partner (SP)*: The term is used when referring to Scientific Societies, clinical teams and/or individual medical experts or researchers, working for HCPs **not** members of the network, accredited by the Executive Committee because of their scientific expertise in specific disease areas covered by the ERN EpiCARE and their active contribution to the network missions.
- *Board of Network Members (BoNM)*: the coordination body for the Network responsible for its governance, as foreseen in the Commission Delegated Decision 2014/286/EU (Annex I).
- *Executive Committee (ExCo)*: the operational decision-making body of the ERN EpiCARE (historically for EpiCARE also called "Steering Committee").
- *Annual Convention*: The annual General Assembly of ERN EpiCARE, open to all health professionals involved with EpiCARE activities and to an ePAG delegation.
- *Coordinator of the ERN*: the medical representative appointed by the ExCo and the BoNM to coordinate all activities of the ERN. The Institution (HCP) employing the coordinator acts as the Coordinating (COO) legal entity of the Network.
- *Working Group (WG)*: Groups of individual health professionals, working for Members, Affiliated or Supporting Partners of the ERN and patient advocates. WGs are the core bodies that develop, define, and deliver the medical and scientific objectives of EpiCARE. Special Interest Groups (**SIGs**) can be created, in response to specific needs, within a thematic WG, at the discretion of the ExCo and/or the WG leaders.
- *Management Team (MT)*: administrative staff financed by the coordination budget and employed by the Network for their expertise in specific domains of project management (such as administration, finances, communication, education, data management, research).



INTRODUCTORY NOTE:

The updated version of the present document is directly related to the “2024 Update_Terms of Reference_EpiCARE”, endorsed by the EpiCARE Executive Committee the day of October 9th, 2024.

It also incorporates several key performance indicators decided by the European Commission and used to assess the fulfilment of grant obligations, both by the ERN as a network and/or to each of its awarded full members or affiliated partners, adapted to the specificities and policy of the ERN EpiCARE.

The ERN EpiCARE is a **network of medical teams (CC or CCC)** belonging to one or more distinct HCPs (Institutions/Hospitals) with global expertise in all domains related to care and research for rare and complex epilepsies.

Criteria for membership application, following calls released by the European Commission, are defined, and whenever needed updated, by the EpiCARE ExCo. They become publicly available on the website of the ERN.

Representative of a CC or CCC at the EpiCARE Board of Network Members (BoNM)

Each medical team (CC) or Consortium (CCC), Member or Affiliated Partner, **is represented at the BoNM by one** health care professional with established expertise in the field of rare and/or complex epilepsies.

He/She:

- Represents the medical team and paramedics at all activities and missions of the ERN EpiCARE and is responsible for the dissemination of all information to the individual members of the local staff.
- Establishes a regular liaison with the Coordinator and the Management team.
- Is expected to regularly encourage individual members of the medical and paramedics staff to directly contribute to WGs and missions of ERN EpiCARE and ePAG activities.
- Is expected to regularly encourage local patient associations and patient advocates to liaise with ERN EpiCARE ePAG group.
- Is expected to make sure that all scientific publications produced by the CC mention the ERN EpiCARE affiliation (see below).
- Is expected to communicate to the Management Team the PDF of all scientific publications of the medical team, for announcement on the EpiCARE website. Free access will be given for “Open Access” publications only.

To facilitate dissemination of information and benefit from their expertise, it is the policy of the ERN EpiCARE to invite Affiliated Partners to attend the Board of Network Members calls and, when financially possible, the Annual Convention.

Full Members and Affiliated Partners of EpiCARE commit to be actively involved in:

EpiCARE Registry (EpiREG): Include all consenting patients with rare and complex epilepsies followed by the team into the EpiCARE Registry in a timely manner.

EpiREG uses a dedicated platform, REDCap, and a pseudonymization tool (SPIDER) to protect patient confidentiality and comply with GDPR regulations.

- Enrichment of the EpiCARE Registry is a major indicator of activity for both Full Members and Affiliated Partners, regularly reported to DG SANTE Europe. As per the Grant Agreement, a regular contribution to the EpiCARE Registry is mandatory. Implementation of a local version of the EpiREG template is an obligation of the HCP/Institution hosting a medical team, member or AP of ERN EpiCARE.
- When, for any legal reasons (national or local), **sharing** of the registry data is not possible, the HCP has the obligation to implement the Common Data Elements registry template developed by the ERN EpiCARE at a local level.

Clinical Patient Management System platform and Case Discussions: Health Professionals (HPs), working for an ERN EpiCARE CC or CCC have the obligation to contribute to case discussions and share their expertise at the request of other HCPs members or partners of the ERN and, to upload the their cases to the Clinical Patient Management System (CPMS),.

- Each medical team, Full Member or Affiliated Partner, is expected to **present a minimum of one case clinical case per year** at the case discussions organized by the network. Medical teams are also requested to **attend and contribute to at least three sessions annually**.
- Full members of EpiCARE have the obligation to **chair or co-chair at least one case discussion** (surgical or non-surgical) **in each period of 2 years**. With the understanding that if no cases are to be brought for discussion by other CCs, the chairing centre must provide a case for discussion, whenever possible with an educational value (including solved cases of a rare or complex epilepsy)
- Affiliated Partners can chair Case Discussion sessions on a voluntary basis.
- Contribution to the Case Discussions at any level is subject to monitoring and evaluation (**Mandatory Performance Indicator**)
- It is mandatory that whoever presents a case for discussion, independently of the platform used, also uploads the case into CPMS and ensures that there is a record of the case discussion and the outcome.
- Case Discussions are considered **a major educational tool**. It is therefore expected from the leaders of the medical teams of EpiCARE to encourage active participation from all members of the staff, particularly of early-career epileptologists.

Contribution to WGs: The EpiCARE network is financed by the European Commission through the ERN health program. To obtain financing for its coordination activities and core missions the network and its members are expected to comply with the work program that was submitted to and validated by the European Commission. **WGs are the core bodies that define and implement the medical and scientific goals of EpiCARE, as described in the Action Plan.**

- The above implies regular participation of members of the staff to the WGs of the network.
- Consequently, it is required that,
 - for **FULL** members **at least 2 Health Providers** and
 - for **AFFILIATED** Partners **at least one Health Provider**

regularly attend and offer their expertise to at least one WG (and/or Task Force and/or Special Interest Group) of their choice and in accordance with their respective expertise.

Contribution to WGs is subject to monitoring and evaluation (**Mandatory Performance Indicator**). Absence of an active member, registered to voluntarily support the work of a WG, from 3 WG meetings in a row, leads to a discussion with the CC leader, with the request of suggesting a replacement.

Contribution to Research & Publications:

Leading a clinical research project and/or regular contribution to projects related to rare and complex epilepsies are major expectations from both full members and affiliated partners, awarded as European Reference Centres. Contribution to fostering research is one of the indicators of activity, subject to monitoring and evaluation (**Mandatory Performance Indicator**).

During a 5-year's period, EpiCARE medical teams (CCs) are requested to:

- participate in a **minimum of one** research project (other than sponsored clinical trials), preferably a project endorsed by the EpiCARE network.
- have published, based on their own data, at least **two scientific publications** (**one** for Affiliated Partners) in peer reviewed journals, and contributed to at least 2 other publications.

Open Access publications, supported by the Institution/Hospital, are to be privileged.

Mentioning of ERN EpiCARE affiliation

All members, independently of their status, have the obligation to **mention in all publications** related to rare and complex epilepsies, "Member of the ERN EpiCARE". It is expected to mention the above as part of the

affiliation. In case, due to local regulations or journal's policy, this is not possible the statement must appear in the Acknowledgments part.

For publications produced as part of a collaborative project of the Network (involving several EpiCARE members) the leading author is requested to also mention in the acknowledgments "This work is generated within the European Reference Network on Rare and Complex Epilepsies (EpiCARE), funded by the European Commission".

For projects, Guidelines, trials or publications having received financial and/or managerial support from EpiCARE, the leading author is requested to acknowledge it by including the statement:

"This study/project/publication/Guidelines/survey has been supported by the European Reference Network on Rare and Complex Epilepsies (EpiCARE), funded by the European Union. Unless explicitly stated, the support does not constitute endorsement of the contents by the ERN EpiCARE, which reflects the views only of the authors".

It is under the responsibility of the representative of the medical team leading a publication to transmit to the MT the PubMed link and a PDF of the publication. Open Access publications are to be privileged and will be made available on the website and promoted through social media.

Collaboration with patient associations:

All members of EpiCARE are engaged to develop close and regular collaborations with patient groups and associations at National and EU levels (**Mandatory Performance Indicator**), to support their actions and to contribute to the dissemination of all relevant information.

- The ePAG leadership and the EpiCARE Management team must be regularly updated on ongoing and newly established collaborations.
- Collaboration with ePAG and support to patient associations are subject to monitoring and evaluation.

Use of the EpiCARE logo and Communications issues

The respect of the Graphic charter of the ERN is mandatory, as well as the presence of the EpiCARE logo together with the EU logo with the mention "funded by the European Union" when EpiCARE is mentioned.

When mentioning EpiCARE on social media, members are expected to tag the corresponding profile: "Epicare ERN" on **Facebook**; @EpiCARE_ERN on **Twitter**; and EpiCARE - European Reference Network for Rare and Complex Epilepsies on **LinkedIn**.

The Communication Manager should be notified when EpiCARE is mentioned in a publication, during a workshop, congress, or conference. Active participation to the global communication of EpiCARE is part of the responsibilities of all members: retweeting or sharing posts on social media, linking EpiCARE's website on your own, disseminating information is strongly recommended.

The website (<https://epi-care.eu>) is the main tool of EpiCARE communication and information should be regularly updated. All health professionals working for EpiCARE medical teams and ePAG representatives are expected to communicate to the Management Team all relevant information

NB: Both the HCPs/Institution hosting an ERN and the Clinical Teams members of an ERN, are regularly subject to audits from independent agencies missioned by the European Commission.

The above-mentioned indicators of activity are evaluated for accuracy and compliance.

Responsibility for non-compliance lies with each Clinical Centre and HCP.

An audit may conclude that the ERN membership should be withdrawn by the Board of Member States.

LIST of PERFORMANCE MEASURES, subject to annual monitoring

TASK-TOPIC	Full Members	Affiliated Partners
EpiCARE Registry (Annual update – local/central)	Mandatory	Mandatory
CPMS (Cases submitted and closed)	1 case/year	1 case/year
Case Discussions - Participation	Contribution to minimum 3 sessions/year	Contribution to minimum 3 sessions/year
Case Discussions -Chair or Co-Chair	1 Case/ 2 years period	Voluntary
Participation in Core WGs	Minimum 2 Members /Medical Team	Minimum 1 Member /Medical Team
Participation in Research Projects	1 Project / 5 years period	1 Project / 5 years period
Lead or senior author of Scientific Publications in Peer Reviewed Journals	2 Publications / 5 years period	1 Publication / 5 years period
Contributions to Scientific Publications in Peer Reviewed Journals	2 Contributions to Publications / 5 years period	2 Contributions to Publications / 5 years period
Collaboration Patient Associations at National and EU levels (ePAG) – (annual survey data collection)	Mandatory	Mandatory
Active Participation in Communication (HCP website and information of health providers); Representation at the Annual Convention	Mandatory	Mandatory
Speaking at an EpiCARE webinar or training sessions	Voluntary	Voluntary
Response to surveys on medical practices; Contribution in authoring/translating Patient Leaflets; Contribution to Guidelines, Recommendations etc.	Mandatory	Mandatory

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