

Glossary and 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.
- *Board of Member States*: 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.
- *Member States*: countries in which the relevant legislation of the European Union applies (EU Member States and EEA countries).
- *Network*: The European Reference Network on Rare and Complex Epilepsies, EpiCARE
- *Health Care Provider (HCP)*: Referring, as appropriate, to an Institution (administration) and/or the multidisciplinary medical team with expertise in rare and complex epilepsies.
- *Board of Network Members (BNM)*: 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 an ePAG delegation.
- *Coordinator of the ERN*: the medical representative appointed by the ExCo and the BNM to coordinate all activities of the ERN.
The HCP employing the coordinator acts as the coordinating legal entity of the Network.
- *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 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 specialized in rare and complex epilepsies. The Board of Member States endorsed a statement on the definitions and types of affiliated partners.
- *Collaborating partner (CP)*: Scientific Societies, medical teams and/or individual experts, working for HCPs not members of the network, designated by the Executive Committee based on their scientific expertise in specific disease areas covered by the ERN EpiCARE.
- *Working Group (WG)*: Groups of individual health professionals, working for Members, Affiliated or Collaborating Partners of the ERN and patient advocates. WGs are the core bodies that develop, define, and deliver the medical and scientific objectives of EpiCARE.
- *Management Team (MT)*: administrative staff supported by the coordination budget and employed by the Network for their expertise in specific domains of project management (such as communication, finances, education, data management, research).

Term

These Terms of Reference are effective from 9th March 2022 and will be applicable until terminated by agreement of ERN EpiCARE Coordinator and the Executive Committee.

Amendment, modification, and variation

These Terms of Reference may be amended, varied, or modified in writing after consultation and agreement by the members of the Executive Committee.

Article 1: Compliance

The Members and Affiliated Partners of the Network:

- shall comply with the criteria and requirements as stated in Commission Delegated Decision 2014/286/EU.
- must not act in breach with their national legislation.
- should respect and be bound by the content of the Network's application and by the rules and procedures agreed upon by the Board of the Network and any other agreement established within the Network.
- agree to GCP guidelines including compliance with GDPR legislation.
- sign the Terms of Reference of the EpiCARE network.

Article 2: Aims of the ERN EpiCARE

The ERN EpiCARE is a network of health care professionals with a high level of expertise in diagnosis and treatment of rare and complex epilepsies, working in specialized health care providers/hospitals (HCPs).

By sharing its expertise and advice on state-of-the-art practices with EU-based medical teams and/or national reference networks, the ERN EpiCARE aims at improving accessibility of detailed diagnostics and treatment suggestions to individuals of all ages with rare and complex epilepsies across Europe. In parallel, development of a close and sustainable partnership with patient advocates (ePAG) is one of the main priorities.

The network contributes between others to:

sharing of expertise on diagnosis and/or treatment for the benefit of patients with rare and/or complex epilepsies, both surgical and non-surgical; the development of National networks in the field of rare and complex epilepsies; the development and/or update of online tools to aid the diagnosis of patients; the development and/or support of clinical trials for better treatments of the epilepsies, both surgical and non-surgical; the development of clinical guidelines and recommendations; the monitoring of standardized outcomes of rare and complex epilepsies; the improvement of awareness and accessibility to protocols and guidelines or recommendations for physicians and individuals, in close collaboration with patient advocates, scientific societies, national and EU authorities; the development of training and educational activities; the development of registries for rare and complex epilepsies; the initiation and/or support of collaborative research in the field.

Article 3: Governance

3.1 Board of Network Members (BNM):

In accordance with the Delegated Decision, the Network has a clear governance and coordination structure. The Network is governed by the Board of the Network Members (Deciding Body). Decision making procedures are defined in 3.2)

The BNM is composed by **one Delegate representing** each of the HCPs (or Consortium of HCPs), Member (full) of the ERN EpiCARE.

The Delegate is designated among **health professionals**, is part of the HCP's staff, and has the mandate to decide and act on behalf of the medical team.

Delegates from Affiliated and/or Collaborating Partners are invited to participate at the meetings of the BNM and express their opinions on all issues.

An ePAG delegation also participates at the BNM.

Representation of a medical team (HCP) can be delegated or provided by proxy.

All individual members of the BNM are bound by the governance policies or rules of procedure decided by the Board.

Roles and responsibilities of the BNM

- Governing & Strategic Decision-Making Body
- Impulse long-term vision & strategies
- Receive and validate the reports of the Executive Committee
- Adopt the action plan, annual activity report, budget orientations of the network
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The BNM meetings are scheduled by the Coordinator at regular intervals (minimum 3 per year: at least 2 online video-conferences and one face-to-face meeting (EpiCARE Annual Convention).

The BNM meetings are chaired by the Coordinator or his/her representative.

Extraordinary meetings of the BNM can be programmed at the request of a simple majority of Delegates representing the full Member HCPS and/or the Coordinator and/or the Executive Committee.
The BNM defines procedures on decision making, including for dispute resolution.

3.2 Decision making procedures

Unless otherwise indicated (see below) **decisions are taken by consensus.**

When needed or requested and at all levels of EpiCARE governance *indicative votes* are privileged. They involve all individual health professionals present at a meeting, independently of the status of the medical team they work for and the ePAG delegation.

For a given topic, upon request of one, or more, Delegates representing a Full Member, or of the Coordinator or of a member of the ExCo, the right to vote may be reserved only to Full member representatives (Delegates).
For decisions of the kind to be effectual at least 70% of Delegates representing Full Members need to attend or being represented.

Decisions of the kind require acceptance by at least 70% of the voting members present or by proxy.

Each Member of the BNM has a voting right equally with all other members.

In case of equality, the voice of the Chair is predominant.

3.3 Executive (Steering) Committee (ExCo):

The ExCo is the **operational decision-making body of EpiCARE**. Members of the ExCo need to be established clinicians or researchers with a strong track record in the field of epileptology.

The ExCo reports to the Annual Convention and at the meetings of the BNM.

Between 2 Annual Conventions of EpiCARE the ExCo:

- Formulates and defines the global strategy and actions plan (including objectives and deliverables)
- Appoints the Coordinator and Deputy Coordinator of the ERN
- Appoints the members of the EpiCARE Research Council (for details refer to the ToR of the Research Council, VI.5 of February 16th 2022) and of the Chairs and Deputy-Chairs of the Working Groups;
- Defines and deliberates on corresponding budget distribution and all other eligible expenses.
- Supervises monitoring and implementation of the action plan.
- Receives input from, and gives feedback to, Working Groups.
- Reports to and asks feedback from the BNM and the Annual Convention.
- Defines criteria of eligibility for new applicants and reviews the applications.
- Reviews and updates as needed the EpiCARE Terms of Reference and the Action Plan.
- Defines the missions and individual tasks of the members of the Management Team.

The ExCo is composed of the following voting members:

- The Coordinator and the Deputy coordinator of EpiCARE
- The Chair and co-chair of the EpiCARE Research Council
- The Chairs of the EpiCARE core WGs (as defined by the action plan)
- Two ePAG representatives

One representative of the following Societies are invited to participate, as *non-voting members*:

European Board of the International League Against Epilepsy (ILAE-EUROPE); the International Bureau for Epilepsy (IBE); the European Academy of Neurology (EAN); and the European Paediatric Neurology Society (EPNS).

At the discretion of the Coordinator, the Research Council and/or WG chairs, individuals actively involved in EpiCARE actions can be invited as non-voting participants.

Working mode of the ExCo

- A minimum of 9 online calls per calendar year.
- Two regular face-to-face annual meetings, one of which held at the occasion of the EpiCARE Annual Convention
- Decision making procedures are detailed in 3.2.

The ExCo meetings are attended by at least one member of the Management Team, also in charge of the minutes.

The online sessions can be recorded.

3.4 EpiCARE Annual Convention (General Assembly)

The Annual EpiCARE Convention is open to all health professionals working for Full, Affiliated or Collaborating partners of EpiCARE and to Patient Advocates (ePAG).

The Annual Convention is organized by the Coordinator and the ExCo with the support of the Management Team. Upon decision of the ExCo tasks related to the organization of the AC may be subcontracted.

The Annual Convention is chaired by the Coordinator. He/she can be represented by the Deputy Coordinator or the Chair or co- Chair of the EpiCARE Research Council.

An *Extraordinary Convention* can be organized at the request of the Coordinator or the Executive Committee or after decision of the BNM.

Reimbursements Policy: Participation of individual members to the Annual Convention is considered a priority, indispensable for the development of an operational network.

The coordination budget is expected to obligatorily cover at least 2 nights' accommodation for: one delegate from each Full Member, Affiliated Partner or Consortium of EpiCARE; the members of the Executive Committee; the Chairs and Deputy-chairs of the Working Groups; a delegation of minimum 10 patient representatives (ePAG). At the discretion of the Coordinator, individual experts actively involved in missions of EpiCARE can also be invited and their expenses covered.

A fixed daily allowance for partial or full reimbursement of travel expenses (excluding taxi and parking expenses) will be proposed in function of the budget, following a decision of the Executive Committee.

Reimbursement of travel expenses directly from HCPs and Patient Associations represented at the annual convention is to be encouraged.

3.5 Coordinator

The *Coordinator* is appointed for a period of 5 years by his/her peers, following proposal(s) of the Executive Committee. Upon request (see Article 3.2) the appointment is submitted to vote at the Annual Convention.

Candidates to the ERN EpiCARE coordination need to be established clinicians or researchers with a strong track record in the field of epileptology, experience in collaboration with patient associations and expertise in strategy development, team building and management.

The Coordinator is expected to devote at least 50% of his/her working time at the service of the ERN.

He/she reports annually to the EpiCARE Annual Convention and monthly to the ExCo.

The mission of Coordinator can be revoked by the ExCo and/or the BNM.

Whenever needed, he/she can be represented by the Deputy coordinator or another member of the ExCo.

The HCP employing the coordinator is the coordinating legal entity of the Network.

Missions:

- Impulses strategies with the Board & ExCo of EpiCARE
- Represents the ERN EpiCARE at all meetings organized by the European Commission, EU DG SANTE and the ERN Coordinators group.
- Chairs the Governance bodies meetings (Annual Convention; BNM; ExCo)
- Is an *ex officio* member of all Working Groups and contributes to their development
- Reports to the EU Commission, to the EC, to the BNM and to the Annual Convention of EpiCARE.
- Oversees the missions of the Management Team and its individual members.
- Works in concertation with the coordinating HCP administration.

Article 4: EpiCARE Research Council (ERC)

The role of ERN EpiCARE Research Council (ERC) is to upscale and support research conducted by EpiCARE members and partners, with an aim to improve the quality and quantity of research into rare and complex epilepsies within the network.

Specific goals include

- stimulating multi-centre studies.
- optimizing ethical, methodological, and statistical approaches.
- improving and optimizing trial feasibility and reliability.
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Are members of the ERC, appointed by the ExCo:

One ILAE representative; EpiCARE coordinator; Four further members as nominated by the ExCo; ECET Chair; Chair Clinical trials and targeted medical therapies (WG7); Registry Chair; Representative Joint ERN/European research Initiatives (e.g. EJPRD, HBP); Two ePAG representatives;

The Research projects manager of EpiCARE and the EpiCARE data manager participate at the meetings of the Research Council and are also in charge of the minutes.

ERC Chair & Co-chair to be appointed from within the group every two years.

A *Terms of Reference* document (V1.5 of February 16th 2022) has been created by the EpiCARE Research Council and endorsed by the ExCo.

Article 5: Working Groups (WG)

They are the core bodies that define and implement the medical and scientific goals of EpiCARE, defined in the Action Plan. New core WGs can be created as needed by decision of the Coordinator, the ExCo or the BNM. If requested by the funding agency they can be grouped under Working Packages. According to the needs, the actions and missions of a WG can be represented under several Working Packages.

The WGs regularly report to the Coordinator, the Executive Committee and at the Annual Convention.

Roles and responsibilities

- Each WG assesses and defines specific objectives, action plans, milestones and deliverables related to its domain of expertise.
- Creates Task Forces and Special Interest Groups of work as needed and coordinates them.
- WG deliverables are under the responsibility of the WG Chair and Deputy-Chairs.
- The core WG Chairs are members of the ExCo, to which they regularly report.

Members

- Chair, an established clinician, or researcher in the field of rare and complex epilepsies.
- A Deputy Chair, ideally an early career clinician or researcher in the field.
- Other Deputy-chairs can be designated by the Chair for WGs covering several missions.
- Active members (in principle unlimited number), health professionals employed by EpiCARE medical teams, independently of the status of the HCP; ePAG representatives; invited experts as needed.

WG Chair and Deputy-chairs are appointed every 4 years by the ExCo, following proposals from the Coordinator, other members of the ExCo, active members of the WG or by application.

Clinicians, researchers, and representatives of advocacy groups become 'active' members upon request.

The Chairs of core WGs are voting members of the ExCo. They can be represented, with full rights, by one of the Deputy-chairs.

Working mode

- One regular face-to-face meeting, at the Annual Convention of the ERN EpiCARE.
- Upon request of the WG Chair or the Coordinator additional face-to-face meetings when justified by the missions of the WG. When a budget is requested, the meeting and budget need agreement of the ExCo and/or the Coordinator.
- At least 5 annual videoconferences, involving the active members of the WG to be organized by the Chair and/or Deputy Chair who also define the agenda.
- 'Active' members are committed to participate regularly to meetings, to contribute to projects, respond to requests of the WG leaders and to contribute to achieve the deliverables.
- The Chair and Deputy-Chair lead and coordinate meetings and activities of the working group and are responsible for requested reports and deliverables.

- The Chair and Deputy-Chair establish a regular liaison with the Management team.
- The meetings are organized with the support of the Management Team. The Minutes are validated by the WG Chair and the ERN Coordinator. Meetings can be recorded.

Article 6: Management Team (MT)

The MT is the administrative body of EpiCARE. The staff is administered by the coordinating HCP or, when appropriate, by a seconded Institution.

The missions of the MT are defined and overseen by the ExCo and/or the Coordinator.

Roles and responsibilities

- Handle administrative and financial issues. Facilitate coordination & monitoring of all ERN activities.
- Contribute to the development and monitor the implementation of the Action Plan.
- Report to the Coordinator, the ExCo and the European Commission.
- Support and monitor ExCo, BNM, Annual Convention and Working Groups meetings.
- Implement Communication Strategy (internal and external) and ensure optimal circulation of information at all levels.
- Monitor & follow up of cross-ERN projects in relation with Coordinators.
- Establish regular contacts with the health professionals coordinating the medical teams' members of EpiCARE, independently of their status.
- Establish regular contacts with the administrations of HCPs represented in ERN EpiCARE.
- Establish a regular liaison with the ePAG advocates group and support ePAG actions agreed by the Coordinator or the ExCo.
- Draft the intermediate, annual and final reports to HADEA and to DG SANTE.
- Being represented at the meetings of the Coordinators with DG SANTE and provide minutes
- Contribute to the coordination between managers of the other ERNs.

For an efficient management of the missions mentioned above it is estimated (one the day of the validation of the present) that **the equivalent of minimum 5-6 FT staff positions** is required.

Considering the missions of the ERN EpiCARE the following competences are considered necessary: Global Strategy development & EU Public Health Policies; Administrative and Finances management; Management of Research activities and projects; Management of CPMS, Registry and Data Sharing activities; Specialization in design and planning of continuing education programs and Guidelines for healthcare personnel; Communication and Dissemination; HelpDesk Secretariat.

The corresponding Full and/or Part Time work equivalents and individual missions are defined (and regularly reviewed) by the Coordinator, in concertation with the ExCo.

The Executive Committee and/or the Coordinator may decide the creation and funding of other MT missions and incorporate the appropriate persons (or subcontractors) with experience in the field.

All MT positions are subject to an open call for tenders, written in at least 2 languages, obligatorily including English, and diffused to all HCPs for further dissemination and published on the EpiCARE website.

Spoken English at a nearly native level is an important selection criterion.

When an individual member of the MT is employed by another HCP (secondment) a contract agreement between the 2 legal entities must be signed.

Article 7: European Patient Advocacy Group (ePAG)

The EpiCARE European Patient Advocacy Group (ePAG) is comprised of patient advocates that represent and are endorsed by a patient organization following the process defined by their proper Rules of Patient Engagement. ePAG is not a legal entity.

A Terms of Reference document has been created by the EpiCARE ePAG, in concertation with EURORDIS and is available upon request.

The main mission of EpiCARE ePAG group is to be involved to those EpiCARE activities requiring patient empowerment. The EpiCARE ePAG is represented at the EpiCARE Executive Committee by the ePAG Coordinator and the ePAG Deputy Coordinator. Full members and Affiliated Partners of ERN EpiCARE are expected to support the ePAG, at both National and EU level, in the development and dissemination of its activities and to inform the wider medical community on the importance to regularly collaborate with patient groups

Article 8: Budget & Legal issues

The annual budget allocated by the EU Commission for the coordination and development of the EpiCARE missions is under the legal responsibility of the coordinating HCP administration. Its use must comply with the general and the specific conditions for each of the budget categories as detailed in the Grant Agreement. National legislation also must be respected.

Costs are divided into four budget categories:

- A. direct personnel costs;
- B. direct costs of subcontracting;
- C. other direct costs;
- D. indirect costs;

All expenses must be made in a way that are eligible to the European Commission and need to correspond to missions of EpiCARE and agreed by the coordinating HCP (Institution).

No expense will be accepted without a prior consultation with the Coordinator and, when required, the ExCo of EpiCARE. This includes all types of travel expenses, registration at congresses, organisation of workshops as well as face-to-face meeting of WGs.

Legal advice from the coordinating institution is required for all types of action potentially engaging the ERN as a network.

Article 9: Organisation of remote meetings

The ERN EpiCARE has a license offering access to a professional platform for remote meetings (ex. TEAMS). Each member of the network can obtain upon request to the MT.

Each person must make sure in advance if he/she can access the meetings (mobile app, installing the app on a computer or access via the internet browser). Individual members may need to ask to the IT Department of their HCP to provide access to the platform used by EpiCARE. When access is refused by the administration the MT must be informed. Meetings planned during working hours are covered by the MT and can be registered upon request.

For Patient case discussions and whenever technically possible the Case Patient Management System (CPMS) platform provided by the EU must be privileged.

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