

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.
- *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).

Term

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

They were updated by the ExCo the 9th of October 2024, to be in accordance with the Grant Agreement N°101156811 – EpiCARE 2023-2027 – EU4H-2023-ERN2-IBA (entered into force with a retroactive effect from 1st October 2023).

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 Full Members and Affiliated Partners of the Network should:

- Comply with the criteria and requirements as stated in Commission Delegated Decision 2014/286/EU.
- Not act in breach with their national legislation.
- Respect and be bound by the content of the Network's Grant Agreement N°101156811 – EpiCARE 2023-2027 – EU4H-2023-ERN2-IBA (entered into force with a retroactive effect from 1st October 2023).
- Respect and be bound by the rules and procedures agreed upon by the Board of the Network Members (BoNM) and any other agreement established within the Network.
- Comply with the Terms of Engagement as defined by the Executive Committee, with reference to the Grant Agreement.
- Comply to Good Clinical Practice guidelines including compliance with GDPR legislation.
- Accept the Terms of Reference of the EpiCARE network.

Article 2: Aims of the ERN EpiCARE

The ERN EpiCARE is a network of clinical centres (CC) with a high level of expertise in diagnosis and treatment of rare and complex epilepsies, working in specialized health care providers/hospitals (HCPs) and accredited by the European Commission.

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. Development of a close and sustainable partnership with patient advocates (ePAG) is one of its 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 natural history studies and 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 a central registry for rare and complex epilepsies; the development and/or support of disease-specific registries and databases; the initiation and/or support of collaborative research in the field.

Article 3: Governance

3.1 Board of Network Members (BoNM):

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

The BoNM is composed by **one Delegate representing** each of the CCs (or Consortium of CCs), Full Member of the ERN EpiCARE. The Delegate is designated among **health professionals**, is part of the HCP's staff, and has the mandate to represent and act on behalf of the medical team. Delegates from Affiliated and/or Supporting Partners are invited to participate at the meetings of the BoNM. They can express their opinions on all issues and participate at indicative votes.

A Patient Advocates (ePAG) delegation also participates at the BoNM.

Representation of a medical team, full member or affiliated partner can be delegated or provided by proxy.

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

Roles and responsibilities of the BoNM

- 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

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

Extraordinary meetings of the BoNM 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 BoNM 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 from one, or more, delegates representing a Full Member, or 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 BoNM 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 BoNM.

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, as needed, Deputy Coordinators of the ERN
- Appoints the members of the EpiCARE Research Council and of the Chairs and Deputy-Chairs of the Working Groups;
- Defines and deliberates on corresponding budget distribution and all other eligible expenses, with reference to the Grant Agreement N° 101156811 – EpiCARE 2023-2027 – EU4H-2023-ERN2-IBA.
- Supervises monitoring and implementation of the action plan.
- Develops and implements a Performance Indicator System.
- Receives input from, and gives feedback to, Working Groups.
- Reports to and asks feedback from the BoNM 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 coordinators 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 is 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 7 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 two members 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 Convention (AC) of the ERN EpiCARE is open to all health professionals working for Full Members, Affiliated Partners and Supporting partners of EpiCARE and to Patient Advocates (ePAG).

Individual experts in the field of rare and complex epilepsies can be invited by the Coordinator or the Executive Committee.

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 delegated to one of the Full Members of the Network and/or subcontracted.

The Annual Convention is chaired by the Coordinator or his/her representative. He/she can be represented by a 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 BoNM.

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

With reference to the reimbursement policies of the European Commission, the coordination budget is expected to cover accommodation and part or all travel expenses for at least: 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. The level of reimbursement for travel expenses is defined annually by the Management team and submitted for validation at the ExCo, with reference to the EU reimbursement policy.

Reimbursement of travel expenses directly from Institution/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 employed by a HCP, full member of the network, in agreement with the corresponding HCP Administration. They 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 at all the ExCo and BoNM calls.

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

He/she can be represented by the Deputy coordinator or another member of the ExCo.

The HCP employing the coordinator is the Coordinating (COO) legal entity of the Network.

Missions:

- Impulses strategies with the BoNM & 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 BoNM 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 (COO).
- Works in concertation with the Deputy-Coordinators.

3.6 Deputy Coordinators

The Medical representatives of the 2 HCP Beneficiaries (BEN) of the running Grant Agreement (KUL-Pr. LAGAE L. and SALK-Pr. TRINKA E.) act as Deputy Coordinators. They support and can represent the Coordinator in all his missions.

Article 4: EpiCARE Research Council (ERC)

The role of ERN EpiCARE Research Council (ERC) is to foster and upscale 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-center studies.
- optimizing ethical, methodological, and statistical approaches.
- improving and optimizing trial feasibility and reliability.

Are members of the ERC, appointed by the ExCo:

The ERN EpiCARE coordinator; the Chair of the WG7 (Clinical Trials and Targeted Medical Therapies); the Chair of the EpiCARE Registry; Four further members as nominated by the ExCo; One ILAE representative; a representative of the European Consortium for Epilepsy Trials (ECET); Two ePAG representatives.

At the discretion of the ExCo and/or the ERC Chairs, representatives of ERN/European research Initiatives (e.g. EJPRD, HBP, ERICA; ERDERA) can be invited to join the ERC.

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 (VI.5 of February 16th 2022) has been created by the EpiCARE Research Council and endorsed by the ExCo.

Article 5: Working Groups (WG)

WGs are the core bodies that define and implement the medical and scientific goals of EpiCARE, as described in the Action Plan.

New core WGs can be created as needed by decision of the Coordinator, the ExCo and/or the BoNM.

According to the needs, the actions and missions of the ERN EpiCARE a WG can be represented under several Working Packages, as defined in the Grant Agreement.

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

Members

- Chair, an established clinician, or researcher in the field of rare and complex epilepsies.
- Co-Chair, ideally early career clinicians or researchers in the field.

- Deputy-chairs can be designated by the EpiCARE Coordinator or by the Chair for WGs to develop specific 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, independently of their affiliation.

WG Chair and co-Chair 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 the co-chair or, when needed, by a representative of their choice, active member of the WG.

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 ensures their coordination.
- 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.

Working mode

- One regular face-to-face meeting, usually 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 2 annual videoconferences, involving the active members of the WG to be organized by the Chair and/or co-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 co-Chair lead and coordinate meetings and activities of the working group and are responsible for requested reports and deliverables.
- The Chair and co-Chair establish a regular liaison with the Management team.
- The meetings are always organized with the support of the Management Team and the HELPDESK. 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, as per Grant Agreement, is employed by the coordinating HCP, other beneficiaries of the grant or, when appropriate, by a seconded Institution.

The missions of the MT are defined and overseen by 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 *ad hoc* European Commission Agencies (DG SANTE; HADEA; other)
- Support and monitor ExCo, BoNM, 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 Institutions (HCPs) represented in ERN EpiCARE.
- Establish a regular liaison with the ePAG advocates group and support ePAG actions agreed by the Coordinator and/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.

With reference to the missions of the ERN EpiCARE the following competences are considered necessary: Administrative and Finances management; Management of Research activities and projects; Management of CPMS, Registry and Data Sharing activities; Design and planning of continuing education programs and Guidelines for healthcare personnel; Communication and Dissemination;

Knowledge on global Strategy development & EU Public Health Policies is strongly encouraged.

A HELPESSK Secretariat can be subcontracted, when necessary. Close collaboration with the MT staff is mandatory.

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.

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 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 administration of the Coordinating HCP (COO) and other grant beneficiaries (BEN).

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 as detailed in the running Grant.

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 HCP is required for all types of new actions potentially engaging the ERN as a network. When required the EU Officer will need to be consulted.

Article 9: Organisation of remote meetings

The ERN EpiCARE has a license offering access to a professional platform for remote meetings (ex. TEAMS; ZOOM).

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/funded by the EU must be privileged.

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