

EpiCARE

Rules for Patient Engagement

[Approved by ePAG eEpiCARE on May 31st 2023]

1. Introduction

According to the European Commission Expert Group (EUCERD) patients and patient representatives should play an active role in the decision and opinion making process of the European Reference Networks (ERNs) and be involved in structural and clinical network activities. The Expert Group recommended that ERNs demonstrate meaningful patient involvement, patient-centeredness and empowerment through recognition of the role of patients, as experts by experience and co-producers of knowledge, in the ERNs structural and clinical activities and therefore demonstrate meeting the legal requirements in the Delegated Acts.

These rules for patient engagement aim at facilitating the effective involvement of patient representatives in the activities of [EpiCARE \(EpiCARE\)](#). They are based on the governance framework developed by EURORDIS for patient engagement in the ERNs and contain specific provisions to adapt them to the governance structure of [EpiCARE](#).

The [EpiCARE](#) ePAG has appointed two ePAG advocates to be involved in each of the ERN work streams, where possible and where appropriate.

This policy does not preclude other patient organisations registered in Europe, patient organisations registered outside Europe and referred to in Sections 16 to 18 from collaborating on specific projects by invitation of the [EpiCARE](#) ePAG in agreement with the Network Board.

The position of ePAG advocate is a voluntary position and does not involve any financial compensation. Travel and accommodation expenses may be reimbursed subjected to prior agreement with [EpiCARE](#) coordination team.

2. Role of EpiCARE 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 organisation following the process described in Sections 11 and 12.

The overarching objective of the ePAG is to ensure that the needs of people living with rare and complex conditions covered by the ERN are included in its strategic and operational delivery. To achieve this goal, the ePAG role is to:

- Represent the voice and interests of patients and families within EpiCARE.
- Ensure a patient-centric approach in the collaborative activities of EpiCARE in the areas of care, education and training, knowledge sharing and research.
- Support the identification of EpiCARE strategic priorities.
- Provide input on ethical issues.
- Support the Network in the dissemination of its activities and information to the wider patient community to ensure transparency.

The structure and composition of the ePAG is described in Annex I.

3. Role of EpiCARE ePAG advocates

ePAG advocates are patient representatives that are active in the ERN governance structure including the Network Board, work streams and working groups. The ePAG advocates role is to:

- Work in partnership with other patient advocates, clinicians and researchers involved in EpiCARE;
- Champion the diversity of views of the EpiCARE patient community, and not just to represent their own disease area nor their own experience;
- Support EpiCARE to disseminate information, primarily to the patient community, but as appropriate to other communities (e.g. healthcare providers, health authorities, clinicians and medical professionals and their professional bodies)
- Contribute to the development of patient information, clinical practice guidelines, other clinical decision support tools and referral pathways;
- Contribute to the development of research priorities and ensure the needs of patients and families are taken into consideration;
- Inform and support patients and families in understanding the complexity of procedures towards early diagnosis, identification of the aetiologies and underlying mechanisms;
- Provide input on ethical issues, and balance patient and clinical needs appropriately;

- Provide training and support to new [EpiCARE](#) ePAG advocates, when and where possible;
- Scout for or make recommendations for new patient organizations to cover under-represented disease groups or patients from other EU countries.

4. Responsibilities of EpiCARE ePAG advocates

ePAG advocates will be required to:

- Participate in [EpiCARE](#) working groups (depending on interests, expertise and availability).
- Participate regularly in the majority of the ePAG calls, and send apologies in advance if unable to attend.
- Report regularly in the ePAG calls and meetings on the progress of the work and projects in which they are directly involved in [EpiCARE](#). If unable to attend, the report should be completed using the available template and sent by email to secretary ahead of the meeting or call.
- Participate in [EpiCARE](#) annual meetings, where possible. Travel and accommodation expenses will be reimbursed subject to the ERN budgetary rules.
- Contribute to identify and develop the ePAG annual objectives and work programme.
- Contribute to the assessment of new applications for membership of the ePAG.
- Respect the confidential nature of the discussions when it is made clear that this is a requirement by the person who is chairing a call or meeting.
- Comply with the [EpiCARE](#) conflict of interest policy.
- In case of any agreement breach, potential issue will be resolved in-between [EpiCARE](#) ePAG, [EpiCARE](#) or EURORDIS as an external mediator.

The core values of ePAG advocates are:

- Respecting the mission of the [EpiCARE](#) and its governance structure;
- Listening to the opinions and requests of others;
- Showing solidarity, mutual respect and support;
- Adhering to the principles of equity and social justice;
- Conducting themselves with professionalism in engaging with the clinical, research leads and fellow patient advocates.

5. ePAG advocates alternates

ePAG advocates may nominate an alternate from ePAG or his/ her own patient organization or a collaborator to attend specific ERN or ePAG meetings. The ERN Coordinator or the ePAG leads shall validate the participation of such alternates in the ERN or ePAG meetings, respectively. Alternates must comply with the [EpiCARE](#) conflict of interest policy and with the core principles lay down in Section 4 when attending ERN [EpiCARE](#) or ePAG meetings.

6. ePAG Leads role and responsibilities

The ERN [EpiCARE](#) ePAG has one ePAG Coordinator and one ePAG Deputy Coordinator who are responsible for coordinating the ePAG group, they represent the ERN [EpiCARE](#) ePAG and the ePAG Community on the ERN [EpiCARE](#) Board.

In addition to the role and responsibilities of the ePAG advocates mentioned in Section 5, the ERN [EpiCARE](#) ePAG Coordinator and ePAG Deputy Coordinator have the following responsibilities:

- Represent the voice of ERN [EpiCARE](#) ePAG advocates and the ePAG Community to the ERN [EpiCARE](#) Board and network meetings.
- Share important news and update the other ERN [EpiCARE](#) ePAG advocates and the ePAG Community on ERN [EpiCARE](#) activities as appropriate.
- Consult with the other ERN [EpiCARE](#) ePAG advocates and the ePAG Community on relevant issues and feedback information to the ERN [EpiCARE](#) Network Coordinator.
- Ensure the sustainability of the ePAG advocates group.
- Assign ePAG advocates to Working Groups.
- Monitor ePAG advocates activities in the Working Groups.
- Coordinate the activities of the whole group, and report shared vision with ERN Coordinator/steering Committee/external parties including the EURORDIS Steering Committee.

Decisions in the ePAG are taken by consensus, but vote is possible if necessary. In the event of non-consensus, the voice of the ePAG Coordinator is predominant.

For these activities Coordinator and Deputy Coordinator nominate a secretary to help with some of the previously mentioned tasks. Furthermore, secretary is responsible for supporting the administrative tasks of the ePAG group, including welcoming the new ePAG advocates or the new members of the ePAG Community, setting up the regular ePAG meetings (agenda, minutes, follow-up actions) and disseminating any relevant information to the ePAG group.

7. Requirements for Patient Organisations

Individuals cannot apply to become an ePAG on a personal basis. Prospective applicants must be **formally endorsed** by a patient organisation that meets following requirements:

- Is legally registered and operates in Europe (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe). This registration requirement can be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.
- Holds non-profit status.
- Has demonstrated/transparent activities such as patient support and/or advocacy activities and/or research.

8. Skills and experience for ePAG advocates

Required skill and experience:

- Have knowledge of, or experience of living with, one of the rare and complex conditions included in the scope of [EpiCARE](#);
- Be willing and motivated to get involved, contribute actively to the discussions and work of the ePAG and the ERN working groups;
- Work effectively and constructively with other patient representatives and clinicians from different EU countries;
- Represent the interests of all represented diseases that are under the scope of the ERN, beyond their own disease.
- Bring independent judgement from a patient representative perspective;
- Have an awareness of, and commitment to, equality, diversity and inclusiveness;
- High level of organisation and self-motivation;
- Understand the need for confidentiality;
- Communicate in English to be able to follow and contribute to meetings.
- Have computer skills and equipment to communicate through email, webinars, and videoconferences.

It is desirable to have experience working in a committee setting with clinicians and patient representatives.

9. Time Commitment

ePAG advocates will be required to attend ePAG calls approximately every month that will generally take place during working hours.

They will also need to attend the calls of the ERN working groups in which they decide to be involved, as well as the ERN annual meeting, that is usually a full 2-day meeting.

In addition, they will need to dedicate time to review and read documents ahead of the meetings and calls. This implies a commitment of typically 2 days per month and can increase to approximately 5 days per month in the case of the ePAG leads.

10. Benefits of becoming an ePAG advocate

ePAG advocates role and position in the ERNs give these representatives the opportunity to:

- Work closely with clinicians, researchers and other patient representatives to transform healthcare services and accelerate research for people living with a rare disease in Europe.
- Participate first-hand in the development of the ERN objectives to ensure that the patients' needs are taken into the account.
- Gain international exposure and expand their international network, specifically across Europe.
- Acquire a good understanding of healthcare models across Europe and European Reference Networks.
- Develop soft skills such as communication, public speaking, conflict resolution, etc. acquired through trainings such as the ones provided by EURORDIS through its Open Academy, EUPATI and others, and through active participation in the ePAG.
- Share and learn from other ePAG advocates and build their own capacities as patient representatives, broadening knowledge both within their own field of rare diseases and beyond.

11. How to apply

Prospective applicants should complete and sign the application form described in Annex II and send it together with the endorsement letter signed by the legal representative of the patient organisation to epag.epicare@gmail.com or fill in the online application form of ePAG EpiCARE or [EURORDIS](#) available in Annex II.

12. Application process

Once received, the applications are processed as follows:

1. EURORDIS ePAG manager shares the application and accompanying documents with the EpiCARE ePAG in case that the application went through EURORDIS.
2. The ERN EpiCARE coordination team will review the information pertaining to the patient organisation to ensure that the requirements described in Section 7 are met.
3. The application is reviewed and discussed by the ePAG. Applicants will be assessed against the required skills and experience outlined in Section 8. Selection will be made on the basis of the content of the application form and accompanying documents.
4. The ePAG may request further information or arrange an informal call with the prospective applicant to get additional information on his or her skills, experience and motivation.
5. In the interest of equality, diversity and inclusion we prioritise applicants that represent a country or a disease not currently represented in the EpiCARE ePAG.
6. Approval of new ePAG advocates is through agreement in the ePAG and in consultation with the ERN EpiCARE Coordinator.
7. All applications will receive a successful or unsuccessful notification.

The appointment of a new ePAG advocate is initially for a six-month period. During this period, the new ePAG advocate will have the opportunity to get familiar with the activities and with his/her role and responsibilities. After this period, the EpiCARE ePAG, in consultation with the Network Coordinator, will validate the appointment of the new ePAG advocate.

Application through EURORDIS is further detailed in Annex III.

13. Introduction for new ePAG advocates

New ePAG advocates should complete an interactive online introduction session delivered by EURORDIS. This webinar lasts an hour and a half and will provide some background information to the European Reference Networks and European Patient Advocacy Groups and the work that they do.

In addition, new ePAG advocates will also receive an introduction on the work of EpiCARE delivered by one of the seasoned ePAG advocates.

14. Duration and renewal of ePAG advocates' mandate

The mandate of ePAG advocates expires at end of each five-year funding period of the ERNs. The mandate of ePAG advocates appointed for a given 5-year period may be renewed by another 5-years by reconfirming their willingness and presenting a new letter of endorsement signed by their patient organisation. ePAG advocates who joined the last year of any 5-year ERN period, will not be required to renew their mandate. The mandate can be varied/extended according to the duration of the periods defined by the EU for ERNs.

ePAGs representing an association or organisation that is registered and operates in European member state can nominate themselves for the role of Coordinator and Deputy Coordinator one month prior the election by sending the nomination/motivation letter. At the election day, voting is anonymous, and all ePAGs have a right to vote. ePAGs who receive the most votes will be appointed as ePAG Coordinator and ePAG Deputy Coordinator after consulting with the [EpiCARE](#) Coordinator. Their mandate may be renewed with the new election within [EpiCARE](#) ePAG and in consultation with the ERN Coordinator. In case of resignation, ePAG Leads will be replaced or new elections will be held.

The mandate of ePAG Coordinator and Deputy Coordinator expires at the end of each five-year funding period of [EpiCARE](#). The mandate can be varied/extended according to the duration of the periods defined by the EU for ERNs, with approval of the [EpiCARE](#) ePAG team and [EpiCARE](#) coordinator.

15. Termination of role of ePAG advocates and voluntary suspension

The mandate of an ePAG advocate shall terminate in any of the following cases:

1. The ePAG advocate sends a notice of resignation to the [EpiCARE](#) ePAG, the ERN Coordinator and to EURORDIS.
2. The Patient Organisation withdraws the endorsement given to the ePAG advocate.
3. The ePAG advocate does not respond to emails, attend meetings or does not contact the ePAG group in a period of 3 months.
4. Mutual agreement between the ePAG, ERN Coordinator, EURORDIS and the ePAG advocate that his or her involvement is not in the best interests of the ERN.

In the circumstances referred to in points 3 and 4 above, before any decision is made to remove someone from being an ePAG advocate:

- the ePAG advocate, his/her endorsing Patient Organisation and EURORDIS must be informed of the reasons why it is proposed to remove them (this includes an opportunity for open discussion), and
- at least one month should be allowed for mediation and any concerns raised to be addressed.

At any time, ePAG advocates can send a notice of temporary suspension to the [EpiCARE](#) ePAG, the ERN Coordinator and to EURORDIS, in case he or she would like to voluntarily step down for a period of time. Where possible, a temporarily absent ePAG should try to find a suitable volunteer to take on his/her activities during this interim period.

16. Collaboration with other (external) patient organisations registered in Europe

External patient organisations registered in Europe that do not have a formal representative in the ePAG may wish to engage with the ePAG. This wider community of patient organisations may be willing to collaborate in specific working groups, on specific tasks (e.g., respond to surveys), help to disseminate information about the ERN across their wider patient community, be consulted occasionally for feedback, and be kept informed on the development of the ERN activities.

These patient organisations may not have a representative formally involved as an ePAG advocate in the [EpiCARE](#) work streams or working groups, but they represent an important component of the ePAG accountability and proper functioning.

Any rare disease patient organisation meeting the following two requirements can contact the ePAG Leads epag.epicare@gmail.com to express their interest to collaborate and/or receive updates from the ePAG and the ERN. They will then be invited by the ERN Board in agreement with the ePAG to collaborate with the group and/or receive updates:

- Is registered in Europe as a patient organisation. This requirement can be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.
- Operates in Europe representing patients and families living with a rare disease that belongs to the scope of the [EpiCARE](#). You may find the list of diseases [here](#).

Patient organisations that meet the above requirements and are invited to collaborate should indicate a contact person who will receive the ePAG notifications and act as the liaison between the patient organisation and the ePAG. Such individuals will not be formally involved in [EpiCARE](#) as ePAG advocates. However, when engaging in the ePAG or ERN activities and projects, they must comply with the [EpiCARE](#) conflict of interest policy and the core principles lay down in Section 4.

The [EpiCARE](#) ePAG is responsible for maintaining the list of the external European patient organisations with whom they engage and sharing this list with their ERN Coordinating team.

17. Collaboration with external patient organisations registered outside Europe

External patient organisations registered and operating outside of Europe representing patients and families living with a rare disease that belongs to the scope of the [EpiCARE](#), may want to collaborate with the ePAG on specific tasks and projects. Where appropriate, the ERN Board in agreement with the ePAG may invite these patient organisations to contribute to a specific project or activity within a specific timeframe.

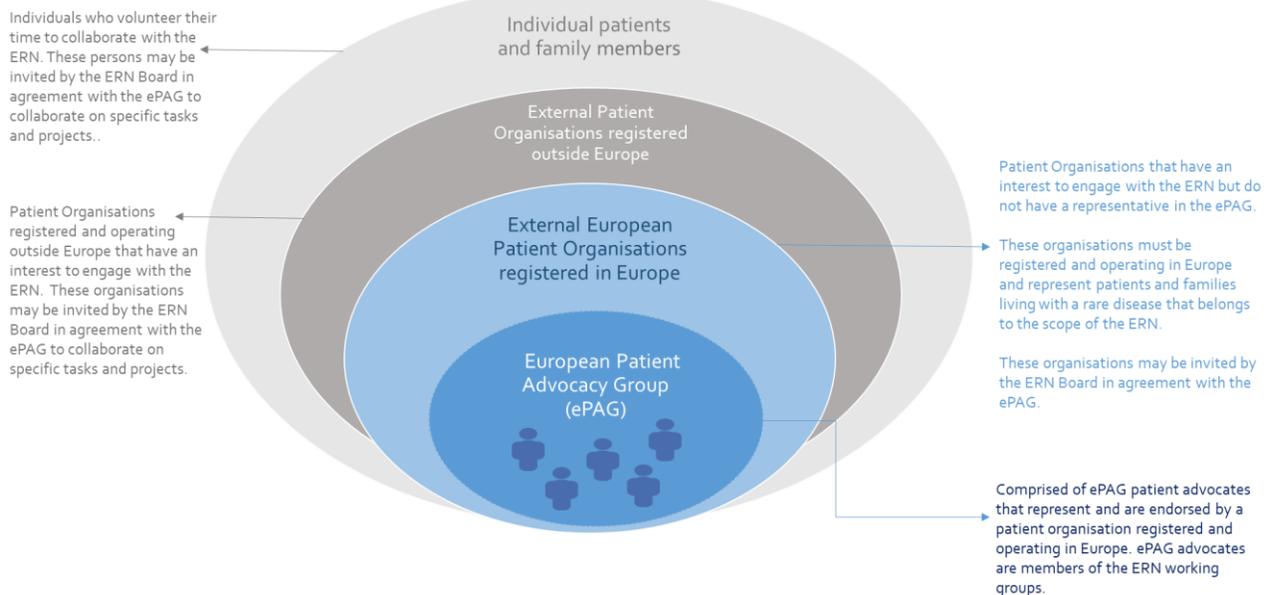
Once invited by the [EpiCARE](#) Board, the patient organisation will contact the ePAG Leads epag.epicare@gmail.com to indicate a contact person who will receive the ePAG notifications and act as the liaison between the patient organisation and the ePAG. Such individuals will not be formally involved in [EpiCARE](#) as ePAG advocates. However, when engaging in the ePAG or ERN activities and projects, they must comply with the [EpiCARE](#) conflict of interest policy and the core principles lay down in Section 4.

The [EpiCARE](#) ePAG is responsible for maintaining the list of the international patient organisations with whom they engage.

18. Collaboration with individual patients and family members

Individual patients or family members may want to volunteer their time to collaborate with the ePAG on specific tasks or projects. Where appropriate, the ERN Board in agreement with the ePAG may invite these persons to contribute to a specific project or activity within a specific timeframe. Such individuals are not formally involved in [EpiCARE](#) as ePAG advocates. However, when engaging in the ePAG or ERN activities and projects, they must comply with the [EpiCARE](#) conflict of interest policy and the core principles lay down in Section 4.

European Patient Advocacy Group and relationships with the wider European and International Patient Community and individual patients and family members.



19. Amendment of the Terms of Reference

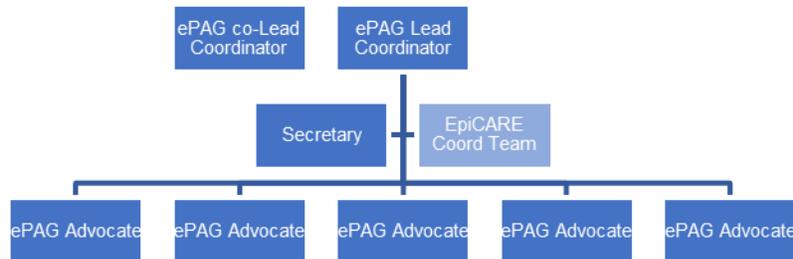
The ePAG on annual basis will make the necessary amendments to ensure they remain fit for purpose.

20. Authority of the EpiCARE Board

Nothing in this document removes the rights of the EpiCARE Network Board to interpret and/or amend its content in the best interest of the Network or to comply with relevant directives or guidance from the European Commission.

Annex I – Composition of the EpiCARE ePAG

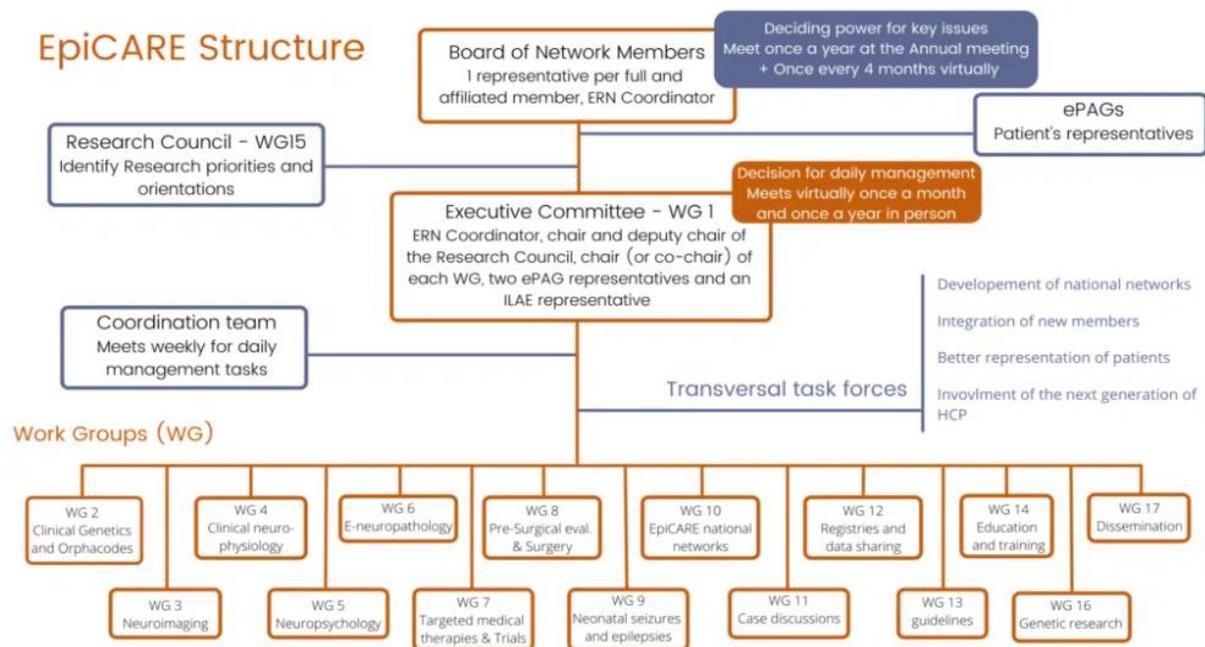
The below diagram illustrates the structure of EpiCARE ePAG. For a list of current advocates in post see the [EpiCARE website here](#):



Note: This diagram is illustrative of the team comprising multiple ePAG Advocates but is not prescriptive in respect of the number that can be appointed.

The ePAG Coordinator and Deputy Coordinator each have a seat on the [EpiCARE Executive Committee](#) and also represent the team on the EURORDIS ePAG Steering Committee.

The nominated ERN [EpiCARE ePAG advocates](#), also named ePAG Work Package leads, (as listed [here](#)) represent the voice of the patients within the ERN [EpiCARE](#) and they contribute actively to the regular activities and meetings in the WG's illustrated in the diagram below – which can also be found on the [EpiCARE website here](#).



Two ePAG representatives are voted in by rotation to sit on the [EpiCARE Research Council](#) every 2 years.

Annex II - ePAG advocate Application Form

Please read the information below and complete the application form. The application will be assessed against the criteria and the candidate's required skills and experience for candidates described in Sections 2-10.

Candidates can apply using the EURORDIS [online application form](#) or ePAG [EpiCARE online application form](#) or by sending the complete documentation to epag.epicare@gmail.com with [application form](#) and signed [endorsement letter](#).

Annex III: ePAG advocate application Process supported by EURORDIS

