

Annex to the ERN-RND Network Agreement regarding the rules for the patient advocacy group

1. Introduction

The rules for organizing the Patient advocacy group within the ERN-RND is based on the constitution of the ERN. Here it is stated: "*Patient advocates and patient organizations are recognized by the European Commission Expert Group for Rare Disease, as integral to the strategic and operational delivery of European Reference Networks in rare diseases (RD ERN) and should play an active role in the networks' decision and opinion-making structures*".

We regard patient representation and partnership with clinicians as a vital tool for the ERN-RND to reach the goal of making expertise accessible and improve health outcome to RND patients all over Europe.

2. ERN-RND Representation in the European Patient Advocacy Group (ePAG)

ERN-RND European Patient Advocacy Group (ePAG) is a patient forum comprised of Patient Organisations (PO) wishing to engage in ERN-RND. All ePAG Patient Advocates, have been endorsed by their respective Patient Organisations to be active in ERN-RND activities and governance board and committees.

ERN-RND ePAG aims to represent the voice of patients within all the disease groups included in the ERN-RND to ensure that the needs of people living with a rare neurological disease, are included in the strategic and operational delivery of the network. We strive to represent a diversity of patient organizations and geography.

In addition, it is the policy of ERN-RND to have no more than two ePAG Advocates for each of the disease groups within the network. This policy does not preclude additional patient representatives participating in particular work packages or, by invitation of the Network Board, to have access to the ERN-RND web-site and/or to attend the ERN-RND Annual Meeting.

3. ERN-RND ePAG Advocates Criteria and Application Process

Anyone, including sitting members of the ePAG, can actively encourage new patient representatives to apply for membership in the group.

Enrolment and approval of new ERN-RND ePAG Advocates should be through a written application (the applicant should include an endorsement letter from his or her Patient Organization and a bio sketch). The application can be sent to the EURORDIS ePAG manager, the RND coordinator or the ePAG coordinator/chair.

The current ePAGs' will subsequently consider applications and approve or reject new members. Applicants are evaluated based on eligibility criteria and the need for new/more members.

Approval of ePAG Advocates is through agreement in the RND-ePAG and in consultation with the RND Network Coordinator and the EURORDIS Patient Engagement Manager

Essential eligible criteria:

- Fluency in English
- Knowledge of one or more of the diseases represented by RND-ERN, either as a patient, close family member of a patient, carer or advocate for a patient organisation representing one of those diseases
- If an association does not yet exist for a disease (is the case for most ultra-rare diseases) the applicant will be evaluated on and can be accepted as ePAG member, given agreement between ePAG, RND Network Coordinator and EURORDIS Patient Engagement Manager.
- Membership of a qualifying patient organisation. Applicants will have to be officially endorsed by one (or more) National Patient Organisation(s) and/or European Federation (s), which is registered in Europe and which operates in Europe. If an association does not yet exist for a disease (is the case for most ultra-rare diseases) the applicant will be evaluated on an ad-hoc basis and can be accepted as ePAG member, given agreement between ePAG, RND Network Coordinator and EURORDIS Patient Engagement Manager.
- Ability to comprehend technical, medical and regulatory issues and converse on a professional level with health care professionals
- Willingness to commit to **a minimum** of 18 days per year to RND-ERN work, ideally more

Desirable criteria:

- Have attended EURORDIS Summer School or EUPATI training or equivalent, or be willing to undertake such training either online or face-to-face.
- Skills or experience in disease areas not currently represented in RND-ERN ePAG
- Relevant skills or experience outside of medical area not currently represented in RND-ERN ePAG (eg data management)
- Geographic affiliation and experience not currently represented in ePAG.



4. Structure

The group elects a coordinator and an alternate. The coordinator represents the group in the ePAG Steering Committee. The group also elects a representative and an alternate for the ERN-RND Board. These designations are made by simple majority voting.

The coordinator is responsible for coordinating the group activities and must work closely with the ERN-RND coordination and the EURORDIS ePAG manager. The coordinator is responsible for setting up meeting agendas, minutes etc.

5. Coverage of Expenses

All duties as an ePAG advocate are unpaid. The group has an annual budget to cover travel costs. The budget is handled by the ePAG in close collaboration with the ERN-RND project manager and Coordinator. Priority is given to cover costs of attending the ERN-RND annual meeting, ERN-RND board meeting, ePAG steering committee meeting and a one day face-to-face meeting for the group to enable internal discussions and build the team identity and spirit.

6. Role and responsibilities of ERN-RND ePAG Advocates

All ePAG Advocates agree to represent the wider patient community and perform the following **role and responsibilities**:

- Work in partnership with the clinicians and researchers within ERN-RND
- Represent the voice of all patients from the rare disease(s) for which they are a Patient Advocate, provide feedback from that rare disease community, and create a bridge between ERN-RND and the that community to improve access to high quality diagnosis, care and treatment.
- Support ERN-RND 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, treatment policies, good practice guidelines and care pathways;
- Contribute to the development of research priorities and ensure they are informed by the needs of patients and families;
- Provide advice on ethical issues, and balance patient and clinical needs appropriately.

All ePAG Advocates also commit to adhering to the following set of **core values**:

- Respecting the mission of the ERN-RND Board 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;



- Having the capacity to be active in ERN-RND and report regularly on their activities

Additionally, all ePAG Advocates must also declare any potential Conflict of Interest in formal meetings or activities and remain independent, irrespective of their personal situation, pathology, and/or association and pharmaceutical industries or other commercial organisations.

They also commit to adhere to the terms of the mediation agreement that may result from a mediation process (described in the [EURORDIS ePAG Constitution](#) and Rules of Procedure). This mediation process is conducted by EURORDIS and is primarily to mediate disputes between Patient Advocates or Patient Organisations.

However, should there be disputes involving clinicians and patients, the ERN-RND Coordinator and the ePAG can jointly ask EURORDIS to mediate, if the dispute cannot be settled within the ERN. The same process, referred to above, would also be used to mediate in these disputes.

7. Termination of role of ePAG Patient Advocates

A Patient Advocate appointment in ERN-RND comes to an end if:

- The Patient Advocate sends a notice of resignation to the ERN-RND ePAG and to EURORDIS, or
- The ePAG does not respond to emails and does not contact the group in a period of 6 months, or
- The ePAG decides, in discussion with EURORDIS, and the ERN-RND Coordinator, that it is in the best interests of ERN-RND that the representative in question should be removed.
- Before any decision is finalized to remove someone from being an ePAG Patient Advocate:
 - both the ePAG Patient Advocate and EURORDIS must be informed of the reasons why it is proposed to remove them, and
 - at least one month should be allowed for mediation and any concerns raised to be addressed.

8. Authority of the ERN-RND Board

Nothing in this document removes the rights of the ERN-RND Network Coordinator and/or Management Board to interpret and/or amend the contents of this annex in the best interests of the Network or to comply with relevant directives or guidance from the European Commission.

