**Rules for patient engagement**

**Template of sections to be included in the ERN Bylaws/Governance rules**

**27/03/2024**

Text and sections highlighted in yellow are optional or need to be tailored to the governance terminology, please read the comments to adjust the template.

Section […]. Levels of patient engagement

Patient organisations and individual patient and family members can be involved in [insert name of ERN] in 2 different levels:

**1. Associate Partners**

Patient organisations that meet the following requirements may apply and be invited by the ERN Coordinator in agreement with the ePAG lead, on behalf of the ePAG, to join [insert name of ERN] as Associate Partners.

1. The organisation is legally registered and operates in [Europe](https://download2.eurordis.org/documents/pdf/EURORDIS_list_European_countries.pdf) (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe), representing patients and families living with a rare disease that belong to the scope of [insert name of ERN]. 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.
2. Has a governing board made up of a majority patients or of family members of patients. 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.
3. Is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies).
4. Holds non-profit status.
5. Has proven activities such as patient support and/or advocacy activities and/or research.

Patient organisations may contact, the ERN project management team to express their interest in engaging as Associate Partners and designating an ePAG advocate. EURORDIS should be made aware of all expressions of interest to kick-start the application process. EURORDIS ePAG managers will send the prospective applicant an application package composed of application form, ERN bylaws, ERN Rules for patient engagement, endorsement letter template, and ERN Conflict of Interest policy.

As part of the application process, these patient organisations will formally endorse an ePAG advocate to be active in [insert name of ERN] working groups. S/he will represent the voice and interests of all patients that fall under the scope of the ERN, beyond their own disease.

The application process as well as the rules of engagement with Associate Partners representatives (ePAG advocates) are detailed in Annex [insert Annex number] of these Bylaws.

If the application is successful, [insert name of ERN] and the patient organisation will sign an Associate Partnership Bilateral Agreement. Once this agreement is signed, the designated patient representative will be able join [insert name of ERN] and European Patient Advocacy Group (ePAG) as an ePAG advocate.

**2. Supporting Partners** In addition to Full Members and Affiliated Partners of the ERN networks, there is another term used to describe organisations or individuals that officially collaborate with ERNs, namely, Supporting Partners. According to the European Commission’s document on terminology issued on 20 June 2018, “it is proposed to use the term Supporting Partner as a generic term to define healthcare providers, medical societies, and any other entity or individual experts which, without having a commercial relation with the ERNs and their Full Members or Affiliated Partners, or with the European Commission, contribute in different ways to the work of the networks. When using the term Supporting Partner it shall be clear that it refers to a collaboration with entities, and individual experts which are neither Full Members nor Affiliated Partners”.

The following patient organisations with no designated patient representative in the ERN, as well as individual patients and family members or social-media patient support groups willing to collaborate with [insert name of ERN] may apply and be invited by the ERN Steering Committee in agreement with the ePAG to join as Supporting Partners.

1. Patient organisations registered in any of the 194 countries that are members of the WHO as non-profit organisations with a governing board made up of a majority of patients or of family members of patients and representing people living with a condition that belongs to the scope of [insert name of ERN] that do not have a formal designated representative in the ePAG.

These patient organisations represent an important component of the ePAG accountability and proper functioning. They may be willing to collaborate 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.

Patient organisations that are invited to collaborate as Supporting Partners should indicate a contact person who will act as the liaison between the patient organisation and the ePAG and ERN. Such individuals will not be formally involved in [insert name of ERN] as ePAG advocates.

1. Individual patients or family members may be invited to collaborate with the ERN and the ePAG on specific tasks or projects. Such individuals are not formally involved in [insert name of ERN] as ePAG advocates.
2. Social media-based patient support groups representing patients and families living with a rare disease that belongs to the scope of the [insert name of ERN], may be invited to collaborate with the ERN and the ePAG by signing up to receive and disseminate relevant information and/or materials.

Patient organisations, individual patients and family members and social media-based patient support groups may contact the ERN project management team to express their interest in engaging as a Supporting partner. The ERN project management team will request a motivation letter and the CV of the contact person who will act as a liaison with the Network, the individual patient or family member or the social media-based support group. The application will be considered by an Evaluation Committee composed by a clinical lead, an ePAG representative and the ERN Project Manager who will approve the collaboration with the Supporting Partner, or advice to the ERN Board when approval in unclear.

The ERN project management team will notify EURORDIS what patient organisations, social media-based support groups and/or individual patients or family members join the Network as Supporting Partners.

Supporting Partners and [insert name of ERN] will sign a collaboration agreement and meet at least once a year concerning the collaboration, expectations, and future directions.

Section […]. Obligations of Associate Partners

Associate Partners commit through their designated ePAG advocate to:

1. Champion the diversity of views of the [insert name of ERN] patient community, and not just to represent their own disease area nor their own experience.
2. Contribute to the overall strategy and mission of the ERN in all its aspects.
3. Participate to [insert name of ERN] annual meetings and relevant network meetings according to the ERN rules and subject to budget availability.
4. Adhere to the decisions of the ERN governance bodies, as far as concerned; and contribute to the reporting activity, as requested in the [insert name of ERN] monitoring procedures.

The role and responsibilities of Associate Partners representatives (ePAG advocates) are detailed in Annex… of these Bylaws.

Section […]. Rights of Associate Partners

* Each Associate Partner is licensed to use the generic ERN logo for [insert name of ERN] purposes.
* [insert name of ERN] Associate Partners shall have one single vote as a group. An ePAG advocate will be elected by the ePAG and will be a full member of the ERN Board to incorporate the voice and opinion of patient and families.

Section […]. Termination of Associate Partnership

An Associate Partner may lose its partnership for one of the following reasons:

1. Voluntary withdrawal. The legal representative of the organisation will write a letter to the ERN Coordinator explaining the reasons for the termination. The termination will be reviewed by the [insert name of ERN] Coordinator and project management team and an email will be sent to the to end the collaboration.
2. If the Associate partner is unable to fulfil essential parts of its bilateral cooperation agreement.
3. If the Associate Partner stops complying with the criteria outlined in Section (…)
4. Unauthorized use of the [insert email of ERN] logo on publications, symposia, advertisements, or in any other manner.
5. Unethical or unprofessional conduct of the designated ePAG advocate in the ERN prejudicial to [insert email of ERN] reputation and purpose.

An Evaluation Committee composed by a clinical lead, an ePAG advocate, a EURORDIS representative and the ERN project manager will examine the case and establish if there are reasons for termination based on the causes listed in 2, 3, 4 and 5. The Evaluation Committee can seek advice from clinicians, ePAG advocates and project managers involved in other ERNs. The Evaluation Committee shall inform the Associate Partner, the ERN Steering Committee, and the ePAG of the reasons for this decision. A letter will be sent by the [insert name of ERN] Coordinating Team with an explanation, after an additional consultation has been offered before, to exchange the views, discuss the change in collaboration and future options.

The loss of Associated Partnership shall lead to the automatic loss of any of the rights and

responsibilities associated with participation in the Network.

Section […]. Obligations of Supporting Partners

Supporting Partners commit to:

1. Collaborate with the ERN on areas of common strategic interest.
2. Help raise awareness about [insert name of ERN] about and contribute to disseminate information/surveys etc
3. Convey their opinions and input being respectful to the viewpoints and opinions of others and ensure criticism is constructive. An open and collaborative debate where all individuals can feel respected and valued is a core principle.
4. At the request of the ERN coordinator, consider attending the [insert name of ERN] annual meetings (with no financial compensation) with no voting rights but an advisory status and informative role.
5. At the request of the [insert name of ERN] Coordinator, consider participating in the development of specific collaborative activities, such as disease area clinical practice guidelines or other clinical decision support tools; ERN registry-related activities; training and education, awareness raising and communication or ERN research activities.
6. At the request of [insert name of ERN] ePAG, consider collaborating on specific tasks and projects to support the day-to-day work of the ePAG.
7. Attend at least an annual review meeting with [insert name of ERN], concerning the collaboration aspects, expectations and future directions.

Section […]. Termination of Supporting Partnership

If a Supporting Partner wishes to terminate his/her collaboration, in case of Conflict of Interest (CoI) or difference of directions, the legal representative of the organisation or, alternatively, the individual should write to the ERN Coordinator explaining the reasons for the termination. The termination will be reviewed by the [insert name of ERN] Coordinator and project management team and then a letter will be sent to the Supporting Partner to end the collaboration.

If [insert name of ERN] wishes to terminate the collaboration due to conflict of interest, difference of directions or other reasons, a letter will be sent by the [insert name of ERN] Coordinating Team with an explanation, after an additional consultation has been offered before, to exchange the views, discuss the change in collaboration and future options.