

EURORDIS European Patient Advocacy Group (ePAG) Constitution and Rules of Procedure

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Common Specifications and Definitions

1. Introduction

European Reference Networks (ERNs) have been established on the **founding principle of patient empowerment and involvement**¹, to improve access, safety and quality of diagnosis, care and treatment for people living with a rare or complex condition, or who require highly specialist interventions that call for the centralisation of cases, expertise and resources². Patient advocates are experts by experience and their participation in ERNs is recognised as integral to represent patients' needs and perspectives in network discussions and activities, and ultimately to support ERNs delivery on their goals.

The EUCERD ERN Recommendations and Addendum³, formally recognised the critical and integral role that patient representatives play as formal members of the decision and opinion making structures of ERNs. As experts by experience, rare disease patients draw on their knowledge of living with a rare disease, enhancing the expertise in clinical services and research networks, building a critical mass of knowledge to tackle the EU rare disease public health priority.

The European Commission led and supported Member States to organise the rare disease clinical and research community to create European Reference Networks through a Call for Applications for ERN and their Healthcare Provider Members (HCP). However, the EC Call for Applications only focused on organising the Full HCP Members under ERNs and not the organisation of the patient community. EURORDIS and the rare disease patient community have worked together for over a decade to develop the concept of European Reference Networks as patient centred networks, rooting patient involvement at all levels and across all ERNs and building on the experience and recognition gained from the pilot ERNs that recognised and valued patient representatives' contribution in rare disease networks.

In 2016, EURORDIS in collaboration with the European rare disease community established 24 **European Patient Advocacy Groups (ePAGs)** as forums to optimise the involvement of patient representatives of the rare disease community in the 24 ERNs. Each ePAG corresponds to the scope of one of the 24 ERNs, aligning patient organisations and clinicians, experts and researchers working on the same rare or complex disease or highly specialised intervention.

¹ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil, Annex 1(2b)

² OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

³ European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

2. Preamble

To organise and coordinate patient involvement in ERNs, this document sets out:

- a. The function and remit of the European Patient Advocacy Groups (ePAGs) and the criteria that patient representatives must fulfil to join an ePAG (**Part 1 - Founding Principles and Membership**) and;
- b. The process for establishing and governing ePAGs, the engagement of Patient Organisations with ePAGs and the recruitment process of ePAG Patient Advocates (**Part 2 - ePAG Rules of Procedure**);

The principles and approach described in this document sets out the **overall framework for patient involvement into ERNs**, ensuring unity, solidarity and equity of patient representation from the rare disease community. Recognising the heterogeneous nature of the rare disease patient community and their diverse needs, this framework for patient involvement into ERNs **can be locally adapted to best meet the specific needs of each ePAG patient community**.

3. Amendment of ePAG Constitution and Rules of Procedure

The ePAG Constitution and Rules of Procedure will be reviewed by the ePAG Steering Committee on an annual basis to ensure they remain fit for propose and adopted by the EURORDIS Board of Directors.

4. Definitions

- a. **European Patient Advocacy Group (ePAG):** A patient forum specific to each European Reference Network, established by EURORDIS to optimise patient involvement in the ERNs' decisions and activities.
- b. **ePAG Patient Community:** The group of Patient Organisations that have registered with EURORDIS to be engaged with a specific European Reference Network.
- c. **ePAG Patient Advocate of a European Reference Network (ePAG Patient Advocate):** A patient representative to a specific European Reference Network and who is active in the ERN governance structure including its working groups.
- d. **Patient Organisations (PO):** Patient Organisation that is registered either at a national or European level and who is active in advocacy work in the European Union.
- e. **ePAG Chair:** Appointed patient representative(s) who chair(s) the ERN Patient Board (please see definition below) and is a formal representative of the ERN Board.
- f. **ePAG Steering Committee:** Transversal Steering Committee of nominated ePAG Patient Advocates from the 24 ePAGs, to provide strategic advice, share experience and knowledge from the 24 ERNs.
- g. **ePAG Transversal Topic Based Groups:** Transversal peer learning groups composed by patient

representatives dedicated to a specific topic, e.g.: clinical guidelines and outcomes, research and registries, eHealth, training and education. These groups are aligned with the Network Coordinators' Transversal Working Groups (please see definition below).

- h. **EURORDIS ERN Team:** EURORDIS internal team that supports the development and coordination of patient involvement into ERNs, providing capacity building, advocacy and communication specifically on ERNs activities.
- i. **Board of Member States (BoMs):** a governing body consisting of representatives from Member States across Europe responsible for the formal designation of European Reference Networks as provided in the Commission Implementing Decision 2014/287/EU⁴.
- j. **European Reference Network (ERN):** a group of highly specialised healthcare providers that have been awarded with the membership of a given Network. Networks focus on 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 healthcare⁵.
- k. **Board of the Network:** the coordination body for each Network responsible for its governance, as foreseen in the Commission Delegated Decision 2014/286/EU³ (Annex I)⁶. All members of the Network must be represented on the Board.
- l. **ERN Patient Board:** A patient board, committee or council that formally reports to the ERN Network Board as defined by the ERN Governance Structure.
- m. **ERN Core Networks:** ERNs are thematic networks covering a number of rare or complex diseases and/or highly specialised interventions or surgery, as defined in their ERN application scope. Each ERN is structured differently to reflect the needs and grouping of their rare diseases into a number of 'Core Networks', also known as Disease Specific Networks or Sub-Thematic Working Groups, (e.g.: ERN-Lung has 9 core networks including Cystic Fibrosis, Pulmonary Hypertension, etc). Each one of these networks have a clinical committee or board of experts in that specific field to coordinate and lead the ERN activities specific to this disease area.
- n. **ERN Transversal Working Groups:** Each ERN has identified a number of transversal working groups on topics and activities that are cross-cutting all their core networks.
- o. **Healthcare Provider (HCP) Member:** A centre of medical expertise / excellence or specialist team treating rare and complex diseases, who has been endorsed by their Member State as an expert centre, is in compliance with the criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) and has been awarded with the membership of a given network.
- p. **Affiliated Partner:** Member States with no Member of a given Network may decide to designate

⁴ OJ L 174, 17.5.2014, p. 79, Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

⁵ OJ L 88, 4.4.2011, p. 45, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

⁶ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

healthcare providers with a special link to a given ERN, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing in the provision of healthcare, Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care or a National Coordination Hub who connects their national healthcare system with ERNs, coordinating information and referrals.

Part 1: Founding Principles & Membership

1. Mandate

Patient representatives and organisations are recognised 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 structures⁷.

2. European Patient Advocacy Groups (ePAGs)

European Reference Networks are comprised of Healthcare Providers Members (HCPs) that have been assessed by the European Commission to be Full Members or Affiliated Partners of their respective ERN. HCP Members are experts for specific rare diseases or highly specialised interventions and organised under one of the 24 ERNs. There is no legal basis for patient representatives or organisations to be formal members in an ERN.

European Patient Advocacy Groups (ePAGs) are patient forums comprised of Patient Organisations (ePAG Patient Community) wishing to engage in a specific ERN and their representatives (ePAG Patient Advocates) are endorsed by their respective Patient Organisations, to be active in ERN activities and governance board and committees. Each European Reference Network has one European Patient Advocacy Group composed by ePAG Patient Advocates.

Patient Organisations who wish to be involved in one of the ERNs may join an ePAG Patient Community. Patient Organisations can endorse a named patient representative (ePAG Patient Advocate) to act on their behalf and in the interests of the specific rare disease community covered by the scope of the ERN. Each ePAG Patient Advocate must commit to fulfilling the remit described in Section 4 below and meet the requirements described in Section 3 (Part 2).

i. Function and Remit of European Patient Advocacy Groups (ePAGs)

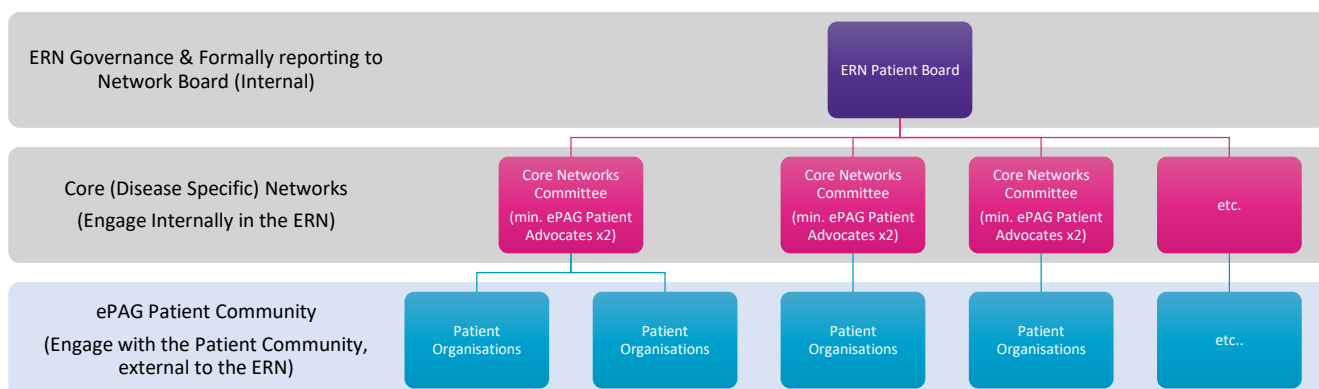
ePAGs aim to represent the voice of patients within ERNs to ensure the needs of people living with a rare disease are included in the strategic and operational delivery of the network. ePAGs create a bridge between the ERN and the patient community, to ultimately ensure that ERN services can answer to the needs and expectations of rare disease patients and therefore improve access to high quality diagnosis, care and treatment.

⁷ European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

ePAGs deliver these aims through their ePAG Patient Advocates undertaking the following activities inside the ERN governance structures:

- Assist the HCP Members of their ERN;
- Contribute to the development of information for patients: treatment policies, good practice guidelines and care pathways to ensure they are patient centred by reflecting and meeting the needs of patients;
- Participate to the development of a monitoring process of the outcomes of the ERN;
- Support the network in the dissemination of information and communication to the wider patient community;
- Contribute to the development of research priorities and ensure they are informed by the needs of patients and families;
- Provide advice on ethical issues on the application of personal data protection rules, compliance of informed consent and handling of complaints;
- Engage with the appropriate patient communities for disease specific activities and projects.

Diagram: Patient involvement into each European Reference Network is organised at three levels as outlined in the example below.



3. ePAG Patient Community

Joining an ePAG Patient Community is open to all patient organisations that register to be active and engage in one of the ERNs.

Each ePAG Patient Community is comprised of Patient Organisations, members and non-members of EURORDIS established in Europe, that register to engage with a specific European Reference Network. Each ePAG Patient Community is active within its wider patient community and commits to communicating, engaging and consulting externally to the ERN, with their respective patient community, specifically:

- Communication and information dissemination on ERN activities;
- Ensure feedback on patient experience in the development of guidelines and pathways;

- Promote the participation of their patient community in ERN activities.

4. ePAG Patient Advocate

ePAG Patient Advocates are active internally to the ERN, within the ERNs governance structures of network boards, committees and working groups. All patient advocates wishing to be involved in an ERN must have knowledge of the working group topic or experience of living with a rare disease that is included in the scope of that ERN.

Each ERN covers a thematic group of rare diseases or highly specialised interventions and is organised into multiple Core Networks. The thematic grouping of ERNs follows the EUCERD's ERN Recommendation's Addendum in their structure and focus. Each ERN Core Network has a committee, in which ePAG Patient Advocates will be active on behalf of their patient organisation AND respective patient communities.

In addition, each ERN has ePAG Patient Advocates who are formal members of the ERN Network Board or Executive Committee and who represent the ePAG in the Network Board discussions.

ePAG Patient Advocates provide their support on a voluntary basis and are unpaid for their work in ERNs. The policy for travel reimbursement for patient involvement in ERNs is set out individually in each ERN. There is no one policy applied across all ERNs; however travel and accommodation costs for patient representatives are normally covered by the ERN for their annual meeting.

i. ePAG Patient Advocates Role

All ePAG Patient Advocates agree to represent the wider patient community and perform the following role and activities:

- Assist the HCP Members within their ERN;
- Represent the voice of all patients within the ERNs ensuring that the needs of people living with a rare disease are included in the strategic and operational delivery of the network;
- Create a bridge between the ERN and the rare disease patient community to; ultimately, improve access to high quality diagnosis, care and treatment.
- Contribute to the development of patient information, treatment policies, good practice guidelines and care pathways;
- Support the network to disseminate information and communicate to the patient community;
- Contribute to the development of research priorities and ensure they are informed by the needs of patients and families;
- ePAG patient advocates provide advice on ethical issues, and balance patient and clinical needs appropriately;
- Ensure transparency in quality of care, safety standards, clinical outcomes and treatment;
- Ensure feedback of patient experience. Engage with the appropriate patient communities for disease specific activities and projects.

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

- Respecting the scope of the mission of the ERN Board, Executive Committee and working groups;
- Listen to the opinions and requests of others;
- Solidarity, mutual respect and support;
- Equity and social justice;
- Conduct themselves with professionalism in engaging with the clinical, research leads and fellow patient advocates;
- Capacity to be active in the ERN and report regularly on their activities;
- Ensure regular communication with their ePAG Patient Community and different relevant stakeholders.

ePAG Patient Advocates must declare any potential Conflicts of Interests in formal meetings or activities and remain independent, irrespective of their personal situation, pathology, and/or association and pharmaceutical industries

5. EURORDIS

EURORDIS will provide support to the establishment and operational delivery of ePAGs, ensuring that the vision, mission and core values of the organisation are respected. Specifically, providing the ePAG Patient Advocates with the necessary tools and training to support them in fulfilling their mission, ensuring regular communication and listening to their opinions.

EURORDIS will coordinate, administrate and support structuring of the patient community into ERNs and their respective ePAG, specifically:

- Engage with the ePAGs and support the recruitment of new ePAG Patient Advocates when identified;
- Provide technical expertise on ERNs, research, digital health, medicine development, etc;
- Raise awareness and capacity building for patient representatives and wider community;
- Engage with National Alliances and European Federations and wider patient community;
- Be a mediator and arbitrator of issues.

EURORDIS has set up an internal ERN Team to support all patient advocates who are active in ERNs. EURORDIS ERN Team is led by EURORDIS Director for Healthcare & ERNs and EURORDIS staff members dedicated to support specific ePAGs, in addition this core team is supported by EURORDIS leads in Public Affairs, Therapeutic Development & Access, Research & Social Policy and Communication Team.

The EURORDIS ERN Team will specifically:

- Engage with the [ePAG Steering Committee](#) to canvass opinion and views to inform advocacy activities towards the European Commission, Member States and ERNs;
- Provide capacity building and training;
- Provide technical support on ERNs activities (e.g.: research and registries, clinical guidelines and outcomes, education and training, etc.);
- Support the administration and organization of patient representatives into ERNs.

6. ERN Patient Board

ERNs are heterogeneous in their scope and, therefore, differ in terms of their governance structure to meet their network-specific needs. Some ERNs have formal Patient Boards, Committees or Councils that report to the ERN Board as defined by its governance rules. The ERN Patient Board members are endorsed patient advocates. Each ERN Patient Board has a set of common terms of reference that has been adapted to meet the specific needs of the ERN. Each ERN Patient Board has appointed patient advocate(s) who chair the ERN Patient Board and who formally represent the patient representatives and their respective communities on the ERN Board.

7. Transversal Patient Involvement

i. ePAG Steering Committee

EURORDIS has set up an ePAG Steering Committee which is a transversal committee of ePAG Patient Advocates from each of the 24 ePAGs. The ePAG Steering Committee's role is to:

- Peer-learning from each other by sharing their experience and knowledge from being active in the 24 ERNs;
- Provide strategic advice to inform and prioritise advocacy activities on behalf of all ePAGs and inform on areas of support and training needs to focus EURORDIS support and advocacy activities based on their collective needs.

ePAG Patient Advocates who are official members of the ePAG Steering Committee, may choose to become EURORDIS Volunteers and have an official permanent mandate to represent EURORDIS. As EURORDIS Volunteers they will have to adhere to the principles and obligations described in the [EURORDIS Charter of Volunteers](#) and report each year the time spent working for EURORDIS. Conversely, EURORDIS staff provide necessary support to help volunteers fulfil their mission. The monetary value corresponding to the time spent by EURORDIS volunteers will be taken into account in EURORDIS accounts as an in kind contribution. To formalise their designation, ePAG Patient Advocates will have to send an email to EURORDIS ERN team expressing their interest to become a EURORDIS Volunteer.

ii. ePAG Transversal Topic-Based Groups (TTGs)

EURORDIS has set up transversal Topic-Based Groups. These are peer learning groups dedicated to a specific topic, e.g.: clinical guidelines and outcomes, research, digital health, training and education. The TTGs are open to ePAG Patient Advocates who are active in their respective ERN transversal working groups for that specific topic.

Part 2: ePAG Rules of Procedure

1. Establishment of European Patient Advocacy Groups

ePAGs were launched in 2016 while the ERN network applications were being developed in answer to the EC Call for ERN Applications. The immediate and pressing priority for the patient community in developing ePAG forums was to ensure that there was sufficient patient capacity to support the establishment of ERNs and foster working partnerships with the clinical and research leads in the ERN formative years.

ePAGs range in size depending on the size and scope of their respective ERNs. However, the minimum level of patient representatives' capacity for each ePAG is **two ePAG Patient Advocates per each of the ERN Core Networks** that sit under the thematic structure of the 24 European Reference Networks. In addition, a **minimum of two ePAG Patient Advocates are appointed to be members of their ERN Network Board** and each of the ERN Transversal Working Groups. The process for identifying patient representatives to be formal members of ERN Boards is specific to each ERN and detailed in the ERNs 'rules of procedure'. These representatives have been agreed by the ERN Network Coordinator, their Network Board members and their ePAG.

ePAGs will initially run for a five-year term before undergoing a review and renewal process in parallel with the first evaluation of ERNs in 2021. This timeframe will allow the ePAGs to establish themselves, connect with the wider patient communities and be part of the development, planning and implementation phase of the ERNs.

2. ePAG Patient Community Registration

To join an ePAG Patient Community, and to collaborate, consult and be kept informed on the development of ERNs, a Patient Organisation should contact EURORDIS ERN team or register via the [online registration portal](#) and indicate which ERN grouping it wishes to be engaged with.

EURORDIS will inform the relevant ePAG and ERN management team of Patient Organisations, who are interested in registering to be engaged with an ERN and of new ePAG Patient Advocate applications, on a continuous basis.

3. Application for new ePAG Patient Advocates

Rare disease Patient Organisations, EURORDIS members and non-members established in Europe, may designate ePAG Patient Advocates. Each of the 24 ePAGs coordinate the recruitment of patient representatives as ePAG Patient Advocates. EURORDIS will engage with the ePAGs to identify gaps in patient representation in the ERNs and support to actively recruit new ePAG Patient Advocates.

The **eligibility criteria** for ePAG Patient Advocates are:

- To be officially endorsed by one or more Patient Organisation and/or a European Federation⁸;
- To be experienced in living with the rare disease included under the scope of the ERN or hold relevant expertise corresponds to the scope of the ERN Transversal Working Groups.
- To agree to meet the criteria and conditions for ePAG Patient Advocates outlined in the ePAG Constitution (see please Section 4, Part 1).
- To agree to adhere to the set of core values adopted in the ePAG Constitution (see please Section 4, Part 1).
- Able to speak fluent English (spoken and written).

4. Process of Approval for ePAG Patient Community and ePAG Patient Advocates

Enrolment of new Patient Organisations in the ePAG Patient Community and approval of ePAG Patient Advocates is through agreement in the ePAG and in consultation with the ERN Network Coordinator.

5. Time commitment

Patient representative involvement in an ERN is an important and unique opportunity to achieve a step-change in care for rare disease patients in Europe. Active involvement in an ERN requires a considerable investment in terms of time and workload for ePAG Patient Advocates in order to achieve meaningful benefits for our community. ePAG Patient Advocates are required to commit time to their role and is estimated as at a **minimum two days per month**. It is recognised that for the patient community, it can be from time to time impossible to meet this level of commitment and every effort will be made to support patient representatives where necessary.

6. ERN Patient Board

Each ERN has designed a specific governance structure to meet the needs of their network. Some ERNs have included a Patient Board (PB) as a formal board in their governance structure – called a Patient Board, Patient Council or Patient Advisory Committee. Each ERN Patient Board has its own terms of reference detailing the organisation and management of the Board. All have appointed patient representative(s) as Chair and Co-Chair. Please see their individual terms of reference for more detail.

7. European Patient Advocacy Groups (ePAG) Steering Committee

EURORDIS will lead the development of an ePAG Steering Committee and provide administrative and technical support. Each ePAG will appoint two ePAG Patient Advocates (lead and alternate) as their representatives on the Steering Committee. The ePAG Patient Advocates appointed to sit on the ePAG Steering Committee will (ideally) be members of the ERN Board.

The ePAG Steering Committee will run for five years before named representatives are renewed.

⁸ EURORDIS can endorse a patient **representative** on a temporary basis until the patient **representative** can be adopted by a patient organisation or a European Federation

8. Disputes

If a dispute arises between patient representatives in the ePAGs, they commit in good faith to try to take steps to resolve the dispute together and supported by EURORDIS. Confidentiality will be guaranteed in any mediation activity in which EURORDIS is requested to engage, however the ERN Coordinator will be informed on a confidential basis in all cases. If mediation is inconclusive and the circumstances are untenable, agreement will be reached on the appropriateness of termination of the ePAG Patient Advocate role in the ERN.

9. Conflicts of interest

ePAG Patient Advocates must comply with their ERN conflicts of interest policy.

10. Resignation of ePAG Patient Advocates

ePAG Patient Advocates can step down from the ePAG at any time through contacting EURORDIS and discussing their decision. EURORDIS will engage with the ePAGs to identify new ePAG Patient Advocates when needed.

11. Termination of role of ePAG Patient Advocates

Patient representative appointment in an ePAG comes to an end if:

- The ePAG Patient Advocate sends a notice of resignation to its ePAG and EURORDIS, or
- The ePAG decides, in discussion with EURORDIS, that it is in the best interests of the ePAG and ERN that the representative in question should be removed.
- Before the ePAG takes any decision to remove someone from being an ePAG Patient Advocate they must:
 1. inform the ePAG Patient Advocate and EURORDIS of the reasons why it is proposed to remove them, and
 2. give at least 1 month for mediation and any concerns raised to be addressed

12. Renewal of ePAG Patient Advocates Term

ePAG Patient Advocates and their appointment representation will be renewed in the last year of the ERNs five-year term. The process for renewal will be developed and agreed in 2021.