European Reference Network | ERN eUROGEN
Rare Urogenital Diseases & Complex Conditions

European Reference Network
for rare or low prevalence complex diseases
Network Urogenital Diseases (ERN eUROGEN)

ERN eUROGEN Rules for Patient Engagement

v. 2024-09-05

TABLE OF CONTENTS

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1. INTRODUCTION

1.1. History

According to the European Union Committee of Experts on Rare Diseases (EUCERD), patients and patient representatives should play an active role in the decision-making and opinion-making process of the European Reference Networks (ERNs) and be involved in structural and clinical network activities. EUCERD 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.

1.2. Purpose of Rules of Engagement

These rules aim at facilitating the effective involvement of patient representatives in the activities of ERN eUROGEN. 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 ERN eUROGEN Governance Statutes.

1.3. Amendments

The ePAG will review the rules annually at their Annual General Meeting (AGM) to ensure they remain fit for purpose and make any necessary amendments (see 2.3).

1.4. Authority of the ERN eUROGEN Strategic Board

Nothing in this document removes the ERN eUROGEN Strategic Board's right to interpret and/or amend its content in the best interest of the ERN or to comply with relevant directives or guidance from the EC.

2. EUROPEAN PATIENT ADVOCACY GROUP (EPAG)

2.1. Role

ERN eUROGEN's aim is that patient perspectives and the needs of people living with rare diseases and complex conditions covered by ERN eUROGEN are integrated into all aspects of the network's activities. To achieve this goal, the ePAG's role is to:

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

2.2. Composition

The ERN eUROGEN European Patient Advocacy Group (ePAG) consists of ePAG Representatives from patient organisations and/or individuals/parents/carers affected by rare uro-recto-genital diseases and complex conditions under ERN eUROGEN's scope. The ePAG Chair is responsible for coordinating the ePAG.

2.3. Meetings

The ePAG meets approximately every two months for approximately 1.5 hours during working hours. ePAG Representatives also attend meetings of the ERN Workstreams and Working Groups in which they decide to be involved, and the annual Strategic Board meeting (SBM), which is usually at least a full-day meeting.

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The ePAG meeting preceding the SBM is used as the ePAG's Annual General Meeting (AGM), where procedural items and governance matters can be dealt with ahead of the SBM, such as amendments to these Rules for Patient Engagement (see 1.3) and renewal of mandates (see 3.2 and 4.3).

2.3.1 Housekeeping Rules to Facilitate Effective Meetings

1. Participants should aim to join meetings from a private location where members of the public cannot overhear them and where there is no background noise.
2. Any items not on the agenda ('Any Other Business') should be declared at the start of the meeting so appropriate time can be allotted.
3. The Chair will raise the agenda items in order and will introduce anyone covering the items.
4. Anyone wishing to comment on/discuss the agenda items should use the meeting's "raise hand" feature and wait for the Chair to call them to speak in turn.

2.4. Decision-Making

Decisions in the ePAG are taken by consensus, but voting is possible if necessary. In the event of non-consensus, the voice of the ePAG Chair is predominant. The ePAG Chair casts two votes on behalf of the ERN eUROGEN ePAG on the ERN eUROGEN Strategic Board.

2.5. Administrative Support

The ERN eUROGEN Business Support Manager is responsible for supporting the administrative tasks of the ePAG group, including welcoming new ePAG Representatives or other members of the patient community, setting up the regular ePAG meetings (agenda, minutes, follow-up actions) and disseminating any relevant information to the ePAG.

3. EPAG CHAIR

3.1. Role and Responsibilities

In addition to the core values and role and responsibilities of the ePAG Representatives mentioned below, the ePAG Chair has the following responsibilities:

- Ensuring the sustainability of the ePAG.
- Coordinating the activities of the ePAG and reporting shared vision to the ERN Coordinator/Strategic Board and the EURORDIS Steering Committee/Transversal Group, etc.
- Sharing important news and updating the ERN eUROGEN ePAG and the wider patient community on ERN eUROGEN activities as appropriate.
- Consulting with the ERN eUROGEN ePAG and the wider patient community on relevant issues and feeding back information to the ERN eUROGEN Coordinator.
- Assigning ePAG Representatives to Working Groups.
- Monitoring ePAG Representatives' activities in the Working Groups
- Representing the voice of ERN eUROGEN ePAG and the wider patient community on the ERN eUROGEN Strategic Board, including casting two votes for the ERN eUROGEN ePAG on the ERN eUROGEN Strategic Board.

3.2. Mandate

The ePAG Chair is appointed for a period of three years. Their mandate may be renewed with the agreement of the ePAG and in consultation with the ERN eUROGEN Coordinator. When transitioning to a new Chair, where possible, they should represent a different Workstream and country than the previous Chair.

4. EPAG REPRESENTATIVES

4.1. Core Values

- Contribute to the overall strategy and mission of the ERN in all its aspects.

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- Champion the diversity of views of the ERN eUROGEN community, and not just represent one's own disease area or experience.
- Respect the confidential nature of the discussions when it is made clear that this is a requirement by the person who is chairing a meeting.
- Conduct oneself with professionalism in engaging with clinicians and fellow patient representatives.
- Listen to the opinions and requests of others and show solidarity, mutual respect and support.
- Adhere to the principles of equity and social justice.
- Convey opinions and input while being respectful of the viewpoints and opinions of others, ensuring criticism is constructive to allow open and collaborative debate where all individuals can feel respected and valued.

4.2. Roles and Responsibilities

The role of all ePAG Representatives is to:

- Respect and comply with ERN eUROGEN's mission and Governance Statutes, including the ERN eUROGEN Conflict of Interest policy, and adhere to the decisions of the ERN Strategic Board.
- Work in partnership with other patient representatives, clinicians and researchers involved in ERN eUROGEN.
- Be active in the ERN eUROGEN organisational structure (see the organisational structure chart on the network's website), including the Strategic Board, Workstreams, Expertise Areas, Work Packages and Working Groups (depending on interests, expertise and availability).
- Participate regularly in the majority of the ePAG meetings and send apologies in advance if unable to attend.
- Report regularly in the ePAG meetings on the progress of ERN eUROGEN work and projects in which they are directly involved. If unable to attend, the update should be sent by email ahead of the meeting.
- Participate in the ERN eUROGEN annual Strategic Board meeting and other relevant network meetings (when face-to-face, subject to budget availability).
- Contribute to identifying and developing the ePAG annual objectives and work programme.
- Contribute, where needed, to ERN registry-related activities, training and education, and the development of patient information, clinical practice guidelines, clinical decision support tools, and referral pathways.
- Contribute to reporting activity, as requested in the ERN eUROGEN monitoring procedures.
- Contribute to the development of research priorities and ensure the needs of patients and families are taken into consideration.
- Support the ERN to disseminate information, primarily to the patient community, but as appropriate to other communities (e.g. healthcare providers, health authorities, clinicians medical professionals and their professional bodies).
- Contribute to other ERN eUROGEN collaborative activities where patient involvement is required, as appropriate.
- Provide input on ethical issues, and balance patient and clinical needs appropriately.
- Scout for or make recommendations for new ePAG Representatives to cover under-represented Expertise Areas.
- Contribute to the assessment of new ePAG Representative applications.

4.3. Mandate

The appointment of new ePAG Representatives is initially for a six-month period. During this period, new ePAG Representatives will have the opportunity to familiarise themselves with the activities and their role and responsibilities. After this period, the ePAG Chair, in consultation with the ERN eUROGEN Coordinator, will validate the appointment of the ePAG Representative.

The mandate of ePAG Representatives lasts for three years. The mandate of ePAG Representatives may be renewed for another three years by reconfirming their willingness and presenting a new letter of endorsement signed by their patient organisation.

4.4. Skills and Experience

4.4.1 Required

ePAG Representatives should have:

- A knowledge of, or experience of living with, one of the rare and complex conditions included in the scope of ERN eUROGEN.
- Willingness and motivation to get involved and contribute actively to the discussions and work of the ePAG and the ERN Working Groups.

- The ability to work effectively and constructively with other patient representatives and clinicians from different EU countries.
- The ability to represent the interests of all Expertise Areas under the scope of ERN eUROGEN beyond their own Expertise Areas.
- The ability to bring independent judgement from a patient-representative perspective.
- An awareness of, and commitment to, equality, diversity and inclusiveness.
- A high level of organisation and self-motivation.
- An understanding of the need for confidentiality.
- The ability to communicate in English to be able to follow and contribute to meetings.
- Computer skills and equipment to communicate through email, webinars, and videoconferences.
- Knowledge, or are willing to acquire knowledge, on the rare disease policy environment.

4.4.2 Desirable

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

4.5. Benefits

Their role in ERN eUROGEN gives all ePAG Representatives the possibility to:

- Work closely with clinicians, researchers, and other patient representatives to transform healthcare services and accelerate research to improve the health outcomes of people living with a rare disease in Europe.
- Participate firsthand in the development of the ERN objectives and infrastructure to ensure that it remains driven by patients' needs.
- Increase their international exposure and expand their international network, specifically across Europe.
- Improve their understanding of healthcare models across Europe and European Reference Networks.
- Further 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 Representatives and build their own capacities as patient representatives, broadening knowledge both within their own field of rare diseases and beyond.

4.6. Time Commitment

As stated above ('Meetings'), ePAG Representatives will be required to attend ePAG calls approximately every two months, which will generally take place for approximately 1.5 hours during working hours. They will also need to attend the calls of the ERN Workstreams and Working Groups in which they decide to be involved, as well as the annual Strategic Board meeting, which is usually at least a full-day meeting. In addition, they will need to dedicate time to reviewing and reading documents, if necessary, ahead of the meetings and calls. This implies a commitment of typically two days per month, depending on projects and activities, and can increase to approximately five days per month in the case of the ePAG Chair.

4.7. Reimbursement

The position of ePAG Representative is a voluntary position and does not involve any financial compensation. However, as outlined in the ERN eUROGEN Reimbursement Factsheet (v.2023-11-06), ERN eUROGEN will reimburse expenses for ePAG Representatives when participating in official ERN duty. In accordance with EC regulations, ERN eUROGEN will reimburse claimants the maximum EC Unit Costs for travel, accommodation, and (for non-catered events) subsistence, regardless of the actual costs.

4.8. Substitutes

ePAG Representatives may nominate a substitute from their own patient organisation to attend specific ePAG or other network meetings if adequately briefed beforehand on the topic area. The ePAG Chair lead shall validate the participation of such substitutes in the ePAG or ERN meetings, respectively. Substitutes must comply with the ERN eUROGEN Conflict of Interest policy (see Governance Statutes) and with the core principles laid down above when attending ePAG or ERN meetings.

5. EPAG APPLICATION PROCESS

5.1. Deciding Whether to Apply

The following information may be helpful:

- EURORDIS Guide: 'Thinking of getting involved in the ERNs as an ePAG advocate?'
- EURORDIS Video: 'European Reference Networks and European Advocacy Patient Groups 101'
- EURORDIS Podcast: ERNs on AIR (particularly episodes 1-4 of ERNs on AIR, not RARE ON AIR episodes, which are different)

5.2. Route 1: Through EURORDIS as Associate Partners

Patient organisations may apply through EURORDIS if the organisation 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) and represents patients and families living with a rare disease that belongs to the scope of ERN eUROGEN. [NB. 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.]

If a patient organisation contacts the ERN eUROGEN Coordination Team expressing their interest in designating an ePAG Representative to be active in ERN eUROGEN, EURORDIS should be made aware to kick-start the application process.

The EURORDIS ePAG manager will send the prospective applicant an application package composed of an application form, an endorsement letter template, the ERN eUROGEN Governance Statutes, the ERN eUROGEN Rules for Patient Engagement, and the ERN eUROGEN Conflict of Interest Disclosure Form.

The prospective applicant should send the EURORDIS ePAG manager:

1. A completed and signed application form.
2. An endorsement letter signed by the legal representative of the patient organisation.
3. The statutes of the patient organisation.
4. A list of the patient organisation's Board of Directors, indicating for each person whether they are a patient or family member of a patient.
5. The patient organisation's most recent Annual Report, including a financial statement.
6. A completed ERN eUROGEN Conflict of Interest Disclosure Form if they have anything to declare.

Once received, the applications are processed as follows:

1. The EURORDIS ePAG Manager shares the application and accompanying documents with the ERN eUROGEN Coordination Team, who in turn share it with an ERN eUROGEN Evaluation Committee composed of the ePAG Chair, the relevant Workstream Lead, the relevant Expertise Area Coordinator, and the Programme Manager.
1. The Coordination Team will review the information pertaining to the patient organisation to ensure that the requirements for patient organisations described in the Governance Statutes are met.
2. The Evaluation Committee reviews and discusses the application. Applicants are assessed against the required skills and experience outlined above. Selection is based on the content of the application form and accompanying documents.
3. The Coordination Team and Evaluation Committee 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.
4. Prospective applicants who represent a country or a disease not currently represented in the ePAG will receive priority.
5. Approval of new ePAG Representatives is through agreement in the ePAG and in consultation with the Coordinator.
6. All applications will receive a successful or unsuccessful notification.
7. If the application is successful, the ERN Coordination Team will send the patient organisation a Patient Engagement Agreement for Associate Partners. Once the agreement is received and signed by the ERN Coordinator and the patient organisation, the applicant becomes an ePAG Representative and can attend ePAG and ERN meetings.

A diagram of this process is given in Annex 1.

5.3. Route 2: Directly through ERN eUROGEN as Supporting Partners

The following can apply directly to the network and join as Supporting Partners[1].

[1] In accordance with 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".

1. Patient organisations that do not meet the requirements to apply through EURORDIS, i.e., those 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 ERN eUROGEN.
2. Individual patients or family members.

If these contact the ERN eUROGEN Coordination Team expressing their interest in designating/being an ePAG Representative to be active in ERN eUROGEN, the ERN eUROGEN Coordination Team will send the prospective applicant an application package composed of the ERN eUROGEN Governance Statutes, the ERN eUROGEN Rules for Patient Engagement, and the ERN eUROGEN Conflict of Interest Disclosure Form.

The prospective applicant should send the ERN eUROGEN Coordination Team:

1. A motivation letter explaining how they would like to collaborate with the ERN.
2. Their CV.
3. A completed ERN eUROGEN Conflict of Interest Disclosure Form if they have anything to declare.

Once received, the applications are processed as follows:

2. The ERN eUROGEN Coordination Team shares the application and accompanying documents with an ERN eUROGEN Evaluation Committee composed of the ePAG Chair, the relevant Workstream Lead, the relevant Expertise Area Coordinator, and the Programme Manager.
3. The Evaluation Committee reviews and discusses the application. Applicants are assessed against the required skills and experience outlined above. Selection is based on the content of the motivation letter and CV.
4. The Evaluation Committee 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. Prospective applicants who represent a country or a disease not currently represented in the ePAG will receive priority.
6. Approval of new ePAG Representatives is through agreement in the ePAG and in consultation with the Coordinator.
7. All applications will receive a successful or unsuccessful notification.
8. If the application is successful, the ERN Coordination Team will send the patient organisation a Patient Engagement Agreement for Supporting Partners. Once the agreement is received and signed by the ERN Coordinator and the applicant, the applicant becomes an ePAG Representative and can attend ePAG and ERN meetings.

The ERN eUROGEN Coordination Team will notify EURORDIS which patient organisations and/or individual patients or family members join the ePAG as Supporting Partners.

6. INDUCTION

6.1. EURORDIS

All new ePAG Representatives should complete an interactive online induction session. EURORDIS delivers these webinars quarterly. They last an hour and a half and provide some background information about the ERNs and ePAGs and the work that they do.

6.2. ERN eUROGEN

In addition, new ePAG Representatives will also receive an information pack about the work of ERN eUROGEN and have a meeting with the ePAG Chair and ERN eUROGEN Programme Manager.

7. SUSPENSION AND TERMINATION

7.1. Voluntary Suspension

At any time, an ePAG Representative can send a notice of temporary suspension to the ePAG Chair and the ERN eUROGEN Coordinator (and, where applicable, to EURORDIS) if they would like to voluntarily step down for a period of time.

7.2. Termination

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

1. The ePAG Representative sends a notice of resignation to the ePAG Chair and ERN Coordinator (and, where applicable, EURORDIS), explaining the reasons for the resignation.
2. The patient organisation (where applicable) withdraws the endorsement given to the ePAG advocate and sends a notice to the ePAG Chair and ERN Coordinator (and, where applicable, EURORDIS), explaining the reasons for the withdrawal.
3. The ePAG Representative does not respond to emails, attend meetings or does not contact the ePAG group for a period of three months.
4. The ePAG Representative is unable to fulfil the roles and responsibilities listed above.
5. The ePAG Representative is unable to respect the core values listed above and/or engages in unethical or unprofessional conduct prejudicial to ERN eUROGEN's reputation and purpose.

7.3. Evaluation Process

In the circumstances referred to in points 3-5 above, before any decision is made to remove someone from being an ePAG Representative, an Evaluation Committee composed of the ePAG Chair, the relevant ERN eUROGEN Workstream Lead, and the ERN eUROGEN Programme Manager (and, where applicable, a EURORDIS representative) will examine the case and establish if there are reasons for termination. The Evaluation Committee may seek advice from other clinicians, ePAG Representatives, and project managers involved in other ERNs. The ePAG Representative (and, where applicable, their endorsing patient organisation) must be informed of the reasons why it is proposed to remove them, including an opportunity for open discussion. At least one month should be allowed for mediation and for any concerns raised to be addressed. If the decision is made to terminate, a final letter confirming the end of the collaboration will be sent to the ePAG Representative (and, where applicable, their endorsing patient organisation).

8. OTHER PATIENT ENGAGEMENT

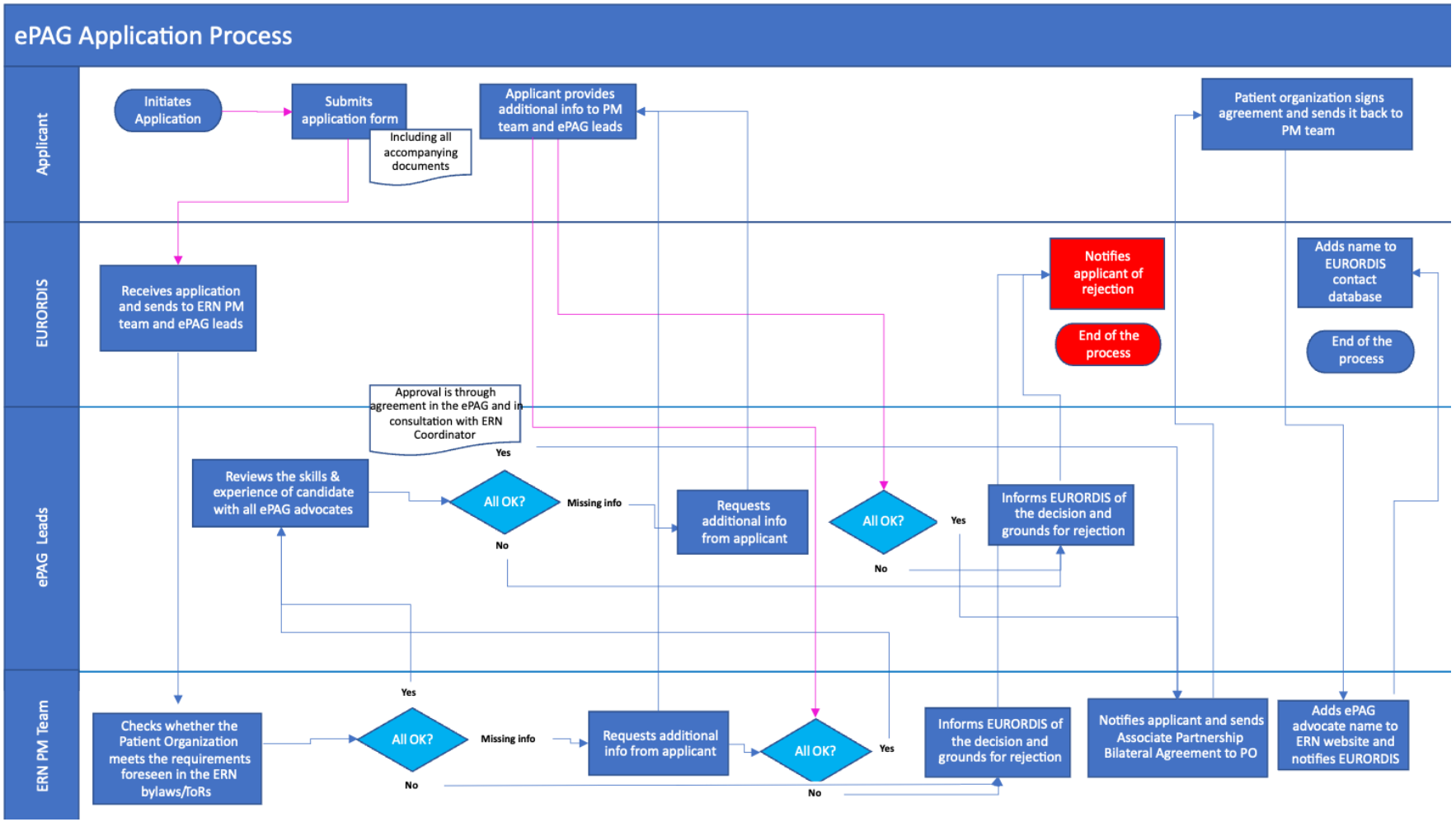
Patient organisations, individual patients or family members, and social media-based patient support groups both inside and outside of Europe may be invited to collaborate with the ERN and the ePAG without being formally involved in ERN eUROGEN as ePAG Representatives. They may be willing to collaborate on specific tasks (e.g., advise on guidelines, respond to surveys), help to disseminate information and/or materials about the ERN across their wider patient community, be consulted occasionally for feedback, and be kept informed on the development of the ERN activities.

Where it is felt necessary by the ePAG and the ERN eUROGEN Coordination Team, Memorandums of Understanding will be signed to outline and formalise the collaboration.

Funded by the European Union

ERN eUROGEN is a European Reference Network (ERN) approved by the ERN Board of Member States (BoMS). For more information about the ERNs and the EU health strategy, please click here. The ERNs are funded by the European Union.

ANNEX 1



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