

ePAG Constitution

EURORDIS approach to structure patient partnership in the European Reference Networks

(31 Aug 2022)

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1. Terms and Definitions

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 healthcare¹.

Board of Member States (BoMs): a governing body consisting of representatives from Member States across EU Member States and European Economic Area responsible for the formal designation of European Reference Networks as provided in the Commission Implementing Decision 2014/287/EU². The Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs).

Patient Organisations (PO): Non-profit organisations that are legally registered and operating in [Europe](#) (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, has a governing board made up of a majority patients or of family members of patients, is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies) and has proven activities such as patient support and/or advocacy activities and/or research. Individual ERNs may waive some of these requirements in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.

Patient partnership: a mutual relationship between persons living with a rare disease and other stakeholders where input from people living with a rare disease or caring for someone with a rare disease routinely and formally informs policy reflections and decisions. Patient partnership implies going beyond empowerment and engagement but considering people living with a rare disease and their advocates as equal partners and actors in policy and programme design and evaluation. For the purposes of this governance framework the terms "patient involvement" and "patient partnership" are used interchangeably.

ERNs Associate Partner - Patient Organisation: Patient Organisation registered and operating in [Europe](#) that has been invited to partner with an ERN, complies with the requirements established by the ERN and has gone through the Network's application process to designate a patient representative to be involved in the ERN activities as an ePAG advocate. An Associate Partner agreement is signed between the ERN and the Patient Organisation to establish the terms of this collaboration.

ERN Supporting Partner - Patients: Patient Organisation with a national, European or international remit with no designated patient representative in the ERN, individual patients and family members or social-media patient support groups that have been invited to collaborate with an ERN. A Supporting

¹ 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

² 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

Partner Agreement is signed between the ERN and the Patient Organisation, individual or support group to establish the terms of this collaboration.

ePAG Advocate: A patient representative to a specific European Reference Network who has been endorsed by an ERN Associate Partner-Patient Organisation to be active in the ERN governance structure including its working groups. For the purpose of this framework, the terms ePAG advocate, patient representative and patient advocate are used interchangeably.

European Patient Advocacy Group (ePAG): A patient group, specific to each European Reference Network, composed by patient advocates that have been endorsed by a Patient Organisation established by EURORDIS to optimise patient involvement in the ERNs' decisions and activities. Some ERNs have formally recognised these groups as part of their governance structure. 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.

ePAG Steering Committee: Transversal working set up and managed by EURORDIS composed by ePAG Advocates from the 24 ePAGs sitting in the ERNs Boards or Executive Committees to provide strategic advice, share experience and knowledge from the 24 ERNs.

ePAG Transversal Topic Based Groups: Transversal peer learning working groups set up and managed by EURORDIS composed by ePAG Advocates dedicated to a specific topic, e.g.: clinical practice guidelines and clinical decision support tools, communication and dissemination, research and registries, training and education, monitoring and evaluation.

ERN Coordinator: the person appointed as the Coordinator of the Network by the Member of a European Reference Network chosen as the coordinating Member as referred to in recital 3 and Article 4 of Delegated Decision 2014/286/EU.

ERN Project Managers: the persons in charge of coordinating the Networks' collaborative activities, financial and technical reporting, monitoring and evaluation.

Board of the ERN: the coordination body for each Network responsible for its governance, as foreseen in the Commission Delegated Decision 2014/286/EU³ (Annex I)³. All members of the Network must be represented on the Board.

ERN Core Networks (or sub-thematic 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.

ERNs Coordinators Group: a working group that brings together the Coordinators of the 24 ERNs to discuss common technical matters.

³ 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

ERN Transversal Working Groups: Transversal working groups set up by the ERN Coordinators, sometimes jointly with the ERNs BoMs, to discuss on topics and activities that are cross-cutting all 24 ERNs e.g.: clinical practice guidelines and clinical decision support tools, legal and ethics, research, training and education, integration of ERNs into national health systems, monitoring and evaluation.

ERN 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.

ERN Affiliated Partner: Member States with no Member of a given Network may decide to designate 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 on 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.

ERN Supporting Partner: 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.

EUCERD: European Union Committee of Experts on Rare Diseases established to support EU policy on rare diseases, and specifically provide policy guidance on the effective implementation of the 2008 EU Commission Communication on Rare Diseases and the 2009 Council (of the European Union) Recommendation on action in the field of rare diseases. In 2013 it was replaced by the European Commission Expert Group on Rare Diseases (CEG –RED) whose mandate terminated in 2016. The EUCERD and CEG-RD brought together representatives from: the 28 EU Member States, Iceland, Norway, Switzerland, the EU Commission, the Committee for Orphan Medicinal Products of the EMA, industry, academia, eight individual experts as well as eight patient advocates.

2. Introduction

European Reference Networks (ERNs) have been established on the founding principle of patient empowerment and involvement⁴, 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 resources⁵. Rare disease patient representatives are experts by experience and their participation in the ERNs is central to represent patients' needs and perspectives in the Networks' discussions and activities, and ultimately to support ERN delivery on their goals.

⁴ 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)

⁵ 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

The European Union Committee of Experts on Rare Diseases (EUCERD) ERN Recommendations and Addendum⁶, formally recognise the critical and integral role that patient representatives play as formal members of the decision and opinion making structures of the 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, and building a critical mass of knowledge to tackle the EU rare disease public health priority.

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 in the strategic and operational delivery of the 24 ERNs. Each ePAG corresponds to the scope of one of the 24 individual ERNs, aligning patient organisations and clinicians, experts and researchers working on the same rare or complex disease or highly specialised intervention. These groups are composed by appointed patient representatives, some of which were elected in 2016 and others who have been co-opted.

ePAGs, bring together over 300 patient representatives who are actively involved in the ERNs. ePAG advocates play a fundamental role to connect the Networks with the wider rare disease patient community and, where relevant, to champion the diversity of views of these wider patient community relevant for each ERN, and not just of their own disease area.

3. Framework to structure patient partnership in the ERNs

This document describes EURORDIS role to support patient partnership in the ERNs. In addition, in collaboration with patient representatives and ERN project managers EURORDIS [has developed four governance templates](#) to structure patient partnership in the ERNs that individual ERNs may adapt to their own specificities:

1. [Sections on rules for patient engagement to be included in the ERN bylaws;](#)
2. [Rules for Associate Partners Representatives \(ePAG advocates\);](#)
3. [Associate Partners agreement between the ERN and Patient Organisations that have designated an ePAG advocate;](#)
4. [Supporting Partners agreement between the ERN and individual patients and family members and patient organisations with no designated ePAG advocate in the ERN.](#)

These four templates, together with the present document, constitute EURORDIS framework to structure patient partnership in the ERNs. A framework that recognises the heterogeneous nature of the rare disease patient community and their diverse needs while ensuring unity, solidarity and equity of patient representation from the rare disease community.

⁶ European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

4. Mandate for patient partnership in the ERNs

According to the EU Committee of Experts on Rare Diseases (EUCERD)⁷, patients and patient representatives should play an active role in the decision and opinion making process of the ERNs and be involved in structural and clinical network activities. The Expert Group recommended that ERNs demonstrate meaningful patient involvement, patient-centredness 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.

5. EURORDIS role to support patient partnership in the ERNs

EURORDIS supports and provides patient representatives involved in the ERNs with the information, knowledge and skills that they need to engage and partner effectively with clinicians in the Networks' collaborative activities, specifically by:

- Creating working groups with ePAG advocates from different ERNs on relevant topics to disseminate information and share knowledge (e.g.: research and registries, clinical practice guidelines, education and training, evaluation and monitoring, etc.);
- Creating opportunities for peer-to-peer learning and developing capacity building activities;
- Developing practical guides to facilitate patient partnership in different ERN-related activities;
- Facilitating team building and partnership approach in the ERNs between patient representatives and clinicians;
- Engaging with patient representatives, clinicians and ERN project managers to assess the value of patient partnership in the ERNs;
- Engaging with the ERN project managers to implement a harmonised approach to patient partnership in the ERNs;
- Supporting the recruitment of new ePAG advocates;
- Facilitating the collaboration between ePAGs, National Alliances and European Federations on ERN matters;
- Mediating in conflicts.

6. EURORDIS ERN & ePAG Team

EURORDIS ERN & ePAG team supports all patient representatives who are active in the ERNs. The team is composed by EURORDIS ERN & Healthcare Director, 1 Senior Patient Engagement Manager, 1 Junior Patient Engagement Manager, 1 part-time Senior Patient Engagement Manager and 1 part-time Senior

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

ERN and Healthcare Advisor. In addition, this core team is supported by EURORDIS leads in Public Affairs, Research, Therapeutic Development & Access and EURORDIS Communications Team.

7. EURORDIS ePAG transversal working groups

EURORDIS has moved progressively from providing hands-on support to individual ePAG groups to supporting patient representatives via cross-ePAG groups working groups (WGs) focusing on transversal topic areas. Currently EURORDIS manages the following ePAG WGs:

1. ePAG Steering Committee
2. Connecting Patients with ERNs Working Group
3. ePAG Clinical Practice Guidelines Working Group
4. ePAG Research and Registries Working Group
5. ePAG Training and Education Working Group
6. ePAG AMEQUIS Task Force
7. ePAG Patient Partnership Working Group

All of the above working groups are open on an ongoing basis to all ePAG advocates. The exception is the ePAG Steering Committee which is only open to 2 advocates per ePAG, who sit on the ERNs Boards or Executive Committees. In each individual ePAG, patient representatives discuss how to distribute the work and who will participate to the different EURORDIS ePAG WGs based on their interests and availability.

5.1 ePAG Steering Committee

EURORDIS has set up an ePAG Steering Committee which is a transversal committee of ePAG advocates from each of the 24 ePAGs.

The ePAG Steering committee is composed by ePAG advocates of the 24 ERNs who sit on the ERNs Boards or Executive Committees and EURORDIS.

This group provides advice to the ERNs, the European Commission (EC) and the ERN Board of Member States (BoMs) on patient partnership and ensures a common approach to involving patients in the ERNs. It does this by:

- identifying, sharing experiences, discussing and making recommendations regarding issues which are common to all or a sub-set of ePAGs.
- reporting on important updates on ERNs-related initiatives to the 24 ePAGs and gathering their feedback.
- identifying areas for additional horizontal ePAG working groups.

ePAG Advocates who are 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 advocates will have to send an email to EURORDIS ERN team expressing their interest to become a EURORDIS Volunteer.

5.2 ePAG transversal topic-based working groups

Through this working group structure, EURORDIS and the patient representatives involved in the ERNs share information and updates, learn from each other, develop materials and support ePAG advocates to engage on important topics. EURORDIS has set up and manages the following transversal working groups:

1. **Connecting Patients with ERNs WG:** facilitates collaboration with Rare Diseases National Alliances to produce communication resources to reach out to patients. to facilitate collaboration between ePAG advocates and Rare Diseases National Alliances, so that the information on ERNs is more easily shared at national level.
2. **ePAG Clinical Practice Guidelines WG:** supports patient partnership in the development and implementation of clinical practice guidelines (CPG) and other clinical decision support tools (CDST).
3. **ePAG Research and Registries WG:** supports patient partnership in research activities.
4. **ePAG Training and Education WG:** develops training & capacity building materials and activities to address ePAG advocates training needs.
5. **ePAG AMEQUIS Task Force:** supports patient partnership in the monitoring, evaluation and quality improvement system of the ERNs.
6. **ePAG Patient Partnership WG:** supports implementation of tools and processes to foster a patient-clinician partnership culture that is similar across all ERNs.

8. Conflict Mediation

If a dispute arises between ePAG advocates, they commit in good faith to try to take steps to resolve the dispute together. They may seek advice from EURORDIS if needed by approaching any member of the EURORDIS ERN team.

If the parties cannot settle the dispute in a satisfactory way, any of them may request EURORDIS to mediate by submitting a Request for Mediation Form (Annex II). Having a dispute mediated by EURORDIS is a voluntary process. When EURORDIS receives a Request for Mediation form, a member of the EURORDIS ERN team will first contact the other party or parties involved and seek their agreement to mediate.

Once the agreement to mediate has been obtained from all parties involved, the mediation process will be conducted following the process described in Annex I. The parties commit to adhere to the terms of the mediation agreement that may result from a mediation process that they voluntarily decide to initiate.

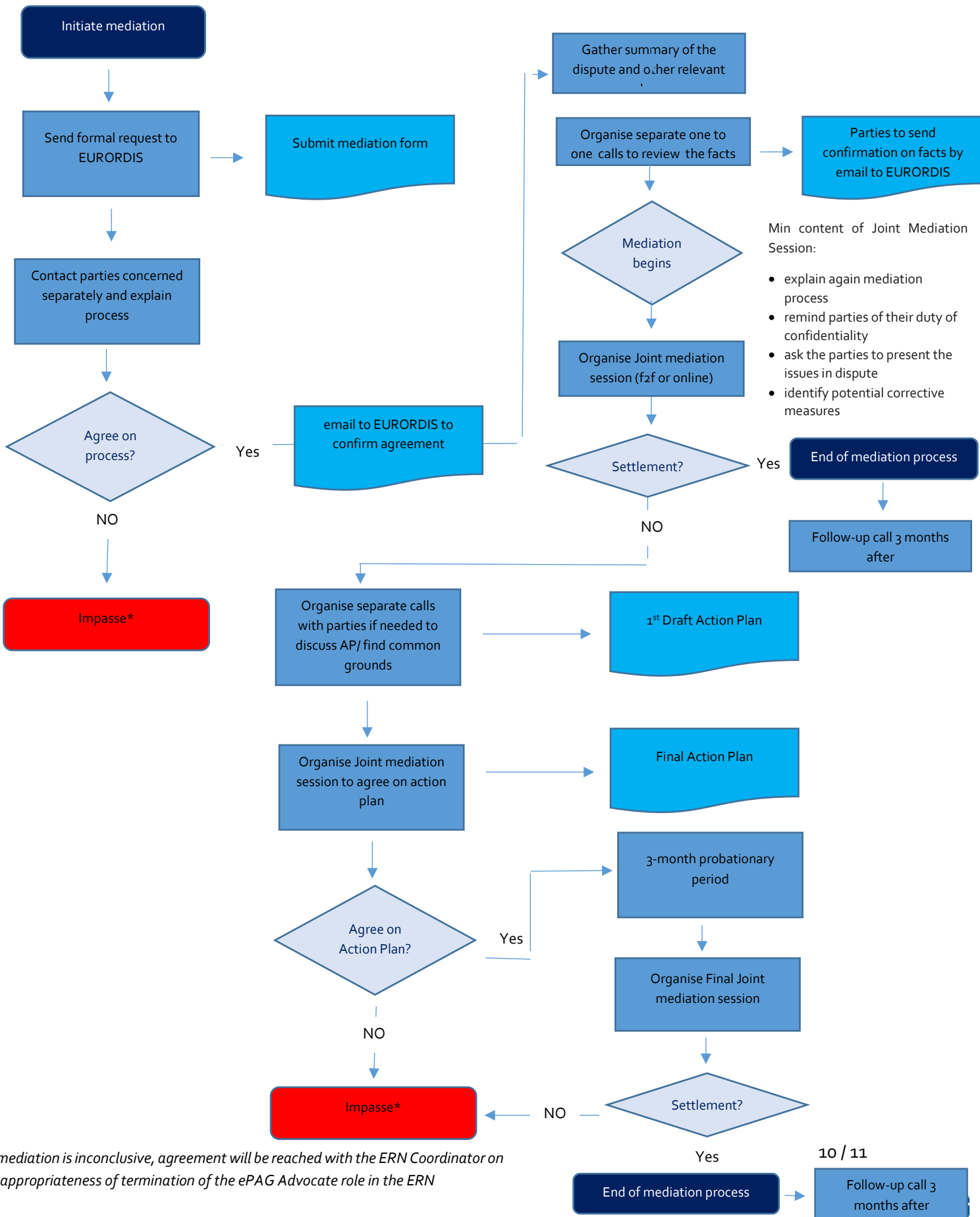
Confidentiality will be guaranteed in any mediation activity in which EURORDIS is requested to engage, however the ERN Coordinator will be informed on a confidential basis in all cases. If mediation is inconclusive and the circumstances are untenable, agreement will be reached with the ERN Coordinator on the appropriateness of termination of the ePAG advocate mandate in the ERN.

In disputes involving clinicians and patients, an ERN Coordinator and the ePAG Chair can jointly ask EURORDIS to mediate if the dispute cannot be settled within the ERN. The same process described in Annex II will be used to mediate in these conflicts.

9. Amendment of ePAG Constitution

The ePAG Constitution will be reviewed by the ePAG Steering Committee on an annual basis to ensure it remains fit for purpose and will be adopted by the EURORDIS Board of Directors.

Annex I: Mediation Process



**If mediation is inconclusive, agreement will be reached with the ERN Coordinator on the appropriateness of termination of the ePAG Advocate role in the ERN*

Annex II: Request for Mediation Form

Having your dispute mediated by EURORDIS is a voluntary process. When EURORDIS receives your Request for Mediation form, a member of the EURORDIS ERN team will contact the other parties and seek their agreement to mediate. You will receive copies of our communications to the other parties.

Once all parties have agreed to the process and mediation is initiated, the parties commit to adhere to the terms of the mediation agreement that may result.

Please fill out the form completely. **Missing information may delay the processing of your request.**

Party seeking mediation:

Name

Surname

Email address

Telephone

Please provide a brief description of the dispute. Include a summary of what occurred, relevant dates, names and titles of all individuals involved, and the settlement requested (*e.g.* resignation of a Chair, selection of new ePAG Advocate or what type of solution you are seeking for).

Please provide the following information for all parties to the dispute:

Name

Email address

Telephone number

Please email this completed form to: ines.hernando@eurordis.org