

## FREQUENTLY ASKED QUESTIONS

### 1. What is an ERN?

A network connecting health care providers and centres of expertise of highly specialised healthcare, for the purpose of improving access to diagnosis, treatment and the provision of high-quality healthcare for patients with conditions requiring a particular concentration of resources or expertise no matter where they are in Europe. For clinicians who network widely already, the ERN will represent the formalisation of their networking structures/practices in highly specialized healthcare. For those without specialist networking communities at present, ERNs will promote expertise and support health care providers in order to bring local, regional and national provision of healthcare closer to the patients.

### 2. What is the role of the Board of MS?

The Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs) and members of the Networks. The BoMS consists of representatives from across the EU Member States and European Economic Area (EEA). The Board's main roles and responsibilities are to:

- Develop and maintain rules of procedure for the BoMS (functioning and decision-making process);
- Review the unfavourable opinion of the Board of the Network on the basis of the criteria and conditions set in point 2 of Annex II to Delegated Decision 2014/286/EU upon request of the Member State of establishment;
- Can decide whether the application of a HCP with unfavourable opinion by the BoN can nevertheless be submitted to the Commission for further assessment;
- Review the assessment reports and recommendations from the IAB;
- Approve proposals for ERNs;
- Approve proposals to add one or more members to an existing ERN;
- Approve the termination of an ERN;
- Decide on the loss of membership of one or more members of an existing ERN;

### 3. What are the roles of healthcare providers/CEs in ERNs?

An ERN is centred on highly specialised healthcare, first and foremost, and is expected to demonstrate:

- knowledge and expertise to diagnose, follow up and manage patients with complex diseases or conditions which necessitate highly specialized healthcare
- evidence of good outcomes of a multi-disciplinary approach to care
- capacity to produce good practice guidelines and to implement outcome measures and
- quality control o research, teaching and training
- collaboration with other centers of expertise and networks

In addition, the Delegated Decision (Annex II) stipulates criteria for all ERN members to meet, with regards to:

- patient empowerment and patient-centred care of organisation, management and business continuity or research and training capacity
- exchange of expertise, information systems and e-health tools or expertise, good practices, quality, patient safety and evaluation

#### **4. Are only rare diseases included in the scope of ERNs?**

The scope of the ERNs, as laid out in the legal basis, is to provide highly specialised healthcare for both patients suffering from "rare diseases" or "low prevalence and complex diseases or conditions". The Networks' objective is to improve the access to diagnosis, treatment and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise.

#### **5. How to apply to become a member of an ERN?**

The applicant HCP should obtain from its Member State (MS) a written statement of endorsement certifying that its participation in the European Reference Network (ERN) is in accordance with its national legislation. The MS is responsible for defining its national process to support eligible Healthcare Providers and ensuring that this process is transparent.

The process how to become a member of an ERN is defined in the ERN Implementing Acts:

- a healthcare provider (HCP) wishing to become a member of an ERN will have to pass an assessment process based on the criteria in ERN Delegated Decision (2014/286/EU) Annex II, on the Implementing Decision (2014/287/EU) and on the amendment to the Implementing Decision (2019/1269).

The membership application process will involve several steps:

- Review the information on the Commission webpage which includes the current framework, the legislative proposal and a many frequently asked questions (FAQ);
- Contact your national representatives in the ERN Board of MS. They will provide you with more specific information on the national endorsement process;
- Fill in the application and self-assessment in the online tool that will be published with the call;
- Include all required documents that are specified in the online tool and in the assessment manual;

Information that the applicant will have to review will include:

- Applicable legislation;
- The scope of the diseases and thresholds established for each Network;
- Information provided by the Networks on their websites;
- Assessment manual and operational criteria;
- Information how to fill out the application and self-assessment in the online tool (to be published).

## **6. How will applications be assessed?**

The applications will have to pass four steps:

1. the eligibility check by the Commission,
2. the assessment by the Board of the Network
3. the assessment by the Independent Assessment Body, and
4. the approval by the Board of Member State.

Applicants will have to provide the endorsement of their Member State. The Assessment Manual for applicant members describes the assessment and the application process.

## **7. What does the conflict of interest policy cover?**

Conflict of interest goes much further than only industries, academia and research institutions. It should cover each stakeholder external to an ERN that interacts with the Network at any stage and at any governance level.

According to the operational criteria for Networks (Measure 1.7.1), each ERN has to establish its own Conflict of Interest Policy, ensuring disclosure of all financial and non-financial conflict of interest related to the treatment or research activities before any engagement commences. Preparatory work to support all ERNs in this area is ongoing under the cross-ERN Working Group on Legal & Ethical issues & relations with Stakeholders.

The ERNs' conflict of interest policy should respect relevant national and European legislation and follow the recommendations and guidelines developed by independent organisations and recognised bodies.

Applicants should follow the ERN rules and procedures on this issue.

### **8. What will be the relationship between ERN and industry?**

There is no specific legal provision when it comes to the involvement of stakeholders, including industry stakeholders with the ERNs. Therefore, the Board of Member States has set up a specific working group to discuss this issue and issued a statement on the issue in 2016, prior to the approval of ERNs. An updated statement on ERNs and industry was adopted by the Board in June 2019.

The introduction of the statement reads as follow: "In recognition of the importance of the role of industry in improving the knowledge of rare conditions and developing diagnostics tools and therapies, the Board of Member States agrees with the engagement of ERNs with industry where appropriate, for example on clinical trials and research projects. However, as there is no legal provision for the collaboration between ERNs and industry, the Board of Member States offers the following guidance" (in nine specific points developed in the 2-pages statement, for applicant ERN members to read).

### **9. Can a third country be a full member of an ERN?**

No. The scope of the legal provisions of the Directive on patient rights to Cross border healthcare and all legal measures related with the ERN implementation, are only applicable to the EU and EEA member states. That implies that other third countries healthcare providers cannot participate as candidates for full membership of a European Reference Network as Affiliated Partners (Associated National Centres or Coordinating Hubs). Nevertheless, one of the criteria that Networks are asked to fulfil is to cooperate with centres and networks of expertise at international level. That would allow non-EU or EEA countries to interact and exchange knowledge or participate in research or training projects, but not to exchange any clinical data of individual patients.

### **10. If a centre does not meet the Criteria defined in the Delegated Act Annex II, what are the options to participate in ERNs?**

For the centres that will not meet the criteria, but nonetheless could contribute to an ERN, the Member State where the centre is located, and only if not having any full member in the

same Network, might take a strategic decision on the convenience to designate this center as an Affiliated Partner (Associated National Centre or Coordination Hub)

### **11. What are the criteria for Affiliated Partners (Associated National Centres and Coordination hubs)?**

One of the roles of the Member States is to designate their Affiliated Partners (Associated National Centres and Coordination hubs).

The Board of Member States in its [paper](#) issued in January 2016 includes the position of Member States on this regard:

### **12. If different wards/ units/ groups belonging to the same HCP wants to join the same ERN, can they together fill in the application forms as HCP X and then specify the different diseases they work on?**

Yes, if different units belong to the same HCP (hospital) they must fill in only one application according to the criteria established by the Network. In case they are applying to different Networks, they must fill in one application per Network.

### **13. Do we need to translate the supporting documentation for HCP proposal (Appendix B, Self-Assessment for Healthcare Providers)?**

Concerning the list of documents required in the self-assessment, the HCPs are requested to provide:

- for some document a full translation in English (EN)
- in some case a summary in English (EN\_Sum) of the documents already available in the original language.
- when no specific indication is provided the documentations can be provided in the **original language**.

The HCP should decide based on the format and availability of information whether the summaries of supporting documentation will be provided as a separate document per measure or as one document for all measures with the same level of details at the request of the Board of the Network and/or IAB.

See table below:

## **APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS**

### **ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE (English Summary of all A measures)**

- Measure 1.1.1** Mission and/or Core Values (1a)\*
- Measure 2.1.1** Organization chart (2a)\*
- Measure 1.7.1** Conflict of Interest Policy (1g)\*
- Measure 2.3.1** Business continuity plan (2c)\*

### **ATTACHMENT B – PATIENT EMPOWERMENT (English Summary of all B measures)**

- Measure 1.1.3** Sample of Patient Education Materials already produced by the Healthcare Provider (1a)\*
- Measure 1.1.5** Written Material Describing Patient and Family Rights and Responsibilities (1a)\*
- Measure 1.3.1** Patient Experience Survey and Sample Patient Experience Reports (1c)\*
- Measure 1.5.1** Examples of Informed Consent Policy and Procedures used by the Healthcare Provider (English translation of one sample + documents in original language) (1e)\*

### **ATTACHMENT C – ORGANISATION OF CARE (English Summary of all C measures)**

- Measure 2.1.3** Existing Policies and Procedures for Managing Cross Border Patients or planned actions and timelines for developing policies and procedures (2a)\*
- Measure 2.6.1** Discharge procedure and Discharge Template (2f)\*
- Measure 5.3.1** List and examples of Clinical Practice Guidelines or Clinical Decision Support tools developed or adopted by the Healthcare Provider related with its area of expertise (5c)\*

### **ATTACHMENT D – QUALITY AND INFORMATION SYSTEM (English Summary of all D measures)**

- Measure 2.5.1** Third party reports issued by local or national bodies or external accreditation or certification bodies and/or inspections on the quality care environments (2c)\*
- Measure 5.1.1** Quality Improvement Plan (5a)\*
- Measure 5.1.2** Current Structure, Process or Outcome Indicators (Dashboard) and their definitions or planned actions and timelines for their development (5a)\*
- Measure 5.1.3** Patient Safety Plan (5a)\*
- Measure 5.1.4** Examples of methodologies used for adverse events analysis (Root Cause Analysis, etc.) and Description of Process Improvement methods (5a)\*

### **ATTACHMENT E – RESEARCH AND TRAINING (English Summary of all E measures)**

- Measure 3.1.2** List of training objectives (3a)\*
- Measure 3.1.3** List of Teaching Staff and Qualifications (3a)\*
- Measure 3.2.2** List of grants and research projects over the last 5 years (3b)\*
- Measure 3.2.3** List of Standard Operating Procedures (SOPs) that govern research activities (3b)\*
- Measure 3.2.4** Research Policy and Procedure (3b)\*

\* Please note the numbers in () correspond to the numbering in the [self-assessment online tool](#)

#### **14. Can a single HCP represent a multidisciplinary team or a consortium of different HCPs?**

Yes. It is possible that a single HCP submits the application on behalf of a consortium (legal or functional) or a multidisciplinary team including members belonging to different HCPs (Centres or Hospitals). One of the HCPs participating shall act as legal and technical representative of the Consortium.

Different members of the consortium will not be considered as different members of the ERNs but as parts of the consortium.

The name of the consortium should be agreed by the Consortium members, and validated by the National Authority in its endorsement letter.

Typical example of a Consortium are two different hospitals that are dealing with the same diseases or conditions but addressing different and complementary age groups (adult and paediatric) or are complementing the technical or human resources for the integral diagnosis or treatment of a given groups of diseases.

However, since the Independent Assessment Body will investigate the authenticity of this agreement both in the documentation review and during on-site visits, it will be the responsibility of the HCP's representative to provide proof of the real collaborative work among the consortium HCPs. Examples of this collaboration may include e.g. sharing resources (human or technical) and patients.

It is also very important for the HCP to explain in its application how this functional collaboration is running at the time of the submission of the application and provide information on the plans of collaboration in the future.

#### **15. Shall each member of the consortium sign the CEO agreement form and the HCP representative form?**

No. The CEO and the Representative of the main member of the consortium shall sign the CEO-Agreement form and the HCP-representative form. His/her data shall be included in the application, and he/she will take the responsibility of the application, and if approved, the participation of the consortium in the Network.

The main member of the consortium, filling in the application form, should include a brief description on the consortium in the Section: 1: 'Consortium':

Unit/Department/Ward name of other healthcare providers members of the consortium' and Section 2: 'Description of area of expertise and healthcare providers contribution to care'. Any complementary documentation related with the consortium agreement, should be kept by the main member of the consortium and provided to the Independent Assessment Body if requested.

Independent Assessment Body when assessing the authenticity of this agreement will check this information.

**16. Does the new healthcare professionals located in the same hospital or consortium of an already approved ERN member need to apply to the call to participate in the network?**

No. The call is for new members not for new healthcare providers or "experts". The integration of new healthcare professionals in the member's team shall be discussed and decided at member or network level according to the internal rules of procedure of the ERNs.

**17. Does current members of the ERNs need to apply to the call to expand their area of expertise / disease coverage?**

No. The procedure for approval of the new expertise/diseases coverage from already approved ERN members within one hospital shall be discussed within the Board of Member States and ERN Coordinators Group.

**18. Does the signing responsible of the Applicant have to be a legal representative?**

No. It shall be a Medical Doctor or a healthcare professional that is leading or representing the concrete area of expertise of the ERN interested to apply.

This person would represent the new member, if approved, in the Board of the Network.

**19. Identification and logo of the ERNs members**

Applicants once approved as members of a European Reference Network will be sub-licensed by the ERN Coordinator in order to use the ERN logo (trademark). The logo is owned by the European Union and should constitute the visual identity of the Networks and their Members.



## 20. Application Form – how to provide complementary information if there is not enough space in the form.

While the applicant fills in the application form, he may encounter limitation of space. In this case:

- a. fill in all the boxes in the Sections with as much information as possible (a summary of the key aspects on the issue);
- b. provide in **Section 8: Comments**, the complementary information, identifying the section that this information refers to, or if needed,
- c. prepare a separate document with complementary information that can be submitted at the request of the Board of the Network or Independent Assessment Body only after the call is finished and the application is eligible. Then in the **Section 8: Comments**, the applicant shall include a sentence: **‘A specific document with complementary information on Section [nr ...] is available on request’**.

### Examples:

**Section 2: Description of area of expertise and healthcare providers contribution to care.** If the content is above the 3000 characters, the applicant shall include a summary of the most important information in the box, and then provide in Section 8 the missing information. If needed, prepare a complementary document that shall be identified as complementary information to the Section 2 and include in section 8: Comments the sentence: **‘A specific document with complementary information on Section 2 is available on request’**.

**5: Healthcare professionals in the multidisciplinary team, same as above example.** In this case the applicant shall provide details of the team members up to 30 members, and if needed provide complementary information in section 8: Comments. If necessary prepare a complementary document that shall be identified as complementary information to the Section 5 and include in section 8: Comments the sentence: **‘A specific document with complementary information on Section 5 is available on request’**.