



European  
Reference  
Networks

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# ERN Assessment Manual for Applicants

## 1. Description and Procedures



Version 1.1 April 2016

## History of changes

Version	Date	Change	Page
1.0	16.03.2016	<ul style="list-style-type: none"> <li>▪ Initial version</li> </ul>	
1.1	21.04.2016	<ul style="list-style-type: none"> <li>▪ Typos correction</li> <li>▪ added this last words in par. 4.1.1 <i>and the submission page of the call</i></li> <li>▪ deleted instruction: <i>The score is not to be provided in the Applicant proposal.</i></li> <li>▪ substituted:               <ul style="list-style-type: none"> <li>• <i>Ensure the final version of the self-assessment has the agreement and signature of the Network Coordinator and <b>CEO of the Healthcare Provider</b> in the self-assessment Declaration Form.</i></li> </ul> </li> </ul> <p>With:</p> <ul style="list-style-type: none"> <li>▪ <i>Ensure the final version of the self-assessment has the agreement and signature of the Network Coordinator and of the <b>Healthcare Provider Representative</b> in the self-assessment Declaration Form.</i></li> </ul>	<p style="text-align: center;">17</p> <p style="text-align: center;">20</p> <p style="text-align: center;">23</p>

## Preamble

This manual was designed to provide Network and Healthcare Provider Applicants with information and guidance on how to submit a proposal and complete the assessment and approval process for European Reference Networks. It is part of **series of nine** documents that include the following:

1. ERN Assessment Manual for Applicants: Description and Procedures
2. ERN Assessment Manual for Applicants: Technical Toolbox for Applicants
3. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Networks
4. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Healthcare Providers
5. Network Application Form
6. Membership Application Form
7. Self-Assessment Checklist for Networks in Active PDF
8. Self-Assessment Checklist for Healthcare Providers in Active PDF
9. Sample Letter of National Endorsement for Healthcare Providers

This series of documents of the Assessment Manual and Toolbox for European Reference Networks has been developed in the framework of a service contract funded under the European Union Health Programme.

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## 1. Introduction

### 1.1 Background

The European Commission (EC) is supporting Member States in the development of European Reference Networks (ERNs) to link existing highly specialised healthcare providers across the European Union (EU). As expertise in rare or low prevalence complex diseases or conditions is scarce and dispersed, ERNs will facilitate timely access to care, both diagnosis and treatment, by centralising knowledge and experience, medical research and training, and resources for these diseases and conditions. The EC has been mandated to define the requirements for ERNs as specified in Article 12 of the Directive 2011/24/EU<sup>1</sup> on patient's rights in cross-border healthcare. As a result, the EC developed the Commission Delegated and Implementing Decisions of 10 March 2014<sup>2</sup> to provide a regulatory framework for establishing, assessing and approving ERNs.

In 2015, an assessment programme for ERNs was developed in consultation with Member States and key stakeholders. To support the assessment programme, an Assessment Manual has also been developed for Applicants in accordance with Article 13 (1)-(2) of the Commission Implementing Decision (2014/287/EU).

### 1.2 Objectives of the Assessment Programme

The assessment programme offers a quality improvement framework that aims to ensure efficient and effective use of resources, improves communication, strengthens collaborative approaches and demonstrates a commitment to quality and safe care. It is a voluntary process that is based on a peer review assessment model. It provides a standardised, transparent, and consistent method for assessing all ERNs under a common regulatory framework. The assessment programme is anchored in best practices and is inspired by existing methods used by other recognised assessment bodies in the European Union (EU) and internationally.

The overall goal of the assessment programme is to improve care for patients with rare or low prevalence complex diseases or conditions by:

- Ensuring Networks and Healthcare Providers demonstrate compliance with the EU legislative requirements
- Undertaking an independent and rigorous assessment process and applying it in a consistent, transparent, and reliable way
- Improving the delivery of high quality healthcare, including timely diagnosis and treatment options

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<sup>1</sup> 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

<sup>2</sup> Implementing Decision 2014/287/EU Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and Delegated Decision 2014/286/EU Commission Delegated Decision 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

- Ensuring patient care is safe
- Facilitating and improving medical training and research
- Improving the patient and family experience
- Encouraging development and learning for all involved
- Identifying and disseminating best practices in the field

### **1.3 Roles and Responsibilities**

Administering the assessment programme is a collaborative and coordinated effort that relies on the participation of multiple stakeholders, each having their respective roles and responsibilities.

#### **1.3.1 European Commission**

The European Commission (EC) is the European Union's (EU) executive body representing the interests of the EU as a whole. The EC's main roles and responsibilities are to:

- Propose and maintain legislation for establishing, assessing, and approving European Reference Networks (ERNs) and their members
- Develop and maintain a detailed manual describing the procedure for assessing and evaluating ERNs and their Members
- Publish the call for interest, register, and track applications for ERNs
- Complete the first part of the eligibility check by verifying that the Applicants meet the minimum requirements described in Article 2(2) and in Article 3(2) and (3) of the Commission Implementing Decision (2014/287/EU)
- Transfer the proposals of eligible Applicants to the Independent Assessment Body (IAB)
- Transfer the positive assessment reports completed by the IAB to the Board of Member States (BoMS) for approval
- Provide the secretariat of the BoMS
- Maintain and publically share a list of all recognized ERNs and their members

The European Commission will make available the outcomes of positive or negative assessments and/or evaluations carried out by the IABs, in accordance with provisions set out in the Commission Implementing Decision (2014/287/EU) and respecting applicable EU data protection legislation.

Member States may decide, based on their national data protection rules and other possible national legal provisions or by-laws, to establish specific procedures to access or request any of their healthcare providers' positive or negative assessment reports.

#### **1.3.2 Board of Member States**

In accordance with Article 13.1 and 15.1 of the Commission Implementing Decision 2014/287/EU and Article Art. 8.11, the Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs). The BoMS consists of representatives from across the EU Member States and European Economic Area (EEA). The main roles and responsibilities of the BoMS are to:

- Develop and maintain rules of procedure for the BoMS (functioning and decision-making process)
- Review the assessment reports and recommendations from the Independent Assessment Body (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

### **1.3.3 Independent Assessment Body**

The Independent Assessment Body (IAB) is an independent assessment organisation appointed by the European Commission (EC) to complete the technical assessment for eligible Networks and Healthcare Providers. Its roles and responsibilities include the following:

- Oversee and maintain policies and procedures to support the technical assessment in line with the Commission Implementing Decision (2014/287/EU)
- Administer the technical assessment based on these policies and procedures
- Recruit and train assessors
- Issue the critical path for the technical assessment including site selection, assessor assignment, and report preparation, respecting established timelines
- Coordinate the assessment activities in partnership with the Applicant
- Support the Assessors to ensure standardisation and consistency of assessment reports
- Finalise assessment reports and recommendations for the Board of Member States (BoMS)
- Review requests for amendments to the assessment reports from the Applicant and issue updated reports, if needed

The IAB will identify an *Assessment Coordinator* as the key contact to liaise with the EC and the Applicant during the assessment process.

### **1.3.4 Assessors**

The Assessors are peer reviewers who complete the documentation review, virtual interviews and on-site audits. As a team, they have the collective responsibility to:

- Act on behalf of the Independent Assessment Body (IAB) and should not pursue any individual or organization interests
- Review, verify, gather, and share information to assess compliance against the Operational Criteria
- Lead the virtual interviews and conduct the on-site audits
- Document findings and make recommendations in the form of a report

### 1.3.5 Member State

The role of the Member State (MS) is to provide a written statement of endorsement for the Healthcare Provider certifying that its participation in the proposal to establish a 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.

### 1.3.6 Applicant

There are two types of Applicants:

- The **Network Applicant**: a group of at least 10 Healthcare Providers located in 8 different Member States who jointly submit a proposal
- The **Healthcare Provider Applicant**: each Healthcare Provider participating in a new Network proposal or wishing to join an approved European Reference Network (ERN)

Throughout this manual, the term “**Applicant**” refers to both the Network and the Healthcare Provider Applicants. The terms “**Network**” and “**Healthcare Provider**” refer to the Network Applicant and the Healthcare Provider Applicant, respectively.

The Network is expected to define and justify the scope and thematic groups of rare or low prevalence complex disease(s) or condition(s) covered based on recognised need and value added, epidemiological data and sources, and/or expert consensus. The Network is also responsible for defining the characteristics required by each of the participating Healthcare Providers, including:

- The healthcare services to be provided for each of the patient groups
- Composition of the multidisciplinary team
- Qualifications of the healthcare professionals within the multidisciplinary team
- Maintenance of competency and expertise of the healthcare professionals
- Specialised resources needed to provide quality patient care (facilities, equipment, and diagnostic services)
- Best practices to be followed

The Applicant also works with the European Commission (EC) and the Independent Assessment Body (IAB) to fulfil the following roles and responsibilities:

- Submit application forms, self-assessments and supporting documentation to the EC in response to the call for interest
- Participate in the technical assessment activities including virtual interviews and on-site audits (if eligible)
- Provide in a timely manner to the EC and/or IAB the evidence needed to demonstrate compliance with the Operational Criteria
- Liaise with the EC and IAB to answer questions, provide missing information and/or notify of any changes relevant to the assessment programme

- Adhere to any other terms and conditions of the EC and IAB

The Network must identify one of its Healthcare Providers to act as the *Coordinating Member*. The Coordinating Member will choose from among the healthcare professionals belonging to its staff a *Network Coordinator* to fulfil the following roles and responsibilities.

***Network Coordinator:***

- Act as the key contact between the Applicant, the EC and the IAB throughout the assessment process
- Follow the instructions in the call for interest and complete all forms in English
- Ensure the application form and self-assessment for Networks are completed with supporting documentation
- Ensure that each Healthcare Provider completes the application form and self-assessment for Healthcare Providers, provides supporting documentation, and obtains a letter of endorsement from its Member State
- Integrate all the application forms from the Healthcare Providers as annexes in the Network application
- Ensure participation from each Healthcare Provider in the virtual interviews
- Ensure the Coordinating Member and selected Healthcare Provider sites participate in the on-site audits
- Coordinate the activities for the technical assessment in collaboration with the Healthcare Providers and the IAB

Each Healthcare Provider must assign a representative to fulfil the following roles and responsibilities.

***Healthcare Provider Representative:***

- Act as the key contact between the Healthcare Provider and the Network Coordinator
- Ensure the application form and self-assessment for Healthcare Providers are properly completed with supporting documentation
- Ensure a letter of endorsement is obtained from its Member State
- Participate in the virtual interviews
- Participate in the on-site audits (if selected)

The following diagram illustrates the relationship between the Coordinating Member and the other Healthcare Providers within the Network.



## 2. Assessment Process for the Applicant

### 2.1 Overview

This section provides an overview of the assessment process used to approve Networks and Healthcare Providers.

### 2.2 Operational Criteria for the Network and Healthcare Providers

#### 2.2.1 Purpose of the Operational Criteria

The central component of the assessment process is the Operational Criteria for the Network and Healthcare Providers. The Operational Criteria provide a common and structured framework to assess compliance with the legislated requirements.

**Tool(s):**

*Annex I* provides a copy of the *Operational Criteria for Networks* and the *Operational Criteria for Healthcare Providers*.

### 2.2.2 Description of the Operational Criteria

There are **two** sets of Operational Criteria:

1. Operational Criteria for the Network
2. Operational Criteria for the Healthcare Providers participating within the Network. These criteria are grouped under the following two sections:
  - General criteria common to all Healthcare Providers
  - Specific criteria defined **by the Network** based on the thematic group of rare or low prevalence complex disease(s) or condition(s) that it covers

The following table summarises the themes covered in the Operational Criteria for the Network and Healthcare Providers.

Themes in the Operational Criteria		
	Network	Healthcare Providers
Themes	<ul style="list-style-type: none"><li>• Establishment of a European Reference Network</li><li>• Highly Specialised Healthcare</li><li>• Governance and Coordination</li><li>• Patient Care</li><li>• Multidisciplinary Approach</li><li>• Good Practice, Outcome Measures, and Quality Control</li><li>• Contribution to Research</li><li>• Continuous Education, Training, and Development</li><li>• Networking and Collaboration</li></ul>	<p><b>General Criteria:</b></p> <ul style="list-style-type: none"><li>• Patient Empowerment and Patient-Centred Care</li><li>• Organisation, Management, and Business Continuity</li><li>• Research, Education and Training</li><li>• Expertise, Information Systems, and e-Health Tools</li><li>• Quality and Safety</li></ul> <p><b>Specific Criteria:</b></p> <ul style="list-style-type: none"><li>• Competence, Experience and Outcomes of Care</li><li>• Human Resources</li><li>• Organisation of Patient Care</li><li>• Facilities and Equipment</li></ul>
Assessment	Each criterion is rated <b>once</b> for the overall Network.	Each criterion is rated <b>individually</b> for each Healthcare Provider within the Network.

Each theme consists of one or more criteria. For each criterion, the following elements are included:

- **Legislated Requirement:** references to the condition(s) and sub-condition(s) in the legislation, i.e. Commission Delegated Decision 2014/286/EU Annex I and II that must be fulfilled

- **Criteria:** operational requirement linked to every condition(s) and/or sub-condition(s) in the legislation
- **Measures:** each criterion is accompanied by one or more measures of performance that need to be in place to meet the criterion - each measure has Guidelines to explain the requirement, Evidence to specify what needs to be collected and observed to meet the requirement, and Method(s) of Assessment to specify how the evidence will be evaluated to determine compliance with the requirement

### 2.2.3 Operational Criteria for the Network

Recognising that most of the Network Applicants are at the entry phase of forming a Network of Healthcare Providers in accordance with the legislation, they will need to demonstrate in their proposal that they have the foundational requirements needed to implement and maintain a successful European Reference Network (ERN). Operational Criteria identified as “core measures” are to be a priority for Networks to ensure a strong foundation for development of a sustainable ERN. The Network will be expected to address these core measures in a detailed and well defined strategy. This strategy must be ready at the time of submission of their application and made available to the IAB at their request. As for the other measures, the Network must demonstrate clear action plans with objectives, timeframes and accountabilities to meet the expectations of a mature Network as defined in the Commission Delegated Decision.

The Assessors will also examine the method and sources used to tailor the defined specific criteria for the Healthcare Providers within the Network’s area of expertise to ensure that they are robust.

### 2.2.4 Operational Criteria for the Healthcare Providers

The Operational Criteria for Healthcare Providers consist of two sections. The first section covers ***general criteria*** that are common to all highly specialised healthcare providers, e.g. organisation and management, research and training, and information systems. To avoid duplication of efforts, Healthcare Providers can submit as evidence at the request of the IAB, for these criteria ***only***, the assessment results from another assessment body<sup>3</sup> based on the following parameters:

- Recent assessment completed by a recognised assessment body within the last 5 years
- Healthcare Provider must demonstrate the equivalence of the prior assessment to the Operational Criteria, e.g. provide a mapping of the Operational Criteria against the requirements from the assessment body
- Written proof that these similar requirements were rated as “met” by the assessment body, e.g. provide a copy of the assessment report or results
- Acceptance of this “proof of assessment” is at the discretion of the Independent Assessment Body (IAB); the Assessors will validate this information during the documentation review, virtual interviews and the on-site audit

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<sup>3</sup> Any formal system of assessment, certification, licensing, etc. recognized by the competent national authorities.

The second section of the Operational Criteria for the Healthcare Providers consists of ***specific criteria*** related to the disease(s) or condition(s) covered by the Network. The Applicant must demonstrate in its proposal how the Network and Healthcare Providers have adapted the following specific requirements to the area of expertise of the Network based on recognised epidemiological data and sources and/or expert consensus:

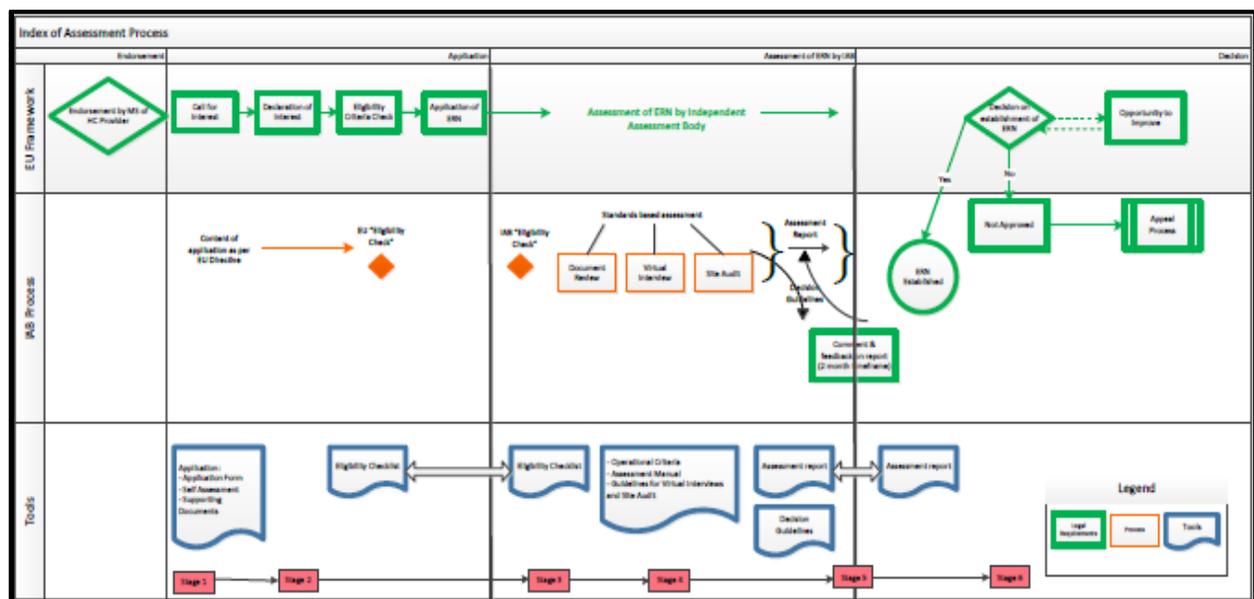
- Competency and expertise
- Qualifications of the healthcare professionals
- Composition of the multidisciplinary team
- Access to specialised resources (facilities, equipment and diagnostic services)
- Best practices to be followed

The Healthcare Provider will be evaluated to ensure that all the specific criteria have been adapted to the disease(s) or condition(s) covered by the Network, and that the Healthcare Provider is meeting these criteria as defined in the Network application. As mentioned above, the method and sources used to establish those specific criteria will be assessed in the Network proposal to ensure their appropriateness.

### 2.3 Assessment and Approval of Applicants (Six-Stage Process)

The assessment process consists of 6 stages and 2 transition points involving the transfer of information between the European Commission (EC) and the Independent Assessment Body (IAB).

The following diagrams provide an overview of the six-stage process from the call for interest to the final approval by the Board of Member States (BoMS). The activities the EC are responsible for are identified in **green**, the activities the IAB are responsible for are in **orange**, and the specific tools that will be used for each stage are identified in **blue**.

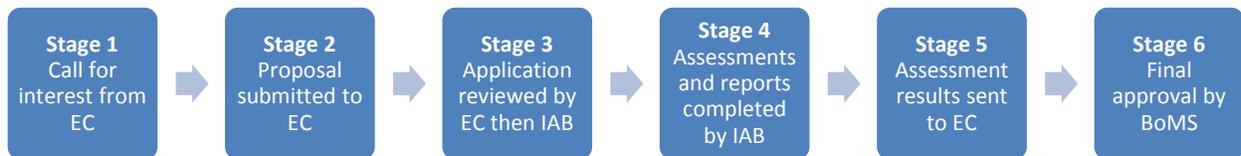


Throughout the process, there are five distinct decision points to determine whether the Network and its Healthcare Providers can progress to the next stage in the assessment. These include the following:

1. The EC completes the first part of the eligibility check to determine if the Network and/or Healthcare Provider(s) can progress to the review by the IAB.
2. The IAB completes the second part of the eligibility check to determine if the Network and/or Healthcare Provider(s) can progress to the technical assessment.
3. The IAB completes the technical assessment, i.e. documentation review and virtual interviews, to determine if the Network and/or Healthcare Provider(s) can progress to the on-site audit.
4. The IAB determines if the results from the technical assessment are positive or negative, and sends the positive assessment reports to the EC for presentation to the Board of Member States.
5. The Board of Member States reviews the results and recommendations from the technical assessment and issues the final decision, i.e. approval as an ERN or a Member of an existing ERN.

## 2.4 Timeline for the Assessment and Approval of Applicants

The assessment process may take between 6 to 8 months to complete, from the call for interest to the final approval of the European Reference Network (ERN) by the Board of Member States (BoMS). Please note that all the timelines in the Manual are provided as a guide and subject to change at the discretion of the European Commission (EC) and the Independent Assessment Body (IAB). The following diagram outlines each stage in the assessment programme.



The following sections of the Manual include detailed procedures for Applicants to follow at each stage of the assessment programme.

### 3. Stage 1: Publication of the Call for Interest

#### 3.1 Description

The first stage of the assessment programme is the call for interest. The European Commission's Directorate-General for Health and Food Safety (DG SANTE) launches a public call for European Reference Networks (ERNs) for rare or low prevalence complex diseases or conditions.

The premise of the European Reference Network (ERN) initiative is to create Networks that would add value to the field of highly specialised healthcare across Europe. Therefore, it is important that Healthcare Providers work together to form a Network under a theme or grouping of diseases or conditions that complements other Networks and Healthcare Providers, avoiding duplication of effort and fragmentation in the field. The strategic paper issued by the ERN Board of Member States in its capacity to approve Networks and Healthcare Providers' applications provides guidance on this subject<sup>4</sup>.

#### 3.2 Instructions for Networks and Healthcare Providers

Calls for interest are published on the EUROPA website (DG SANTE). The call for interest includes a detailed description of the call and conditions for an ERN proposal, links to application documents such as the application forms, self-assessments, checklists, etc., deadline for submission, and contact information for queries.

The Network Coordinator and Healthcare Provider Representatives can download this information from the portal and distribute it to key individuals for completion.

The deadline for submission is generally ***3 months following the posting*** of the call for interest. The specific deadlines for submission will be published with each call for interest.

### 4. Stage 2: Preparing the Proposal for a European Reference Network

The ERN proposal consists of application forms, self-assessments with supporting documentation, and letters of endorsement by the Member States that must be submitted ***within the deadline*** of the call for interest.

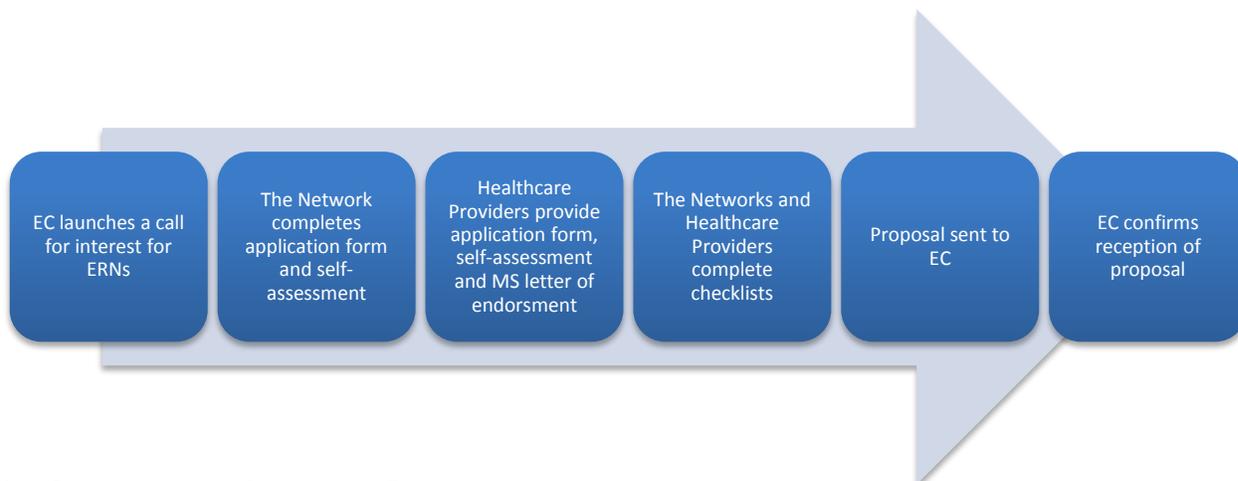
The Network Coordinator in collaboration with the Healthcare Provider Representatives, need to define the purpose and objectives of the proposed ERN. This should include the characteristics required to respond to the specific criteria for each participating Healthcare Provider, including the Coordinating Member. There are some resources already published that will help in this exercise.<sup>5</sup> To be considered for the establishment of an ERN, a minimum of 10 Healthcare Providers from 8 Member States (MS) are

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<sup>4</sup> [http://ec.europa.eu/health/ern/docs/ern\\_board\\_implementationstrategy\\_en.pdf](http://ec.europa.eu/health/ern/docs/ern_board_implementationstrategy_en.pdf)

<sup>5</sup> The following is a non-exhaustive list of recommended resources to help guide this work: ERN implementation strategies issued by the ERN Board of Member States, EUCERD Recommendations to the European Commission and the Member States on European Reference Networks for Rare Diseases (2013), Addendum to the EUCERD Recommendations of January 2013 (2015), .

needed to participate in the proposal. The following diagram summarises the key steps of this stage in the assessment process.



## 4.1 Completing the Application Forms

### 4.1.1 Description

All Applicants are required to complete application forms. **Two** separate application forms are available under the documents section in the call for interest: one form for the Network, i.e. **Network Application Form**; and a separate form for each participating Healthcare Provider, i.e. **Membership Application Form**. The application forms include a description of the purpose of the Network, area of expertise and scope of services, epidemiology of the disease(s) or condition(s), the added-value of the Network, and common objectives in line with Annexes I and II in the Commission Implementing Decision (2014/287/EU).

For those Network Applicants wishing to apply for funding to support the establishment of the ERN, a separate application form must be completed. Details and guidelines on how to apply can be referred to on the EUROPA website (DG SANTE) and the submission page of the call.

### 4.1.2 Instructions for the Network and Healthcare Providers

The Network, as a whole, must first complete **one** Network Application Form and circulate the completed form to the Healthcare Providers. As a next step, **each** Healthcare Provider (including the Coordinating Member of the Network) must complete its Membership Application Form and provide a written statement of endorsement from its Member State. Once complete, the Membership Applications Forms are integrated as appendices into the Network Application Form to complete the proposal.

The ERN Board of Member States has provided valuable guidance<sup>6</sup> on some concrete aspects of the application process including specific references to the role of Affiliated Partners<sup>7</sup> and how they should

<sup>6</sup> [http://ec.europa.eu/health/ern/docs/ern\\_board\\_implementationstrategy\\_en.pdf](http://ec.europa.eu/health/ern/docs/ern_board_implementationstrategy_en.pdf)

<sup>7</sup> Affiliated partners = Associated national centres; Collaborative national centres; National coordination hubs

be linked to the approved ERNs. The addition of Affiliated Partners and the relevant process will take place only after the approval of the ERN by the Board and following the formal designation of each of the Affiliated Partners by its national authorities. **Therefore, only Healthcare Providers applying for full membership should be included as applicants in the Network proposal.**

The Applicant should clearly address the following items in the application forms to help support a strong proposal for a European Reference Network (ERN):

- Describe the purpose, goals and objectives of the Network and how it will add value to the field of highly specialised healthcare
- Describe the area of expertise of the Network and scope of services of the Healthcare Providers, e.g. diagnostic tests, therapeutic procedures, and follow-up
- Explain why a Network is needed for a specific disease/condition or group of disease(s)/condition(s)
- Tailor the specific requirements in the Operational Criteria for Healthcare Providers to the Network's area of expertise, and explain the methods used to complete this work

The Applicant should identify in the application forms the measures set for each specific criterion based on the area of expertise of the Network. For example, one of the specific criteria requires Healthcare Providers to maintain their competence in the Network's area of expertise. Therefore, the Applicant should provide its actual volume of activity per year to maintain their competence and experience within their area of expertise to demonstrate its fulfilment of the thresholds set by the Network.

***Tip(s):***

It is recommended that the Network Coordinator and each Healthcare Provider Representative work in a collaborative, coordinated fashion to ensure a complete, comprehensive and robust proposal. The documentation should be reviewed as a package to ensure there are no contradictions between the *Network Application Form* and the *Membership Application Form(s)*.

***Tool(s):***

***Annex II*** includes a copy of the Application Forms for the Network and Healthcare Providers.

#### **4.2 National Endorsement by the Member State**

Each Healthcare Provider that is interested in forming or joining an approved European Reference Network (ERN) must have a written statement from its Member State (MS) certifying that its participation in the proposal to establish a European Reference Network **is in accordance with the Member States national legislation.**

Proposals without the written statement will be considered incomplete and will be ineligible to proceed to the technical assessment.

## 4.3 Completing the Self-Assessment for Networks and Healthcare Providers

### 4.3.1 Description

The Network and Healthcare Providers are required to complete a self-assessment against the Operational Criteria. There are 2 self-assessment tools: **one** for the Network and **one** for the Healthcare Provider. The self-assessment is available under the documents section in the call for interest.

The self-assessment is a valuable step that can be completed prior to the call for European Reference Networks (ERNs). It provides an opportunity for both the Network and each participating Healthcare Provider to assess themselves against the specific legislated criteria and conditions before submitting their proposal to the European Commission (EC).

The self-assessment offers guidance on the type of information needed to demonstrate compliance with the requirements. The information submitted through the self-assessment will support a thorough documentation review by the Assessors and help the Assessment Coordinator plan the on-site audit.

Network Coordinators and Healthcare Provider Representatives should ensure that any self-assessment is made and agreed to with the involvement of Network members and the Healthcare Provider multidisciplinary teams.

### 4.3.2 Preparing for the Self-Assessment

The Network Coordinator must establish a team of Healthcare Provider representatives to complete the self-assessment on behalf of the Network. Similarly, each Healthcare Provider must designate a multidisciplinary team to complete the self-assessment on behalf of the Healthcare Provider. To complete the self-assessment, Applicants must follow the *“Instructions for Completing the Self-Assessment”* included in the self-assessment tool.

#### ***Tip(s):***

The Network Coordinator is encouraged to plan the following activities to help ensure an efficient self-assessment process:

- Begin planning for the self-assessment as far ahead as possible of the submission deadline
- Become familiar with the Operational Criteria, and read through the entire document before starting the self-assessment
- Maintain a list of the Healthcare Provider Representatives with contact information. Coordinate and collaborate with all representatives.
- Develop a timeline and ensure there is sufficient time to complete the self-assessment
- Plan bi-weekly teleconferences with the Healthcare Provider Representatives to monitor progress

**Tool(s):**

**Annex III** provides the following **two** tools to support the self-assessment with instructions for completion:

- Self-Assessment for the Network
- Self-Assessment for the Healthcare Providers

### 4.3.3 Writing the Self-Assessment

The self-assessment lists all the Operational Criteria for Networks and Healthcare Providers. The Applicant is asked to self-assess against each criterion by using the following rating scale and scoring guidelines.

Rating	Guidelines
<b>0: No activity / Not Implemented</b>	<b>All Criteria:</b> this rating is used when there is no action plan in place or there is insufficient evidence to support compliance. This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).
<b>1: Partially Implemented</b>	<b>All Criteria:</b> this rating is used when there is an action plan in place or there is some evidence to support compliance. This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).
<b>2: Fully Implemented</b>	<b>All Criteria:</b> this rating is used when there is sufficient evidence to support compliance. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).

The Applicant needs to provide evidence to support compliance for each rating. The self-assessment specifies the types of documentation that need to be ready at the time of submission of the application. These documents listed in **Annex IV, Appendix B** are not to be uploaded at the time the application is submitted, but must be ready to be submitted as evidence at the start of the technical assessment.

The Applicant, by signing and submitting the application form(s), certify the existence of these documents and assumes the obligation to provide them to the IAB, when requested. Failure to provide the required documents to the IAB will result in the exclusion of the Applicant.

Additional documentation may be requested during the on-site audit. Hyperlinks to supporting documentation may be provided in the self-assessment.

If a criterion is considered partially implemented or not implemented, the applicant should provide information on any actions taken or need to be taken to meet the requirement with timeframes and responsibilities. The self-assessment score is calculated through the formulas set up in the self-assessment tool. The same rating scale will be used by the IAB Assessors during the technical assessment.

Applicants should review their self-assessment results and evaluate their readiness to participate in the assessment process before submitting their proposal to the European Commission. If an Applicant determines that it is not ready to respond to the call for proposal based on the self-assessment results, it is encouraged to develop an action plan to address areas for improvement with clear objectives, leads and timeframes for subsequent calls for interest.

As described previously in the Manual, Healthcare Providers can submit as evidence the assessment results from another assessment body.<sup>8</sup> These criteria should be clearly identified in the self-assessment with supporting documentation at the IAB’s request.

**Tip(s):**

When writing the self-assessment, the evidence should be specific, objective and concise. It is recommended to share strengths, challenges, steps to address areas for improvement. The Applicant should briefly explain each rating provided in the self-assessment and reference any supporting documentation, as required.

**4.3.4 Self-Assessment Examples**

***Self-Assessment for the Network***

The following is an example of how to complete the self-assessment against the Operational Criteria for the Network. If a requirement is not fully in place, the Applicant should explain the actions to be taken to meet the requirement with a defined timeline. The following symbol  means that the Applicant needs to prepare or collect a specific document as evidence of compliance and be ready to submit it at the IAB’s request, at the start of the technical assessment.. The document provided should be referenced in the section for comments. Hyperlinks to documentation can also be provided.

HIGHLY SPECIALISED HEALTHCARE					
1.1 The Network provides highly specialised healthcare for one or more rare or low prevalence complex diseases or conditions in the areas of diagnosis, treatment, and follow-up.					
Measurement Elements	0	1	2	Comments	 *
1.2.1 The thematic group(s) and disease(s) or condition(s) within the Network’s scope are defined and documented.	<input type="checkbox"/>	<input type="checkbox"/>	<b>X</b>	The Network’s area of expertise is available online [Link].	
1.2.2 The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.	<input type="checkbox"/>	<input type="checkbox"/>	<b>X</b>	All Healthcare Providers worked together to develop the attached vision statement for the Network.	<b>X</b>

<sup>8</sup> Any formal system of assessment, certification, licensing, etc. recognized by the competent national authorities

### Self-Assessment for the Healthcare Providers

The following is an example of how to indicate in the self-assessment that one or more of the **general criteria** in the Operational Criteria for Healthcare Providers has been assessed by another assessment body. The name of the assessment body, evidence of its recognition by a competent national authority, and date of assessment must be indicated in the section for comments. As supporting documentation, the Healthcare Provider must provide, at the IAB’s request, a mapping showing how the Operational Criteria are equivalent to the requirements from another assessment body, and a copy of the assessment report or results demonstrating that the Healthcare Provider has met the requirement(s).

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE					
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients’ rights and preferences are respected.					
Measurement Elements	0	1	2	Comments	 *
1.1.1 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	<input type="checkbox"/>	<input type="checkbox"/>	<b>X</b>	This requirement was evaluated by [Name of Assessment Body] on [Date].  Refer to mapping with the Operational Criteria, and Assessment Report (attached).	

#### 4.4 Validating the Self-Assessment Results Internally

Prior to finalising and submitting the self-assessment, a process to validate the results internally by the Applicant should be followed. The purpose of the internal validation is to:

- Provide a level of quality assurance
- Confirm that the self-assessments are accurate and therefore can be shared externally
- Identify any inconsistency in practice across the Network
- Identify areas of best practice that could be shared across the Network

It is the Network’s responsibility to determine how the internal validation will be completed. The Network must ensure that the process used meets the following requirements:

- The process is fair and robust
- The process is agreed to by all Healthcare Providers
- Accountability for the self-assessment is agreed to by the Chief Executive Officer of the Healthcare Provider
- The process includes patient and family involvement

At the conclusion of the internal validation, the following actions should be taken by the Network and/or Healthcare Provider:

- Check and record any changes in the self-assessment
- Ensure that each section is complete and ready for submission
- Ensure the final version of the self-assessment has the agreement and signature of the Network Coordinator and of the Healthcare Provider Representative in the self-assessment *Declaration Form*.

#### 4.5 Submitting the Application Forms, Self-Assessments and Supporting Documentation

All application forms, self-assessments, and supporting documentation should be sent by the Healthcare Provider Representatives to the Network Coordinator for verification and submission. The completed proposal should be submitted online by the Network. The box below provides a list of the documents that should be submitted at the time of the application.

#### DOCUMENTS TO BE UPLOADED AT THE TIME OF APPLICATION

- ONE NETWORK APPLICATION FORM
- ONE MEMBERSHIP APPLICATION FORM FOR EACH HEALTHCARE PROVIDER (INCLUDING THE COORDINATING MEMBER)
- ONE NETWORK SELF-ASSESSMENT
- ONE SELF-ASSESSMENT PER HEALTHCARE PROVIDER
- ONE LETTER OF ENDORSEMENT FOR EACH HEALTHCARE PROVIDER (INCLUDING THE COORDINATING MEMBER)

ALL OTHER SUPPORTING DOCUMENTATION LISTED IN **ANNEX IX, APPENDIX B** OF THE SELF-ASSESSMENT SHOULD BE SUBMITTED DIRECTLY TO THE IAB, AT ITS REQUEST.

New or updated Network proposals **will not be accepted** at any step of the assessment process once the application has been submitted.

Upon submission, a confirmation is sent to the Network Coordinator to confirm the receipt of the proposal. A unique proposal number is assigned for tracking purposes. The email will include instructions on how to monitor the status of the proposal along with the login ID and password. It is the Network Coordinator's responsibility to share this information with the Healthcare Provider Representatives.

### **Tool(s):**

Two checklists are provided for the Network and Healthcare Providers to ensure all necessary steps have been completed before submitting the proposal to the European Commission (EC) (See **Annex IV** for a copy of the checklist).

## **4.6 Applying for Membership to an Existing Network**

A similar process applies for Healthcare Providers that are interested in becoming a member of an existing Network. Existing Networks should be open at any time to any Healthcare Provider wishing to apply to become a member provided they meet the criteria requirements. The membership application process for any ERN must support easy access for approved Healthcare Providers to join, within a framework that treats all Applicants equally.

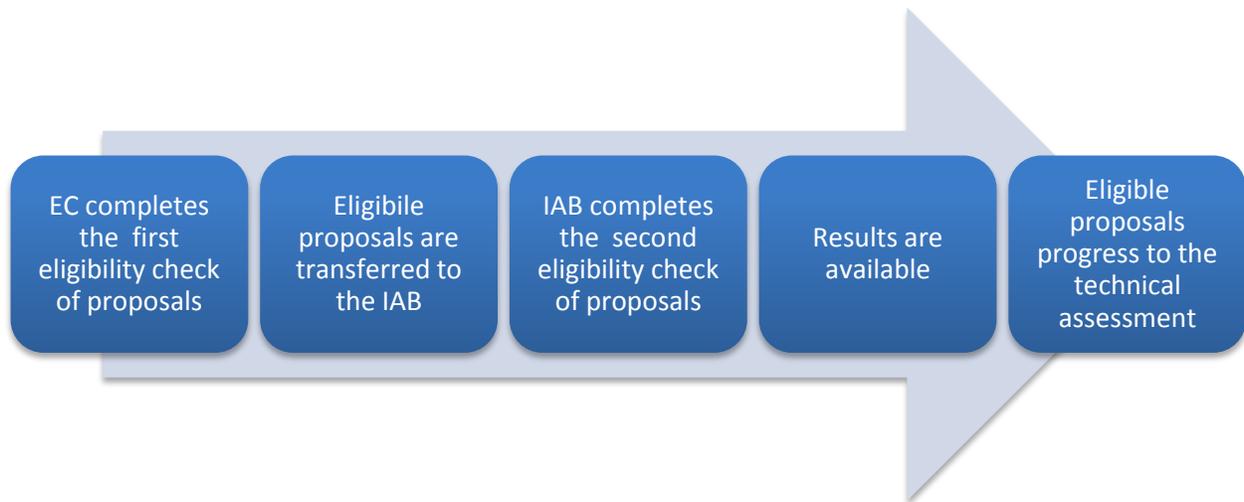
The following is an overview of the steps completed by the Healthcare Provider:

1. The Healthcare Provider Representative shares the proposal with the Network Coordinator for review and submission to demonstrate its support for the proposal.
2. Each Healthcare Provider must submit a completed proposal consisting of the application form, self-assessment and a letter of endorsement from its Member State. Similarly, the Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in **Annex IV, Appendix B**. These documents should be made available to the IAB, at their request.
3. A unique proposal number will be assigned to the Healthcare Provider to track the status of the proposal.
4. The EC will send an acknowledgement of the receipt of the proposal to the Healthcare Provider Representative and the Network Coordinator after receiving it.
5. The EC will proceed with the eligibility check.

New or updated proposals from Healthcare Providers **will not be accepted** at any step of the assessment process once the application has been submitted.

## **5. Stage 3: Determining Eligibility of the Applicant**

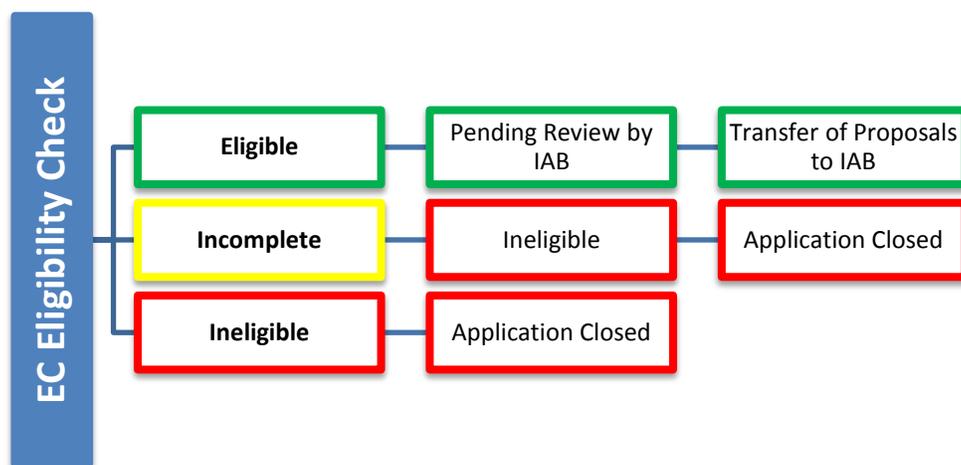
Both the European Commission (EC) and Independent Assessment Body (IAB) are responsible for determining the eligibility of Network and Healthcare Provider Proposals. The following diagram summarises the key steps of this stage in the assessment process.



## 5.1 Verification of the Proposal by the European Commission

### 5.1.1 Description

The European Commission (EC) completes the first part of the eligibility check of the proposal. This step represents the **first decision point** in the assessment process as illustrated in the diagram below.



### 5.1.2 Steps Completed by the European Commission

The European Commission (EC) completes an initial review of the proposals for completeness. The EC verifies that the Applicant meets the following minimum requirements:

- ✓ The Network includes a minimum of 10 Healthcare Providers from 8 Member States
- ✓ The Network and all Healthcare Providers have completed the application forms and self-assessments with supporting documentation as per the requirements in Annex I and Annex II of the Implementing Decision (2014/287/EU)
- ✓ Each Healthcare Provider has a written statement of endorsement from its Member State

Once the EC has reviewed the proposal, the Network Coordinator is notified about the status of its application. The notification provides information on the status of the eligibility check.

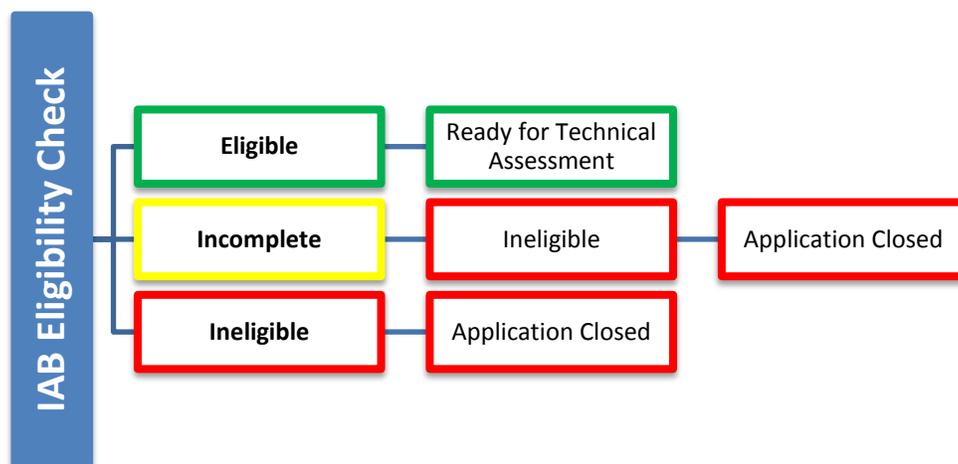
Only those proposals that meet the minimum requirements are shared with the IAB for further assessment. The assessment stops at this stage for ineligible or incomplete proposals.

Eligible Healthcare Providers can only progress to the next stage if the Network continues to meet the minimum requirement of 10 Healthcare Providers from 8 Member States. If not, the assessment process stops at this stage for the Network and all the Healthcare Providers.

## 5.2 Validation of the Proposal by the Independent Assessment Body

### 5.2.1 Description

This is the first transition point between the EC and IAB. The IAB completes the second part of the eligibility check of the proposal. This step represents the second decision point in the assessment process as illustrated in the diagram below.



### 5.2.2 Steps Completed by the Independent Assessment Body

Once the proposal is received from the European Commission (EC), the Independent Assessment Body (IAB) assigns an Assessment Coordinator as the key contact between the IAB and the Network Coordinator. Depending on the size of the Network, the Assessment Coordinator assigns a minimum of two assessors to determine if the proposal meets the following requirements:

- ✓ The content of the Network application fulfills the requirements of Annex I for the Implementing Decision

- ✓ The content of the Healthcare Provider Application fulfills the requirements of Annex II of the Implementing Decision
- ✓ The Network fulfills the requirement to provide highly specialized healthcare. All Healthcare Provider Applicants must share the same area of expertise as per the Network’s area of expertise.

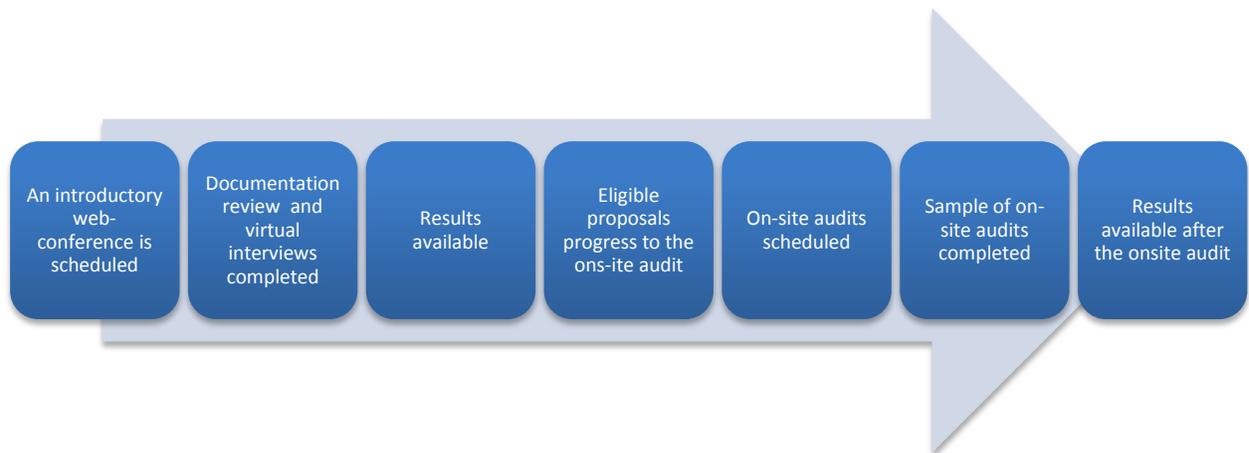
The Assessment Coordinator updates the checklist from the EC. A report with an updated copy of the checklist is provided to the Network Coordinator with a decision on whether the proposal is eligible to proceed to the next stage in the assessment.

The assessment **stops** at this stage for ineligible proposals.

Only eligible Healthcare Providers can progress to the next stage if the Network continues to meet the minimum requirement of 10 Healthcare Providers from 8 Member States. If not, the assessment process **stops** at this stage for the Network and all the Healthcare Providers.

## 6. Stage 4: Technical Assessment of the Proposal

Eligible proposals progress to Stage 4 of the assessment completed by the Independent Assessment Body (IAB) and led by the assigned Assessment Coordinator. The following diagram summarises the key steps of the technical assessment.



The IAB coordinates the following activities included in the technical assessment of the Applicant: documentation review, virtual interviews and on-site audits. The purpose of this stage of the process is to assess compliance with the Operational Criteria for Networks and Healthcare Providers.

To initiate the technical assessment, the Assessment Coordinator works with the Network Coordinator to schedule an introductory web-conference with the Healthcare Provider Representatives. This is an opportunity for the Assessment Coordinator to provide background information on the assessment, answer questions, obtain any clarifications, and summarise next steps. Prior to the web-conference, the

Network Coordinator must provide the applicable supporting documentation. Failure of the Applicant to provide this information, at the request of the IAB, will result in an ineligible proposal.

### 6.1 Peer-Review Model

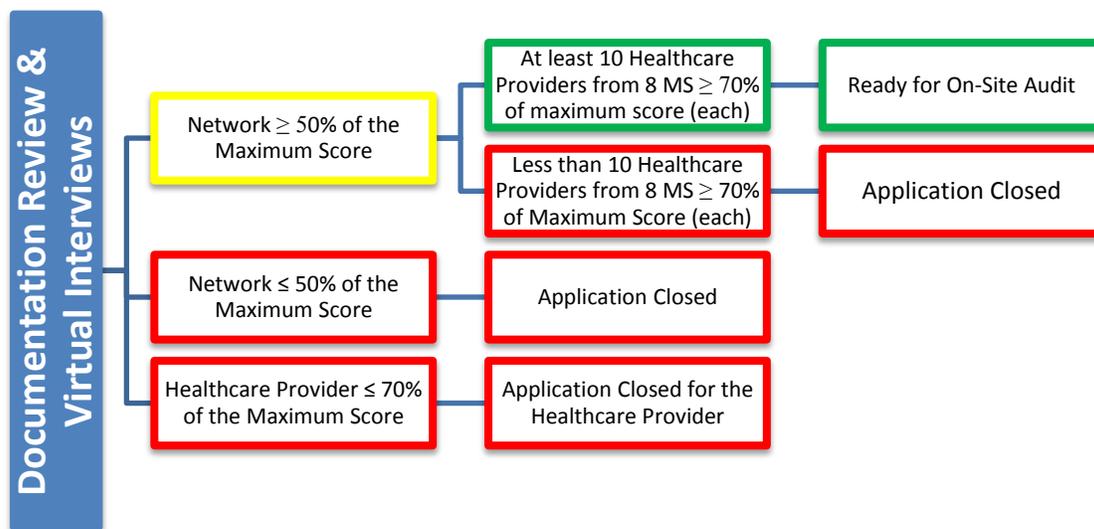
Peer review means having the work of one or more individuals evaluated by experts from the same field. This model helps provide credibility to the assessment and ensure that standards for patient care are evaluated by healthcare professionals with expertise and experience in the area of rare or low prevalence complex diseases or conditions.

The composition of the assessor team depends on the size of the Network and the geographic location of its members. A minimum of two assessors are needed to complete the technical assessment with one assessor appointed as the team leader. For example, a team of two to three assessors is needed to evaluate a Network of 10 Healthcare Providers from 8 Member States.

### 6.2 Documentation Review and Virtual Interviews

#### 6.2.1 Description

The team of assessors complete the documentation review and virtual interviews to determine if the Network and Healthcare Providers comply with the Operational Criteria. Applicants with a positive assessment progress to the validation of the findings through a sample of on-site audits. This step represents the **third decision point** in the assessment as illustrated in the diagram below.



#### 6.2.2 Steps Completed by the Independent Assessment Body and the Assessors

The Assessors complete a comprehensive documentation review of all the application forms, self-assessments, and any supporting documentation submitted by the Network and each Healthcare Provider.

As a complement to the documentation review, the Assessors also complete virtual interviews with the Network Coordinator and Healthcare Provider Representatives. Virtual interviews are conducted via web-conference. During the virtual interviews, the Assessors have an opportunity to ask questions and/or request clarifications on the information submitted by the Applicant.

The purpose of the documentation review and virtual interviews is to:

- ✓ Verify that the process used to complete the self-assessment was robust
- ✓ Verify that self-assessments have been completed in a similar manner across Healthcare Providers, as applicable
- ✓ Verify that there is sufficient evidence provided
- ✓ Rate compliance with the operational criteria

The team leader, in collaboration with the Assessment Coordinator, provides a preliminary report on the results from the documentation review and virtual interviews.

The preliminary report will be made available to the Network Coordinator. The Applicant has an opportunity to comment on the results and submit missing information or request amendments after the posting. The Assessment Coordinator, in consultation with the Assessors, reviews any new information and makes changes or adjustments as necessary.

The technical assessment **stops** at this phase for the Network in either one of these cases:

- The Network receives a negative assessment
- Less than 10 Healthcare Providers from 8 Member States receive a positive assessment

Only Networks and Healthcare Providers with a positive assessment can progress to the next stage of the assessment process where the assessor team validates the results from the documentation review and virtual interviews through a sample of on-site audits.

***Tool(s):***

***Annex V*** provides a *Guide for Completing Virtual Interviews* with Applicants.

## **6.3 On-Site Audit**

### **6.3.1 Preparing for the On-Site Audit**

A sample of Healthcare Providers is selected for the on-site audit to validate the information obtained through the documentation review and virtual interviews. The Coordinating Member must participate in the on-site audit. Once sites have been selected, Applicants are notified through the *Network Coordinator* about the dates and times of the on-site audit.

The Assessment Coordinator develops an on-site audit schedule in collaboration with the *Network Coordinator*. In preparation for the on-site audit, the Assessment Coordinator requests from the

Healthcare Providers the required documentation or information that should be sent in advance or made available the day of the on-site audit.

The following list provides general guidance to the types of on-site documentation the Assessors may wish to access during the on-site audit. These include:

- Terms of reference for the Network Board
- Sample of education and training materials
- Clinical practice guidelines
- Access to general, administrative and clinical policies (via intranet if applicable)
- Sample of patient records
- Patient registries
- Sample of recent publications

In preparation for the on-site audit, a teleconference is scheduled between the Assessment Coordinator, the assessor team, the Network Coordinator, and the Healthcare Provider Representatives to go over the arrangements for the audit. This includes developing, revising and finalising the on-site audit schedule. The Assessment Coordinator works with the assessor team to arrange accommodation and travel as needed. The Assessment Coordinator will coordinate with the Healthcare Provider Representative the following logistics for each of the on-site audits:

- Meet the assessor team upon arrival or assign a delegate
- Ensure the Healthcare Provider Representative for the site is available to answer queries and provide additional documentation as required
- Identify a private room for the assessor team to work in (e.g. review documentation and complete ratings)
- Provide site directions

***Tool(s):***

The Assessment Coordinator provides the Network Coordinator with an on-site audit checklist to help the Applicant complete the key steps in preparation for the on-site audit (**Annex VI**).

***Tip(s):***

It is recommended that the Network Coordinator complete the checklist before the on-site audit. Healthcare Providers are encouraged to involve patients and/or their national authorities in the on-site audit.

### **6.3.2 Carrying out the On-site Audit**

The audit schedule identifies the clinical areas to visit, the activities to complete and the name of the Assessor responsible for auditing the site. In general, a site audit is carried out in one to two days. Time

is also allocated in the audit schedule for assessors to complete ratings and prepare an overview of the findings. Some of the on-site audit activities include:

- An brief introductory meeting with the leaders of the organisation
- A discussion with the multidisciplinary team
- A tour of the site including the environments of care
- Clinical documentation review (e.g. chart or patient files, clinical practice guidelines)
- Patient tracer (i.e. simulated care path of the patient) to review information related to referrals, use of clinical practice guidelines, transfer of patient information across borders, etc.
- Debrief to provide an overview of the findings from the audit

***Tool(s):***

***Annex VII*** provides a template for the on-site audit schedule and lists the documents reviewed by the assessors on-site.

### **6.3.3 Rating Scale and Guidelines**

The Assessors use a rating scale to assess compliance against the Operational Criteria. The Assessors apply the same rating scale used in the self-assessment. Applying the same rating scale provides a consistent approach for rating compliance against the Operational Criteria from the perspective of the Applicant (self-assessment) and the assessors (technical assessment).

## **6.4 Assessment Results**

### **6.4.1 Decision Guidelines**

For a Network to obtain a positive assessment, the following conditions must be met:

- An **overall compliance rate of 50% of the maximum score.**
- A rating of “1” for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.
- There should be **no measurement elements under any theme rated as “0”.**
- **A minimum of 10 HCP from 8 Member States in a Network must receive a positive assessment** against the Healthcare Provider Decision Guidelines.

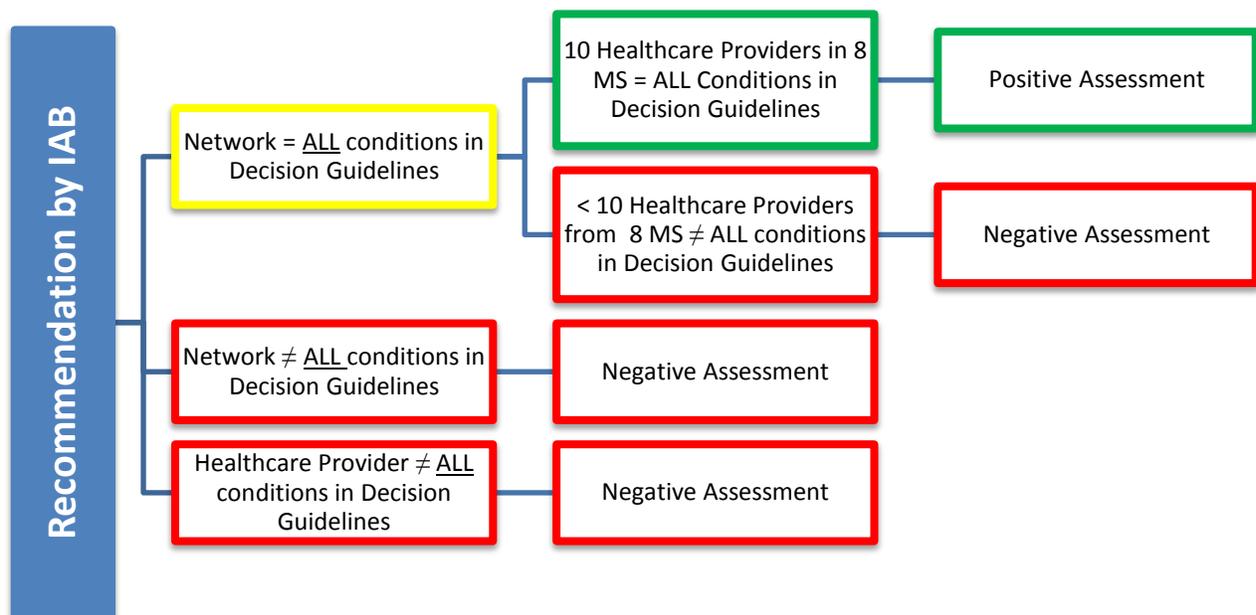
If the Network is unable to meet **all** of the above conditions, this will result in a negative assessment for both the Network and the Healthcare Provider. The Board of MS will be informed in general terms of the Networks with a negative assessment report.

For Healthcare Provider(s) to obtain a positive assessment, the following conditions must be met:

- **An overall compliance rate of 70%** of the maximum score of the Healthcare Care Provider general and specific operational criteria.

- Each theme under the ***General Criteria*** must achieve **70%** compliance against the maximum score.
- Each theme under the ***Specific Criteria*** must achieve **80%** compliance against the maximum score.
- There should be **no measurement elements under any theme rated as “0”**.
- A rating of “1” for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.

If the Healthcare Provider is unable to meet **all** of the above conditions, this will result in a negative assessment. Only Healthcare Providers and their respective Network Applicants with a positive assessment can progress to the next stage as illustrated in the diagram below. This step represents the **fourth decision point** in the assessment process. The results are summarised in individual assessment reports for the Network and Healthcare Providers as outlined in the following section.



#### 6.4.2 Assessment Report

The Independent Assessment Body (IAB) works with the Assessors to prepare a final assessment report. Common reports for the Network as well as individual reports to each Healthcare Provider are provided. Also included are the assessor ratings against the Operational Criteria, strengths and areas for improvement. All the reports are uploaded to the portal once they are ready. The Assessment Coordinator notifies the Network Coordinator that the reports are ready for review.

**Tool(s):**

**Annexes VII and IX** provide templates for the assessment reports for Networks and Healthcare Providers. Refer to **Annex X** to obtain the Decision Guidelines for approving a Network or Healthcare Provider.

### **6.4.3 Applicant Submission of Comments**

Applicants have an opportunity to review and comment on the findings in the assessment reports to ensure that the Independent Assessment Body (IAB) has not misinterpreted or missed information. Amendments may be requested up to **2 months** of receiving the reports.

Any changes from the Healthcare Providers must be sent through the Network Coordinator to share with the Assessment Coordinator. Any proposed amendments are discussed with the assessor team. The report is modified only if there is clear evidence of misinterpretations by the assessors.

### **6.4.4 Negative Assessments**

An Applicant with a negative assessment cannot progress to the next stage of the assessment. If as a result of a negative assessment, the Network no longer meets the minimum requirements of having 10 Healthcare Providers from 8 Member States, the European Commission will ask Member States to encourage their Healthcare Providers to join the Network in order to help reach the required number(s) of Healthcare Providers. Additional time may be provided for the Network to meet this requirement at the discretion of the European Commission and the BoMS. The Network and its respective members, i.e. Healthcare Providers cannot proceed to the next stage until the Network fulfils this minimum requirement. The Board of MS will be informed in general terms of the Networks with a negative assessment report.

## **7. Stage 5: Transfer of Assessment Report to the European Commission**

Once notification is received from the IAB, The European Commission verifies that all the necessary information linked to positively assessed Applicants is available and then notifies and make the reports available to the Board of Member States (BoMS). This is the **second transition point** between the IAB and the EC.

## **8. Stage 6: Approval by the Board of Member States**

The Board of Member States (BoMS) reviews all positive assessment reports and recommendations received from the Independent Assessment Body (IAB). They decide whether or not to approve proposals for a European Reference Network, their membership, and termination of an ERN. Rules of

procedure to support Board decision-making are defined by the BoMS<sup>9</sup>. This step represents the **fifth decision point** in the assessment.

Once decided, both the Applicant and the IAB will be notified, in writing, the outcome of the decision. All decisions of the BoMs are considered final. Should their decision differ from the recommendations made by the IAB, reasons for this will be clearly stated in writing and included in the notification to the IAB and the Applicant.

If a Healthcare Provider is “not approved”, the European Commission (EC) shall verify whether the minimum number of Healthcare Providers and Member States set out in Article 2(2) are still reached. If not, the EC shall ask the Network to find new members. In this instance, the BoMS may choose to **defer the decision** to approve the Network.

If approved, the EC will sign a licence contract for the use of the ERN logo.

## 9. Approval of Members to Existing ERNs

The same procedure will be followed to approve new members to existing Networks as described in section 8 of the Manual.

## 10. Loss of Membership or Termination of a Network

### 10.1 Loss of Membership or Voluntary Withdrawal from a Network

A Healthcare Provider may lose its membership to a European Reference Network (ERN) if any **one** of the following conditions occurs:

- The Healthcare Provider voluntarily chooses to withdraw from the Network
- By decision of the Board of a Network
- The Healthcare Provider’s participation in the Network no longer complies with national legislation
- A Healthcare Provider refuses to be evaluated, in accordance with Article 14 of the Implementing Decision 2014/287/EU
- The Healthcare Provider receives a negative evaluation report
- The Network is terminated.

If the Healthcare Provider no longer complies with national legislation, the relevant MS must inform the European Commission (EC) in writing along with the reasons for the lack of compliance. In instances where the Healthcare Provider voluntarily withdraws, is asked to withdraw, or refuses to be evaluated, the Board of the Network must also inform the EC in writing, along with the reasons for the withdrawal.

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<sup>9</sup> Consult the Board of MS tab in the ERN dedicated website of the European Commission

The loss of membership due to a negative evaluation must be approved by the Board of Member States (BoMS). In this situation, the EC will inform the Board of the Network and the Healthcare Provider Representative, in writing, along with the reasons why.

The EC will notify the Independent Assessment Body (IAB), as well of the change in status. The Members' status will be changed in the portal and modified on all public websites posting the list of approved Networks and Members.

The EC shall also verify whether the minimum of number of Healthcare Providers and Member States set out in Article 2(2) are still reached. If not, it shall ask the Network to find new members within a set timeframe. The timeframe is at the discretion of the EC.

## **10.2 Termination of a European Reference Network**

A European Reference Network (ERN) may be terminated if, any **one**, of the following conditions occurs:

- One of the minimum numbers set out in Article 2(2) of the Implementing Decision 2014/287/EU is no longer met
- The Network receives a negative evaluation
- By decision of the Board of the Network
- If the Network Coordinator fails to request and evaluation of the Network within a five year period following its approval or refuses to be evaluated, in accordance with Article 14 of the Implementing Decision 2014/287/EU

The termination of the Network must be approved by the BoMS.

In instances where the Network refuses to be evaluated or decides to voluntarily terminate its status, the Board of the Network must inform the European Commission (EC) in writing, along with the reasons for the withdrawal. Where necessary, the EC will inform the BoMS of the "termination of a Network".

## **11. Public Release of Information**

### **11.1 Guidelines for the Use of Logo**

The European Commission (EC) will license the use of a unique graphic identifier, i.e. ERN Logo, to successful Applicants. Approved European Reference Networks and their Members shall use this logo for activities organized by the Network, on websites, written material such as brochures, newsletters, email signatures, and other similar material according to the terms of the licence.

Unauthorized use of this official Logo is prohibited. The ERN Logo is proprietary to the European Union and may only be used by approved Applicants.

### **11.2 Confidentiality of Information**

The contents of all materials and information furnished for review during the assessment process are considered confidential. The contents of those documents and the resulting outcomes of the assessment should only be disclosed under appropriate circumstances according to the rules of confidentiality of the EC and IAB.

### **11.3 Publishing Assessment Results and Exchanging Information with the Public**

The EC publically identifies those Applicants who have been approved as European Reference Networks and Healthcare Providers and maintains a list on the public website for external stakeholders, patients, families and the general public to access.

When a Healthcare Provider submits an application to establish a Network and /or become a member of an existing Network, it agrees to disclose publically its approved status to assist stakeholders, patients and families in making appropriate decisions about their care.

Applicants are required to represent their status accurately and without ambiguity. Applicants are approved or not approved as a Network and/or Member. The EC does not rank Healthcare Providers based on the results of the assessment.

Approved Applicants must clearly indicate in their publications that an approved status is separate and distinct from all other types of accreditation, certification, commissioning, and licensing programmes. Approval as a Network and/or applicant may not necessarily be a reflection of the quality of care provided to patients.

## 12. Glossary of Terms

**Applicant:** the Network and Healthcare Providers that are responding to the call for interest for European Reference Networks.

**Healthcare Provider:** a highly specialised healthcare provider that is applying to join a new or existing European Reference Network.

**Healthcare Provider Representative:** a person representing the Healthcare Provider in the proposal to form or join a European Reference Network.

**Assessment Coordinator:** a staff member from the Independent Assessment Body (IAB) acting as the key contact between the IAB, the European Commission and the Applicant.

**Assessment Programme:** a six-stage process to evaluate applications to form a European Reference Network (ERN) or join an existing ERN.

**Board of Member States (BoMS):** a governing body consisting of representatives from Member States across the European Union responsible for the formal designation of European Reference Networks.

**Board of the Network:** a governing body consisting of representatives from each member to provide oversight for the European Reference Network.

**Complex Disease or Condition:** a particular disease or disorder which combines a number of factors, symptoms, or signs that requires a multidisciplinary approach and well-planned organisation of services over time because it implies one or several of the following circumstances: a large number of possible diagnoses or management options and comorbidities; difficult interpretation of clinical and diagnostic test data; a high risk of complications, morbidity, or mortality related to either the disease, the diagnostic procedure, or the management of the disease.

**Network Coordinator:** a person from the Coordinating Member who acts on behalf of the Network to coordinate activities with the European Commission and the Independent Assessment Body related to the assessment programme either directly or through a designate.

**European Commission (EC):** the executive body of the European Union responsible for proposing legislation and implementing decisions.

**European Reference Network (ERN):** a group of highly specialised healthcare providers that are in compliance with the list of criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) and have been awarded with the membership of an ERN.

**European Union (EU):** a formal political and economic union of Member States.

**Highly Specialised Healthcare:** healthcare that involves high complexity of a particular disease or condition in its diagnosis or treatment or management and high cost of the treatment and resources involved.

**Independent Assessment Body (IAB):** a third-party organisation contracted by the European Commission to complete the technical assessment of the Network and Healthcare Providers.

**Member of a European Reference Network:** highly specialised healthcare providers that are in compliance with the list of criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) and have been approved as a member of a European Reference Network.

**Network:** a group of Healthcare Providers responding to a call for interest to be approved as a European Reference Network (ERN).

**Operational Criteria:** a list of requirements for Networks and Healthcare Providers based on the Commission Delegated and Implementing Decisions of 10 March 2014.

**PACE-ERN:** The Partnership for Assessment of Clinical Excellence in European Reference Network (PACE-ERN) is formed by the European Organisation for Rare Diseases (EURORDIS), the European Hospital and Healthcare Federation (HOPE) and Accreditation Europe.

**Toolbox:** a list of tools provided to support the assessment programme.