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Independent Assessment Body
ERN Assessment Manual

1. Description and Procedures

An initiative of the European Commission

This manual is designed to provide the Independent Assessment Body (IAB) with information and guidance on how to complete the assessment for European Reference Networks. It is subjected to further changes and additions.

The specific contracts established by the European Commission with the selected Independent Assessment Bodies will provide further description of the actions to be performed and the deliverables to be produced by the IAB and will prevail to the content of this Manual.

It is part of **series of six** documents that include the following:

1. Independent Assessment Body ERN Assessment Manual: Description and Procedures
2. Independent Assessment Body ERN Assessment Manual: Technical Toolbox
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. Assessor Checklist for Networks
6. Assessor Checklist for Healthcare Providers

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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[1] on patient's rights in cross-border healthcare. As a result, the EC developed the Commission Delegated and Implementing Decisions of 10 March 2014[2] 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 the Independent Assessment Body in accordance with Article 13 (1)-(2) of the Commission Implementing Decision (2014/287/EU).

The purpose of this manual is to describe the methods and procedures for completing the independent assessment of Networks and Healthcare Provider Applicants. It is to be used to help guide the process.

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:

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[1] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

[2] 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 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
- 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
- Establish the conditions, publish a competitive call for tender and select and contract the Independent Assessment Bodies
- 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 IAB, 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 8.11 of its rules of procedure, the Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs). It 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)
- Amend the assessment report based on Healthcare Provider comments, as necessary, and explain whether those comments justify a change in the assessment

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. It 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 Healthcare Provider participation 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, if selected
- 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.

1.4   Independence and Conflicts of Interest

Participation as a board member, assessor, and/or staff member, etc. within the assessment process can at times create situations that may result in conflicts of interest or questions regarding the objectivity and credibility of the assessment. Procedures should be put in place by the IAB to:

- Maintain credibility in the assessment and confidence in decisions made by the European Commission, IAB, assessors, and staff of the IAB
- Assure fairness and impartiality in decision making, and
- Avoid the appearance of impropriety

Individuals representing the IAB must not participate in any decision-making capacity if they have or have had a close and active association with the Applicant. Close and active association includes, but is not limited to:

- Current or past employment as faculty, staff, or consultant to the Applicant
- Current or past discussion of employment or negotiation of employment with the Applicant
- Attendance as a student at the institution

- Involvement of a close family member as an employee, patient and/or family member of a patient, or
- Any reason that hinders the individual in making an unbiased decision

Procedures to address real or perceived conflicts of interest will include the following:

1. The IAB will maintain a record of all known conflicts of interest for every individual involved in the assessment process. This record will be used to select assessors.
2. Each individual representing the IAB in the assessment process will sign a confidentiality and conflict of interest statement. The procedures on conflict of interest and confidentiality will be discussed at the start of the assessment with the Applicant and the beginning of the on-site audit.
3. Each individual involved in the assessment must disclose in writing any real or perceived conflicts of interest as soon as they become evident.
4. The IAB will follow documented procedures to respond to such declarations in a timely way to ensure that the declared interests neither influence nor are perceived to influence decision making.
5. The IAB will maintain a record of all individuals who excuse themselves from any portion of the assessment due to a conflict of interest.

Refer to **Annex "A" in the Technical Toolbox** for a *Sample Conflict of Interest and Confidentiality Statement* to be used for assessors.

2.   The Assessment Process for the Applicant

2.1   Overview

The assessment will be performed by the IAB based on the methods and procedures included in this manual. This assessment is not a certification or an accreditation process. Its only aim is to verify whether the requisites established in the legal acts are in place. The intent and scope of the assessment is to:

1. Verify that the content of the application for each Network fulfils the requirements set out in Annex I of the Implementing Decision 2014/287/EU
2. Verify that the content of the application for each Healthcare Provider fulfils the requirements set out in Annex II of the Implementing Decision 2014/287/EU.
3. Determine whether the Network fulfils the requirement for providing highly specialized healthcare as defined in point 1(a) of Annex I of the Delegated Decision.
4. Verify whether the Network fulfils the criteria and conditions described in Annex I of the Delegated Decision 2014/286/EU by assessing compliance against the *Operational Criteria for European Reference Networks*.

5. Verify whether the Network fulfils the criteria and conditions described in Annex II of the Delegated Decision 2014/286/EU by assessing compliance against the *Operational Criteria for Healthcare Providers*.

Refer to **Annex "B"** in the Technical Toolbox for the *Implementing Decision 2014/287/EU* and the *Delegated Decision 2014/286/EU*.

Once appointed by the European Commission, the IAB agrees to comply with the requirements in the legislation and this manual. The manual integrates all the technical guidance tools, supporting documents and templates to be used along with the sequence of all possible interdependent and linked procedures at every stage of the assessment process. The IAB will document and implement their policies and procedures in conformity with these requirements.

2.2 Operational Criteria for the Networks 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. All Networks and Healthcare Providers selected for the technical assessment are assessed against the same operational criteria.

Refer to **Annex "C"** for the *Operational Criteria to Assess Compliance with EU Legislation for Networks* and the *Operational Criteria to Assess Compliance with EU Legislation 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 1. Establishment of a European Reference Network 2. Highly Specialised Healthcare 3. Governance and Coordination 4. Patient Care 5. Multidisciplinary Approach 6. Good Practice, Outcome Measures, and Quality Control 7. Contribution to Research 8. Continuous Education, Training, and Development 9. Networking and Collaboration	*General Criteria:* 1. Patient Empowerment and Patient-Centred Care 2. Organisation, Management, and Business Continuity 3. Research, Education and Training 4. Expertise, Information Systems, and e-Health Tools 5. Quality and Safety *Specific Criteria:* 6. Competence, Experience and Outcomes of Care 7. Human Resources 8. Organisation of Patient Care 9. Facilities and Equipment
Assessment	Each criterion is rated <u>once</u> for the overall Network.	Each criterion is rated <u>individually</u> 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
- **Guideline**: each measure has guidelines to further 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

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 should 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.

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[3] based on the following parameters:

- Recent assessment completed by a recognised assessment body within the last 5 years
- Healthcare Provider demonstrates 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. a copy of the assessment report or results; in this instance, the Assessment Coordinator will request a copy of the assessment report or results **within 3 days of its first contact** with the Applicant. This information is to be submitted in conjunction with all other supporting documentation requested by the IAB.
- Acceptance of this "proof of assessment" is at the discretion of the Independent Assessment Body (IAB); the Assessors should validate this information during the documentation review, virtual interviews and the on-site audit

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

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

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[3] Any formal system of assessment, certification, licensing, etc. recognized by the competent national authorities.

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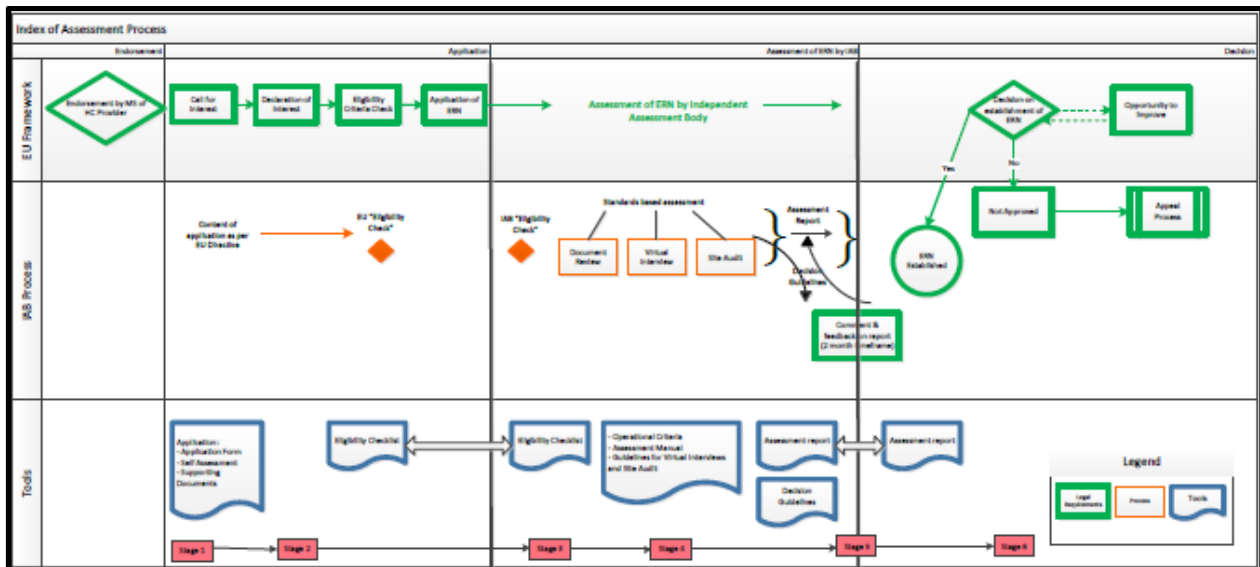
Throughout the process, there are five distinct decision points to determine whether the Network and its Healthcare Providers can progress to the next stage in the assessment. These include the following:

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 selected Healthcare Provider(s) can progress to the on-site audit.
4. The IAB determines if the results from the 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 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). The following diagram outlines each stage in the assessment programme.

Stage 1 Call for interest from EC		Stage 2 Proposal submitted to EC		Stage 3 Application reviewed by EC then IAB		Stage 4 Assessments and reports completed by IAB		Stage 5 Assessment results sent to EC		Stage 6 Final approval by BoMS
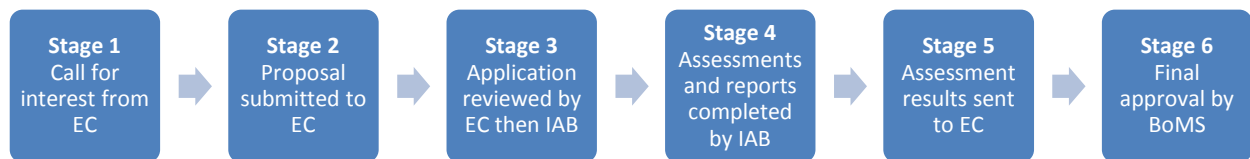
The following sections of the Manual include detailed procedures for IAB to follow at each stage of the assessment process.

3.   Stage 1: Publication of the Call for Interest

The first stage of the assessment process is the call for interest.[4]   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[5].

Procedures to support the call for interest are as follows:

1. The European Commission's Directorate-General for Health and Food Safety (DG SANTE) launches a public call for European Reference Networks (ERNs).
2. The calls for interest are published on the EUROPA website (DG SANTE). The first call will be published within 2 years following the entry into force of the Implementing Decision 2014/287/EU, i.e. 2016. Subsequent calls will be published at the discretion of the Commission, following consultation with Member States.

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[4] Commission Implementing Decision 2014/287/EU, Article 2
[5] http://ec.europa.eu/health/ern/docs/ern_board_implementationstrategy_en.pdf
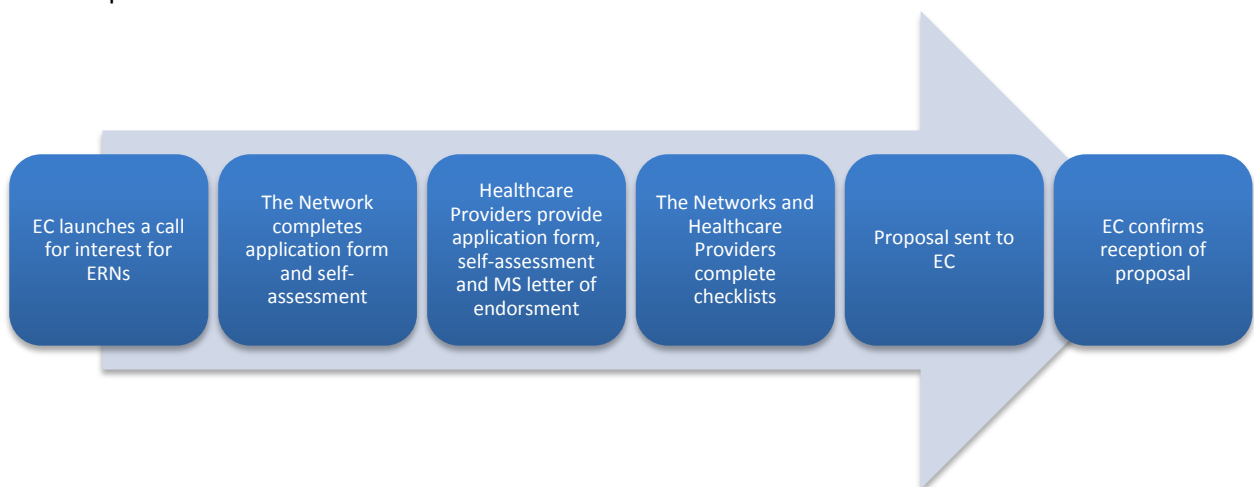
3. To access the portal, potential applicants can visit the EUROPA website. The call for interest includes a detailed description of the call and conditions for an ERN proposal, links to application documents such as the application forms, self-assessments, checklists, etc., deadline for submission, and contact information for queries.
4. The Network Coordinator and Healthcare Provider Representatives can download this information from the portal and distribute it to key individuals for completion.
5. 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, and letters of endorsement by the Member States that must be submitted **within the deadline** of the call for interest. The supporting documents listed in Appendix B of the Self-Assessments for both the Network and HealthCare Providers will be provided to the IAB at its request..

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 guide Applicants in this exercise.[6]

To be considered, a minimum of 10 Healthcare Providers from 8 Member States (MS) are needed to participate in the ERN proposal. The following diagram summarises the key steps of this stage in the assessment process.

| EC launches a call for interest for ERNs | The Network completes application form and self-assessment | Healthcare Providers provide application form, self-assessment and MS letter of endorsment | The Networks and Healthcare Providers complete checklists | Proposal sent to EC | EC confirms reception of proposal |

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[6] 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), .

4.1 Completing the Application Forms

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).

The process for completing the application form is as follows:

1. The Network, as a whole, must first complete **one** *Network Application Form* and circulate the completed form to the Healthcare Providers.
2. As a next step, **each** Healthcare Provider (including the Coordinating Member of the Network) must complete its *Membership Application Form*.
3. Once complete, the Membership Application Forms for the Healthcare Providers are integrated as appendices into the Network Application Form to complete the proposal.

The ERN Board of Member States has provided valuable guidance[7] on some concrete aspects of the application process including specific references to the role of Affiliated Partners[8] and how they should 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 will be considered 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 also provide 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

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[7] http://ec.europa.eu/health/ern/docs/ern_board_implementationstrategy_en.pdf
[8] Affiliated partners = Associated national centres; Collaborative national centres; National coordination hubs

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.

Refer to the *Network Application Form* and the *Membership Application Form* available under the documents section in the call for interest.

Grants to support the approved ERN's networking activities may be launched by the EC using the appropriated funding sources.

For those Network Applicants wishing to respond to a call for grants, 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 in the submission webpage of the call..

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**.[9]

Procedures to support this process include the following:

1. It is the responsibility of the Healthcare Provider to obtain the written statement of endorsement.
2. The written statement is to be included with the application form and submitted to the European Commission.
3. Membership applications without the written statement will be considered incomplete and will be ineligible to proceed to the technical assessment.
4. The decision process and format used to support Healthcare Providers is a national responsibility defined by the MS.

Refer to the *Sample Template for the Endorsement Letter* available under the documents section in the call for interest.

4.3 Completing the Self-Assessment

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[9] Commission Implementing Decision, Article 3(3).

The Network and Healthcare Provider Applicants 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 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. It provides a mechanism for the IAB to assess compliance against the Operational Criteria. 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.

4.3.1 Preparing for the Self-Assessment

A self-assessment template is available under the documents section in the call for interest. All application forms must be accompanied with self-assessments and submitted to the European Commission (EC)*.*

The Network Coordinator must establish a team of Healthcare Provider representatives to complete the self-assessment on behalf of the proposed 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.

Refer to the *Self-Assessment Form for European Reference Networks* and the *Self-Assessment Form for Healthcare Provider Applicants* available under the documents section in the call for interest.

4.3.2 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
0: No activity / Not Implemented	*All Criteria:* 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).
1: Partially Implemented	*All Criteria:* 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).
2: Fully Implemented	*All Criteria:* 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 a concise explanation for each rating. If a criterion is considered fully implemented, the Applicant should explain the evidence available to support compliance. 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 ***Self-Assessments for both the Network and the Healthcare Provider, Appendix B*** are <u>not</u> 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, at the start of the technical assessment. Failure to provide the required documents to the IAB will result in the exclusion of the Applicant. The IAB may request additional information and/or proof of compliance with the requirements throughout the assessment process. Documents may also be provided through hyperlinks.

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.[10] These criteria should be clearly identified in the self-assessment with supporting documentation at the IAB's request.

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[10] Any formal system of assessment, certification, licensing, etc. recognized by the competent national authorities

4.3.3 Validating the Results of the Self-Assessment Internally

Prior to finalizing 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 Applicant
- 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 the Healthcare Provider Representative in the self-assessment *Declaration Form*. Refer to the Self-Assessment template available under the documents section in the call for interest for a copy of the *Declaration Form*.

4.4 Submitting the Application Forms, Self-Assessments and Supporting Documentation

A checklist is provided as a tool for Applicants to ensure that all the necessary steps are completed before submitting the application package to the European Commission for review

Procedures for submitting the application forms, self-assessments, and supporting documentation include the following:

1. The completed application package must be submitted online by the Network Coordinator **on or before the deadline** for submission.
2. Once in the portal, the application forms, self-assessments, and supporting documentation can be submitted. All of the documents listed in the box below must be included for the proposal to be considered complete.
3. 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.
4. The EC will proceed with the eligibility check.

5. The EC will assign, by specific contracts, the assessment of each eligible Network proposal to a concrete IAB and will provide the IAB access to the application forms and documentation.

6. Once the notification is received, IAB will assign an Assessment Coordinator to the Applicant and two assessors.

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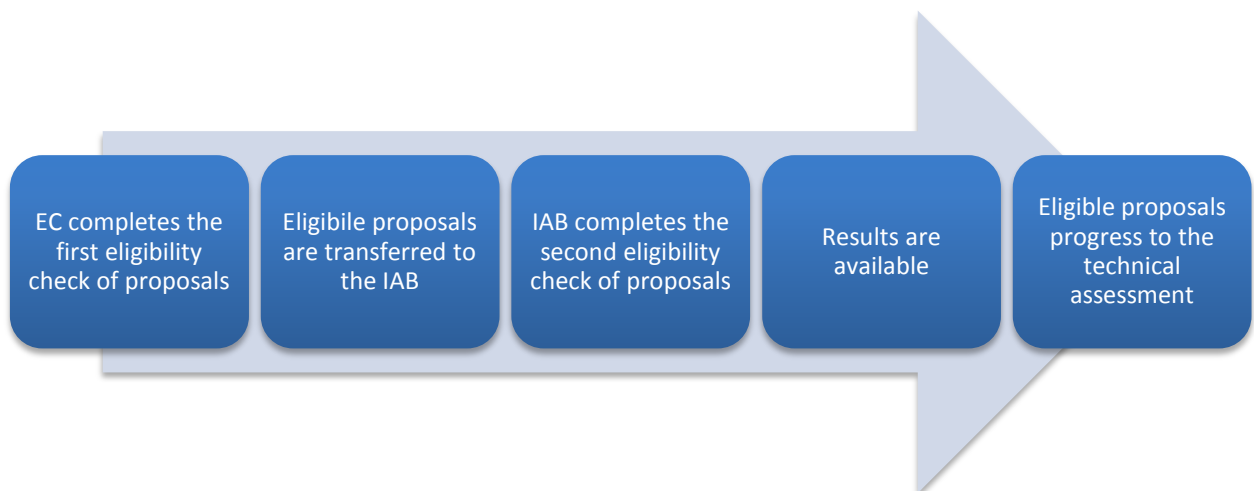

DOCUMENTS TO BE UPLOADED AT THE TIME OF APPLICATION

- ❒ 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 *SELF-ASSESSMENTS FOR NETWORK AND HEALTHCARE PROVIDES APPENDIX B* OF THE SELF-ASSESSMENT SHOULD BE SUBMITTED DIRECTLY TO THE IAB, AT ITS REQUEST. THESE DOCUMENTS SHOULD BE REQUESTED BY THE IAB AT THE START OF THE TECHNICAL

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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.

EC completes the first eligibility check of proposals	Eligibile proposals are transferred to the IAB	IAB completes the second eligibility check of proposals	Results are available	Eligible proposals progress to the technical assessment

5.1   Verification of the Proposal by the European Commission

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.
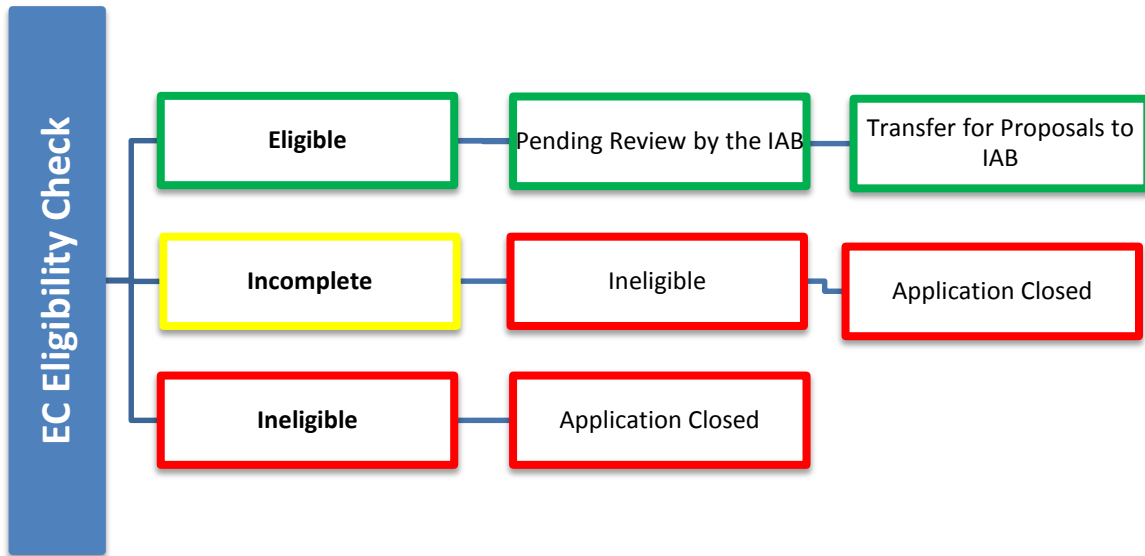
To determine the Applicant's eligibility to progress to the technical assessment, the following activities must first be carried by the EC:

1. The European Commission (EC) completes an initial review of the proposals for completeness. The EC verifies that the proposal 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 as per the requirements in Annex I and Annex II of the Implementing Decision (2014/287/EU)
    *   Each Healthcare Provider has a valid written statement of endorsement from its Member State

2. Once the EC has reviewed the proposal, the Network Coordinator and the Assessment Coordinator are notified about the status of its application. The notification provides information on the status of the eligibility check.
3. If the proposal is incomplete, it is *"Deemed Ineligible"* and the application is closed. The assessment **stops** at this stage for ineligible or incomplete proposals.
4. If the proposal meets the requirements set out in the legislation, the status of the application is adjusted to "*Pending review by the IAB"* and the application moves to the next stage of review.

5. 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

This is the **first transition** point between the EC and IAB. The EC provides the contracted Independent Assessment Body (IAB) with access to the proposal and the checklist results. This step represents the **second decision point** in the assessment process as illustrated in the diagram below.
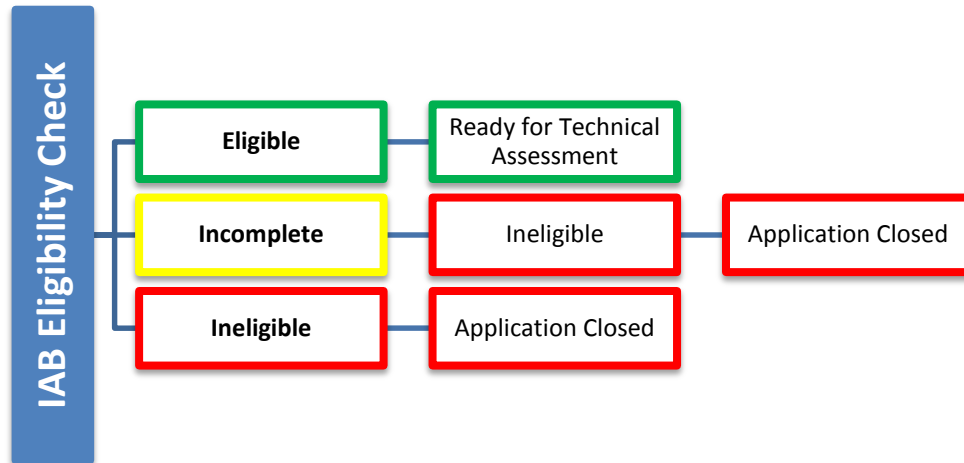
To complete the eligibility check, the IAB must carry out the following activities:

1. The Assessment Coordinator accesses all the required documentation and assigns a minimum of two assessors. The number of assessors is determined based on the size and scope of the proposal.
2. The assessors complete a more thorough desk top review of all documents submitted using the *"Eligibility Checklist for Networks"* and/or the *"Eligibility Checklist for Healthcare Providers"* to verify that the proposal meets the following minimum requirements :

   • The content of the Network application fulfills the requirements of Annex I;
   • The content of the Healthcare Provider application fulfills the requirements of Annex II; and
   • The proposal fulfills the requirement to provide highly specialized healthcare. All Healthcare Providers must share the same area of expertise as per the Network's area of expertise.

3. If the proposal meets all requirements, the status is changed and the proposal is *"Deemed Eligible"* to move to the next stage. If the proposal is incomplete or the requirements are not met, it is *"Deemed Ineligible"*. 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.
4. The Assessment Coordinator updates the checklist from the EC.

Refer to **Annex "D"** to obtain the *Eligibility Checklist for European Reference Networks* and the *Eligibility Checklist for Healthcare Providers*.

5.3   Informing Applicants of the Results

Once the eligibility check is complete, the IAB informs the EC and sends all completed documents.   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 technical assessment. The report includes the following:

·   A copy of the complete eligibility statement
·   The rationale for the decision
·   The right to review the documents and respond, as applicable.

For "ineligible" applications, all communication and enquiries by the Applicant will be directed to the EC.

Refer to **Annex "D"** to obtain the *Eligibility Statement Template.*

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.

An introductory web-conference is scheduled → Documentation review and virtual interviews completed → Results available → Eligible proposals progress to the ons-ite audit → On-site audits scheduled → Sample of on-site audits completed → Results available after the onsite audit
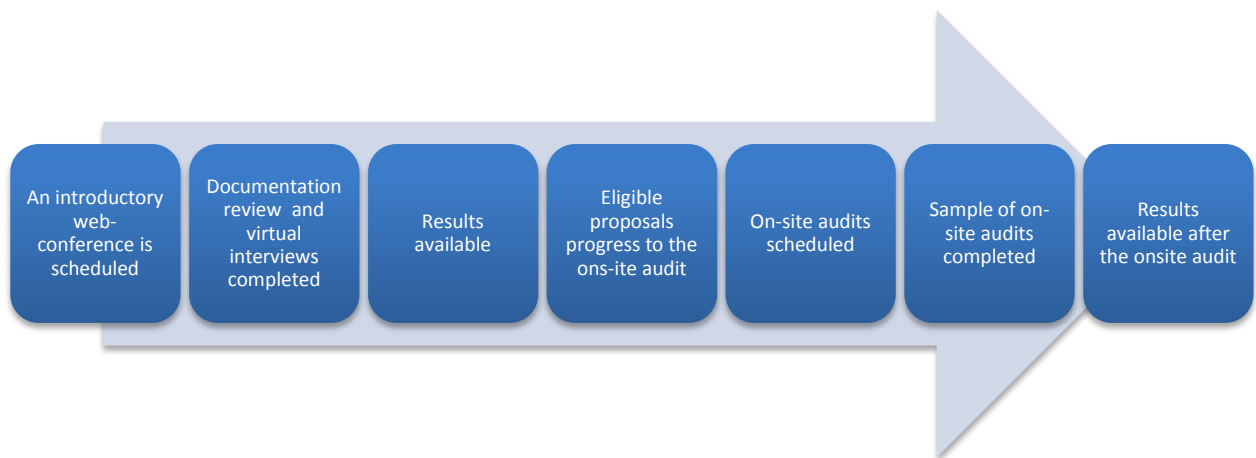
The IAB coordinates the following activities included in the technical assessment of the Applicant: documentation review, virtual interviews and on-site audits. The length of time it takes to complete the assessment depends on the size and scope of the proposal and the number of Applicants who respond to the call for interest.

The purpose of this stage is to assess compliance with the Operational Criteria for Networks and Healthcare Providers. In doing so, the IAB will verify whether:

- The Network fulfils the other criteria and conditions set out in Annex I to the Delegated Decision 2014/286/EU, and/or
- The Healthcare Provider fulfils the other criteria and conditions set out in Annex II to the Delegated Decision 2014/286/EU

To initiate the process, the Assessment Coordinator works with the Network Coordinator to schedule an introductory web-conference with the selected 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 Assessment Coordinator will request all applicable supporting documentation that is required to complete the documentation review from the Network Coordinator and selected Healthcare Provider Representatives. Failure of the Applicant to provide this information, at the request of the IAB, will result in an ineligible proposal.

Refer to *Self-Assessment Form for European Reference Networks* and the *Self-Assessment Form for Healthcare Provider Applicants, **Appendix B*** for the list of supporting documentation required.

6.1   Peer-Review Model

6.1.1 Description of the 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..

6.1.2 Required Qualifications of the Assessors

The qualifications of the assessors are defined in the contract between the EC and the IAB. As a general principle, the Assessors are senior healthcare professionals with one or more of the following qualifications:

- A university degree in quality, healthcare, public health administration, or healthcare management and at least 10 years of professional experience in the area of audits and certification, accreditation or licensing of healthcare providers at national level.
- A university degree in medicine and master and/or medical specialty in healthcare or public health with at least 10 years of relevant professional experience in healthcare quality and in

particular in the field of accreditation, certification, licensing or external assessment or evaluation of healthcare providers.

- A university degree and a master degree in the area of healthcare or public health with at least 5 years of professional experience in performing quality assurance reviews or audits, evaluation of clinical information and documentation including medical record reviews or peer review reports and writing of clinical and quality performance reports.

Assessors should also have knowledge of the European healthcare system and regulations, experience providing care to patients and families with rare or low prevalence complex diseases or conditions, and working knowledge of English with excellent writing skills.. Assessors must also demonstrate a combination of soft skills related to adaptability, analytical thinking, patient focus, communication, organisation and teamwork.

The Assessor Team Leader is a senior healthcare professional with a relevant university degree specialised in the area of quality, healthcare, public health administration of healthcare management, and a minimum of 10 years of professional experience. Experience in the area of audits and certification, accreditation, or licensing of healthcare providers at national level should be included. Team leaders are also expected to have additional soft skills related to management and conflict resolution and have a C2 level of English.

All assessors must complete a comprehensive orientation on the assessment programme to ensure a common understanding of the requirements in the operational criteria for Networks and Healthcare Providers, and consistency in ratings and comments prior to completing any assessments.

Refer to **Annex "L"** for the *Independent Assessor and Assessment Coordinator Core Competencies.*

6.1.3 Guideline for the Assessor Selection Process

This section is provided as a guideline to support the IAB in the selection process and may complement already existing processes with the IAB to recruit and select assessors. Assessors may be selected using a 4-step process. This includes the following:

Step 1 - Application
Prospective assessors are asked to complete an application form and provide a copy of their most recent Curriculum Vitae as well as a copy of the organizational chart identifying their position in their organization to the IAB. An initial review of the CV is completed by senior staff to determine whether the candidate is a good fit with the Assessor Core Competencies and the recruitment priorities. The IAB may then invite the candidate to participate in a telephone interview.

Step 2 - Interview
Qualified candidates will be invited to participate in a telephone interview for a more thorough assessment of their suitability to be an assessor.

Step 3 - Reference Check

Following the interview, successful candidates will be asked to provide contact information for a reference from their supervisor. The supervisor will be asked to participate in a telephone interview. An additional reference check may be required from a colleague.

Step 4 - Assessment During Orientation

Following the reference check, successful candidates are invited to participate in an orientation program as defined by the IAB. This orientation program is used to further assess and give feedback on the core competencies. Aspects of an assessment are role played over the course of the orientation program.
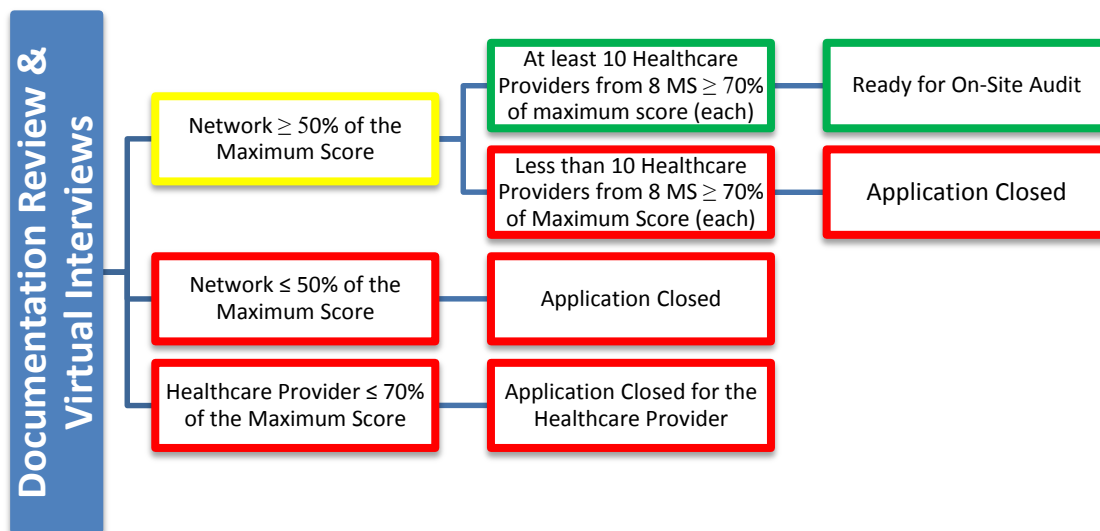
The IAB may use already existing policies and procedures in place to support this process.

6.1.4 Ongoing Training and Competency Review

The IAB will ensure assessor consistency by providing an initial orientation and training session followed by yearly continued education to keep assessors up-to-date on advances in assessment. This ongoing training and supervision helps ensure that the assessment is an educational process, not just a compliance exercise.

6.2 Documentation Reviews and Virtual Interviews

The team of assessors complete the documentation review and virtual interviews to determine if the Network and selected 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.

Documentation Review & Virtual Interviews

- Network $\geq$ 50% of the Maximum Score
  - At least 10 Healthcare Providers from 8 MS $\geq$ 70% of maximum score (each) → Ready for On-Site Audit
  - Less than 10 Healthcare Providers from 8 MS $\geq$ 70% of Maximum Score (each) → Application Closed
- Network $\leq$ 50% of the Maximum Score → Application Closed
- Healthcare Provider $\leq$ 70% of the Maximum Score → Application Closed for the Healthcare Provider

6.2.1 Selecting the Healthcare Providers

Based on the number of Networks and Healthcare providers applications received and compliance with the eligibility criteria, a decision will be made by the European Commission on the number of healthcare providers proceeding with the documentation review and virtual interviews. This decision takes into account the efficiency of the process and the need for a balanced investment of time and resources devoted to this phase of the assessment process.

A stratified and representative sample of Healthcare Providers per Network application will be selected taking in account the size of the Network, the number of HCPs (Hospitals) and its participation in different networks and the Member State representation.

6.2.2 Completing the Documentation Review and Virtual Interview

As a first step, the assessors complete a comprehensive documentation review of the application forms, self-assessments, and any supporting documentation submitted by the selected Applicants.

As a complement to the documentation review, the assessors also complete virtual interviews with the Network Coordinator and *selected* Healthcare Provider *Representatives*. Consideration will be given to the governance structure of the Network, when selecting those individuals who will participate in the virtual interview. Virtual interviews are conducted via web-conference and are about two to three hours in length. 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 Provider Applicants, as applicable;
- Verify that there is sufficient evidence provided; and
- Rate compliance with the operational criteria and/or confirm ratings based on the documentation review.

The procedures for completing the documentation review and virtual interviews will include the following:

1. The Assessment Coordinator will convene a panel of three or more assessors from the pool of experts available. The Assessment Coordinator will also schedule a virtual interview with the Network.
2. The assessors complete an independent detailed desk-top review of the all documentation. During this review, they may work with the Assessment Coordinator to request further information, if required, from the Network Coordinator and/or Healthcare Provider Representative(s); or obtain the advice of specialist clinicians, where necessary.

3. Following the review, virtual interviews with the Network Coordinator and Healthcare Provider Representative(s) will be completed using the *Interview Guide for Completing Virtual Interviews with Applicants*.

4. The Assessors rate compliance with the operational criteria based on the information provided using the *Checklist for Assessors*. Any rating of "0" or "1" must be explained.

5. The assessors specify whether their preliminary ratings reflect a positive assessment based on the *Decision Guidelines for Applicants*.

6. Once complete, the Assessment Coordinator convenes the panel of assessors to discuss and agree on the findings for each Applicant. Following the meeting, the Assessment Coordinator works with the assessors to summarise the findings in a preliminary report for the Network and **for each** of the selected Healthcare Providers using the *Preliminary Assessment Summary Form in* **Annex "F".** In instances where the documentation review results in a negative assessment for any one Healthcare Provider, a new sample of Healthcare Providers will be selected for review equivalent to the number of negative assessments. The review will be completed following the same steps as described above.

7. Once complete, the Assessment Coordinator convenes the panel of assessors to discuss and agree on the findings for each Applicant included in the extra sample.

8. Following the meeting, the Assessment Coordinator works with the assessors to summarise the findings using the *Preliminary Assessment Summary Form in* **Annex "F"**

9. The Assessment Coordinator submits a copy of the report to the EC, the Network Coordinator and the Healthcare Provider Representatives.

11. The technical assessment **stops** at this phase for both the Network and Healthcare Provider in ***either*** one of these cases:

    a. The Network receives a negative assessment based on the Decision Guidelines; or
    b. Less than 10 Healthcare Provider Applicants from 8 Member States receive a positive assessment.

    In addition, the technical assessment may **stop** for an individual Healthcare Provider that receives a negative assessment.

12. **Only** Applicants with a positive assessment can progress to the on-site audits. For Networks, an overall compliance rate of 50% of the maximum score must be achieved to proceed. For Healthcare Providers, a minimum of 70% of the maximum score must be achieved for the general operational criteria and a minimum of 80% of the maximum score must be achieved for the specific criteria.

Refer to **Annex "E"** to obtain the *Interview Guide for Completing Virtual Interviews with Applicants* and **Annex "F"** to obtain the *Assessor Checklist for Networks and Healthcare Providers.*

6.3   On-site Audit

6.3.1 Criteria for Selecting Sites

A sample of Healthcare Providers is selected by European Commission for the on-site audit to validate the information obtained through the documentation review and virtual interviews. The sample will include all Healthcare Providers acting as the Coordinating Member of a Network and a sample of HCPs taking in account their geographical distribution

6.3.2 Preparing for the On-site Audit

The Assessment Coordinator will assign a team of assessors from the pool of experts available. The team of assessors will be made up of a multidisciplinary group of clinicians, and/or managers based on the IAB Terms of Reference. As much as possible, the assessors will be trained and working in the same discipline as the group they are assessing.

The composition of the assessor team depends on the size of the Network and the location of the Healthcare Providers. The team of assessors will include a team leader. The team leader is the key contact between the assessor team, Assessment Coordinator, and the Network Coordinator and is responsible for presenting preliminary recommendations at the end 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.

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

The Assessment Coordinator provides the Network Coordinator and the Healthcare Provider Representative with a checklist to help the Applicant complete the key steps in preparation for the audit.

Prior to the on-site audit(s), the following information must be made available to the assessor team in electronic form:

- Documents and supporting evidences
- Assessor Checklist and Scoring Tool with pre-populated compliance ratings from the documentation review.

In addition the assessor team must also receive:

- Directions and contact information

On-site audit schedule Refer to **Annex "G"** to obtain a copy of the *On-site Audit Checklist.*

6.3.3 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 including travel time. 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 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

Refer to **Annex "H"** for the *Patient Tracer Method and Guide for Assessors.*

6.3.4 Rating Scale and Guidelines

Once on-site, the assessors will confirm compliance against the operational criteria. The prepopulated *Assessor Checklist and Scoring Tool* must be used to support this process.   The assessors apply the same rating scale as outlined in the table below.

Rating	Guidelines
0: No activity / Not Implemented	**All Criteria:** 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).
1: Partially Implemented	**All Criteria:** 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).
2: Fully Implemented	**All Criteria:** 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 assessor applies a rating based on whether there was sufficient evidence from the documentation reviews, virtual interviews and on-site audits (if applicable) to demonstrate compliance with the criterion. When rating the operational criteria for the Network, the assessor also determines whether the practice has been implemented consistently across the Network.

Refer to **Annex "F"** to obtain the *Assessor Checklist and Scoring Tool*

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 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.
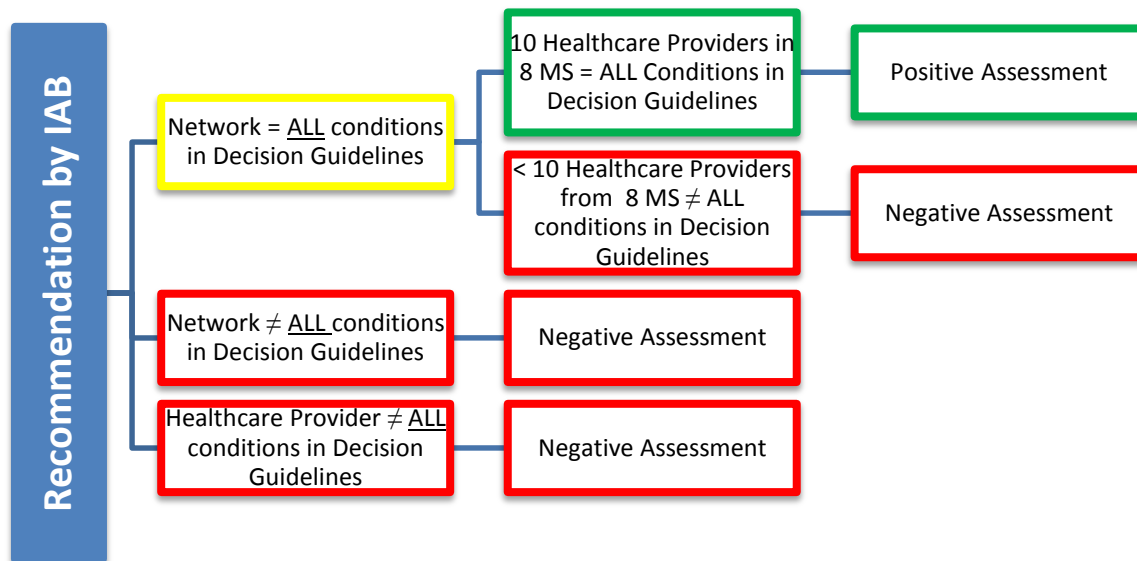
This step represents the **fourth decision point** in the assessment process. The results are summarised in individual assessment reports for the Network and Healthcare Providers as outlined in the following section.

Refer to **Annex "K"** to obtain the _Decision Guidelines for approval of a European Reference Network or Healthcare Provider Applicant._

6.4.2 Assessment Report

The assessor team must submit its findings and recommendations to the IAB at the end of the on-site audits. To ensure fairness, consistency, and quality assurance of the process, the following procedures must be completed:

1. The Assessment Coordinator reviews the findings and recommendations to check for accuracy and consistency.
2. The IAB prepares a common assessment report for the Network and/or one individual report for _**each**_ Healthcare Provider based on the assessment tasks performed and the information collected by the assessors from the eligibility check, documentation reviews, virtual interviews and on-site audits as applicable.   The report includes assessor ratings against the operational criteria and comments on strengths and areas for improvement. Both the Team Leader and the Assessment Coordinator must sign off on the final report(s).
3. All the reports should be ready _**within 2 weeks**_ of the on-site audit. The Assessment Coordinator sends the final to the EC, to the Network Coordinator and the Healthcare Provider Representatives. .

Refer to **Annex "I"** and **Annex "J"** to obtain the _Assessment Report Template for Networks and Healthcare Provider Applicants_.

6.4.3 Applicant Submission of Comments

The Healthcare Provider may send comments to the IAB **within two** _**months**_ of receiving the assessment reports. On receiving the comments, the IAB shall amend its assessment reports explaining whether the comments justify a change in its assessment.

A copy of the adjusted report is submitted to the EC, who will notify the ERN Board of MS.

Negative Assessments

An Applicant with a negative assessment cannot progress to the next stage. 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 EC 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 EC 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 BoMS will be informed in general terms of the Networks and Healthcare Providers with a negative assessment report.

7. Stage 5: Transfer of the 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 of Networks and Healthcare Provider Applicants

8.1 Approval Procedure for 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[11].
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.

9. Public Release of Information

9.1 Confidentiality of Information

The contents of all materials and information furnished for review during the assessment process are considered privileged information. The contents of those documents and the resulting outcomes of the assessment should only be disclosed under appropriate circumstances. Guidelines for maintaining confidentiality of all information received from Applicants should include the following:

- All persons involved with the IAB must perform their duties under the highest standard of ethical behaviour.
- Information provided by the Applicants is for the confidential use of the European Commission and the IAB and will not be disclosed without specific written authorization of the Applicant.

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[11] Consult the Board of MS tab in the ERN dedicated website of the European Commission

- All communications between the Applicant and the assessors regarding approval of the Applicant as a Network and/or Member of a Network must be re-directed to the IAB or European Commission, as appropriate.
- All persons involved with the IAB will abide by the rules of the Applicant and applicable legislation when reviewing patient information. Review of patient charts and patient information will only be for the expressed purpose of conducting the assessment.
- The IAB policies on confidentiality will be presented at the start of every meeting with the Applicant. Prior to conducting a documentation review and/or on-site audit, members of the assessment team will sign confidentiality agreements.
- 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.

10. 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.

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