

ERN Assessment Manual for Applicants

Description and Procedures



History of changes

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Glossary of Terms

Applicant: the Healthcare Provider that is responding to the call for interest for joining the existing European Reference Networks.

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 process to evaluate applications to 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 (BoN): a body responsible for the governance of the Network composed of representatives from each Member in the 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.

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.

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

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.

Network: a group of Healthcare Providers approved as a European Reference Network (ERN).

Network Coordinator: a person from the ERN 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.

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.

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Stage 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). Due to scarce and dispersed expertise on complex or rare diseases and conditions, ERNs were created to facilitate timely access to care, to both diagnosis and treatment, by centralising knowledge and experience, medical research and training, and resources for these diseases and conditions. As specified in Article 12 of the Directive 2011/24/EU¹ on patient's rights in cross-border healthcare, the EC shall define the requirements for ERNs. The Commission Delegated², Implementing Decisions of 10 March 2014³ and Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU⁴ to provide a regulatory framework for establishing, assessing and approving ERNs.

The assessment programme of ERNs was developed in consultation with the Member States and key stakeholders since 2015, and has recently been updated with the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU. The assessment manual for the Applicants has been created in accordance with Article 13 (1)-(2) of the Commission Implementing Decision (2014/287/EU) and Article 1a of the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU.

1.2. Objectives of the Assessment Programme

The assessment programme is based on a peer review assessment model. It provides a standardised, transparent, and consistent method for assessing all Healthcare Providers (HCPs) 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;
- Helping to improve the delivery of high quality healthcare, including timely advice for the diagnosis and treatment options and the provision of safe care;

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 C(2014) 1408 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

³ C(2014) 287 Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

⁴ Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

- 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 Applicant

The **Healthcare Provider Applicant (HCP Applicant)**: each Healthcare Provider wishing to join an approved European Reference Network (ERN)

Throughout this manual, the term “**Applicant**” refers to the Healthcare Provider Applicant. The term “**Healthcare Provider**” refers to the Healthcare Provider Applicant.

The **Applicant** works with the Board of the Network (BoN), the European Commission (EC) and the Independent Assessment Body (IAB) to fulfil the following roles and responsibilities:

- Submit an application form, self-assessments, Member State's written statement (letter of endorsement), and supporting documentation to the to the EC and/or the IAB in response to the call for interest;
- Provide comments on the draft opinion of the BoN **within one month**;
- 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 to the IAB the evidence needed to demonstrate compliance with the Operational Criteria;
- Liaise with the BoN and the 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 the IAB;

The Applicant has the right to contest the unfavourable opinion of the BoN or the IAB through its National Authority. The National Authority decides whether to request that the BoMS overrule the opinion.

1.3.2 Board of the Network

In accordance with Article 3 of Delegated Decision 2014/286/EU and Article 1a of Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU, the Board of the Network (BoN) is a body responsible for the governance of the Network, composed of representatives from each Member of the Network. The BoN main responsibilities are:

- Carry out a peer review on the basis of the criteria and conditions set out in point 2 of Annex II to

- Delegated Decision 2014/286/EU;
- Prepare a positive or negative opinion within the timelines specified in Article 5 of the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU for the HCP that wish to join its Network;
- Complete all forms in English;

1.3.3 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 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.

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

1.3.5 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, give access, register, and track applications for HCPs to join the existing ERNs;
- Receive all HCP draft applications with the final unfavourable opinion of the BoN and transfer it to the BoMS;
- Receive overruled applications by the BoMS and the negative opinions;
- Complete 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 IAB;
- Transfer the positive assessment reports completed by the IAB to the BoMS for approval;
- Provide the secretariat of the BoMS;
- Maintain and publically share a list of all new recognized members of existing ERNs;

The EC 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.

1.3.6 Independent Assessment Body

The Independent Assessment Body (IAB) is an independent assessment organisation appointed by the 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 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.

1.3.7 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 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

Stage 2: Publication of the Call for Interest

2.1. 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 healthcare providers wishing to join the European Reference Networks (ERNs) for rare or low prevalence and complex diseases or conditions.

24 ERNs covering all major rare disease groups were launched in March 2017, including 956 highly specialised healthcare units from 313 hospitals located in 26 countries (25 EU Member States plus Norway). Each Network has a Coordinator and the 24 of them are gathered within the ERN Coordinators group (ERN-CG) establishing a common ground on several key technical and organisational aspects of the Networks activities.

2.2. Instructions for 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 applying to an existing Network, links to the application IT tool and documents such as the application forms, self-assessments, deadline for submission, and contact information for queries.

The deadline for submission of applications will be published with each call for interest.

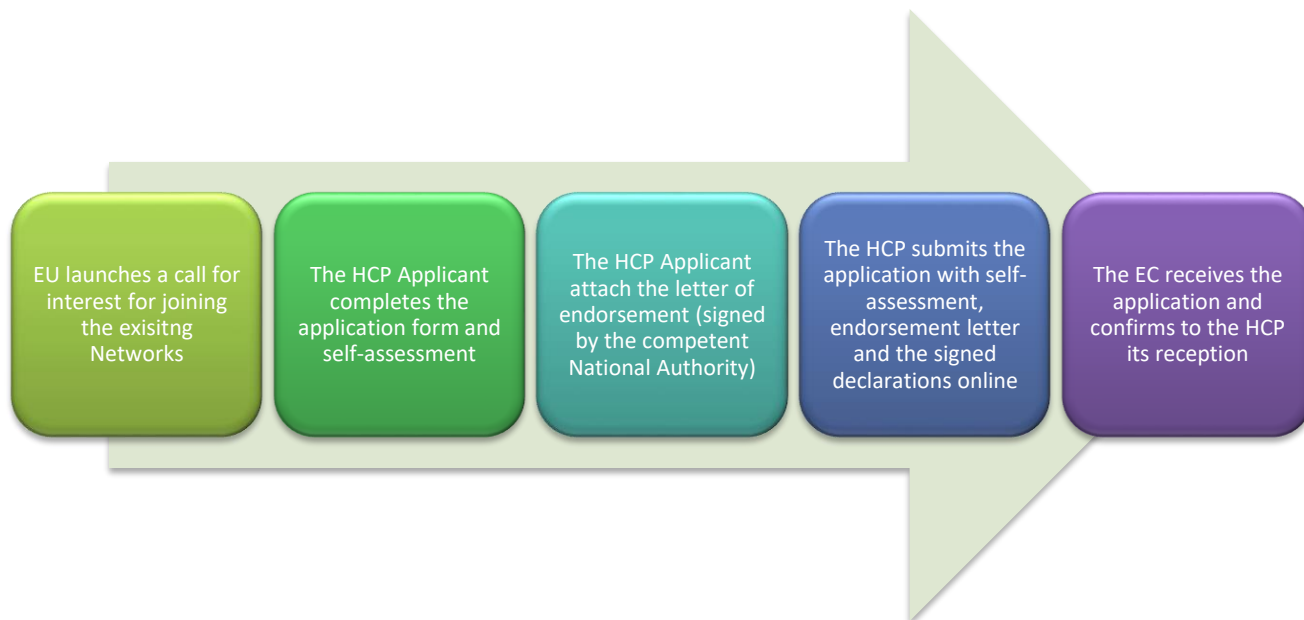
Stage 3: Application for joining an existing Network

3.1. Applying for Membership to an Existing Network

The Applicant must fill in the online application tool that consists of:

- application form,
- self-assessment,
- declaration of the CEO or Director of the Hospital where the applicant is located,
- declaration by the representative of the applicant,
- and letter of endorsement by the Member State National Authority.

These must be submitted **within the deadline of the call of interest** and the required documents must be signed. **Applications sent by different means will not be accepted.**



The following is an overview of the steps completed by the Healthcare Provider until the Application is provided to the IAB:

- The Healthcare provider submits a completed Application consisting of the application form, self-assessment, signed statement of the CEO, signed statement by the Applicant representative and a letter of endorsement from its Member State. The Healthcare Provider must prepare all the supporting documentation listed in **Annex I, Appendix B**. These documents should be made available to the BoN and the IAB, at their request;
- A unique Application number will be assigned to the Healthcare Provider to track its status;
- The system will send an acknowledgement of the receipt of the completed Application to the Healthcare Provider;
- The EC will proceed with the eligibility check;
- The EC provides the BoN the eligible Applications;
- The BoN send to the Applicant favourable or unfavourable decision;
- The Healthcare provider replies to comments within 1 month if the decision is unfavourable;
- The BoN has 1 month to provide a final decision on the Application.
- Applications with a favourable opinion are transferred for the assessment of the IAB.

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

3.2. Description of the online tool

The filling instructions are detailed in a specific document available on the website⁵.

3.3. Description of an Application Form

All Applicants are required to complete an online application. All required information and documents shall be filled in and uploaded using the online tool. No other means will be accepted at this stage.

The applicant shall attach to the Application declarations that shall be **downloaded, filled in and signed** by the CEO and the Healthcare Provider Representative (content of both declarations is available in **Annex IV**).

The application form includes a description of the HCP activities, area of expertise and scope of services, epidemiology of the disease(s) or condition(s), research activities, etc.

3.4. National Endorsement by the Member State

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

Applications without the written endorsement statement or with an endorsement not signed by the officially nominated National authority will be considered incomplete and will be ineligible to proceed to the technical assessment.

A template of the Endorsement Letter is provided in **Annex III** and it is **mandatory** to include all the information required in this template. The National Authority may include further information or logos.

3.5. Completing the Self-Assessment for Healthcare Providers

3.5.1. Description

The Healthcare Providers are required to complete a self-assessment against the Operational Criteria (a summary table is provided in **Annex II**). The self-assessment is available in the online application in a separate tab together with the Membership application form.

The self-assessment is a valuable step; it provides an opportunity for the applicant Healthcare Providers to assess themselves against the specific legislated criteria and conditions before submitting the application to the 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 to plan the on-site audit.

⁵ https://ec.europa.eu/health/ern/consultations/2019_call_membership_en

Healthcare Providers should ensure that the self-assessment is made and agreed with the involvement of the Healthcare Providers' multidisciplinary teams.

3.5.2. Preparing for the Self-Assessment

To complete the self-assessment, Applicants must follow the "Instructions for Completing the Self-Assessment" included in **Annex I**.

3.5.3. Filling the Self-Assessment

The self-assessment lists all the Operational Criteria for 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.
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.
2: Fully Implemented	All Criteria: this rating is used when there is sufficient evidence to support compliance.

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 I, Appendix B** are not to be uploaded together with the application but must be ready to be submitted as evidence at the start of the technical assessment.

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

Additional documentation considered necessary by the BoN, the IAB or the EC might be requested before or during the on-site audit and at any time of the assessment process. If the Applicant will fail to provide the requested additional information, it will be considered as a mayor issue for the outcome of the assessment process.

If a criterion is considered partially implemented or not implemented, the applicant must 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 IAB Assessors will use the same rating scale during the technical assessment.

Applicants shall 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.

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

3.5.4. Self-Assessment Example

Self-Assessment for the Healthcare Providers

The following is an example of how to indicate in the self-assessment that another assessment body has assessed one or more of the general criteria in the Operational Criteria for Healthcare Providers. 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).

1.a: The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients’ rights and preferences are respected.
Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.
Fully implemented
Comment
<i>This requirement was evaluated by [Name of Assessment Body] on [Date].</i>

3.5.5. Validating the Self-Assessment Results Internally

Prior to finalising and submitting the self-assessment, the Applicant should follow a process to validate the results internally. 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

At the conclusion of the internal validation, the Healthcare Provider should take the following actions:

- Check and record any changes in the self-assessment
- Ensure that each section is complete and ready for submission

3.6. Submitting the Application Forms, Self-Assessments and Supporting Documentation

The application form, self-assessment, and supporting documentation must be submitted by the Healthcare Provider in due time respecting the deadline fixed in the call. The box below provides a list of the documents that must be submitted at the time of the application.

Documents to be filled in and/or updaloaded during the application process

Membership Application Form

Self-assessment

Letter of Endorsement

Signed Declarations by the Hospital CEO and by the HCP Representative

All other supporting documentation should be submitted directly to the BN, IAB or EC, at their request

Before submission, the Applicant shall make sure the Application contains attached all requested documents dully signed. The Application will be considered ineligible if the responsible parties do not sign the declarations. The Applicant may also provide to the National Competent Authority a copy of the Application before or after submitting the Application in accordance with the national procedures. The Applicants are encouraged to contact their National nominated authorities to clarify the requirements of the national procedure. The information is available on the website⁶.

⁶ https://ec.europa.eu/health/ern/consultations/2019_call_membership_en

Upon submission, a notification is sent to the EC to alert about the submission of the HCP application. A unique Application number is assigned for tracking purposes.

A checklist is provided for the Healthcare Providers to ensure that all necessary steps have been completed before submitting the proposal to the EC (See *Annex I* for a copy of the checklist).

Stage 4: Assessment Process for the Applicant

4.1. Overview

This section provides an overview of the assessment process used to approve Healthcare Providers to join an existing ERN.

4.2. Operational Criteria for the Healthcare Providers

4.2.1. Purpose of the Operational Criteria

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

Annex II provides a summary table of the *Operational Criteria for Healthcare Providers*. A separate document explaining in detail the *Operational Criteria for Healthcare Providers* is available on the website⁷.

4.3. Assessment and Approval of Applicants

The assessment process consists of main stages and four transition points involving the transfer of information between the Applicant, the BoN, the EC and the IAB.

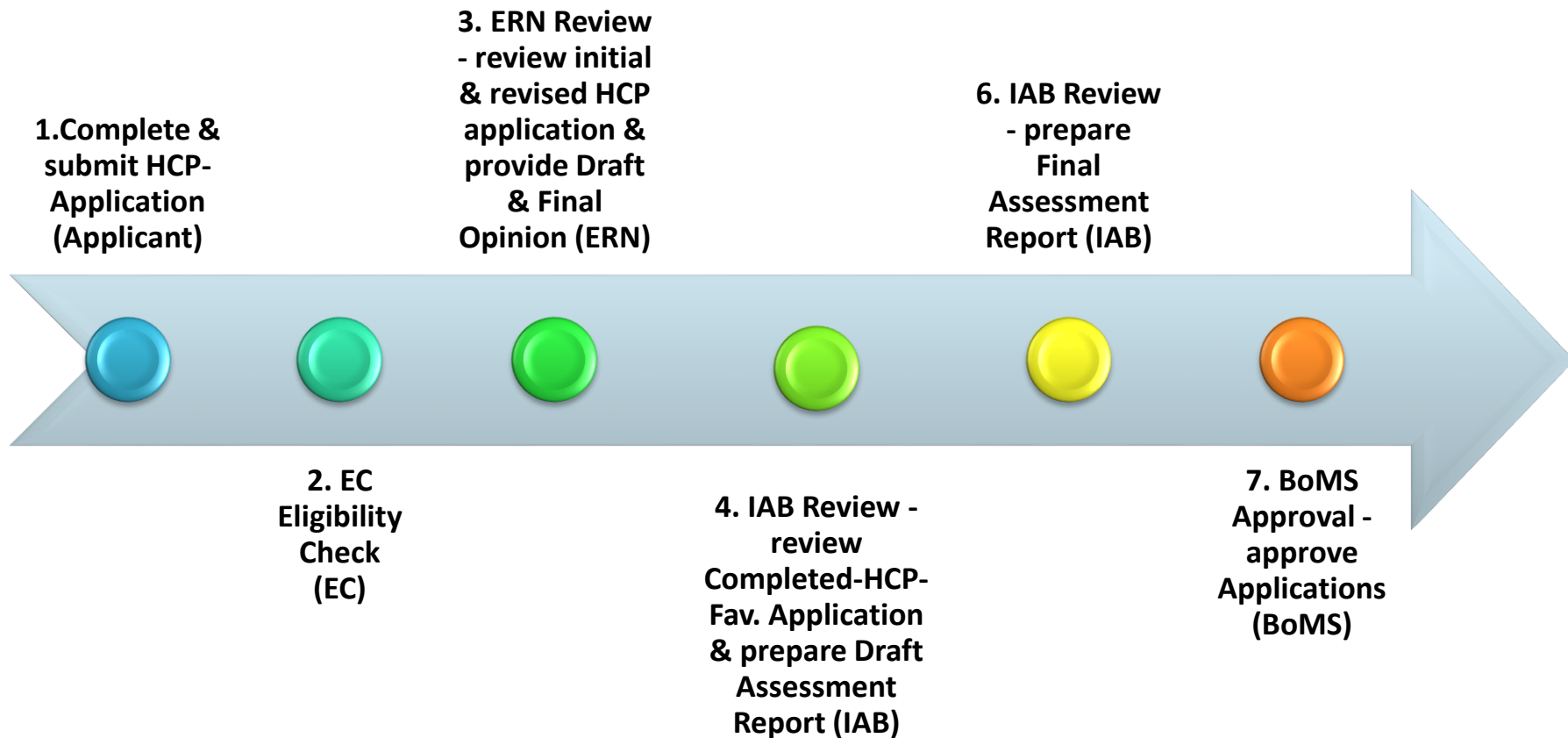
The assessment of the application consists of the following steps:

1. The application is received by the EC and checked for eligibility. Only eligible applications will pass to the next step of the assessment;
2. The eligible applications are received by the BoN that the Healthcare Provider wishes to join;
3. The BoN shall provide the Applicant with a draft opinion within three months;
4. The Applicant have the possibility to reply within one month to the draft opinion;
5. The BoN sends a final opinion to the Applicant within four months from the date of receiving the eligible application.
6. The BoN will take into account comments received from the Applicant for the preparation of the final opinion; the deadline of four months can be extended to five months in case the Network receives comments to the draft opinion;
7. If the BoN fails to send the draft opinion or deliver the final opinion within the deadlines set, the final opinion should be deemed favourable;

⁷ https://ec.europa.eu/health/ern/consultations/2019_call_membership_en

8. If the BoNs' opinion is unfavourable, the Applicant may contact its National Authority. It would be for the National Authority to decide whether to ask the BoMS to overrule it;
9. Applications with a favourable opinion are provided to the IAB;
10. The IAB completes the second part of the eligibility check to determine if the Healthcare Provider can progress to the technical assessment.
11. The IAB completes the technical assessment, i.e. documentation review and virtual interviews, to determine if the Healthcare Provider can progress to the on-site audit.
12. 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.
13. If the result of the IAB's technical assessment is negative, the Applicant may contact its National Authority, which will decide whether to ask the BoMS to overrule the decision.
14. The BoMS reviews the results and recommendations from the technical assessment and issues the final decision: the approval as a Member of an existing ERN.

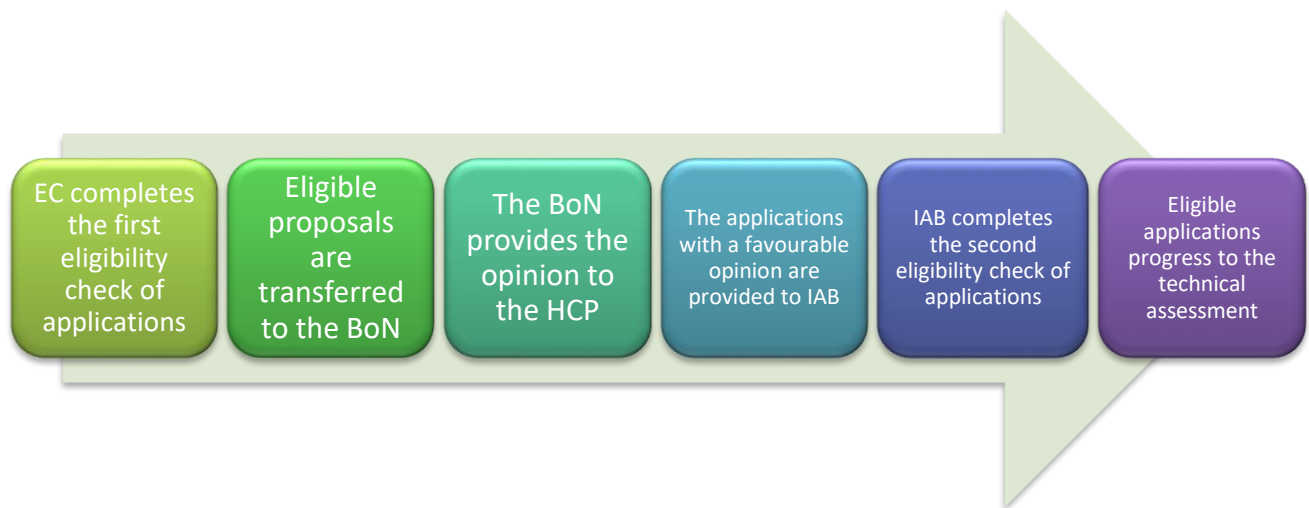
The following diagrams provide an overview of the process from the call for interest to the final approval by the BoMS.



Stage 5: Determining Eligibility of the Applicant

Both the EC and the IAB are responsible for determining the eligibility of the applications. The following diagram summarises the key steps of this stage in the assessment process.

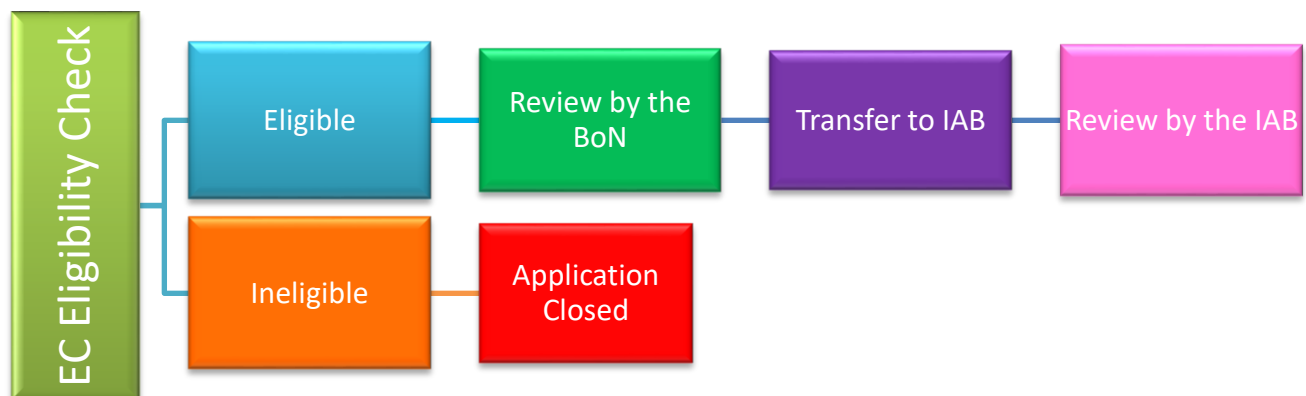
The following diagram outlines each stage in the assessment programme:



5.1. Verification of the Proposal by the European Commission

5.1.1. Description

The EC completes the first part of the eligibility check of the applications. 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 applications for completeness. The EC verifies that the Applicant meets the following minimum requirements:

- the Healthcare Provider have completed the application form and self- assessment as per the requirements in Annex I and Annex II of the Implementing Decision (2014/287/EU);
- the Healthcare Provider attached a written statement of endorsement from its Member State;
- the Healthcare Provider attached declaration forms with the signatory of the CEO and HCP representative.

Once the EC has reviewed the completed applications, the HCP is notified by the online system about the status of its application.

Only those applications meeting the minimum requirements are shared with the BoN for their opinion and transferred to the IAB for further assessment. The assessment stops at this stage for ineligible or incomplete applications.

5.2. Assessment of the Application by the Board of Network

5.2.1. Description

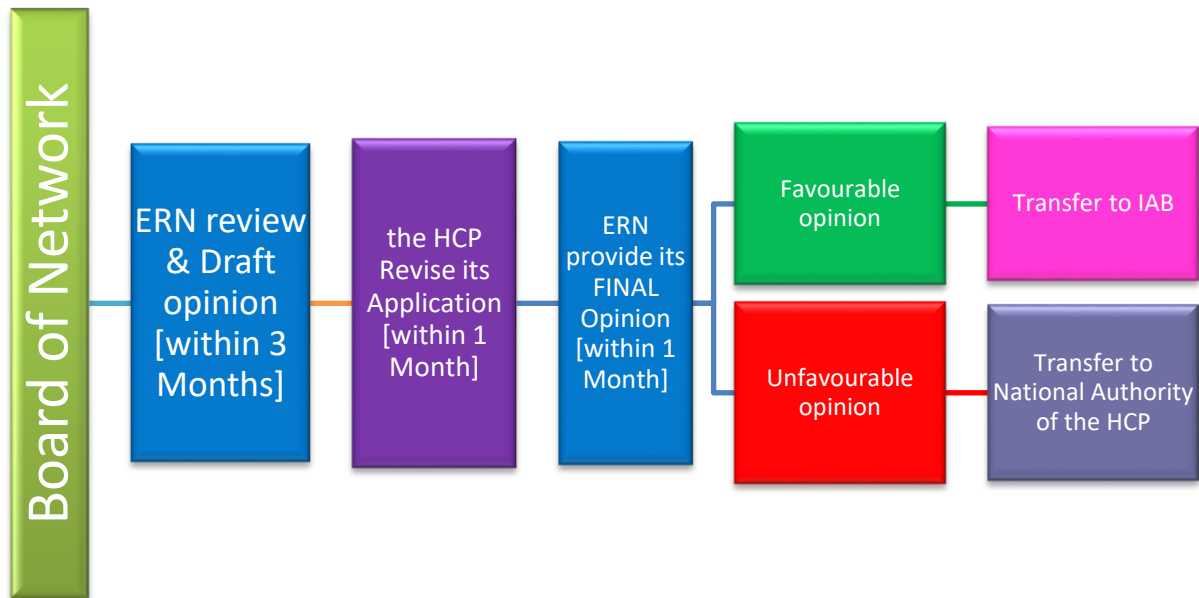
The BoN assesses the eligible applications against the criteria and conditions set out in point 2 of Annex II to Delegated Decision 2014/286/EU.

The specific criteria available under the link summarize the initial criteria and thresholds that 24 ERNs provided in 2016 during their application process:

https://ec.europa.eu/health/sites/health/files/ern/docs/specificcriteria_en.xlsx

5.2.2. Steps completed by the Board of Network:

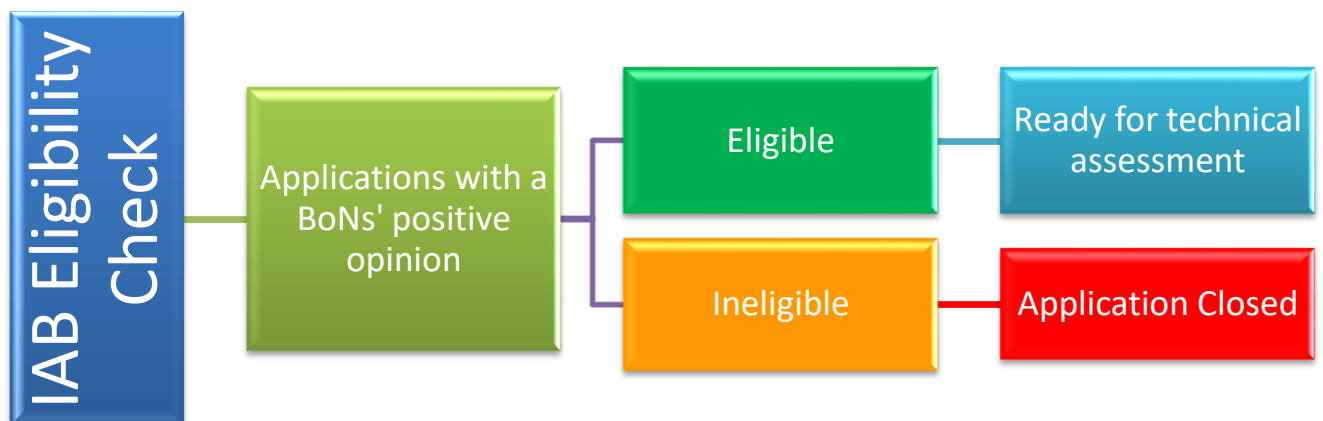
- The Board of Network receives eligible applications from the EC, from that moment on, **the clock starts**.
- The BoN review the applications, request complementary information or documents to the Applicant when needed and prepare a draft opinion per application.
- This is then send to the Applicant through the IT system **within three months**.
- The Applicant reviews the comments received and revises its application **within one month**.
- The BoN receives notification through the IT system that the Applicant made comments and/or revised its application. The BoN have **one month** to prepare its Final Opinion.
- If the BoN fails to provide the draft opinion or deliver its final opinion within the deadline set, the final opinion should be deemed favourable.



5.3. Validation of the Application by the Independent Assessment Body

5.3.1. Description

The IAB receives only the applications with the positive opinion from the ERN Board of Network and completes the second part of the eligibility check of the applications.



5.3.2. Steps Completed by the Independent Assessment Body

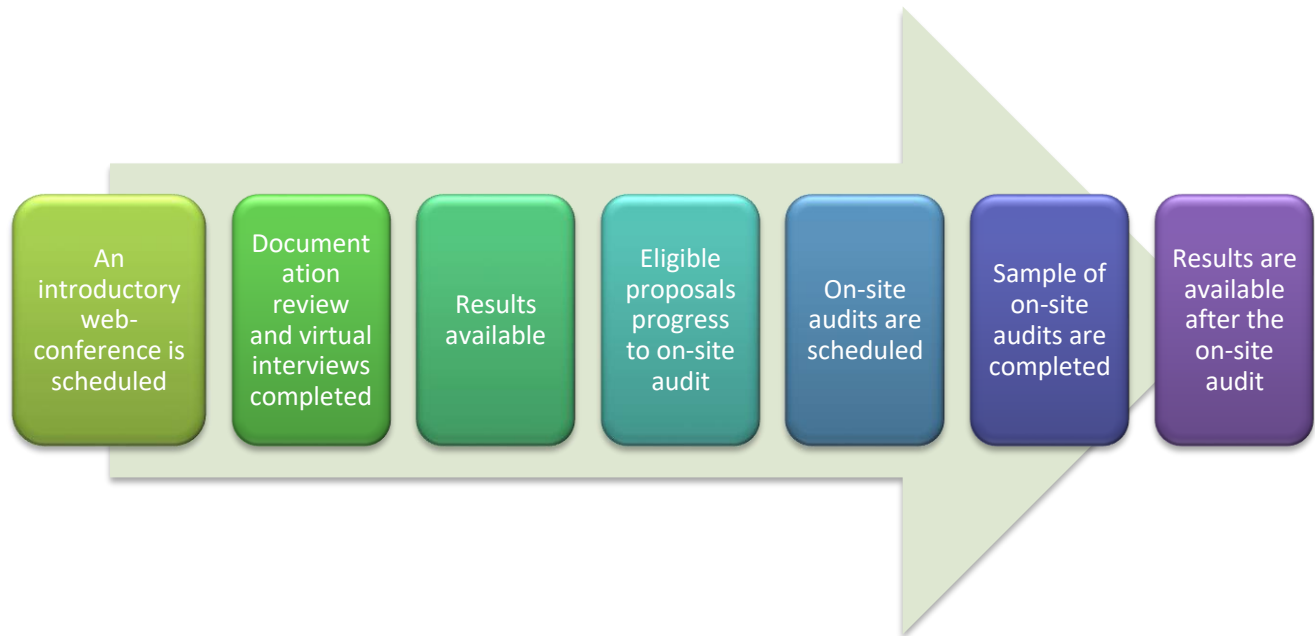
- Once the IAB receives the application, it assigns an Assessment Coordinator as the key contact between the IAB and the Network Coordinator.
- The Assessment Coordinator updates the checklist from the EC and provides the Applicant with a

report with an updated copy of the checklist and a decision on whether the proposal is eligible or not to proceed to the next stage in the assessment.

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

Stage 6: Technical Assessment of the Proposal

Eligible proposals progress to the assessment, completed by the 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 Healthcare Providers.

To initiate the technical assessment, the Assessment Coordinator works with the Healthcare Provider Representative to schedule an introductory web-conference. 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 Applicant must provide the supporting documentation. Failure of the Applicant to provide this information at the request of the IAB, will result in an ineligible proposal.

Depending on the number of applicants, the EC may decide to establish a representative sample to proceed to the next steps of the process of assessment (documentation review and audit)

The documentation provided by all eligible applicants will be filed by the IAB for any further review or assessment by the BoN, the IAB or the EC.

6.1. Peer-Review Model

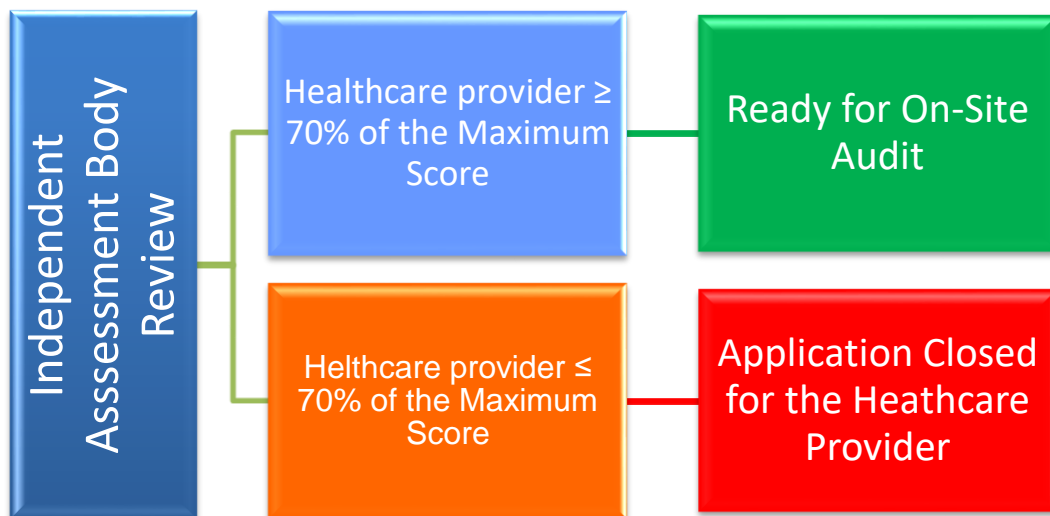
Peer review means having the work of one or more individuals evaluated by experts from the same field. This model helps providing credibility to the assessment and ensures that standards for patient care are evaluated by healthcare professionals with the necessary expertise and experience in the area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

The composition of the assessor team depends on the number of Applicants wishing to join the same Network and on their geographic location. A minimum of two assessors are needed to complete the technical assessment with one assessor appointed as the team leader. Ideally, the same team should assess all the applications to the same network.

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 Healthcare Provider complies 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 the application forms, self- assessments, and any supporting documentation submitted by the Healthcare Provider on IAB request.

As a complement to the documentation review, the Assessors also perform virtual interviews with the

Healthcare Provider Representative. 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 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 of the documentation review and virtual interviews.

The preliminary report will be made available to the Applicant. 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.

Only 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.

6.3. On-Site Audit

6.3.1. Preparing for the On-Site Audit

The IAB will contact those applicants selected in the sample for the on-site audit to validate the information obtained through the eligibility check, documentation review and virtual interviews and will notify them about the dates and times of the on-site audit.

The Assessment Coordinator prepares an 'on-site audit schedule'. The Assessment Coordinator requests from the Healthcare Provider the required documentation or information that to 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 may include:

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

In preparation for the on-site audit, a teleconference is scheduled between the Assessment Coordinator, the assessor team, and the Healthcare Provider Representative 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

Tip(s): It is recommended that the Healthcare Provider Representative completes 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 lasts 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 CEO or management representative and the Healthcare Provider Representative 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) with full respect to data protection rules.
- 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.

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

- **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 at least 70%** compliance against the maximum score.
- **Each theme under the Specific Criteria must achieve at least 80%** compliance against the maximum score.
- There should be **no element under any theme rated as “0”**.
- A rating of “1” for any given 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 the above conditions, this will result in a negative assessment. Only Healthcare Providers 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 IAB works with the Assessors to prepare a draft assessment report. Each Healthcare Provider receives an individual report which includes 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 Applicant that the reports are ready for review.

6.4.3. Applicant Submission of Comments

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

Any change from the Healthcare Provider must be sent to the Assessment Coordinator following their instructions. Any proposed amendment is discussed with the assessor team. The assessors modify the report only if there is clear evidence of misinterpretations.

6.4.4. Final Assessment report

Once the previous step finalised, the IAB will produce a **Final Assessment report** for each eligible Applicant including the information and final assessment of the different steps of the procedure as applicable (eligibility phase, documentation review and on-site audits).

6.4.5. Negative Assessments

An Applicant receiving a final negative assessment cannot progress to the next stage of the assessment. The BoMS will be informed on the Applicants with a negative assessment report.

Stage 7: Transfer of the Assessment Report to the European Commission

Once the EC receives the notification from the IAB, it verifies that all necessary information linked to positively assessed Applicants is available and notifies and presents the reports to the BoMS.

Stage 8: Approval by the Board of Member States

The BoMS reviews all positive assessment reports and recommendations of the IAB and decides on the approval of a Healthcare Provider to join an existing European Reference Network. Rules of procedure applicable to the decision-making process are set by the BoMS⁸.

The EC will notify the Applicant, the Network coordinator and the IAB, in writing, on the decision of the BoMS. All decisions of the BoMs are considered final. Should a decision differ from the recommendations made by the IAB, the reasons for it will be clearly stated in writing and included in the notification to the IAB and the Applicant.

The EC will delegate in the ERN Coordinator the signature of a licence contract for the use of the ERN logo by the successful Applicant.

Stage 9: Loss of Membership or Termination of a Network

9.1. Loss of Membership or Voluntary Withdrawal from a Network

As established in the Commission Implementing Decision 2014/287/EU in Article 12, a Healthcare Provider may lose its membership to a European Reference Network (ERN) if any of the following conditions occurs:

- The Healthcare Provider voluntarily chooses to withdraw from the Network
- By decision of the Board of a Network based on its rules of procedures
- 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

⁸ Consult the Board of MS tab in the ERN dedicated website of the European Commission:
https://ec.europa.eu/health/ern/board_member_states_en

- 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 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 BoN must also inform the EC in writing, along with the reasons for the withdrawal.

The BoMS must approve the loss of membership due to a negative evaluation. In this situation, the EC will inform the BoN and the Healthcare Provider Representative, in writing, along with the reasons of the loss of membership.

The loss of membership due to a decision of the BoN will be justified in written, communicated to the National Authority of the Healthcare provider and to the EC. The EC will inform in written the BoMS, about the reasons of the loss of membership, as stated by the BoN.

The Members' status will be changed in the EC databases and public webpages, and the access rights to the ERN IT tools (e.g. CPMS, ECP etc.) will be deactivated. The ERNs shall update as well the information of their databases and public webpages accordingly.

The EC will also verify whether the minimum of number of Healthcare Providers and Member States of the affected Network set out in Article 2(2) are still reached. If not, the EC will, in consultation with the BoMS decide on the procedure to find new members within a set timeframe. The timeframe is at the discretion of the EC.

Stage 10: Public Release of Information

10.1. Guidelines for the Use of Logo

The EC will allow the sub-license of the use of a unique graphic identifier, i.e. ERN Logo, to successful Applicants including the name of the Network and of the Healthcare Provider. Only approved Members of the ERNs can 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. The EC delegates the use of the license to the ERN coordinator who are responsible to sublicense its use to the new approved members through the signature of a sublicensing agreement.

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

10.2. Confidentiality of Information

The content of all material and information furnished for review during the assessment process is considered confidential. The content of those documents and the resulting outcomes of the assessment can only be disclosed under appropriate circumstances according to the rules of confidentiality of the EC and IAB.

The personal data will be treated in accordance to the EU data protection legislation and rules.

10.3. Publishing Assessment Results and Exchanging Information with the Public

The EC publically identifies those Applicants who have been approved as a Member of an ERN and maintains a list on the public website accessible for external stakeholders, patients, families and the public in general.

When a Healthcare Provider submits an application to 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 shall provide explicit agreement and consent to the use of their personal data and contact details for any action related with the assessment process and their role as members of the ERNs including communication actions developed by the EC.

Applicants are required to represent their status accurately and without ambiguity. The EC does not rank Healthcare Providers based on the results of the assessment. Applicants are *approved or not approved* as Members of an ERN.

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.

Annex I

SELF-ASSESSMENT CHECKLIST FOR HEALTHCARE PROVIDERS

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex II (b), the membership application to join a Network must be submitted in response to a call for interest published by the Commission and must include the completed application form with the self-assessment questionnaire and supporting documentation.

The self-assessment provides Healthcare Providers with the opportunity to evaluate themselves against the criteria and conditions to fulfil as detailed in the **Operational Criteria for the Assessment of Healthcare Providers** document before submitting their application to the European Commission.

In addition, the self-assessment provides a mechanism for both the IAB and the Healthcare Provider to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

INSTRUCTIONS AND RECOMMENDATIONS FOR COMPLETING THE SELF-ASSESSMENT

1. Establish a multidisciplinary team consisting of the Healthcare Provider's Representative and care provider representation.
The team should discuss and agree on the self-assessment information to be include in the IT form. This exercise as a team increases the value of the process and accuracy of the information. It is estimated to take approximately three to four meetings with time allocated between meetings pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointed to organize the group, assign tasks, and coordinate the self-assessment effort.
As the self-assessment will be filled for submission in the online application, it is advised that the team use a paper form to collect the information agreed during the preparatory process.
2. Read and review the Operational Criteria in its entirety before beginning the Self-Assessment process. If possible, make copies and send them to team members before the first meeting.
3. Discuss each individual element in the Self-Assessment Checklist and evaluate the progress in implementing it. As necessary, verify the level of implementation with other individuals outside of the team. Document this information in the "Comments" section of the checklist.
4. Once consensus is reached, complete the table below by marking the box that most appropriately captures the current status of compliance with the criterion, using following rating scale and scoring guide:

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.
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.
2: Fully Implemented	All Criteria: this rating is used when there is sufficient evidence to support compliance.

- Repeat the process for each element. Once complete, tally up the score for each section using the template provided in **Appendix A**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

Use this information to develop an Action Plan to improve readiness to submit the application and complete the assessment process.

Prior to finalizing, filling, and submitting online the self-assessment, a process to validate the results internally 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;

- At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.
- Complete the self-assessment online form.
- Submit the completed Self-Assessment along with the Application Form ***no later than the deadline*** for applications in response to the Call for Expression Interest. The Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in **Appendix B**. These documents should be made available to the BoN, IAB or EC, at their request

APPENDIX A: SCORING TABLE (THIS IS A SAMPLE ONLY)

Self-Assessment Scoring Table			
GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30	0	Percent of Total	0%
Organisation, Management, and Business Continuity			
Total Score out of a Possible 20	0	Percent of Total	0%
Research, Education and Training			
Total Score out of a Possible 24	0	Percent of Total	0%
Expertise, Information Systems, and E-health Tools			
Total Score out of a Possible 12	0	Percent of Total	0%
Quality and Safety			
Total Score out of a Possible 18	0	Percent of Total	0%
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8	0	Percent of Total	0%
Human Resources			
Total Score out of a Possible 8	0	Percent of Total	0%
Organization of Patient Care			
Total Score out of a Possible 12	0	Percent of Total	0%
Facilities and Equipment			
Total Score out of a Possible 8	0	Percent of Total	0%
OVERALL			
Subtotal Score for General Criteria	0	Percent of Total	0%
Subtotal Score for Specific Criteria	0	Percent of Total	0%
GRAND TOTAL SCORE out of a Possible 140	0	Percent of Total	0%

APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS

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

Measure 1.1.1 Mission and/or Core Values **(1a)***

Measure 2.1.1 Organization chart **(2a)***

Measure 1.7.1 Conflict of Interest Policy **(1g)***

Measure 2.3.1 Business continuity plan **(2c)***

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

Measure 1.1.3 Sample of Patient Education Materials already produced by the Healthcare Provider **(1a)***

Measure 1.1.5 Written Material Describing Patient and Family Rights and Responsibilities **(1a)***

Measure 1.3.1 Patient Experience Survey and Sample Patient Experience Reports **(1c)***

Measure 1.5.1 Examples of Informed Consent Policy and Procedures used by the Healthcare Provider
(English translation of one sample + documents in original language) (1e)*

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

Measure 2.1.3 Existing Policies and Procedures for Managing Cross Border Patients or planned actions and timelines for developing policies and procedures **(2a)***

Measure 2.6.1 Discharge procedure and Discharge Template **(2f)***

Measure 5.3.1 List and examples of Clinical Practice Guidelines or Clinical Decision Support tools developed or adopted by the Healthcare Provider related with its area of expertise **(5c)***

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

Measure 2.5.1 Third party reports issued by local or national bodies or external accreditation or certification bodies and/or inspections on the quality care environments **(2c)***

Measure 5.1.1 Quality Improvement Plan **(5a)***

Measure 5.1.2 Current Structure, Process or Outcome Indicators (Dashboard) and their definitions or planned actions and timelines for their development **(5a)***

Measure 5.1.3 Patient Safety Plan **(5a)***

Measure 5.1.4 Examples of methodologies used for adverse events analysis (Root Cause Analysis, etc.) and Description of Process Improvement methods **(5a)***

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

Measure 3.1.2 List of training objectives **(3a)***

Measure 3.1.3 List of Teaching Staff and Qualifications **(3a)***

Measure 3.2.2 List of grants and research projects over the last 5 years **(3b)***

Measure 3.2.3 List of Standard Operating Procedures (SOPs) that govern research activities **(3b)***

Measure 3.2.4 Research Policy and Procedure **(3b)***

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

Annex II

SUMMARY DESCRIPTION OF THE OPERATIONAL CRITERIA

The following table summarises the themes covered in the Operational Criteria for the Healthcare Provider.

Themes in the Operational Criteria	
<p>General Criteria:</p> <ul style="list-style-type: none"> ➤ Patient Empowerment and Patient-Centred Care ➤ Organisation, Management and Business Continuity ➤ Research, Education and Training ➤ Expertise, Information Systems and e-Health Tools ➤ Quality and Safety 	<p>Specific Criteria:</p> <ul style="list-style-type: none"> ➤ Competence, Experience and Outcomes of Care ➤ Human Resources ➤ Organisation of Patient Care ➤ Facilities and Equipment
Assessment	Each criterion is rated <u>individually</u>

The Operational Criteria for Healthcare Providers consist of **two** sections. The first section covers general criteria that are common to all specialised healthcare providers (e.g. organisation and management, research and training, and information systems). The second section consists of specific criteria concerning the condition(s) or disease(s) covered by the Network. The Healthcare Provider must adapt the requirements in these criteria related to competency and expertise, qualifications of the healthcare professionals, composition of the multidisciplinary team, and access to specialised resources (facilities, equipment and diagnostic services) specific to the Network’s area of expertise based on recognised sources, and/or expert consensus. The Healthcare Provider should follow these requirements as defined by the Network.

For each criterion, the following elements are included:

- **Legislative 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;
- **Criterion:** operational requirement linked to every condition and/or sub-condition in the legislation;
- **Measure:** 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; the expected measure(s) of performance that would need to be put in place to meet the criterion;
- **Guideline:** guidance and further explanation on how to reach the particular measure of performance;
- **Evidence:** what will be collected and observed to determine if the measure of performance is met; and

- **Method of Assessment:** how the evidence will be collected and evaluated to determine compliance with the measure.

EVIDENCE OF COMPLIANCE

For those **general** criteria that are common to all, the results of other accreditation and/or certification schemes may be accepted as evidence of compliance only if the national authority formally recognizes them. In this instance, the Healthcare Provider must demonstrate that the accreditation and/or certification meet the criteria and conditions set out in this document and that it has been completed within the last 4 years. All accreditation and/or certification reports should be appended as a part of the supporting documentation and submitted during the application process. The *Assessment Manual and Technical Toolbox for Applicants* provides more detailed and specific instructions on how other accreditation and/or certification schemes may be used as supporting evidence.

For the **specific** criteria and conditions outlined in this document, the Network defines the requirements. As evidence, the Healthcare Provider must demonstrate compliance with these requirements.

Each BoN has identified the list of diseases covered by the network and defined a list of the applicable criteria and thresholds for the below five dimensions, 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 information of each of the ERNs' list of diseases and specific criteria is published and available in the call webpage.

ANNEX II - SUMMARY TABLE: Operational Criteria for the Assessment of Health Care Providers

1. General criteria and conditions for applicants for membership of a Network

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

No.	Criteria	No.	Measure(s)
1.1	The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.	1.1.1	The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.
		1.1.2	Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.
		1.1.3	Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.
		1.1.4	The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.
		1.1.5	The Healthcare Provider gives patients and their families' written information about their rights and responsibilities.
		1.1.6	There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.
1.2	The Healthcare Provider provides patients with clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients.	1.2.1	Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.
1.3	The Healthcare Provider regularly collects information on patient care experience within the Network's area of expertise and uses this information to make ongoing improvements.	1.3.1	The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. . This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the public.
1.4	The Healthcare Provider protects the privacy and confidentiality of patient health information.	1.4.1	The Healthcare Provider ensures access to medical records and clinical information complies with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.
1.5	Patient informed consent to share personal health information complies with the requirements set out in Article 2(e) of the Directive 2014/286/EU.	1.5.1	If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.

1.6	The Healthcare Provider maintains transparency by providing information to patients and the public about clinical outcomes, treatment options, and quality and safety standards that are in place.	1.6.1	The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.
		1.6.2	All data sources are accessible to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.
		1.6.3	Every patient is provided with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.
		1.6.4	The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.
1.7	The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.	1.7.1	The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.
2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY			
No.	Criteria	No.	Measure(s)
2.1	The organization follows a documented set of organization and management rules and procedures for services provided within the Network's area of expertise.	2.1.1	Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.
		2.1.2	The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.
		2.1.3	There are policies and procedures for managing cross border patients within the Network's area of expertise.
2.2	The Healthcare Provider shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, including how these are calculated.	2.2.1	The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.
2.3	The Healthcare Provider has a business continuity plan.	2.3.1	The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.
2.4	The Healthcare Provider establishes procedures and/or inter- agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.	2.4.1	There are procedures for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.
		2.4.2	When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.

2.5	The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.	2.5.1	Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.
2.6	There are policies and procedures in place to communicate with clinicians post discharge, including cross border.	2.6.1	The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.
		2.6.2	Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.

3. RESEARCH, EDUCATION AND TRAINING

No.	Criteria	No.	Measure(s)
3.1	The Healthcare Provider participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.	3.1.1	The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.
		3.1.2	The Healthcare Provider has a defined set of objectives for its education and training activities.
		3.1.3	The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.
		3.1.4	Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.
		3.1.5	The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.
3.2	The Healthcare Provider has the capacity to carry out research activities and demonstrated research experience.	3.2.1	The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.
		3.2.2	The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.
		3.2.3	The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.
		3.2.4	There is a procedure to review the ethical implications of research activities.

3.2.5	The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.
3.2.6	The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and
3.2.7	The Healthcare Provider evaluates the effectiveness of research activities.

4. EXPERTISE, INFORMATION SYSTEMS, AND e-HEALTH TOOLS

No.	Criteria	No.	Measure(s)
4.1	The Healthcare Provider is able to exchange expertise with other providers and provide support to them.	4.1.1	The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.
		4.1.2	The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.
4.2	The Healthcare Provider safeguards the use of medical data within the Network's area of expertise.	4.2.1	The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the <u>Delegated Decision 2014/286/EU</u> .
4.3	The Healthcare Provider fosters the use of telemedicine and other e-health tools within and outside its facility.	4.3.1	To support the use of telemedicine and other e-health tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations.
4.4	The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.	4.4.1	The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).
		4.4.2	The Healthcare Provider has procedures in place to monitor and maintain data quality.

5. QUALITY AND SAFETY

No.	Criteria	No.	Measure(s)
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5.1	The Healthcare Provider regularly monitors the quality and safety of the care it provides to patients with rare or low prevalence complex diseases or conditions.	5.1.1	The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.
		5.1.2	The Healthcare Provider regularly collects and monitors process and outcome indicators.
		5.1.3	The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise.
		5.1.4	There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to <u>make ongoing improvements</u> .
		5.1.5	The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.
5.2	The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.	5.2.1	There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.
5.3	The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.	5.3.1	The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard <u>evidence-based procedure</u> .
		5.3.2	The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.
		5.3.3	Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.

Specific operational criteria and conditions for applicant providers with regard to the area of expertise, disease or condition of the Networks they wish to join

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

No.	Criteria	No.	Measure(s)
6.1	The Healthcare Provider maintains its competence in the Network's area of expertise.	6.1.1	The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.

		6.1.2	To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.
6.2	The Healthcare Provider demonstrates good clinical care and outcomes.	6.2.1	There is evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.
		6.2.2	The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network

7.HUMAN RESOURCES

No.	Criteria	No.	Measure(s)
7.1	The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.	7.1.1	The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care
		7.1.2	There is a sufficient number of staff with the necessary qualifications to perform the specialized function.
		7.1.3	Each core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year
		7.1.4	The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.

8.ORGANIZATION OF PATIENT CARE

No.	Criteria	No.	Measure(s)
8.2	Comprehensive care is delivered by a multidisciplinary and specialised care team.	8.2.1	The Healthcare Provider documents the characteristics of the multidisciplinary team.
		8.2.2	There is a designated leader and chair of the multidisciplinary team.
		8.2.3	There are documented procedures to support the organisation and functioning of the multidisciplinary care team.
		8.2.4	There are regular structured meetings between multidisciplinary team members.

8.2.5	Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.
8.2.6	The multidisciplinary team evaluates its performance on an annual basis.

9. FACILITIES AND EQUIPMENT

No.	Criteria	No.	Measure(s)
9.3	The Healthcare Provider has the necessary facilities and equipment to attend to patients specific to the area of expertise, disease, or condition as defined by the Network.	9.3.1	The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.
		9.3.2	There is access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.
		9.3.3	There is access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.
		9.3.4	Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.

Annex III

TEMPLATE LETTER OF ENDORSEMENT FOR HEALTHCARE PROVIDERS

<Date>

<Contact Person>

<Address>

SUBJECT: Healthcare Provider National Endorsement

Dear Sir/Madam,

I, **<Insert National Authority>** as nominated by the **< Insert competent National Body on ERNS (if different than National Authority) >** certify that **<Insert Healthcare Provider's Name>** participation in the call for membership to existing European Reference Networks **<NAME OF ERN>** launched by the European Commission in 2019 is in accordance with the Member State's national legislation.

Sincerely,

<Signature of Representative>

<Insert Name of Representative of the National Authority>

Annex IV

CONTENT OF THE DECLARATION FORMS

(shall be download from the online tool)

DECLARATION FOR THE CHEF EXECUTIVE OFFICER (CEO)

Application for Healthcare Provider membership in a European Reference Network

Agreement and Signature:

Having read the call for interest for Healthcare Providers to join the existing European Reference Networks for rare or low prevalence, complex disease(s) or condition(s), and the accompanied application document:

I, undersigned, confirm that the HCP applicant will be supported by the management of this institution with the necessary means to carry out the activities related to the Network goals. This support includes the recognition of the time devoted by the healthcare professionals to fulfil those activities as part of their standard working time.

Please indicate the name of the network(s) that the Healthcare Provider wishes to join:

Network		Network		Network	
ERN BOND	<input type="checkbox"/>	ERN-RND	<input type="checkbox"/>	ERN ITHACA	<input type="checkbox"/>
ERN CRANIO	<input type="checkbox"/>	ERN-Skin	<input type="checkbox"/>	ERN MetabERN	<input type="checkbox"/>
ENDO-ERN	<input type="checkbox"/>	ERN EURACAN	<input type="checkbox"/>	ERN PaedCan	<input type="checkbox"/>
ERN EpiCare	<input type="checkbox"/>	ERN EuroBloodNet	<input type="checkbox"/>	ERN RARE-LIVER	<input type="checkbox"/>
ERKNet	<input type="checkbox"/>	ERN eUROGEN	<input type="checkbox"/>	ERN ReCONNET	<input type="checkbox"/>
ERN-EYE	<input type="checkbox"/>	ERN EURO-NMD	<input type="checkbox"/>	ERN RITA	<input type="checkbox"/>
ERNICA	<input type="checkbox"/>	ERN GENTURIS	<input type="checkbox"/>	ERN TRANSPLANT-CHILD	<input type="checkbox"/>
ERN-LUNG	<input type="checkbox"/>	ERN GUARD-HEART	<input type="checkbox"/>	VASCERN	<input type="checkbox"/>

Please complete the below in BLOCK CAPITALS:

Name of Healthcare Provider as per application form	
Country of Healthcare Provider as per application form	
CEO	
Title, Name and Surname	
Signature	
Date	

This form must be printed, signed and uploaded to all membership applications via the SANTE Data Collection Platform

DECLARATION FOR THE HEALTHCARE PROVIDER REPRESENTATIVE

Application for Healthcare Provider membership in a European Reference Network Agreement and Signature:

Having read the call for interest for Healthcare Providers to join the existing European Reference Networks for rare or low prevalence, complex disease(s) or condition(s), and the accompanied application document:

I undersigned, confirm that will commit to fulfil the tasks and responsibilities as member of the ERN in accordance with the rules established by the Board of the Network and to provide all the necessary information requested by the ERN Coordinator and the European Commission in order to fulfil the assessment, monitoring and evaluation requirements of the Network. I understand that the lack of compliance with these commitments could imply the termination of the membership to the Network.

Please indicate the name of the network(s) that the Healthcare Provider wishes to join:

Network		Network		Network	
ERN BOND	<input type="checkbox"/>	ERN-RND	<input type="checkbox"/>	ERN ITHACA	<input type="checkbox"/>
ERN CRANIO	<input type="checkbox"/>	ERN-Skin	<input type="checkbox"/>	ERN MetabERN	<input type="checkbox"/>
ENDO-ERN	<input type="checkbox"/>	ERN EURACAN	<input type="checkbox"/>	ERN PaedCan	<input type="checkbox"/>
ERN EpiCare	<input type="checkbox"/>	ERN EuroBloodNet	<input type="checkbox"/>	ERN RARE-LIVER	<input type="checkbox"/>
ERKNet	<input type="checkbox"/>	ERN eUROGEN	<input type="checkbox"/>	ERN ReCONNET	<input type="checkbox"/>
ERN-EYE	<input type="checkbox"/>	ERN EURO-NMD	<input type="checkbox"/>	ERN RITA	<input type="checkbox"/>
ERNICA	<input type="checkbox"/>	ERN GENTURIS	<input type="checkbox"/>	ERN TRANSPLANT-CHILD	<input type="checkbox"/>
ERN-LUNG	<input type="checkbox"/>	ERN GUARD-HEART	<input type="checkbox"/>	VASCERN	<input type="checkbox"/>

Please complete the below in BLOCK CAPITALS:

Name of Healthcare Provider as per application form		
Country of Healthcare Provider as per application form		
	HCP Representative	Sub Representative
Title, Name and Surname		
Signature		
Date		

This form must be printed, signed and uploaded to all membership applications via the SANTE Data Collection Platform