ASSESSMENT MANUAL

European Health and Digital Executive Agency (HaDEA). Unit EU4Health/SMP Food. Tenders CHAFEA/2019/HEALTH/18

TABLE OF CONTENT

GLOSSARY OF TERMS 3

CHAPTER 1. GENERAL PROCESS AND PROCEDURES 4

1.1 Background 4
1.2 Objectives of the Assessment Process 4
1.3 Roles and Responsibilities 4
1.4 Assessment Process 7
1.5 Confidentiality of Information 20
1.6. Legislation 20
1.7 Reading guide 21

CHAPTER 2. PROCESS AND PROCEDURES: APPLICANTS 22

2.1 Roles and responsibilities of the Applicant 22
2.2 Call for Interest 22
2.3 National Endorsement by the Member State 23
2.4 Submission of Application to European Commission 23
2.5 Verification of Completeness of Application by the European Commission 25
2.6 Peer Review of Clinical Excellence of Healthcare Providers by the Board of Network 25
2.7 Technical Assessment by Independent Assessment Body 26
2.8 Communication of Assessment Outcomes 27
2.9 Approval by the Board of Member States 28
2.10 Publication of List of Established Networks and their Members 29
2.11 Funding for European Reference Networks 29
2.12 Join an ERN as an Affiliated Partner 30

CHAPTER 3. PROCESS AND PROCEDURES: EUROPEAN COMMISSION 31

3.1 Roles and responsibilities of the European Commission 31
3.2 Call for Interest 31
3.3 Verification of Completeness of Application by the European Commission 31
3.4 Communication of Assessment Outcomes 32
3.5 Loss of Membership of Termination of an ERN 32

CHAPTER 4. PROCESS AND PROCEDURES: BOARD OF NETWORKS & NETWORK COORDINATORS 33

4.1 Roles and responsibilities for the Board of Network and Network Coordinators 33
4.2 Peer Review of Clinical Excellence of Healthcare Providers by the Board of Network 33
4.3 Decision - Possibilities for Appeal 34
4.4 Loss of Membership of Termination of an ERN 34

CHAPTER 5. PROCESS AND PROCEDURES: INDEPENDENT ASSESSMENT BODIES 35

5.1 Roles and responsibilities of the Independent Assessment Body and Assessors 35
5.2 Technical Assessment by Independent Assessment Body 36
5.3 On-site Audit 38
5.4 Communication of Assessment Outcomes 40
5.5 Assessors 41

CHAPTER 6. PROCESS AND PROCEDURES: MEMBER STATES AND THE BOARD OF MEMBER STATES 42

6.1 Roles and responsibilities of the (Board of) Member States 42
6.2 National Endorsement by the Member State 42
6.3 Appeal in case of a negative opinion or assessment 43
6.4 Approval by the Board of Member States 43
6.5 Loss of Membership or Termination of an ERN 44

CHAPTER 7. TECHNICAL TOOLBOX: OVERVIEW OF ANNEXES 45

Glossary of Terms

Applicant: the Network and the Healthcare Providers that are responding to the call for interest for European Reference Networks OR 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 keycontact between the IAB, the European Commission and the Applicant.

Assessment Process: 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 Healthcare Provider Member in the Network.

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

European Reference Network (ERN): virtual networks involving Healthcare Providers across Europe.

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.

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

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

Independent Assessment Body (IAB): an independent assessment organisation appointed by the EC to complete the technical assessment for eligible Networks and Healthcare Providers. The IAB coordinates the assessment activities, supports the assessors and finalises the assessment reports and recommendations for the Board of Member States.

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 of the Network.

Operational Criteria: a list of requirements for Networks and Healthcare Providers based on the Commission Delegated 2014/286/EU and Implementing Decisions 2014/287/EU and 2019/1269/EU.

Rare or 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.

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

Chapter 1. General process and procedures

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, experience, medical research, training and resources for these diseases and conditions. Following the legislation[1], the EC defines the requirements for ERNs and provides a regulatory framework for establishing, assessing and approving ERNs[2].

The premise of the ERN initiative is to create Networks that would add value to the field of highly specialised healthcare across Europe. Therefore, it is important that new Networks complement existing Networks, avoiding duplication of effort and fragmentation in the field.

The assessment process of ERNs was developed in consultation with the Member States and key stakeholders since 2015 and has been updated in 2021. [3] This assessment manual has been created in accordance with the legislation.[4]

1.2 Objectives of the Assessment Process

The overall goal of the assessment process 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.
- 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 process is a collaborative and coordinated effort that relies on the participation of multiple stakeholders, each having their respective roles and responsibilities. These stakeholders and their respective roles and responsibilities are explained in this manual.

[1]Article 12 of the Directive 2011/24/EU on patient's rights in cross-border healthcare
[2]The Commission Delegated and Implementing Decisions 2014/287/EU; Commission Implementing Decision (EU) 2019/1269 amending the Implementing Decision 2014/287/EU
[3] Commission Implementing Decision (EU) 2019/1269 amending Implementing Decision 2014/287/EU
[4] Article 13 (1)-(2) of the Commission Implementing Decision 2014/287/EU; Article 1a of the Commission Implementing Decision (EU) 2019/1269 amending Implementing Decision 2014/287/EU

1.3.1 Applicant

There are two types of calls for interest, leading to different types of applications:

- A call for the creation of new Networks.
- A call for Healthcare Provider membership for existing ERNs.

In the first case, both a Network application and applications of all the individual Healthcare Providers creating the new Network are required. For the second type of call, Healthcare Provider Applicants are operating individually. There is an additional step in the assessment process for Healthcare Providers wishing to join an existing ERN (see section 1.4.2 and Figure 6).

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

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

When applying to a call for new Networks, Applicants creating a new Network (Network or HCP applicant) need to fulfil the following roles and responsibilities:

- Submit application form, self-assessment, the Member State's written endorsement statement (only for the individual HCPs; not for Network as a whole) and supporting documentation to the European Commission (EC) in response to the call for interest.
- Participate in the technical assessment activities including virtual interviews and on-site/online audits (if eligible).
- Provide in a timely manner to the EC and/or Independent Assessment Body (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 process.

Note: a new Network exists of at least 10 Healthcare Providers located in 8 different Member States (who jointly submit the proposal).

Healthcare Provider applicants wishing to join an existing European Reference Network (ERN) need to fulfil some **additional** roles and responsibilities:

- Provide comments on the draft opinion of the Board of the Network (BoN) within one month.
- Adhere to any other terms and conditions of the EC and the IAB.

The role of the Applicant is explained in more detail in Chapter 2.

1.3.2 European Commission

The European Commission (EC)'s roles and responsibilities relevant for the applicant, are to:

- Publish the call for interest and track applications for HCPs to join the existing ERNs.

- Complete the eligibility check of all Applicants by verifying that the Applicants meet the minimum requirements.[5]
- Make the outcomes of favourable or unfavourable assessments and/or evaluations carried out by the IABs available, in accordance with the legislation.[6]

The role of the EC is explained in more detail in Chapter 3.

1.3.3 Board of Network

Each ERN has its own Board of Network (BoN), which is composed of representatives from each Member of the Network. The BoNs main responsibilities are to:

- Carry out a peer review[7] of clinical excellence of HCPs wishing to join an existing ERN;
- Prepare a positive or negative opinion regarding the peer review within the timelines specified in the legislation.[8]

The role of the BoN is explained in more detail in Chapter 4.

1.3.3 Network Coordinator

In case of an application for new Networks, the Network must identify one of its Healthcare Providers to act as the Coordinating Member. The Coordinating Member will choose from the healthcare professionals belonging to its staff, a Network Coordinator to fulfil the following roles and responsibilities:

- Ensure that the application form and self-assessment are complete and submitted in the right way.
- Act as a key contact for all parties involved;
- Ensure participation of Healthcare Providers in virtual interviews and on-site/online audits (if selected) and coordinate these activities.
- Ensure a timely opinion of the Network on the Applicant.

The role of the Network coordinator is explained in more detail in Chapter 4.

1.3.4 Independent Assessment Body and Assessors

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

- 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.
- Finalise assessment reports and recommendations for the Board of Member States (BoMS).
- Review requests for amendments to the assessment reports from the Applicant and issue updated reports, if needed.

The IAB will identify an Assessment Coordinator as the key contact to liaise with the EC and the Applicant during the assessment process. The Assessors are peer reviewers who complete the documentation review, virtual interviews and on-site/online audits.

[5] Article 2(2) and in Article 3(2) and (3) of the Commission Implementing Decision (2014/287/EU)
[6] Commission Implementing Decision (2014/287/EU) and EU data protection legislation
[7] Point 2 of Annex II to Delegated Decision 2014/286/EU
[8] Article 5 of the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU

The role of the IAB and assessors is explained in more detail in Chapter 5.

1.3.5 Member State

The role of the Member State (MS) is to:

- Provide the Applicant with a written statement of endorsement and the corresponding completed checklist to certify that participation of the Applicant in the European Reference Network (ERN) is in accordance with its national legislation.
- Define its national process to support eligible Healthcare Providers and ensuring that this process is transparent.

The role of the Member State is explained in more detail in Chapter 6.

1.3.6 Board of Member States

The Board of Member States (BoMS) consists of representatives from the EU Member States and the European Economic Area (EEA), i.e. Norway. The main roles and responsibilities of the BoMS are to:

- Review the unfavourable opinion of the BoN[9] upon request of the Member State and make a decision after re-assessing the application and all other available documentation.
- Review the favourable assessment reports and recommendations from the IAB.
- Review the unfavourable decisions of the IAB upon request of the Member State and make a decision after re-assessing the application and all other available documentation.
- Approve applications for ERNs or add members to an existing ERN.
- Approve the termination of an ERN.
- Decide on the loss of membership of one or more HCP members of an existing ERN.

The role of the BoMS is explained in more detail in Chapter 6.

1.4 Assessment Process

The assessment process consists of main steps, decisions and transition points involving the transfer of information between the Applicant, the EC, the BoN, the IAB and the BoMS.
This section provides an overview of the assessment process used to approve new Networks and their Healthcare Providers (1.2.1) and the process to approve Healthcare Providers to join an existing ERN (1.2.2). The difference in the assessment process for a Healthcare Provider Applicant creating a new Network together with other Applicants and a Healthcare Provider Applicant who is individually applying to become a member of an existing ERN is that the latter is assessed by the Board of Network (BoN) of the existing ERN, before progressing to the assessment by the Independent Assessment Body (IAB) (see Figure 6).

A graphical representation of the assessment process from the call for interest to the final approval and the publication of the list of established networks and their members is shown in the following flowcharts (Figure 1a and Figure 1b).

The activities of the EC are identified in **red**; of the Member States in **gold**; of the Applicants in **blue;** of the Board of Network in **green;** of the Independent Assessment Body in **yellow**; of the ERN Board of Member States in **purple**; and the specific tools that will be used for each stage are identified in **grey.**

[9]On the basis of the criteria and conditions set in point 2 of Annex II to Delegated Decision 2014/286/EU

Figure 1a: Flowchart of the overall assessment process to approve new Networks and their

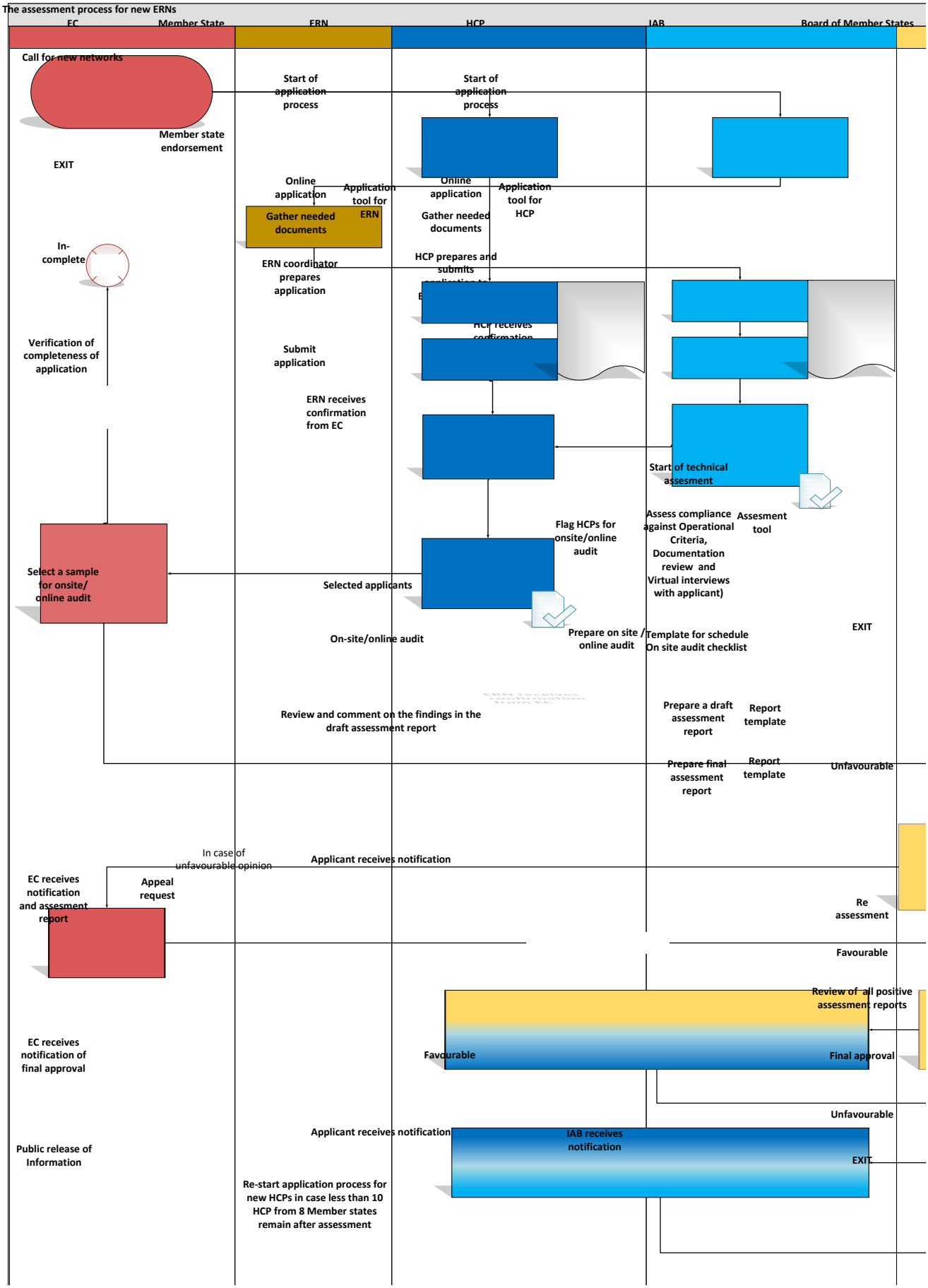
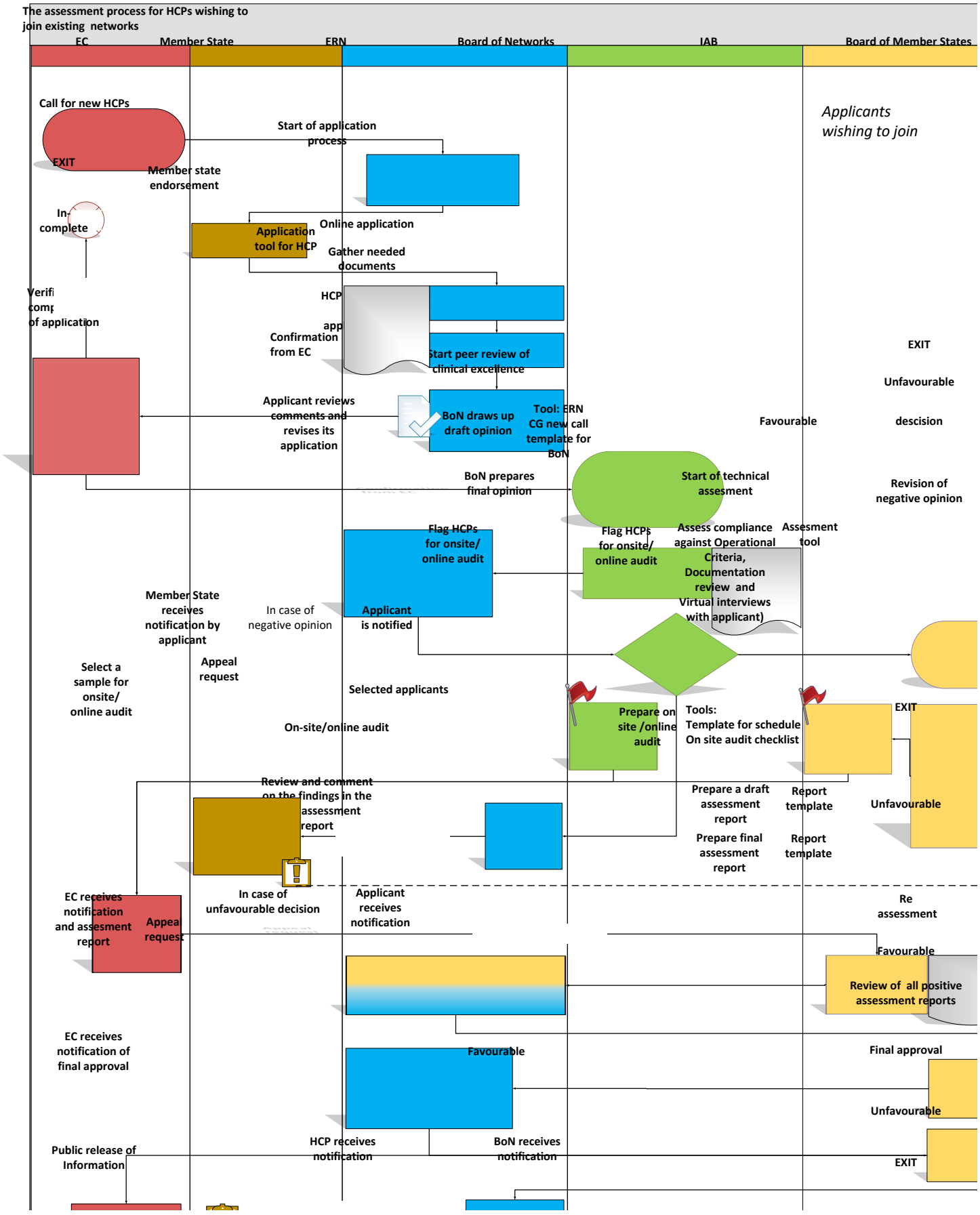


Figure 1b: Flowchart of the overall assessment process to approve Healthcare Provider



1.4.1 Assessment Process to approve new Networks and their Healthcare Providers

The assessment of the Network application and the application of its Healthcare Providers (call for new Networks), consists of the following steps:

1. The EC launches the call for interest for new Networks.
2. The Member States provide the Healthcare Provider with a Letter of Endorsement as part of the application.
3. The applications are received by the EC and checked for eligibility. Only eligible applications will pass to the next step of the assessment.
4. The eligible applications are received by the IAB who verifies the applications to determine if the Network and/or Healthcare Provider(s) can progress to the technical assessment.
5. The IAB completes the technical assessment, i.e. documentation review and virtual interviews, to determine if the Network and/or Healthcare Provider(s) can progress to the next stage of the assessment process.
    - A selection of favourable applicants receive an on-site/online audit as part of the technical assessment.
6. Communication of assessment outcomes:
    - The IAB drafts a preliminary report and sends it to the Applicant.
    - The Applicant has the possibility to reply to the draft opinion within two months.
    - The IAB will take into account any comments received from the Applicant for the preparation of the final report.
    - The IAB makes the final report.
    - The IAB determines if the results from the technical assessment are positive or negative, and sends the positive assessment reports to the EC.
    - If the result of the IAB's technical assessment is negative, the Applicant has the right to contest it through its National Authority. The National Authority decides whether the application should be reassessed by the BoMS. The BoMS makes a decision after re-assessing the application and all other available documentation.
7. The BoMS review the results and recommendations from the technical assessment and issues the final decision: the approval of a Network and its Members.
8. The EC publicly identifies those Applicants who have been approved as European Reference Networks and 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. The EC also delegates the ERN Coordinator the signature of a license contract for the use of the ERN logo by the successful Applicant.

Graphical representations of the most important steps (which are detailed versions of the overall assessment flowchart, Figure 1a) are shown below:

- A graphical representation of the call for interest, the endorsement by the Member State, the submission of application(s) and verification of completeness by the EC for a call for new Networks is shown in Figure 2.
- A graphical representation of the technical assessment by the IAB of Network Applicants and their Healthcare Providers is shown in Figure 3.
- A graphical representation of the communication of assessment outcomes, final approval and publication of Networks and their Healthcare Provider Applicants is shown in Figure 4.

Figure 2: Flowchart of Steps 1-4 of the assessment process for a call for new Networks

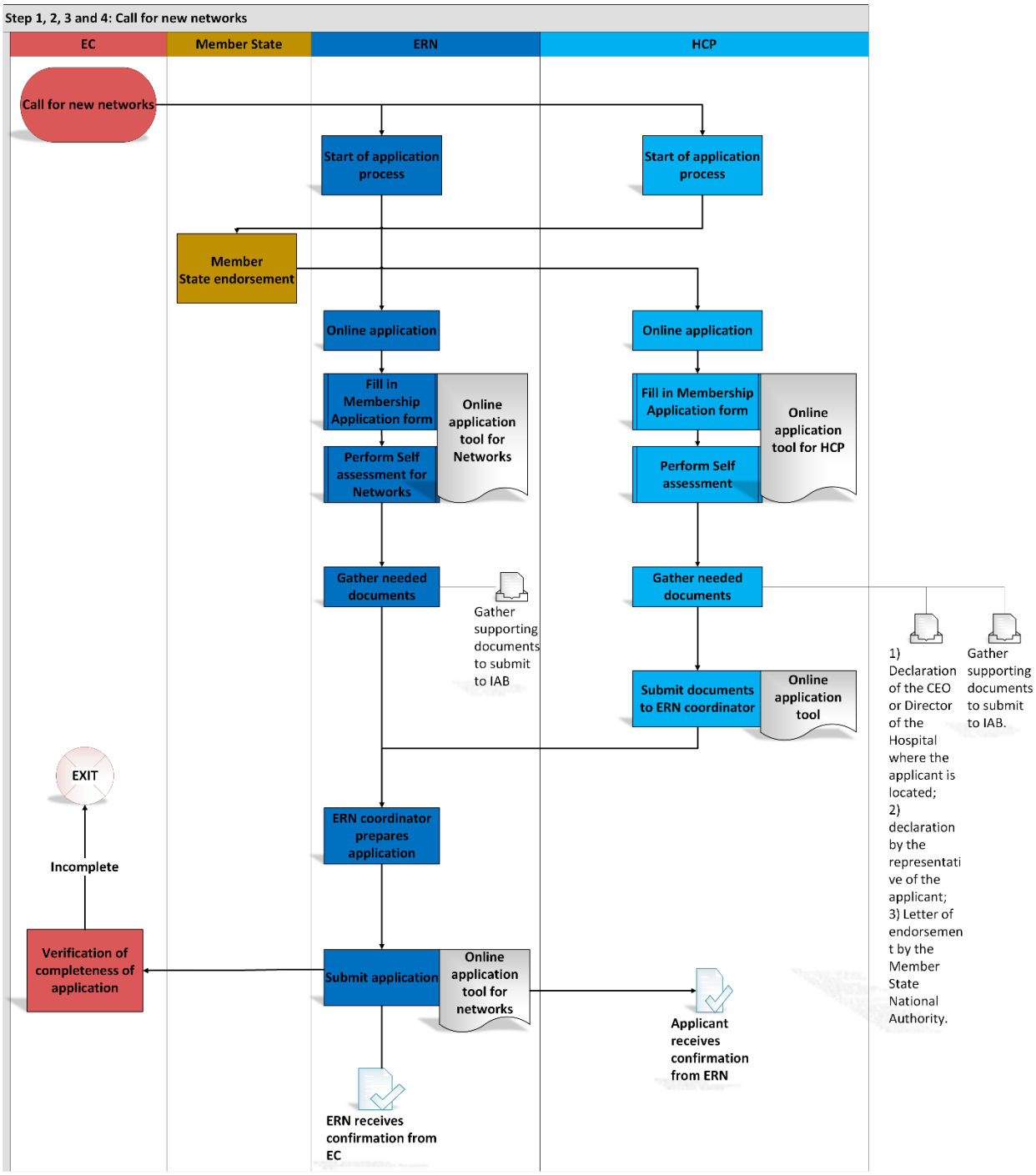


Figure 3: Flowchart of Step 5 of the assessment process for Network Applicants and their Healthcare Providers: technical assessment by IAB

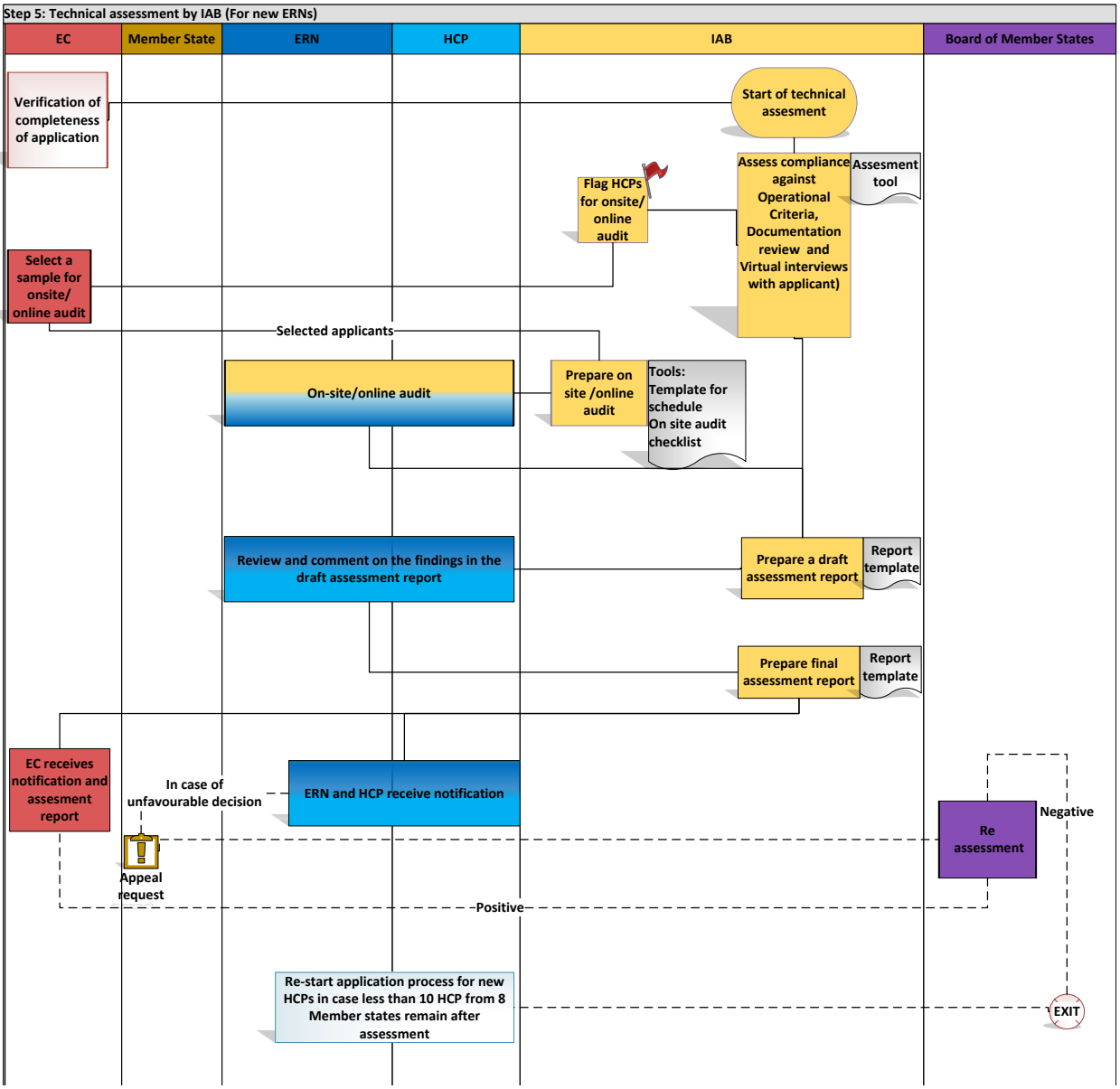
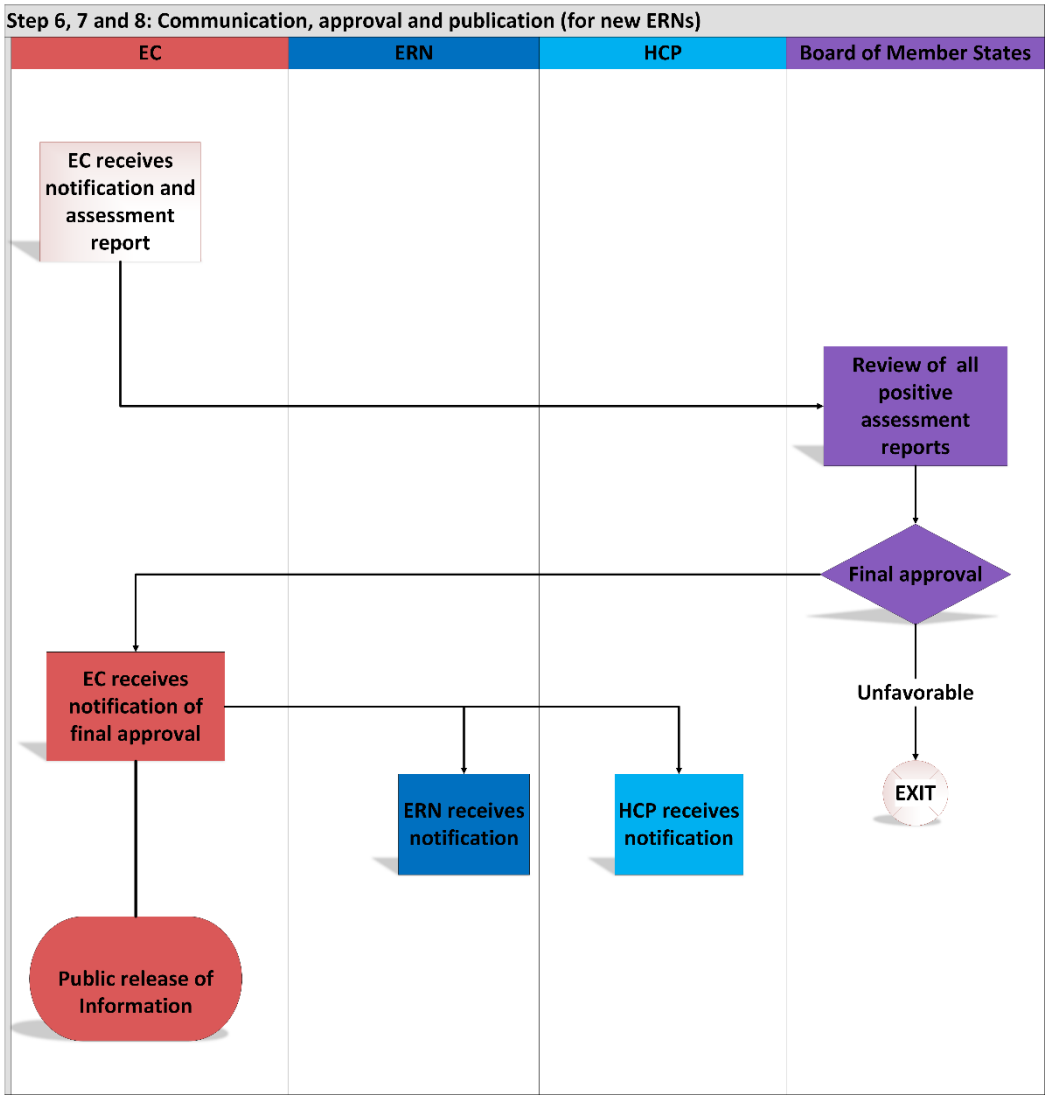


Figure 4: Flowchart of Steps 6, 7 and 8 of the assessment process for Network Applicant and their Healthcare Providers: Communication of assessment outcomes, final approval and publication



1.4.2 Assessment Process for the Healthcare Provider Applicant wishing to join an existing ERN

The assessment of the application of a Healthcare Provider wishing to join an existing Network (call for ERN membership), consists of the following steps:

1. The EC launches the call for interest for ERN membership for Healthcare Providers to join existing ERNs.
2. The Member States provide the Healthcare Provider with a Letter of Endorsement as part of the application.
3. The Healthcare Provider submits the application to the European Commission.
4. The application is received by the EC and checked for eligibility. Only eligible applications will pass to the next step of the assessment.
5. The eligible applications are received by the BoN that the Healthcare Provider wishes to join. The BoN checks the application against the specific criteria.
    - The BoN shall provide the Applicant with a draft opinion within three months.
    - The Applicant has the possibility to reply within one month to the draft opinion.
    - The BoN sends a final opinion to the Applicant within four months from the date of receiving the eligible application.

- The BoN will take into account any 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.
- 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.
- If the BoN's opinion is unfavourable, the Applicant has the right to contest this opinion through its National Authority. The National Authority decides whether the application should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation;

6. Applications with a favourable opinion are provided to the IAB. If the application is still eligible, the IAB completes the technical assessment, i.e. documentation review and virtual interviews, to determine if the Healthcare Provider can progress to the next stage of the assessment process.
    - A selection of favourable applicants receive an on-site/online audit as part of the technical assessment.
7. Communication of assessment outcomes:
    - The IAB drafts a preliminary report and sends it to Applicant.
    - The Applicant has the possibility to reply to the draft opinion within two months.
    - The IAB will take into account comments received from the Applicant for the preparation of the final report.
    - IAB makes final report.
    - The IAB determines if the results from the technical assessment are positive or negative, and sends the positive assessment reports to the EC.
    - If the result of the IAB's technical assessment is negative, the Applicant has the right to contest it through its National Authority. The National Authority decides whether the application should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation.
8. The BoMS review the results and recommendations from the technical assessment and issues the final decision: the approval as a member of an existing ERN.
9. The EC publicly identifies those Applicants who have been approved as European Reference Networks and as a Member of an ERN and maintains a list on the public website accessible for the public. The EC also delegates the ERN Coordinator the signature of a license contract for the use of the ERN logo by the successful Applicant.

Graphical representations of the most important steps (which are detailed versions of the overall assessment flowchart, Figure 1a) are shown below:

- A graphical representation of the call for interest, the endorsement by the Member State, the submission of application(s) and verification of completeness by the EC for Healthcare Provider Applicants wishing to join an existing ERN is shown in Figure 5.
- A graphical representation of the peer review of clinical excellence by the BoN (step 5) is shown in Figure 6.
- A graphical representation of the technical assessment of Healthcare Provider Applicants wishing to join an existing ERN (step 6) is shown in Figure 7.
- A graphical representation of the communication of assessment outcomes, final approval and publication for Healthcare Provider Applicants wishing to join an existing ERN is shown in Figure 8.

Figure 5: Flowchart of Steps 1-4 of the assessment process for Healthcare Provider Applicants wishing to join an existing ERN

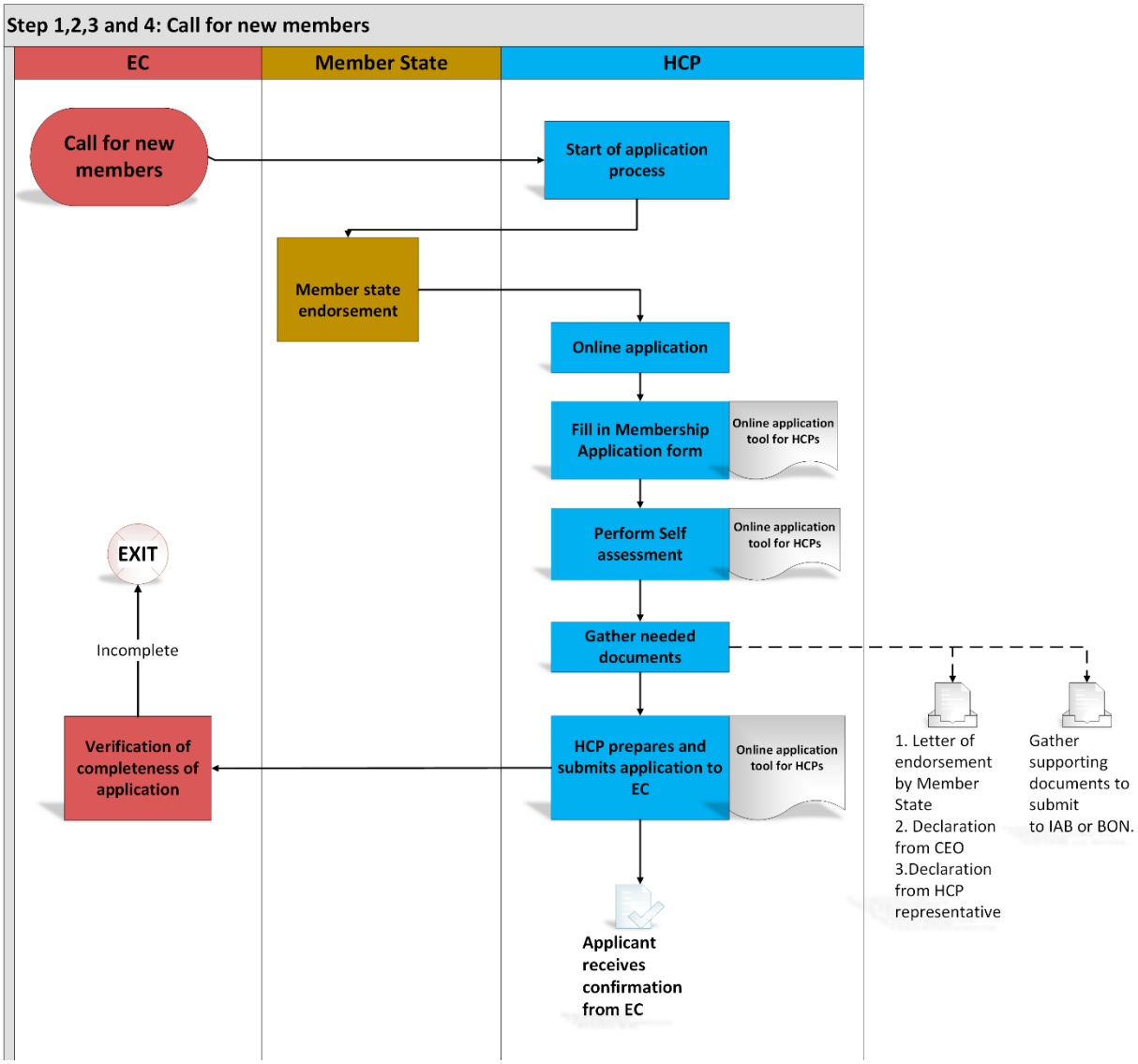


Figure 6: Flowchart of Step 5 of the assessment process: peer review of clinical excellence of the Healthcare Provider Applicant wishing to join an existing ERN by the Board of Network

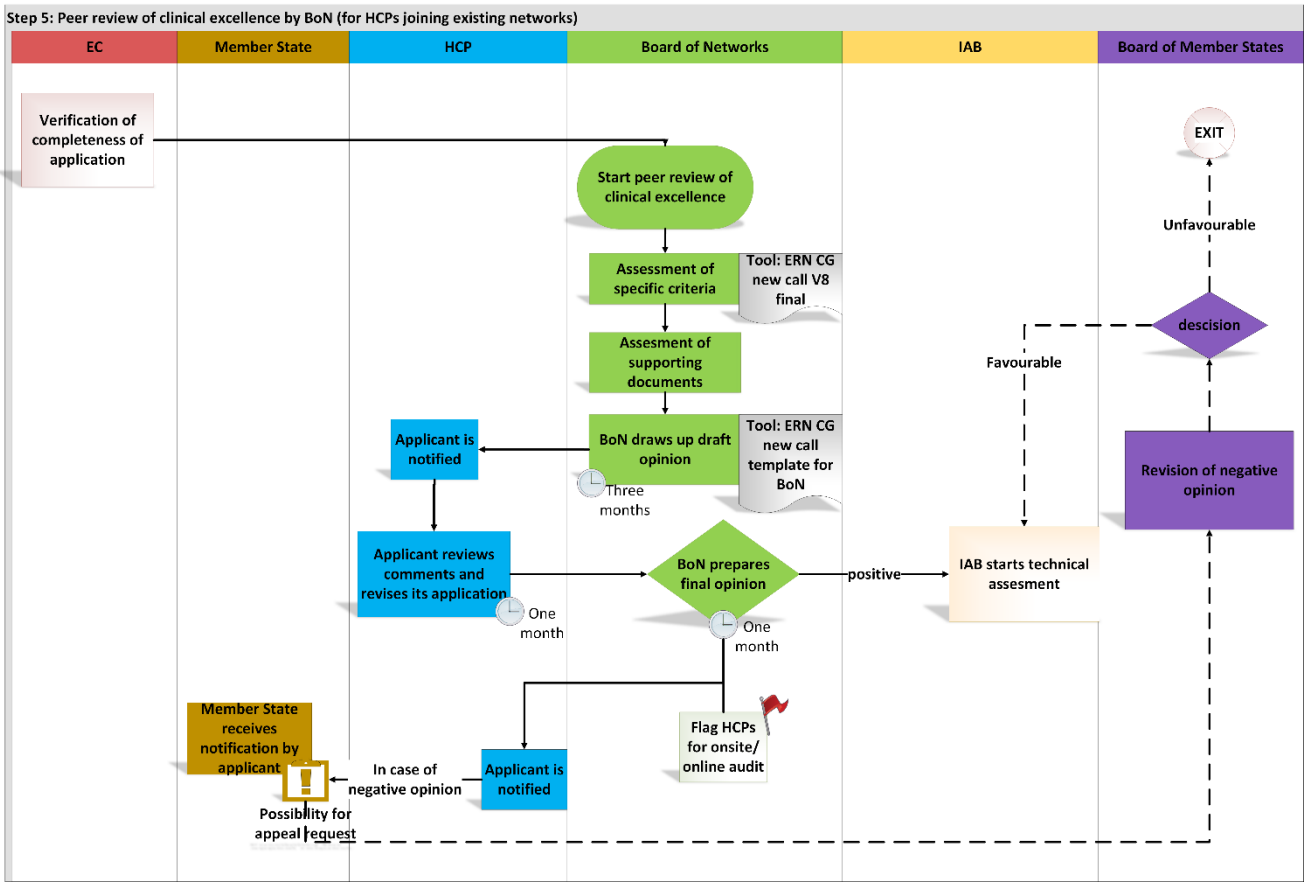


Figure 7: Flowchart of Step 6 of the assessment process for Healthcare Provider Applicants wishing to join an existing ERN: technical assessment by IAB

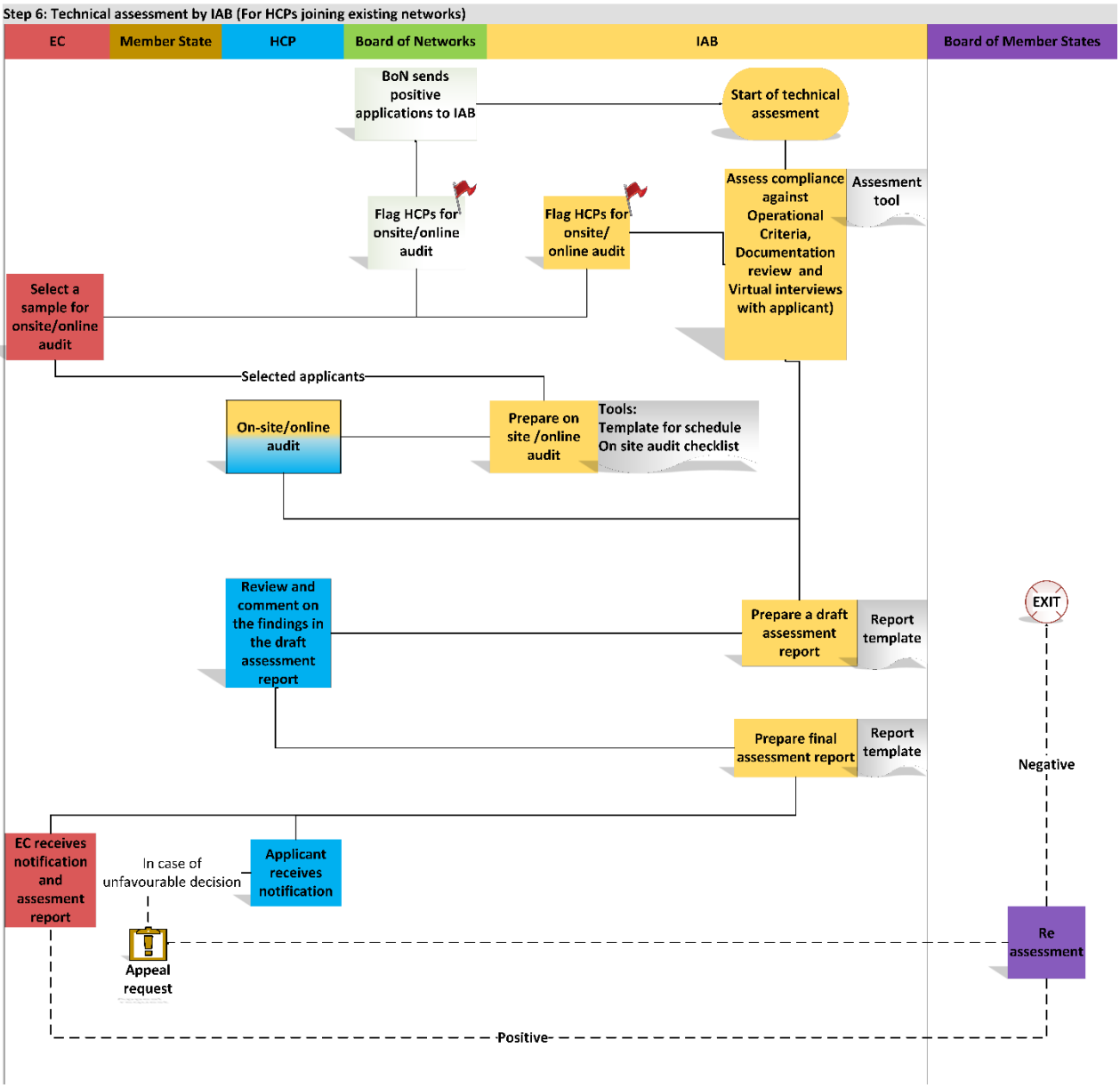
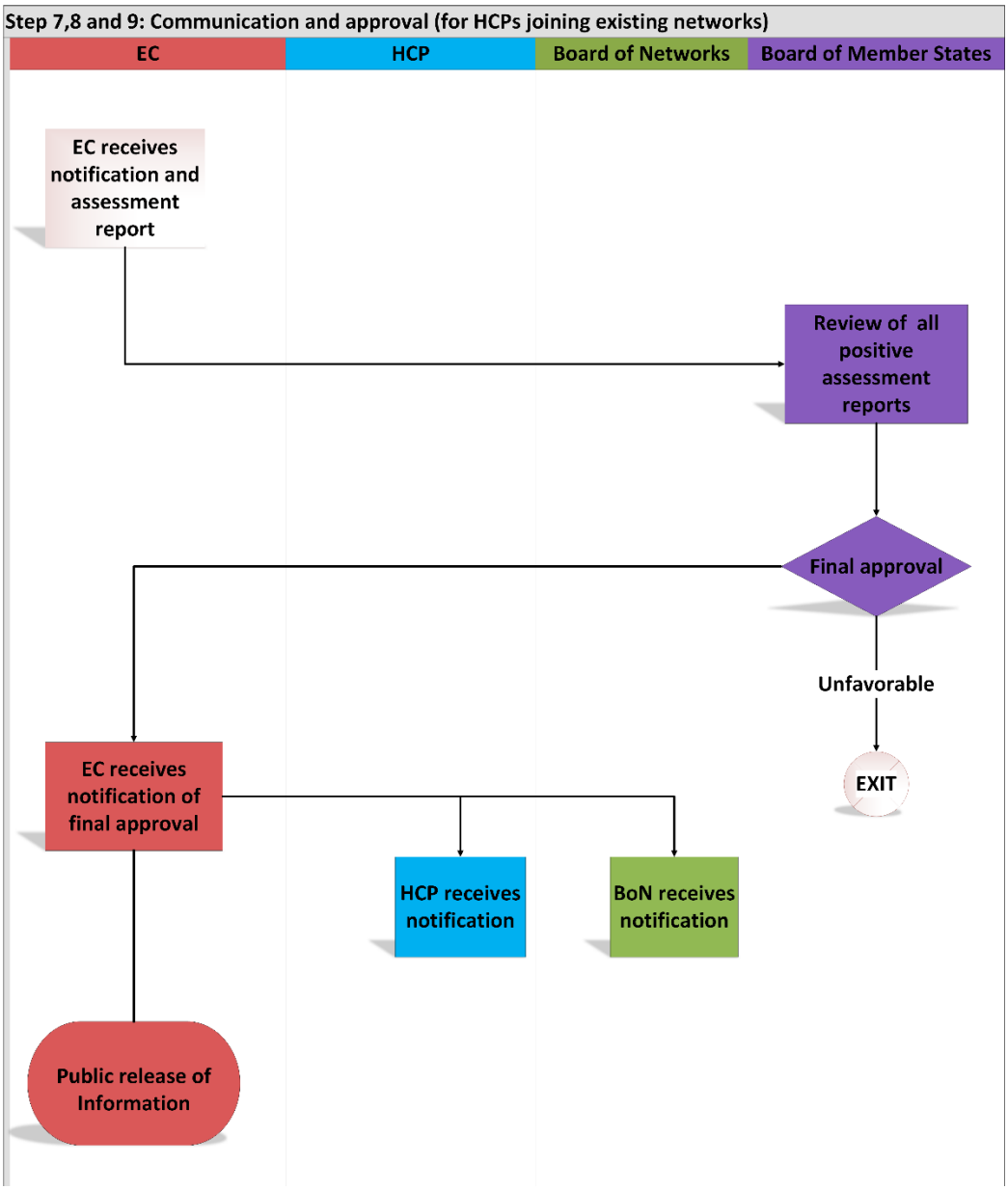


Figure 8: Flowchart of Steps 7, 8 and 9 of the assessment process for Healthcare Provider Applicants wishing to join an existing ERN: Communication of assessment outcomes, final approval and publication



1.4.3 Operational Criteria

The central component of the assessment process is the Operational Criteria for Networks and Healthcare Providers. The Operational Criteria provide a common and structured framework to assess compliance with the legislated requirements and consist of one or more measures of performance. The Operational Criteria for Networks and Healthcare Providers are described in ***Annex 1a*** *Operational Criteria for Networks* and ***Annex 1b*** *Operational Criteria for Healthcare Providers* respectively.

Operational Criteria for Networks

For the Operational Criteria for Networks, some measures have been categorized as "a minimum requisite for eligibility". The Network must ensure that they are in full compliance with these measures at the time the application is submitted. Without this, Network Applicants will not be eligible to proceed to the technical assessment. Other measures are identified as "core measures" and must be in place at the time of application or addressed in an implementation strategy to realise the measure within one year of the formal establishment of the Network.

For all remaining measures, a clearly defined action plan and set timelines for achievement will be accepted initially as evidence.

Operational Criteria for 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. Some are assessed at hospital level, while most are assessed at the Healthcare Provider level. To avoid duplication of efforts, the results of other accreditation and/or certification schemes may be accepted as evidence of compliance but only if they are formally recognized by the national authority[10] (for requirements see Chapter 5, section 5.2.2).

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, e.g. composition of the multidisciplinary team, best practices to be followed. The Healthcare Provider will be assessed to ensure that all the specific criteria have been adapted to the disease and that the Healthcare Provider is meeting the thresholds for these criteria as defined in the Network application.

1.5 Confidentiality of Information

The content of all material and information furnished for review during the assessment process is considered confidential. The content of these 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 with the EU data protection legislation and rules.

1.6. Legislation

The relevant legislation to support the information in this manual can be accessed through the following links:

- **Delegated Decision 2014/286/EU**
- **Implementing Decision 2014/287/EU**
- **Implementing Decision 2019/1269/EU**

[10] 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.

1.7 Reading guide

In the following Chapters (2 - 6) the specific activities, steps and procedures that have to be carried out by the different stakeholders involved in the assessment process are described.

The relevant chapters for the different stakeholders are:

Chapter 2: Applicants
Chapter 3: European Commission (EC)
Chapter 4: Board of Network (BoN) and /or the Network Coordinator (NC)
Chapter 5: Independent Assessment Body (IAB) and Assessors
Chapter 6: Member States (MS) and the Board of Member states (BoMS)

Specific tools (checklists, templates, instructions, forms etc.) to be used by the stakeholders in the assessment process, are summarised in the form of a Technical Toolbox and are listed in Chapter 7.

Chapter 2. Process and Procedures: Applicants

2.1 Roles and responsibilities of the Applicant

As described in the previous Chapter, there are two types of calls for interest: 1) a call for the creation of new Networks and 2) a call for Healthcare Provider membership for existing ERNs. In the first case, both a Network application and applications of all the individual Healthcare Providers creating the new Network are required. These Healthcare Provider applications are submitted jointly with the Network application, by the designated Network coordinator. For the second type of call, Healthcare Provider Applicants are operating individually. The difference in the assessment process for a Healthcare Provider Applicant creating a new Network together with other Applicants and a Healthcare Provider Applicant who is individually applying to become a member of an existing ERN is that the latter is assessed by the Board of Network (BoN) of the existing ERN, before progressing to the assessment by the Independent Assessment Body (IAB).

All applicants need to fulfil the following roles and responsibilities:

- Submit application forms, self-assessments, the Member State's written endorsement statement (only for the individual HCPs; not for Network as a whole) and supporting documentation to the European Commission (EC) in response to the call for interest.
- Participate in the technical assessment activities including virtual interviews and on-site-/online 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 process.

Healthcare Provider applicants wishing to join an **existing** European Reference Network (ERN) need to fulfil some **additional** roles and responsibilities:

- Provide comments on the draft opinion of the BoN within one month;
- Adhere to any other terms and conditions of the EC and the IAB.

In addition, each **Healthcare Provider** must assign a **representative** to fulfil the following roles and responsibilities during the assessment process:

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

2.2 Call for Interest

The first step of the assessment process is the call for interest, published on the EUROPA website by the European Commission's Directorate-General for Health and Food Safety (DG SANTE). The Applicant can find the conditions for applying, links to the application IT tool and required documents, deadlines for submission and contact information in the call for interest on the website.

2.3 National Endorsement by the Member State

Each Healthcare Provider applicant must have a written statement, including a corresponding completed checklist, from its Member State (MS) certifying that its application **is in accordance with the Member States national legislation**.

Steps to be completed by the **Applicant** include:

- The Applicant sends a template of the Letter of endorsement to the National Authority, including guidance and a checklist.
- Once received back from the National Authority, the Applicant submits the Letter of endorsement including the completed checklist together with the other relevant documentation.

A **mandatory** template of the Endorsement Letter is provided in ***Annex 10*** *Checklist and Template Letter of Member State Endorsement for Healthcare Providers* and on the EUROPA website**.** The National Authority may include further information or logos. Applications without a written endorsement statement or completed checklist signed by the National authority will be considered incomplete and therefore ineligible to proceed to the next step.

2.4 Submission of Application to European Commission

A graphical representation of the submission of the application for new Networks and for Healthcare Providers wishing to join an existing ERN is shown in Chapter 1, Figure 2 and Figure 5 respectively.

Healthcare provider Applicants 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.
- Letter of endorsement and completed checklist by the Member States' National Authority.

These must be submitted **within the deadline of the call for interest** and the required documents must be signed. Applications sent by different means will not be accepted. For the Network application, only the application form and self-assessment are relevant.

Two checklists are provided for the Network and Healthcare Providers to ensure all necessary steps have been completed before submitting the proposal to the European Commission (EC) (see ***Annex 11a*** *Application Checklist for Networks* and ***Annex 11b*** *Application Checklist for Healthcare Providers*).

2.4.1 Completing the Self-Assessment for Networks and Healthcare Providers

In both cases of creating a new Network and Healthcare Providers wishing to join an existing ERN, the Network and/or Healthcare Providers Applicants are required to complete a self-assessment against the Operational Criteria (see Chapter 1, section 1.2.3, ***Annex 1a*** *Operational Criteria for Networks* and ***Annex 1b*** *Operational Criteria for Healthcare Providers*). There are two self-assessment tools: one for the Network and one for the Healthcare Provider. The self-assessment for Healthcare Providers is available in the form of an online application under the documents section in the call for interest, together with the Membership application form (discussed in the next section, 5.4).

To complete the self-assessment tool, Applicants must follow the "Instructions for Self-Assessment" included in (***Annex 2a*** *Instructions for Self-Assessment for Networks* and ***Annex 2b*** *Instructions for Self-Assessment for*

Healthcare Providers). The Applicant is asked to self- assess against each criterion by using the rating scale and scoring guidelines described in these Annexes, and must explain and substantiate the given ratings in the comments-fields (mandatory for each score). The IAB Assessors will use the same rating scale during the technical assessment.

For the self-assessment for Healthcare Providers, a business continuity plan needs to be submitted as required documentation. If the institution does not have such a plan available, applicants can use ***Annex 13*** *Template Business Continuity Plan*.

2.4.2 Description of the Online Application Form

The instructions for filling in the online tool are detailed in a specific document available on the website. A description on how to access the application form and create a new Application, can also be found in ***Annex 3*** *Instructions for Application*.

The applicant shall attach to the Application the declarations to be **downloaded, filled in and signed** by the CEO and the Healthcare Provider Representative (***Annex 12a*** *Checklist and Declaration form for the CEO* and ***Annex 12b*** *Checklist and Declaration form for Healthcare Provider Representative* respectively). 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.

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. This is only applicable to Healthcare Provider wishing to join an existing ERN. For Applicants creating a new Network, there is no online tool developed (yet).

2.4.3 Submitting the Application form, Self-Assessment(s) and Supporting Documents

The application form, self-assessment, and supporting documentation must be submitted by the Network coordinator – in case of a call for new Networks – or by the Healthcare Provider – in case of a call for membership of an existing ERN – in due time respecting the deadline fixed in the call. The applicant:

- Uses the Application Checklist for a completeness check (See ***Annex 11a*** *Application Checklist for Networks* and ***Annex 11b*** *Application Checklist for Healthcare Providers*).
- Makes sure the Application contains attached all requested fully signed documents before submission (the Application will be considered ineligible if the responsible parties do not sign the declarations).
- May provide to the National Authority a copy of the Application before or after submitting the Application, in accordance with the national procedures (only for Healthcare Provider Applicants).
- Is encouraged to contact their National Authority to clarify the requirements of the national procedure (only for Healthcare Provider Applicants; information is available on website).

Upon submission, a notification is sent to the EC and a unique application number is assigned for tracking purposes.

2.4.4 Monitoring the Application

The monitoring instructions are detailed in a specific document available on the website. A description on how to monitor the application process and how to respond to feedback requests can also be found in ***Annex 4*** *Instructions for monitoring Application Status*.

2.5 Verification of Completeness of Application by the European Commission

The European Commission (EC) completes the first part of the eligibility check of the applications by verifying if:

- All required forms are completed.
- All required documentation is submitted.
- In case of a Network Applicant: if the minimum numbers of participating Healthcare Providers and Member States are met.

This step represents the first decision point in the assessment process. For more detailed information see Chapter 3. A graphical representation of the verification of the application for new Networks and for Healthcare Providers wishing to join an existing ERN is shown in Chapter 1, Figure 2 and Figure 5 respectively.

Once the EC has reviewed the applications, the Network Coordinator and/or the Healthcare Provider is notified about the status of its application. Only applications that meet the minimum requirements progress to the next stage of assessment. The assessment stops at this stage for ineligible or incomplete proposals. It is not possible to appeal to the decision of the EC.

2.6 Peer Review of Clinical Excellence of Healthcare Providers by the Board of Network

The Board of Network (BoN) assesses the eligible applications against the required specific criteria and conditions[11]. A graphical representation of the peer review of clinical excellence by the BoN is shown in Chapter 1, Figure 6. This step only applies to Healthcare Providers applying to join an existing ERN and not for Healthcare Providers applying to create a new Network.
The ERN-specific thresholds for the specific criteria (e.g. ERN-specific patient numbers) are developed by the Networks themselves and are provided in ***Annex 5*** *Instructions regarding Specific criteria per Network.*

2.6.1 Steps Completed by the Applicant

The Applicant must:

- Provide complementary information or documents when requested by the BoN.
- Review the BoN's comments received through the IT system and comment on the findings in the draft opinion (if necessary) **within one month**.

The BoN has **one month** to prepare its final opinion. If any comments were provided by the Applicant, the deadline may be extended by one month (i.e. 5 months for the whole process). For more information on the specific peer review process by the BoN see Chapter 4, section 4.2.

2.6.2 Decision - Possibilities for Appeal

The Applicant has the right to contest an unfavourable opinion of the BoN through its National Authority. The National Authority decides whether the application that received a final negative opinion by the BoN should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation.

[11] Point 2 of Annex II of the Delegated Decision 2014/286/EU

2.7 Technical Assessment by Independent Assessment Body

The IAB coordinates the following activities included in the technical assessment of the Applicant: documentation review, virtual interviews and on-site/online audits. A graphical representation of the technical assessment by the IAB for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 3 and Figure 7 respectively.
The purpose of this stage of the process is to assess compliance with the Operational Criteria for Networks and/or for Healthcare Providers. The documentation provided by eligible applicants will be filed by the IAB for any further review or assessment by the BoN, the IAB or the EC.

2.7.1 Verification of Application by IAB

The IAB receives the eligible applications from the EC – in case of applications to create a new Network – or applications with a positive opinion from the ERN Board of Network – in case of applications to become a member of an existing ERN – and verifies the applications.

The Assessment Coordinator:

- Verifies if Applicants meet the minimum requirements.
- Provides Applicants with a report with a copy of the checklist and a decision on whether the application is eligible or not to proceed to the next stage in the assessment.

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

2.7.2 Documentation Review and Virtual Interviews

Steps Completed by the Independent Assessment Body
To initiate the technical assessment, the Assessment Coordinator works with the Healthcare Provider Representative to schedule an introductory web-conference, 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.

During the technical assessment, the Assessors review the applications by:

- Completing a comprehensive documentation review of the application forms, self-assessments and any supporting documentation submitted by the Network and/or each Healthcare Provider.
- Completing virtual interviews with the Network Coordinator and/or Healthcare Provider Representatives to ask questions and/or request clarifications on the information submitted by the Applicant (see ***Annex 6*** *Interview Guide for Completing Virtual Interviews*).

For more information see Chapter 5, section 5.2.2.

Preliminary report
A preliminary report on the results from the documentation review and virtual interviews will be made available to the Network Coordinator – in case of a call for new Networks – or to the Healthcare Provider Applicant – in case of a call for membership of an existing ERN. The Applicant has an opportunity to comment on the results and submit missing information or request amendments. The Assessment team reviews any new information and makes changes or adjustments as necessary.

Only Networks and Healthcare Providers with a positive assessment can progress to the next stage of the assessment process. The technical assessment of new Networks **stops** at this phase for the Network in either of these cases:

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

2.7.3 On-site/online Audit

To validate the results from the documentation review and virtual interviews, a sample of Healthcare Providers is selected for an on-site/online audit, which represents the third decision point in the assessment. Once sites have been selected, Applicants are notified through the Network Coordinator – in case of a Network proposal – or by the IAB – in case of a Healthcare Provider wishing to join an existing ERN – about the dates and times of the on-site audit.

Preparing for On-site/Online Audit

The following steps are taken in preparation of the on-site audit:

- The Assessment Coordinator prepares an 'on-site audit schedule', when applicable in collaboration with the Network Coordinator.
- The Assessment Coordinator requests from the Healthcare Provider the required documentation/information to be sent in advance or to be made available the day of the on-site audit (for required documentation, see ***Annex 14*** *On-site Audit Schedule Template*).
- A teleconference between the Assessment Coordinator, the Assessor Team, the Network Coordinator (when applicable) and the Healthcare Provider Representative to go over the arrangements for the audit is scheduled.
- The Healthcare provider completes activities **in preparation** for the on-site audit (see ***Annex 7*** *On-site audit checklist for Networks and Healthcare Providers*).

Carrying Out the On-sit/Online Audit

During the on-site/online audit, clinical areas are visited and activities like a discussion with the multidisciplinary team, a clinical documentation review and patient tracers are completed. ***Annex 14*** *On-site Audit Schedule Template* provides a template for the on-site/online audit schedule including the audit activities and lists of the documents reviewed by the assessors on-site/online. In general, an on-site audit lasts one to two days and an online audit lasts maximum one day.

Rating Scale and Guidelines

The Assessors apply the same rating scale to assess compliance against the Operational Criteria as used in the self-assessment by the Applicant. For information on this rating scale see Chapter 5, section 5.3.

2.8 Communication of Assessment Outcomes

A graphical representation of the communication of assessment outcomes for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8 respectively.

2.8.1 Decision Guidelines

All Applicants need to meet certain conditions, in terms of scoring, to progress to the next stage of the assessment process (see ***Annex 9*** *Decision Guidelines for the Approval of a Network or Healthcare Provider*). This step represents the **fourth decision point** in the assessment process. The results are summarised in the assessment report as outlined in the following section.

2.8.2 Assessment Reports for Network and Healthcare Provider Applicants

In case of application for a new Network, common reports for the Network as well as individual reports to each Healthcare Provider are provided. In case of application for membership of an existing Network by a Healthcare Provider, each Applicant receives an individual report. Included in the reports are the assessor ratings against the Operational Criteria and strengths and areas for improvement. All reports are uploaded to the portal once they are ready. The Assessment Coordinator notifies the Network Coordinator or Healthcare Provider applicant that the reports are ready for review.

2.8.3 Applicant Submission of Comments

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

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

2.8.4 Final Assessment Report

Once the previous step is 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/online audits).

2.8.5 Decision - Possibilities for Appeal

An Applicant receiving a final negative assessment cannot progress to the next stage of the assessment. If as a result of a negative assessment, the Network no longer meets the minimum requirements of having 10 Healthcare Providers from 8 Member States, the 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 on the Networks and Applicants with a negative assessment report.

The Applicant has the right to contest the unfavourable decision of the IAB through its National Authority. The National Authority decides whether the application that received a final negative decision by the IAB should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation.

2.9 Approval by the Board of Member States

2.9.1 Steps Completed by the Board of Member States

A graphical representation of the final approval for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8 respectively. The BoMS review all positive assessment reports and recommendations of the IAB and decide whether or not to approve proposals for a European Reference Network, or a Healthcare Provider to join an existing ERN.

2.9.2 Final Decision

The EC will notify the Applicant, the Network coordinator or the BoN (in case of membership to an existing ERN), 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 rules of procedure applicable to the decision-making process are set by the BoMS, and can be found in ***Annex 9*** *Decision Guidelines for the Approval of a Network or Healthcare Provider* and on the ERN dedicated website of the European Commission: https://ec.europa.eu/health/ern/board_member_states_en. For information on the rules and procedures regarding loss of ERN membership or termination of an ERN see Chapter 6, section 6.5.

2.10 Publication of List of Established Networks and their Members

2.10.1 Publishing Assessment Results and Exchanging Information with the Public

The EC publicly identifies those Applicants who have been approved as European Reference Networks and 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. A graphical representation of the publication of approved new Networks and their Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8 respectively.

When a Healthcare Provider submits an application to become a member of an existing Network, it agrees to disclose publicly 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 a Network and/or Member. 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.

In case of loss of the membership, 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.

2.10.2 Guidelines for the Use of Logo

The EC will allow the sublicense of the use of the ERN Logo, including the name of the Network and the Healthcare Provider, to approved Applicants. This logo can be used 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 license. The EC delegates the use of the license to the ERN coordinators 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.

2.11 Funding for European Reference Networks

For those Network Applicants wishing to apply for funding to support the establishment of the ERN, a separate

application form must be completed. In the current situation, the ERN coordinator can apply to be granted financial assistance from the budget of the European Union, in the form of co-funding through a five-year Framework Partnership Agreement (FPA) once the ERN is approved, however this may change in the future. Criteria that must be met in order to be granted funding, include exclusion criteria, selection criteria and award criteria. More detailed information on the conditions and criteria and guidelines on how to apply can be found on: ec.europa.eu/research/participants/data/ref/other_eu_prog/hp/hp_call_proposals_ern-fpa-2016_en.pdf.

2.12 Join an ERN as an Affiliated Partner

Healthcare Providers that are not eligible for full ERN-membership, have the possibility to become an affiliated partner to an ERN, if approved by their Member State. The Member State designates a Healthcare Provider as Associated National Centres, Coordination Hubs or Collaborative National Centres to a given ERN.

A priority is given to affiliated partners from Member States with no full member in a specific ERN. The affiliation process is an open procedure allowing Member States to identify and designate affiliated partners on a national level at any time. Detailed information on the specific conditions and requirements for affiliated partners can be found on: ec.europa.eu/health/sites/default/files/ern/docs/boms_affiliated_partners_en.pdf

Chapter 3. Process and Procedures: European Commission

3.1 Roles and responsibilities of the European Commission

The European Commission (EC) is the European Union's (EU) executive body representing the interests ofthe 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 overruled applications by the BoMS and the negative opinions.
- Complete the eligibility check by verifying that the Applicants meet the minimum requirements[12]
- Transfer the eligible applications to the IAB.
- Maintain and publicly share a list of all new recognized members of existing ERNs.
- Make available the outcomes of positive or negative assessments and/or evaluations carried out by the IABs, in accordance with the legislation.[13]

3.2 Call for Interest

A graphical representation of the call for interest for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 2 and Figure 5 respectively.

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) launches the public call for European Reference Networks (ERNs) or for Healthcare Providers wishing to join the ERNs. Before a call is launched, the Member States should have been consulted by the EC to decide on the appropriate timing for the publication of subsequent calls for interest. The call must include:

- A detailed description of the call.
- Conditions for applying to become a new Network or for applying to an existing Network.
- Links to the application IT tool.
- Documents such as the application forms, self-assessments, deadline for submission.
- The deadline for submission of applications must be established.

3.3 Verification of Completeness of Application by the European Commission

The EC completes the first part of the eligibility check of the applications. This step represents the **first decision point** in the assessment process. A graphical representation of this step for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 2 and Figure 5 respectively.

[12] Article 2(2) and Article 3(2) and (3) of the Commission Implementing Decision (2014/287/EU).
[13] Commission Implementing Decision (2014/287/EU) and applicable EU data protection legislation

Steps Completed for a Network Application

The EC completes an initial review of the applications for completeness (see ***Annex 17*** *Eligibility Checklist for Networks and HCP applicants*) and verifies that the Applicant meets the minimum requirements:

- The Network includes a minimum of 10 Healthcare Providers from 8 Member States.
- The Network and all Healthcare Providers have completed the application forms and self-assessments with supporting documentation as per the requirements.[14]
- Each Healthcare Provider has a written statement of endorsement from its Member State.

Steps Completed for Healthcare Provider Applications

The EC completes an initial review and verifies that the Applicant meets the minimum requirements:

- the Healthcare Provider has completed the application form and self- assessment as per the requirements in.[15]
- the Healthcare Provider attached a written statement of endorsement including a corresponding completed checklist from its Member State.
- the Healthcare Provider attached declaration forms and completed checklists with signatures of the CEO and HCP representative.

In case applications meet the minimum requirements, the EC transfers:

- Applications of eligible Networks together with the applications of the Networks' Healthcare Provider Applicants to the Independent Assessment Body (IAB).
- Applications of eligible Healthcare Provider Applicants to the Board of Network (BoN)

3.4 Communication of Assessment Outcomes

A graphical representation of the communication of assessment outcomes for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8, respectively.

3.4.1 Transfer of the Assessment Report to the EC

Once the EC receives the notification from the IAB, it verifies that all necessary information linked to positively assessed Network and/or Healthcare Provider Applicant is available and notifies the BoMS for approval.

3.4.2 Publication of List of Established Networks and their Members

Guidelines for the use of the ERN logo and Publication of approved Applicants are described in Chapter 2, section 2.10.2.

3.5 Loss of Membership of Termination of an ERN

In case of loss of a membership or termination of an ERN, the EC:

- Informs the BoN and the Healthcare Provider Representative in writing, if the Healthcare Provider no longer complies with national legislation.
- Informs the BoMS in writing, in case of the loss of membership due to a decision of the BoN.
- Informs the BoMS on the termination of an ERN.

For the conditions for loss of membership and terminating an ERN see Chapter 6, section 6.5.

[14] Annex I and Annex IIImplementing Decision (2014/287/EU)
[15] Annex I and Annex II Implementing Decision (2014/287/EU)

Chapter 4. Process and Procedures: Board of Networks & Network Coordinators

4.1 Roles and responsibilities for the Board of Network and Network Coordinators

The Board of Network (BoN) is a body responsible for the governance of the Network, composed of representatives from each Member of the Network.[16] The BoNs main responsibilities are:

- Carry out a peer review of clinical excellence on the basis of the criteria and conditions set out in the legislation[17] and request complementary information or documents when needed.
- Prepare a positive or negative opinion within **three months**[18] for the HCP that wishes to join an existing ERN.
- Prepare a final opinion within **one month**. If any comments were provided by the Applicant, the BoN will take these into account and may extend the deadline by **one month** (i.e. 5 months instead of 4 for the whole process).

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:

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

4.2 Peer Review of Clinical Excellence of Healthcare Providers by the Board of Network

The Board of Network (BoN) assesses the eligible applications against the specific criteria and conditions set out in the legislation[19] using ***Annex 8*** *Instructions for Reviewing Application and Report Decisions (online)* and in ***Annex 15*** *Instructions and Scoring Table for Peer reviewing specific criteria*

[16] Article 3 Delegated Decision 2014/286/EU; Article 1a Commission Implementing Decision (EU) 2019/1269, amending Implementing Decision 2014/287/EU
[17] Point 2 of Annex II Delegated Decision 2014/286/EU
[18] Article 5 CommissionImplementing Decision (EU) 2019/1269, amending Implementing Decision 2014/287/EU
[19] point 2 Annex II of the Delegated Decision 2014/286/EU

HCP. The ERN-specific thresholds for the specific criteria are available in ***Annex 5*** *Instructions regarding Specific criteria per Network (Excel).*
This peer review step only applies to Healthcare Providers wishing to join an existing ERN and not to Healthcare Providers creating a new Network. The BoN maintains a list of Healthcare Providers that may require further attention during an on-site/online audit.

A graphical representation of the peer review by the BoN for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 6.

4.3 Decision - Possibilities for Appeal

The Applicant has the right to contest an unfavourable opinion of the BoN through its National Authority. The National Authority decides whether the application that received a final negative opinion by the BoN should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation.

4.4 Loss of Membership of Termination of an ERN

For the conditions for loss of membership and terminating an ERN see Chapter 6, section 6.5.
If the Healthcare Provider voluntarily withdraws from an ERN, is asked to withdraw, or refuses to be evaluated, the BoN must inform the EC in writing, along with the reasons for the withdrawal. In case an ERN refuses to be evaluated or decides to voluntarily terminate its status, the BoN must inform the European Commission (EC) in writing, along with the reasons for the withdrawal.

Chapter 5. Process and Procedures: Independent Assessment Bodies

5.1 Roles and responsibilities of the Independent Assessment Body and Assessors

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:

- Recruit and train assessors.
- Verify the applications.
- Oversee and maintain policies and procedures to support the technical assessment in line with the legislation.[20]
- Conduct the technical assessment based on these policies and procedures.
- 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 **Assessors** are peer reviewers who complete the documentation review, virtual interviews and on-site/online audits. As a team, they have the collective responsibility to:

- Act on behalf of the Independent Assessment Body (IAB) (i.e. 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.

Participation as an assessor 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 to address real or perceived conflicts of interest should be put in place by the IAB:

- 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.
- Each individual representing the IAB in the assessment process will sign a confidentiality and conflict of interest statement (See ***Annex 16*** *Sample Conflict of interest and Confidentiality Statement*). The procedures on conflict of interest and confidentiality will be discussed at the start of the assessment with the Applicant and at the beginning of the on-site audit.
- Each individual involved in the assessment must disclose in writing any real or perceived conflicts of interest as soon as they are aware of one.
- 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.
- The IAB will maintain a record of all individuals who excuse themselves from any portion of the assessment due to a conflict of interest.

[20] Commission Implementing Decision (2014/287/EU)

5.2 Technical Assessment by Independent Assessment Body

A graphical representation of the technical assessment by the IAB for a call for new Networks and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 3 and Figure 7 respectively.

Before the start of the technical assessment, the IAB assigns an Assessment Coordinator as the key contact between the IAB and the Network Coordinator, who will:

- Access all the required documentation.
- Assigns a minimum team of two assessors, that:
    - Consists of a multidisciplinary group of clinicians, and/or managers based on the IAB Terms of Reference.
    - Works in the same discipline as the Applicant(s), as much as possible.
    - Has an appointed team leader who is the key contact between the assessor team, Assessment Coordinator, and the Healthcare Providers' Representative(s) and presents the preliminary recommendations at the end of the on-site audit.

In case of a call for new Networks, the composition of the assessor team depends on the number of Applicants creating the Network and their geographic location. Ideally, the same team should assess all applications to the same network.

5.2.1 Verification of Application by IAB

The IAB receives only the applications with the positive opinion from either EC (in case of a call for new Networks) or from the Board of Network (in case of a call for Healthcare Provider membership of existing ERNs). The IAB verifies the applications by completing a thorough review of all documents submitted using (use ***Annex 17*** *Eligibility Checklist for Networks and HCP applicants*). The Assessment Coordinator updates this checklist if necessary.

If the application meets all minimum requirements (listed below), it is "Deemed Eligible". If the application is incomplete or the requirements are not met, it is "Deemed Ineligible". Only eligible Healthcare Providers can progress to the next stage: documentation review and virtual interviews.

Minimum requirements for Network applications:

- The content of the Network application fulfils the requirements.[21]
- The content of the individual Healthcare Provider Applications fulfil the requirements.[22]
- The Network fulfils the requirement to provide highly specialized healthcare. All Healthcare Provider Applicants must share the same area of expertise as the Network.

Minimum requirements for Healthcare Providers applicants:

- The Healthcare Provider has completed the application form and self- assessment as per the requirements.[23]
- The Healthcare Provider attached a written statement of endorsement including the corresponding completed checklist from its Member State.
- The Healthcare Provider attached declaration forms with the signature of the CEO and HCP representative.

[21] Annex I Implementing Decision (2014/287/EU)
[22] Annex II Implementing Decision (2014/287/EU)
[23] Annex I and Annex II Implementing Decision (2014/287/EU)

5.2.2 Documentation Review and Virtual Interviews

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

- The Assessment Coordinator schedules an introductory web-conference, to provide background information on the assessment, answer questions etc. For this purpose, the Applicant must provide the supporting documentation. Failure to provide this information will result in an ineligible proposal.
- The Assessors complete an independent comprehensive documentation review of the application forms, self- assessments, and other supporting documentation submitted to:
    - Verify that the process used to complete the self-assessment was robust.
    - Verify that self-assessments have been completed in a similar manner across Healthcare Providers (only in case of applications to create a new Network).
    - Verify that there is sufficient evidence provided.
- Assessors may request further information from the Network Coordinator and/or Healthcare Provider Representative(s); or obtain the advice of specialist clinicians.
- Following the review, virtual interviews with the Network Coordinator and Healthcare Provider Representative(s) will be completed using ***Annex 6*** *Interview Guide for Completing Virtual Interviews*.
- Based on the documentation review and virtual interviews, the Assessors rate compliance with the operational criteria (see ***Annex 1a*** *Operational Criteria for Networks* and ***Annex 1b*** *Operational Criteria for Healthcare Providers*) based on the information provided using ***Annex 18*** *Self-assessment Checklist for independent Assessors* and ***Annex 19*** *Assessment tool for independent Assessors (Excel)*.
- The assessors specify whether their preliminary ratings reflect a positive assessment based on ***Annex 9*** *Decision Guidelines for the Approval of a Network or Healthcare Provider*.
    - In case of assessing applications for new Networks: if the documentation review results in a negative assessment for any of Healthcare Provider Applicants, a new sample of Healthcare Providers will be selected for review equivalent to the number of negative assessments.
- The team leader provides a preliminary report on the results of the documentation review and virtual interviews (see ***Annex 18*** *Self-assessment Checklist for independent Assessors*), which will be made available to the Network Coordinator – in case of a call for new Networks – or the Applicant. The Applicant has the opportunity to comment on the results or request updates or corrections by providing new evidence. The Assessment Coordinator, in consultation with the Assessors, reviews any new information and makes changes or adjustments as necessary.
- The Assessment Coordinator submits a copy of the report to the Network Coordinator and the Healthcare Provider Representatives.
- The Assessment Coordinator makes a list of Healthcare Providers that may require further attention during an on-site/online audit.

The documentation provided by eligible applicants will be filed by the IAB for any further review or assessment by the BoN, the IAB itself or the EC. Only Applicants with a positive assessment (see box below) can progress to the next stage of the assessment process: on-site/online audits.

Positive assessment for **Networks**:
An overall compliance rate of 50% of the maximum score must be achieved to proceed. At least 10 Healthcare Provider Applicants from 8 Member States must receive a positive assessment

Positive assessment for **Healthcare Provider Applicants**:
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.

Evidence of Compliance
Healthcare Provider Applicants need to show their compliance with the *general* and *specific* Operational Criteria (***Annex 1a*** *Operational Criteria for Networks* and ***Annex 1b*** *Operational Criteria for Healthcare Providers*). To avoid duplication of efforts, Healthcare Providers can submit as evidence, for the *general* criteria, the assessment results from other assessment/accreditation bodies based on the following conditions:

- The national authority formally recognises the assessment/accreditation body.
- The assessment has been completed within the last 5 years.
- The 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.
- The Healthcare Provider provides a copy of the assessment report or results (within 3 days of the first contact with the Assessment Coordinator).
- 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 ERN-specific thresholds for the specific criteria are defined by the Network itself and published by the EC.

5.3 On-site Audit

A sample of Healthcare Providers with a positive assessment is selected for the on-site/online audit to validate the information obtained through the documentation review and virtual interviews.

Preparing for On-site Audit
In preparation of the on-site audit, the Assessment Coordinator will:

- Prepare an 'on-site audit schedule' (See ***Annex 14*** *On-site Audit Schedule Template*) in collaboration with the Network Coordinator or *Healthcare Providers' Representative(s)*.
- Schedule a teleconference between the Assessment Coordinator, the assessor team and the Healthcare Provider Representatives to revise and finalise the on-site audit schedule.
- Request 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 (for the required documentation see ***Annex 14*** *On-site Audit Schedule Template*).
- Work with the assessor team to arrange accommodation and travel as needed.
- Coordinate with the Healthcare Provider Representative the logistics for the on-site audits as described in ***Annex 7*** *On-site audit checklist for Networks and Healthcare Providers.*
- Provide the Healthcare Provider Representative(s) with a checklist to help to complete the key steps in preparation for the audit (See ***Annex 7).***

Carrying out the On-site/online 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, an online audit may last one day. Time is also allocated in the audit schedule for assessors to complete ratings and prepare an overview of the findings. For the activities that need to be carried out during the on-site audit see ***Annex 14*** *On-site Audit Schedule Template* and ***Annex 20*** *Patient Tracer Method and Guide for assessors*.

Rating Scale and Guidelines

The Assessors rate compliance against the Operational Criteria, based on the information provided using ***Annex 18*** *Self-assessment Checklist for independent Assessors and* ***Annex 19*** *Assessment tool for independent Assessors (Excel).* The Assessors apply the same rating scale used in the self-assessment, to ensure a consistent approach (outlined in the table below) and score 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. The Assessors also take the comments provided by the Applicants, which are mandatory for each score, into account when scoring.

Rating	Guidelines
0: No activity / Not Implemented	All Criteria: this rating is used if the answer is "rarely" or "never" to the specific measure and/or 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).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	All Criteria: this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or 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).* Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	All Criteria: this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to supportcompliance. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • A single negative observation may not prevent a score of "fully met". • Network Applicants must ensure that they are in compliance with these requirements by either having it in place or addressed within a detailed and well-defined implementation strategy within one year of the formal establishment of the Network

5.4 Communication of Assessment Outcomes

A graphical representation of the Communication of assessment outcomes for Network Applicants and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8 respectively.

Network and Healthcare Provider Applicants need to meet all of the conditions stated in ***Annex 9*** *Decision Guidelines for the Approval of a Network or Healthcare Provider*. If Applicants are unable to meet all conditions, this will result in a negative assessment. Only Applicants with a positive assessment can progress to the next stage. This step represents the fourth decision point in the assessment process.

5.4.1 Draft 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:

- The Assessment Coordinator reviews the findings and recommendations to check for accuracy and consistency.
- The IAB prepares a report based on the assessment tasks performed and the information collected from the eligibility check, documentation reviews, virtual interviews and on-site audits, if 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) (See ***Annex 22a*** *Assessment Report Template for Networks* and ***Annex 22b*** *Assessment Report Template for Healthcare Providers*). In case of a call for new Networks, the IAB provides a common report for the Network and individual reports for each Healthcare Provider Applicant creating the Network.
- All the reports should be ready within 2 weeks of the on-site/online audit. The Assessment Coordinator sends the final report to the Network Coordinator and/or the Healthcare Provider Representatives.

5.4.2 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. Corrections may be requested up to 2 months of receiving the reports.

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

5.4.3 Final Assessment Report

Once the previous step is 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.

5.4.4 Decision

Only Applicants with a positive assessment progress to the next stage of the assessment process. Applicants with a final negative assessment have the right to contest the unfavourable opinion of the IAB through its National Authority. For more information see Chapter 6, section 6.3.

5.4.5 Transfer of the Assessment Report to the EC

The IAB must notify the European Commission on the positive assessments: this is the second transition point between the IAB and the EC. The EC subsequently verifies that all the necessary information linked to positively assessed Applicants is available.

5.5 Assessors

5.5.1 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 the qualifications and knowledge listed in ***Annex 21*** *Assessor core competencies*. Assessors must have experience in the area of audits and certification, accreditation, or licensing of Healthcare Providers at national level. In addition to the required qualifications for assessors, the Assessor Team Leader is expected to have additional skills related to management and conflict resolution.

All assessors must complete a comprehensive orientation on the assessment process to ensure a common understanding of the requirements in terms of the Operational Criteria for Networks and Healthcare Providers and consistency in ratings, prior to completing any assessments (for more information see ***Annex 21*** *Assessor core competencies).*

5.5.2 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 the advances in assessment. This ongoing training and supervision helps to ensure that the assessment is an educational process and not merely a compliance exercise.

Chapter 6. Process and Procedures: Member States and the Board of Member States

6.1 Roles and responsibilities of the (Board of) Member States

The **Board of Member States** (BoMS) has the responsibility of approving European Reference Networks (ERNs) and members of the Network.[24] 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 Board of Network (BoN), upon request of the Member State, and make a decision after re-assessing the application and all other available documentation.
- Review the assessment reports and recommendations from the IAB.
- Review the unfavourable decisions of the IAB, upon request of the Member State, and make a decision after re-assessing the application and all other available documentation.
- Approve applications for ERNs.
- Approve applications 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.

The role of the **Member State** (MS) is to:

- Provide a written statement of endorsement including the corresponding completed checklist for the Healthcare Provider certifying that its participation in the European Reference Network (ERN) is in accordance with its national legislation.
- Defining its national process to support eligible Healthcare Providers and ensuring that this process is transparent.
- Upon request of the Applicant, the National Authority can decide to ask the BoMS to reassess an unfavourable opinion by the BoN or a negative assessment by the IAB.
- 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.

6.2 National Endorsement by the Member State

Each Healthcare Provider that is interested in forming a new 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 or its application to join an existing European Reference Network **is in accordance with the Member States national legislation**.

The Member State (National Authority) receives the template of the Letter of endorsement from the Healthcare Provider, including guidance and a checklist. Subsequently, the Member State:

- Completes the checklist by confirming, amongst others:
    - There are no limitations or exclusions regarding the Member State for the specific call.
    - There has been contact between the healthcare provider and the ERN about a potential application.

[24] Article 38.11, 13.1 and 15.1 Commission Implementing Decision 2014/287/EU

    - The healthcare provider is aware of the content of the healthcare provider's membership application
- Fills out the template of the Letter of endorsement.
- Signs the Letter of endorsement.
- Sends the Letter of endorsement back to the Applicant.

The complete checklist, template of the Endorsement Letter and the accompanying instructions are provided in ***Annex 10*** *Checklist and Template Letter of Member State Endorsement for Healthcare Providers.* It is **mandatory** for Applicants to use this template. The Member State may include further information or logos.

A graphical representation of the endorsement by the Member State for a call for new Networks and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 2 and Figure 5 respectively.

6.3 Appeal in case of a negative opinion or assessment

The Applicant has the right to contest the unfavourable opinion of the BoN or the negative assessment by the IAB through its National Authority. The National Authority decides whether the application that received a final negative opinion by the BoN should be reassessed by the BoMS, which makes a decision after re-assessing the application and all other available documentation. A graphical representation of the peer review by the BoN for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 6.

6.4 Approval by the Board of Member States

The BoMS review all positive assessment reports and recommendations of the IAB and decide whether or not to approve applications for a European Reference Network and applications for ERN membership and decides on the approval of a Healthcare Provider to join an existing European Reference Network (see ***Annex 9*** *Decision Guidelines for the Approval of a Network or Healthcare Provider*). Rules of procedure applicable to the decision-making process are set by 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.

If a Healthcare Provider, part of a Network application, 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. Rules of procedure applicable to the decision-making process are set by the BoMS, and can be found on the ERN dedicated website of the European Commission: https://ec.europa.eu/health/ern/board_member_states_en.

A graphical representation the final approval by the BoMS for a call for New Networks and for Healthcare Provider Applicants wishing to join an existing ERN is shown in Chapter 1, Figure 4 and Figure 8 respectively.

6.5 Loss of Membership or Termination of an ERN

6.5.1 Loss of Membership or Voluntary Withdrawal from a Network

As established in the legislation[25], a Healthcare Provider may lose its membership to an ERN if any of the following conditions occurs:

- The Healthcare Provider voluntarily chooses to withdraw from the Network.
- By decision of the Board of 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.[26]
- 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. The BoMS must approve the loss of membership due to a negative evaluation.

6.5.2 Termination of a European Reference Network

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

- One of the minimum numbers – i.e. 10 Healthcare Providers over 8 Member States –is no longer met.[27]
- The Network receives a negative evaluation.
- By decision of the Board of Network (BoN).
- If the Network Coordinator fails to request and evaluation of the Network within a five year period following its approval or refuses to be evaluated.[28]

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

[25] Article 12 Commission Implementing Decision 2014/287/EU
[26] Article 14 Implementing Decision 2014/287/EU
[27] Article 2(2) Implementing Decision 2014/287/EU
[28] Article 14 Implementing Decision 2014/287/EU

Chapter 7. Technical Toolbox: overview of Annexes

Guidance documentation:

Annex 1 Operational Criteria

- Annex 1a Operational Criteria for Networks;
- Annex 1b Operational Criteria for Healthcare Providers

Annex 2 Instructions for Self-Assessment

- Annex 2a Instructions for Self-Assessment for Networks
- Annex 2b Instructions for Self-Assessment for Healthcare Providers

Annex 3 Instructions for Application

Annex 4 Instructions for monitoring Application Status

Annex 5 Instructions regarding Specific criteria per Network (Excel)

Annex 6 Interview Guide for Completing Virtual Interviews

Annex 7 On-site Audit Checklist for Networks and Healthcare Providers

Annex 8 Instructions for Reviewing Application and Report Decisions (online)

Annex 9 Decision Guidelines for the Approval of a Network or Healthcare Provider

Tools for Applicants:

Annex 10 Checklist and Template Letter of Member State Endorsement for Healthcare Providers

Annex 11 Application Checklist

- Annex 11a Application Checklist for Networks
- Annex 11b Application Checklist for Healthcare Providers

Annex 12 Declaration forms for Healthcare Providers

- Annex 12a Checklist and Declaration form for the CEO
- Annex 12b Checklist and Declaration form for Healthcare Provider Representative

Annex 13 Template Business Continuity Plan

Annex 14 On-site Audit Schedule Template

Tools for Assessors (Independent Assessment Body, European Commission and Board of Network)

Annex 14 On-site Audit Schedule Template

Annex 15 Instructions and Scoring Table for Peer reviewing specific criteria HCP

Annex 16 Sample Conflict of interest and Confidentiality Statement

Annex 17 Eligibility Checklist for Networks and HCP applicants

Annex 18 Self-assessment Checklist for independent Assessors

Annex 19 Assessment tool for independent Assessors (Excel)

Annex 20 Patient Tracer Method and Guide for assessors

Annex 21 Assessor core competencies

Annex 22 Assessment Report Template

- Annex 22a Assessment Report Template for Networks
- Annex 22b Assessment Report Template for Healthcare Providers