

# EVALUATION MANUAL



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## Symbols



European Commission



Independent Evaluation Body



European Reference Networks



Healthcare Provider Team



Tools

These symbols refer to the actors involved in that stage of the evaluation process

This symbol refers to the tools that can be used in that stage of the evaluation process. In the text, the tools are highlighted in **blue**

## Glossary of Terms

**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.

**Criterion:** quality requirement which describes an "enhanced practice" which is both aspirational and achievable.

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

**European Reference Network (ERN):** European Reference Networks (ERNs) are virtual networks involving Healthcare Providers across Europe.

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

**Evaluation Process:** a process to determine the worth or significance of the work and actions developed by the ERNs.

**Healthcare Provider (HCP):** healthcare organisation with highly specialised services and professionals that belong to one or more European Reference Networks.

**Healthcare Provider Representative:** a person representing the Healthcare Provider in the Network.

**Healthcare Provider Team (HCP team):** a highly specialised group of professionals from a healthcare provision organisation that belongs to 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 Evaluation Body (IEB):** an independent assessment organisation appointed by the EC to perform the external evaluation of Networks and Healthcare Providers.

**IEB Coordinator:** a staff member from the Independent Evaluation Body (IEB) acting as the keycontact between the IEB, the European Commission and the Network.

**Measurable Element (ME):** the aspect or level of performance specified in each criterion.

**Core ME:** those that should have been accomplished or implemented at the time of the evaluation.

**Extended ME:** the remainder MEs that refer to important areas in which Networks or their Members should work and whose level of development can serve as an indicator of their maturity status.

**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 evaluation process.

## 1 Introduction

### 1.1 Background:

The European Reference Networks (ERNs) are virtual networks bringing together healthcare providers across Europe to tackle complex or rare medical conditions that require highly specialized treatment and a concentration of knowledge and resources.

ERNs are set up under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare<sup>1</sup>, which not only sets rights for patients seeking healthcare abroad including reimbursement for treatment in another EU Member State but also promotes cooperation in healthcare among Member States.

Article 12(1) of the above-mentioned Directive 2011/24/EU requires the Commission to support Member States in the development of European Reference Networks (ERNs) between healthcare providers (HCPs) and centres of expertise, by establishing the legal framework for such Networks. Moreover, Article 12(4) (b) of Directive 2011/24/EU calls on the Commission to develop the criteria for establishing and evaluating the Networks.

Further to the Directive, the Commission adopted on 10 March 2014 the Delegated Decision 2014/286/EU setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil, as well as the Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks amended by the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019.

24 ERNs approved by the ERN Board of Member States were launched in March 2017, including more than 900 highly specialised healthcare units from around 300 hospitals located in 25 EU Member States and in Norway covering major disease groups, from bone disorders to haematological diseases, from paediatric cancer to immunodeficiency. One member of each Network acts as Coordinator.

The above-mentioned Implementing Decision 2014/287/EU requires that, using an Evaluation Manual, an Evaluation Body appointed by the Commission should evaluate the Networks and their Members five years after their initial approval or last evaluation.

The evaluation refers to the process of determining the worth or significance of the work and actions developed by the ERNs.

The evaluation process shall be transparent and independent from the policy making and developed by a third party, the Independent Evaluation Body (IEB), to enhance credibility.

The Evaluation Body should assess the fulfilment of the criteria and conditions set out in Delegated Decision 2014/286/EU, the accomplishment of objectives set out in Article 12(2) of Directive 2011/24/EU and the outcomes and performance of the Networks and the contribution of their Members measured through the ERN monitoring system including the achievement of

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

the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements (SGAs) managed by the European Health and Digital Executive Agency (HaDEA). This appraisal shall be reflected in evaluation reports on the Networks and their Members.

The evaluation process is part of the AMEQUIS framework, a continuous quality improvement cycle of actions integrating the monitoring system of the ERNs and the assessment and evaluation processes.

## 1.2 Objectives of the evaluation process

The general objective of the evaluation process is to verify and assess:

- a) The fulfilment of the criteria and conditions set out in Delegated Decision 2014/286/EU
- b) The accomplishment of the objectives set out in Article 12(2) of Directive 2011/24/EU
- c) The outcomes and performance of the Network and the contribution of each Member
- d) The achievement of the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements (SGAs)

All these evaluation elements must be integrated into an evaluation report that shall include **conclusions** on the following aspects of the Network:

- **Structure:** How is the ERN covering the areas it stated it would (including geographical, diseases and conditions, and patient population).
- **Maturity:** At what stage of development is the network regarding its purpose, governance, leadership, learning and sustainability; level of integration into national health systems.
- **Activity:** To what degree has the ERN completed the activities it planned to perform; scale and ambition of the achievements.
- **Impact:** What has been the value added to the patients' experience, both receiving services with each member, and their pathway through the network; impact locally, use of ERN tools.

The evaluation of the individual Members of the Network should assess

- If the HCP continues to provide specialized and quality care
- If the HCP team maintains the necessary levels of activity and experience
- What has been the contribution of the HCP team to the Network
- The value of the ERN for the HCP.

## 1.3 Agents involved in the evaluation process:

Different agents are involved in the evaluation process, both at the political-institutional domain and at the more technical domain:

- **European Commission (EC):** The EC appoints the IEB that will conduct the evaluation, provides the institutional support, and oversees the whole process.
- **Board of Member States (BoMS):** The BoMS receives information from the EC regarding

the evaluation process and has to approve any termination of a Network or loss of membership on account of a negative evaluation.

- **Independent Evaluation Body (IEB):** The IEB carries out all the activities included in the external evaluation process, including organisational, managerial, and logistic issues, as well as the specific technical evaluation.
- **European Reference Network (ERN):** At ERN level, the ERN coordinator as well as other members of the Board and the coordinators of the different work packages will have to provide information to the evaluation team during the process; ERN patient representatives will also be interviewed. At HCP level, the HCP representative and other members of the multidisciplinary team will be involved for the self-evaluation and the audits.

## 2 Overview of the evaluation process

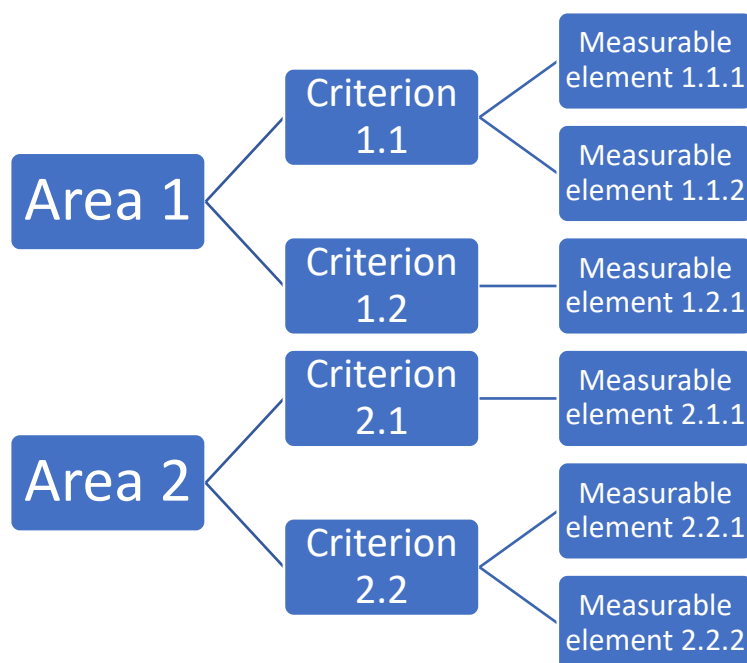
### 2.1 Evaluation criteria for Networks and their Members

The evaluation procedure is mainly based on verifying to which extent the Networks and their Members meet quality requirements related to the achievement of the objectives for which they were constituted.

Quality requirements are formulated as **criteria**, which describe an "enhanced practice" which is both aspirational and achievable.

The **measurable elements (ME)** are used to assess the aspect or level of performance specified in each criterion.

The criteria are grouped in several areas related to the different goals and objectives included in the evaluation:



Two sets of criteria have been elaborated, one for the evaluation of the Networks and the other for the evaluation of the HCP teams. The structure of both sets of criteria is presented in the tables below.

Some of the measurable elements are considered as “**core**” and should have been accomplished or implemented at the time of the evaluation. The remainder measurable elements refer to important areas in which Networks or their Members should work and whose level of development can serve as an indicator of their maturity status.

| EVALUATION CRITERIA FOR NETWORKS |              |           |             |
|----------------------------------|--------------|-----------|-------------|
| AREA                             | No. CRITERIA | No. ME    | No. core ME |
| Governance and coordination      | 4            | 15        | 10          |
| Clinical care                    | 3            | 9         | 5           |
| Quality and patient safety       | 2            | 3         | 0           |
| Patient centred care             | 3            | 6         | 3           |
| Contribution to research         | 3            | 7         | 4           |
| Education and training           | 2            | 6         | 4           |
| Networking and dissemination     | 3            | 6         | 4           |
| <b>TOTAL</b>                     | <b>20</b>    | <b>52</b> | <b>30</b>   |

| EVALUATION CRITERIA FOR HCP TEAMS            |              |           |             |
|----------------------------------------------|--------------|-----------|-------------|
| AREA                                         | No. CRITERIA | No. ME    | No. core ME |
| Patient centred care                         | 9            | 19        | 8           |
| Organisation and management                  | 5            | 10        | 4           |
| Research, education, and training            | 2            | 11        | 6           |
| Exchange of expertise, ICT, and eHealth      | 3            | 7         | 3           |
| Quality and safety                           | 2            | 9         | 2           |
| Competence, experience, and outcomes of care | 1            | 4         | 4           |
| Human resources                              | 2            | 4         | 2           |
| <b>TOTAL</b>                                 | <b>24</b>    | <b>64</b> | <b>29</b>   |

The evidence and findings obtained to respond to the fulfilment of the criteria should serve to draw conclusions about the performance of the Network and the HCP teams during the last five years.

## 2.2 General description of the evaluation process

According to Implementing Decision 2014/287/EU Art. 15, the ERN Coordinator requests the EC to be evaluated and the EC appoints the IEB that will conduct the evaluation.

Before the evaluation formally starts, the IEB will have to prepare all the organisational, managerial, and logistical arrangements for the evaluation, such as the training of the evaluators and the set-up of an online tool for the submission of documents and information by the ERNs and HCPs.

Prior to the formal announcement of the start of the evaluation by the EC and the IEB, the ERN Coordinators will have information available about the planned evaluation and the different steps/timelines and will be able to inform the Members and patient representatives about the evaluation procedure and agree on responsibilities, activities, and deadlines.

The deadline to perform the submission of the information and evidence requested to ERNs and their Members will be included in the formal announcement of the start of the evaluation procedure.

The different activities of the evaluation process can be summarized in the following **main steps**:

### Step 1. Self-evaluation



Each ERN and each Member to be evaluated will carry out a self-evaluation focused on the criteria and measurable elements of the different thematic areas and will send it to the IEB through the on-line tool.

The purpose of the self-evaluation is that each Network and each HCP team carry out a process of reflection on the activities performed during these five years in order to verify to what extent they have developed their mission and fulfilled the proposed objectives.

### Step 2. Technical evaluation



The IEB is responsible for carrying out the activities of the external evaluation of both the Networks and each of the HCP teams to be evaluated:

#### A. Network evaluation:

- Document review: self-evaluation and documents provided by the EC and the ERN
- Online meetings/interviews with ERN and grants work-packages coordinators
- Online meeting/interview with ERN patient representatives

#### B. HCP team evaluation:

- Document review: self-evaluation and evidence provided by the HCP
- On-site audit<sup>2</sup>

### Step 3. Elaboration of the evaluation reports



The IEB will make a global report for the Network and an individual report for each of its evaluated Members. Besides, a whole ERN system evaluation report has to be elaborated.

As established in the Implementing Decision 2014/287/EU 14.7, the Board of Member States may request an improvement plan from those Members/Networks whose evaluation has not been satisfactory and offer the Member/Network in question one year to remedy the shortcomings identified before carrying out a new evaluation.

- #### A. Draft evaluation report:
- will be sent to Network coordinator/Member of the Network/Commission. They have two months to provide feedback as well as to prepare improvement plans when requested by the IEB.

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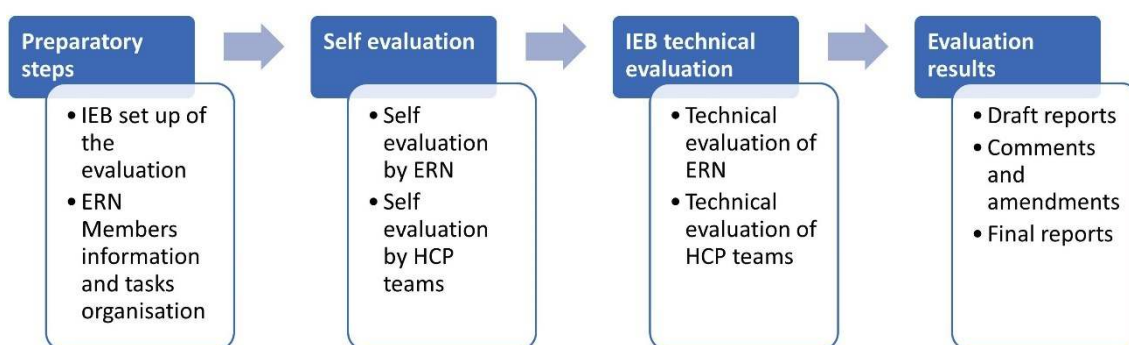
<sup>2</sup> The possibility of online audits should be considered in case of pandemic or other exceptional situations.

- B. Final evaluation report: will be sent to Network coordinator/Member of the Network/Commission. If applicable, the improvement plan and its assessment will be annexed to the final evaluation report.

## 2.3 Timeline for the evaluation process:

The evaluation process may take between 10 to 12 months, from the appointment of the Independent Evaluation Body to the issuance of the final evaluation reports. The deadlines and timeline are subject to change at the discretion of the European Commission and the Independent Evaluation Body.

The following diagram outlines the different phases of the evaluation process:



The following sections of the Manual include specific details for the ERN and HCP teams as well as for the IEB regarding each stage of the evaluation process.

## Evaluation process for ERNs and HCPs

### 3 Preparation for the set-up of the evaluation



#### Evaluation manual and toolbox

According to Implementing Decision 2014/287/EU Art. 15, the ERN Coordinator requests the EC to be evaluated and the EC appoints the IEB that will conduct the evaluation.

It is expected that there will be informal communication between the EC and the ERN coordinator, so that this one has information about the planned evaluation and the different steps/timelines before the formal announcement of the start of the evaluation.

The evaluation manual and toolbox will be available beforehand and, therefore, the ERN coordinator will be able to inform and discuss with the Members representatives about the evaluation procedure and agree on responsibilities, activities, and deadlines.

### 4 Self-evaluation of ERNs and HCP teams



#### Evaluation manual and toolbox:

- Operational criteria for evaluation of ERNs and HCP teams
- Self-evaluation form and guidelines for ERNs and HCP teams
- List of documents to be prepared by ERNs and HCP teams
- Scoring guidelines

Online tool and online tool user guide

#### 4.1 Formal announcement of the start of the evaluation



The formal announcement of the beginning of the evaluation process and the deadline for the submission of the documents will be carried out jointly by the EC and the IEB.

An **on-line tool** will be available for Networks and their Members to submit their information.

## 4.2 Self-evaluation of ERNs and their Members



The self-evaluation entails to review each of the criteria and their measurable elements and to justify their level of compliance, providing the corresponding evidence, and scoring them according to the indications contained in the tools [self-evaluation guidelines for ERNs and HCPs](#) and [scoring guidelines](#).

The tool [self-evaluation form](#) can be used to prepare the self-evaluation in advance and organize the evidence documentation or information to be submitted.

The [list of documents to be prepared by ERNs and their members](#) also facilitates information regarding the evidence that can be provided.

### 4.2.1 Submission via the online tool

All the information included in the self-evaluation template has to be submitted via the [online tool](#) provided by the IEB.

Each Member must incorporate their own self-assessment and it is the responsibility of the Network coordinator to include the self-assessment of their ERN, as well as to ensure that all Members to be evaluated have completed their assessments.

### 4.2.2 Validation of the self-evaluation results internally by the ERN coordinator

Before the final submission of the self-evaluations, the ERN coordinator has to validate them formally following the online process set up by the IEB.

With this formal validation, the submission of the self-evaluations is completed.

## 4.3 Verification and confirmation by the IEB



The IEB will verify that all the self-evaluations submitted are complete and contain all formal requirements.

The IEB will request any additional missing information.

## 5 Technical evaluation by the IEB



### Evaluation manual and toolbox:

- Guidelines to prepare interviews
- Guidelines to prepare on site/online audits

The IEB is appointed by the EC to carry out the external evaluation process. It is important to facilitate a fluid communication of the IEB with all the Network stakeholders so that the different activities can be properly planned.

The evaluation approach is different at the Network level and at the Member level, so the activities that will be carried out during both technical evaluations to obtain the necessary information are described separately.

### 5.1 Network technical evaluation



To assess the level of development of the Network's objectives over the past five years, in addition to the information contained in the self-evaluation, the evaluators will review other documentation provided by the EC and a sample of the deliverables generated by the Network in the framework of the grants received. They will also meet with the coordinators and patient representatives.

These evaluation activities are briefly described below.

#### 5.1.1 Document review:

The following documents generated both in the initial assessment and throughout the five years of activity will be thoroughly reviewed:

- Initial assessment application and report (particularly the assessors' comments and recommendations). *To be provided by the EC.*
- ERN monitoring indicators. *To be provided by the EC.*
- Grants reports: objectives outlined, tasks performed by the different work packages, results achieved. *To be provided by the EC.*
- A sample of the deliverables generated (i.e., websites, reports, educational materials...). *To be selected by the evaluators and provided by the Network.*
- Information included in the self-evaluation of the Network. *Submitted by the Network.*

This documentary review will serve to provide evidence on the fulfilment of the operational criteria and the objectives established by the Network for the five years. During the review of the documentation, the IEB evaluators will determine what information they need to complete or contrast later through interviews and online meetings.

### 5.1.2 Virtual interview with ERN and work-packages coordinators:

Over the last 5 years, each Network has worked on achieving its objectives by developing a series of EC-funded projects. The planning and execution of these projects has been carried out by distributing tasks among different work-packages.

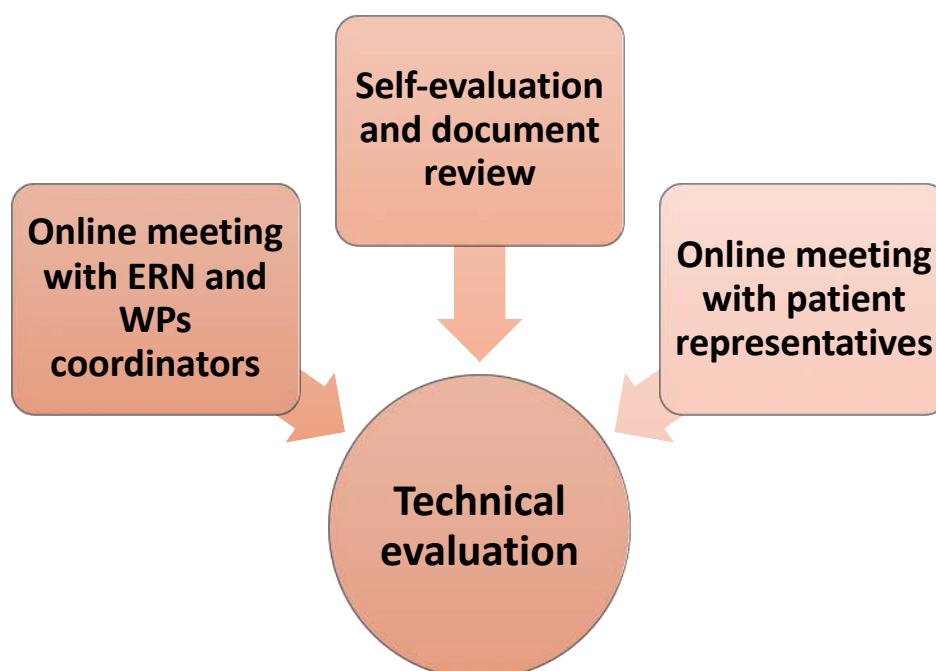
The evaluators shall plan to conduct one or more interviews with the Network coordinator and with the coordinators of the different work packages in order to obtain additional information, for example, on the governance of the network, the organization and distribution of tasks, the results obtained, the difficulties in the operation of the network, etc.

The interviews will be prepared directly with the IEB evaluators, but the [guidelines to prepare interviews](#) can be used to get an idea of the possible dynamics and contents.

### 5.1.3 Virtual interview with patient representatives:

The objective of this interview is to contrast with the patient representatives their level of participation in the different actions of the Network, including the field of governance and strategic planning.

The ERN coordinator should facilitate communication between the IEB and patient representatives for interview planning.



## 5.2 HCP team technical evaluation



The IEB evaluators will review the information and evidence provided through the self-evaluation on the contribution of each Member to the mission of the Network and on the

adjustment of their care processes to the required quality levels. Members' evaluation methodology focuses on two sources of information:

#### 5.2.1 Document review:

The following documents will be thoroughly reviewed:

- Initial assessment application and report. *To be provided by the EC*
- Monitoring indicators provided by the Member to the ERN in the last 3 years. *To be provided by the Member/ERN as available*
- Information and evidence included in the self-evaluation of the Member. *Submitted by the Member.*

#### 5.2.2 Onsite audit:

The evaluators will visit the HCP Member to perform an onsite audit in order to collect supplementary evidence needed to assess the accomplishment of some measurable elements.

The [guidelines to prepare onsite audits](#) can provide guidance to the HCP Member on how to organize and facilitate the visit of the IEB team.

The main activities to be carried out during the onsite visit are the following:

- Direct observation of the facilities and the provision of care.
- Meeting/interview with the multidisciplinary team
- Meeting/interview with a group of patients
- Review of patient clinical registries
- Documentary review



#### Document review

- Initial assessment application
- Monitoring indicators
- Self evaluation and evidence included



#### On site audit

- Direct observation
- Meetings/interviews
- Clinical records/document review

## 6 Evaluation results



### Evaluation manual and toolbox:

- Network evaluation report template
- HCP evaluation report template
- Decision guidelines
- Improvement plan template

### 6.1 Draft evaluation reports



The evaluation process finalizes with the preparation of an evaluation report of the Network and each of its Members.

The evaluation is not intended to obtain a "positive or negative" result, but to detect whether the development of the Network during the five years has been satisfactory, and if the ERN Members have actively contributed to it while providing highly specialized, quality, and safe care.

The essential elements to assess, that the development of the Network and the contribution and performance of its Members have been satisfactory, will be the adequate fulfilment of the measurable elements established as "core" (see [decision guidelines](#)). The remainder measurable elements will serve to determine the degree of maturity of the Network as well as the quality of the performance of its Members, indicating those areas in which progress should be made in the following period.

In case the result is not satisfactory, the Implementing Decision 2014/287/EU 14.7 establishes that the Board of Member States may offer the Network/Member in question one year to remedy the shortcomings identified before carrying out a new evaluation. To facilitate this process, the IEB will request the Network/Member in question to elaborate an improvement plan that will be reviewed and assessed by the IEB prior to submitting the final report to the EC.

#### 6.1.1 Draft evaluation report for HCP

It includes the summary and a detailed review of the results of the evaluation of the HCP team as well as the comments and recommendations provided by the evaluation team (see [HCP evaluation report template](#)):

- o Conclusions of the evaluation team
- o Overall compliance with the operational criteria
- o Results of the HCP in the measurable elements from each area
- o Detailed results of each criterion and areas for improvement
- o Outcome of the evaluation (scoring table): indicating the specific score of core MEs and score of those MEs that identify HCP contribution to the mission of the Network
- o Result (according to the [decision guidelines](#)): satisfactory or needing improvement.

### 6.1.2 Draft evaluation report for ERN

It includes the summary and a detailed of the results of the evaluation of the Network and its Members as well as the comments and recommendations provided by the evaluation team (see [Network evaluation report template](#)):

- Conclusions of the evaluation team
- Overall compliance with the operational criteria by the ERN and the HCPs
- Results of the Network in the measurable elements (MEs) from each area
- Detailed results of each criterion and areas for improvement
- Evaluation of the achievement of the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements.
- Summary of the evaluation results of the Members of the Network
- Outcome of the evaluation:
  - Scoring table of operational criteria for the ERN (including specific score of core MEs)
  - Qualitative assessment of the accomplishment of the objectives initially selected by the ERN
  - Result of the evaluation according to the [decision guidelines](#): satisfactory or needing improvement

## 6.2 Final evaluation reports for ERN and HCPs



### 6.2.1 Submission of comments to the draft evaluation reports

The IEB sends the draft evaluation report on each Network to the Commission, the Board of the Network, and the Members of the Network.

The IEB sends the draft evaluation report of each Member to the Commission and the Member addressed by the report.

The Network Coordinator and the ERN Members may send comments to the IEB **within two months of receiving the draft evaluation report**.

### 6.2.2 Submission of improvement plans

When the result of the evaluation is that the Network/Member needs improvement, the IEB will request the Network/Member to prepare an improvement plan.

The improvement plan can be developed using the [improvement plan template](#) and will be sent to the IEB within two months of receiving the draft evaluation report.

The IEB will review the improvement plan and include the assessment of the improvement plan in the final evaluation report.

### **6.2.3 Issuance of final evaluation reports**

The IEB reviews the comments received and, if needed, justifies the amendment of the evaluation report for the Network or the Member.

The IEB sends the final evaluation report of each Network to the Commission, the Board of the Network, and the Members of the Network.

The IEB sends the final evaluation report of each Member to the Commission and the Member addressed by the report.

If applicable, the improvement plan and its assessment are annexed to the final evaluation report.

## Evaluation process for IEBs

### 7 Preparation for the set-up of the evaluation



#### Evaluation manual and toolbox

The IEB will have to consider several organisational, managerial, and logistic issues during this preparatory stage:

**Training of evaluators:** After selection, evaluators will need to be trained and oriented to their role. The initial training programme could cover topics such as:

- AMEQUIS model
- Interpretation and scoring of the operational criteria
- Evaluation process
- Verification methodologies of the evaluation criteria
- Interviewing and observation skills
- Documentation review
- Behaviour during the evaluation process
- Report writing techniques
- How to proceed if conflicts of interest show up

The consistency of the scoring of the criteria between different evaluators will give them self-confidence and assurance to the organizations evaluated. Therefore, it is recommended that concordance tests be performed to check inter-rater reliability.

#### Organisational issues regarding the evaluation team:

- A specific team should be set up for the whole evaluation process of each ERN, considering the different tasks and steps.
- When distributing the tasks among the different members of the team it should be considered that the same persons must assume the whole evaluation process for those HCP teams that will receive an onsite audit.
- Continuous technical support for the evaluators must be available during the process, for instance, to discuss doubts regarding interpretation of some criteria or measurable elements as well as any finding during the on-site visit.

#### Communication and logistic issues. At least the following will need to be considered:

- An online tool will have to be set up for the submission of documents and information by the Networks and their Members during the evaluation process (see [self-evaluation forms](#)). The development of this tool will have to consider the specific steps of the evaluation process as well as the validating role of the Network Coordinator. A user guide for the tool will also have to be developed.
- Direct communication with the European Commission will be necessary during the project through the officially established channels.

- Access to direct communication channels between the evaluator team and the IEB coordination will be necessary during the whole process, and particularly important while conducting on-site audits.
- To ensure secure access to documentation and on-line information for the evaluators.
- Tools and capacity to organise and support simultaneous videoconferences with different stakeholders.
- Establish early communication channels with ERN coordinators and HCP representatives to setup on-line meetings and on-site visits.
- Organise travel and accommodation arrangements for evaluators during onsite audits.
- To consider the possibility of online audits in case of pandemic or other exceptional situations.
- Administrative support to the evaluation teams.

## 8 Self-evaluation of ERNs and HCPs



### Evaluation manual and toolbox:

- Self-evaluation form and guidelines for ERNs and their Members
- List of documents to be prepared by ERNs and their Members
- Scoring guidelines

Online tool and online tool user guide

### 8.1 Formal announcement of the start of the evaluation



The formal announcement of the beginning of the evaluation process and the deadline for the submission of the documents will be carried out jointly by the EC and the IEB.

An **on-line tool** will be available for Networks and their Members to submit their information.

### 8.2 Self-evaluation of ERNs and their Members



The self-evaluation entails to review each of the criteria and their measurable elements and to justify their level of compliance, providing the corresponding evidence, and scoring them according to the indications contained in the tools **self-evaluation guidelines for ERNs and HCPs** and **scoring guidelines**.

The tool **self-evaluation form** can be used to prepare the self-evaluation in advance and organize the evidence documentation or information to be submitted.

The [list of documents to be prepared by ERNs and their Members](#) also facilitates information regarding the evidence that can be provided.

#### **8.2.1 Submission via the online tool**

All the information included in the self-evaluation template has to be submitted via the [online tool](#) provided by the IEB.

Each Member must incorporate their own self-assessment and it is the responsibility of the Network coordinator to include the self-assessment of their ERN, as well as to ensure that all Members to be evaluated have completed their assessments.

#### **8.2.2 Validation of the self-evaluation results internally by the ERN coordinator**

Before the final submission of the self-evaluations, the ERN coordinator has to validate them formally following the online process set up by the IEB.

With this formal validation, the submission of the self-evaluations is completed.

#### **8.3 Verification and confirmation by the IEB**



The IEB will verify that all the self-evaluations submitted are complete and will request any additional missing information.

## 9 Technical evaluation by the IEB



### Evaluation manual and toolbox:

- Operational criteria for evaluation of ERNs and HCP teams
- Scoring guidelines
- Guidelines to prepare interviews
- Guidelines to prepare on site audits

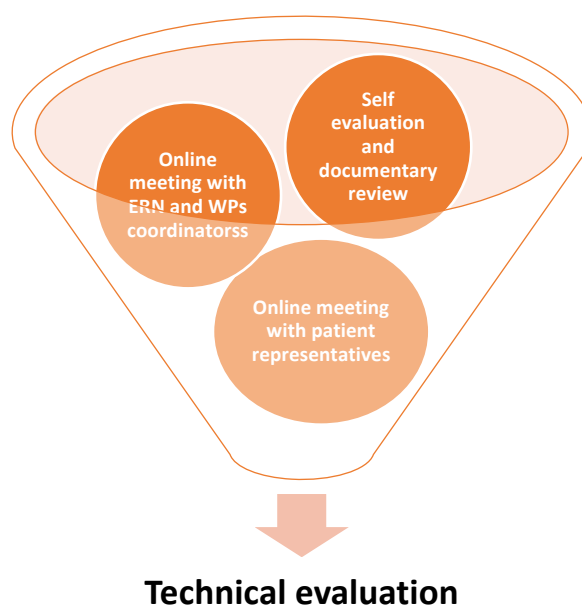
The IEB is appointed by the EC to carry out the external evaluation process. It is important to establish a fluid communication between the IEB and all the Network stakeholders so that the different activities can be properly planned.

The evaluation approach is different at the Network level and at the HCP team level, so the activities that will be carried out during both technical evaluations to obtain the necessary information are described separately.

### 9.1 Network technical evaluation



To evaluate the Network, different sources of information can be used whose integration will contribute to obtaining a more complete picture of the level of accomplishment of the Network's objectives over the past five years. In addition to the information contained in the self-evaluation, the evaluators will review other documentation provided by the EC and a sample of the deliverables generated by the Network. They will also interview the ERN and grants work packages coordinators and patient representatives.



### 9.1.1 Document review:

The following documents generated both in the initial assessment and throughout the five years of activity will be thoroughly reviewed:

**a) Assessment application and final report.** *To be provided by the EC.*

The application contains information about the Network area of expertise and its objectives. When applying to establish an ERN, the Network had to select at least three of the objectives set out in Article 12(2) of Directive 2011/24/EU to be pursued.

The **assessors' comments and recommendations** included in the final assessment report contribute initial hints regarding improvement issues to be implemented from the beginning.

**b) ERN monitoring indicators collected in the last three years.** *To be provided by the EC.*

A basic common **set of 18 indicators**<sup>3</sup> has been defined for the continuous monitoring and improvement of ERNs activity. They have been collected since 2019 and should be reviewed during the evaluation process. The indicators can provide evidence for some measurable elements.

**c) Grants reports.** *To be provided by the EC.*

The EU has been supporting the ERNs implementation using grants and technical assistance under the 3rd EU Health Programme that are managed by the European Health and Digital Executive Agency (HaDEA). The **periodic technical reports** submitted by the ERN coordinator include extensive information regarding the activities carried out to achieve the objectives of the Network and the deliverables produced under the frame of these grants.

The thorough review of these technical reports will provide a good amount of **evidence for the operational criteria** as well as **raise specific questions for the subsequent interviews**.

Specifically, two requirements should be verified:

- i. That the activities carried out by the different work packages in the first 5 years are clearly described.
- ii. That the ERN has evaluated the achievement of the objectives established in the initial strategic plan for the first 5 years.

**d) A sample of the deliverables generated** (i.e., websites, reports, educational materials...).  
*To be selected by the evaluators and provided by the Network.*

The technical reports elaborated in the frame of the grants include an initial planning of tasks and deliverables for the different work-packages as well as the final outcomes describing which ones have eventually been produced. The evaluation team should select and review **a sample of these deliverables** (always including the ERN website) and check if they suit their original purpose.

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<sup>3</sup> [https://ec.europa.eu/health/sites/default/files/ern/docs/continuous\\_monitoring\\_en.pdf](https://ec.europa.eu/health/sites/default/files/ern/docs/continuous_monitoring_en.pdf)

The IEB should verify if expected deliverables have been produced in a timely manner. For that purpose, the following must be assessed:

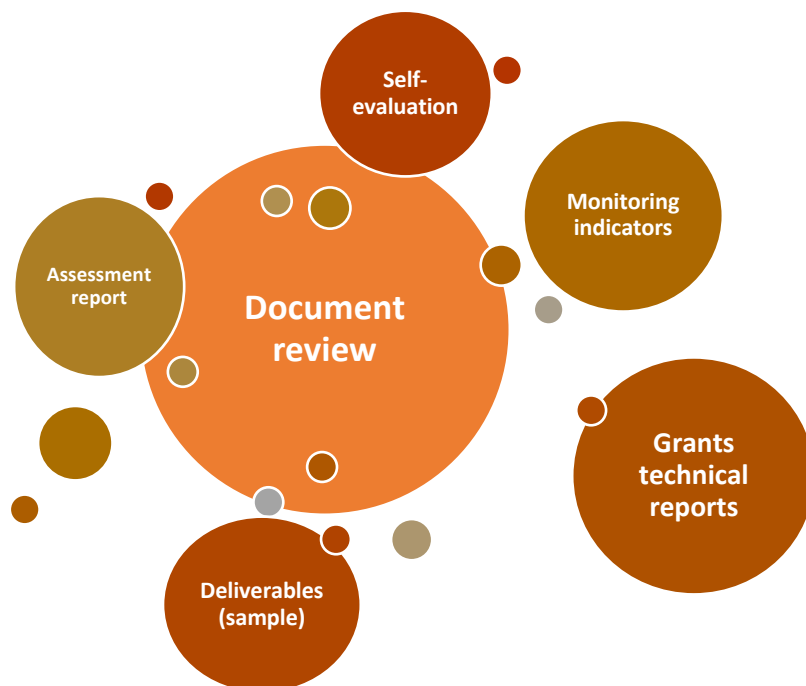
- i. % of deliverables produced from the initially planned
- ii. That the deliverables produced suit their original purposes: the web must be reviewed as well as a sample of at least 8 other deliverables from different work packages. Some of them may have been included as evidence for the MEs.

**e) Information included in the self-evaluation of the Network.** *Submitted by the Network.*

The self-evaluation submitted by the Network coordinator will include information and **evidence related to the different operational criteria** and the accomplishment of the objectives initially selected by the Network.

This documentary review will serve to provide evidence on the fulfilment of the operational criteria and the objectives established by the Network for the five years. During the review of the documentation, the IEB evaluators will also determine what information they need to complete or contrast later through interviews and online meetings.

The document review will allow for the initial scoring of the measurable criteria using the directions included in the [scoring guidelines](#).



**9.1.2 Virtual interview with ERN and work-packages coordinators:**

Over the last 5 years, each Network has worked on achieving its objectives, among other things, by developing a series of EC-funded projects. The planning and execution of these projects has been carried out by distributing tasks among different work-packages.

The evaluation team shall plan to conduct one or more interviews with the Network coordinator and with the coordinators of the different work packages in order to obtain additional

information, for example, on the governance of the network, the organization and distribution of tasks, the results obtained, the difficulties in the operation of the network, etc.

The interviews will be prepared directly by the evaluation team according to their information needs, but the [guidelines to prepare interviews](#) may serve as support.

### 9.1.3 Virtual interview with patient representatives

The objective of this interview is to contrast with the patient representatives their level of participation in the different actions of the Network, including the field of governance and strategic planning.

The ERN coordinator should facilitate communication between the IEB and patient representatives for interview planning.

## 9.2 HCP team technical evaluation



The IEB evaluators will review the information and evidence provided through the self-evaluation on the contribution of each Member to the mission of the Network and on the adjustment of their care processes to the required quality levels. The methodology for the HCP team evaluation focuses on the information obtained during the document review and the supplementary information collected during the onsite audit.

### 9.2.1 Document review:

The following documents will be thoroughly reviewed:

**a) Initial assessment application.** *To be provided by the EC.*

The application contains information on the area of expertise of the HCP team, patients served, or highly specialized procedures performed during the previous years, and composition and qualifications of the multidisciplinary team. The evaluation process must assess that the HCP team maintains the necessary levels of activity and experience.

**b) Monitoring indicators provided by the Member to the ERN in the last 3 years.** *To be provided by the Member/ERN as available*

The indicators provided will supply evidence for some measurable elements and also for the contribution of the HCP team to the ERN activities.

**c) Information and evidence included in the self-evaluation of the HCP team.** *Submitted by the Member.*

The self-evaluation submitted by the HCP team will include information and evidence related to the different operational criteria regarding the HCP team contribution to the fulfilment of the objectives of the ERN.

The document review will allow for the scoring of the measurable criteria using the directions included in the [scoring guidelines](#).

### 9.2.2 On site audit:

The evaluators will visit the HCP team to perform an onsite audit in order to collect supplementary evidence needed to assess the accomplishment of some measurable elements.

The [guidelines to prepare on site audits](#) can provide some guidance on how to organize and proceed during this visit.

The main activities to be carried out during the onsite visit are the following:

- Direct observation of the facilities and the provision of care.
- Meeting/interview with the multidisciplinary team
- Meeting/interview with a group of patients
- Review of patient clinical records
- Document review



### Document review

- Initial assessment application
- Monitoring indicators
- Self evaluation and evidence included



### On site audit

- Direct observation
- Meetings/interviews
- Clinical records/document review

## 10 Evaluation results



### Evaluation manual and toolbox:

- Network evaluation report template
- HCP evaluation report template
- Improvement plan template
- ERN System evaluation report outline
- Decision guidelines

### 10.1 Draft evaluation reports



The evaluation process finalizes with the preparation of an evaluation report of the Network and each of the HCP teams.

The evaluation is not intended to obtain a "positive or negative" result, but to detect whether the development of the Network during the five years has been satisfactory and if the ERN Members have actively contributed to it while providing highly specialized, quality, and safe care.

The essential elements to assess that the development of the Network and the contribution and performance of its Members have been satisfactory will be the adequate fulfilment of the measurable elements established as "core"<sup>4</sup>. The remainder measurable elements will serve to determine the degree of maturity of the Network as well as the quality of the performance of its Members, indicating those areas in which progress should be made in the following period.

In case the result is not satisfactory, the Implementing Decision 2014/287/EU 14.7 establishes that the Board of Member States may offer the Network/Member in question one year to remedy the shortcomings identified before carrying out a new evaluation. To facilitate this process, the IEB will request the Network/Member in question to elaborate an improvement plan (see [improvement plan guidelines and template](#)) that will be reviewed and assessed by the IEB prior to submitting the final report to the EC.

#### 10.1.1 Draft evaluation report for HCP teams

It includes the summary and a detailed review of the results of the evaluation of the HCP team as well as the conclusions, comments and recommendations provided by the evaluation team (see [HCP evaluation report template](#)):

- Conclusions of the evaluation team
- Overall compliance with the operational criteria
- Results of the HCP in the measurable elements from each area

<sup>4</sup> The measurable elements considered as "core" should have been accomplished or implemented at the time of the evaluation.

- Detailed results of each criterion and areas for improvement
- Outcome of the evaluation (scoring table): indicating the specific score of core MEs and score of those MEs that identify HCP contribution to the mission of the Network
- Result (according to the [decision guidelines](#)): satisfactory or needing improvement.

### 10.1.2 Draft evaluation report for ERNs

It includes the summary and a detailed review of the results of the evaluation of the Network and its Members as well as the conclusions, comments and recommendations provided by the evaluation team (see [evaluation report template for Networks](#)):

- Conclusions of the evaluation team
- Overall compliance with the operational criteria by the ERN and the HCPs
- Results of the Network in the measurement elements from each area
- Detailed results of each criterion and areas for improvement
- Evaluation of the achievement of the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements.
- Summary of the evaluation results of the Members of the Network
- Outcome of the evaluation:
  - Scoring table of operational criteria for the ERN (including specific score of core MEs)
  - Qualitative assessment of the accomplishment of the objectives initially selected by the ERN
  - Result of the evaluation according to the [decision guidelines](#)

## 10.2 Final evaluation reports



### 10.2.1 Submission of comments to the draft evaluation reports

The IEB sends the ***draft evaluation report of each Network*** to the Commission, the Board of the Network, and the Members of the Network.

The IEB sends the ***draft evaluation report of each HCP team*** to the Commission and the Member in question.

The Network Coordinator and the ERN Members may send comments to the IEB ***within two months of receiving the draft evaluation report***.

### 10.2.2 Submission of improvement plans

When the result of the evaluation is that the Network/Member needs improvement, the IEB will request the Network/Member to prepare an improvement plan.

The improvement plan can be developed using the [improvement plan template](#) and will be sent to the IEB within two months of receiving the draft evaluation report.

The IEB will review the improvement plan and include the assessment of the improvement plan in the final evaluation report.

### **10.2.3 Issuance of final evaluation reports**

The IEB reviews the comments received and, if needed, justifies the amendment of the evaluation report for the Network or the Member.

The IEB sends the final evaluation report on each Network to the Commission, the Board of the Network, and the Members of the Network.

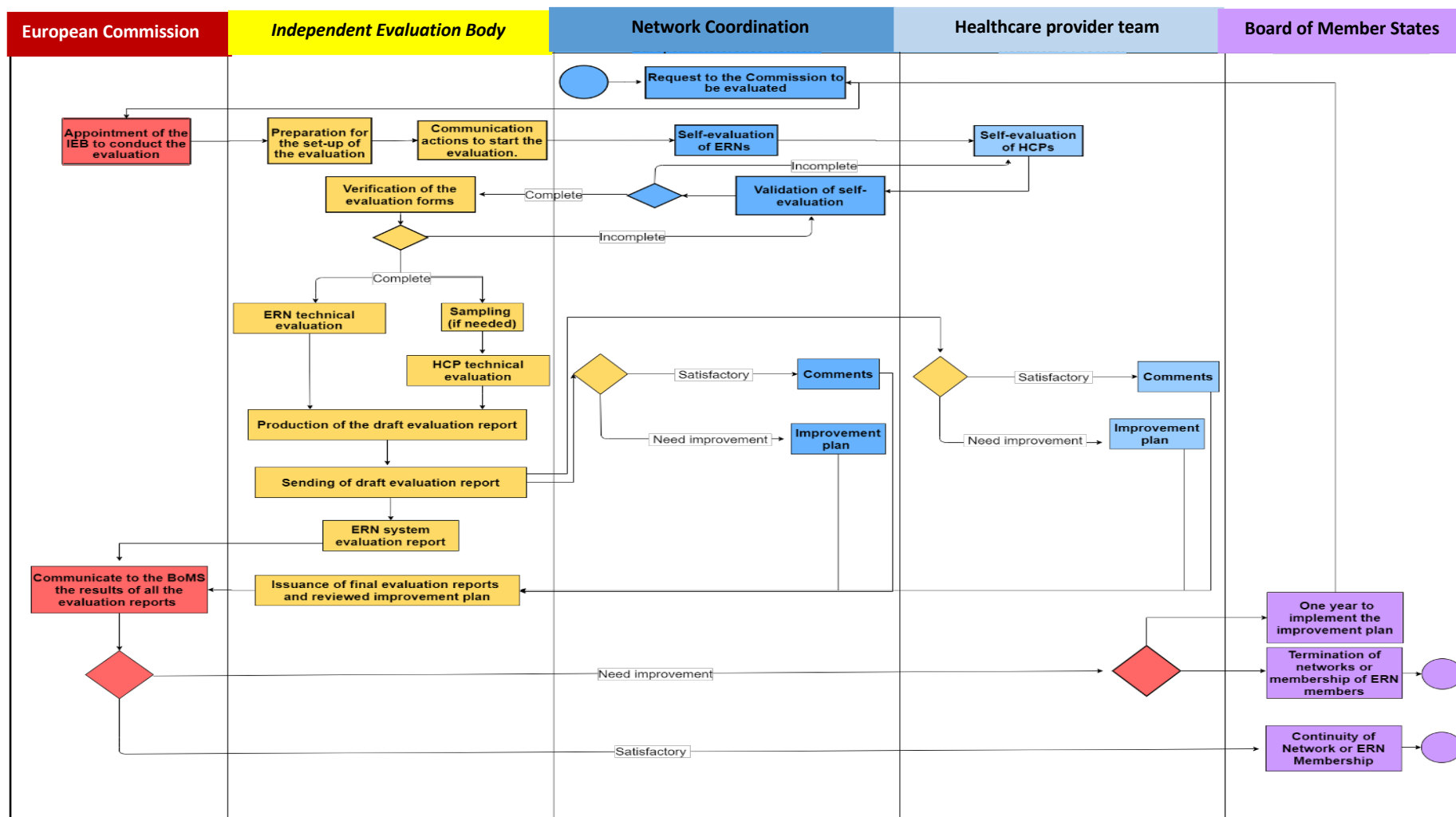
The IEB sends the final evaluation report on each Member to the Commission and the Member in question.

If applicable, the improvement plan and its assessment are annexed to the final evaluation report.

### **10.2.4 ERN system evaluation report**

Based on the results obtained in the evaluation of the Networks, the IEB will prepare for the EC a global evaluation report of the European Reference Networks system using the [ERN system evaluation report outline](#) as a guide.

## 11 Flowchart of the evaluation process



## 12 Annexes

### 12.1 Toolbox for the evaluation

This document is included separately