

Re-evaluation Annex: overview of the re-evaluation process after the Improvement Plan implementation



Contents

1.	Introduction	3
1.1.	Background	3
1.2.	Objectives and scope of the re-evaluation	3
2.	Overview of the re-evaluation process	4
2.1.	General description of the re-evaluation process	4
2.2.	Timeline for the re-evaluation process	5
3.	Preparation for the re-evaluation	5
4.	Self-evaluation.....	5
4.1.	Submission via the OEIT	5
4.2.	Acknowledgement by the ERN Coordinator	6
5.	Technical evaluation by the IEB	6
5.1.	Documentary review.....	6
5.2.	Interviews and audits.....	6
5.2.1.	Online interviews	6
5.2.2.	Half-day audits	6
5.2.3.	Full-day audits	7
6.	Evaluation results.....	7
6.1.	Draft evaluation reports	7
6.2.	Final evaluation reports	7
6.3.	Future of the HCPs in the ERN System.....	7

1. Introduction

1.1. Background

The Implementing Decision 2014/287/EU establishes criteria for evaluating European Reference Networks (ERNs) and Healthcare Providers (HCPs) to determine the significance of their contributions in facilitating the exchange of information and expertise.

As stated in Article 14(7) of Delegated Decision 2014/287/EU, ERNs and HCPs that receive a final "Needs Improvement" result are required to submit an Improvement Plan (IP). The IP must address all CORE Measurable Elements (MEs) that have been scored "1" or "0" as indicated in the Final Evaluation Report by the Independent Evaluation Body (IEB). A template for the IP is provided in Section 16 of the Technical Toolbox to help remedy the identified shortcomings.

The IEB categorizes the submitted IPs based on the quality and consistency of the actions included, according to the criteria detailed in Table 1.

Table 1. Classification of the IPs

Category	Criteria
Risky	Numerous documentary issues and/or critical issues were found.
Acceptable	A clear intention to solve the problems is shown, and future evidence will be easy to provide, but attention is needed for specific requirements such as monitoring data and the use of CPMS.
Suitable	A clear intention to solve the issues is shown, and future evidence will be easy to provide.

As stated in Article 14(7) of Implementing Decision 2014/287/EU, the Board of Member States (BoMS) may offer the Network or the Member in question one year to implement the submitted IP. This decision will determine which ERNs and HCPs will undergo a re-evaluation after one year of implementation of the IP.

This document, serving as an Annex to the Evaluation Manual, outlines the methodology for the re-evaluation process. It is an adaptation of the existing activities within the evaluation process, as detailed in the Evaluation Manual and Technical Toolbox.

1.2. Objectives and scope of the re-evaluation

The general objective of the re-evaluation process is:

- To assess the implementation of the submitted IP, including the proposed actions to take and the results of these actions.
- To evaluate the current compliance of the core MEs that did not achieve an optimal score during the fifth-year evaluation.

The scope of the re-evaluation is the actions implementation one year after the BoMS decision and

2. Overview of the re-evaluation process

2.1. General description of the re-evaluation process

Before the re-evaluation formally begins, the IEB must prepare all organizational, managerial, and logistical arrangements for the evaluation. This includes training the evaluators and adapting the Online Exchange Information Tool (OEIT) for document submission and scoring.

The re-evaluation process can be summarized in the following steps:

Step 1. Self-evaluation

- Provide comments and evidence of the IP implementation, including the suggested evidence in the IP Assessment.
- Score the pending core MEs.
- Provide the required evidence of fulfilment of the pending core MEs, as specified for each ME in the Technical Toolbox.

Step 2. Technical evaluation

The technical evaluation will be divided into 2 different steps:

- **Documentary Review:** Evaluators will review the evidence and comments provided by the HCPs during the self-evaluation stage.
- **Interviews/Audits:** Evaluators will conduct interviews and audits to gain deeper insights into the HCPs' work.

The type of interaction (interview or audit) with HCPs will depend on the category the IP received during the IP assessment:

- **Suitable:** 90-minute online interview
- **Acceptable:** a half-day online / onsite audit
- **Risky:** a full-day onsite audit

Following the sampling methodology described in section 7 of the Technical Toolbox, approximately 20% of the HCPs whose IP was categorized as Acceptable will undergo a half-day onsite audit, while the remaining will undergo a half-day online audit, corresponding to a Partial Evaluation.

Step 3. Elaboration of the re-evaluation reports

The IEB will develop a report with the results of the evaluation. This report will be an updated version of the one produced during the evaluation, with the scores and results updated accordingly as well as the comments and recommendations provided by the evaluation team.

- A. **Draft evaluation report:** The report will be sent to the ERN Coordinator/HCP representative/Commission. A one-month period will be available to submit comments on the report.

- B. **Final re-evaluation report:** the scores will be changed accordingly taking into consideration the submission of comments on the draft reports. The final evaluation reports will be sent to the ERN Coordinator/HCP representative/Commission.

For those that receive a "Needs Improvement" result after the re-evaluation, the BoMS will determine their future within the ERN system.

2.2. Timeline for the re-evaluation process

The re-evaluation process is set to take around 7 months. The deadlines and timeline are subject to change at the discretion of the European Commission and the IEB.

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



Figure 1. Timeline for the re-evaluation process

3. Preparation for the re-evaluation

To properly prepare for the re-evaluation three reference documents are available to consult at the HCPs' and ERNs' convenience:

- **Evaluation Manual:** Outlines the different phases of the evaluation process.
- **Technical Toolbox:** Contains the operational criteria, list of required documents, scoring guidelines, templates, and evaluation guidelines.
- **Re-evaluation Annex:** Details the key aspects of the re-evaluation process.

In addition to these documents, a user guide for the OEIT and a Frequently Asked Questions document are also available.

4. Self-evaluation

4.1. Submission via the OEIT

The information included in the self-evaluation template must be submitted via the OEIT provided by the IEB. This template will be adapted to only show those core MEs that did not obtain the optimal score during the evaluation exercise.

Additionally, evidence and comments must be uploaded to support the implementation of the IP and the scoring of the MEs. This documentation should align with the evaluators' comments and suggested evidence indicated in the IP assessment (annexed to the Final Evaluation Report).

4.2. Acknowledgement by the ERN Coordinator

Before the final submission of the self-evaluation, the ERN coordinator must validate the HCPs' self-evaluations using the online process established by the IEB. It is also recommended that the ERN coordinator includes a comment on the HCP's participation and activity in the ERN's activities.

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

5. Technical evaluation by the IEB

The IEB evaluators will review the information and evidence provided through the self-evaluation to evaluate the implementation of the improvement actions included in their IP and their contribution to the mission of the ERN. Taking into consideration the lessons learnt, the existing methodology has been adapted to fit the purpose of the re-evaluation. This technical evaluation process will comprise 2 steps: document review, and interviews/audits.

5.1. Documentary review

The following documents will be thoroughly reviewed:

- Information and documents included in the self-evaluation about the IP implementation, including the suggested evidence in the IP Assessment
- Information and documents included in the self-evaluation about the HCPs' compliance with the different MEs, including the required evidence described in the Technical Toolbox

5.2. Interviews and audits

5.2.1. [Online interviews](#)

For IPs categorised as **Suitable** during the IP Assessment, the second step of the technical evaluation will consist of a **90-minute online interview**. Evaluators will have an online meeting with the HCP team to tackle different issues:

- Answer questions raised during the documentary review
- Request additional documentation
- Comment the most important discrepancies and / or progress

5.2.2. [Half-day audits](#)

For IPs categorised as **Acceptable** during the IP Assessment, the second step of the technical evaluation will consist of a **half-day online / onsite audit**. A sample of HCPs, determined using the sampling methodology described in section 7 of the Technical Tollbox, will undergo a half-day onsite audit. The remaining HCPs will have a half-day onsite audit.

The activities to be conducted during the audits are the following:

- Open meeting with a representative of the hospital administration
- Interview / meeting with the HCP team
- Review of patient clinical records (anonymisation will be required)
- Interview with collaborating patient representatives
- Direct observation of the healthcare facilities (only for onsite visits)

5.2.3. Full-day audits

For IP categorised as **Risky** during the IP Assessment, the second step of the technical evaluation will consist of a **full-day onsite audit**. The activities to be conducted during the audits are the following:

- Open meeting with the hospital administration
- Interview / meeting with the HCP team
- Review of patient clinical records (anonymisation will be required)
- Interview with collaborating patient representatives
- Direct observation of the healthcare facilities (only for onsite visits)

6. Evaluation results

The re-evaluation process will conclude with the development of the evaluation reports. These reports aim to determine whether the HCPs' contribution to the network during the five years has been satisfactory and if the HCPs have contributed to the delivery of highly specialised quality, and safe care.

These reports will include the summary of the results of the HCP team, considering the new scores resulting from the re-evaluation and a detailed review of the MEs in the scope of this process. Additionally, the evaluation team will provide conclusions, comments, and recommendations, incorporating relevant information from the evaluation of the IP implementation.

The following sections will be found:

- Introduction
- Evaluation summary
- Conclusions of the evaluation team
- Results overview
- Final Outcome of the Evaluation
- Improvement Plan Implementation

6.1. Draft evaluation reports

The draft evaluation reports will be sent to the HCP representative, ERN Coordinator, and Commission. Following this communication, HCPs will have a one-month period to submit comments on the MEs for which they disagree with the obtained score. It is important to note that during this comment submission period, no additional evidence will be accepted—only written comments.

6.2. Final evaluation reports

The IEB reviews the comments received and, if necessary, justifies any amendments to the evaluation report for the Network or the Member. After the comment submission period and the re-scoring of the MEs, the Final Evaluation Reports will be sent to the HCP representative, ERN Coordinator, and Commission. The final result can be either *Satisfactory* or *Needs Improvement*.

6.3. Future of the HCPs in the ERN System

The European Commission will be responsible of communicating to the BoMS the results of all re-evaluation reports. Based on these results, the BoMS will decide their future within the ERN system.