

ERNs & HCPs Re-evaluation FAQ

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Acronyms

Andalusian Agency for Healthcare Quality (ACSA)

Board of Member States (BoMS)

European Foundation for Quality Management (EFQM)

European Reference Networks (ERNs)

European Union (EU)

Healthcare Provider Centres (HCPs)

IDOM Consulting, Engineering, Architecture (IDOM)

Improvement Plan (IP)

Independent Evaluation Body (IEB)

Measurable Elements (ME)

Network Coordinators (NC)

Not Applicable (NA)

Online Exchange Information Tool (OEIT)

Project Managers (PM)

General Process of the Evaluation

1. Key dates of the re-evaluation process.

The general schedule involving the re-evaluation process involves the following stages:

1. Preparatory steps, which started on 7th November 2024
2. Self-evaluation of the HCPs, which starts on 2nd December 2024 and finishes on 12th January 2024. The NC will have an additional week (19th January) for the acknowledgement of the HCPs' self-evaluation.
3. Technical evaluation will start after the self-evaluation. This stage includes performing audits and interviews and will be conducted, after the revision of documentation by the evaluators, between February 3rd, 2025, and March 2nd, 2025.
4. Re-evaluation results, from mid-March to the end of May 2025.

These key tasks and dates were presented in the Webinar (27th November 2024). However, the deadlines and timeline are subject to change at the discretion of the European Commission and the Independent Evaluation Body (IEB).

2. Composition of the IEB and profile of the auditors.

The Consortium consisting of IDOM Consulting, Engineering, Architecture (IDOM) and the Andalusian Agency for Healthcare Quality (ACSA) has been appointed by the European Union (EU) Commission as the IEB to perform the technical evaluation of the ERN and their Members. The pool of experts that will perform the evaluation consists of professionals with:

- Over 10 years of professional experience
- Experience in quality or healthcare management

Apart from this, the chosen evaluators have a proven track-record of working within the ERN System.

3. Where can we find Manuals and other forms?

Both, the Evaluation Manual, and the Technical Toolbox were published in February 2022. Apart from this, an annex with the methodology to follow during this re-evaluation has been included. This is an Evaluation Manual Annex that you'll receive along with the OEIT guide.

Additionally to being sent after the webinar, they've been uploaded to the OEIT (<https://www.ern-assessment.com/>), and, if requested, may be sent by the helpdesk.

4. To which period does this re-evaluation exactly apply? Will all actions up to the start of the re-evaluation be considered?

Evidence collected should be comprised in a 12-month period after the BoMS decision made on the 15th of December 2024.

Communication

5. Which is the contact point for queries during the re-evaluation process?

An Evaluation Coordinator will be allocated to each HCP. These Evaluation Coordinators can be contacted through two different channels:

- For any internal communication or information related to the evaluation methodology, the communication area of the OEIT may be used
- For any technical problems, suggestions, or logistical issues, via email or telephone: helpdesk@ern-evaluation.eu, phone number: +34 946 89 73 45

6. How can we contact the evaluators?

For any internal communication with the evaluators, the communication area of the OEIT may be used. HCPs will be able to contact evaluators once the technical evaluation stage starts.

7. In terms of language, would it be possible that evaluators are provided in the mother language of the country?

Efforts have been made to allocate projects taking into consideration language barriers. Nevertheless, this is not always possible.

8. Are the evaluators physicians or surgeons who are familiar with pathologies and hospital processes?

Evaluators have been accurately chosen and they are mostly clinicians and/or people trained in healthcare auditing and have an insight into the ERN System.

9. How is it possible to update contact information and the platform access?

For this, you can contact us through this email: helpdesk@ern-evaluation.eu

Self-evaluation

10. What's the goal of this re-evaluation process?

The aim is to re-evaluate those HCPs that submitted an IP after the first round of evaluation and assess their compliance to the ERN networks.

11. Concerning the re-evaluation, do we have to answer only in the process the areas where improvement has to be done?

Yes, only the measurable elements that did not obtain an optimal score in the first round of evaluation will be evaluated.

12. Are there any actions crucial to passing the evaluation?

For the implementation of the improvement plan, it is crucial for HCPs to upload the evidence that was suggested during the IP assessment alongside a comment with the actions taken by the HCP and

the results of these actions. For the scoring of the MEs, HCPs should upload the required evidence as stated in the Technical Toolbox alongside a comment.

13. What kind of evidence should be included in the self-evaluation?

HCPs need to add any document that support the explanation related to the fulfilment of the improvement plan (IP) and their compliance with the MEs.

This evidence can adopt different formats:

- Documents that describe how the HCP carries out different processes, activities, etc.
- List of indicators, guidelines, and protocols, list of patient associations, etc. In both cases, the document or the link that allows the evaluator to access the document should be attached.

14. What language should the evidence and self-evaluation form be written in?

The self-evaluation must be filled in English. All the documents provided by the HCPs as evidence should be in English or in the original language with a summary in English in which all of the contents of the document are explained.

Self-evaluation and IP for HCPs

15. The HCP is the whole institute, however, there are different ERNS within an institute. Who is doing what?

By HCP, what's meant is the hospital clinical unit that is enrolled in a specific ERN. The HCPs need to do the self-evaluation and the ERN coordinator will do the acknowledgement.

16. What's been the criteria that determined the samples of HCPs that will undergo a half-day onsite audit?

A half-day onsite audit will be conducted for a sample of the total of IPs classified as *Acceptable*. The criteria considered to calculate and select the HCPs to be visited are the following:

- The sample size will represent at least 20% of the total population (IPs classified as *Acceptable*).
- The selection of the sample will be based on the type of MEs that each HCP has in the re-evaluation. The selection of these HCPs will prioritise those HCPs that have to re-evaluate the most MEs related to an onsite audit.

Interviews/Audits

17. When will the meetings be? The scheduling with patient visits is difficult

The time of the interviews/audits will be agreed on between the HCP and the evaluation team.

18. What is it meant by “hospital administration”? This is normally not a department involved in the ERNs at all and might not even know what an ERN is.

It is believed that having a short interview with the hospital administration will be helpful to get a sense into hospital's activity as a whole. Apart from this, some MEs ask for information about the hospital, so this interview is beneficial.

19. Can you please provide an overview of the HCPs that require an online and/or onsite visit? Also, can this be shared with the coordination team and with the HCP members that are selected for this online/onsite audit?

The information of which HCPs will have an interview, a half-day audit, and full-day audit was sent on the week of the 18th November 2024 through the OEIT to ERNs. HCPs were also informed about the type of re-evaluation process they will undergo. The HCPs that will have a half-day onsite audit will be announced shortly after the webinar.

20. Could you please specify from what group of patients do you need the medical records?

The medical records should be of those with a disease within the scope of the HCP's activities.