



BOARD OF MEMBER STATES ON ERNS

26 JANUARY 2022, 9:00-12:00

VIDEO-CONFERENCING VIA WEBEX

DRAFT MINUTES

CO-CHAIRS: EUROPEAN COMMISSION AND AUSTRIA		
9.00-9.10 Dial-in		
1	9.10 – 9.15	Opening of the meeting <ul style="list-style-type: none">- <i>Welcome</i>
2	9.15 – 10.00	Introduction of the Evaluation Criteria for the evaluation of ERNs <ul style="list-style-type: none">- <i>Presentation of the Operational Criteria by Nivel + FAD (10min)</i>- <i>Q&A</i>
3	10.00 – 11.30	Discussion & agreement of the Operational Criteria for the evaluation of ERNs
4	11.30 – 11.40	Info points <ul style="list-style-type: none">- <i>EU4H ERN Grants</i>- <i>Joint Action on integration into national systems - EU4H 2022</i>- <i>Conference on rare diseases under the French presidency</i>
5	11.40 – 12.00	Brainstorming on future implications of the evaluation
12.00 End of the meeting		

1. Opening of the meeting

The Commission welcomed the participants and the Member States' Co-chair explained that the main aim of the meeting was the discussion and agreement of the Operational criteria for the evaluation of ERNs.

The Commission explained that the Implementing Decision on ERNs requires the evaluation of ERNs and their members (HCPs) at least every 5 years and briefly explained the objectives of the evaluation. The Commission explained that the evaluation may result in a positive outcome or the need for improvement. In case the outcome of the evaluation of an ERN or HCP is negative, the network or HCP will have to present a plan to remediate the situation and will be re-evaluated after one year. BoMS will

have the last word on the future of the HCP or ERN. In the extreme event that the shortcomings had not been addressed after one year, the ERN may be terminated or the concerned HCP may lose membership.

The Commission explained that the Independent Evaluation Body that will carry out the evaluation will be appointed through a Framework Contract. An open call for the framework contract will be launched in the next weeks.

Member States asked if an HCP that would lose membership could become an Affiliated Partner or would need to abandon the ERN system completely. The Commission confirmed that becoming an Affiliated Partner (AP) could be an option if that HCP would fulfil the requirements to be Affiliated Partner. This option could also be considered for consortiums in which one of the members would lose membership. There was a question asking if APs and National Hubs (NH) would be evaluated. The Member States' Co-chair explained that only full members will be evaluated and although AP and NH could be taken into consideration as part of the evaluation of the networks (ERNs), they will not be evaluated individually. The Commission also confirmed that the new members that had joined the ERNs in 2022 will not be evaluated individually in this exercise but in the next round of evaluation, in 2027.

NL asked if HCPs would be evaluated per sub-theme of expertise given that they can be excellent in one sub-theme and not so active in another. The AMEQUIS contractor explained that HCPs would be evaluated for compliance with the minimum requirements for the themes and sub-themes using their corresponding set of measurement elements.

2. Introduction of the Evaluation Criteria for the evaluation of ERNs

The contractor of AMEQUIS presented briefly the overall AMEQUIS project and more in detail the part of the project concerning the periodic evaluation.

The Commission and the consortium explained that all key stakeholders had had the opportunity to comment on all documents of the AMEQUIS project during the extensive stakeholder consultation and during a number of dedicated meetings with stakeholders. Especially the ERN coordinators and ERN members were closely involved and consulted and one of the ERNs helped to run a pilot project in order to fine tune details of the evaluation such as guidelines. In addition, the ERN Coordinators had sent a joint letter to AMEQUIS and their suggestions were taken into account.

With regard to the periodic evaluation of ERNs and their members, the main objective of the evaluation is to verify to which extent the ERNs and their members fulfil the requirements and objectives for which they were created. The evaluation will be based on "areas", and for each area there will be a set of criteria being evaluated. Each criterion will have measurable elements, which are divided in "core elements" and "other elements". The evaluation will be based only on the "core elements", which will be scored from 0-2. To receive a positive evaluation assessment, HCPs and ERNs will have to reach a minimum total score and a minimum number of highly scored elements. The overall evaluation will result into "satisfactory" or "needs improvement" conclusion of the evaluation.

The consortium clarified that the evaluation of the "other elements" will not be used to score the overall evaluation but will be included in the report so that it could be used for quality improvement. In future evaluations, it is expected that some of the "other elements" may become "core elements".

LT asked if there was any estimation on the number of HCPs that may result in "needs improvement". The consortium explained that this will depend on the outcome of the evaluation by the independent evaluation body. This said, in general it can be estimated that only a few HCPs would be found non-compliant in view of the preliminary information currently available e.g. from the monitoring exercise.

PL explained that there seems to be a different understanding in the specific criteria for self-assessment between the ERNs and HCPs evaluated in the call in 2019 and 2016, as the answers were significantly different between them. The consortium explained that AMEQUIS includes further documentation containing guidance and examples of what will be measured, which should assure an equal understanding by all members in the future exercises.

CZ commented that some of the criteria were not really specific for rare diseases and that they might be already evaluated by the national authorities as part of other processes. CZ further suggested that, it may be useful to start a discussion among the Member States on a general common quality system for health care, which would go beyond the rare diseases.

3. Discussion & agreement of the Operational Criteria for the evaluation of ERNs and their members

The document with the Operational criteria was circulated to the BoMS before the meeting and submitted for approval. After the initial discussion, each criterion was discussed in detail and the text of some of them was adjusted for better understanding. The most important agreed changes regarding criteria were the following:

- Turn criterion 1.2.2 for ERNs (“There is an internal assessment of HCPs' participation”) into core element;
- Delete criterion 7.2.1 for ERNs (“the ERN provides accessible information highlighting sites for cross border expert advice and patients’ referral”);
- Turn criterion 1.6.3 for HCPs (“The information necessary for the follow-up of the patient after the treatment is provided”) into core element;
- Turn criterion 1.6.6 for HCPs (“Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure”) into core element.

There was also an agreement on the need to use consistent terminology throughout the document.

The document was agreed by the BoMS in principle, subject to the above points being taken into account. It was agreed that final revised version of the Operational criteria document taking the above points into account will be sent after the meeting by the secretariat to the BoMS for written approval.

Meeting participants:

Members: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Slovakia, Spain, Sweden.

European Commission: DG SANTE

External companies: FAD, Nivel