Technical Toolbox: overview of Annexes for the Evaluation process

Overview of Annexes

1. Operational Criteria for Networks

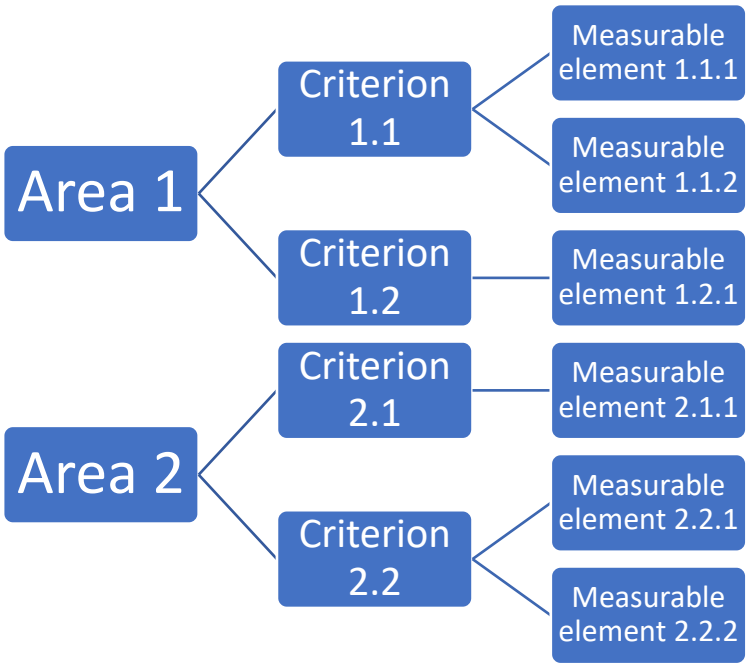
INTRODUCTION

The evaluation of the European Reference Networks (ERNs) is based on verifying to which extent the ERNs and their Members (Healthcare Providers, HCPs) meet those quality requirements relevant 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 classified in several dimensions or thematic areas related to the different goals and objectives included in the evaluation:



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

Two sets of criteria have been elaborated, one for the evaluation of the Networks and the other for the evaluation of the HCP teams. Each criterion has been made “operational” through one or several MEs. Therefore, an operational criterion includes the criterion and the MEs.

This document presents the operational criteria for the Networks and specific guidance to score the level of performance or achievement of the practices described in them.

OVERVIEW

A total of 20 operational criteria with 52 measurable elements classified in 7 areas have been developed:

EVALUATION CRITERIA FOR NETWORKS			
AREA	**Number of criteria**	**Total number of ME**	**Total number of core ME**
1. Governance and coordination	4	15	10
2. Clinical care	3	9	5
3. Quality and patient safety	2	3	0
4. Patient centred care	3	6	3
5. Contribution to research	3	7	4
6. Education and training	2	6	4
7. Networking and dissemination	3	6	4
TOTAL	**20**	**52**	**30**

As mentioned before, 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 (“extended” ME) refer to important areas in which the Networks should work and whose level of development can serve as an indicator of their maturity status.

As shown in the table above, each criterion may include core and extended ME.

Each Operational Criterion is presented in the Manual with the following structure:

- Thematic area to which the criterion belongs
- Guidelines: intention and rationale for the criterion
- Measurable elements that compose it and **suggested** evidence that the Network can provide in each case and that will serve the evaluator to score the ME

Symbols included in the description of the operational criteria

Core measurable element

Scoring

The degree of compliance with each ME is scored using a 3-point scale (0, 1 and 2). To minimize the variability between the evaluators, a tool is provided for the assignment of each of the categories.

Rating	Guidelines
0: No activity / Not developed	***All Criteria:*** **this rating is used if the answer is "scarcely" or "none" to the specific measure and/or when there are no actions in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented by any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. When there are multiple requirements in one measure, less than 50% are present.
1: Partially developed	***All Criteria:*** **this rating is used if the answer is "incomplete" or "partway" to the specific measure and/or when there are some actions 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 does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully developed	***All Criteria:*** **this rating is used if the answer is "totally" or "completely" to the specific measure and/or when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance covers the whole period of time in which the requirement is applicable • All actions required have been implemented or are underway • When there are multiple requirements in one measure, all are present.

1. GOVERNANCE AND COORDINATION

1.1. The ERN has established a clearly defined governance framework that ensures appropriate ERN coordination and oversight.

Guidelines

It is essential for the governance of the ERN, that it has a frame of reference to carry out the basic tasks of coordination and supervision. Within this framework, the objectives, activities and relationships between HCPs and ERN etc., are determined.

For this, the Network must have developed a framework that ensures effective coordination between its Members and the necessary infrastructure to carry it out. Efficiency increases when the Network distributes tasks among all its Members, thereby creating a high degree of involvement in the development of the project.

Measurable Elements

1.1.1. The structure and the implementation of the rules of procedure of the ERN's coordination board have facilitated the organization of tasks and the incorporation of new Members.	
Evidence	a) Structure: Describe the governance of the ERN (i.e., attach a figure, roles of governing bodies) b) Reflect whether the current governance is appropriate for the ERN or needs to be updated c) Rules of procedure (may have different names: terms of reference, Network agreement…)

1.1.2. An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality improvement, evaluation, meetings, and other activities.	
Evidence	Describe current structure and resources (management, logistical support, IT infrastructure…) available to support the ERN coordination and governance.

1.1.3. Mechanisms to maintain or enhance the level of collaboration between the ERN members as well as its affiliates have been put into practice.	
Evidence	Describe the collaboration mechanisms or strategies that have been used: i.e., workshops, meetings, calls, surveys…

1.1.4. HCPs have been involved in specific ERN-related tasks, sharing responsibilities among all the Members of the ERN.	
Evidence	Mention which HCPs have been involved in the different tasks carried out by the ERN distributed in the work-packages or working groups: include a table with this information (involvement in tasks and leading roles).

1.2. The ERN has developed regular evaluation and monitoring processes enabling the assessment of the ERN's progress.

Guidelines

The culture of evaluation is one of the pillars for continuous improvement across all areas of an organization, including healthcare and research, and in the case of ERNs it is essential for the development of collaborative processes between groups of experts.

The evaluation can provide objective data on the progress of the project, and at the same time collect information from the Network to facilitate the promotion of benchmarking among its Members and standardize the level of development, for each Member, across the different areas of study and interest for patients and their families.

Regular evaluation and monitoring processes require identifying and disseminating the evaluation criteria. Specific to the monitoring process of the ERNs, the criteria have focused on the specific indicators of the monitoring system, and also include elements added by the Network to collect information necessary for the management of the group.

Measurable Elements

1.2.1. An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the ERN and its Members.	
Evidence	Include the dashboard[1] and the data collected since the establishment of the ERN. At least the 18 monitoring indicators from the last 3 years; the percentage of HCPs that have participated in monitoring exercise in the last 3 years

1.2.2. There is an internal assessment of HCPs' participation.	
Evidence	a) Briefly describe the assessment process (for example, indicators of their actual participation in the activities of the Network; termination process…). b) Attach the outcomes

[1] Dashboard here refers to how the progress of the Network is monitored, for instance tracking the collection of indicators and the performance of tasks.

1.2.3. HCP professionals' satisfaction with the performance of the ERN is periodically evaluated.	
Evidence	a) Briefly describe the assessment process (survey or any other method). b) Attach the outcomes.

1.3. The ERN has established mechanisms for the integration of patient organizations in the strategic actions.

Guidelines

It is essential to identify the different patient organizations related in one way or another to the areas of interest of the ERN, and to establish contact with as many as possible as long as they have a recognized level of representation.

The level of participation and the degree of collaboration of these patient organizations should be evaluated periodically to understand the nature of the collaboration and the need, if any, to introduce changes in the collaboration mechanisms.

Measurable Elements

1.3.1. Patient representatives have been included in the governance framework of the ERN.	
Evidence	Describe the specific role of patient representatives in the current governance of the Network (where and how they are involved).

1.3.2. The Board has incorporated the opinion of patients and families when outlining strategies.	
Evidence	Explain in which issues the patients and families' input has been requested and which opinions were incorporated.

1.3.3. Patients and support groups are major stakeholders in ERN-related activities.	
Evidence	a) Is this participation formal and continuous? Provide some examples. b) Acknowledgement of patients' coauthorship in ERN deliverables

1.3.4. The ERN monitors and evaluates the involvement of patients in the activities of the ERN.	
Evidence	Specific methodology to collect information regarding the participation of patient representatives in the ERN activities (i.e., satisfaction surveys; specific monitoring indicators). Attach the outcomes.

1.4. The ERN has implemented actions to ensure its sustainability.

Guidelines

The ERN and its Members must work to ensure the Network's permanence, both from an economic point of view and for sustaining the interest among patients and Member States (e.g., via continuous research updates and the promotion of accessibility across all patients, in particular cross border patients).

There are various methodologies that facilitate the identification of future opportunities and threats, and the Network can use any methodology that it considers useful and accessible. One such methodology is a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis. This analysis would allow the identification of opportunities to put into practice, during the next five years, the financial plan developed. It is recommended to share the analysis and the proposals with the Members of the Network and also with the national authorities and health systems.

Measurable Elements

1.4.1. The ERN has identified goals, opportunities, and threats for the future.	
Evidence	SWOT analysis or any other evidence.

1.4.2. The ERN has evaluated its own organisational and economic viability.	
Evidence	SWOT analysis or any other formal evaluation performed in order to obtain well-founded conclusions.

1.4.3. The ERN has developed a financial plan to meet its objectives including funding efforts and a justified distribution of resources across members.	
Evidence	Include the financial plan.

1.4.4. The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for its long-term sustainability.	
Evidence	Describe the formal connections attained.

2. CLINICAL CARE

2.1. The ERN has developed a strong clinical care management strategy: Clinical guidelines, care pathways and best practices for clinical care and transitions.

Guidelines

The scientific evidence provided by the Clinical Guidelines must be disseminated to all Members of the Network and other relevant stakeholders and regularly updated, so that best practices are standardized across all EU countries. To this end, the management of the Network must design the most appropriate mechanisms in each case to facilitate the participation of all its Members in the search and update of the evidence, and provide training for its implementation, considering the peculiarities and different levels of development of the participating countries. The result of this effort must be the identification of clinical guidelines and best practices so that every HCP can adapt them to their specific context, and protocols and pathways are generated for the continuous improvement of care for patients with rare diseases.

It is the task of the Network to monitor the implementation of the guidelines by the HCPs, and when necessary, to provide additional information and support the implementation process.

Measurable Elements

2.1.1. The ERN has developed or adapted (from other sources) and disseminated clinical guidelines and other types of clinical decision-making tools in collaboration with the HCPs.	
Evidence	List of clinical guidelines disseminated. Monitoring indicators 6.1 and 6.2 (Version 7.5))

2.1.2. The ERN has implemented guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.	
Evidence	List of guidelines/protocols/best practices implemented to support transition and continuity of care from childhood to adulthood.

2.1.3. The ERN has developed recommendations for care pathways[2] based on the needs of patients, clinical evidence, and on the available organizational, professional, and technological resources.

[2] A care pathway is a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period. The aim of a care pathway is to enhance the quality of

Evidence	List of the clinical pathways developed and present a specific example.

2.1.4. The ERN has worked on recommendations for cross-border care pathways to ensure equality in the access to care within its area of expertise, according to the legislation applicable.	
Evidence	Examples of recommendations for care pathways including cross-border elements Examples of additional evidence (taking into account that support from Member States may be needed to fully develop this ME): mapping exercise of the procedures that are in place in the different HCPs; any initiative carried out in order to develop this issue

2.1.5. The ERN follows up the implementation of care pathways to encourage consistent use across its Members.	
Evidence	Results of the follow-up.

2.1.6. Guidelines, care pathways, and protocols are rechecked and updated if needed at least every three years.	
Evidence	Periodicity of the guidelines, pathways, and protocols recheck and update: mention the date of the last recheck and update for each one.

care across the continuum by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources.

Defining characteristics of care pathways include:

1. An explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics;
2. the facilitation of the communication among the team members and with patients and families;
3. the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives;
4. the documentation, monitoring, and evaluation of variances and outcomes; and
5. the identification of the appropriate resources.

(Source: European Pathway Association. https://e-p-a.org/care-pathways/)

2.2. The ERN has implemented a multidisciplinary approach to care.

Guidelines

The potential of the Networks resides in collaboration. Among the most beneficial aspects of collaboration is having access to advice from disciplines that may not be well represented across all HCP teams. Therefore, the Network should design an effective process to advise especially complex cases, in which multiple disciplines can be consulted or share other points of view.

Measurable Elements

2.2.1. The ERN has implemented a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.	
Evidence	Self-reflection regarding the performance of the current system/process Monitoring indicators 3.1 and 3.2 (Version 7.5)

2.3. The ERN has established mechanisms for the integration of eHealth and Information Communication Technology (ICT) clinical tools.

Guidelines

The incorporation of new technologies can help improve communication, accessibility, and efficiency in the work of HCP members. Therefore, the Network should support and promote the use of technologies such as telemedicine, e-Health records, remote consultation, health information portals, electronic transfer of prescriptions, and multidisciplinary eMeetings.

Measurable Elements

2.3.1. The ERN promotes the use of technologies such as telemedicine, e-Health records, remote consultation, health information portals, electronic transfer of prescriptions, and multidisciplinary e-Meetings designed according to the needs and requirements of patients and families.	
Evidence	Explain the activities carried out to promote it.

2.3.2. The ERN has implemented the CPMS to share clinical data, images, and additional information. If the ERN uses any other system, this should be compatible in all its centres and must meet national and European legal requirements.	
Evidence	Mention if the ERN uses CPMS or other systems. Include results of tools used/consultations performed; links to national hubs or national centres… Monitoring indicator 2.2 (Version 7.5).

3. QUALITY AND PATIENT SAFETY

3.1. The ERN has defined a quality and patient safety strategy.

Guidelines

Quality and safety are deeply embedded in the daily work of all healthcare professionals. The Network develops guidelines for the improvement of the quality and safety of the patients' care to be adopted by all HCPs. In this way, all Members are aligned in the main goals for improvement.

Measurable Elements

3.1.1. The strategy includes specific objectives and recommended activities for their achievement.	
Evidence	Include the strategy or any document including objectives for improvement and the recommended activities to be performed. The strategy should be linked with the actions that emerged from the results of the assessment, monitoring system, evaluation, and the deliverables of the working groups for the grants.

3.2. The ERN has implemented quality and patient safety indicators to monitor clinical performance and outcomes of care.

Guidelines

The Network can suggest indicators to measure quality and safety to monitor clinical processes, performance and outcomes of care that must be reported with the periodicity established by the Network. With the same periodicity, an analysis of the results must be carried out to identify areas of improvement.

Measurable Elements

3.2.1. The ERN has selected a pool of measures (indicators) to monitor clinical processes, performance or outcomes of care.	
Evidence	Set of selected indicators.

3.2.2. The indicators are periodically reported, and the information is used for collective reflection on outcomes to learn and improve.	
Evidence	Include the analysis performed on the indicators reported during the last complete year.

4. PATIENT CENTRED CARE

4.1. The ERN has implemented mechanisms to empower patients through patient education and engagement.

Guidelines

Patient participation in the governance of the Network is promoted. One of the aspects that contributes to empowering patients is providing them with the information that allows them to participate in the decisions that affect them, and the training actions for patients so that they become knowledgeable about their disease and have the capacity for self-management.

In this sense, the role of the Network is relevant in identifying the processes that should be the object of training activities related to lifestyle, diet, use of devices, administration of drugs, etc. that empower the patient. The training processes must be designed taking into account the possible cognitive barriers and accompanied by didactic material using traditional resources and incorporating new technologies. Co-creation with patient representatives is an essential issue to be considered.

Measurable Elements

4.1.1. Educational resources for patients addressing disease management, coping skills and other practical skills, have been developed and disseminated.	
Evidence	Attach all the educational resources developed and explain how they have been disseminated. Mention which of them have been co-designed with patients. Specific indicator on patient education, if collected. The scope of education can include the different resources aimed at patients and patient representatives related to the different activities performed by the Network (navigation of the system, patient pathways, general knowledge about the disease…).

4.1.2. The ERN produces tailored information on patient safety standards and safety measures for patients and families to reduce or prevent errors.	
Evidence	Attach the specific information developed (flyers, online information, etc.).

4.2. The ERN has developed strategies for patient involvement.

Guidelines

Given that patient participation causes improved health outcomes, enhanced quality of life, and delivery of more appropriate and cost-effective services, if patients are regarded as equal partners in healthcare, they would actively participate in their own health care process, and more carefully monitor their own care.

Patients are therefore one of the best sources of information to identify which may be the best strategies to achieve greater involvement in their care and treatment.

Network partnership with patient representatives and organizations in the production of documents and actions related to their care will improve access to information, treatment, care, and support for people living with rare diseases.

Measurable Elements

4.2.1. The ERN collaborates with patient organisations to develop and implement care pathways, guidelines, protocols, and indicators.	
Evidence	List of actively involved patient organisations and activities developed with them (i.e., development of clinical guidelines, development, and implementation of clinical indicators…) Acknowledgment of co-authorship in guidelines or other documents produced. Related measurements included in the e-PAG Impact Assessment Framework, if used.

4.2.2. The ERN has undertaken initiatives to improve the safety and quality of care in collaboration with patient organizations.	
Evidence	Explain the initiatives carried out to improve safety and quality with the active involvement of patient organizations: i.e., developing the quality and safety strategy; developing the improvement plans at ERN level; developing and piloting the ePAG impact assessment framework; developing PROMs/PREMs… Acknowledgement of patient participation in the activities performed in the network.

4.3. The ERN has implemented actions to measure and learn from patient experience.

Guidelines

The Network should define a common tool to be used by all Members to collect and analyse data and support the benchmarking of information about patient experience.

Different methodologies can be proposed to measure the experience of the patient with their care process, which can be complementary and will depend on the available resources and accessibility to patients. Among them are focus groups, satisfaction surveys, patient social networks and, more importantly, PREMs and PROMs questionnaires.

Whatever the methodology and the periodicity of the measurement, it is necessary to follow the steps of the Plan-Do-Study-Act (PDSA) cycle and analyse the results to identify opportunities for improvement.

Measurable Elements

4.3.1. The ERN has established a standardised common tool or methodology for measuring the patient and family experience.	
Evidence	Describe the tool or any methodology used to collect and improve the patient experience: i.e., PREMs, patient journeys, patient storytelling…

4.3.2. The ERN periodically evaluates the needs and barriers to care experienced by patients and families and uses this information to implement actions to improve care.	
Evidence	Include the information collected last year and how it was used for improvement. The information could be obtained through many ways: workshops, regular calls with e-PAG representatives, surveys, reports…

5. CONTRIBUTION TO RESEARCH

5.1. The ERN has implemented strategic actions to fill research gaps and promote innovation in medical science.

Guidelines

It is part of the Network's mission to identify existing research gaps and propose new lines of research that can be led by the Network.

The process of identifying research gaps and prioritizing lines of research should include patients and other relevant stakeholders who can provide valuable information.

Also, part of the mission of the Network is the establishment of training actions among HCPs that ensure the availability of a future workforce with the knowledge and skills to lead research.

Measurable Elements

5.1.1. Research gaps and opportunities have been identified and a research agenda has been developed.	
Evidence	Include the research agenda for the previous 5 years. Monitoring indicators 5.1 and 5.2. (Version 7.5) and list of publications.

5.1.2. The ERN has actively involved patients and other stakeholders in identifying research gaps and developing the agenda.	
Evidence	Include the strategies/actions used for patient and other stakeholders' involvement in the identification of research gaps and the development of the agenda. Examples: emails asking for patients' feedback, minutes from meetings, participation in the informed consent… Acknowledgement in the authorship of publications.

5.1.3. The ERN maintains ongoing technical oversight and discussions with HCPs to closely monitor and provide feedback on the research throughout the process.

Evidence	Explain the activities performed with HCPs to monitor research initiatives.

5.1.4. The ERN implements actions to provide the future workforce with knowledge and skills to lead research.	
Evidence	Describe the actions that have been carried out to improve capacities for research: i.e., young researchers training and practice; involving specific fellow in the research; training on research methodologies, statistics, etc.

5.2. The ERN has developed a framework for collaborative research across the ERN.

Guidelines

The ERN fosters collaborative instrumental efforts (multicentre trials, participation in EU projects, etc.) amongst its Members, Affiliated Partners and relevant patient, professional and research organisations.

Measurable Elements

5.2.1. The ERN fosters collaborative instrumental efforts (multicentre trials, participation in EU projects, etc.) amongst its Members, Affiliated Partners and relevant patient, professional and research organisations.	
Evidence	List of **collaborative** research projects and participants; joint proposals; papers and reports; trials registration… Indicators on projects: trials and observational studies

5.3. The ERN reinforces research and epidemiological surveillance through setting up shared registries and databases.

Guidelines

Advances in research are made based on the availability of reliable, objective, and representative data of the population studied in each case. The low prevalence of rare diseases makes it difficult to access the data, and the low statistical power makes it difficult to draw conclusions and contribute new knowledge. This is why it is essential to share the data with all the Members of the Network and to create registries and databases at the EU level.

The Network promotes the development of shared registries that will be relevant for the epidemiology of rare diseases and for determining future lines of research.

Measurable Elements

5.3.1. The ERN works to establish an EU wide solution for data sharing.	
Evidence	Explain which data can be shared and from which sources. Describe efforts done or advances in future data sharing.

5.3.2. The ERN promotes the development of comprehensive registries and databases.	
Evidence	Indicate which registries and databases the ERN has developed in the last five years. Describe actions carried out to receive funding and implement the registries.

6. EDUCATION AND TRAINING

6.1. The ERN has identified education, training, and professional development gaps within its area of expertise and has defined and addressed priority areas for teaching and training.

Guidelines

Although all the professionals in the Network and the HCPs are experts in the respective rare diseases, professional training is essential for continuous learning.

Here too, the role of the Network is relevant in identifying the education, training, and professional development gaps within its area of expertise, to plan the most appropriate training actions.

The training plan begins by identifying the areas of deficit and their subsequent prioritization and establishing a calendar to carry them out throughout the period of operation of the Network.

The training can be of a general nature or aimed at specific groups and in all cases it is necessary to have input from the participants to assess the usefulness, applicability, and relevance.

Measurable Elements

6.1.1. The ERN has identified education, training, and professional development gaps within its area of expertise and defined priority areas for teaching and training.	
Evidence	Describe the priority areas for teaching and training.

6.1.2. Plans have been implemented to address the priority areas for teaching and training in collaboration with Members, scientific societies, and other partners.	
Evidence	Describe the activities developed during the 5 years. Monitoring indicators 4.1 and 4.2 (Version 7.5).

6.1.3. The plans have been evaluated and the areas of improvement identified have been addressed in the plans for the coming years.	
Evidence	Regular evaluation performed (usefulness, applicability, relevance) according to the plan (i.e., satisfaction surveys).

6.1.4. ERN members periodically meet to review and share best practices, and discuss new evidence-based treatments, therapies, and healthcare technologies.	
Evidence	Explain how the Network plans and performs these meetings (webinars, workshops). Provide minutes, agendas, or summaries of the meetings.

6.2. The ERN has enhanced educational activities and training opportunities across Europe for HCPs within and outside the ERN.

Guidelines

The training actions should be extended to other professionals besides the members of the Network, such as affiliates and other healthcare providers from the EU Member States, thus increasing the dissemination of knowledge to healthcare professionals who carry out their work in these areas, even if they are not integrated into the Network.

It is foreseeable that with a good marketing of the training actions a progressive increase of participants will be achieved.

Measurable Elements

6.2.1. Actions oriented to improve access to the educational resources available across Europe have been carried out.	
Evidence	Describe the coverage of the educational activities within and outside the Network, taking into account the ERNs Mobility Programme.

6.2.2. The participation of specialized healthcare professionals from Member States with insufficient number of patients or lacking technology or expertise has been facilitated and increasingly achieved.	
Evidence	Describe the coverage of the educational activities outside the Network. Examples of what can be provided as evidence: Describe how the training has been open to professionals outside the Network Provide programmes that show that the webinars and training activities are open out of the ERN List of participants The number of countries involved National bodies involvement

7. NETWORKING AND DISSEMINATION

7.1. The ERN has developed a robust networking system for national and international collaboration and sharing of knowledge, best practices, expertise, and resources.

Guidelines

At the origin of this project is the mission of developing collaborative multidisciplinary work as a means of combining efforts, skills, knowledge, and clinical care work. For this reason, the collaboration that the Network must create must involve not only the HCP members, but also any centre of reference or expertise in the EU Collaborations with affiliate partners are preferred, but also with scientific societies, social care providers, and diagnostic centres.

Measurable Elements

7.1.1. The ERN has enhanced the collaboration with other ERNs and HCPs to exchange and disseminate knowledge, best practices, clinical expertise, or other resources.	
Evidence	Mention the networks and healthcare providers with which the ERN collaborates and the nature of the collaboration. Examples: Working Monitoring group; ERICA project; transversal working groups; ERN managers meeting; conferences with other ERNs. Collaborations at national level can also be included.

7.1.2. The ERN has developed collaboration strategies with Affiliated Partners from Member States with an insufficient number of patients or lacking technology or expertise to develop their skills.	
Evidence	Mention the strategies used to involve Affiliated partners: How the ERN is implementing the strategy; how they are engaged and interested to participate; barriers and facilitators for participation…

7.1.3. The ERN has developed partnerships with other stakeholders of interest, such as scientific societies, centres of expertise, diagnostic laboratories, patient organisations, social care providers, industry, affiliated research groups or national healthcare authorities.	
Evidence	Mention any initiative carried out to develop these partnerships. Examples: Establish an expert panel (including scientific societies); mapping patient organisations that are not covered by the ERN (efforts done to find the organisations); any effort done for partnership; any

	initiative to improve partnership with important stakeholders with the objective of promote the ERN; national alliances; approach to social and psychological providers…

7.2. The ERN has developed information and dissemination strategies regarding referrals across Member States.

Guidelines

The result of the collaboration is the identification of expertise from different locations in the EU, to establish a network of expert centres that can develop cross-border healthcare initiatives for the provision of care to patients in special situations. Roadmaps should provide alternative referrals favouring either the expertise of the referral centre or the accessibility of patients to the services they need.

The Network must ensure that the centres to which patients are referred use the protocols and pathways established and agreed within the Network.

Measurable Elements

7.2.1. The ERN provides accessible information highlighting sites and roadmaps for cross border expert advice and patients' referrals.	
Evidence	Examples of information provided to facilitate access to cross-border expert advice.

7.3. The ERN gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside itself.

Guidelines

The Network must develop a clear communication strategy for the dissemination of its activities, good practices, knowledge, etc. to increase its visibility and raise awareness about its added value for the European Union.

For this purpose, the Network must develop a communication plan, identifying the target groups to whom the information must be directed and tailor this information according to their needs.

Measurable Elements

7.3.1. The ERN has defined and implemented a comprehensive communication and dissemination strategy.	
Evidence	Describe the different mechanisms for communication and dissemination included in the strategy. Monitoring indicator 7.1 and 7.2 (Version 7.5). Examples: Website, flyers, newsletters; posters; slides sent to all HCPs (tools for disseminate ERNs); social media; any kind of initiatives addressed to engage all Member States; s; dissemination webinars; conferences where the ERN has been presented Indicator included in ePAG assessment framework, if used.

7.3.2. The ERN has developed actions to align information across target groups, i.e., defining audience, message, and methods to achieve the maximum level of inclusiveness of different groups.	
Evidence	Describe the target groups identified and the actions carried out: for example, tools used for each stakeholder (i.e., lay materials for citizens, patients, general community)

2. Operational Criteria for Healthcare Providers

INTRODUCTION

The evaluation of the European Reference Networks (ERNs) is based on verifying to which extent the ERNs and their Members (Healthcare Providers, HCPs) meet those quality requirements relevant to the achievement of the objectives for which they were constituted.

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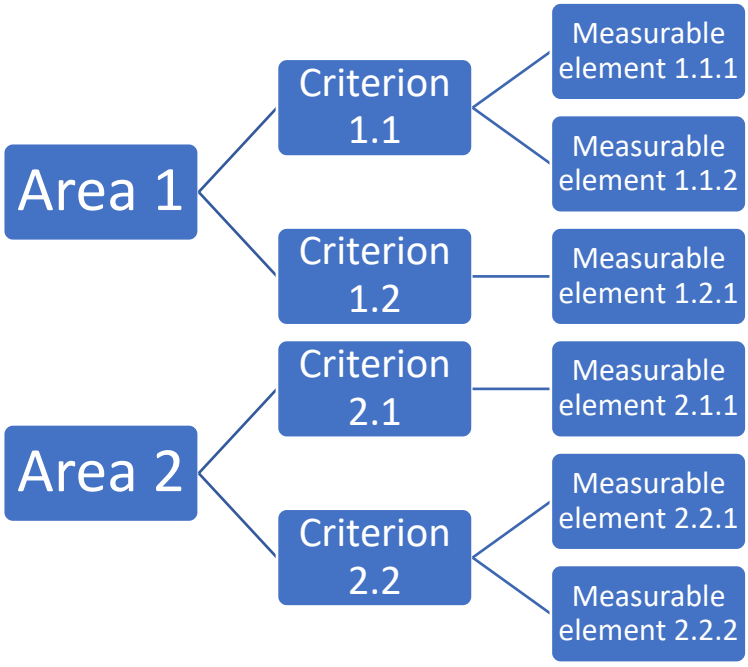
The Measurable Elements (ME) are used to assess the aspect or level of performance specified in each criterion.

The criteria are classified in several dimensions or thematic areas related to the different goals and objectives included in the evaluation:



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

Two sets of criteria have been elaborated, one for the evaluation of the Networks and the other for the evaluation of the HCP teams. Each criterion has been made “operational” through one or several MEs. Therefore, an operational criterion includes the criterion and the MEs.

This document presents the operational criteria for HCPs and specific guidance to score the level of performance or achievement of the practices described in them.

OVERVIEW

A total of 24 operational criteria with 64 measurable elements classified in 7 areas have been developed:

EVALUATION CRITERIA FOR THE HCP TEAM			
AREA	**Number of Criteria**	**Total number of ME**	**Total number of core ME**
1. Patient centred care	9	19	8
2. Organisation and management	5	10	4
3. Research, education, and training	2	11	6
4. Exchange of expertise, Information systems and e-Health	3	7	3
5. Quality and safety	2	9	2
6. Competence, experience, and outcomes of care	1	4	4
7. Human resources	2	4	2
TOTAL	**24**	**64**	**29**

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 ("extended" ME) refer to important areas in which the Networks should work and whose level of development can serve as an indicator of their maturity status.

As shown in the table above, each criterion may include core and extended ME.

Each Operational Criterion is presented in the Manual with the following structure:

- Thematic area to which the criterion belongs
- Guidelines: intention and rationale for the criterion
- Measurable elements that compose it and suggested evidence that the HCP can provide in each case and that will serve the evaluator to score the ME
  - The Scoring guide provides specific indications to rate each ME

Symbols included in the description of the operational criteria

Core measurable element

Measurable element to be evaluated during the onsite audit

Measurable element that identifies the HCP team contribution to the mission of the Network

Scoring

The degree of compliance with each ME is scored using a 3-point scale (0, 1 and 2). To minimize the variability between the evaluators, a tool is provided for the assignment of each of the categories.

Rating	Guidelines
0: No activity / Not developed	***All Criteria:*** **this rating is used if the answer is "scarcely" or "none" to the specific measure and/or when there are no actions in place or there is insufficient evidence to support compliance.** Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. • When there are multiple requirements in one measure, less than 50% are present.
1: Partially developed	***All Criteria:*** **this rating is used if the answer is "incomplete" or "partway" to the specific measure and/or when there are some actions in place or there is some evidence to support compliance.** Considerations: • Evidence of compliance does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully developed	***All Criteria:*** **this rating is used if the answer is "totally" or "completely" to the specific measure and/or when there is sufficient evidence to support compliance**. Considerations: • Evidence of compliance covers the whole period of time in which the requirement is applicable • All actions required have been implemented or are underway • When there are multiple requirements in one measure, all are present.

1. PATIENT CENTRED CARE

1.1. The HCP team has implemented strategies to ensure that care is patient-centred, and that patients' rights, and preferences are respected.

Guidelines

Patient-centred care is considered one of the central dimensions of quality in hospital services. It is defined as care that establishes a collaboration between professionals, patients, and their families to ensure that decisions respect the patient needs and preferences and that patients have the education and support they need to make decisions and participate in their care.

Patient and family[3] centred care is a necessity to obtain effective, efficient, and sustainable care in the long term. An intrinsic part of patient-centred care is that patients are aware of their rights and responsibilities and that they receive information that is understandable.

For the care process to be patient-centred, patients have to know the characteristics of the facilities and the organizational aspects that they will follow in order to be cared for.

Measurable Elements

1.1.1. The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.	
Evidence	Specific written information provided to the patients. Verify during the visit (online/onsite) in the session with discharged patients and outpatients.
Scoring guide	0: The HCP team does not provide evidence about the information it provides. 1: The HCP team provides evidence, but 1 or 2 of the required elements are missing (facility, organisation, or specific area of expertise). 2: The HCP team provides evidence, and it contains the 3 required elements (facility, organisation or specific area and expertise).

[3] Family: the person(s) with a significant role in the patient's life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision maker if authorized to make care decisions for a patient if the patient losses decision-making ability.

1.1.2. The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand.	
Evidence	Verify during the visit (online/onsite) in the session of patients. 
Scoring guide	0: Less than 50% of the patients present in the session claim to have received the information. 1: Between 50% -80% of the patients present in the session claim to have received the information. 2: More than 80% of the patients present in the session claim to have received the information.

1.2. The HCP team provides educational activities for patients and their families with the aim of improving knowledge of the disease and the capacity for self-management to face the different aspects of their disease.

Guidelines

The impact of patient care can be enhanced when patients and families are better acquainted with their health process, allowing for greater participation in decision-making.

Identifying patients' educational needs and implementing educational activities based on those needs is key to providing high quality care.

To guarantee the continuity of care and knowledge of these activities by the multidisciplinary team, they must be recorded in the clinical history.

Measurable Elements

1.2.1. Patient and family educational needs are addressed in a defined process.	
Evidence	Indicate the process for identifying educational needs in patients and family members, and the potential barriers to education.
Scoring guide	0: It does not provide evidence of the process to identify educational needs and the identification of barriers. 1: It provides evidence of the process to identify needs, but not on the process to identify barriers. 2: It provides evidence of the process to identify needs and barriers.

1.2.2. Education activities are recorded in the medical record	
Evidence	Verify during the onsite visit using a sample of 3 clinical records in given patients who have required educational activities on medication, medical devices, pain management or rehabilitation.
Scoring guide	0: None of the 3 medical records reviewed have recorded the completion of the education activities. 1: 1 or 2 of the 3 medical records reviewed have recorded the completion of the education activities. 2: Al of the 3 medical records reviewed have recorded the completion of the education activities.

1.3. The HCP team provides patients with clear and transparent information about the complaints' procedures and remedies and ways of redress available for both domestic and foreign patients.

Guidelines

The possibility of making a complaint is a right of patients, as well as that they have an answer adapted to their needs and knowledge in a set time. Furthermore, complaints are also a source of information that can be useful for quality management and for establishing improvement strategies.

Measurable Elements

1.3.1. The information about complaints, violation of the rights, and concern of the care and/or safety of patients and their families is periodically analysed and integrated into a continuous quality improvement process. An annual report is made on the complaints and the improvement actions carried out.	
Evidence	Attach last year's report and proposed improvement actions if applicable.
Scoring guide	0: It does not provide a report for the last year on the improvement actions taken based on the evaluation of patients' complaints. 1: It provides the last year's report with the proposed improvements, but these have not yet been implemented. 2: It provides the last year's report with the proposed improvements, and these have been implemented or are in the process of being implemented. NA: There were no claims over the previous year

1.4. The HCP team regularly collects information on patient care experience or satisfaction within the ERN's area of expertise and uses this information to make ongoing improvements.

Guidelines

Patient experience is an important component of patient-centred care and collecting and analysing it periodically enables the HCP team to give patients a voice in a structured way. This information is essential to introduce improvements from the patient's perspective that, on occasions, are not sufficiently perceived by the team.

A satisfaction evaluation also allows us to capture the vision of patients about the services received.

Whereas patient satisfaction is a subjective measure (of perception), patient experience is a more objective measure. In measuring satisfaction, we can ask patients or relatives how they have perceived the treatment of professionals, and in the measurement of experience we will ask more objective questions, such as, for example, if the professional who has cared for the patient has presented himself.

The HCP team can use one of the methodologies or both depending on its priorities.

Measurable Elements

1.4.1. The HCP team routinely measures patient and family satisfaction using the ERN common tool.	
Evidence	Attach the results of the latest patient satisfaction assessment and the identified improvement actions if applicable.
Scoring guide	0: It does not provide results from the latest evaluation on satisfaction of patients and families. 1: It provides results from the latest evaluation on the satisfaction of patients, but not families (surveys or other methodologies). 2: It provides results from the latest evaluation on the satisfaction of patients and families (surveys or other methodologies).

1.5. The HCP team obtains the patient's informed consent to provide clinical risk treatments and procedures.

Guidelines

Informed consent to medical treatment is an important patient right: patients have the right to receive information and ask questions about recommended treatments. It can also be one of the most effective ways to foster patient participation in decisions that affect their health care process. The patient must comprehend the benefits, risks, and alternatives to diagnostic and therapeutic procedures. The consent document should be easy to understand and written in a language known by the patient.

Normally, surgical procedures, anaesthesia and the use of blood and blood products will require informed consent. The HCP team will decide which procedures require consent and will provide the consent form to the patient or they family member when appropriate.

When conducting research with patients, obtaining informed consent is also required and patients should also be informed about the benefits, risks, and alternatives. The process of obtaining informed consent is central to patient safety and quality of care, and the patient always has the right to waive her participation. For the adequate follow-up of the patients by those who carry out the research and by other professionals who may intervene, consent must be documented in the clinical record.

Measurable Elements

1.5.1. The Informed Consent (IC) is documented in the patient's medical record, including the risks, benefits, and alternatives to the procedure to be performed, and must be understandable to patients.	
Evidence	Verify during the onsite visit in a sample of 3 medical records of patients who have undergone a risky procedure.
Scoring guide	0: None of the 3 patients' medical records who have undergone a risk procedure have the IC in their documentation. 1: 1 or 2 of the 3 patients' medical records who have undergone a risk procedure have the IC in their documentation with the elements required by the ME. 2: The 3 patients' medical records who have undergone a risk procedure have the IC in their documentation with the elements required by the ME.

1.5.2. The document to obtain IC for research must contain information on the risks, benefits, and alternatives to the procedure to be performed, and conflicts of interest (financial or non-financial).	
Evidence	Attach the IC document template for patients included in research studies.
Scoring guide	0: It does not provide the IC model for research. 1: It provides the IC model, but does not have all the sections that are specified in the ME. 2: Provides the IC model and has the requirements specified in the ME.

1.5.3. The patients' medical records included in a clinical trial contain information about their participation in it.	
Evidence	Verify during the onsite visit in a sample of 3 medical records from patients included in a clinical trial.
Scoring guide	0: None of the 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial. 1: 1 or 2 of the 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial. 2: The 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial.

1.6. The HCP team maintains transparency by providing information to patients about clinical outcomes, treatment options, and quality and safety standards that are in place.

Guidelines

The HCP teams have to provide information about the patient's journey throughout the care process in the different languages of the population served, including: the steps they have to take for the diagnosis and treatment, and the coordination systems with other levels of care where the patients are going to be cared for. This information is documented in the medical record.

Measurable Elements

1.6.1. The HCP team provides comprehensive diagnostic and treatment information.	
Evidence	Verify during the visit (online/onsite) in the patient session.
Scoring guide	0: Less than 50% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment. 1: Between 50% -80% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment. 2: More than 80% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment.

1.6.2. Information is provided in the language of the different populations served.	
Evidence	Verify during the visit (online/onsite) in the session with the professionals.
Scoring guide	0: Information is only provided in the main official language of the country. 1: Information is provided in the official language of the country and can also be provided in English. 2: Information is provided in the official language of the country and means are available to provide it in the patient's and family's own language. NA: No patient from another country with a different language has been treated.

1.6.3. The information necessary for the follow-up of the patient after the treatment is provided	
Evidence	a) Provide some examples of the information provided to three patients for the follow-up after treatment. b) Verify during the visit (online/onsite) in the patient session.
Scoring guide	0: a) No examples are provided. b) Less than 50% of the patients present in the session claim to have received information about the follow up. 1: a) Only 1 or 2 examples are provided. b) Between 50% -80% of the patients present in the session claim to have received information about the follow up. 2: a) 3 examples are provided. b) More than 80% of the patients present in the session claim to have received information about the follow up.

1.6.4. The HCP team provides information on coordinating care with other levels of care.	
Evidence	Verify during the visit (online/onsite) in the interview with the professionals.
Scoring guide	0: They do not provide information on how to coordinate with other levels of care. 1: They provide information on coordination but do not include all the levels of care to which you can refer your patients (primary care, other hospitals, rehabilitation services, etc.). 2: They provide information on coordination with all the levels of care to which you can refer your patients.

1.6.5. The information provided to the patient and the family on the follow up and coordinating care with other levels of care is included in the clinical record.	
Evidence	Verify during the onsite visit in a sample of 3 HC from discharged patients and outpatients.
Scoring guide	0: None of the 3 medical records reviewed contains details on the information provided on the follow up and coordinating care.

	1: 1 or 2 of the 3 medical records reviewed contain details on the information provided on follow up and coordinating care. 2: The 3 medical records reviewed contain details on the information provided on follow up and coordinating care.

1.6.6. Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure	
Evidence	Provide the HCP policy/procedure and an example of disclosure to patients performed
Scoring guide	0: No policy or example is provided. 1: Either the policy or an example is provided, but not both. 2: Both the policy and an example are provided

1.7. The HCP implements a pain identification and management protocol.

Guidelines

In many patients, pain is part of their experience and can have negative physical and psychological effects. In hospitalized patients this becomes more evident when surgical or invasive procedures are performed. It is in these patients where it is expected that there will be procedures in place to detect the presence of pain, such as scales adapted to the characteristics of the patients, especially for younger patients and for those with cognitive or sensory difficulties.

Pain identification has to lead to pain management with the measures that have been established in the protocol.

Measurable Elements

1.7.1. In hospitalised patients with rare diseases or complex patients, pain is regularly identified with a standardised scale as established in the hospital`s protocol.	
Evidence	Verify during the onsite visit in a sample of 3 HC from discharged patients.
Scoring guide	0: None of the 3 medical records has a pain assessment registered 3 times a day throughout their stay. 1: In 1 or 2 of the 3 medical records, the pain assessment is registered 3 times a day throughout their stay. 2: The 3 medical records have registered the pain assessment 3 times a day throughout their stay. N.A: all patients receive care in an outpatient department

1.8. A policy is implemented to encourage patient and family involvement.

Guidelines

Patient involvement can lead to better health outcomes and can improve quality of care and patient safety. The HCP team has to encourage patient engagement in healthcare decisions, in healthcare services organizations and in health research.

To achieve patient participation, it is essential to provide complete information about the disease and the treatment alternatives and take into account the preferences and values of the patients. The HCP team facilitates the decision-making process for patients and families, taking these elements into account.

Measurable Elements

1.8.1. Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making.	
Evidence	Indicate the process followed for patients' involvement.
Scoring guide	0: It does not provide any evidence on how the process is carried out to encourage participation and decision making. 1: It provides evidence about participation in the care process OR in decision making. 2: It provides evidence about participation in the care process AND in decision making.

1.9. The HCP team collaborates and carries out activities with patient associations.

Guidelines

Informing, defending the rights of patients, improving the professional-patient relationship, facilitating access to care ... are some of the objectives pursued by patient associations and other community resources.

The HCP team provides information on community resources and associations of pathologies that are attended by the team that allow patients to access educational consultations, counselling services and psychological care and other services that help patients improve their autonomy and biopsychosocial care.

Measurable Elements

1.9.1. The HCP team provides information on patients' associations and that can support the patient and their family.	
Evidence	Specific information provided about patients' associations (examples) Verify during the visit in the session with professionals.
Scoring guide	0: Professionals do not show evidence of the information provided to patients and their families about patients' associations. 1: Professionals show evidence of the information provided about patients' associations. 2: Professionals show evidence of the information provided about patients' associations.

1.9.2. The HCP team collaborates and carries out activities with patients' associations.	
Evidence	List the associations you work with, and the main activities carried out in the period. *Monitoring indicator number 1.4.*
Scoring guide	0: The list of patients' associations with which collaborative activities have been maintained during the 2019-2021 period is not provided. 2: The list of patients' associations with which collaborative activities have been maintained during the 2019-2021 period is provided.

2. ORGANISATION AND MANAGEMENT

2.1. The HCP team follows policies and procedures to manage the services offered to cross-border patients, including easy access to information regarding any tariffs that may be in place.

Guidelines

The healthcare provider team should follow the set cross border policies and procedures established by the Network and the national authorities It is very important for the patient and the family to have complete information about cross border care and the implications it has in services provided and expected benefits, as well as from an economic perspective about any tariffs that may be in place for the reimbursement of care.

Policies and procedures should be in accordance with those set out in the legislation of the Member State of treatment and as described in the Directive 2011/24 and Social Security Regulation 883.

The HCP team informs and facilitates the care of cross border patients to the affiliated centres and carries out training and dissemination activities among the professionals and patients of these centres.

Measurable Elements

2.1.1. The HCP team establishes collaboration with affiliated centres in neighbouring countries for cross-border care or for training / dissemination of information for professionals and patients.	
Evidence	List the HCP's affiliated centres in neighbouring countries for cross-border care.
Scoring guide	0: It does not provide the list of its affiliated centres for cross border patients, nor the list of centres or professionals to which it disseminates the information generated in the Network. 1: It provides the list of affiliated centres, but not that of centres or professionals to which the information generated on the network is disseminated. 2: It provides the list of its affiliated centres and the list of other centres or professionals to which it disseminates the information generated in the Network. NA: It is not possible to have affiliates.

2.1.2. The HCP team establishes and maintains a set of policies and procedures addressing aspects for the management and health care services of cross border patients.	
Evidence	List the policies and the procedures established for cross border patients.
Scoring guide	0: It does not provide the policies and the procedures established for cross border patients. 2: It lists the policies AND procedures.

2.1.3. The HCP team shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, as well as services provided and expected benefits.	
Evidence	Include examples of the information provided to patients and their families.
Scoring guide	0: It does not include any example. 1: It includes 1 example. 2: It includes more than 1 example. N.A: tariffs do not apply at the point of healthcare delivery

2.2. The HCP team implements procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.

Guidelines

In some cases where part of the care cannot be performed by the team itself, the HCP team has to refer patients to other centres that have the necessary technology or training for diagnosing and managing patients.

The HCP team must agree with these centres on the details of the procedure for the referral of patients, especially the clinical data to be included in the reports. For the follow-up of the patient, the information about the referral must be included in the medical record.

Measurable Elements

2.2.1. When necessary, the HCP team has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.	
Evidence	a) Indicate the external centres or highly specialized units to which you can refer patients and if it is for diagnosis, treatment, or delivery of care. Comment if, in your opinion, you have been able to refer the patients with this need.
Scoring guide	0: It does not provide the list of external units to which it refers patients. 1: It provides the list of external units, but without specifying if it is for diagnosis, treatment, or delivery of care. 2: It provides the list of external units specifying the purpose for each of them (diagnosis, treatment, or delivery of care). NA: It has all the necessary services in their HCP.

2.2.2. The HCP team sends the receiving organization a written summary about the patient's clinical condition and the interventions carried out in the hospital from which he/she is referred. The process is recorded in the medical record.	
Evidence	Verify during the onsite visit by reviewing a sample of 3 HC of patients who have been transferred to another organisation.

Scoring guide	0: None of the 3 medical records reviewed has the transfer document with all the items required in the ME. 1: 1 or 2 of the 3 medical records reviewed have the transfer document with all the items required in the ME. 2: The 3 medical records reviewed have the transfer document with all the items required in the ME.

2.3. The HCP team has policies and procedures implemented to communicate post discharge with clinicians, including cross border.

Guidelines

The patient's discharge document is an essential instrument for coordination with other levels of care that provides relevant clinical information for the continuity of patient journey.

Clinicians in local hospitals, general practitioners and/or primary care providers must receive this information.

Patient discharge also addresses patient and family education and training related to the patient's needs for ongoing care and services.

Measurable Elements

2.3.1. Discharge reports contain at a minimum: diagnoses; significant physical findings; diagnostic, surgical and medical procedures performed; medication received at discharge; and follow-up instructions.	
Evidence	Present 3 discharge reports (anonymized copies). Verify during the onsite visit 3 medical records of discharged patients.
Scoring guide	0: None of the 3 medical records reviewed have ALL the items required in the ME. 1: 1 or 2 of the 3 medical records reviewed DO NOT have ALL the items required in the ME. 2: The 3 medical records reviewed have ALL the items required in the ME.

2.3.2. The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.	
Evidence	Verify during the onsite visit 3 discharge reports of discharged cross border patients.
Scoring guide	0: None of the 3 discharge reports reviewed are in English. 1: 1 or 2 of the revised discharge reports are in English. 2: The 3 revised discharge reports are in English. NA: no cross-border patient has been seen in the last 5 years.

2.4. The HCP team is integrated into national networks.

Guidelines

One of the relevant objectives of integration with national networks is strengthening dissemination of information on ERNs, national care pathways, referral systems and health system organization for rare and complex diseases among medical, nursing, and allied health professionals according to the needs of the MS.

The HCP team collaborates with national centres in the dissemination and training on the diseases that are treated within the framework of the ERN at the national level.

Measurable Elements

2.4.1. The HCP team collaborates in training or dissemination activities with centres which are not members of the ERN.	
Evidence	Indicate the activities carried out at national level.
Scoring guide	0: It does not provide information on training or dissemination activities to other centres in its country on topics specific to its Network. 2: It provides information on training or dissemination activities to other centres in its country on topics specific to its Network.

2.5. The HCP team uses CPMS and includes all the information required.

Guidelines

The use of CPMS facilitates the improvement of the diagnosis and treatment of ERN patients and multidisciplinary work through communication between healthcare professionals. The CPMS must contain at least the detection of physical, psychological, and social needs of the patients, and the treatment plan and the completed sign off.

Measurable Elements

2.5.1. The HCP team shares patient information or participates in panels of complex cases through the CPMS with other members of the ERN.	
Evidence	Indicate the number of patients entered into CPMS.
Scoring guide	0: It has not contributed any patients to CPMS in 2019, 2020 and 2021. 1: It has contributed some patients to the CPMS, but not in each of the following years: 2019, 2020 and 2021. 2: It has contributed patients to the CPMS, in each of the following years: 2019, 2020 and 2021.

2.5.2. The CPMS of each patient includes: **a) physical needs** **b) social needs** **c) psychological needs** **d) treatment and care plan** **e) sign off completed**	
Evidence	Verify during the onsite visit on a sample of 3 medical records of patients included in the CPMS.
Scoring guide	0: None of the registries of the lasts three years has all the information ("a" to "e") 2: 80% registries of the last three years have all the information ("a" to "e")

3. RESEARCH, EDUCATION AND TRAINING

3.1. The HCP team participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.

Guidelines

Education and training are key to guarantee the continuous development of knowledge and skills of professionals for both patient care and research.

The HCP teams annually define objectives and educational activities related to the type of patients represented by the ERN and the objectives are aligned with those of the ERN. They must also participate actively in the activities organized by the ERN.

The HCP identifies educational needs for each professional. The process of identifying individualized needs makes their approach more effective in achieving the training objectives.

Training activities must be carried out both within the HCP team and should be provided to other external actors that play a role in the care of patients with rare diseases.

Measurable Elements

3.1.1. The HCP team has a defined set of objectives for its education and training activities aligned with the ERN.	
Evidence	State the HCP's educational and training goals.
Scoring guide	0: It does not provide information on objectives for its education and training activities aligned with the ERN, intended for staff and other care professionals 2: It provides information on objectives for its education and training activities aligned with the ERN, addressed to staff

3.1.2. The HCP team regularly detects the training needs of the staff members.	
Evidence	Indicate what process the HCP team has followed to identify training needs.
Scoring guide	0: It does not report the process. 2: It reports the process followed.

3.1.3. Education and training activities are delivered to providers involved in the same chain of care within and outside the HCP's facility.	
Evidence	Indicate the training activities carried out in the period, with and without credits. Monitoring indicator number 4.1 and 4.2.
Scoring guide	0: It does not provide the activities carried out 2: It provides a list of the activities carried out

3.1.4. The HCP team participates in the training activities organised by the ERN.	
Evidence	Indicate the training activities organised by the Network in which you have participated.
Scoring guide	0: It does not provide information or has not participated in any training activity of the Network 2: It provides information on the activities in which it has participated.

3.2. The HCP team has the capacity to carry out research activities and demonstrated research experience in the framework of the ERN.

Guidelines

An essential facet of HCP teams is research on the diseases they care. The HCP team must ensure that those conducting research in the organization satisfy the qualifications established to do so.

The degree of contribution of the HCP team in the research and the information provided to patients for their participation in clinical trials and observational studies will be evaluated.

The results of the studies should be disseminated in the scientific community so that others can benefit from the advances achieved. The team shares the results with patient associations and other community-based organisations in a lay language.

Registries are key in rare disease research and the HCP team must share the data of the patients it cares for with existing registries or databases for research.

Measurable Elements

3.2.1. The HCP team leads and/or participates in research activities and clinical trials, at both national and international level, within the ERN's area of expertise.	
Evidence	List the research activities of the Network in which the HCP team has participated (i.e., clinical trials and observational prospective studies). Include your answer in table 11 of the application form.
Scoring guide	0: There is no participation in any of the Network's research activities 2: There is participation in clinical trials or observational prospective studies
3.2.2. The HCP team ensures that records from research activities and clinical trials are safely stored.	
Evidence	Verify during the onsite visit in a sample of 3 medical records of patients included in clinical trials.
Scoring guide	0: None of the 3 medical records of clinical trial are safely stored. 1: 1 or 2 of the 3 medical records of clinical trials are safely stored. 2: All 3 medical records of clinical trials are safely stored.

3.2.3. The HCP team involves patients and / or their representatives in the most relevant aspects of the research process.	
Evidence	Indicate the process followed to involve patients and families included in research studies.
Scoring guide	0: It does not provide any evidence on how the process to involve the patient and their family in research studies carried out (clinical trials and observational prospective studies) 2: It provides information on how the process is carried out to involve the patient and their family in research studies (clinical trials and observational prospective studies)

3.2.4. The HCP team shares the results, in a timely manner, from its research activities and clinical trials through scientific publications.	
Evidence	List the peer reviewed publications in scientific journals within the knowledge framework of the Network in which you have participated.
Scoring guide	0: No publication has been produced within the framework of the Network in the last 5 years 2: 1 or more publications have been produced within the framework of the Network in the last 5 years (attach the link or reference of the publication/s)

3.2.5. The results should be disseminated to patient associations in lay language.	
Evidence	Indicate the publications/results of research within the framework of the Network that have been sent to patients' associations, adapted for clear understanding.
Scoring guide	0: Publications/results were not sent to patient associations 1: Some publications/results were sent (attach email reference) 2: All publications/results were sent (attach email reference) N.A: there is no patient associations for some specific diseases or conditions

3.2.6. The HCP team provides patients' information for the registries or databases promoted by the ERN.	
Evidence	Indicate how many patients you have incorporated into the registries or databases of the Network.
Scoring guide	0: No patients were added to the registries or databases developed by the Network 2: 1 or more patients were added to the registries or databases developed by the Network

3.2.7. The HCP team is contributing to disseminate the ERN activities.	
Evidence	Indicate what your contribution has been. For example, in social media, website, flyers and materials, attendances to congresses and conferences disclosing the ERN, etc.
Scoring guide	0: It does not provide information. 1: It provides information, but it has only used 1 channel for dissemination 2. It provides information and contribution to dissemination is made in several ways.

4. EXCHANGE OF EXPERTISE, INFORMATION SYSTEMS AND e-HEALTH

4.1. The HCP team is able to exchange expertise with other providers and provide support to them.

Guidelines

A broad and deep knowledge about the rare or complex disease(s) or condition(s) should be maintained and used to provide health care professionals the information about the disease or condition they demand. Health care professionals may include clinicians at local hospitals, local referring physicians and general practitioners, other specialist centres, etc.

Measurable Elements

4.1.1. The HCP team offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.	
Evidence	Attach the list of other professionals and caregivers or healthcare facilities with whom you maintain an advisory service.
Scoring guide	0: It does not provide the list of other professionals and caregivers with whom it maintains an advisory service. 2: It provides a list of other professionals and caregivers with whom it maintains an advisory service.

4.2. The HCP team fosters the use of telemedicine and other e-health tools within and outside its facility.

Guidelines

Telemedicine and e-health tools are very useful in health care and, particularly, in the activities of the HCP due to the location of the patients, which, on occasions, can be far from the place where the HCP team is located.

Not all professionals are familiar with these tools, so it is essential to establish a protocol of good practices that allows homogenizing their use and improving quality.

Similarly, not all patients can connect through these tools and the criteria of those who are candidates to use them must be defined. The criteria must take into account the health literacy, technological, cognitive, or sensory barriers of the patients.

Patients must be guaranteed that these tools will respect the confidentiality of the information.

The minimum interoperability requirements include the technical specifications to support: transmission speed and bandwidth; image storage, retrieval, and transmission; physical location of the equipment and room requirements.

Measurable Elements

4.2.1. The HCP team uses telemedicine and other e-health tools.	
Evidence	a) Indicate the procedures in which telemedicine can be used. b) Indicate the e-health tools you use.
Scoring guide	0: It does not provide the list of Telemedicine procedures or the e-health tools it uses. 1: It contributes only one of the 2 lists. 2: It provides the 2 lists.

4.2.2. Professional telemedicine guidelines available are used to guarantee the homogeneity of its use.	
Evidence	Provide the guidelines used. Verify during the visit (online/onsite) in the interview with the professionals.

Scoring guide	0: There are no guidelines for procedures performed with telemedicine. 2: Guidelines are available for procedures performed with telemedicine.

4.2.3. The HCP team should identify inclusion and exclusion criteria for potential telehealth patients.	
Evidence	Indicate the criteria that apply.
Scoring guide	0: There are no inclusion and exclusion criteria for potential telehealth patients. 2: There are criteria for inclusion and exclusion of potential telehealth patients.

4.2.4. Patients and family members who access telehealth have the right to have their privacy guaranteed.	
Evidence	Verify during the visit (online/onsite) in the interview with the professionals.
Scoring guide	0: Professionals do not clearly specify the mechanisms used to guarantee privacy. 2: Professionals explain the mechanisms used to guarantee privacy.

4.2.5. When surveying patient and family satisfaction, satisfaction with the services provided by telehealth should be included, when appropriate.	
Evidence	Survey content.
Scoring guide	0: The satisfaction surveys do not evaluate satisfaction with telemedicine procedures and other e-health tools. 2: The satisfaction surveys evaluate satisfaction with telemedicine procedures and other e-health tools.

4.3. The HCP team codes the information, and the information system is aligned with nationally and internationally recognised systems when appropriate in the framework of the ERN.

Guidelines

This coding system is in line with nationally and internationally recognised systems, when appropriate. This may include the International Classification of Diseases and Complementary Codes and/or Orphanet Classification.

Measurable Elements

4.3.1. The HCP team uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s), agreed within the ERN.	
Evidence	Explain if you use the coding system agreed in the Network.
Scoring guide	0: The diagnostic coding system agreed in the Network is not used. 1: Not all diagnoses are coded with the coding system agreed upon in the Network. 2: All diagnostics are coded with the coding system agreed upon in the Network.

5. QUALITY AND SAFETY

5.1. The HCP team regularly monitors and improves the quality and safety of the care provided to patients with rare or low prevalence complex diseases or conditions.

Guidelines

Quality and safety are rooted in the daily work of all staff in the HCP team. Developing quality improvement and patient safety strategies includes data aggregation and analysis to support patient care and HCP team management. Indicators can provide information on the functioning of the relevant areas of the HCP team for quality and safety improvement strategies.

The strategies should include measurable quality and safety objectives aligned with the ERN and the display of the activities necessary to achieve the objectives. The description of the staff components responsible for the objectives is recommended.

Safety strategies should include the most common preventive actions in risk management such as: hand hygiene, prevention and control of healthcare related infection, prevention of medication errors (completed medical orders, process of administration, identified high-risk medications), ensuring safe surgery (verification, time out and sign out), and unequivocal identification of patients, etc.

One of the safety improvement strategies is learning to analyse adverse events. The HCP can analyse adverse events and complications to make process improvements that minimize their occurrence. For the learning to be effective, the results will be shared with the team.

There may be a structured reporting system for all the services of a centre which the HCP team may be able to use, but even if there is not or if there are difficulties in using the centre's system, the HCP should investigate the root cause of all critical incidents or adverse events and implement corrective or preventive actions.

Measurable Elements

5.1.1. The HCP team applies a strategy of quality and safety improvement, which includes specific objectives and recommended activities for the achievement of the objectives	
Evidence	Attach the quality and safety strategy, it should describe: 1) concrete and measurable objectives of quality and safety, and 2) the actions for each objective. The objectives and activities must contemplate those established in the Network's strategy.

Scoring guide	0: It does not provide the quality and safety improvement strategy and its alignment with the Network strategy. 1: It provides the quality and safety improvement strategy but does not follow the objectives established by the Network and the actions to implement these objectives. 2: It provides the quality and safety improvement strategy with the objectives and actions established by the Network.

5.1.2. The main objectives of the strategy on quality and safety improvement include: **a) Hand hygiene** **b) Prevention and control of healthcare related infections** **c) Prevention of medication errors (completed medical orders, process of administration, identified high-risk medications)** **d) Ensure safe surgery (verification, time out and sign out)** **e) Unequivocal identification of patients**	
Evidence	Assess during the visit (online/onsite) in the interview with professionals.
Scoring guide	0: Professionals know the protocols of the 5 procedures, but do not explain how they are implemented. 1: Professionals know the protocols of the 5 procedures, but do not clearly explain (with examples) how each of them are implemented. 2: Professionals know the protocols of the 5 procedures and clearly explain (with examples) their application.

5.1.3. The quality and safety strategies are implemented, and the results obtained are evaluated.	
Evidence	Attach the result of the evaluation of the quality strategies from last year.
Scoring guide	0: It does not provide information on the results of the quality and safety strategies for the last year. 1: It delivers results for some but not all of the last year goals. 2: It provides results for all of the last year goals.

5.1.4. There is a procedure in place to report, document, investigate, and learn from adverse events and complications.	
Evidence	a) Do you have access to an adverse event reporting system? b) How many events related to the diseases that you care for in the framework of the Network have you reported in the last 5 years? c) Is a comprehensive analysis of all serious adverse events carried out?
Scoring guide	0: It does not provide information regarding the management of adverse events by the HCP member. 1: It describes the adverse event management system but does not indicate the number of incidents reported in the last 5 years, or if it has carried out an analysis in any case. 2: It describes the adverse event management system, indicates the number of incidents reported made in the last 5 years and when an analysis has been carried out on all of them. NA: There were no adverse events in the last 5 years.

5.1.5. The HCP team uses this information to make ongoing improvements.	
Evidence	Indicate whether you have identified and implemented improvement actions after analysing the reported adverse events. List the improvement actions identified and specify whether they have been implemented, if any.
Scoring guide	0: No improvement actions have been defined. 1: Improvement actions have been defined, but they have not been implemented. 2: Improvement actions have been identified and implemented.

5.1.6. All healthcare personnel are familiar with the system for reporting safety incidents and adverse events.	
Evidence	Assess during the visit (online/onsite) in the interview with professionals.

Scoring guide	0: Professionals do not know the system used in their organization to report adverse events. 1: Professionals know the system used in their organization to report adverse events, but they have not reported any adverse events during 2019, 2021 and 2021. 2: All of the professionals in the team know the system used in their organization to report adverse events and use it.

5.1.7. A procedure is implemented to provide information on adverse events with patient damage to patients and their families.	
Evidence	Assess during the visit (online/onsite) in the interview with professionals. 
Scoring guide	0: The HCP member does not have or explain the process to communicate adverse events to patients and families. 2: The HCP member arranges and explains the process for communicating adverse events to patients and families.

5.2. The HCP team adopts and uses clinical practice guidelines in their area of expertise.

Guidelines

To improve clinical care, clinical practice guidelines represent an essential instrument that will contribute to the standardization of care processes, the risk reduction, the provision of clinical care in a timely manner, the efficient use of resources and the provision of consistently high-quality care using evidence-based practices.

An assessment of compliance with clinical practice guidelines should be carried out because it represents essential information for the proper management of patients treated by the HCP team. Their better compliance will increase the likelihood that the care will be of higher quality and safety.

The Healthcare team obtains and considers patient and family input when developing / adopting and/or selecting guidelines. Patients and families are consulted to determine whether the method of adopting guidelines follows a patient-centred approach. Patient and family input is used to select guidelines that are appropriately linked to improved patient experience.

Measurable Elements

5.2.1. The HCP team adopts and implements clinical practice guidelines and decision-making tools developed or adapted by the ERN.	
Evidence	Indicate which clinical guidelines and decision-making tools developed or adapted by the ERN, and their respective updates have been implemented in your patients, as well as other good practices recommended by the Network.
Scoring guide	0: It has not implemented any of the clinical guidelines and decision-making tools developed or adapted by the ERN 1: It has implemented some guidelines and decision-making tools, but not all those that correspond to its area of expertise. 2: It has implemented all the clinical guidelines and decision-making tools developed or adapted by the ERN and that correspond to their area of expertise. N.A: the ERN has not developed or adapted any clinical guideline or clinical decision-making tool

5.2.2. An annual evaluation on adequate compliance of the clinical practice guidelines is carried out using the indicators agreed in the ERN.	
Evidence	Indicate the results of the evaluation of adequate compliance with the clinical practice guidelines from last year.
Scoring guide	0: It does not provide any information on the results of the evaluation indicators of the clinical practice guidelines evaluated from last year. 1: Information is provided, but not on all the guidelines or all the indicators corresponding from last year. 2: Information is provided on all the indicators of all the guidelines evaluated from last year.

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

6.1. The HCP team maintains its clinical competence in the ERN's area of expertise.

Guidelines

The diagnostic and treatment capacity of patients may be conditioned by the volume of activities with a certain type of patient or procedures that are performed. The HCP team must demonstrate that it cares for a number of patients and performs a number of procedures that allows to maintain experience in professional practice.

To contribute to the knowledge of the clinical outcomes of the ERN, the HCP team should provide information on the results of the own monitoring indicators and the clinical indicators established by the Network.

Measurable Elements

6.1.1. To maintain its competency and expertise, the HCP team serves the minimum/optimal number of patients per year as defined by the ERN based on professional/technical standards or recommendations.	
Evidence	Attach the annual data (from the last 3 years), of the number of patients of the group of diseases you serve. Include the reference data agreed by the Network for each of the items.
Scoring guide	0: It does not provide the number of patients for the last three years. 2: It provides the number of patients for the last three years and is equal to or greater than the reference value agreed by the Network.

6.1.2. To maintain its competency and expertise, the HCP team serves the minimum/optimal number of procedures per year as defined by the ERN based on professional/technical standards or recommendations.	
Evidence	Attach the annual data (from the last 5 years), of the number of procedures of the group of diseases you serve. Include the reference data agreed by the Network for each of the items.
Scoring guide	0: It does not provide the number of procedures performed in 2019, 2020 and 2021.

	1: It provides the number of procedures performed in 2019, 2020 and 2021, but not the reference value agreed by the Network. 2: It provides the number of procedures performed in 2019, 2020 and 2021, and the reference value agreed by the Network.

6.1.3. The HCP team regularly collects, and monitors process and outcome indicators as established in the ERN.	
Evidence	a) Attach the result of the monitoring indicators reported periodically to the European Commission for the last 3 years
Scoring guide	0: It does not provide information on the results of the monitoring indicators, established by the Network. 2: It provides information on the monitoring indicators established by the Network for the last 3 years.

6.1.4. The HCP team is actively involved in the activities organized for the development of the ERN.	
Evidence	Attach the activities or working groups of the Network in which you have participated.
Scoring guide	0: It does not provide information. 1: It provides information, but it shows they participated in less than 3 activities or working groups. 2: It provides information on their participation in more than 3 activities or working groups.

7. HUMAN RESOURCES

7.1. The HCP has a team of trained professionals with the required competencies within the ERN's area of expertise.

Guidelines

If there have been changes in the staff of the HCP team since the assessment was carried out, documentation on the new staff should be included. Documentation includes type of professionals, number of professionals, specific qualifications, and skills. The required skills and competencies are defined by the Network and is consistent with the HCP team area of expertise.

Professional competencies are evaluated annually, and areas of improvement are identified for all components of the HCP team.

Measurable Elements

7.1.1. The HCP team identifies and documents the skills and professional qualifications required for the new staff in the multidisciplinary team performing activities critical to the quality of patient care.	
Evidence	If there has been any change in the multidisciplinary team, with respect to those reported in the assessment, indicate their qualifications.
Scoring guide	0: It does not provide information on the new professionals' qualifications. 1: It provides information on the new staff but does not meet the requirements of the Network. 2: It provides information on the new staff and complies with the requirements of the Network. NA: There has been no change in professionals since the assessment.
7.1.2. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.	
Evidence	Verify during the visit (online / onsite) in the interview with professionals. See 3 examples.
Scoring guide	0: There is no process to ensure the maintenance of the necessary skills for the performance of their specialised tasks. 1: There is a process, but it is not done routinely and systematically. 2: There is a systematic process that is annually performed on all team members.

7.2. The HCP team delivers a comprehensive care by a multidisciplinary and specialised team.

Guidelines

There are procedures in place to identify all patients where a multidisciplinary team discussion is needed, including undiagnosed/unclear cases. There are referral criteria in place that define when to send a case to the team for consideration. These include: the type of patients to be discussed; the clinical questions needed to be addressed; what information is required for the discussion; and when to refer the patient to another team, i.e., from a local team to a specialist team.

All team members have dedicated time included in their workload to attend team meetings. Core team members are present for all cases where their input is needed. Extended members and non- members may attend for those cases that are relevant to them. Decisions of the multidisciplinary clinical sessions on a determined patient are recorded in their medical record.

Measurable Elements

7.2.1. There are regular structured meetings between multidisciplinary team members.	
Evidence	Indicate the number of sessions scheduled / year carried out by the multidisciplinary team (clinical, organisational, scientific sessions, etc.).
Scoring guide	0: It does not provide information about the regular meeting scheduling calendar. 2: It provides the regular meeting scheduling calendar.

7.2.2. The decisions of the multidisciplinary clinical sessions on a given patient are recorded in their medical record.	
Evidence	Verify during the onsite visit in 3 HC of patients that they have been assessed by the team.
Scoring guide	0: In none of the 3 medical records have the decisions of the multidisciplinary team meetings been recorded. 1: In 1 or 2 of the 3 medical records, the decisions of the multidisciplinary team meetings have been recorded. 2: The decisions of the multidisciplinary team meetings have been recorded in all 3 medical records.

3. Self-evaluation guidelines for ERNs and HCPs

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 specific guidance included in the toolbox (see ***scoring guidelines for the Network*** and ***scoring guidelines for the HCP team***).

One self-evaluation at ERN level and one self-evaluation from each Member of the Nework are expected to be delivered.

The self-evaluation process should help each ERN and its Members to reflect on the activities carried out during the last five years and to assess to which extent they have achieved the objectives they had planned, and the mission entrusted to the Network.

During the self-evaluation, the measurable elements of each criterion must be scored, and the score assigned must be justified with the corresponding evidence. This facilitates the objectification of the answers and that the information provided can be more useful for the evaluators.

3.1 Network self-evaluation guidelines

The self-evaluation will be submitted via the on-line tool. Nonetheless, a ***self-evaluation form*** is included in the toolbox to facilitate the previous collection of information.

The self-evaluation includes 3 main sections:

A. This section includes specific questions for the identification of the Network, its members and stakeholders and about the activity carried out. Information is also requested on the barriers encountered for the development of the Network, leaving a final section for the coordinator to make any comment he/she deems appropriate.

B. The second section contains all the criteria and measurable elements with the scoring options. The ***scoring guidelines for the Network*** provide specific guidance for the scoring process. Besides, there is an area for comments and another one to add the corresponding evidence for each ME:

In the "**Comments**" section, the Network coordinator can enter the explanations they deem appropriate related to the requirements of each ME and, if applicable, those specific and differential aspects of the Network that must be considered in the scoring.

In any case, it is recommended that the comments be concise since they will also serve the evaluation team of the Independent Evaluation Body (IEB) to confirm or modify the score.

C. The last section, "**Evidence**", is intended to incorporate the references that show compliance with the ME. This evidence can adopt different ways:

- Documents that describe how the Network carries out different processes or activities, flyers, etc.

- List of indicators, guidelines and protocols, patient associations, affiliated partners, etc.

In both cases, you can attach the document or the link that allows the IEB evaluator to access the document.

In many cases, these may be documents already prepared by the Network over a period of 5 years (ie. Mission or Strategic planning), or information that is part of broader technical reports (grant reports) and of which only the specific information requested by the ME should be included or just indicate in which pages of the report it can be found.

Some MEs do not require the provision of evidence, but simply to provide the explanation that is formulated in the document **"Operational criteria for ERNs and HCPs evaluation"** and that must be answered in the "comments" section. The ***Operational criteria for ERNs and HCPs evaluation*** document also includes suggested evidence for the different measurable elements.

The ***list of documents to be prepared by ERNs and their Members*** also mentions some of the evidence that can be provided.

D. This section includes a qualitative self-assessment regarding the level of accomplishment of the objectives from Article 12(12) of Directive 2011/24/EU that the ERN had selected in the initial application. The reflection performed to answer the previous section should facilitate to carry out this task as objectively as possible.

E. This section intends to gather final reflections and inputs regarding the contribution of ERN Members, the whole ERN system or any additional comment or suggestion that could enrich and improve the results of the evaluation.

3.2 HCP team self-evaluation guidelines

The self-evaluation will be submitted via the on-line tool. Nonetheless, a ***self-evaluation form*** is included in the toolbox to facilitate the previous collection of information.

The self-evaluation includes 2 main sections:

A. This section includes specific questions for the identification of the HCP team, the area of expertise, services provided and activity. Information is also requested about the barriers encountered for the involvement of the HCP in the activities of the Network, leaving a final section for the HCP representative to make any comment he/she deems appropriate.

B. The second section contains all the criteria and measurable elements with the scoring options. The ***scoring guidelines for the HCP team*** provide specific guidance for the scoring process. Besides, there is an area for comments and another one to add the corresponding evidence for each ME:

In the "**Comments**" section, the HCP representative can enter the explanations they deem appropriate related to the requirements of each ME and, if applicable, those specific and differential aspects of the HCP that must be considered in the scoring.

In any case, it is recommended that the comments be concise since they will also serve the evaluation team of the Independent Evaluation Body (IEB) to confirm or modify the score.

C. The last section, "**Evidence**", is intended to incorporate the references that show compliance with the ME. This evidence can adopt different ways:

- Documents that describe how the HCP carries out different processes, activities, flyers, etc.
- List of indicators, guidelines and protocols, patient associations, etc.

In both cases you can attach the document or the link that allows the IEB evaluator to access the document.

The ***list of documents to be prepared by ERNs and their Members*** includes some of the evidence that can be provided.

4. Self-evaluation form for the Network

A. SELF EVALUATION OF THE NETWORK: GENERAL INFORMATION			
I. BASIC INFORMATION OF THE NETWORK			
1	Network's name		
2	Address of ERN coordinator		
3	Country		
4	Network coordinator Title First name Last name Tel e-mail		
5	Members and roles of the ERN coordination team: Name: Role: Name: Role: Name: Role: Name: Role:		
II. MEMBERS OF THE NETWORK			
5.	Please list the HCPs that belong to your Network (all) and the contact data of the HCP representative (only for HCPs to be evaluated: those starting their ERN membership in 2017)		

Name of HCP	Country	Name of representative[4]	Mail and phone contact[4]

[4] Only for those HCPs to be evaluated

A. SELF EVALUATION OF THE NETWORK: GENERAL INFORMATION			

6.	Please describe the organization of the Board/Governing body and the roles/responsibilities assumed by each member, as well as the work-packages that they have coordinated, if any, as well as other work-packages coordinators if they are not members of the Board

Board member	**Role/Responsibilities**	**Work-packages/tasks/working groups that they have coordinated**
Work-packages/tasks coordinators who are not in the Board		

7	Please list the Network patient representatives

A. SELF EVALUATION OF THE NETWORK: GENERAL INFORMATION			
Name of patient representative and affiliation	**Country**	**Disease area**	**Mail and phone contact**

III. KNOWLEDGE AND EXPERTISE FOR THE NETWORK AND HCPs.	
8	Please mention if there has been any change in the specific criteria requested to the Members of the Network in the last 5 years and explain which in the following sections

Minimum thresholds (Patients and procedures)	Qualifications for the core multidisciplinary healthcare team	Qualifications for the extended multidisciplinary healthcare team members	Equipment, infrastructure, and IT

IV. ACTIVITY	
9	Please list the originally estimated annual activity for the main areas of expertise of the Network and the list of real data in 2021

Activity	Estimated annual activity at the beginning	Real activity in 2021

B. SELF EVALUATION OF THE NETWORK: CRITERIA

1 GOVERNANCE AND COORDINATION

1.1 The ERN has established a clearly defined governance framework that ensures appropriate ERN coordination and oversight

Measurable Elements	0	1	2	Comments	[5]
1.1.1 The structure and the implementation of the rules of procedure of the ERN's coordination board have facilitated the organization of tasks and the incorporation of new members.	☐	☐	☐		
1.1.2 An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality improvement, evaluation, meetings, and other activities.	☐	☐	☐		
1.1.3 Mechanisms to maintain or enhance the level of collaboration among the ERN members as well as their affiliates have been put into practice.	☐	☐	☐		
1.1.4 HCPs have been involved for specific ERN-related tasks, sharing responsibilities among all the Members of the ERN.	☐	☐	☐		

1.2 The ERN has developed regular evaluation and monitoring processes enabling the assessment of the ERN's progress

Measurable Elements	0	1	2	Comments	
1.2.1 An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the ERN and its Members.	☐	☐	☐		
1.2 2 There is an internal assessment of HCPs' participation	☐	☐	☐		
1.2.3 HCP professionals' satisfaction with the performance of the ERN is					

[5] The Symbol indicates the requirement to have ready at the time of the self-evaluation a specific document as evidence of compliance. These documents are to be submitted at the request of the IEB.

periodically evaluated	☐	☐	☐		
1.3 HCP professionals' satisfaction with the performance of the ERN is periodically evaluated					
Measurable Elements	**0**	**1**	**2**	**Comments**	
1.3.1 Patient representatives have been included in the governance framework of the ERN.	☐	☐	☐		
1.3.2 The Board has incorporated the opinion of patients and families when outlining strategies.	☐	☐	☐		
1.3.3 Patients and support groups are major stakeholders in ERN-related activities.	☐	☐	☐		
1.3.4 The ERN monitors and evaluates the involvement of patients in the activities of the ERN.	☐	☐	☐		
1.4 The ERN has implemented actions to ensure its sustainability					
Measurable Elements	**0**	**1**	**2**	**Comments**	
1.4.1 The ERN has identified goals, opportunities, and threats for the future.	☐	☐	☐		
1.4.2 The ERN has evaluated its own organizational and economic viability.	☐	☐	☐		
1.4.3 The ERN has developed a financial plan to meet its objectives including funding efforts and a justified distribution of resources across members.	☐	☐	☐		
1.4.4 The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for its long-term sustainability.	☐	☐	☐		
2 CLINICAL CARE					
2.1 The ERN has developed a strong clinical care management strategy: Clinical guidelines, care pathways and best practices for clinical care and transitions					

Measurable Elements	0	1	2	Comments	
2.1.1 The ERN has developed or adapted (from other sources) and disseminated clinical guidelines and other types of clinical decision-making tools in collaboration with the HCPs.	☐	☐	☐		
2.1.2 The ERN has implemented guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.	☐	☐	☐		
2.1.3 The ERN has developed recommendations for care pathways based on the needs of patients, clinical evidence, and on the available organizational, professional, and technological resources.	☐	☐	☐		
2.1.4 The ERN has worked on recommendations for cross-border care pathways to assure equality in the access to care within its area of expertise, according to the legislation applicable.	☐	☐	☐		
2.1.5 The ERN follows up the implementation of care pathways to encourage consistent use across its Members.	☐	☐	☐		
2.1.6 Guidelines, care pathways, and protocols are rechecked and updated if needed at least every three years.	☐	☐	☐		
2.2 The ERN has implemented a multidisciplinary approach to care					
Measurable Elements	**0**	**1**	**2**	**Comments**	
2.2.1 The ERN has implemented a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.	☐	☐	☐		

2.3 The ERN has established mechanisms for the integration of eHealth and Information and Communication Technologies (ICT) clinical tools

Measurable Elements	0	1	2	Comments	
2.3.1 The ERN promotes the use of technologies such as telemedicine, e-Health records, remote consultation, health information portals, electronic transfer of prescriptions, multidisciplinary e-Meetings designed according to the needs and requirements of patients and families	☐	☐	☐		
2.3.2 The ERN has implemented the CPMS to share clinical data, images, and additional information. If the ERN uses any other system, this should be compatible in all its centres and must meet national and European legal requirements.	☐	☐	☐		

3 QUALITY AND PATIENT SAFETY

3.1 The ERN has defined a quality and patient safety strategy

Measurable Elements	0	1	2	Comments	
3.1.1 The strategy includes specific objectives and recommended activities for their achievement.	☐	☐	☐		

3.2 The ERN has implemented quality and patient safety indicators to monitor clinical processes, performance and outcomes of care

Measurable Elements	0	1	2	Comments	
3.2.1 The ERN has selected a pool of measures (indicators) to monitor clinical processes, performance and outcomes of care.	☐	☐	☐		
3.2.2 The indicators are periodically reported, and the information is used for collective reflection on outcomes to learn and improve.	☐	☐	☐		

4 PATIENT CENTRED CARE

4.1 The ERN has implemented mechanisms to empower patients through patient education and engagement

Measurable Elements	0	1	2	Comments	
4.1.1 Educational resources for patients addressing disease management, coping skills and other practical skills, have been developed and disseminated	☐	☐	☐		
4.1.2 The ERN produces tailored information on patient safety standards and safety measures for patients and families to reduce or prevent errors.	☐	☐	☐		

4.2 The ERN has developed strategies for patient involvement

Measurable Elements	0	1	2	Comments	
4.2.1 The ERN collaborates with patient organisations to develop and implement care pathways, guidelines, protocols, and indicators.	☐	☐	☐		
4.2.2 The ERN has undertaken initiatives to improve the safety and quality of care in collaboration with patient organizations.	☐	☐	☐		

4.3 The ERN has implemented actions to measure and learn from patient experience

Measurable Elements	0	1	2	Comments	
4.3.1 The ERN has established a standardised common tool or methodology for measuring the patient and family experience.	☐	☐	☐		
4.3.2 The ERN periodically evaluates the needs and barriers to care experienced by patients and families and uses this information to implement actions to improve care	☐	☐	☐		

5 RESEARCH

5.1 The ERN has implemented strategic actions to fill research gaps and promote innovation in medical science

Measurable Elements	0	1	2	Comments	
5.1.1 Research gaps and opportunities have been identified and a research agenda has been developed.	☐	☐	☐		
5.1.2 The ERN has actively involved patients and other stakeholders in identifying research gaps and developing the agenda.	☐	☐	☐		
5.1.3 The ERN maintains ongoing technical oversight and discussions with Members to closely monitor and provide feedback of the research throughout the process.	☐	☐	☐		
5.1.4 The ERN implements actions to provide the future workforce with knowledge and skills to lead research.	☐	☐	☐		

5.2 The ERN has developed a framework for collaborative research across the ERN

Measurable Elements	0	1	2	Comments	
5.2.1 The ERN fosters collaborative instrumental efforts (multicentre trials, participation in EU projects, etc.) amongst its Members, Affiliated Partners and relevant patient, professional and research organisations.	☐	☐	☐		

5.3 The ERN reinforces research and epidemiological surveillance through setting up of shared registries and databases

Measurable Elements	0	1	2	Comments	
5.3.1 The ERN works to establish an EU wide solution for data sharing.	☐	☐	☐		
5.3.2 The ERN promotes the development of comprehensive registries and databases.	☐	☐	☐		

6 EDUCATION AND TRAINING

6.1 The ERN has identified education, training, and professional development gaps within its area of expertise and has defined and addressed priority areas for teaching and training

Measurable Elements	0	1	2	Comments	
6.1.1 The ERN has identified education, training, and professional development gaps within its area of expertise and defined priority areas for teaching and training.	☐	☐	☐		
6.1.2 Plans have been implemented to address the priority areas for teaching and training in collaboration with Members, scientific societies, and other partners	☐	☐	☐		
6.1.3 The plans have been evaluated and the areas of improvement identified have been addressed in the plans for the coming years.	☐	☐	☐		
6.1.4 ERN members periodically meet to review and share best practices, and discuss new evidence-based treatments, therapies, and healthcare technologies	☐	☐	☐		

6.2 The ERN has enhanced educational activities and training opportunities across Europe for HCPs within and outside the ERN.

Measurable Elements	0	1	2	Comments	
6.2.1 Actions oriented to improve access to the educational resources available across Europe have been carried out	☐	☐	☐		
6.2.2 The participation of specialized healthcare professionals from Member States with insufficient number of patients or lacking technology or expertise has been facilitated and increasingly achieved	☐	☐	☐		

7 NETWORKING AND DISSEMINATION

7.1 The ERN has developed a robust networking system for national and international collaboration and sharing of knowledge, best practices, expertise, and resources.

Measurable Elements	0	1	2	Comments	
7.1.1 The ERN has enhanced the collaboration with other ERN and HCPs to exchange and disseminate knowledge, best practices, clinical expertise, or other resources.	☐	☐	☐		
7.1.2 The ERN has developed collaboration strategies with Affiliated Partners from Member States with an insufficient number of patients or lacking technology or expertise to develop their skills.	☐	☐	☐		
7.1.3 The ERN has developed partnerships with other stakeholders of interest, such as scientific societies, centres of expertise, diagnostic laboratories, patient organisations, social care providers, industry, affiliated research groups or national healthcare authorities.	☐	☐	☐		

7.2 The ERN has developed information and dissemination strategies regarding referrals across Member States.

Measurable Elements	0	1	2	Comments	
7.2.1 The ERN provides accessible information highlighting sites and roadmaps for cross border expert advice and patients' referrals.	☐	☐	☐		

7.3 The ERN gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside itself.

Measurable Elements	0	1	2	Comments	
7.3.1 The ERN has defined and implemented a comprehensive communication and dissemination strategy.	☐	☐	☐		
7.3.2 The ERN has developed actions to align information across target groups, i.e., defining audience, message, and methods to	☐	☐	☐		

achieve the maximum level of inclusiveness of different groups.					

C. SELF EVALUATION OF THE NETWORK: ACCOMPLISHTMENT OF OBJECTIVES		
Please mark the objectives (at least 3) selected from Article 12(12) of Directive 2011/24/EU that the ERN had selected in the initial application. Describe the main accomplishments achieved in the past 5 years and rate the level of accomplishment of the objectives after the 5 years.		
Objectives	**Main accomplishments in the past 5 years**	**Level of accomplishment**
☐ *to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to contribute to the pooling of knowledge regarding sickness prevention.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to facilitate improvements in diagnosis and the delivery of high-quality, accessible, and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing

☐ *to maximise the cost-effective use of resources by concentrating them where appropriate.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to reinforce research, epidemiological surveillance like registries and provide training for health professionals*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge, and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network.*		☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing

D. ADDITIONAL INFORMATION
Please mention any barriers encountered by the Network to get meaningful contribution of HCP members.
Please provide your reflections regarding the whole ERN system.
Any additional information they would like to provide regarding the evaluation process.

5. Self-evaluation form for HCPs

A. SELF EVALUATION OF HEALTHCARE PROVIDERS: GENERAL INFORMATION			
I. BASIC INFORMATION OF THE HEALTHCARE PROVIDER			
1	Network's name		
2	Healthcare Provider's name		
3	Address		
4	Country		
5	Healthcare Provider representative as a member of the Board of the Network Title First name Last name Tel e-mail		
II AREA OF EXPERTISE OF THE HEALTHCARE PROVIDER			
6.	Please list the specific disease (s), condition (s) and highly specialised intervention (s) covered by the Healthcare Provider. Specific the code/ICD/Orphanet classification (s) if available		
Sub-Thematic Areas of Expertise	**Rare or Complex Disease (s), Condition (s), or Highly Specialised Intervention (s)**		**Code / ICD / Orphacode Group of codes[6]**

[6] There is no need to detailed reference to all codes. The coding Chapters/Blocks are sufficient. See ICD 10-CM.

A. SELF EVALUATION OF HEALTHCARE PROVIDERS: GENERAL INFORMATION	
7	Types of services covered by the Healthcare Provider within the Network's area of expertise. Please select all that apply.

☐ Prevention ☐ Acute Care ☐ Ambulatory services

☐ Diagnostic services ☐ Interventional therapeutic services ☐ Rehabilitation

☐ Social care services ☐ Palliative care services ☐ Others

III. ACTIVITY OF THE HEALTHCARE PROVIDER

8	Number of patients with the rare or complex disease (s), condition (s) or highly specialised intervention (s) seen by the Healthcare Provider each year

Specific condition	Measure	2019	2020	2021	Minimum number established by the Network[7]
Specific condition 1	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				
Specific condition 2	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				
Specific condition 3	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				
Specific condition 4	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				
Specific condition 5	Number of patients/year				
	Number of new patients/year				

[7] According to the specific criteria set by the ERN for the assessment process

A. SELF EVALUATION OF HEALTHCARE PROVIDERS: GENERAL INFORMATION					
	Number of procedures/year				
Specific condition 6	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				
Specific condition 7	Number of patients/year				
	Number of new patients/year				
	Number of procedures/year				

9	Please indicate the research activities and clinical trials, at both national and international level, within the Network's area of expertise in which the HCP has participated in the framework of the Network

10	Please indicate the results of the *monitoring indicators*[8] provided to the Network in the last 3 years			
Name of indicator		**2019**	**2020**	**2021**

[8] ERN Continuous Monitoring and Quality Improvement System (ERN CMQIS)

A. SELF EVALUATION OF HEALTHCARE PROVIDERS: GENERAL INFORMATION			

11	Please indicate the results of the *clinical indicators*[9] agreed in the framework of your Network for last year.
Name of indicator	2021

IV. ADDITIONAL INFORMATION	
12	Have you received any type of support (resources) from your hospital, Health Administration or Member State for your activities related to the Network? Please explain
13	Mention what aspects have hindered your participation in the Network or have prevented a more active participation.
14	Any additional information you would like to provide regarding the evaluation process.

[9] Specific indicators for the ERN, if any

B. SELF EVALUATION OF HEALTHCARE PROVIDERS: CRITERIA

1 PATIENT CENTRED CARE

1.1 The HCP team has implemented strategies to ensure that care is patient-centred, and that patients' rights, and preferences are respected.

Measurable Elements	0	1	2	Comments	10
1.1.1 The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.	☐	☐	☐		
1.1.2 The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand	☐	☐	☐		

1.2 The HCP team provides educational activities for patients and their families with the aim of improving knowledge of the disease and the capacity for self-management to face the different aspects of their disease.

Measurable Elements	0	1	2	Comments	
1.2.1 Patient and family educational needs are addressed in a defined process	☐	☐	☐		
1.2.2 Education activities are recorded in the medical record	☐	☐	☐		

[10] The Symbol indicates the requirement to have ready at the time of application a specific document as evidence of compliance. These documents are to be submitted at the request of the IEB

1.3 The HCP team provides patients with clear and transparent information about the complaints' procedures and remedies and ways of redress available for both domestic and foreign patients.

Measurable Elements	0	1	2	Comments	
1.3.1 The information about complaints, violation of the rights, and concern of the care and/or safety of patients and their families is periodically analysed and integrated into a continuous quality improvement process. An annual report is made on the complaints and the improvement actions carried out.	☐	☐	☐		

1.4 The HCP team regularly collects information on patient satisfaction within the ERN's area of expertise and uses this information to make ongoing improvements.

Measurable Elements	0	1	2	Comments	
1.4.1 The HCP team routinely measures patient and family satisfaction using the ERN common tool.	☐	☐	☐		

1.5 The HCP team obtains the patient informed consent to provide clinical risk treatments and procedures.

Measurable Elements	0	1	2	Comments	
1.5.1 The Informed Consent (IC) is documented in the patient's medical record, including the risks, benefits, and alternatives of the procedure to be performed, and must be understandable to patients	☐	☐	☐		
1.5.2 The document to obtain IC for research must contain information on the risks, benefits, and alternatives of the procedure to be performed, and conflicts of interest (financial or not financial)	☐	☐	☐		
1.5.3 The patients' medical records included in a clinical trial contain information about their participation in it.	☐	☐	☐		

1.6 The HCP team maintains transparency by providing information to patients about clinical outcomes, treatment options, and quality and safety standards that are in place.

Measurable Elements	0	1	2	Comments	
1.6.1 The HCP team provides comprehensive diagnostic and treatment information	☐	☐	☐		
1.6.2 Information is provided in the language of the different populations being served.	☐	☐	☐		
1.6.3 The information necessary for the follow-up of the patient after the treatment is provided	☐	☐	☐		
1.6.4 The HCP team provides information on coordinating care with other levels from care.	☐	☐	☐		
1.6.5 The information provided to the patient and the family on the follow up and coordinating care with other levels of care.is included in the clinical record.	☐	☐	☐		
1.6.6 Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure	☐	☐	☐		

1.7 The HCP implements a pain identification and management protocol.

Measurable Elements	0	1	2	Comments	
1.7.1 In hospitalised patients with rare diseases or complex patients, pain is regularly identified with a standardised scale as established in the hospital`s protocol.	☐	☐	☐		

1.8 Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making.

Measurable Elements	0	1	2	Comments	
1.8.1 Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making.	☐	☐	☐		

1.9 The HCP team collaborates and carries out activities with patient associations.

Measurable Elements	0	1	2	Comments	
1.9.1 The HCP team provides information on patients' associations that can support the patient and family	☐	☐	☐		
1.9.2 The HCP team collaborates and carries out activities with patients' associations	☐	☐	☐		

2 ORGANISATION AND MANAGEMENT

2.1 The HCP team follows policies and procedures to manage the services offered to cross-border patients, including an easy access to information regarding any tariffs that may be in place.

Measurable Elements	0	1	2	Comments	
2.1.1 The HCP team establishes collaboration with affiliated centres in neighbouring countries for cross-border care or for training / dissemination of information for professionals and patients.	☐	☐	☐		
2.1.2 The HCP team establishes and maintains a set of policies and procedures addressing aspects for the management and health care services of cross border patients.	☐	☐	☐		
2.1.3 The HCP team shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, as well as services provided and expected benefits.	☐	☐	☐		

2.2 The HCP team implements procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.

Measurable Elements	0	1	2	Comments	
2.2.1 When necessary, the HCP team has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.	☐	☐	☐		
2.2.2 The HCP team sends the receiving organization a written summary about the patient's clinical condition and the interventions carried out in the hospital from which he/she is referred. The process is recorded in the medical record	☐	☐	☐		

2.3 The HCP team has policies and procedures implemented to communicate post discharge with clinicians, including cross border.

Measurable Elements	0	1	2	Comments	
2.3.1 Discharge reports contain at a minimum: diagnoses, significant physical findings; diagnostic, surgical and medical procedures performed, medication received at discharge, and follow-up instructions.	☐	☐	☐		
2.3.2 The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.	☐	☐	☐		

2.4 The HCP team is integrated into national networks.

Measurable Elements	0	1	2	Comments	
2.4.1 The HCP team collaborates in training or dissemination activities with centres **which are not members of the ERN**	☐	☐	☐		

2.5 The HCP team uses CPMS and includes all the information required.

Measurable Elements	0	1	2	Comments	
The HCP team shares patient information or participates in panels of complex cases through the CPMS with other members of the ERN.	☐	☐	☐		
The CPMS of each patient includes: a) physical needs b) social needs c) psychological needs d) treatment and care plan e) sign off completed	☐	☐	☐		

3 RESEARCH, EDUCATION AND TRAINING

3.1 The HCP team participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.

Measurable Elements	0	1	2	Comments	
3.1.1 The HCP team has a defined set of objectives for its education and training activities aligned with ERN	☐	☐	☐		
3.1.2 The HCP team regularly detects the training needs of the staff members.	☐	☐	☐		
3.1.3 Education and training activities are delivered to providers involved in the same chain of care within and outside the HCP's facility.	☐	☐	☐		
3.1.4 The HCP team participates in the training activities organised by the ERN.	☐	☐	☐		

3.2 The HCP team has the capacity to carry out research activities and demonstrated research experience in the framework of the ERN.

Measurable Elements	0	1	2	Comments	
3.2.1 The HCP team leads and/or participates in research activities and clinical trials, at both national and international level, within the ERN's area of expertise.	☐	☐	☐		
3.2.2 The HCP team ensures that records from research activities and clinical trials are safely stored.	☐	☐	☐		
3.2.3 The HCP team involves patients and / or their representatives in the most relevant aspects of the research process.	☐	☐	☐		
3.2.4 The HCP team shares the results, in a timely manner, from its research activities and clinical trials through scientific publications	☐	☐	☐		
3.2.5 The results should be disseminated to patient associations in lay language.	☐	☐	☐		
3.2.6 The HCP team provides patients' information for the registries or databases promoted by the ERN.	☐	☐	☐		
3.2.7 The HCP team is contributing to disseminate the ERN activities	☐	☐	☐		

4. EXCHANGE OF EXPERTISE, INFORMATION SYSTEMS, AND e-HEALTH

4.1 The HCP team is able to exchange expertise with other providers and provide support to them.

Measurable Elements	0	1	2	Comments	
4.1.1 The HCP team offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients'	☐	☐	☐		

treatment.					

4.2 The HCP team fosters the use of telemedicine and other e-health tools within and outside its facility.

Measurable Elements	0	1	2	Comments	
4.2.1 The HCP team uses telemedicine and other e-health tools.	☐	☐	☐		
4.2.2 Professional telemedicine guidelines available are used to guarantee the homogeneity of its use.	☐	☐	☐		
4.2.3 The HCP team should identify inclusion and exclusion criteria for potential telehealth patients.	☐	☐	☐		
4.2.4 Patients and family members who access telehealth have the right to have their privacy guaranteed.	☐	☐	☐		
4.2.5 When surveying patient and family satisfaction, satisfaction with the services provided by telehealth should be included, when appropriate.	☐	☐	☐		

4.3 The HCP team codes the information, and the information system is aligned with nationally and internationally recognised systems when appropriate in the framework of the ERN.

Measurable Elements	0	1	2	Comments	
4.3.1 The HCP team uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s), agreed within the ERN.	☐	☐	☐		

5 QUALITY AND SAFETY

5.1 The HCP team regularly monitors and improves the quality and safety of the care provided to patients with rare or low prevalence complex diseases or conditions.

Measurable Elements	0	1	2	Comments	
5.1.1 The HCP team applies a strategy of quality and safety improvement, which includes specific objectives and recommended activities for the achievement of the objectives.	☐	☐	☐		
5.1.2 The main objectives of the strategy of quality and safety improvement include: a) Hand hygiene b) Prevention and control of healthcare related infection c) Prevention of medication errors (completed medical orders, process of administration, identified high-risk medications) d) Ensure safe surgery (verification, time out and sign out) e) Unequivocal identification of patients	☐	☐	☐		
5.13 The quality and safety strategies are implemented, and the results obtained are evaluated.	☐	☐	☐		
5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications	☐	☐	☐		
5.1.5 The HCP team uses this information to make ongoing improvements.	☐	☐	☐		
5.1.6 All healthcare personnel are familiar with the system for reporting safety incidents and adverse events.	☐	☐	☐		
5.1.7 A procedure is implemented to provide information on adverse events with patient damage to patients and their families.	☐	☐	☐		

5.2 The HCP team adopts and uses clinical practice guidelines in their area of expertise.

Measurable Elements	0	1	2	Comments	
5.2.1 The HCP team adopts and implements clinical practice guidelines and decision-making tools developed or adapted by the ERN.	☐	☐	☐		
5.2.3 An annual evaluation on adequate compliance of the clinical practice guidelines is carried out using the indicators agreed in the ERN.	☐	☐	☐		

6 COMPETENCE, EXPERTISE AND OUTCOMES OF CARE

6.1 The HCP team maintains its clinical competence in the ERN's area of expertise.

Measurable Elements	0	1	2	Comments	
6.1.1 To maintain its competency and expertise, the HCP team serves the minimum/optimal number of patients per year as defined by the ERN based on professional/technical standards or recommendations	☐	☐	☐		
6.1.2 To maintain its competency and expertise, the HCP team serves the minimum/optimal number of procedures per year as defined by the ERN based on professional/technical standards or recommendations	☐	☐	☐		
6.1.3 The HCP team regularly collects, and monitors process and outcome indicators as established in the ERN.	☐	☐	☐		
6.1.4 The HCP team is actively involved in the activities organized for the development of the ERN.	☐	☐	☐		

7 HUMAN RESOURCES

7.1 The HCP has a team of trained professionals with the required competencies within the ERN's area of expertise.

Measurable Elements	0	1	2	Comments	
7.1.1 The HCP team identifies and documents the skills and professional qualifications required for the new staff in the multidisciplinary team performing activities critical to the quality of patient care.	☐	☐	☐		
7.1.2 There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.	☐	☐	☐		

7.2 The HCP team delivers a comprehensive care by a multidisciplinary and specialised team.

Measurable Elements	0	1	2	Comments	
7.2.1 There are regular structured meetings between multidisciplinary team members.	☐	☐	☐		
7.2.2 The decisions of the multidisciplinary clinical sessions on a determined patient are recorded in their medical record.	☐	☐	☐		

6. List of documents and other evidence suggested to be prepared by the Networks and their Members

NETWORK

EVIDENCE/DOCUMENT		ME
1	Rules of procedure	ME 1.1.1
2	Description of the current support infrastructure	ME 1.1.2
3	Collaboration mechanisms that have been used between the Network members as well as its affiliates	ME 1.1.3
4	List of HCP members who have been involved in the different tasks carried out by the ERN and their distribution in the work-packages or working groups	ME 1.1.4
5	Briefly description of the internal assessment process for HCP members and the outcomes	ME 1.2.2
6	Briefly description of the assessment process for HCP professionals' satisfaction and the results obtained	ME 1.2.3
7	Description of the patient involvement mechanism	ME 1.3.1
8	List the issues about the patients and families' input been requested	ME 1.3.2
9	Description of how the level of collaboration withing the network is monitored	ME 1.3.4
10	Description of identified goals, opportunities, and threats for future at network level	ME 1.4.1
11	Description of how the organizational and economic viability of the Network has been assessed.	ME 1.4.2
12	Financial Plan.	ME 1.4.3
13	Description of the connections attained with other existing networks, authorities, health systems, etc. for the long-term sustainability.	ME 1.4.4
14	List of clinical guidelines and clinical decision-making tools disseminated	ME 2.1.1
15	List of guidelines/protocols/best practices to support transition and continuity of care	ME 2.1.2
16	List of care pathways recommendations developed	ME 2.1.3
17	Recommendations for care pathways including cross-border elements developed	ME 2.1.4
18	Results of the follow-up of the implementation of care pathways	ME 2.1.5
19	Description of activities carried out to promote the use of ICT clinical tools	ME 2.3.1
20	The strategy or any other document regarding the quality and patient safety approach	ME 3.1.1
21	List the measures (indicators) selected to monitor clinical processes, performance and outcomes of care	ME 3.2.1
22	The analysis performed out of the indicators reported during the last year	ME 3.2.2
23	List and brief description of educational resources developed	ME 4.1.1
24	List of collaborating patient organisations and activities developed with them	ME 4.2.1
25	Description of initiatives carried out to improve safety and quality	ME 4.2.2

	EVIDENCE/DOCUMENT	ME
26	Description of the tool used for measuring the patient and family experience	ME 4.3.1
27	Analysis of needs and barriers to care for patients and families and the improvement actions carried out	ME 4.3.2
28	Research agenda for the previous 5 years and publications	ME 5.1.1
29	Description of the strategies for patients and other stakeholders involvement in the identification of research gaps	ME 5.1.2
30	Description of activities performed with HCP members to closely monitor and provide feedback on the research.	ME 5.1.3
31	Actions implemented to equip the future workforce with knowledge and skills to lead the investigation.	ME 5.1.4
32	List of collaborative projects and participants.	ME 5.2.1
33	Registries and databases that the ERN has developed	ME 5.3.2
34	List of priority areas for education and training	ME 6.1.1
35	Description of the annual teaching and training activities developed during the 5 years in collaboration with Members, scientific societies, and other partners	ME 6.1.2
36	Description of the evaluation of the teaching and training activities developed	ME 6.1.3
37	Description how you plan and perform review meetings with Members	ME 6.1.4
38	Description of the coverage of the educational activities within and outside the Network	ME 6.2.1 and 6.2.2
39	List the networks and centres of expertise with which the ERN collaborates and the nature of the collaboration	ME 7.1.1
40	List the Affiliated Partners with which the ERN collaborates	ME 7.1.2
41	List the stakeholders with which the ERN collaborates	ME 7.1.3
42	Examples of information provided to facilitate access to cross-border expert advice.	ME 7.2.1
43	Description of the communication and dissemination strategy	ME 7.3.1
44	Describe the target groups identified for communication identified and how the information has been tailored	ME7.3.2

HCP TEAM

	SUGGESTED EVIDENCE/ DOCUMENT	ME
1	Specific written information provided to the patients.	ME 1.1.1
2	Process to identify the educational needs of patients	ME 1.2.1
3	Last year report of patients' complaints and proposed improvement actions if applicable.	ME 1.3.1
4	Results from the last year assessment of the experience or satisfaction of patients and families.	ME 1.4.1
5	Template document of informed consent for research	ME 1.5.2
6	HCP policy/protocol regarding disclosure to patients	ME 1.6.6
7	Description of process followed for patients' involvement in their care process	ME 1.8.1
8	Specific information provided about patients' associations (examples)	ME 1.9.1
9	List of patient associations and a brief explanation of the activities carried out	ME 1.9.2
10	List of affiliated centres in neighbouring countries for cross-border care	ME 2.1.1
11	List of policies and procedures established for cross border patients	ME 2.1.2
12	List of centres or highly specialized units outside to which you can refer patients	ME 2.2.1
13	3 anonymized copies of discharge reports	ME 2.3.1
14	Training activities at national level (list and a brief explanation of each)	ME 2.4.1
15	List of educational and training goals aligned with ERN and addressed to staff and other care professionals	ME 3.1.1
16	The process followed to identify training needs.	ME 3.1.2
17	List of training activities within and outside the Healthcare Provider's facility (list and a brief explanation of each)	ME 3.1.3
18	List the training activities organised by the Network in which you have participated and what has the participation consisted of	ME3.1.4
19	List of research activities of the Network in which you have participated (clinical trials and observational prospective studies).	ME 3.2.1
20	Description of the process followed to involve patients and families included in research studies.	ME 3.2.3
21	List of peer reviewed publications in scientific journals in the framework of the Network in which you have participated	ME 3.2.4
22	List of other professionals and caregivers with whom you maintain an advisory service.	ME 4.1.1
23	List of procedures in which telemedicine can be used in your HCP team	ME 4.2.1
24	List of e-health tools (list and a brief explanation of each)	ME 4.2.1
25	Telemedicine guidelines used	ME 4.2.2
26	Inclusion and exclusion criteria for potential telehealth patients.	ME 4.2.3
27	Quality and safety strategies: objectives and actions carried out in the period	ME 5.1.1
28	Results of the evaluation of the quality program from last year.	ME 5.1.3
29	Description of the improvement actions after analysing the reported adverse events	ME 5.1.5
30	List of clinical guidelines (developed or adapted by the ERN) that have been implemented in your patients. You can include other good practices recommended by the Network.	ME 5.2.1

31	Results of the evaluation of adequate compliance with the clinical practice guidelines from last year.	ME 5.2.2
32	Annual data (from the last 5 years), of the number of patients of the group of diseases you serve. Include the reference data agreed by the Network for each of the items.	ME 6.1.1[11]
33	Annual data (from the last 5 years), of the number of procedures of the group of diseases you serve. Include the reference data agreed by the Network for each of the items.	ME 6.1.2[11]
34	a) Result of the monitoring indicators reported periodically to the European Commission for the last 3 years b) Result of the clinical indicators established by the Network.	ME 6.1.3[11]
35	List activities or working groups of the Network in which you have participated (list and a brief explanation of each)	ME 6.1.4

[11] This evidence is requested as general information in the self-evaluation form

7. Sampling methodology for on-site / on-line visits

If necessary, on-site visits could only be conducted in a sample of the HCPs.

Step 1: calculate the sample size of HCPs to be evaluated from the total population (N = 844) based on scientific and practical criteria, using a 95% confidence level. Regarding statistical precision for visits, two options are proposed, each one targeting a desired precision:

1) Precision of 0.06%: sample size of 267 HCPs (31.8% of the population)

2) Precision of 0.07%: sample size of 196 HCPs (23.2% of the population)

Table 1 shows the number of HCPs per ERN to be sampled for the 2 options presented above.

Table 1. Weighted distribution of HCPs for each ERN for onsite audits

Name of ERN	Total number of members per ERN for 2022 evaluation	SCENARIO 1: n = 267 Total number of HCPs visited for precision = 0.06%	SCENARIO 2: n = 196 Total number of HCPs visited for precision = 0.07%
BOND	27	**9**	**6**
CRANIO	22	**7**	**5**
Endo-ERN	62	**20**	**14**
EpiCARE	24	**8**	**6**
ERKNet	33	**10**	**8**
ERNICA	19	**6**	**4**
EURACAN	59	**19**	**14**
EuroBloodNet	60	**19**	**14**
euROGEN	23	**7**	**5**
EYE	25	**8**	**6**
GENTURIS	20	**6**	**5**
GUARD-HEART	22	**7**	**5**
ITHACA	34	**11**	**8**
RARE-LIVER	24	**8**	**6**
LUNG	50	**16**	**12**
MetabERN	63	**20**	**15**
EURO-NMD	57	**18**	**13**
PaedCAN	54	**17**	**13**
ReCONNET	25	**8**	**6**
RITA	20	**6**	**5**
RND	31	**10**	**7**
Skin	46	**15**	**11**
TRANSPLANT-CHILD	17	**5**	**4**
VASCERN	27	**9**	**6**
Total	**844**	**267**	**196**

Step 2: Weighted distribution of visits among the Networks

Evaluations by country in each ERN
Total number of HCPs from a country in the ERN/Total number of HCPs in the ERN

Step 3: selection of HCPs from each ERN

Selection criteria: At least 1 HCP from each country per ERN. If the required size is not enough to have 1 HCP from each country, they will be randomly chosen from the list of countries

The remaining HCPs are weighted based on the number of HCPs per country in the respective ERN and selected accordingly. Nonetheless, this remaining sample could also include specific HCPs selected by the IEB evaluators during the documentation review, particularly those with more need for improvement or because was flagged by the board of the network.

8. Scoring guidelines for the Network

This tool is intended to guide the evaluators while using the scoring categories for the evaluation criteria. It describes the categories specifically and objectively so that the margin for interpretation remains narrow. It includes explanatory examples that could be useful for the evaluators' training.

The degree of compliance with each ME is scored using a 3-point scale (0, 1 and 2):

Rating	Guidelines
0: No activity / Not developed	***All Criteria:*** **this rating is used if the answer is "scarcely" or "none" to the specific measure and/or when there are no actions in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented by any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. • When there are multiple requirements in one measure, less than 50% are present.
1: Partially developed	***All Criteria:*** **this rating is used if the answer is "incomplete" or "partway" to the specific measure and/or when there are some actions 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 does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully developed	***All Criteria:*** **this rating is used if the answer is "totally" or "completely" to the specific measure and/or when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance covers the whole period of time in which the requirement is applicable • All actions required have been implemented or are underway • When there are multiple requirements in one measure, all are present.

Some **examples** can be:

Measurable element 1.1.2: An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality improvement, evaluation, meetings and other activities.

The Network is expected to describe the current resources available (management, administrative support, IT tools….) for the collection of monitoring indicators, organization of meetings, etc.

- 0: if the ERN does not provide information about this infrastructure or the resources for these tasks are very low.
- 1: if there are resources for some tasks but not for all.
- 2: if the resources are sufficient for the tasks.

Measurable element 4.1.2: The ERN produces tailored information on patient safety standards and safety measures for patients and families to reduce or prevent errors.

The Network is expected to provide some specific information developed, like flyers, online information, for instance on hand hygiene, patient identification, prevention of medication errors, others.

- 0: if the ERN does not provide any informative materials developed
- 1: if the ERN provides them, but they are not well adapted for the patients or the subjects addressed are very limited
- 2: if the ERN provides adequate information developed

Measurable element 1.2.3: HCP professionals' satisfaction with the performance of the ERN is periodically evaluated.

The Network is expected to provide the data periodically evaluated on the satisfaction of the HCP teams.

- 0: If the ERN does not provide information, that is, satisfaction has not been measured.
- 1: if the ERN provides information, but it has only been measured once
- 2: if the ERN provides information for at least 2 measurements in different periods

9. Scoring guidelines for the HCP team

This tool is intended to guide the evaluators while using the criteria. It will describe the categories specifically and objectively so that the margin for interpretation remains narrow.

The degree of compliance with each ME is scored using a 3-point scale (0, 1 and 2):

Rating	Guidelines
0: No activity / Not developed	***All Criteria:*** **this rating is used if the answer is "scarcely" or "none" to the specific measure and/or when there are no actions in place or there is insufficient evidence to support compliance.** Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. • When there are multiple requirements in one measure, less than 50% are present.
1: Partially developed	***All Criteria:*** **this rating is used if the answer is "incomplete" or "partway" to the specific measure and/or when there are some actions in place or there is some evidence to support compliance.** Considerations: • Evidence of compliance does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully developed	***All Criteria:*** **this rating is used if the answer is "totally" or "completely" to the specific measure and/or when there is sufficient evidence to support compliance**. Considerations: • Evidence of compliance covers the whole period of time in which the requirement is applicable • All actions required have been implemented or are underway • When there are multiple requirements in one measure, all are present.

To facilitate this scoring process for the evaluation team, the ***Operational criteria for ERNs and HCPs evaluation*** document has incorporated the scoring categories suggested for the evaluation of each measurable element (ME).

In some cases, a fourth category is introduced when the ME may not be applicable to HCP teams, such as "not applicable" (NA). In some ME, the evaluation is dichotomous, and the scoring will be 0 or 2.

Several mechanisms are used to assess compliance with the MEs by the HCPs teams:

- Information reported in the self-evaluation
- Onsite or online audit: professionals' interview, patients interview and review of medical records

Below there is an example of each of them.

1. Self-evaluation

Measurable element 3.2.7: The HCP team is contributing to disseminate the ERN activities.

The suggested scoring is:

- 0: The HCP does not provide information
- 1: The HCP provides information, but has only used 1 channel for dissemination
- 2. The HCP provides information, and contribution to dissemination is made in several ways.

2. Professionals' session

Measurable element 1.6.4: The HCP team provides information on coordinating care with other levels of care.

- 0: They do not provide information on how to coordinate with other levels of care.
- 1: They provide information on coordination but do not include all the levels of care to which they can refer their patients (primary care, other hospitals, rehabilitation services, etc.).
- 2: They provide information on coordination with all the levels of care to which they can refer their patients.

3. Patients' session

Measurable element 1.6.3: The information necessary for the follow-up of the patient after the treatment is provided

- 0: Less than 50% of the patients present in the session claim to have received information about the follow up.
- 1: Between 50% -80% of the patients present in the session claim to have received information about the follow up.
- 2: More than 80% of the patients present in the session claim to have received information about the follow up.

4. Review of medical records

Measurable element 2.3.2. The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.

The proposed evaluation methodology is the review of 3 discharge reports of discharged cross border patients. The suggested scoring is:

- 0: None of the 3 discharge reports reviewed are in English.
- 1: 1 or 2 of the revised discharge reports are in English.
- 2: The 3 revised discharge reports are in English.
- NA: no cross-border patient has been seen in the last 5 years.

10. Guidelines to prepare virtual interviews

[With Network Coordinator and Work Package Coordinators]

This interview will take place once the evaluation team has performed the documentation review of the Network.

Purpose

The main objective will be to complete the information available (self-evaluation, grant reports and additional documents), and therefore to properly evaluate the work developed by the ERN during the 5 years period.

Possible contents

- Respond to questions raised by the ERN about the content of the criteria
- Request clarification on the responses and comments of the self-evaluation
- Request the provision of new documentation or extension of the same when the attached one does not allow for proper assessment of the evaluation criteria
- Comment on the most important discrepancies that may exist between the initial evaluation of the IEB and the self-evaluation

Proposed attendees

Coordinator of the Network and responsible of the work packages.

Before virtual interview

The evaluation team will contact the Network coordinator through an email or phone call, to inform about the interview and the recommended attendees. In addition, the evaluation team will propose a period of 1 week for the coordinator to choose the most convenient day and time for the Network and to allow the presence of all the expected attendees.

The coordinator will be informed on the objectives of the interview and the main topics to be discussed, as well as, if necessary, the documentation that at the discretion of the IEB is required to complete the self-evaluation, or any additional information that requires prior preparation by the coordinator and his team.

The evaluation team will prepare a previous script of the interview that will be sent to the coordinator of the Network.

Expected duration

The duration should not exceed 2 hours, although it will depend on the number of doubts and issues that have to be solved. When it is not possible to address all the issues in one meeting, an additional date and time will be agreed for another interview, but this should take place as soon as possible, so as not to delay the evaluation.

During the virtual interview

- Test the technology 15 minutes prior to the call.
- Brief introduction by the evaluation team.

- Brief introduction of participants themselves.
- Request the feedback of the attendees regarding the self-evaluation.
- If you want to record the session, the permission of the attendees will be requested.
- The evaluation team will ask questions about the topics in which they have doubts or for which they require additional information.
- On the part of the evaluation team, it is important to maintain a relaxed attitude that favours dialogue and allows the free expression of the attendees.
- Before finishing the interview, the evaluation team will make a summary of the topics discussed, confirming with the attendees the information received.
- When not all the issues foreseen by the IEB have been resolved, a second interview will be agreed.

After the interview

The information obtained in the interview will be used by the evaluation team to review the initial assessment of the criteria, introducing the necessary changes.

11. Guidelines to prepare onsite/online audits

The Evaluation Coordinator of the Independent Evaluation Body (IEB) will select the evaluation team for the onsite audit. It is highly recommended that the audit be carried out by the same evaluators that have performed the self-evaluation review.

Purpose

The main objective of the audit is to obtain information on those criteria that cannot be directly assessed from the information included in the self-evaluation because the source of information is either an interview with patients or professionals or the medical record.

During the audit an additional on-site document review can also be included at the discretion of the evaluation team if they consider that the information included in the self-evaluation should be completed.

Methodology

Group interviews with patients and professionals could be conducted both onsite and online, but the review of medical records is highly recommended to be carried out onsite. The IEB will decide in each case the most efficient alternative.

1. Group interview with patients

In this case, the online alternative is suggested as the most advisable, due to the difficulty of bringing patients together and because it will also allow the inclusion of cross-border patients.

Interview Preparation

- Participants: patients treated of any of the specific conditions assumed by the HCP team evaluated, within the framework of the processes defined by the Network.
- Population: patients treated and discharged or treated on an outpatient basis for the last 3 years, in order to minimize memory bias. In the case of the paediatric population if they are under 14 years of age, the interview will be conducted with one of the parents.
- Selection: a number between 6 to 8 patients is recommended and whenever possible of different specific conditions. The selection must be random: for this the evaluator will previously contact the HCP representative, to suggest the requirements for selection. For example, patients of different specific conditions, to include patients of each of the 3 years evaluated, hospitalized and outpatients and some cross border patient if the HCP team has cared for this type of patients.

The session will be conducted in English, so the presence of an interpreter (with no conflict of interest with the hospital) may be necessary.

- Recruitment: it will be carried out by the HCP team itself, after discussing the selection requirements with the evaluation team.

The HCP team must request the written consent of each participant. If the interview is to be

recorded, this aspect will have to be included in the consent. When contacted for the recruitment, patients will be explained the objectives of the session and its expected length.

- The evaluation team will prepare the interview script, which should include the topics of those measurable elements (ME) whose source of information is the patient. They are:

MEs to be evaluated during the interview with patients	ME 1.1.2 ME 1.6.1 ME 1.6.3 ME 4.2.5

- Choose the virtual video conference system that is most easily accessible to participants
- Recommended length: 60 minutes.

During the interview

It is not recommended that any professional from the HCP team attends the interview, to avoid bias.

Before logging in, the evaluation team must verify that all attendees have signed the consent.

- The evaluation team will introduce themselves at the beginning of the session and comment on the objectives.
- A few minutes will be taken for each of the patients to introduce themselves.
- Attendees should be reminded that they can express their opinion freely and that the anonymity of opinions will be maintained.
- Next, the evaluation team will ask the questions of their script and promote the participation of all attendees in each of the topics.
- Before the end of the session, the evaluation team will agree with the attendees on the result of the answers, considering that the answers that have had the greatest consensus will be chosen and not include individual opinions.
- It is important not to exceed the expected time.

After the interview

The evaluation team will review and rate each ME based on the majority opinions of the attendees. They will follow the guidelines suggested in the scoring guide of the respective ME.

2. Group interview with professionals

This can be carried out both online and onsite since the professionals belong to the same centre.

Interview Preparation

The evaluation team will contact the HCP representative through an email or phone call, informing of the objectives of the interview and the ME that will be reviewed and jointly set a date to facilitate the presence of all the expected attendees.

- The evaluation team will prepare the script of the interview, which must include the topics of those measurable elements (ME) whose source of information is the professional. They are:

MEs to be evaluated during the interview with professionals	ME 1.6.2 ME 1.6.4 ME 1.9.1 ME 2.5.1 ME 4.2.2 ME 4.2.4 ME 5.1.2 ME 5.1.7 ME 5.1.8 ME 7.1.3

- The evaluation team should recommend the HCP representative to have available for the interview some documents that can facilitate the required evidence, such as the safety protocols (ME 5.1.2) or information on the reporting system of patient safety incidents (ME 5.1.7 and 5.1.8)
- Participants: the HCP representative and all members of the multidisciplinary team deemed appropriate to provide information.
- Expected duration: 60-90 minutes.

During the interview

- The evaluation team will introduce themselves at the beginning of the session and comment on the objectives.
- A few minutes will be taken for each of the attendees to introduce themselves.
- Next, the evaluation team will ask the questions included in their script and promote the participation of all attendees in the assessment of each of the topics.
- Before the end of the session, the evaluation team will check the result of the answers with the attendees.

After the interview

The evaluation team will review each of the MEs that have been discussed during the interview and will score them following the guidelines suggested in the scoring guide of the respective MEs.

3. Medical records review

To perform the review of medical records the most recommended option is the onsite visit.

Preparation of the review medical records

- The evaluation team will prepare the contents of the medical records review, which must include the following measurable elements (ME):

MEs to be evaluated during the medical records review	ME 1.2.2 ME 1.5.1 ME 1.5.3 ME 1.6.5 ME 1.7.1 ME 2.2.2 ME 2.3.1 ME 2.3.2 ME 2.5.2 ME 3.2.2 ME 7.2.2

- The coordinator of the HCP team will prepare a list of all the patients of the different specific conditions that the HCP team cares for. Inpatients and outpatients from the last 3 years will be included. The following information shall be specified in the list:
    a) specific condition
    b) age
    c) if the patient has been part of a clinical trial (3.2.2)
    d) if the patient has been transferred to another centre (2.2.2)
    e) if the patient is cross border (2.3.2)
    f) if the patient has been included in the CPMS (2.5.2)

  In NO case will the name of the patient be included. A code will be agreed between the evaluation team and the coordinator to identify each case.

- This list will be sent to the evaluation team that will make a random selection of the necessary cases and will send the selection to the coordinator with enough time so that the HCP team can have the medical records available on the day of the review.
- Number of medical records selected: Most MEs are common to all types of patients, and 3 medical records will be sufficient.
- Selected medical records. The conditions from "c to e" are specific for this type of patients and 3 cases will have to be selected from each situation. These same medical records can be used to evaluate the rest of the ME.

Cases of patients included in the CPMS will be reviewed in that system.

During the review

- The review will be carried out with the presence and assistance of the team members that the HCP representative deems appropriate.
- The evaluation team will verify in each case if the contents of each of the MEs indicated above are met.
- Before the end of the session, the evaluation team will check the results of their review with the professionals present.

After the session

The evaluation team will assess each of the MEs that have been reviewed in the medical records and will score them following the guidelines suggested in the scoring guide of the respective ME.

Suggested agenda

The three types of activities could be carried out either on site or online, even though an onsite visit facilitates a deeper evaluation, and the online review of medical records could be hindered by regulation or data protection limitations, as well as depending on the medical record system used. Therefore, there can be 3 options:

- Option 1: on site audit
- Option 2: mixed method (online and onsite)
- Option 3: online audit

In all cases, logistically the HCP team will need some time for the preparation of the audit. Therefore, the evaluation team should contact the HCP representative as soon as possible to schedule the audit.

- Group interview with patients. It is advisable to provide about 3 weeks for the HCP team to recruit patients.
- Session with professionals. It will be scheduled only after the self-evaluation review has been carried out
- Review of medical records. It will be scheduled only after the self-evaluation review has been carried out. The possible preparation times to consider are:

  a) Elaboration of the list of patients (1 week)
  b) Selection of cases by the IEB (2 days)
  c) Location of the selected medical records. If the centre has electronic medical records, the location can be immediate. If the medical records are on paper, it is convenient to allow at least 3 days so that they can be available for the evaluation team.

On site audit

The onsite visit is carried out in 1 single day, so it requires a good coordination between the evaluation team and the HCP. The contents suggested to be included in the agenda are:

Presentation of the evaluation team and confirmation of the agenda of the day	30 minutes
Presentation of the multidisciplinary team	30 minutes
Interview with professionals	90 minutes
Interview with patients	60 minutes
Review of medical records	120 minutes
Optional: tour of the facilities and review of pending documents (if applicable)	60 minutes
Feedback of the visit to the multidisciplinary team	30 minutes

12. Decision guidelines

The measurable elements (ME) specify and make explicit the operational criteria and each of them has to be rated with a 0/1/2 score:

0: not developed
1: partially developed
2: fully developed

All ME will be evaluated and scored but only those considered as “core” will be taken into account for the final result: either “satisfactory” or “needs improvement plan”.

To obtain a “satisfactory” result, the ERN or the HCP must:

- Get a score of 1 or 2 in 90% of “core” ME. This means that only 3 MEs can be scored “0” for ERNs and for HCPs.
- Get an average score at least 70% of the highest possible score in the group of core ME. This means a score of at least 42 for ERNs and 40 for HCPs:

	No. ME	No. core ME	Maximum no. of core MEs scored “0”	Highest possible score for core ME	70% (satisfactory)
ERN	53	30	3	60	42
HCP	64	29	3	58	40

13. Network evaluation report template

Evaluation summary

[Network Name]

Coordinating Member

[Name and Address of Coordinating Member]

Healthcare Providers

The following Healthcare Providers of the Network have been evaluated:

- *[List name of each Healthcare Provider and Member State. Highlight those that received an on-site audit]*

Virtual interviews with Coordination Board dates: [Coordination Board interview Date]

Board Members and task leaders interviewed: [List name of each Member and role]

Virtual interviews with Patient Representatives dates: [Patient Representatives interview Date]

Patient Representatives interviewed: [List names of each representative and affiliation]

Evaluation Team

The following evaluation team completed the technical evaluation:

[List evaluators and organisation affiliation. Highlight team leader]

- [Name of Evaluator 1]
- [Name of Evaluator 2]
- […]

[Include map of the geographical coverage of the Network (HCPs and affiliated centres)]

Conclusions of the evaluation team

The evaluation team provided the following conclusions regarding the development and achievements of the Network.

1. **Accomplishment of the objectives of the Network** [evaluation team comments]

2. **Development and achievements of the Network** [evaluation team conclusions]

Structure: [How is the ERN covering the areas it stated it would - geographical, diseases and conditions, 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]

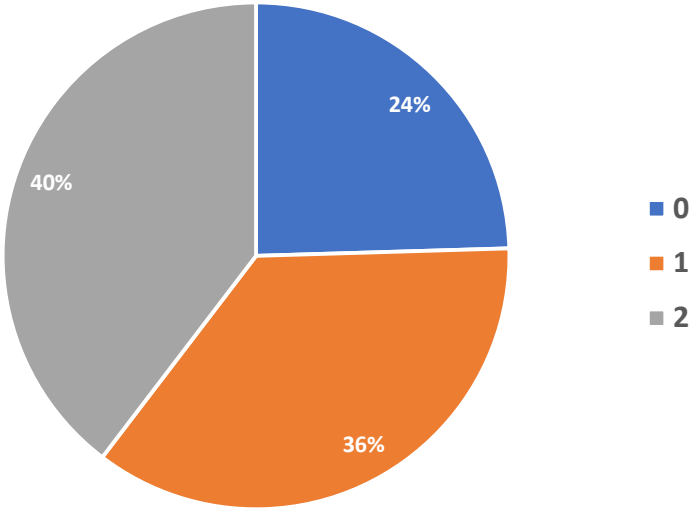
Impact: [What has been the value added to the patients' experience, both receiving services with each member, and their pathway through the network; impact locally, use of ERN tools]

3. **Outstanding findings that can be useful to other Networks** [evaluation team comments]

Overall compliance with the operational criteria

1. Overall compliance with operational criteria for the Network

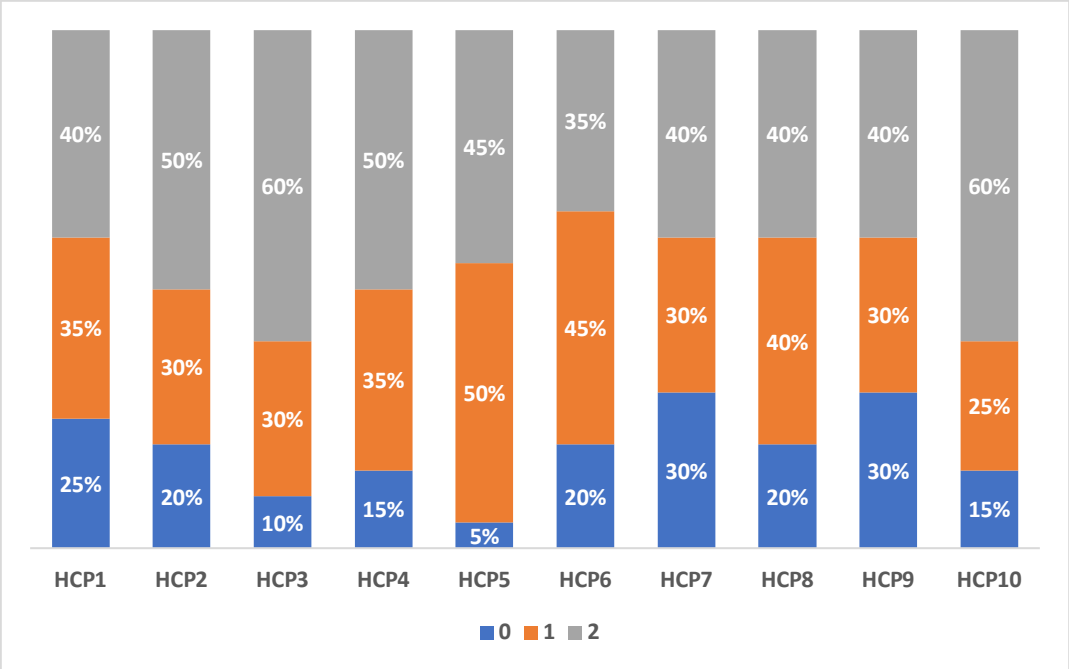
Based on the assessment of compliance against the operational criteria for Networks, the following graph represents the overall distribution of the ratings for the Network. Please see Appendix A for more information on the rating scale used by the evaluation team.



Legend
0: No Activity / Not Implemented or developed
1: Partially Implemented or developed
2: Fully Implemented or developed

2. Overall compliance with operational criteria for Healthcare providers

Compliance was also assessed for each Healthcare provider (HCP) team in the Network against the operational criteria for HCP teams. The following graph represents the distribution of the ratings against the criteria for each HCP team.

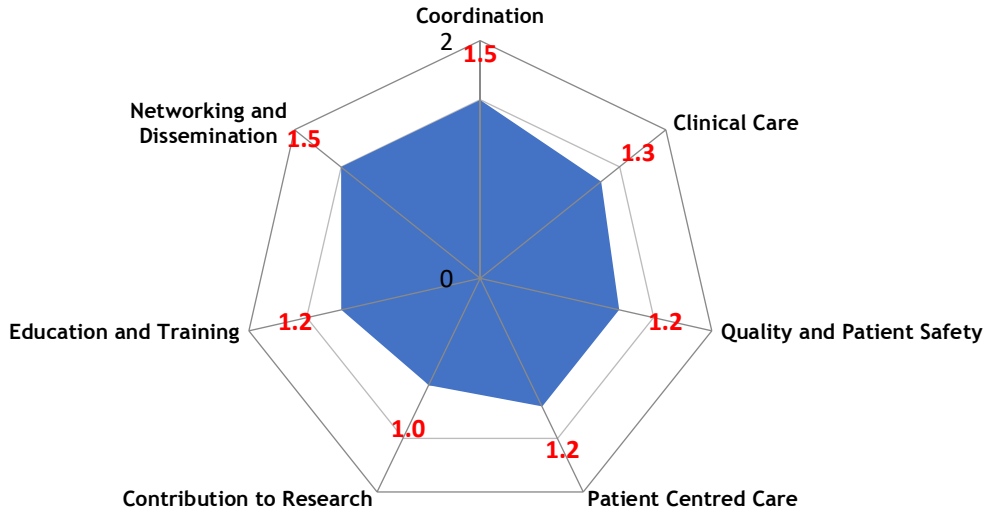


3. Overview by areas for the Network

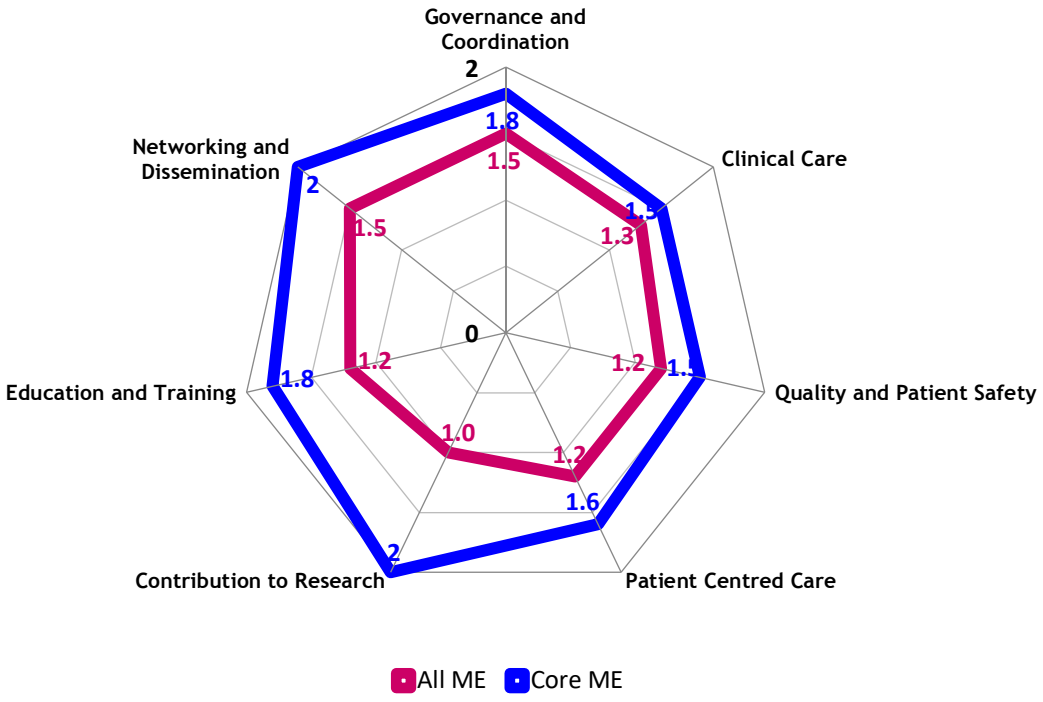
The Operational Criteria for the Network are grouped into the following seven thematic areas:

1. Governance and Coordination
2. Clinical Care
3. Quality and Patient Safety
4. Patient Centred Care
5. Contribution to Research
6. Education and Training
7. Networking and Dissemination

Each area consists of one or more criteria with measurable elements in line with the Commission Implementing Decision (2014/287/EU). The following graph represents the Network's average rating for each area (average of the score of all MEs in each area), being 0 the lowest rate and 2 the highest rate.



Some of the measurable elements are considered as "core" and should have been accomplished or implemented at the time of the evaluation. The following graph compares the Network's average rating for all the MEs in each area with the average rating obtained by the core MEs in the same area.



Detailed results for each area. Operational criteria for the Network

1. Score of each measurable element and average score of the area

The following tables show the Network's compliance with the measurable elements in each area. Based on the evaluators' findings, strengths can be highlighted. Core ME are tagged with ♥

Two overall results are shown at the end of the table:

- Area average rating (all MEs in the area)
- Average core rating: (only core MEs)

Governance and Coordination *(EXAMPLE ONLY)*	Rating
1.1.1 The structure and the implementation of the rules of procedure of the ERN's coordination board have facilitated the organization of tasks and the incorporation of new Members. ♥	2
1.1.2 An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality control, evaluation, meetings and other activities. ♥	1
1.1.3 Mechanisms to maintain or enhance the level of collaboration between the ERN members as well as its affiliates have been put into practice. ♥	2
1.1.4 HCPs have been involved in specific ERN-related tasks, sharing responsibilities among all the Members of the ERN. ♥	1
1.2.1 An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the ERN and its Members. ♥	2
1.2.2 There is an internal assessment of HCPs' participation. ♥	1
1.2.3 HCP professionals' satisfaction with the performance of the ERN is periodically evaluated	0
1.3.1 Patients representatives have been included in the governance framework of the ERN. ♥	1
1.3.2 The Board has incorporated the opinion of patients and families when outlining strategies. ♥	1
1.3.3 Patients and support groups are major stakeholders in ERN-related activities. ♥	1
1.3.4 The ERN monitors and evaluates the involvement of patients in the activities of the ERN.	0
1.4.1 The ERN has identified goals, opportunities, and threats for the future. ♥	2
1.4.2 The ERN has evaluated its own organisational and economic viability .	0
1.4.3 The ERN has developed a financial plan to meet its objectives including funding efforts and a justified distribution of resources across members	1
1.4.4 The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for its long-term sustainability.	1

Governance and Coordination *(EXAMPLE ONLY)*	Rating
Average Rating	1.1
Core MEs Average Rating	1.5

Strengths: [Related to the area. Evaluation team comments]

[Repeat for each area in the operational criteria for the Network]

2. Score of each criterion and areas for improvement

The following tables show the Network's compliance with each criterion and the evaluation team recommendations for improvement. [Evaluator should always include findings and comment on areas for improvement in all criteria that have not reached the maximum score]

Criterion	Average Rating	Findings and areas for improvement
1.1 The ERN has established a clearly defined governance framework that ensures appropriate ERN coordination and oversight	2	
1.2 The ERN has developed regular evaluation and monitoring processes enabling the assessment of the Network's progress	1	[Evaluator comments]
1.3 The ERN has established mechanisms for the integration of patient organizations in the strategical actions	2	
1.4 The ERN has implemented actions to ensure its sustainability	1	[Evaluator comments]
[… all criteria]		

Evaluation of the achievement of the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements

[The evaluator includes findings regarding the review of the grant reports]

Criterion	Findings
The activities carried out by the different work packages in the last 5 years are clearly described	[Evaluator comments]
The ERN has evaluated the achievement of the objectives established in the initial strategic plan for the next 5 years	[Evaluator comments]
Expected deliverables have been produced in a timely manner:	[Evaluator comments]
% of deliverables produced from the initially planned	[Evaluator comments]

The deliverables produced suit their original purposes	[Evaluator comments]

Summary of the evaluation of the Members of the Network

The operational criteria for the HCP teams are grouped into the following seven thematic areas:

1) Patient Centred Care
2) Organisation and Management
3) Research and Training
4) Exchange of Expertise, Information Systems, and eHealth
5) Quality and Safety
6) Competence, Experience, and Outcomes of Care
7) Human Resources

1. Average score of all the HCPs in each area

Each area consists of one or more criteria with measurable elements in line with the Commission Implementing Decision (2014/287/EU). The following graph represents the average rating of all the Healthcare provider teams in each area.

2. Average score of all the HCPs in each measurable element in each area

The following tables show the average rating of all the HCPs with the measurable elements in each area. Core ME are tagged and those ME that are related with specific contribution to the Network are tagged

Three overall results are shown at the end of the table:

- Area average rating (all MEs in the area from all HCPs)
- Core MEs average rating (core MEs in the area from all HCPs)

– Contribution ME Average Rating (MEs contributing to the Network in the area from all HCPs)

Strengths and suggestions for improvement are also noted in each area.

Patient-Centred Care *(EXAMPLE ONLY)*	Measurable Elements Average Rating
1.1.1 The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.	2
1.1.2 The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand	2
[…]	
1.4.1 The HCP team routinely measures patient and family experience using the ERN common tool.	1
[…all ME in the area]	
Area Average Rating	**1.7**
Core MEs Average Rating	**2**
Contribution MEs Average Rating	**1**

Strengths: [Related to the area. Evaluation team comments]

Suggestions for improvement: [Related to the area. Evaluation team comments]

[Repeat for each area in the operational criteria for Healthcare Providers]

3. Outcome of the evaluation for HCPs

The following table provides a summary of the outcome of the evaluation for each Healthcare Provider.

Healthcare Provider	Outcome of the Evaluation
1. [Insert HCP Name]	Satisfactory/Needs improvement
2.	Satisfactory/Needs improvement
3.	Satisfactory/Needs improvement
4.	Satisfactory/Needs improvement
5.	Satisfactory/Needs improvement
6.	Satisfactory/Needs improvement
…..	

Outcome of the evaluation for the Network

The following table shows the total score for all ME in each area as well as the total score for core ME

Scoring Table			
Governance and Coordination			
Total score out of a possible 30	**N**	Percent of Total	**%**
Core score out of a possible 20	**N**	Percent of Total	**%**
Clinical Care			
Total score out of a Possible 18	**N**	Percent of Total	**%**
Core score out of a possible 10	**N**	Percent of Total	**%**
Quality and Patient Safety			
Total score out of a possible 6	**N**	Percent of Total	**%**
Patient Centred Care			
Total score out of a possible 12	**N**	Percent of Total	**%**
Core score out of a possible 6	**N**	Percent of Total	**%**
Contribution to Research			
Total score out of a possible 14	**N**	Percent of Total	**%**
Core score out of a possible 8	**N**	Percent of Total	**%**
Education and Training			
Total score out of a possible 12	**N**	Percent of Total	**%**
Core score out of a possible 8	**N**	Percent of Total	**%**
Networking and Dissemination			
Total score out of a possible 12	**N**	Percent of Total	**%**
Core score out of a possible 8	**N**	Percent of Total	**%**
Overall			
Grand total out of a possible 104	**N**	Percent of Total	**%**
Core total out of a possible 60	**N**	Percent of Total	**%**

Number of core ME scored <1: **N**

Considering all the information reviewed during the evaluation process, the level of accomplishment of the objectives that the ERN originally selected in the application for the initial assessment is the following:

[*The evaluation team marks and rates the original objectives (at least 3) and removes the others*]

Objectives set out in Article 12(2) of Directive 2011/24/EU	
☐ *to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to contribute to the pooling of knowledge regarding sickness prevention.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to maximise the cost-effective use of resources by concentrating them where appropriate.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to reinforce research, epidemiological surveillance like registries and provide training for health professionals*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing
☐ *to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network.*	☐ Excellent ☐ Very good ☐ Acceptable ☐ Poor ☐ Failing

Based on the overall score and detailed findings in this report, the result of the evaluation of the Network is:

☐ **SATISFACTORY**

☐ **NEEDS IMPROVEMENT**

Next steps

Instructions related to sending comments to the IEB, deadlines and next steps of the process

In case of unsatisfactory result, instructions for the improvement plan

Appendices

A. Scoring guidelines
B. Decision rules
C. Improvement plan template

14. Healthcare provider team evaluation report template

Evaluation summary

[Healthcare Provider's Name]

On-site Audit dates (if applicable): [Visit Start Date–Visit End Date]

Network

[Name of the Network]

Healthcare Provider Representative

[Name of HCP Representative]

Evaluation Team

The following evaluation team completed the technical evaluation:

[List evaluators and organisation affiliation]

- [Name of Evaluator 1*]
- [Name of Evaluator 2]

*Team Leader

Conclusions of the evaluation team

The evaluation team provided the following overall comments regarding the Healthcare Provider (HCP).

Participation and involvement in the Network: [evaluation team comments]

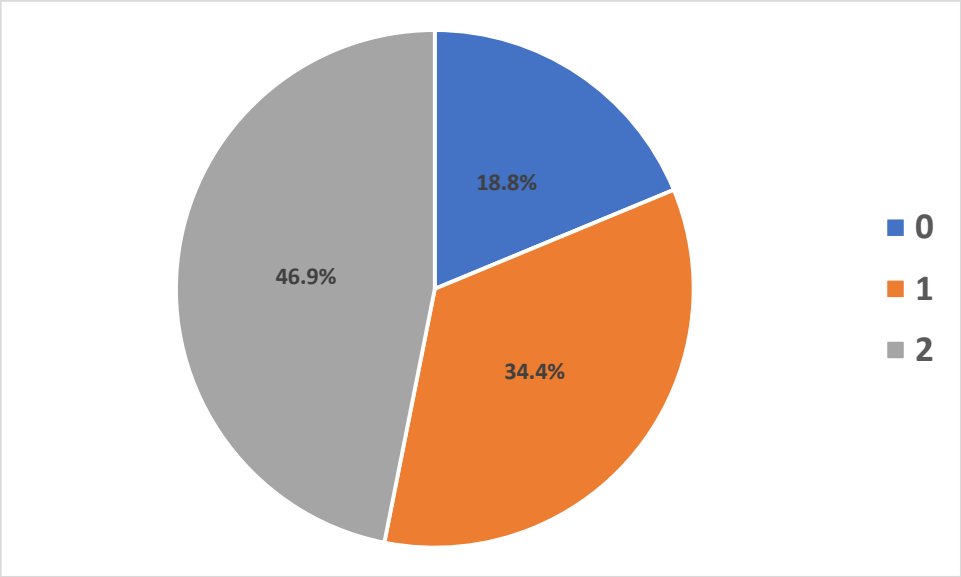
Strengths and suggestions for improvement: [evaluation team comments]

Outstanding practices that can be useful to other healthcare providers: [evaluation team comments]

Overall compliance with the operational criteria

1. Overall compliance with operational criteria for the HCP

Based on the assessment of compliance against the operational criteria for Healthcare providers, the following graph represents the overall distribution of the ratings for the HCP. Please see Appendix A for more information on the rating scale used by the evaluation team.



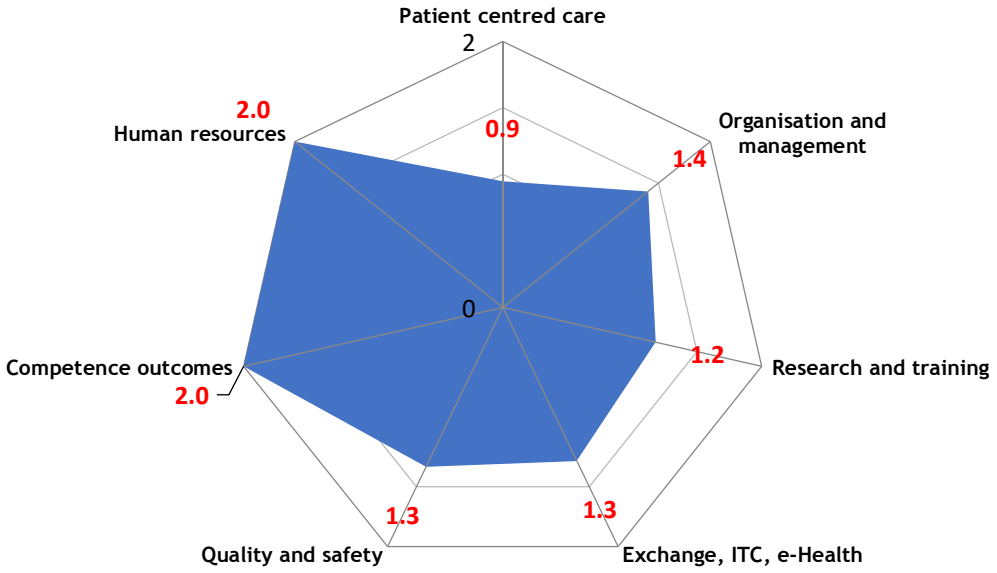
Legend
0: No Activity / Not Implemented
1: Partially Implemented
2: Fully Implemented

2. Overview by areas

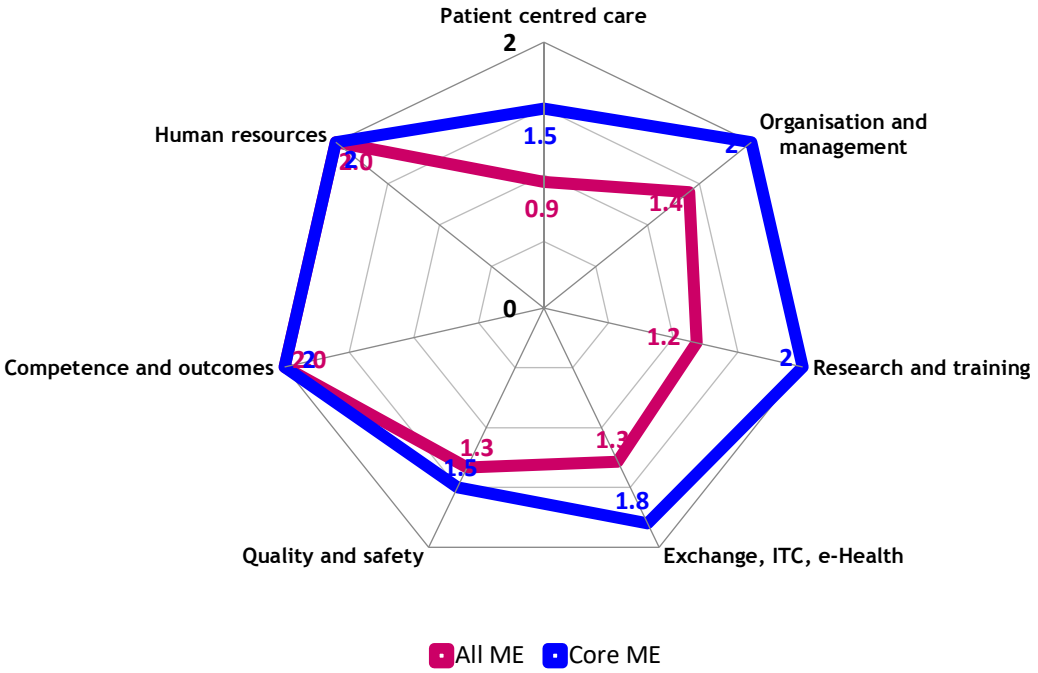
The Operational Criteria for the Healthcare Providers are grouped into the following seven areas:

1. Patient Centred Care
2. Organisation and management
3. Research, education and training
4. Exchange of expertise, information systems and eHealth
5. Quality and safety
6. Competence, experience and outcomes of care
7. Human resources

Each area consists of one or more criteria with measurable elements in line with the requirements of the Commission Implementing Decision (2014/287/EU). The following graph represents the Healthcare Provider's overall compliance with the Operational Criteria by area (average of the score of all MEs in each area), being 0 the lowest rate and 2 the highest rate.



Some of the measurable elements are considered as "core" and should have been accomplished or implemented at the time of the evaluation. The following graph compares the HCP's average rating for each area and the average rating of only the area core ME.



Detailed results for each area

1. Score of each measurable element and average score of the area

The following tables show the HCP's compliance with the measurable elements in each area. Core MEs are tagged and those MEs that are related with specific contribution to the Network are tagged

Three overall results are shown at the end of the table:

- Area average rating (all MEs in the area)
- Core MEs average rating (core MEs in the area)
- Contribution MEs Average Rating (MEs contributing to the Network in the area)

Based on the evaluation team's findings, strengths can be highlighted.

Patient-Centred Care *(EXAMPLE ONLY)*	Evaluator Rating
1.1.1 The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.	2
1.1.2 The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand	2
[…]	
1.4.1 The HCP team routinely measures patient and family experience using the ERN common tool.	1
[…all ME in the area]	
Area Average Rating	**1.7**
Core MEs Average Rating	**2**
Contribution MEs Average Rating	**1**

Strengths: [Related to the area. Evaluation team comments]

[Repeat for each area in the operational criteria for Healthcare Providers]

2. Score of each criterion and areas for Improvement

The following tables show the HCP's compliance with each criterion and the evaluation team recommendations for improvement. *[Evaluator always includes findings and comments on areas for improvement in all criteria that have not reached the maximum score]*

Criterion	Average Rating	Findings and areas for Improvement
1.1	2	
1.2	1	[Evaluator comments]
2.1	0	[Evaluator comments]
2.2	2	
[… all criteria]		

Outcome of the evaluation

The following table shows the total score for all ME in each area as well as the total score for core ME and of those ME that identify HCP contribution to the mission of the Network.

Scoring Table			
Patient centred care			
Total score out of a possible 38	**N**	Percent of Total	**%**
Core score out of a possible 16	**N**	Percent of Total	**%**
Contribution score out of a possible 4	**N**	Percent of Total	**%**
Organisation and management			
Total score out of a Possible 20	**N**	Percent of Total	**%**
Core score out of a possible 8	**N**	Percent of Total	**%**
Contribution score out of a possible 4	**N**	Percent of Total	**%**
Research, education and training			
Total score out of a possible 22	**N**	Percent of Total	**%**
Core score out of a possible 12	**N**	Percent of Total	**%**
Contribution score out of a possible 14	**N**	Percent of Total	**%**
Exchange of expertise, ICT and e-Health			
Total score out of a possible 14	**N**	Percent of Total	**%**
Core score out of a possible 6	**N**	Percent of Total	**%**
Contribution score out of a possible 4	**N**	Percent of Total	**%**

Scoring Table			
Quality and safety			
Total score out of a possible 18	**N**	Percent of Total	**%**
Core score out of a possible 4	**N**	Percent of Total	**%**
Contribution score out of a possible 6	**N**	Percent of Total	**%**
Competence, experience and outcomes of care			
Total score out of a possible 8	**N**	Percent of Total	**%**
Core score out of a possible 8	**N**	Percent of Total	**%**
Contribution score out of a possible 4	**N**	Percent of Total	**%**
Human resources			
Total score out of a possible 8	**N**	Percent of Total	**%**
Core score out of a possible 4	**N**	Percent of Total	**%**
Overall			
Grand total out of a possible 128	**N**	Percent of Total	**%**
Core total out of a possible 58	**N**	Percent of Total	**%**
Contribution total out of a possible 36	**N**	Percent of Total	**%**

Number of core ME scored <1: **N**

Based on the overall score and detailed findings in this report, the result of the evaluation of the Network is:

☐ **SATISFACTORY**

☐ **NEEDS IMPROVEMENT**

Next steps

Instructions related to sending comments to the IEB, deadlines and next steps of the process

In case of unsatisfactory result, instructions for the improvement plan

Appendices

A. Scoring guidelines
B. Decision rules
C. Improvement plan template

15. ERN System evaluation report outline

Based on the results obtained in the evaluation of the Networks, the IEB will prepare a global evaluation report of the European Reference Networks system for the Commission. Suggestions for the outline of this report are presented below.

1. Map of geographical coverage of each network (HCPs and affiliated centres)
2. Overall system results (data and charts)
   - Overall results at the thematic area (operational criteria) level
   - Results disaggregated by networks and thematic areas
   - Overall results of each criterion (calculating exclusively its core MEs)
   - Results disaggregated by networks and criteria (calculating exclusively their core MEs)
   - Overall results of the HCP teams' MEs reflecting their contribution to the ERN
   - Results disaggregated by network of the MEs of the HCP teams that reflect their contribution to the ERN
3. Analysis of strengths and areas of improvement by thematic areas
   - Include possible examples of "outstanding contributions" by specific networks in specific areas
4. Assessment of the achievement of the objectives of the Directive
   - Analysis of the selection of objectives by the ERN
   - Qualitative assessment of the level of achievement attained in each objective
5. Conclusions on
   - Structure of the system: [How is the system covering the areas it stated it would - geographical, diseases and conditions, patient population]
   - Maturity of the system: [At what stage of development is the system regarding its purpose, sustainability, and level of integration into national health systems]
   - Activity of the system: [Scale and ambition of the activities performed]
   - Impact of the system: [What has been the value added to the patients' experience and their pathway through the system]
6. Opportunities for improvement of the system detected by the IEB (i.e. opportunities for better integration of processes, efforts and resources)
7. Annex: network/HCP/affiliated centres sheets for each country

16. Improvement plan guideline and template

General directions

An Improvement Plan (IP) must be submitted for 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 detailed description of the sustainable IP with the action(s) that will be implemented to achieve full compliance with the ME’s requirement should be elaborated.

The description of the improvement plan consists of 4 sections. You should complete Section I to IV in the template for every ME that requires an IP.

1. **Section I: Identification of the measurable element**

Identify each of the MEs with a score of "0" or "1", referring to the area and criterion to which it belongs. Include those findings or areas for improvement highlighted by the evaluation team.

2. **Section II: Plan development**

The basic elements of the improvement plan should be described in detail:

- Planned actions and areas in which they should be implemented
- Persons who assume responsibility for the different actions and their execution
- Timetable for the development of the proposed actions

3. **Section III: Communication/ Education**

Description of the communication/education plan to inform/train the professionals, patients or institutions affected by the different actions of the improvement plan for the full implementation of the process.

4. **Section IV: Monitoring**

Description of how the plan will be monitored and how its effectiveness will be evaluated in relation to the expected improvement, indicating which indicators will be used.

This section should also indicate when the monitoring reports and final results will be presented, as well as the mechanism for communicating these results to the professionals, patients and institutions involved in the improvement plan.

The improvement plan must be submitted within 2 months of receipt of the evaluation report.

Improvement plan template

SECTION I: Identification		
Measurable element		
Criterion		
Area		
Evaluation findings/areas for improvement:		
SECTION II: Development		
Planned actions and areas for implementation (what and where)	**Responsible** (who) (Name and title)	**Completion date** (when)
SECTION III: Communication		
Education or notification items and intended subjects of the communication	**Responsible** (who) (Name and title)	**Completion date** (when)
SECTION IV: Monitoring		
Describe the method implemented or planned to evaluate the effectiveness of the Improvement Plan and/or improvement actions.		
Include the performance indicators that will be used to assess compliance with the plan and how often the compliance assessment will be made.		
Indicate the expected result of compliance.		
Indicate the expected reporting period.		
Describe how the data will be disseminated to stakeholders involved in the plan.		

17. Conflict of Interest and Confidentiality Statement

By requesting the evaluation, the Network and the HCP give permission to the Independent Evaluation Body (IEB) to access all the information required to verify compliance with the criteria.

The evaluation team is responsible for reviewing and assessing compliance with the criteria through the review of the documentation and performing an onsite or online audt.

The members of the evaluation team are professionals selected for their knowledge, experience and principled qualities and in the exercise of their functions they are called to conduct themselves assuming the highest ethical standards.

The evaluator assumes the commitment and responsibility implied by this evaluation process, which aims to assess the performance of the Networks and HCP teams during the 5 years prior to the evaluation.

Conflicts of interest

In all matters relating to evaluation work, the independence of the evaluation team must not be affected by personal or external interests. This independence may be altered, for example, by external pressures or influences, personal prejudices about individuals, institutions, projects or programs, recent employment relationships with the evaluated organisation, or personal or financial situations that could give rise to conflicts of loyalty or interest.

When evaluating an HCP team, there should be no such conflicts of interest between the institution and the member of the evaluation team. If it exists, it is the responsibility of this member to inform the evaluation coordinator and not to participate in the evaluation.

Examples of potential conflicts of interest include:

- Financial relationships: Be or have been part of the clinical, research, management, or support staff of any healthcare provider of the ERN to be evaluated.
- Have completed specialized training in any evaluated HCP of the Network.
- Have opted to occupy a position in any HCP of the ERN in the last years.
- Be part of the coordination body of another ERN.
- Have or have had ties to any HCP that could result in conflict.
- Specific personal problems.

Confidentiality

Confidentiality is a key aspect of audit processes. The evaluation team will have to review various types of documents, which may contain information of different levels of sensitivity for their protection and handling. Thus, the spectrum can be extended from publicly accessible data that can be freely consulted on the centre's website to information of a more sensitive nature, such as personal data (i.e., those contained in medical records), particularly those documents subject to specific treatment conditions according to the General Data Protection Regulation of the European Union, such as the health data of patients included in the clinical records.

The non-public information of these processes is, in general, considered private and confidential information, and will be subject to professional secrecy, without its content being provided to third parties, with the limitations established where appropriate by law and those derived from the requirements established by the European Commission for the evaluation process.

> **Confidential information**: includes all non-public information that is given to the member of the evaluation team, as well as the actions and deliberations in which the member participates or of which the member has knowledge, both directly and indirectly, as a result of the evaluating activity.

Therefore, evaluators should actively prevent the unauthorized disclosure of any non-public information obtained during the evaluation, as well as ensure the anonymity of all individuals contacted and/or interviewed in the evaluation.

The members of the evaluation team have the duty to safeguard and guarantee the security of the documentation provided to them by the HCP team and by the Network prior to the audit visit, as well as all the notes and information generated during it.

> **Confidential documents**: includes all drafts, preparatory information, documents and any other material, together with the information contained therein, to which the evaluator has access, both directly and indirectly, as a result of participating in the activities of an evaluation team. In addition, any minutes or annotations made by the evaluator in relation to the confidential information will be treated as confidential documents.

Basic behaviour

Below are some general guidelines of behaviour to be considered during the audit, which can contribute to reinforce the image of professionalism that is expected of the members of the evaluation team.

- The evaluator must be prepared for the visit, which implies being familiar with the documentation.
- The work must be planned in such a way as to ensure that the results reflect the reality of the visit. It is necessary to set a work agenda and respect it.
- At the onsite visit, each team member must carry the identification provided by the IEB, throughout the audit visit.
- It is important to maintain punctuality in team meetings and other sessions that may take place.
- The interaction between the evaluator and the members of the HCP team should take place on a professional level within the evaluative framework and be based on the mutual will to seek a full understanding.
- Avoid "personalizing" the evaluation, making comparisons with other Networks or HCP evaluated.

Conflict of interest statement

5. Statement of Policy

Individuals representing the Independent Evaluation Body (IEB) must not participate in any decision-making capacity if they have had a close and active association with the organisation being evaluated. Close and active association includes, but is not limited to:

- Be or have been part of the clinical, research, management, or support staff of any healthcare provider of the ERN to be evaluated.
- Have completed specialized training in any evaluated HCP of the Network.
- Have opted to occupy a position in any HCP of the ERN in the last years.
- Be part of the coordination body of another ERN.
- Have or have had ties to any HCP that could result in conflict.
- Specific personal problems.

Each individual involved in the evaluation must disclose in writing any real or perceived conflicts of interest as soon as they become evident.

6. Potential Conflict of Interest Statement

To the best of my knowledge and belief, except as disclosed herewith neither I nor any person with whom I have or had a personal or business relationship is engaged in any transaction or activity or has a relationship that may represent a potential competing or conflict interest, as defined in the statement of policy.

Further, to the best of my knowledge and belief, except as disclosed herewith, neither I nor any person with whom I have or had a personal business, or compensate professional relationship intends to engage in any transaction, to acquire any interest in any organization or entity, to become the recipient of any substantial gifts or favours that might be covered by the statement of policy regarding conflicts of interest.

(A) Without exception ☐
(B) Except as described in the attached statement ☐

Signature:

_____

Print Name:

_____

Date:

_____

Confidentiality agreement

The contents of all materials and information furnished for review during the evaluation process are considered privileged information. The contents of those documents and the results of the evaluation should only be disclosed under appropriate circumstances.

I hereby agree and acknowledge that I shall maintain in the strictest confidence all patient-specific or confidential, proprietary information which may become known to me by virtue of my participation in any activities relating to my role as an evaluator including, but not limited to, patient-specific data, records, personnel data, internal files, verbal communications and/or other information. I shall not voluntarily disclose directly or indirectly any such information.

I shall make no voluntary disclosures of discussions, deliberations, records or other information except to persons authorised to receive it in the conduct of the independent evaluation.

In the event of a breach or threatened breach of this confidentiality agreement, the Independent Evaluation Body <insert name>, as applicable, and as it deems appropriate, may pursue any action available to address such noncompliance.

Signature:

_____

Print Name:

_____

Date:

_____

18. Legislation of interest

1. Directive 2011/24/EU Art. 12

2014/287/EU: Commission Implementing Decision of 10 March 2014 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

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2014_147_R_0007

2. Commission Delegated Decision 2014/286/EU

2014/286/EU: Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

http://data.europa.eu/eli/dec_del/2014/286/oj

3. Commission Implementing Decision 2014/287/EU Art. 14-15

Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending 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

http://data.europa.eu/eli/dec_impl/2019/1269/oj