



European  
Reference  
Networks

Share. Care. Cure.

## ERN Assessment Manual for Applicants

### 8. Self-Assessment Checklist for Healthcare Providers in Active PDF



*An initiative of the*



## Preamble

This document contains the Self-Assessment Checklist for Healthcare Providers in Active PDF. It is part of series of nine documents that include the following:

1. ERN Assessment Manual for Applicants: Description and Procedures
2. ERN Assessment Manual for Applicants: Technical Toolbox for Applicants
3. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Networks
4. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Healthcare Providers
5. Network Application Form in Active PDF
6. Membership Application Form in Active PDF
7. Self-Assessment Checklist for Networks in Active PDF
8. Self-Assessment Checklist for Healthcare Providers in Active PDF
9. Sample Letter of National Endorsement for Healthcare Providers

This series of documents of the Assessment Manual and Toolbox for European Reference Networks has been developed in the framework of a service contract funded under the European Union Health Programme.

## SELF-ASSESSMENT CHECKLIST FOR HEALTHCARE PROVIDERS

### INTRODUCTION

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex II (b), the membership application to join a Network must be submitted in response to a call for interest published by the Commission and must include: the completed application form with the self-assessment questionnaire and supporting documentation required in the assessment manual (See page 23 of the *ERN Assessment Manual for Applicants*).

The self-assessment provides Healthcare Providers with the opportunity to evaluate themselves against the specific legislated criteria and conditions before submitting their application to the European Commission.

In addition, the self-assessment provides a mechanism for both the Independent Assessment Body and the Healthcare Provider to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

### DESCRIPTION OF THE SELF-ASSESSMENT TOOL

The following self-assessment checklist is divided into nine (9) distinct sections. These include the following:

#### ***General criteria and conditions for Healthcare Providers<sup>1</sup>***

1. Patient Empowerment and Patient Centred Care
2. Organisation, Management, and Business Continuity
3. Research, Education, and Training
4. Expertise, Information Systems, and e-Health Tools
5. Quality and Safety

#### ***Specific criteria and conditions for Healthcare Providers with regard to the area of expertise, disease or condition<sup>2</sup>***

6. Competence, Experience, and Outcomes of Care
7. Human Resources
8. Organisation of Patient Care
9. Facilities and Equipment

---

<sup>1</sup> Commission Delegated Decision (2014/286/EU) – Annex II

<sup>2</sup> Commission Delegated Decision (2014/286/EU) – Annex II

These nine (9) sections are based on the requirements set out in the Delegated Decision 2014/286/E Annex II. Each section includes multiple items to help the Healthcare Provider evaluate its readiness to submit an application. These items are based on those Operational Criteria that the European Commission and Independent Assessment Body will use to assess compliance with the legislation. Note that a complete self-assessment must accompany the Application Form for the application to be considered.

## INSTRUCTIONS FOR COMPLETING THE SELF-ASSESSMENT

1. Establish a multidisciplinary team consisting of the Healthcare Provider's Representative and care provider representation.

The team should be given sufficient time to complete the self-assessment. Completing the self-assessment as a team increases the value of the process and accuracy of the information. It is estimated to take approximately three to four meetings with time allocated between meetings pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointed to organize the group, assign tasks, and coordinate the self-assessment effort.

2. Read and review the Operational Criteria in its entirety before beginning the Self-Assessment process. If possible, make copies and send them to team members before the first meeting.
3. Discuss each individual element in the Self-Assessment Checklist and evaluate the progress in implementing it. As necessary, verify the level of implementation with other individuals outside of the team. Document this information in the "Comments" section of the checklist.
4. Once consensus is reached, complete the table below by marking the box that most appropriately captures the current status of compliance with the criterion, using following rating scale and scoring guide:




Rating	Guidelines
<b>0: No activity / Not Implemented</b>	<b>All Criteria:</b> this rating is used when there is no action plan in place or there is insufficient evidence to support compliance. This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).
<b>1: Partially Implemented</b>	<b>All Criteria:</b> this rating is used when there is an action plan 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).
<b>2: Fully Implemented</b>	<b>All Criteria:</b> this rating is used 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).





5. Repeat the process for each element. Once complete, tally up the score for each section using the template provided in **Appendix A**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.
6. Use this information to develop an Action Plan to improve readiness to submit the application and complete the assessment process.
1. Prior to finalizing and submitting the self-assessment, a process to validate the results internally should be followed. The purpose of the internal validation is to:
  - Provide a level of quality assurance;
  - Confirm that the self-assessments are accurate and therefore can be shared externally;
  - Identify any inconsistency in practice across the Network; and
  - Identify areas of best practice that could be shared across the Network.

It is the Network's responsibility to determine how the internal validation will be completed. The Network must ensure that the process used meets the following requirements:


- The process is fair and robust;
  - The process is agreed to by all Healthcare Providers;
  - Accountability for the self-assessment is agreed to by the Chief Executive Officer of the Healthcare Provider; and
  - The process includes patient and family involvement.
7. At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.
  8. Complete and sign the *Declaration Form* in **Appendix C** of the self-assessment.
  9. Submit the completed Self-Assessment along with the Application Form **no later than the deadline** for applications in response to the Call for Expression Interest. The Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in **Appendix B**. These documents should be made available to the IAB, at their request.

## THE SELF-ASSESSMENT CHECKLIST TOOL FOR HEALTHCARE PROVIDERS



1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE			
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.1.1 The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.			
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.			
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.			
1.1.4 The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.			

1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.			
1.1.6 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.			
<b>1.2 The Healthcare Provider provides patients with clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients.</b>			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.2.1 Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.			
<b>1.3 The Healthcare Provider regularly collects information on patient care experience within the Network's area of expertise and uses this information to make ongoing improvements.</b>			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.3.1 The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.			


**1.4 The Healthcare Provider protects the privacy and confidentiality of patient health information.**



Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.4.1 The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.			

**1.5 Patient informed consent to share personal health information complies with the requirements set out in Article 2(e) of the Directive 2014/286/EU.**

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.5.1 If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.			




**1.6 The Healthcare Provider maintains transparency by providing information to patients and the general public about clinical outcomes, treatment options, and quality and safety standards that are in place.**

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.6.1 The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.			
1.6.2 All relevant information must be provided to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.			


1.6.3 Every patient is provided with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.			
1.6.4 The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.			
<b>1.7 The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.</b>			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.7.1 The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.			

## 2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY



2.1 The organization follows a documented set of organization and management rules and procedures for services provided within the Network's area of expertise.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.			
2.1.2 The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.			
2.1.3 There are policies and procedures for managing cross border patients within the Network's area of expertise.			


**2.2 The Healthcare Provider shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, including how these are calculated.**





Measure Elements	Rating (0 or 1 or 2)	Comments	 *
2.2.1 The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.			

**2.3 The Healthcare Provider has a business continuity plan.**

Measure Elements	Rating	Comments	 *
2.3.1 The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.			




**2.4 The Healthcare Provider establishes 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.**

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
2.4.1 There are procedures for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.			




2.4.2 When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.			
<b>2.5 The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.</b>			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
2.5.1 Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.			
<b>2.6 There are policies and procedures in place to communicate with clinicians post discharge, including cross border.</b>			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
2.6.1 The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.			
2.6.2 Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.			

### 3. RESEARCH, EDUCATION AND TRAINING

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

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
3.1.1 The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.			
3.1.2 The Healthcare Provider has a defined set of objectives for its education and training activities.			
3.1.3 The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.			
3.1.4 Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.			
3.1.5 The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.			


**3.2 The Healthcare Provider has the capacity to carry out research activities and demonstrated research experience.**

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
3.2.1 The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.			
3.2.2 The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.			
3.2.3 The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.			
3.2.4 There is a procedure to review the ethical implications of research activities.			
3.2.5 The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.			


<p>3.2.6 The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.</p>			
<p>3.2.7 The Healthcare Provider evaluates the effectiveness of research activities.</p>			


#### 4. EXPERTISE, INFORMATION SYSTEMS, AND E-HEALTH TOOLS

4.1 The Healthcare Provider is able to exchange expertise with other providers and provide support to them.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
4.1.1 The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.			
4.1.2 The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.			






4.2 The Healthcare Provider safeguards the use of medical data within the Network's area of expertise.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
4.2.1 The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the Delegated Decision 2014/286/EU.			

4.3 The Healthcare Provider fosters the use of telemedicine and other e-health tools within and outside its facility.			
4.3.1 To support the use of telemedicine and other e-health tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations.			
4.4 The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
4.4.1 The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).			
4.4.2 The Healthcare Provider has procedures in place to monitor and maintain data quality.			

## 5. QUALITY AND SAFETY

5.1 The Healthcare Provider regularly monitors the quality and safety of the care it provides to patients with rare or low prevalence complex diseases or conditions.


Measure Elements	Rating (0 or 1 or 2)	Comments	 *
5.1.1 The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.			
5.1.2 The Healthcare Provider regularly collects and monitors process and outcome indicators.			
5.1.3 The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise.			
5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements.			

5.1.5 The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.			
5.2 The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.			
Measure Elements	Rating (0 or 1 or 2)	Comments	📄 *
5.2.1 There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.			
5.3 The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.			
Measure Elements	Rating (0 or 1 or 2)	Comments	📄 *
5.3.1 The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure.			📄


<p>5.3.2 The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.</p>			
<p>5.3.3 Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.</p>			

## 6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

### 6.1 The Healthcare Provider maintains its competence in the Network's area of expertise.


Measure Elements	Rating (0 or 1 or 2)	Comments	 *
6.1.1 The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.			
6.1.2 To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.			

### 6.2 The Healthcare Provider demonstrates good clinical care and outcomes.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
6.2.1 There is evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.			
6.2.2 The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.			


## 7. HUMAN RESOURCES

7.1 The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
7.1.1 The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.			
7.1.2 There is a sufficient number of staff with the necessary qualifications to perform the specialized function.			
7.1.3 Each core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.			
7.1.4 The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.			

## 8. ORGANIZATION OF PATIENT CARE


### 8.2 Comprehensive care is delivered by a multidisciplinary and specialised care team.


Measure Elements	Rating (0 or 1 or 2)	Comments	 *
8.2.1 The Healthcare Provider documents the characteristics of the multidisciplinary team.			
8.2.2 There is a designated leader and chair of the multidisciplinary team.			
8.2.3 There are documented procedures to support the organisation and functioning of the multidisciplinary care team.			

8.2.4 There are regular structured meetings between multidisciplinary team members.			
8.2.5 Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.			
8.2.6 The multidisciplinary team evaluates its performance on an annual basis.			

## 9. FACILITIES AND EQUIPMENT

9.3 The Healthcare Provider has the necessary facilities and equipment to attend to patients specific to the area of expertise, disease, or condition as defined by the Network.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
9.3.1 The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.			
9.3.2 There is access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.			
9.3.3 There is access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.			
9.3.4 Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.			

\* The Symbol  indicates the requirement to have ready at the time of the application a specific document as evidence of compliance. These documents are to be submitted at the request of the IAB. See Appendix B for the full listing of supporting documentation required.

## APPENDIX A: SCORING TABLE

Self-Assessment Scoring Table			
GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30		Percent of Total	
Organisation, Management, and Business Continuity			
Total Score out of a Possible 20		Percent of Total	
Research, Education and Training			
Total Score out of a Possible 24		Percent of Total	
Expertise, Information Systems, and E-health Tools			
Total Score out of a Possible 12		Percent of Total	
Quality and Safety			
Total Score out of a Possible 18		Percent of Total	
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8		Percent of Total	
Human Resources			
Total Score out of a Possible 8		Percent of Total	
Organization of Patient Care			
Total Score out of a Possible 12		Percent of Total	
Facilities and Equipment			
Total Score out of a Possible 8		Percent of Total	
OVERALL			
<b>Subtotal Score</b> for General Criteria		Percent of Total	
<b>Subtotal Score</b> for Specific Criteria		Percent of Total	
<b>GRAND TOTAL SCORE</b> out of a Possible 140		Percent of Total	

## APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS

### ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- **Measure 1.1.1** Mission and/or Core Values
- **Measure 2.1.1** Organization chart
- **Measure 1.7.1** Conflict of Interest Policy
- **Measure 2.3.1** Business continuity plan

### ATTACHMENT B – PATIENT EMPOWERMENT

- **Measure 1.1.3** Sample of Patient Education Materials
- **Measure 1.1.5** Written Material Describing Patient and Family Rights and Responsibilities
- **Measure 1.3.1** Patient Experience Survey and Sample Patient Experience Reports
- **Measure 1.5.1** Informed Consent Policy and Procedure

### ATTACHMENT C – ORGANISATION OF CARE

- **Measure 2.1.3** Policies and Procedures for Managing Cross Border Patients or planned actions and timelines for developing policies and procedures
- **Measure 2.6.1** Discharge procedure and Discharge Template
- **Measure 5.3.1** Clinical Practice Guidelines

### ATTACHMENT D – QUALITY AND INFORMATION SYSTEM

- **Measure 2.5.1** Third party reports and/or inspections on the quality care environments
- **Measure 5.1.1** Quality Improvement Plan
- **Measure 5.1.2** Process and Outcome Indicators (Dashboard) and their definitions
- **Measure 5.1.3** Patient Safety Plan
- **Measure 5.1.4** Detailed Example of Root Cause Analysis and Description of Process Improvement
- 

### ATTACHMENT E – RESEARCH AND TRAINING

- **Measure 3.1.2** List of teaching objectives
- **Measure 3.1.3** List of Teaching Staff and Qualifications
- **Measure 3.2.2** List of grants and research projects over the last 5 years
- **Measure 3.2.3** List of Standard Operating Procedures (SOPs) that govern research activities
- **Measure 3.2.4** Research Policy and Procedure

## APPENDIX C: DECLARATION FORM

TO BE COMPLETED BY THE PERSON LEADING THE SELF-ASSESSMENT					
<b>Person Leading the Self-Assessment</b>					
Name:					
Title:					
Contact Email:					
<b>Assessment Purpose</b>					
Application Type	Initial Approval Network and/or Healthcare Provider Renewal				
<b>Self Assessment</b>					
Date:					
Outcome	Full Compliance with the Operational Criteria Partial Compliance with the Operational Criteria Not Yet Compliant with the Operational Criteria				
<b>Notes Relevant to the Self-Assessment (if any)</b>					
<b>Signature of the Network Coordinator</b>					
Signature:					
<b>Declaration</b>					
I confirm that this self-assessment is an accurate and true reflection of the compliance status of the Healthcare Provider against the Operational Criteria and that all supporting documentation listed in <b>Appendix B</b> are prepared and ready for submission, at the IAB's request.					
Signature:		Name:		Date:	