

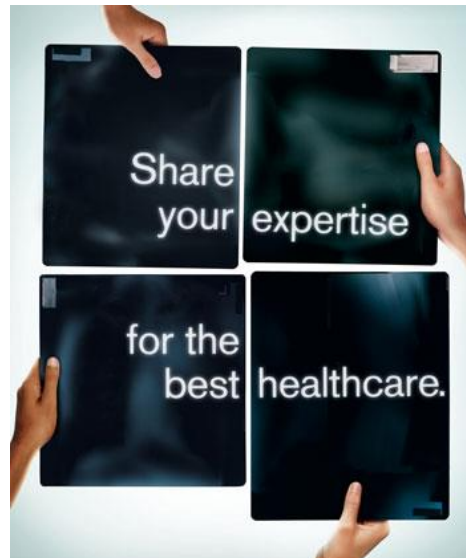


European
Reference
Networks

Share. Care. Cure.

ERN Assessment Manual for Applicants

4. - Operational Criteria for the Assessment of Healthcare Providers



An initiative of the



History of changes

Version	Date	Change	Page
1.0	16.03.2016	▪ Initial version	
1.1	21.04.2016	▪ Typos correction	

Preamble

This manual includes the operational criteria that healthcare providers wishing to apply for membership of ERN should fulfil. It is part of series **of nine documents** that include the following:

1. ERN Assessment Manual for Applicants: Description and Procedures
2. Technical Toolbox for Applicants
3. Operational Criteria for the Assessment of Networks
4. Operational Criteria for the Assessment of Healthcare Providers
5. Network Application Form
6. Membership Application Form
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.

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BACKGROUND

As expertise in rare or low prevalence complex diseases or conditions is scarce and dispersed, the European Commission (EC) together with the Member States is working to establish European Reference Networks (ERNs) to link existing specialised healthcare providers. ERNs will help facilitate access to diagnosis and treatment by centralising knowledge and experience, medical research and training, and resources in the area of rare or low prevalence complex diseases or conditions. The premise for establishing ERNs is that expertise should be brought closer to the patients' home. The EC has been mandated to define the requirements for ERNs as specified in Article 12 of the Directive 2011/24/EU on patient's rights in cross-border healthcare. As a result, the EC developed the Commission Delegated and Implementing Decisions of 10 March 2014.

The Commission Implementing Decision (2014/287/EU) on European Reference Networks (ERN) adopted on 10 March, 2014 determines the process for the assessment, approval and establishment of ERNs.

PURPOSE OF THE OPERATIONAL CRITERIA

The central component of the assessment programme is the Operational Criteria for Networks (ERNs) and Healthcare Providers. The operational criteria describe the conditions that must be met to meet the requirements outlined in the Commission Delegated Decision 2014/286/EU. The purpose of the operational criteria is to provide a common framework to assess Networks' and Healthcare Providers' compliance with this legislation.

The operational criteria help ensure consistency across assessments of the Network and Healthcare Provider Applicants, support the self-assessment process, and promote ongoing quality improvement. All Networks and Healthcare Provider Applicants are evaluated against the same operational criteria.

DESCRIPTION OF THE OPERATIONAL CRITERIA

The Operational Criteria for Healthcare Providers consist of **two** sections. The first section covers general criteria that are common to all specialised healthcare providers (e.g. organisation and management, research and training, and information systems). The second section consists of specific criteria with regards to the condition(s) or disease(s) covered by the Network. The Healthcare Provider must adapt the requirements in these criteria related to competency and expertise, qualifications of the healthcare professionals, composition of the multidisciplinary team, and access to specialised resources (facilities, equipment and diagnostic services) specific to the Network's area of expertise based on recognised sources, and/or expert consensus. The Healthcare Provider should follow these requirements as defined by the Network.

For each criterion, the following elements are included:

- **Legislative Requirement:** references to the condition(s) and sub-condition(s) in the legislation, i.e. Commission Delegated Decision 2014/286/EU Annex I and II that must be fulfilled;
- **Criterion:** operational requirement linked to every condition and/or sub-condition in the legislation;
- **Measure:** the expected measure(s) of performance that would need to be put in place to meet the criterion;
- **Guideline:** guidance and further explanation on how to reach the particular measure of performance;
- **Evidence:** what will be collected and observed to determine if the measure of performance is met; and
- **Method of Assessment:** how the evidence will be collected and evaluated to determine compliance with the measure.

EVIDENCE OF COMPLIANCE

For those **general** criteria that are common to all, the results of other accreditation and/or certification schemes may be accepted as evidence of compliance only if they are formally recognized by the national authority. In this instance, the Healthcare Provider must demonstrate that the accreditation and/or certification meet the criteria and conditions set out in this document and that it has been completed within the last 4 years. All accreditation and/or certification reports should be appended as a part of the supporting documentation and submitted during the application process. The *Assessment Manual and Technical Toolbox for Applicants* provides more detailed and specific instructions on how other accreditation and/or certification schemes may be used as supporting evidence.

For the **specific** criteria and conditions outlined in this document, the requirements are defined by the Network. As evidence, the Healthcare Provider must demonstrate compliance with these requirements.

Operational Criteria to Assess Compliance with EU Legislation

General criteria and conditions for applicants for membership of a Network¹

1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE		
1 (a) as regards patient empowerment and patient-centred care, applicant providers must:		
Criteria		
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.		
Legislated Requirement	No.	Measure(s)
1 (a) (i) have put strategies in place to ensure that care is patient-centred, that patients' rights (such as the right to informed consent; the right to information concerning their own health; the right to access to their medical records; the right to privacy; the right to complain and the right to obtain compensation, the right to be empowered and to participate (for example, through customer relations management strategies, patient education strategies and active engagement strategies for patients and families throughout the healthcare institution)) are respected;	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (a) (ii) provide clear and transparent information about complaint procedures and the remedies and forms of redress available to both domestic and foreign patients;	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (a) (iii) ensure feedback on patient experience and the active evaluation of patient experience;	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.
Criteria		
1.4 The Healthcare Provider protects the privacy and confidentiality of patient health information.		

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

Legislated Requirement	No.	Measure(s)
1 (a) (iv) apply personal data protection rules and ensure access to medical records and clinical information in compliance with EU data protection provisions and national implementing measures and in particular with Directive 95/46/EC;	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (a) (v) ensure that the informed consent of the data subject complies with the requirements set out in Article 2(e) of this Delegated Decision, in particular informed consent given freely, unambiguously and explicitly by the subject or his/her legal representative after being informed of the purpose, nature, significance and implications of the use of his/her personal and health data, if personal health data is exchanged under this Delegated Decision, and being informed of his/her rights under the applicable data protection rules. The given consent should be duly documented;	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (a) (vi) ensure transparency, including providing information about clinical outcomes, treatment options and the quality and safety standards put in place.	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 data sources are accessible 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.
Criteria		
1.7 The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.		
Legislated Requirement	No.	Measure(s)
1 (a) (vi) ensure transparency, including providing information about clinical outcomes, treatment options and the quality and safety standards put in place.	1.7.1	The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.

1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

Legislated Requirement

2014/286/EU Annex II (a) (i)

1.1 CRITERIA

The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.

1.1.1 MEASURE

The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.

Guideline

This may be demonstrated in the Healthcare Provider's mission and/or core values. Patient centred care approaches may also be reflected in protocols and care planning, professional education and training, patient information material, etc.

Evidence

- Mission or Core Values
- Patient information material

Method of Assessment

- Documentation Review
- Semi-structured Interview(s) with Member Representative(s)

1.1.2 MEASURE

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.

Guideline

A single named key clinician at a given time is identified for each individual patient and the name and contact number of the current clinician is recorded in the patient's case notes and shared with the patient and their family. Information is also provided to the patient and their family about the role of each member of the multidisciplinary team in a format that is easy to understand. It should be clear which clinician, i.e. doctor, has overall responsibility for the care of each patient.

Evidence

- Examples of Patients' Notes

- Clinical audits and/or chart reviews

Method of Assessment

- Onsite Audit (Tracer Methodology)

1.1.3 MEASURE

Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.

Guideline

The level of understanding, literacy, language, disability, and culture are considered when providing education material to patients and their families. Processes to verify patients' understanding include encouraging and allowing time for questions, having the patient and their family repeat back information, ensuring a linguistic or cultural match, wherever possible, using visuals or videos where possible, and creating an ongoing exchange where confirming understanding is a recurring event. Patient education material may be developed in collaboration with patient organizations.

Evidence

- Patient Education Materials
- Method of Assessment
- Onsite Audit (Documentation Review)

1.1.4 MEASURE

The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.

Guideline

The information should include a summary of the following: services offered; the nature of the disease, treatment and possible complications, how to access the center; information about the staff and collaborating consultants; other members and involved stakeholders such as patient organizations, scientific societies, and universities, etc.

Evidence

- Patient Information Materials
- Method of Assessment
- Documentation Review

1.1.5 MEASURE

The Healthcare Provider gives patients and their families written information about their rights and responsibilities.

Guideline

Patient and their family rights include the right to have privacy and confidentiality protected; be aware of how patient information is used; have access to their medical records; be treated with respect and care; have cultural practices and spiritual beliefs be respected; and to be free from discrimination based on race, religion, culture, or gender.

Patient and their family rights regarding care include the right to refuse care or refuse to have certain people involved in their care; participate in all aspects of their care, as appropriate, and make personal choices; informed consent; have a support person or advocate involved in their care, when needed; take part in or refuse to take part in research or clinical trials; receive safe, competent service; and raise concerns about the quality of service.

Patient and their family responsibilities include treating others with respect, providing accurate information, reporting safety risks, and observing rules and regulations, as appropriate.

Patients and their families should be given information about their rights and responsibilities at the earliest possible point in their trajectory of care.

Evidence

- Written Material Describing Patient and Family Rights and Responsibilities

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

1.1.6 MEASURE

There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.

Guideline

Unanticipated outcomes and complications are disclosed to the affected patients and their families in accordance with the set policy. Support is provided to patients and their families, as appropriate. The Policy should include: what events are to be disclosed; to whom the disclosure should be made; when a disclosure should take place; who should disclose; events where a disclosure is not required; and supports available to clinicians when an event occurs.

Evidence

- Organization Policy and Process on Disclosure

Method of Assessment

- Onsite Audit (Documentation Review)

Legislated Requirement

2014/286/EU Annex II (a) (ii)

1.2 CRITERIA

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.

1.2.1 MEASURE

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.

Guideline

An environment where patients and their families feel comfortable raising concerns or issues is promoted. The Healthcare Provider may provide access to a neutral, objective person from whom patients and their families can seek advice or consultation.

There is a procedure to investigate and respond to complaints and claims that patients' rights have been violated, and respond to patient and their family concerns in a timely way. The Healthcare Provider can demonstrate evidence of proactive remedial actions to a complaint or concern. The degree to which a complaint has been actioned and service improvements made as a result would demonstrate the commitment to patient centred care. Standards for response times are clearly defined, documented, and followed.

Evidence

- Patient Information material on how to file a complaint
- Complaints Policy

Method of Assessment

- Onsite Audit (Documentation Review)
- Onsite Audit (Tracer Methodology)

Legislated Requirement

2014/286/EU Annex II (a) (iii)

1.3 CRITERIA

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.

1.3.1 MEASURE

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.

Guideline

Patient experience and perceptions of service quality are important predictors of clinical and patient outcomes and quality. Patients' perceptions of the quality of healthcare services are an essential component of delivering effective outcomes². Pending the Network's area of expertise and variation in the profile of patients served across Healthcare Providers, a supplemental set of questions may be added to a standardized core set. The Healthcare Provider may involve patient organizations in the design and dissemination of the patient experience questionnaire.

The patient experience results of all Members would support ongoing quality improvement within the Network.

Evidence

- Patient Experience Survey
- Patient Experience Reports
- Action Plan for Improvement

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU Annex II (a) (iv)

1.4 CRITERIA

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

1.4.1 MEASURE

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.

² Literature review report (task 1.1)

Guideline

The EU Data Protection Directive (also known as Directive 95/46/EC) is a directive adopted by the European Union designed to protect the privacy and protection of all personal data collected for or about citizens of the EU, especially as it relates to processing, using, or exchanging such data. The Healthcare Provider routinely monitors and evaluates record keeping practices, including the accuracy and effectiveness of these practices, and examines any privacy breaches.

Evidence

- Confidentiality and Privacy Policies and Procedures
- Privacy and Record Keeping Audits

Method of Assessment

- Documentation Review
- Onsite Audit

Legislated Requirement

2014/286/EU Annex II (a) (v)

1.5 CRITERIA

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

1.5.1 MEASURE

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.

Guideline

Informed consent is given freely, unambiguously and explicitly by the patient or their legal representative after being informed of the purpose, nature, significance and implications of the use of their personal health information. The given consent should be duly documented.

Evidence

- Informed Consent Policy and Procedure
- Informed Consent Forms
- Medical Record Audit or Chart Review

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

Legislated Requirement

2014/286/EU Annex II (a) (vi)

1.6 CRITERIA

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.

1.6.1 MEASURE

The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.

Guideline

Transparency is the free, uninhibited flow of information that may be open to the scrutiny of others. Evidence supports the premise that greater transparency throughout the system is not only ethically correct but will lead to improved outcomes, fewer errors, more satisfied patients, and lower costs. There are four domains of transparency: between patients and clinicians; amongst clinicians; amongst Healthcare Providers; and with the general public.

Evidence

- Patient Information Material

Method of Assessment

- Documentation Review

1.6.2 MEASURE

All relevant information must be provided to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.

Guideline

Patient access to information within the Network's area of expertise is facilitated in a proactive way, according to the Healthcare Provider's policy and applicable legislation. The processes to access information are patient-centred and support easy access. Patients have opportunities to discuss the information, ask questions, and provide feedback. A patient registry is a collection—for one or more purposes—of standardized information about a group of patients who share a disease, condition or experience.

Evidence

- Policies and procedures for accessing information

Method of Assessment

- Documentation Review

1.6.3 MEASURE

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.

Guideline

This information is made available to patients when obtaining informed consent for treatment. Risks to patients include those associated with medicines, medical technologies clinical, management and equity. When presenting this information, patients and their families are given time to reflect and ask questions.

Evidence

- Informed Consent Policy and Procedure
- Patient Information Material

Method of Assessment

- Documentation Review

1.6.4 MEASURE

The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.

Guideline

The Healthcare Provider systematically and consistently collects data on key parameters of patient safety, including the use of medicines and medical technology products specific to the Network's area of expertise, and publicly releases figures every year.

Evidence

- Patient Information Material or Videos

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU Annex II (a) (vi)

1.7 CRITERIA

The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.

1.7.1 MEASURE

The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.

Guideline

A conflict of interest occurs when an individual has competing professional or personal interests that may make it difficult for them to fulfil their duties fairly. Healthcare professionals are made aware of what constitutes a conflict of interest, the process for declaring conflicts of interest, and the steps that may be taken to resolve or mitigate the effects of the conflict of interest.

Evidence

- Conflict of Interest Policy

Method of Assessment

- Documentation Review

2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY		
1b with regard to organisation, management and business continuity, applicant providers must:		
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (b) (i) apply transparent and explicit organisation and management rules and procedures, including in particular the procedures for managing cross-border patients in their area of expertise;	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (b) (ii) ensure that tariffs are transparent;	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.
Criteria		
2.3 The Healthcare Provider has a business continuity plan.		
Legislated Requirement	No.	Measure(s)
1 (b) (iii) have a business continuity plan over a given time frame, including ensuring <ul style="list-style-type: none"> - the provision of essential medical care in the case of unexpected resource failure, or access or referral to alternative resources if necessary - the maintenance of the stability and technical capacity and expertise of the provider, such as a plan for managing human resources and updating technology 	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.
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (b) (iv) ensure coordination with and easy access of the provider to other resources or specific units or services necessary for managing patients;	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.
Criteria		
2.5 The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.		
Legislated Requirement	No.	Measure(s)
1 (b) (v) have good general facilities, such as surgery theatres, an intensive care unit, an isolation unit, an emergency ward and laboratories;	2.5.1	Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.

Criteria		
2.6 There are policies and procedures in place to communicate with clinicians post discharge, including cross border.		
Legislated Requirement	No.	Measure(s)
1(b) (vi) have the capacity to communicate with relevant post-discharge services, including the capacity for cross-border communication.	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.

2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY

Legislated Requirement

2014/286/EU Annex II (b) (i)

2.1 CRITERIA

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

2.1.1 MEASURE

Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.

Guideline

The organization chart outlines key personnel and roles and functions within the Network's area of expertise. It includes the selection of one person to represent the Healthcare Provider within the Network Board and the rules, procedures, and organisation of the Network. .

Evidence

- Organization chart
- Rules of procedure of the Healthcare Provider and the Network

Method of Assessment

- Documentation Review

2.1.2 MEASURE

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.

Guideline

These include, at a minimum, all elements required by the legislated general and specific criteria to be fulfilled by Healthcare Providers. These should address organization of the service; patient evaluation and treatment; personnel appraisal and continuing education; supply and management of therapeutic products, laboratory agents, and medical devices, as applicable; etc. The Healthcare Provider regularly reviews these policies and procedures based on a set schedule to ensure they are current and contain up to date references.

Evidence

- Policies and Procedures or planned actions and timelines to develop policies and procedures

Method of Assessment

- Documentation Review

2.1.3 MEASURE

There are policies and procedures for managing cross border patients within the Network's area of expertise.

Guideline

The Healthcare Provider should follow the set cross border pathway established by the Network. Procedures should include: collaborating with other Members within the Network to standardize discharge summary content; optimizing the use of technologies such as telemedicine and e-Health records; managing language issues; developing and documenting set care plans; and assigning a contact person to coordinate care for each patient.

Evidence

- Policies and Procedures for Managing Cross Border Patients or planned actions and timelines for developing policies and procedures

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU Annex II (b) (ii)

2.2 CRITERIA

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.

2.2.1 MEASURE

The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.

Guideline

When a patient receives cross border healthcare, it is essential for the patient and family to know in advance of treatment the rules that apply. This will help the patient and their family make an informed choice about service and avoid any misunderstanding. The rules that apply are 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.

Evidence

- Patient Information Materials

Method of Assessment

- Documentation Review

Legislated Requirement

2014 286/EU Annex II (b) (iii)

2.3 CRITERIA

The Healthcare Provider has a business continuity plan.

2.3.1 MEASURE

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.

Guideline

The business continuity plan is based on the results of a business impact analysis, and includes the identification of time-sensitive critical functions and applications, associated resource requirements, and interdependencies. A business continuity plan is developed and implemented in order to continue critical operations during and following an unexpected resource failure.

Unexpected resource failure may include utilities such as electricity, potable water, sterile water, fuel, medical gases, vacuum systems, and systems such as elevators/escalators; heating, ventilation, and cooling; steam for sterilization; and communication equipment, e.g. telephones, facsimile machines, mobile phones, pagers, and intercoms; and information systems.

The Healthcare Provider collects and analyzes data as a part of its facilities management programs to support planning for replacing or upgrading medical technology, equipment, and systems, and reducing risks in the environment specific to the Network's area of expertise. Clinical leads or experts may work with regional hospitals to develop succession plans. Succession planning increases the availability of experienced and capable providers that are prepared to assume these roles as they become available.

Evidence

- Business continuity plan

Method of Assessment

- Documentation Review

Legislated Requirement

2014 286/EU Annex II (b) (iv)

2.4 CRITERIA

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.

2.4.1 MEASURE

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.

Guideline

The Healthcare Provider informs patients about who to contact in the event of an emergency or when treatment is needed outside of normal working hours. Depending on the type of disease or condition, this may include: access to a clinician with expertise in the disease or condition and diagnostic and treatment services within the Healthcare Providers area of expertise.

A "suitable hospital ward" may include inpatient, ambulatory, urgent care and emergency, and inpatient units within the Healthcare Provider organization with established referrals protocols to support access to complementary emergent services of other Healthcare Providers, when appropriate. The appropriate units are staffed by personnel familiar with the care of patients within the Network's area or expertise. Teams in various units, such as admitting or emergency wards, are made aware of arrangements for the care of patients within the Network's area of expertise to enable prompt referral to the multidisciplinary team.

Evidence

- Emergency and After Hour Procedures
- Referral Protocols
- Patient Information Materials

Method of Assessment

- Documentation Review
- On-site Audit (Tracer Methodology)

2.4.2 MEASURE

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.

Guideline

There are documented procedures and/or formal agreements between the Healthcare Provider, i.e. centre of expertise, and other highly specialised providers and/or services such as proton therapy, special radiotherapy, burn care, hyperbaric chambers, etc. necessary for diagnosing and managing patients across the disease trajectory.

Evidence

- Formal Agreements between Healthcare Providers and/or Procedures

Method of Assessment

- Documentation Review

Legislated Requirement

2014 286/EU Annex II (b) (v)

2.5 CRITERIA

The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.

2.5.1 MEASURE

Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.

Guideline

Facilities may include surgery theatres, intensive care units, isolation units, emergency wards, laboratories, etc.

Evidence

- Appearance of Facilities
- Third party reports and/or inspections on the quality care environments
- Valid License of Healthcare Facilities, as applicable

Method of Assessment

- Onsite Audit (Tour of Facility or Unit)

Legislated Requirement

2014 286/EU Annex II (b) (vi)

2.6 CRITERIA

There are policies and procedures in place to communicate with clinicians post discharge, including cross border.

2.6.1 MEASURE

The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.

Guideline

- The Healthcare Provider uses a standard discharge summary template with pre-established categories. Procedures for follow-up post discharge are documented in patient pathways, including cross border pathways. Local clinicians may include: clinician in local hospitals, general practitioners and/or primary care providers. Clear discharge instructions should also be provided to patients and their families using a standard template.

Evidence

- Discharge procedure
- Discharge Template

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

2.6.2 MEASURE

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.

Guideline

The use of ICT tools can facilitate the sharing of information post discharge and help to share information across borders. It involves the secure transmission of medical data and information, through text, sound, images, or other forms needed to support follow-up of patients. Telemedicine and tele-expertise encompass a wide variety of services. Other services may include: e-visits, remote consultation, electronic health record systems, health information portals, and electronic transmission of prescriptions. These same tools may also be applied throughout the patient pathway from referral to discharge.

Evidence

- Technologies Used

Method of Assessment

- Semi-structured Interview with Healthcare Provider Representative

3. RESEARCH, EDUCATION AND TRAINING		
1.C. with regard to research and training capacity, applicant providers must:		
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1(c) (i) have the capacity to provide academic, university or specialised level training;	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.
1 (c) (ii) have human, technical and structural capacity, skill mix and resources;	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.
1 (c) (iv) carry out teaching and education activities related to the area of expertise aimed at improving the knowledge and technical capacity of the healthcare providers involved in the same chain of care within and outside the provider facility, such as continuing medical education and distance learning.	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.
Criteria		
3.2 The Healthcare Provider has the capacity to carry out research activities and demonstrated research experience.		
Legislated Requirement	No.	Measure(s)
1 (c) (iii) have research capacity, and demonstrated research experience or production in the area of expertise of the Network, at national and international level.	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.
	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.
	3.2.7	The Healthcare Provider evaluates the effectiveness of research activities.

3. RESEARCH, EDUCATION AND TRAINING

Legislated Requirement

2014/286/EU Annex II 1 (c) (i, ii, and iv)

3.1 CRITERIA

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.

3.1.1 MEASURE

The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.

Guideline

The Healthcare Provider should ensure that there are a sufficient number of cases to support education and training activities. This may be achieved through cooperation between centres of expertise. Staff involved in the teaching of residents must hold an appointment acceptable to the university and to the Healthcare Provider.

Evidence

- Written agreement of affiliation or letters of intent between the university and/or academic centre and the Healthcare Provider, as applicable; and/or as required by relevant legislation or by-laws
- List of joint positions between clinical services and the university

Method of Assessment

- Documentation Review

3.1.2 MEASURE

The Healthcare Provider has a defined set of objectives for its education and training activities.

Guideline

The objectives are reviewed, updated, and/or modified on an annual basis.

Evidence

- List of teaching objectives

Method of Assessment

- Documentation Review

3.1.3 MEASURE

The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.

Guideline

Resources should include qualified staff to provide appropriate supervision, technology to support various methods of teaching and training, and clinical services and/or education sites used for teaching and training are organized to promote education function. The type and number of resources are determined based on the volume and type of teaching and training activities and the number of students, and/or as required by relevant legislation and by-laws, as applicable.

Evidence

- List of Teaching Staff and Qualifications
- Description of Site Resources to Support Education and Training

Method of Assessment

- Documentation Review
- On Site Audit and Tour

3.1.4 MEASURE

Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.

Guideline

- Providers outside the facility may include general and specialised physicians, helping to prevent delays in diagnosis and inadequate follow-up of patients.

Evidence

- List of teaching and training activities carried out in the past year, including the date, type of activity, and targeted professionals.

Method of Assessment

- Documentation Review

3.1.5 MEASURE

The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.

Guideline

The effectiveness of education and training activities may be measured by satisfaction, acquired knowledge or skills, and/or demonstrated competence. Where possible, the Healthcare Provider is accredited and/or certified for its teaching and training activities. Compliance with set

standards for education and training protects the integrity of the learning experience and ensures that education and training providers are credible and competent.

Evidence

- List of Measures and results over the last three years
- Accreditation or Certification

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU Annex II 1 (c) (ii-iii)

3.2 CRITERIA

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

3.2.1 MEASURE

The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.

Guideline

Resources should include sufficient numbers of qualified staff; adequate facilities to support the duration of the research project or clinical trial; available patient data, biologic samples, and the potential to recruit a suitable number of subjects; and electronic systems to support data collection and analysis. Evidence may also include a specific budget allocated towards research, organogram including a research department or research units such as immunology, molecular biology, genetics, etc.

Evidence

- List of Research Staff and Qualifications, e.g. MDs, PhDs, technicians, etc
- Description of Site Facilities to Support Research

Method of Assessment

- Documentation Review
- On Site Audit and Tour

3.2.2 MEASURE

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.

Guideline

This may include: basic scientific research, translational research, clinical research, orphan drug research, social science research, etc.

Evidence

- List of grants and research projects over the last 5 years
- Number of research projects

Method of Assessment

- Documentation Review

3.2.3 MEASURE

The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.

Guideline

Standard Operating Procedures (SOPs) provide, at a minimum good clinical practice standards in clinical trials and other research. The Standards of Practice are based on internationally accepted standards for the designing, conducting, recording and reporting of clinical trials and research. Compliance with this standard provides assurance that the rights, safety and well-being of research participants are protected and that clinical trial and research data are credible. The SOPs should include procedures for obtaining and documenting patient informed consent.

Evidence

- Standard Operating Procedures (SOPs)

Method of Assessment

- Documentation Review

3.2.4 MEASURE

There is a procedure to review the ethical implications of research activities.

Guideline

The procedure includes set criteria for determining when a research project requires ethics approval and methods to assess the implications of patient participation.

The Healthcare Provider should have in place or have access to a body, such as Research Ethics Board or Committee, which reviews and approves research proposals to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines as set by the Member State.

All research proposals involving human participants should be reviewed and approved by a Research Ethics Board or Committee. Items reviewed and approved by the Ethics Board or Committee should include informed consent, inclusion/exclusion criteria, and side/toxic effects.

Evidence

- Defined criteria for ethics approval
- Research Policy and Procedure
- Research Ethics Board or Committee Terms of Reference and Meeting Minutes

Method of Assessment

- Onsite Audit (Documentation Review)

3.2.5 MEASURE

The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.

Guideline

The Healthcare Provider maintains a list of research projects and clinical trials it participates in. Documentation should include the name of the project, funding entity, budget, timeframe, and care providers who participate as the principle investigator(s) or collaborator(s) on the project.

Evidence

- Demonstration of Information System Used to Collect Data

Method of Assessment

- Onsite Audit (Documentation Review)

3.2.6 MEASURE

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.

Guideline

These publications are linked to the Network's area of expertise and include those care providers who participated in the research.

Evidence

- Number of articles published over the last 5 years about the rare disease or condition
- List of centres and associations that receive information and method of dissemination

Method of Assessment

- Documentation Review

3.2.7 MEASURE

The Healthcare Provider evaluates the effectiveness of research activities.

Guideline

This may include monitoring research production, performance of research projects, and overall return on investment such as the outcomes of research activities.

Evidence

- List of Measures and performance over the last three years

Method of Assessment

- Documentation Review

4. EXPERTISE, INFORMATION SYSTEMS, AND e-HEALTH TOOLS		
1d with regard to the exchange of expertise, information systems and e-health tools, applicant providers must:		
Criteria		
4.1 The Healthcare Provider is able to exchange expertise with other providers and provide support to them.		
Legislated Requirement	No.	Measure(s)
1 (d) (i) be able to exchange expertise with other healthcare providers and to support them;	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.
Criteria		
4.2 The Healthcare Provider safeguards the use of medical data within the Network's area of expertise.		
Legislated Requirement	No.	Measure(s)
1 (d) (ii) have established procedures and a framework for ensuring the management, safeguarding and exchange of medical data, including established outcomes, process indicators and patient registers for the specific area of expertise in accordance with the EU data protection legislation, in particular with Directive 95/46/EC, and with Article 2(e) of this Delegated Decision;	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.
Criteria		
4.3 The Healthcare Provider fosters the use of telemedicine and other e-health tools within and outside its facility.		
Legislated Requirement	No.	Measure(s)
1 (d) (iii) be able to foster the use of telemedicine and other e-health tools within and outside their facilities, by fulfilling the minimum interoperability requirements and when possible, using agreed standards and recommendations;	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.
Criteria		
4.4 The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.		
Legislated Requirement	No.	Measure(s)
1 (d) (iv) use a standardised information and coding system in line with nationally or internationally recognised systems, for example International Classification of Diseases and complementary codes when appropriate.	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.

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

Legislated Requirement

2014/286/EU (d) (i)

4.1 CRITERIA

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

4.1.1 MEASURE

The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.

Guideline

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, and other specialist centres, etc.

Evidence

- Advisory Service
- Procedures and Strategies to Disseminate Knowledge

Method of Assessment

- Documentation Review
- Onsite Audit (Semi structured Interview with Member Representative and Healthcare Professionals)

4.1.2 MEASURE

The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.

Guideline

Keeping accurate records of clinical information is essential to the effective delivery of care. The handling of data for rare or low prevalence complex diseases or conditions may be complex in several areas. The Healthcare Provider should be able to collect all required information as set by the Network Board and in accordance with data protection laws.

Evidence

- Policies and procedures for clinical documentation
- Patient Database

Method of Assessment

- Documentation Review
- Onsite Audit (observation of the database and/or chart reviews)

Legislated Requirement

2014/286/EU (d) (ii)

4.2 CRITERIA

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

4.2.1 MEASURE

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.

Guideline

The Healthcare Provider is able to send and receive secure clinical information electronically between care providers to support coordinated care. This includes clinical outcome data, process indicators, and patient registers for the Network's specific area of expertise.

The EU Data Protection Directive 95/46/EC aims to keep private and protect all personal data collected for or about citizens of the EU, especially as it relates to processing, using, or exchanging such data. The Healthcare Provider should have procedures in place to ensure: data collected is used only for stated purpose(s) and for no other purposes; personal data is not disclosed or shared with third parties without patient informed consent; once collected, personal data is kept safe and secure from potential abuse, theft, or loss; patients are informed as to the party or parties collecting such data, where applicable; and patient access to their personal data.

Evidence

- Policies and Procedures

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU (d) (iii)

4.3 CRITERIA

The Healthcare Provider fosters the use of telemedicine and other e-health tools within and outside its facility.

4.3.1 MEASURE

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.

Guideline

The Healthcare Provider participates in activities to advance best practice in the use of telemedicine to support the care to patients within the Network's area of expertise. Where possible, the Healthcare Provider uses telemedicine technology to facilitate consultations between centres within different domains specific to the area of expertise such as PACs systems, teleradiology, telecardiology, teledermatology, etc. When using telemedicine and other e-Health tools, the Healthcare Provider follows set Standard Operating Procedures and protocols. 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.

Evidence

- Telemedicine Standard Operating Procedures and Protocols, where possible
- Description of Telemedicine Activities

Method of Assessment

- Documentation Review
- Onsite Audit

Legislated Requirement

2014/286/EU (d) (iv)

4.4 CRITERIA

The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.

4.4.1 MEASURE

The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).

Guideline

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. Given that systems are not yet available within all countries, evidence may include an agreement amongst all Healthcare Providers within the Network on the use of the most appropriate coding system.

Evidence

- Information and Coding System for Rare or Low Prevalence Complex Disease or Condition

Method of Assessment

- Onsite Audit (Semi-structured Interview)

4.4.2 MEASURE

The Healthcare Provider has procedures in place to monitor and maintain data quality.

Guideline

This should include both quality assurance activities undertaken before data collection to ensure that the data are of the highest possible quality at the time of collection; and quality control activities undertaken during and after data collection aimed at identifying and correcting sources of data errors, such as audits and the generation of regular data integrity reports that monitor errors in coding, data reliability and accuracy, and data completeness. Healthcare professionals are given information about their role and responsibilities in maintaining data quality.

Evidence

- Data Quality Procedures

Method of Assessment

- Onsite Audit (Documentation Review)

5. QUALITY AND SAFETY		
1e with regard to expertise, good practices, quality, patient safety and evaluation, applicant providers must:		
Criteria		
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.		
Legislated Requirement	No.	Measure(s)
1 (e) (i) have a quality assurance or management system and plans including governance and evaluation of the system;	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.
1 (e) (ii) have a patient safety programme or plan consisting of specific goals, procedures, standards and process and outcome indicators focusing on key areas, such as information, a system for reporting on and learning from adverse events; training and education activities; hand hygiene; healthcare related infections; medication errors and the safe use of medication; safe procedures and surgery; safe patient identification	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.
Criteria		
5.2 The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.		
Legislated Requirement	No.	Measure(s)
1 (e) (iii) commit itself to using the best knowledge- and evidence-based health technologies and treatments;	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.
Criteria		
5.3 The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.		
Legislated Requirement	No.	Measure(s)
1 (e) (iv) develop and use clinical guidelines and pathways in their area of expertise.	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.
	5.3.2	The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.
	5.3.3	Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.

5. QUALITY AND SAFETY

Legislated Requirement

2014/286/EU Annex II (e) (i)-(ii)

5.1 CRITERIA

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.

5.1.1 MEASURE

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.

Guideline

The system should include: routine monitoring of performance based on set timeframes; managing complaints and periodic surveys of patients' opinions about their care; analyzing and reporting critical incidents and adverse events; periodic analysis and global assessment of policies and procedures, adequacy of staff skills and need for training, and adequacy of facilities; and conducting systematic clinical and quality audits to assess compliance with policies and procedures established specific to the Network's area of expertise. Based on results, annual objectives and a quality improvement work plan are developed. Progress towards achieving the annual objectives is monitored.

Evidence

- Quality Assurance or Management System
- Quality Improvement Plan
- List of audits, including their findings and status of recommendations, completed in the past year within the Network's area of expertise
- Description of Process Improvements

Method of Assessment

- Documentation Review

5.1.2 MEASURE

The Healthcare Provider regularly collects and monitors process and outcome indicators.

Guideline

The Healthcare Provider follows set parameters and definitions for data collection reporting agreed to at the Network, appropriate regional, and/or national level. At a minimum, indicators

should include: morbidity, mortality, adverse events related to treatment, and patient-reported outcomes. Critical factors for consideration regarding patient reported outcomes include: frequency and timing of the application of the tool used and its validity and reliability.

Evidence

- Process and Outcome Indicators (Dashboard) and their definitions
- Patient Reported Outcome Measures
- Sample Indicator Report that includes quarterly or biannual data over the past year, as appropriate

Method of Assessment

- Documentation Review

5.1.3 MEASURE

The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise.

Guideline

The patient safety programme should include specific goals, procedures, standard, and process and outcome indicators. Areas of focus may include: delays in diagnosis, disruption in continuity, healthcare related infections, medication errors, safe use of medication, safe surgical procedures, safety education and training, etc. There are multidisciplinary processes and forums in place for reporting, analyzing, sharing, and using safety data for improvement.

Evidence

- Patient Safety Plan
- Patient Safety Reports
- Patient Safety and Quality Committee Minutes

Method of Assessment

- Documentation Review

5.1.4 MEASURE

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.

Guideline

The Healthcare Provider should investigate the root cause of all critical incidents or adverse events and implement corrective or preventive actions.

Evidence

- Detailed Example of Root Cause Analysis and Description of Process Improvement

Method of Assessment

- Documentation Review
- Onsite Audit

5.1.5 MEASURE

The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.

Guideline

The Healthcare Provider collaborates with the Network to establish common performance and outcome measures. Once set, the Healthcare Provider shares performance and outcome data at a Network level to facilitate benchmarking and the sharing for best practice across its Members and monitoring the Network's performance, as a whole.

Evidence

- Examples of measures collected at the Network level or planned actions and timelines for establishing a common set of measures

Method of Assessment

- Documentation Review

Legislated Requirement

2014/286/EU Annex II (e) (iii)

5.2 CRITERIA

The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.

5.2.1 MEASURE

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.

Guideline

This may include biannual meetings composed of clinicians and patient representatives. The results are used to make ongoing improvements in patient care.

The Healthcare Provider uses standardised procedures and protocols, where possible, to support patient care and assess clinical outcomes. Standardised procedures and protocols should be based in best knowledge and evidence and may be developed by the Network and/or regional, national, and international level.

Evidence

- Mechanisms used to review and share best practice information
- List of standardised procedures and protocols

Method of Assessment

- Semi-structured Interviews
- Documentation Review

Legislated Requirement

2014/286/EU Annex II (e) (iv)

5.3 CRITERIA

The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.

5.3.1 MEASURE

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.

Guideline

Best practices information and shared outcome data are considered when developing and selecting clinical practice guidelines. Guidelines may be developed and/or selected by a committee, council, or individual who makes recommendations. The process for selecting guidelines is standard and formal. It may include using content experts; a consensus panel; or use of a standard instrument, e.g. AGREE.

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

Evidence

- Procedure for developing/selecting and updating clinical practice guidelines
- Methods used to obtain patient and their family input
- Clinical Practice Guidelines

Method of Assessment

- Documentation Review

5.3.2 MEASURE

The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.

Guideline

This may include participation in consensus and/or training workshops at the Network level, diffusing guidelines and recommendations among care providers, and putting in place methods to monitor implementation of the guideline.

Evidence

- Implementation of clinical practice guidelines

Method of Assessment

- Onsite Audit (Semi-structured Interview with Member Representative)

5.3.3 MEASURE

Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.

Guideline

The review process includes accessing the most up-to-date research and information and determining its relevance through literature reviews, content experts, etc. Research information may include intervention research, program evaluations, or clinical trials.

Evidence

- Procedure for developing/selecting and updating clinical practice guidelines

Method of Assessment

- Documentation Review

Specific Criteria and Conditions to be Fulfilled

Specific operational criteria and conditions for applicant providers with regard to the area of expertise, disease or condition the Networks they wish to join focus on:

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE		
2a with regard to competence, experience and outcomes of care, applicant providers must:		
Criteria		
6.1 The Healthcare Provider maintains its competence in the Network's area of expertise.		
Legislated Requirements	No.	Measure(s)
2 (a) (i) document competence, experience and activity (e.g. the volume of activity, referrals and accumulated experience and when possible, the minimum/optimal number of patients/year, in accordance with professional/technical standards or recommendations);	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.
Criteria		
6.2 The Healthcare Provider demonstrates good clinical care and outcomes.		
Legislated Requirements	No.	Measure(s)
2 (a) (ii) provide evidence of good clinical care and outcomes according to available standards, indicators and knowledge, and evidence that the treatments offered are recognised by international medical science in terms of their safety, value and potential positive clinical outcome.	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.

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

Legislated Requirement

2014/286/EU Annex II 2 (a) (i)

6.1 CRITERIA

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

6.1.1 MEASURE

The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.

Guideline

This may include, as an example, volume of activity, number of referrals, and accumulated experience such as the number of published reports and peer-reviewed publications demonstrating its activity and experience.

Evidence

- Caseload Activity and Key Process and Outcome Indicators
- Demonstration of Information System Used to Collect Data

Method of Assessment

- Documentation Review and Onsite Audit (documentation review)

6.1.2 MEASURE

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.

Guideline

Competency may be systematically self-defined by the Network based on published evidence or the consensus of experts with validation from national or international experts.

Evidence

- Policy, guideline or standard that defines the minimum number of patients or procedures
- Evidenced based rationale to support target for minimum number of patients or procedures
- Number of referrals and volume of patients seen per year and/or procedures completed for the last three years
- Anonymized Registry of Visited/Treated Patients

Method of Assessment

- Documentation Review
- On-site Audit

Legislated Requirement

2014/286/EU Annex II 2 (a) (ii)

6.2 CRITERIA

The Healthcare Provider demonstrates good clinical care and outcomes.

6.2.1 MEASURE

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.

Guideline

Evidence may be demonstrated through scientific publications and/or the results of clinical trials.

Evidence

- Documentation and description of treatment protocols used and the evidence to support their use
- Anonymized Registry of Visited/Treated Patients

Method of Assessment

- Documentation Review
- On-site Audit

6.2.2 MEASURE

The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.

Guideline

Evidence may be demonstrated in the routine publication of mortality, morbidity, survival rates, loss of function and quality of life measures. Variations in the data are routinely analysed and changes are made to patient care processes, as necessary.

Evidence

- Performance and outcome indicators, data definitions, data collection methods, and interpretation
- Last two years of published data

Method of Assessment

- Documentation Review

7. HUMAN RESOURCES		
7b with regard to the specific human, structural and equipment resources and the organisation of care, applicant providers must document:		
Criteria		
7.1 The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.		
Legislated Requirement	No.	Measure(s)
7 (b) (i) the characteristics of human resources such as type, number, qualifications and skills.	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.

7. HUMAN RESOURCES

Legislated Requirement

2014/286/EU Annex II 2 (b) (i)

7.1 CRITERIA

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

7.1.1 MEASURE

The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.

Guideline

Documentation includes type of professionals, number of professionals, specific qualifications, and skills. The required skills and competencies are defined by the Network, evidence-based, and consistent with the Healthcare Providers area of expertise. This should include contingency plans for situations of temporary loss of specific expertise.

Evidence

- Documentation of professionals and their qualifications

Method of Assessment

- Documentation Review

7.1.2 MEASURE

There is a sufficient number of staff with the necessary qualifications to perform the specialized function.

Guideline

This includes diagnosis, treatment, information, observation, nursing, rehabilitation, etc. The number and type of qualified medical specialists and other healthcare and allied professionals to perform the specialized function are defined by the Network. For the treatment of children, medical specialists and other healthcare and allied professionals have experience with the treatment of children. There is a clear description of the functional and operational structure of the human resources dedicated to Network's area of expertise.

Evidence

- List of professionals and their qualifications
- Description of functional and operational structure of human resources

Method of Assessment

- Documentation Review

7.1.3 MEASURE

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.

Guideline

The Healthcare Provider follows a documented standard that defines the minimum number as established by the Network. The documented standard is in accordance with the type of disease or condition and is evidence-based. The Healthcare Provider regularly monitors and tracks activity and implements actions to address areas for improvement.

Evidence

- Documented Standard
- Volume of activity per health care professional over the last two years
- Annual Report of the Volume of Patients discussed by the MDT

Method of Assessment

- Documentation Review

7.1.4 MEASURE

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.

Guideline

Credentials, qualifications, and competencies are verified, documented, and up-to-date. Designations, credentials, competency assessments, and training are monitored and maintained to ensure safe and effective delivery of care. Professional requirements are kept up-to-date, in accordance with organizational policies and professional body regulatory requirements.

Evidence

- Human Resource Records
- Competency Assessments completed in the last two years, as applicable

Method of Assessment

- Documentation Review

8. ORGANIZATION OF PATIENT CARE		
8b with regard to the specific human, structural and equipment resources and the organisation of care, applicant providers must document:		
Criteria		
8.1 Comprehensive care is delivered by a multidisciplinary and specialised care team.		
Legislated Requirement	No.	Measure(s)
8 (b) (ii) the characteristics, organisation and functioning of the specific multidisciplinary healthcare team.	8.1.1	The Healthcare Provider documents the characteristics of the multidisciplinary team.
	8.1.2	There is a designated leader and chair of the multidisciplinary team.
	8.1.3	There are documented procedures to support the organisation and functioning of the multidisciplinary care team.
	8.1.4	There are regular structured meetings between multidisciplinary team members.
	8.1.5	Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.
	8.1.6	The multidisciplinary team evaluates its performance on an annual basis.

8. ORGANIZATION OF PATIENT CARE

Legislated Requirement

2014/286/EU Annex II 2 (b) (ii)

8.1 CRITERIA

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

8.1.1 MEASURE

The Healthcare Provider documents the characteristics of the multidisciplinary team.

Guideline

The composition of the multidisciplinary team is specific to the area of expertise, rare disease or condition and defined by the Network. All relevant professions/disciplines are represented in the team. This can include core and extended team members. Members have the level of expertise and specialisation required by the multidisciplinary team. The role and responsibilities of each team member are clearly defined and included in their job description.

Evidence

- Documentation and description of the multidisciplinary team
- Sample job profile

Method of Assessment

- Documentation Review and Onsite Audit (Documentation Review)

8.1.2 MEASURE

There is a designated leader and chair of the multidisciplinary team.

Guideline

The responsibilities of the team leader should include setting clear objectives and defining what is expected of team members; ensuring that others in the organisation have an understanding of the role of the team; negotiating locally for adequate resources to support the team; and escalating issues that may impact the safety of patient recommendations, etc.

- Evidence
- Terms of Reference

Method of Assessment

- Documentation Review

8.1.3 MEASURE

There are documented procedures to support the organisation and functioning of the multidisciplinary care team.

Guideline

The purpose of the multidisciplinary team and its expected outputs are clearly defined. There are policies and procedures or guidelines that describe how the team functions; who the core and extended team members are; how members should work together; how changes in clinical practice will be managed; and how the team will communicate following the meetings to patients and other care providers. There are processes in place to record the team's recommendations and the actual treatment given, and to alert the team to serious treatment complications and adverse or unexpected patient events. The policies, procedures or guidelines are reviewed annually.

Evidence

- Documented Procedures

Method of Assessment

- Onsite Audit

8.1.4 MEASURE

There are regular structured meetings between multidisciplinary team members.

Guideline

All team members have dedicated time included in their job 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. The team leader ensures that there is adequate representation at each meeting to make safe recommendations about patients. A register of attendance for all meetings should be maintained.

Evidence

- Meeting Minutes

Method of Assessment

- Onsite Audit

8.1.5 MEASURE

Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.

Guideline

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. The timeframes for review are defined in an operational policy and are based on nationally agreed upon protocols for clinical review, where possible.

Evidence

- Operational Policy and Procedures
- Patient Records

Method of Assessment

- Onsite Audit - Tracer Methodology

8.1.6 MEASURE

The multidisciplinary team evaluates its performance on an annual basis.

Guideline

This may include monitoring the proportion of patients discussed without sufficient information to make recommendations and the proportion of patients who received recommendations from the team. Significant discrepancies in pathology, radiology or clinical findings between local and specialist multidisciplinary teams should also be monitored and be subject to audit. Where possible, the team may benchmark itself against other multidisciplinary teams. As a part of this evaluation, the team may periodically reflect on whether patients have adequate and timely access to treatments and other aspects of care. The results of the evaluation are used to make improvements in multidisciplinary team functioning.

Evidence

- Policies and procedures

Method of Assessment

- Documentation Review

9. FACILITIES AND EQUIPMENT		
9b with regard to the specific human, structural and equipment resources and the organisation of care, applicant providers must document:		
Criteria		
9.1 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.		
Legislated Requirement	No.	Measure(s)
9 (b) (iii) specific equipment within the centre or easily accessible (such as radiotherapy laboratories or hemodynamic facilities), including the capacity, when appropriate and based on the area of expertise, to process, manage and exchange information and biomedical images (such as in the case of radiology x-ray machines, microscopy, video-endoscopy and other dynamic explorations) or clinical samples with external providers.	9.1.1	The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.
	9.1.2	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.
	9.1.3	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.
	9.1.4	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.

9. FACILITIES AND EQUIPMENT

Legislated Requirement

2014/286/EU Annex II 2 (b) (iii)

9.1 CRITERIA

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.

9.1.1 MEASURE

The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.

Guideline

Equipment and facilities may include radiotherapy laboratories or hemodynamic facilities, day hospitals, hospitalization units, nurseries, operation theatre, and other tools for supporting the diagnosis.

Evidence

- Available facilities and equipment

Method of Assessment

- Documentation Review
- Onsite Audit

9.1.2 MEASURE

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.

Guideline

This may include access to microbiology, virology, biochemistry, haematology and blood bank services, as appropriate. Laboratories must be able to analyse blood cells, biopsy tissue, and plasma and urine samples, as applicable. Access to diagnostic services should ensure that specific enzyme functions can be assayed and genetic testing is available, where necessary.

The Healthcare Provider should maintain a comprehensive list of collaborating laboratories and diagnostic services including the responsible diagnostic specialists and their qualifications. Consideration should be given to whether or not the laboratories or diagnostic services are certified or accredited.

Evidence

- Laboratory Services available
- Activity and Number of Samples or Tests Performed

Method of Assessment

- Documentation Review
- Onsite Audit (Facility Tour)

9.1.3 MEASURE

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.

Guideline

This should include, at a minimum, ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI).

Evidence

- Diagnostic Technologies available

Method of Assessment

- Documentation Review
- Onsite Audit (Facility Tour)

9.1.4 MEASURE

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.

Guideline

The Healthcare Provider has the technical capacity to handle, store, print, and transmit secure information in biomedical imaging. It includes a file format definition and a network communications protocol. The Healthcare Provider follows set standard for exchanging medical information with outside facilities.

Evidence

- Specialised Technologies available

Method of Assessment

- Documentation Review

GLOSSARY OF TERMS

Board of Member States: a governing body consisting of representative from Member States across Europe responsible for the formal designation of European Reference Networks.

Centre of Expertise: a healthcare provider defined and decided by the Member States as the expert in a complex disease or condition decided through their respected national legislation.

Collaborative/Associated National Centres: Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given Network, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing in the provision of healthcare or as Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care.

Complex Disease or Condition: a particular disease or disorder which combines a number of factors, symptoms, or signs that requires a multidisciplinary approach and well-planned organisation of services over time because it implies one or several of the following circumstances: a large number of possible diagnoses or management options and comorbidities; difficult interpretation of clinical and diagnostic test data; a high risk of complications, morbidity, or mortality related to either the disease, the diagnostic procedure, or the management of the disease.

Clinical Referral Pathway: a data-driven, evidence-based decision making process which supports clinicians and administrators to define standards and introduce processes to improve the referral experience.

Diagnosis Pathway: a clinical decision support tool that provides an overview of the presentation and clinical work-up for a specific disease or condition to be used as a tool by healthcare professionals.

European Commission (EC): the executive body of the European Union (EU) responsible for proposing legislation and implementing decisions.

European Union (EU): a formal political and economic union of Member States.

European Reference Network (ERN): a group of highly specialised healthcare providers that are in compliance with the list of criteria and conditions laid down in Article 5 of the Commission Delegated Decision (March 10, 2014) and have been awarded with the membership of a given Network. ERNs improve access to diagnosis, treatment and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.

Healthcare Provider: All applicants wishing to join or who has been awarded membership to a Network.

Highly specialised healthcare: healthcare that involves high complexity of a particular disease or condition in its diagnosis or treatment or management and high cost of the treatment and resources involved.

Independent Assessment Body (IAB): a third-party organisation mandated by the EC to implement the technical proposal for ERNs.

Informed Consent: Under the framework of European Reference Networks, any freely given, specific, informed and explicit indication of a subject's wishes by which he/she, either by a statement or by a clear affirmative action, signifies agreement to the exchange of her or his personal and health data between healthcare providers and Members of a ERN as provided in the Delegate Decision.

Learned Society: A learned society (also known as a learned academy, scholarly society, or academic association) is an organization that exists to promote an academic discipline or profession or a group of related disciplines or professions. Membership may be open to all, may require possession of some qualification, or may be an honor conferred by election. Their activities typically include holding regular conferences for the presentation and discussion of new research results and publishing or sponsoring academic journals in their discipline. Some also act as professional bodies, regulating the activities of their members in the public interest or the collective interest of the membership.

Member of a Network: Healthcare providers that are in compliance with a list of criteria and conditions laid down in Article 5 of this Decision and have been awarded with the membership of a given Network.

National Assessment Program: an organization with the mandate to assess, accredit, certify or designate healthcare providers at the national or regional level (e.g. accreditation or certification body, national health council).

Operational Criteria: a list of requirements for ERNs based on the EC ERN Decisions.

PACE-ERN: The Partnership for Assessment of Clinical Excellence in European Reference Network (PACE-ERN) is formed by the European Organisation for Rare Diseases (EURORDIS), the European Hospital and Healthcare Federation (HOPE) and Accreditation Europe. PACE-ERN is contracted by the EC to develop the technical proposal for ERNs.

Patient Pathways: a multidisciplinary management tool based on evidence-based practice for a specific group of patients with a predictable clinical course, in which the different tasks (interventions) by the professionals involved in the patient care are defined, optimized and sequenced either by hour (ED), day (acute care) or visit (homecare). Outcomes are tied to specific interventions. Patient pathways also known as *clinical pathways*, also known as *care pathways*, *critical pathways*, *integrated care pathways*, or *care maps*, are one of the main tools used to manage the quality in healthcare concerning the standardization of care processes. It has been shown that their implementation reduces the variability in clinical practice and improves outcomes.

Shared Care Approach: defined as the joint participation of primary care physicians and specialty care physicians in the planned delivery of care. Shared care has been implemented in various clinical settings to enhance the delivery of services, especially in areas affected by shortages in specialist services. Shared care presents an opportunity to provide patients with the benefits of specialist intervention combined with continuity of care.

ANNEX I - SUMMARY TABLE: Operational Criteria for the Assessment of Health Care Providers

1. General criteria and conditions for applicants for membership of a Network

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

No.	Criteria	No.	Measure(s)
1.1	The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.	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.
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.	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.
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.	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.	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.	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.	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 data sources are accessible 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.
1.7	The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.	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			
No.	Criteria	No.	Measure(s)
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.	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.	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.	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.	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.
2.5	The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.	2.5.1	Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.
2.6	There are policies and procedures in place to communicate with clinicians post discharge, including cross border.	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

No.	Criteria	No.	Measure(s)
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.	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.	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.
		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.
		3.2.7	The Healthcare Provider evaluates the effectiveness of research activities.
4.EXPERTISE, INFORMATION SYSTEMS, AND e-HEALTH TOOLS			
No.	Criteria	No.	Measure(s)
4.1	The Healthcare Provider is able to exchange expertise with other providers and provide support to them.	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.	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.	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			
No.	Criteria	No.	Measure(s)
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.	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.	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.	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.
		5.3.2	The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.
		5.3.3	Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.

Specific operational criteria and conditions for applicant providers with regard to the area of expertise, disease or condition of the Networks they wish to join

6.COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

No.	Criteria	No.	Measure(s)
6.1	The Healthcare Provider maintains its competence in the Network's area of expertise.	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.	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

No.	Criteria	No.	Measure(s)
7.1	The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.	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			
No.	Criteria	No.	Measure(s)
8.2	Comprehensive care is delivered by a multidisciplinary and specialised care team.	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			
No.	Criteria	No.	Measure(s)
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.	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.