

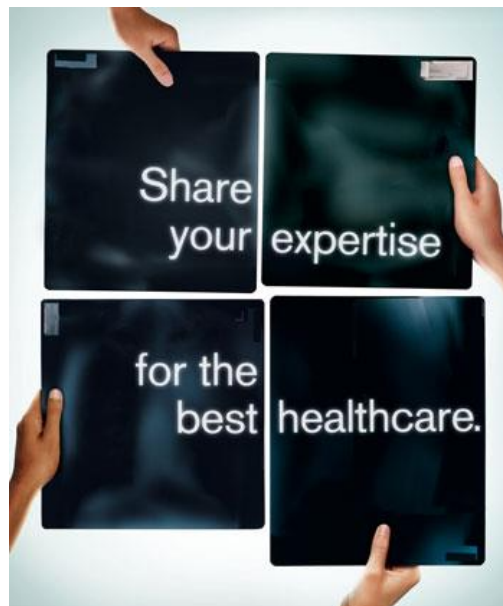


European  
Reference  
Networks

Share. Care. Cure.

# ERN Assessment Manual for Applicants

## 3.- Operational Criteria for the Assessment of Networks



*An initiative of the*



## History of changes

<b>Version</b>	<b>Date</b>	<b>Change</b>	<b>Page</b>
1.0	16.03.2016	▪ Initial version	
1.1	21.04.2016	▪ Typos correction	

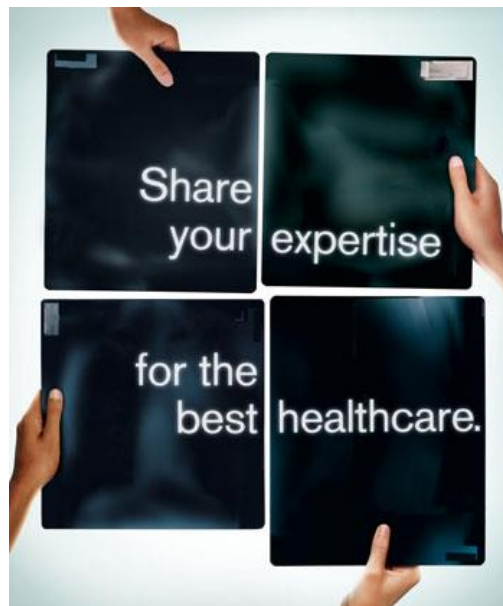


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## 3.- Operational Criteria for the Assessment of Networks



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## Preamble

This manual contains the operational Criteria for the Assessment of Networks. It is part of series **of nine** documents that include the following:

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

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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 and associated measures were designed based on the following key principles:

- To be objective;
- To be measurable;
- To be specific and clear;
- To be achievable;
- To improve patient and family experience; and
- To encourage continuous quality improvement.

The Operational Criteria for Networks consists of **eight** subsections or themes. Each theme includes one or more criterion that the Network must comply with. 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.

A variety of activities are completed by the Independent Assessment Body (IAB) to evaluate compliance against the Operational Criteria as described in the *Assessment Manual and Technical Toolbox for Applicants*.

## EVIDENCE OF COMPLIANCE

For the initial application, some of the measures have been designated as **core measures**. For these measures, Network Applicants must ensure that they are in compliance with these requirements by either having it in place or addressed within a detailed and well-defined implementation strategy within one year of the formal establishment of the Network. For all remaining measures, a clearly defined action plan and set timelines for achievement of the measure will be accepted initially as evidence. For all subsequent or future evaluations, to maintain its status, the Network must ensure they are in full compliance with the requirements outlined in this document. For core measures not in place at the time of submission of the application, the implementation strategy, action plans, and timelines for completion should be summarized in the self-assessment. In addition, links may be provided in the self-assessment. Detailed implementation strategies and plans must be made available at any point during the assessment process at the request of the Independent Assessment Body (IAB).



This symbol is used to designate those measures that are considered “**core measures**”.

In addition to the above, some measures have been categorized as a **minimum requisite for eligibility**. The Network must ensure that they are in full compliance with these measures at the time the application is submitted. Without this, Network Applicants will not be eligible to proceed to the technical assessment.



This symbol is used to designate those measures identified as a **minimum requisite for eligibility**.

Operational Criteria to Assess Compliance with EU Legislation  
*Criteria and conditions to be fulfilled by the European Reference Network<sup>1</sup>*

1. ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK		
Legislated Requirement	No.	Criteria
<b>CHAPTER II Establishment of European Reference Networks Article 2.2</b> Any group of at least 10 healthcare providers established in at least 8 Member States may collectively respond by the deadline indicated in the call for interest with an application containing a proposal to establish a Network in a given field of expertise.	1.1	The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.
		<b>Measure(s)</b>
	1.1.1	The Network is comprised of a minimum of 10 Members across 8 Member States.

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



# 1. ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK

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## Legislated Requirement

2014/287/EU Chapter II Article 2.2

### 1.1 CRITERIA

The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.



#### 1.1.1 MEASURE

---

The Network is comprised of a minimum of 10 Members across 8 Member States.

##### Guideline

The combined scope of all Members should cover the full range of services throughout the trajectory of care needed for patients living with a rare or low prevalence complex disease or condition specific to the Network's area of expertise. Other Healthcare Providers may become Affiliated Partners in order to have access to good practice guidelines for diagnosis, care and treatment; and involvement in research activities. The 10 members include Healthcare Providers approved as "full members" by the European Reference Network Board of Member States. Potential Affiliated Partners will not be considered as applicant Healthcare Providers. The addition of Affiliated Partners will take place only after the approval of the ERN by the Board and following the formal designation of each of the Affiliated Partners by its national authorities.

##### Evidence

- List of Applicant Healthcare Providers and their Member States

##### Method of Assessment

- Eligibility Check
- Documentation Review

<b>2.HIGHLY SPECIALISED HEALTHCARE</b>		
<b>2 In order to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU, each Network shall:</b>		
<b>Criteria</b>		
2.1 The Network provides highly specialised healthcare for one or more rare or low prevalence complex diseases or conditions in the areas of diagnosis, treatment, and follow-up.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
2.(a) provide highly specialised healthcare for rare or low prevalence complex diseases or conditions	2.1.1	The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.
	2.1.2	The Network's area of expertise is highly specialised and well defined and the expected gains of centralising care for these patients can be demonstrated.
	2.1.3	The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.

## 2. HIGHLY SPECIALISED HEALTHCARE

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### Legislated Requirement

2014/286/EU Annex I (1) (a)

#### 2.1 CRITERIA

The Network provides highly specialised healthcare for one or more rare or low prevalence complex diseases or conditions in the areas of diagnosis, treatment, and follow-up.



##### 2.1.1 MEASURE

The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.

##### Guideline

Rare diseases or complex conditions are diseases or conditions with a particularly low prevalence; the European Union considers diseases to be rare when they affect not more than 5 per 10 000 persons in the European Union. The relevance of the Network and its expected added value for EU citizens is based on the diseases that are included within its scope. The Network's scope may include low prevalence and complex diseases or conditions requiring highly specialized healthcare that are not typically considered under the traditional concept of rare diseases. Grouping Healthcare Providers into broader thematic Networks will help address the lack of expertise in many of these areas. In defining the thematic groups, there are several source documents that can help guide this work.<sup>2</sup>

##### Evidence

- Thematic Area(s) of the Network
- Diseases or conditions covered by the Network
- Prevalence and/or overall incidence per year (estimate of the number of known patients), where available
- Number of Patients seen for diagnosis, for treatment, and for follow-up

##### Method of Assessment

- Eligibility Check
- Documentation Review

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<sup>2</sup> Strategic Conclusions of the ERN Board of Member States ([http://ec.europa.eu/health/ern/board\\_member\\_states/index\\_en.htm](http://ec.europa.eu/health/ern/board_member_states/index_en.htm))  
Recommendations of the Commission Expert Group on Rare Diseases ([http://ec.europa.eu/health/rare\\_diseases/expert\\_group/index\\_en.htm](http://ec.europa.eu/health/rare_diseases/expert_group/index_en.htm))  
Addendum to the EUCERD Recommendations of January 2013 (2015) on European Reference Networks  
([http://ec.europa.eu/health/rare\\_diseases/docs/20150610\\_erns\\_eucerdaddendum\\_en.pdf](http://ec.europa.eu/health/rare_diseases/docs/20150610_erns_eucerdaddendum_en.pdf))



### 2.1.2 MEASURE

---

The Network's area of expertise is highly specialised and well defined and the expected gains of centralising care for these patients can be demonstrated.

#### Guideline

'Highly specialised healthcare' involves high complexity of a particular disease or condition in its diagnosis, treatment, or management and cost of the treatment and resources involved. Due to the complexity of the disease, i.e. combines a number of factors, symptoms, or signs, a multidisciplinary approach and well planned organisation of services over time is required to address the large number of possible diagnoses or management options and comorbidities; difficult interpretation of clinical and diagnostic tests data; high risk of complications, morbidity, or mortality related to the problem, the diagnostic procedure or the management.

The criteria for expertise and specialisation should be explicit and supported by documented clinical and scientific evidence. Factors that should be considered are: diagnosis and/or treatment requires special competence, is resource demanding, i.e. high cost of treatment and resources, and requires a concentration of knowledge; potential for increased cost efficiency and quality of care; the disorder, condition, and/or treatment has a low prevalence or incidence; centralisation of service and collaboration across the Network will improve conditions for research and development, ensure availability, and improve continuity of care.

The Network may identify expertise related to the rare or low prevalence complex disease or condition by conducting a mapping exercise to identify potential partners; existing resources; partners valuable to the ERN such as expert clinics, registries, diagnostic and treatment services; and existing stakeholders, e.g. patient organizations, scientific or professional organizations, learned societies, etc. They may also include providers of services that require a large capital investment such as laboratories, radiology, or nuclear medicine.

#### Evidence

- Description of the rare or low prevalence complex disease(s) or condition(s), gaps in knowledge about the physiopathology of the disease(s), current problems in the diagnosis and treatment, expected gains or added value of centralising care, and the Network's highly specialised expertise
- Number of scientific publications, research projects, and clinical trials on the Network's area of expertise

#### Method of Assessment

- Eligibility Check
- Documentation Review



### 2.1.3 MEASURE

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The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.

### Guideline

In accordance with Article 12(2) of 2011/24/EU, a Network must select its objectives from the list laid down in the Directive, and demonstrate that it has the necessary competencies to pursue them effectively. These objectives include exploiting innovations in medical science and health technologies; pooling of knowledge; facilitating improvements in diagnosis and delivery of healthcare; maximizing the cost-effective use of resources; reinforcing research and epidemiological surveillance; facilitating mobility of expertise; development of quality and safety benchmarks and spread of best practices; and helping Member States with an insufficient number of patients with a particular medical condition.

The initial strategic plan includes measurable goals and objectives and timeframes for achievement. It is developed with input from its Applicant Members and potential participants in the future ERN Board, e.g. partner organizations, patients and families, and members of the multidisciplinary team(s) involved in delivering care to patients with rare or low prevalence complex diseases or conditions. The plan defines how the Network monitors its progress in achieving its goals and objectives on an annual basis and considers additional diseases, countries, or new members to be added, new areas of expertise, and/or an expansion of its current expertise. The strategic plan should be updated and finalised after the ERN approval by the Bo MS and revised every three to five years.

### Evidence

- Mission and Vision Statement
- Initial Strategic Plan

### Method of Assessment

- Documentation Review

<b>3.GOVERNANCE AND COORDINATION</b>		
<b>3. In order to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU, each Network shall:</b>		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Criteria</b>
3(b) have a clear governance and coordination structure including at least the following:	3.1	The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.
	<b>No.</b>	<b>Measure(s)</b>
3(b) (i) the Members' Representatives who will represent them within the Network Each Member shall choose its representative from among the health professionals belonging to its staff	3.1.1	There is one designated representative for each applicant member of the Network.
3(b) (ii) the Board of the Network that will be responsible for its governance. All Members of the Network must be represented on the Board.	3.1.2	The Network is governed by a Board composed of one representative from each Member in the European Reference Network.
	3.1.3	The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.
	3.1.4	The Board monitors the activity, outcomes, and initiatives of the Network and its Members in regards to their specific, predefined role.
	3.1.5	The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.
	3.1.6	The Network has a defined strategy for integrating new Members approved by the ERN Board of Member States and Affiliated Partners designated by the Competent National Authorities.
3 (b) (iii) the Coordinator of the Network, chosen from among the health professionals belonging to the staff of the coordinating Member, who will chair the meetings of the Board and represent the Network.	3.1.7	There is one Member within the Network designated as the Coordinating Member. One person is appointed by the Coordinating Member to act as the "Coordinator" of the Network.

## 3. GOVERNANCE AND COORDINATION

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### Legislated Requirement

2014/286/EU Annex I (1) (b) (i-iii)

#### 3.1 CRITERIA

The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.



##### 3.1.1 MEASURE

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There is one designated representative for each applicant member of the Network.

###### Guideline

Each applicant Member's representative is selected from among health care professionals belonging to its staff. The chosen representative should have the capacity or mandate to decide and act in the name of the Healthcare Provider and have knowledge of the scope of the Network and the Healthcare Provider's area of expertise. Each representative should have in writing, at minimum, its specific role; the obligation to attend Board meetings and represent their providers, follow the rules of procedure established by the Board, and pursue the Network's goals, objectives, and procedures. This may also include the obligation to implement established guidelines and pathways; participation in audits; adhere to the Network's quality criteria, and provide the relevant data and information to support monitoring and periodic evaluation.

###### Evidence

- List of applicant Members and their representatives
- Organogram showing representation, membership and structure of the Network
- Written Statements of Members Role and Responsibilities
- CV and Professional Background of the Representatives

###### Method of Assessment

- Documentation Review



##### 3.1.2 MEASURE

---

The Network is governed by a Board composed of one representative from each Member in the European Reference Network.

###### Guideline

The Board of the Network produces and adopts the rules of procedure, work plans and progress reports, and any other documents related to the activities of the Network; oversees the

development of the strategic plan and production of a periodic activity report; and integrates new Members and affiliated partners into the Network.

#### Evidence

- Board Terms of Reference

#### Method of Assessment

- Documentation Review

### 3.1.3 MEASURE

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The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.

#### Guideline

In general, the Board's responsibilities are strategic and focused on decisions that affect the Network's long-term sustainability. The rules and procedures include the functioning and coordination of the Board; the role of the Coordinator and the Member representatives; and possible Committee structures, as applicable, e.g. Steering or Coordination Committee. They should also include how information about the Network will be updated and made public such as the scope, e.g. thematic area of expertise, diseases or groups of diseases covered; overall structure and characteristics; and contact information, e.g. address and contact details of the Coordinating Member, each Member representative, and any Associated and Collaborative Partners. This may be published on a website, as an example.

The Board has a documented process for membership renewal and the addition of new Member representatives following approval of the ERN Board of MS.

The Board of Directors reviews and updates its policies and/or rules of procedure on an annual basis.

#### Evidence

- Board policies or rules of procedure
- Information Posted on the Network Website

#### Method of Assessment

- Documentation Review
- Onsite Audit



### 3.1.4 MEASURE

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The Board monitors the activity, outcomes, and initiatives of the Network and its Members in regards to their specific, predefined role.



### Guideline

There is a process to monitor compliance with the criteria and conditions set out in Annex II of the European Union Delegated Act 2014/286/EU. The process may include seeking feedback from the Network's members and reviewing achievements and results relative to the Network's strategic objectives.

### Evidence

- Network Monitoring System and Indicators

### Method of Assessment

- Documentation Review

## 3.1.5 MEASURE

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The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.

### Guideline

Mechanisms may include establishing patient and family advisory councils, patient and family experience surveys, linking with patient associations and self-help groups, or hearing directly from patients and families about their experience(s) with the Network such as patient stories, receiving summary reports of patient and family complaints, feedback from online communities, or including a patient feedback form on the Network's website, etc.

### Evidence

- Examples of mechanisms used to hear from patients/families

### Method of Assessment

- Semi-structured interviews



## 3.1.6 MEASURE

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The Network has a defined strategy for integrating new Members approved by the ERN Board of Member States and Affiliated Partners designated by the Competent National Authorities.

### Guideline

The integration of new Members includes sharing the know-how and procedures of the Network in a way that supports new Members swiftly becoming fully operational in their interaction within the Network.

For Affiliated Partners, i.e. Associated or Collaborative National Centers or Coordination Hubs, the Board should establish specific procedures for their effective integration and active participation within the Network. The strategy for integration should include a model of written cooperation agreements to be signed by the Affiliated Partners including, at a minimum, their specific role and obligation to follow the rules and procedures established by the Network. This may also include: implementing established guidelines and pathways; adhering to the Network's

quality criteria; attendance at Network training sessions; contribution to the overall data collection of the Network, and participating in research activities, clinical trials, and the development of guidelines, as applicable.

Bilateral agreements among Network Members and/or cooperation agreements with partners should be in accordance with the legal basis of the Member State from which the organization originates, as well as, the regulations set by the Cross-Border Directive and Delegated Acts.

#### Evidence

- Strategy for the Integration of New Members and Affiliated Partners
- Rules of Procedure of the Network Board

#### Method of Assessment

- Documentation Review



### 3.1.7 MEASURE

---

There is one Member within the Network designated as the Coordinating Member. One person is appointed by the Coordinating Member to act as the “Coordinator” of the Network.

#### Guideline

The Coordinating Member should be chosen on the basis of proven ability to coordinate and lead a Network as well as the medically relevant activities in the field of expertise. The best Coordinating Member may not necessarily be the one with the largest volume of patients, rather the one that has the capacity to fulfil all the key functions of coordination and to develop, promote, and expand the Network, as necessary.

The Coordinator is selected from among the health professionals belonging to the Coordinating Member. The Coordinator, assisted by the Board, supports and facilitates coordination within the Network and with other Healthcare Providers. The Coordinator chairs the meetings of the Board and represents the Network. The Coordinator may also be supported by a Steering or Coordination Committee established by the Board.

#### Evidence

- Name of Coordinating Member and Network “Coordinator”
- Board Rules of Procedure

#### Method of Assessment

- Eligibility Check and Documentation Review
- Onsite Audit of the Coordinating Member

<b>4.PATIENT CARE</b>		
<b>4. To fulfil the requirement set out in point (i) of Article 12 (4) (a) of Directive 2011/24/EU (“have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes”), the Network must:</b>		
<b>Criteria</b>		
4.1 The Network promotes good quality and safe patient care by fostering timely and pertinent diagnosis, treatment, follow-up and management across the Network.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
4 (a) promote good quality and safe care to patients suffering from certain diseases and conditions by fostering proper diagnosis, treatment, follow-up and management of patients across the Network;	4.1.1	The Network works with its Members to establish clear patient pathways based on the needs of patients, clinical evidence, and best use of resources.
	4.1.2	The Network promotes and/or facilitates the use of information and communication technology (ICT) tools to provide care to patients within its area of expertise.
	4.1.3	The Network facilitates the transfer of knowledge on safe, evidence-based, effective and innovative medicine.
	4.1.4	The Network promotes the safe use of highly specialized diagnostic techniques and services and the application of recognized international quality standards, certification, and accreditation schemes.
	4.1.5	The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.
<b>Criteria</b>		
4.2 The Network empowers and involves patients in order to improve the safety and quality of care.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
4(b) empower and involve patients in order to improve the safety and good quality of the care they receive.	4.2.1	The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families.
	4.2.2	The Network collaborates with patient associations to improve the safety and quality of care.
	4.2.3	The Network disseminates information on patient safety standards and safety measures to patients and families to reduce or prevent errors.
	4.2.4	The Network provides accessible means for patients and families to report possible safety incidents or adverse events and express their views about the care received and their experience, including safety concerns.
	4.2.5	The Network collaborates with its Members to establish a standardised common tool for measuring patient experience.

## 4. PATIENT CARE

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### Legislated Requirement

2014/286/EU Annex I (2) (a)

#### 4.1 CRITERIA

The Network promotes good quality and safe patient care by fostering timely and pertinent diagnosis, treatment, follow-up and management across the Network.



##### 4.1.1 MEASURE

The Network works with its Members to establish clear patient pathways based on the needs of patients, clinical evidence, and best use of resources.

##### Guideline

The Network should clearly establish how it will deliver benefit to the whole patient pathway and connect to the patients' healthcare centres in their country of origin to facilitate cross-border healthcare. Patient pathways refer to the route a patient follows from the first contact with a healthcare professional to diagnosis, treatment, and follow-up. They provide a timeline where every event relating to the patients' disease can be entered such as consultations, diagnosis, treatment, medications, diet, assessment, and education, when applicable. The pathway provides an outline of the events likely to happen on the patients' journey and can be used to inform the patient and plan services.

Network pathways should help to improve the timeliness of diagnosis, define treatment options, and plan care. This may also include defining multidisciplinary diagnostic pathways; defining specific pathways for undiagnosed patients; monitoring actual diagnostic trajectories of patients in order to identify gaps and difficulties; and monitoring wait times to access diagnostic services (e.g. laboratories and technology), obtain confirmation of results when needed, and share results with patients and families. The Network regularly monitors and reports delayed and misdiagnosis and collaborates with its Members to make ongoing improvements.

To improve diagnosis and care in the field of rare diseases or low prevalence complex conditions, appropriate and accurate information, adapted to the needs of professionals and affected persons, should be developed and disseminated. The Network collaborates with its Members to disseminate general information about the rare disease(s) and/or low prevalence complex condition(s) and provides guidance/instruction documents or decision aids to healthcare professionals on how to appropriately manage patients' needs including referral criteria and recommendations on resources to be considered. The national competences and entitlements and the applicable EU legislation should be respected. The Network collaborates

with patient organizations to improve access to care and inform patients and families about patient pathways.

#### Evidence

- Patient Pathways and/or Planned actions and timelines to establish pathways

#### Method of Assessment

- Documentation Review

### 4.1.2 MEASURE

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The Network promotes and/or facilitates the use of information and communication technology (ICT) tools to provide care to patients and share pertinent data within its area of expertise.

#### Guideline

The Network must clearly describe and provide evidence as to how it will use information and communication technology (ICT) to provide care, access to expertise, and support the development, sharing, and spread of best practice. This may include the use of ICT tools to support telemedicine and teleexpertise. Telemedicine involves the use of ICT to provide a healthcare service directly to a patient. Teleexpertise is the provision of expertise at a distance through the use of ICT tools, from an expert professional to another expert and/or non-expert professional in different locations by sending information on a patient's case such as x-rays, images, and patient files. Other potential services may include: call centres for patients, remote consultation/e-visits, or videoconferences between professionals.

#### Evidence

- Examples of the use of ICT tools

#### Method of Assessment

- Semi-structured Interviews
- Onsite Audit (Tracer Methodology)

### 4.1.3 MEASURE

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The Network facilitates the transfer of knowledge on safe, evidence-based, effective and innovative medicine.

#### Guideline

The Network collaborates with its Affiliated Partners, academia, research centres, health technology agencies, government and other relevant partners to facilitate clinical research; generate and disseminate knowledge; and contribute to the production of evidence and collect data and clinical information. The Network promotes the use, where appropriate, of safe and scientifically assessed diagnostic techniques and medical and surgical treatments such as medicines, health technologies, and new developments in treatment. The Network may stay abreast of new scientific developments via articles in scientific journals, participation in

(inter)national committees and working groups, participation and/or contribution to organizing (inter)national congresses.

- Evidence
- Strategic Plans or Documented Actions to Promote Good Quality and Safe Care
- Method of Assessment
- Semi-structured Interview with Network Coordinator

#### 4.1.4 MEASURE

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The Network promotes the safe use of highly specialized diagnostic techniques and services and the application of recognized international quality standards, certification, and accreditation schemes.

##### Guideline

The Network should identify and promote the use of best practices and internationally recognized certification and accreditation schemes, e.g. ISO, CEN, etc., for highly specialized diagnostic technologies within its area of expertise. For example, regarding laboratory testing facilities, the Network should promote their participation in quality assurance programmes and adherence to quality assurance standards such as specimen shipping, tracking documentation, and the validity and quality of the testing.

##### Evidence

- List of Diagnostic Technologies and Services Certified or Accredited through National, European, and/or International Programs provided by Network Members, where applicable.
- Documentation of the Quality Assurance Schemes used by each of the Diagnostic Technologies and Services or integrated into written agreements.

##### Method of Assessment

- Documentation Review

#### 4.1.5 MEASURE

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The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.

##### Guideline

The Network collaborates with its Members, Affiliated Partners, and patient organizations to develop, disseminate, and implement these guidelines and protocols. The Network identifies and monitors a quality indicator for transitions of care.

##### Evidence

- Guidelines and/or protocols (developed or endorsed by the Network) and/or planned actions and timelines to establish guidelines
- Results of Clinical Audits to ensure use

#### Method of Assessment

- Documentation Review
- On site Visit (Tracer Methodology)

## Legislated Requirement

2014/286/EU Annex I (2) (b)

### 4.2 CRITERIA

The Network empowers and involves patients in order to improve the safety and quality of care.

#### 4.2.1 MEASURE

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The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families.

##### Guideline

In collaboration with patient organizations, the Network develops and provides access to information adapted to the specific needs of patients and families. This should include addressing the needs of patients and families from different cultures and ethnic groups and best practices regarding health literacy issues. The Network compiles a Directory of its members and this information is made easily available and accessible to the public such as, through the use of web-based technology. Efforts should be made to ensure information shared is consistent across the various communication tools and channels used.

##### Evidence

- Directory of Members
- Sample of information provided to patients and families, i.e. Brochures, Web-site

##### Method of Assessment

- Semi-structured Interview with Network Coordinator
- Documentation Review

#### 4.2.2 MEASURE

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The Network collaborates with patient associations to improve the safety and quality of care.

##### Guideline

Areas of collaboration may include: working to improve service excellence based on the expressed needs and expectations of patients, obtaining patient and family input into trajectories of care, and training representatives from patient associations to empower patient safety leaders within the Network's area of expertise.

In addition, the Network collaborates with patient associations to disseminate information and raise awareness about the common standards of care; risks associated with the procedures and

treatment related to their disease or condition; and adverse events and their causes most frequently associated with their care. This may include developing tools, leaflets, or videos to encourage patients and families to ask questions and educational campaigns to raise awareness and improve health literacy.

#### Evidence

- Examples of Improvement Initiatives

#### Method of Assessment

- Semi-structured Interview with Network Coordinator

### 4.2.3 MEASURE

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

#### Guideline

The Network systematically and consistently collects data from its Members on the key parameters of patient safety, including the use of medicines and medical technologies, communication issues, and breaches in continuity of care, and publicly release figures every year within the Network's area of expertise.

#### Evidence

- Published Annual Reports and/or Planned actions and Timelines for Patient Safety Data Collection and Reporting

#### Method of Assessment

- Documentation Review

### 4.2.4 MEASURE

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The Network provides accessible means for patients and families to report possible safety incidents or adverse events and express their views about the care received and their experience, including safety concerns.

#### Guideline

The Network should collaborate with its Members to provide patient access to adverse events notification systems making the best use of IT technology and social media as well as conventional methods.

#### Evidence

- Examples of Methods Used

#### Method of Assessment

- Semi-structured Interview with Network Coordinator
- Documentation Review



## 4.2.5 MEASURE

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The Network collaborates with its Members to establish a standardised common tool for measuring patient experience.

### Guideline

The Network defines a plan to develop a common tool for gathering and analysing data across its Members and support benchmarking of patient experience information.

### Evidence

- Patient Experience Survey(s) and/or planned activities and timelines to establish a common tool

### Method of Assessment

- Documentation Review

<b>5.MULTIDISCIPLINARY APPROACH</b>		
<b>5 To fulfil the requirement set out in point (ii) of Article 12 (4) (a) of Directive 2011/24/EU (“follow a multi-disciplinary approach”), the Network must:</b>		
<b>Criteria</b>		
5.1 The Network promotes and follows a multidisciplinary approach to care for rare or low prevalence complex diseases or conditions.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
5 (a) identify areas and best practices for multi-disciplinary work;	5.1.1	The Network identifies and shares best practices for providing multidisciplinary care.
5 (b) be made up of multi-disciplinary healthcare teams;	5.1.2	Patient care is delivered across the Network using multidisciplinary healthcare teams.
5 (c) offer and promote multi-disciplinary advice for complex cases.	5.1.3	The Network has a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.

## 5. MULTIDISCIPLINARY APPROACH

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### Legislated Requirement

2014/286/EU Annex I (3) (a)-(c)

#### 5.1 CRITERIA

The Network promotes and follows a multidisciplinary approach to care for rare or low prevalence complex diseases or conditions.

##### 5.1.1 MEASURE

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The Network identifies and shares best practices for providing multidisciplinary care.

###### Guideline

The Network defines a model for hosting regular multidisciplinary or clinical audit meetings through various means, including electronic platforms to provide advice and share best practices. The model should include standard operational procedures (SOPs) for organising virtual meetings; a systematic registry of meetings; and a record of patient cases discussed, professionals who participated, and resulting decisions.

###### Evidence

- Examples of best practices
- Integrated Care Pathways
- Clinical Guidelines

###### Method of Assessment

- Documentation Review
- Semi-structured Interview



##### 5.1.2 MEASURE

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Patient care is delivered across the Network using multidisciplinary healthcare teams.

###### Guideline

A multidisciplinary healthcare team is a group of health professionals from several fields of healthcare, combining skills and resources, each providing specific services and expertise, collaborating on the same case with shared goals, and coordinating the healthcare provided to the patient.

The Network should develop a guide and set of recommendations on how to organise and manage multidisciplinary teams within its area of expertise. This guide should include a set of common indicators and an information system to monitor and evaluate the performance of these teams to ensure consistent and equitable care across all patients served by the Network.

The information gathered is used to identify strengths and areas for improvement, where relevant.

In addition, the Network works with its Members to bring together or coordinate access to multidisciplinary competencies and skills to serve the specific medical, psychological, rehabilitation, and palliative care needs of patients and families throughout the trajectory of care. The Network may establish formal collaboration agreements between units and functional areas across the Network, healthcare organizations, and/or regions. Agreements specify mutual responsibilities and the mutual obligations across functional areas. They include how to access services and the name of the healthcare professionals involved in providing continuity of care. The type and structure of the agreements may vary across Networks pending their area of expertise.

#### Evidence

- Guides/Recommendations on Multidisciplinary Teams
- Written Agreements and/or Letters of Intent

#### Method of Assessment

- Documentation Review

### 5.1.3 MEASURE

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The Network has a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.

#### Guideline

There are clinical networking structures in place to support multidisciplinary care. As an example, the Network may establish a single clinical networking group. The purpose of this group would be to provide clinical opinion on complex issues related to the rare disease(s) or condition(s) and to assist with the development of a comprehensive care plan when needed.

#### Evidence

- Documented Process for Offering Multidisciplinary advice

#### Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

<b>6.GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL</b>		
<b>6 To fulfil the requirement set out in point (iii) of Article 12 (4) (a) of Directive 2011/24/EU (“offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control”), the Network must:</b>		
<b>Criteria</b>		
6.1 The Network offers specialised clinical expertise and produces good practice guidelines for rare or low prevalence complex diseases or conditions.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
6 (a) exchange, gather and disseminate knowledge, evidence and expertise within and outside the Network, in particular on the different alternatives, therapeutic options and best practices with regard to the provision of services and the treatments available for each particular disease or condition;	6.1.1	The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network.
	6.1.2	Representatives from each Member meet periodically to review and share best practices, and discuss new evidence-based treatments, therapies, and health care technologies.
<b>Criteria</b>		
6.2 The Network collaborates with its Members and other relevant partners to bring healthcare within its area of expertise closer to its patients.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
6 (b) promote expertise and support healthcare providers in order to bring local, regional and national provision of healthcare closer to patients;	6.2.1	The Network shares expertise and supports healthcare providers in order to bring local, regional and national provision of care to patients closer to home.
<b>Criteria</b>		
6.3 The Network develops and/or implements clinical guidelines and cross border patient pathways.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
6 (c) develop and implement clinical guidelines and cross-border patient pathways;	6.3.1	The Network has a formal process for developing or selecting and disseminating clinical guidelines.
	6.3.2	The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools.
	6.3.3	The Network develops cross border pathways in collaboration with its Members.
	6.3.4	The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.
<b>Criteria</b>		
6.4 The Network implements quality controls and monitors clinical outcome measures of care for rare or low prevalence complex diseases or conditions.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
6 (d) design and implement outcome and performance indicators;	6.4.1	The Network develops and regularly monitors performance and outcome indicators. The information is used to support ongoing quality improvement.
6.(e) develop and maintain a quality, patient safety and evaluation framework.	6.4.2	The Network develops and maintains a quality, patient safety, and evaluation framework.

## 6. GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL

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### Legislated Requirement

2014/286/EU Annex I (4) (a)

### 6.1 CRITERIA

The Network offers specialised clinical expertise and produces good practice guidelines for rare or low prevalence complex diseases or conditions.



#### 6.1.1 MEASURE

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The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network.

##### Guideline

The activities in this area should specifically address the different alternatives, therapeutic options, and best practices for each particular disease or condition within the Network's area of expertise. A variety of tools may be used by Networks to disseminate knowledge, best practice evidence, and clinical expertise. These include: discussion groups or forums for case discussions between experts and a non-expert healthcare professional; web/teleconferencing; intranet sites used as a repository for draft documents under discussion by experts; and professional FAQs, etc. To support these activities, Networks may strengthen their collaboration with its Affiliated Partners.

##### Evidence

- Tools used and best practices shared within/outside the Network and/or planned activities and timelines

##### Method of Assessment

- Semi-structured Interviews

#### 6.1.2 MEASURE

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Representatives from each Member meet periodically to review and share best practices, and discuss new evidence-based treatments, therapies, and health care technologies.

##### Guideline

Meetings may include other stakeholders such as government representatives, patient representatives, healthcare professionals, researchers, etc., and can be carried out in person and/or virtually. Collaboration amongst partners and all stakeholders is essential given the limited understanding of rare or low prevalence complex diseases or conditions to exchange

information, experiences and expertise. Minutes of these meetings should be disseminated within the Network and shared with the interested parties.

#### Evidence

- Planned Actions, Draft Contents, and Timelines of the Meetings
- Examples of clinical or therapeutic best practices, protocols and policies adopted from meetings

#### Method of Assessment

- Documentation Review

## Legislated Requirement

2014/286/EU Annex I (4) (b)

### 6.2 CRITERIA

The Network collaborates with its Members and other relevant partners to bring healthcare within its area of expertise closer to its patients.



#### 6.2.1 MEASURE

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The Network shares expertise and supports healthcare providers in order to bring local, regional and national provision of care to patients closer to home.

#### Guideline

Expertise must travel instead of the patient, when possible. The dissemination of expertise to increase the knowledge and capacity of healthcare providers should be one of the Networks' main goals. This would facilitate the provision of quality healthcare closer to home.

Network activities in this area may include conducting research and/or collaborating with Healthcare Providers to evaluate different approaches to care closer to home; working with healthcare providers, such as primary care practitioners, to implement a shared care approach and/or other models of integrated care delivery; empowering patients across the Network with self-management education; promoting and/or facilitating the use of technologies such as to support tele-consultations, training, and education; raising awareness amongst healthcare professionals of what specialist services are available in their local hospitals.

The Network facilitates and provides advice on cross border health care among its Members, and/or organizations in other countries, where patients or biological samples can be referred. This may include sharing information about the relevant Healthcare Providers within its Network and how to access them.

Affiliated partners, such as national coordination hubs, should be specifically addressed as they can play a key role in supporting and facilitating the provision of highly specialized healthcare.

#### Evidence

- Examples of shared care arrangements, patient self-management education, research initiative, etc. and/or planned activities and timelines

#### Method of Assessment

- Semi-structured interviews
- Documentation Review

## Legislated Requirement

2014/286/EU Annex I (4) (c)

### 6.3 CRITERIA

The Network develops and/or implements clinical guidelines and cross border patient pathways.



#### 6.3.1 MEASURE

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The Network has a formal process for developing or selecting and disseminating clinical guidelines.

#### Guideline

Clinical Guidelines comprise recommendations on the care of patients with specific conditions, based on the best available research, evidence, and practice/experience. Where there are existing clinical guidelines that are agreed upon nationally, regionally, or locally, the Network adopts these requirements, where appropriate.

The process for developing or selecting clinical guidelines may include using content experts; a consensus panel; Grades of Recommendation Assessment, Development and Evaluation (GRADE); or the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument, which allows Networks to evaluate the methodological development of clinical guidelines from six perspectives: scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence.

When developing and/or selecting clinical guidelines, the Network obtains patient and family input. 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

- Clinical Guidelines and/or planned activities and timelines for developing Guidelines
- Examples of how patient and family input is obtained

#### Method of Assessment

- Documentation Review
- Semi-structured Interview with the Network Coordinator



### 6.3.2 MEASURE

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The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools.

#### Guideline

The Network Board should define specific rules and procedures to ensure transparency and adherence to ethics requirements. In particular, the Board should define a strong policy on the declaration and management of conflict of interest of the participants in the development of such tools given the high ethical standards and social responsibility required. A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest of the science or the patient will be unduly influenced by a secondary interest. Conflict of interest may distort the interpretation of results and evidence, the analysis of data, and the development of research methods. To ensure fairness, this policy should respect relevant National and European legislation and follow the recommendations and guidelines developed by independent organisations and recognised bodies.

#### Evidence

- Policy on the declaration and management of conflict of interest regarding clinical guidelines, patient pathways, and clinical decision making tools

#### Method of Assessment

- Documentation Review
- Semi-structured interview with Network Coordinator



### 6.3.3 MEASURE

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The Network develops cross border pathways in collaboration with its Members.

#### Guideline

The Network obtains input from its Members and patient associations to identify areas of focus. The pathways should include relevant contact points for services, hospitals, and multidisciplinary teams at referral, diagnosis, care and treatment, transition, and follow-up. This should also include, where relevant, any services, hospitals, or multidisciplinary teams outside those associated with the Network.

#### Evidence

- Cross Border Pathways and/or planned actions and timelines to develop cross border pathways

#### Method of Assessment

- Documentation Review

### 6.3.4 MEASURE

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The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.

#### Guideline

The Network should establish both process and clinical outcome measures before implementing any clinical guideline or pathway. Process measures evaluate how well a Healthcare Provider is implementing related processes of care. Outcomes measures look at measurable changes in a patient's condition as a result of treatment or other interventions.

#### Evidence

- Planned List of Process and Outcome Measures
- Examples of guidelines and pathways where implementation is to be monitored

#### Method of Assessment

- Documentation Review

## Legislated Requirement

2014/286/EU Annex I (4) (d)-(e)

## 6.4 CRITERIA

The Network implements quality controls and monitors clinical outcome measures of care for rare or low prevalence complex diseases or conditions.



### 6.4.1 MEASURE

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The Network develops and regularly monitors performance and outcome indicators. The information is used to support ongoing quality improvement.

#### Guideline

The Network should plan and agree on a set of performance indicators. Performance indicators may include both structure and process measures. Areas of focus may include: volume of patients seen (by Member); patient demographic information; morbidity and comorbidities of patients on admission; throughput; wait times such as timeliness of diagnosis, access to technologies, and surgical interventions; practice related measures such as length of stay; outcomes and recovery such as morbidity and mortality; re-admission rates; patient experience; and quality of life measures.

#### Evidence

- List of performance and outcome indicators and their definitions
- Sample of Quarterly Reports

#### Method of Assessment

- Documentation Review



### 6.4.2 MEASURE

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The Network develops and maintains a quality, patient safety, and evaluation framework.

#### Guideline

The Quality, Patient Safety, and Evaluation Framework describe the quality and patient safety structure, functions, responsibilities and accountabilities within the Network. It provides information and guidance to the Network for selection and measurement of achievements in service quality, clinical outcomes, risk mitigation, and adverse events reporting within its area of expertise. It is not intended to be a detailed procedure for designing or implementing quality and patient safety initiatives. The framework is reviewed on a regular basis to ensure continued alignment with the strategic direction of the Network.

In addition, Networks may implement external quality assurance schemes in order to improve quality standards and monitor compliance of its Members with guidelines.

#### Evidence

- Quality and Safety Framework (including Adverse Events Reporting System)
- Policies and Standard Operating Procedures

#### Method of Assessment

- Documentation Review
- Semi-structured Interview with Network Coordinator

7.CONTRIBUTION TO RESEARCH		
7 To fulfil the requirement set out in point (iv) of Article 12 (4) (a) of Directive 2011/24/EU (“make a contribution to research”), the Network must:		
Criteria		
7.1 The Network provides evidence of ongoing research for rare or low prevalence complex diseases or conditions.		
Legislated Requirement	No.	Measure(s)
7 (a) identify and fill research gaps;	7.1.1	The Network identifies where there are research gaps and carries out activities to fulfil these gaps.
7 (b) promote collaborative research within the Network;	7.1.2	The Network promotes and supports collaborative research amongst its Members, Affiliated Partners, and relevant patient, professional and research organisations.
	7.1.3	The Network keeps its Members, partners, and patient organizations informed about new research projects and clinical trials.
7 (c) reinforce research and epidemiological surveillance, through setting up of shared registries.	7.1.4	The Network supports at all appropriate levels, including the community level, the establishment of specific disease or condition information networks, shared registries, and databases.

## 7. CONTRIBUTION TO RESEARCH

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### Legislated Requirement

2014/286/EU Annex I (5) (a)-(c)

#### 7.1 CRITERIA

The Network provides evidence of ongoing research for rare or low prevalence complex diseases or conditions.



##### 7.1.1 MEASURE

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The Network identifies where there are research gaps and carries out activities to fulfil these gaps.

###### Guideline

The Network works with its Members, patient associations, and other stakeholders such as industry, research institutions, pan-European infrastructures, policy makers, and government, to set its priorities for research. The Network's research priorities or areas of focus are reviewed on an annual basis and changes are made, as necessary.

###### Evidence

- Network's research priorities and action plans

###### Method of Assessment

- Documentation Review

##### 7.1.2 MEASURE

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The Network promotes and supports collaborative research amongst its Members, Affiliated Partners, and relevant patient, professional and research organisations.

###### Guideline

The Network should identify research priorities specific to its area of expertise and develop a strategic research plan with timelines and concrete research projects. Cooperation with other Networks and centres of expertise or Healthcare Providers should be encouraged.

Promoting and supporting collaborative research may include coordinating access to data and biological samples for regional, national, and international collaborations; establishing stronger linkages between research and industry efforts in the Network's area of expertise; and helping to promote collaboration among clinicians, geneticists, epidemiologists, and patients to improve knowledge on different aspects of the rare disease or condition and ensure research translation.

The Network works with its Members and Affiliated Partners to involve patients as active partners in research within its area of expertise. Patients and families are advocates and hold much of the information on care experience; can engage in the design research activities and help organize campaigns for the donation of biologic samples and recruitment of patients; and disseminate research results to the community, etc.

The economy of scale and the structure of the Network should help to successfully apply for research grants such as the research programme Horizon 2020 of the EU.

#### Evidence

- Strategic Research Plan
- Examples of how the Network supports collaborative research and facilitates translation of research into care

#### Method of Assessment

- Documentation Review
- Semi-structured interviews

### 7.1.3 MEASURE

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The Network keeps its Members, partners, and patient organizations informed about new research projects and clinical trials.

#### Guideline

The Network should develop an action plan to disseminate information on research projects and clinical trials to enable provider participation and patient recruitment across the European Union. The plan should include the production of an annual report on the status of research projects and clinical trials and their respective findings, as applicable.

#### Evidence

- Planned Activities and Timelines to Disseminate Information
- Annual Report on Research Projects and Clinical Trials and/or planned actions and timelines to develop the Report

#### Method of Assessment

- Documentation Review

### 7.1.4 MEASURE

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The Network supports at all appropriate levels, including the community level, the establishment of specific disease or condition information networks, shared registries, and databases.

#### Guideline

Patient registries and databases are critical to clinical research in the field of rare diseases and low prevalence complex conditions, to improve patient care, and healthcare planning. They help

to pool data in order to achieve a sufficient sample size for epidemiological and/or clinical research. They are vital to assess the feasibility of clinical trials, to facilitate the planning of appropriate clinical trials, and to support the enrolment of patients. At a minimum, the primary purpose of data collection should be to obtain pertinent clinical information from the patient and to interchange this information between professionals who care for these patients. In addition, the system should be used to assess the quality and clinical outcomes of care across its Members. The Network should develop a plan to support the establishment of information networks, shared registries, and/or databases. It should integrate and build on existing resources, where necessary, to avoid duplication. International terminologies should be used, where possible, to support interoperability and data sharing.

The Network should consider recommendations and guidelines issued by relevant organizations and advisory bodies, e.g. *Parent Joint Action Guidelines* or the *EUCERD Core Recommendations on Rare Disease Patient Registration and Data Collection*, and take advantage of the platforms and solutions offered by EU institutions such as the JRC Platform for Rare Diseases or Cancer.

#### Evidence

- Planned actions and timelines for Patient Registries and/or Databases
- Current Developments in Patient Registries and/or Databases, where applicable
- Examples of initiatives to promote inter-operability, where possible

#### Method of Assessment

- Documentation Review
- Semi-structured Interview with Network Coordinator

<b>8.CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT</b>		
<b>8 To fulfil the requirement set out in point (v) of Article 12 (4) (a) of Directive 2011/24/EU (“organise teaching and training activities”), the Network must:</b>		
<b>Criteria</b>		
<b>8.1</b> The Network, in collaboration with partners, organises continuous education, training, and development activities.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
8 (a) identify and fill training gaps;	8.1.1	The Members work together to identify and fulfil education, training, and professional development gaps within the Network’s area of expertise.
8 (b) encourage and facilitate the development of training and continuous education programmes and tools for health care providers involved in the chain of care (within or outside the Network).	8.1.2	The Network facilitates and supports the development and use of standardized continuous education training programmes and tools for healthcare providers within and outside the Network.
	8.1.3	The Network, in collaboration with partners, provides education and training to healthcare professionals, allied health professionals, and non-healthcare professionals within its area of expertise.



## 8. CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT

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### Legislated Requirement

2014/286/EU Annex I (6) (a)-(b)

### 8.1 CRITERIA

The Network, in collaboration with partners, organises continuous education, training, and development activities.



#### 8.1.1 MEASURE

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The Members work together to identify and fulfil education, training, and professional development gaps within the Network's area of expertise.

##### Guideline

The Network, in collaboration with partners, systematically identifies education, training, and professional development needs and plans activities on an annual basis.

##### Evidence

- Gap Analysis Methodology
- Annual Education Work plan

##### Method of Assessment

- Documentation Review
- Semi-structured Interview with Network Coordinator

#### 8.1.2 MEASURE

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The Network facilitates and supports the development and use of standardized continuous education training programmes and tools for healthcare providers within and outside the Network.

##### Guideline

The Network has a strategy to develop and/or promote the use of standardized continuous education training programmes and tools. This may include the development of educational resources for training purposes such as e-learning modules, interactive tools, and simulation techniques, etc.

##### Evidence

- Network Strategy
- Examples of standard programmes and tools used and/or planned activities and timelines

#### Method of Assessment

- Documentation Review

### 8.1.3 MEASURE

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The Network, in collaboration with partners, provides education and training to healthcare professionals, allied health professionals, and non-healthcare professionals within its area of expertise.

#### Guideline

The content and method used is adapted to the learner, promotes a multidisciplinary team approach, and patient centred care. This may include multidisciplinary workshops in order to encourage the uptake of good practice guidelines and raise awareness about quality standards of care.

#### Evidence

- Examples of education and training modules, where possible

#### Method of Assessment

- Documentation Review

<b>9.NETWORKING AND COLLABORATION</b>		
<b>9 To fulfil the requirement set out in point (vi) of Article 12 (4) (a) of Directive 2011/24/EU (“collaborate closely with other centres of expertise and networks at national and international level”), the Network must:</b>		
<b>Criteria</b>		
<b>9.1</b> The Network collaborates closely with other Centres and Networks at both a national and international level.		
<b>Legislated Requirement</b>	<b>No.</b>	<b>Measure(s)</b>
9 (a) exchange and disseminate knowledge and best practices, in particular by supporting national centres and networks;	9.1.1	The Network exchanges and disseminates knowledge and best practices with other Networks and Centres of Expertise.
9 (b) set up networking elements, such as communication tools, and methodologies to develop clinical guidelines and protocols; exchange clinical information in accordance with EU data protection provisions and national implementing measures, in particular Directive 95/46/EC, and Article 3 of this Delegated Decision; develop training alternatives and models and operation and coordination practices, etc.;	9.1.2	The Network develops a communication plan and establishes communication tools to support collaboration with other organizations.
9 (c) collaborate with Associated National Centres and Collaborative National Centres chosen by Member States with no Member of a given Network, particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU.	9.1.3	The Network collaborates with Affiliated Partners, i.e. Associated National Centres, Collaborative National Centres or National Coordination Hubs, chosen by Member States.

## 9. NETWORKING AND COLLABORATION

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### Legislated Requirement

2014/286/EU Annex I (a)-(c)

#### 9.1 CRITERIA

The Network collaborates closely with other Centres and Networks at both a national and international level.



##### 9.1.1 MEASURE

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The Network exchanges and disseminates knowledge and best practices with other Networks and Centres of Expertise.

###### Guideline

Establishing collaborations with learned societies, patient organizations, and other European Reference Networks can improve the sharing and dissemination of expertise concerning the rare or low prevalence complex disease(s) or condition(s). Sharing networking experiences with other ERNs and other types of rare or low prevalence complex disease networks, e.g. research networks, networks of excellence, can also potentially improve networking capacities. The Network should agree on a strategy or plan in this area that identifies the possible collaborations and methods of exchanging and disseminating knowledge and best practice.

###### Evidence

- Planned actions and timelines for establishing collaborations
- Examples to date of collaborations with other Networks and National Centres, where applicable

###### Method of Assessment

- Documentation Review

##### 9.1.2 MEASURE

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The Network develops a communication plan and establishes communication tools to support collaboration with other organizations.

###### Guideline

The Network has a clear strategy for communication that describes its purpose, the thematic areas it will cover, what it hopes to deliver, and methods to increase its visibility and raise awareness about its added value to the European Union. For example, visibility may be assured via the Orphanet database and the national help lines.

The Network should develop an action plan with specific timelines for setting up communication tools and methodologies. The collaboration with other organizations at a national and international level should address the development of clinical guidelines and protocols; the exchange of clinical information; and the development of training alternatives, models of operation and coordination practices. When exchanging clinical information, the Network does so in accordance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC. Communication tools may include: face to face contact with partners, newsletters, conference calls, meetings, and workshops; a dedicated Network web site linked to the ERN IT platform provided by the European Commission; and repositories or virtual information centres for specific rare or low prevalence complex diseases or conditions. As an example, the Network may maintain a directory of expert centres and services and share this information. This may include both a directory of the Members and Affiliated Partners, and any other Centre of Expertise specific to the Network's area of expertise.

#### Evidence

- Communication Strategy and Plan
- Examples of communication tools that will be or are currently used

#### Method of Assessment

- Semi-structure Interviews
- Documentation Review



### 9.1.3 MEASURE

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The Network collaborates with Affiliated Partners, i.e. Associated National Centres, Collaborative National Centres or National Coordination Hubs, chosen by Member States.

#### Guideline

The importance of Affiliated Partners designated by the Member States and their engagement with the Network should be stated as a clear objective from the outset. The Network must have transparent rules of procedure to facilitate Affiliated Partner engagement. These rules should describe how Affiliated Partners can interact, participate, and contribute to the Network. Network proposals must describe how Affiliated Partners may interact, participate, and contribute to the Network. To ensure inclusivity, the rules of procedure by which Affiliated Partners enter and engage with the Network must be transparent and clearly defined. The operational models underpinning engagement with Affiliated Partners, e.g. 'hub and spoke' models, must be clearly described and show how they support interaction and deliver wider geographical and thematic spread. The process to affiliate such Partners can only take place after the Network approval by the Board of Member States and following the formal designation of each of the Affiliated Partners by its National authorities.

The Network should be open to potential Affiliated Partners and procedures must be agreed upon within the Network to facilitate their active involvement in developing clinical guidelines, research and training, registering data in common registries, in clinical trials, and providing

healthcare pending their capacity. This contribution could be recognised in shared research, grants and publications, in shared educational activities or in exchange programmes for clinical staff.

#### Evidence

- Rules of Procedure and Entrance Pathways for Affiliated Partners

#### Method of Assessment

- Documentation Review

## GLOSSARY OF TERMS

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**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 Network

ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK			
No.	Criteria	No.	Measure(s)
1.1	The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.	1.1.1	The Network is comprised of a minimum of 10 Members across 8 Member States.
HIGHLY SPECIALISED HEALTHCARE			
No.	Criteria	No.	Measure(s)
2.1	The Network provides highly specialised healthcare for one or more rare or low prevalence complex diseases or conditions in the areas of diagnosis, treatment, and follow-up.	2.1.1	The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.
		2.1.2	The Network's area of expertise is highly specialised and well defined and the expected gains of centralising care for these patients can be demonstrated.
		2.1.3	The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.
GOVERNANCE AND COORDINATION			
No.	Criteria	No.	Measure(s)
3.1	The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.	3.3.1	There is one designated representative for each applicant member of the Network.
		3.3.2	The Network is governed by a Board composed of one representative from each Member in the European Reference Network.
		3.3.3	The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.
		3.3.4	The Board monitors the activity, outcomes, and initiatives of the Network and its Members in regards to their specific, predefined role.
		3.3.5	The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.
		3.3.6	The Network has a defined strategy for integrating new Members approved by the ERN Board of Member States and Affiliated Partners designated by the Competent National Authorities.
		3.3.7	There is one Member within the Network designated as the Coordinating Member. One person is appointed by the Coordinating Member to act as the "Coordinator" of the Network.

<b>PATIENT CARE</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
4.1	The Network promotes good quality and safe patient care by fostering timely and pertinent diagnosis, treatment, follow-up and management across the Network.	4.1.1	The Network works with its Members to establish clear patient pathways based on the needs of patients, clinical evidence, and best use of resources.
		4.1.2	The Network promotes and/or facilitates the use of information and communication technology (ICT) tools to provide care to patients within its area of expertise.
		4.1.3	The Network facilitates the transfer of knowledge on safe, evidence-based, effective and innovative medicine.
		4.1.4	The Network promotes the safe use of highly specialized diagnostic techniques and services and the application of recognized international quality standards, certification, and accreditation schemes.
		4.1.5	The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.
4.2	The Network empowers and involves patients in order to improve the safety and quality of care.	4.2.1	The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families.
		4.2.2	The Network collaborates with patient associations to improve the safety and quality of care.
		4.2.3	The Network disseminates information on patient safety standards and safety measures to patients and families to reduce or prevent errors.
		4.2.4	The Network provides accessible means for patients and families to report possible safety incidents or adverse events and express their views about the care received and their experience, including safety concerns.
		4.2.5	The Network collaborates with its Members to establish a standardised common tool for measuring patient experience.

<b>MULTIDISCIPLINARY APPROACH</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
5.1	The Network promotes and follows a multidisciplinary approach to care for rare or low prevalence complex diseases or conditions.	5.1.1	The Network identifies and shares best practices for providing multidisciplinary care.
		5.1.2	Patient care is delivered across the Network using multidisciplinary healthcare teams.
		5.1.3	The Network has a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.
<b>GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
6.1	The Network offers specialised clinical expertise and produces good practice guidelines for rare or low prevalence complex diseases or conditions.	6.1.1	The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network.
		6.1.2	Representatives from each Member meet periodically to review and share best practices, and discuss new evidence-based treatments, therapies, and health care technologies.
6.2	The Network collaborates with its Members and other relevant partners to bring healthcare within its area of expertise closer to its patients.	6.2.1	The Network shares expertise and supports healthcare providers in order to bring local, regional and national provision of care to patients closer to home.
6.3	The Network develops and/or implements clinical guidelines and cross border patient pathways.	6.3.1	The Network has a formal process for developing or selecting and disseminating clinical guidelines.
		6.3.2	The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools.
		6.3.3	The Network develops cross border pathways in collaboration with its Members.
		6.3.4	The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.
6.4	The Network implements quality controls and monitors clinical outcome measures of care for rare or low prevalence complex diseases or conditions.	6.4.1	The Network develops and regularly monitors performance and outcome indicators. The information is used to support ongoing quality improvement.
		6.4.2	The Network develops and maintains a quality, patient safety, and evaluation framework.

<b>CONTRIBUTION TO RESEARCH</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
7.1	The Network provides evidence of ongoing research for rare or low prevalence complex diseases or conditions.	7.1.1	The Network identifies where there are research gaps and carries out activities to fulfil these gaps.
		7.1.2	The Network promotes and supports collaborative research amongst its Members, Affiliated Partners, and relevant patient, professional and research organisations.
		7.1.3	The Network keeps its Members, partners, and patient organizations informed about new research projects and clinical trials.
		7.1.4	The Network supports at all appropriate levels, including the community level, the establishment of specific disease or condition information networks, shared registries, and databases.
<b>CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
8.1	The Network, in collaboration with partner organisations, organises continuous education, training, and development activities.	8.1.1	The Members work together to identify and fulfil education, training, and professional development gaps within the Network's area of expertise.
		8.1.2	The Network facilitates and supports the development and use of standardized continuous education training programmes and tools for healthcare providers within and outside the Network.
		8.1.3	The Network, in collaboration with partners, provides education and training to healthcare professionals, allied health professionals, and non-healthcare professionals within its area of expertise.
<b>NETWORKING AND COLLABORATION</b>			
<b>No.</b>	<b>Criteria</b>	<b>No.</b>	<b>Measure(s)</b>
9.1	The Network collaborates closely with other Centres and Networks at both a national and international level.	9.1.1	The Network exchanges and disseminates knowledge and best practices with other Networks and Centres of Expertise.
		9.1.2	The Network develops a communication plan and establishes communication tools to support collaboration with other organizations.
		9.1.3	The Network collaborates with Affiliated Partners, i.e. Associated National Centres, Collaborative National Centres or National Coordination Hubs, chosen by Member States.