European Commission

European Reference Networks

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Glossary of Terms

Affiliated Partner: Associated national centres, Collaborative national centres or National coordination hubs linked to the ERN. The addition of Affiliated Partners and the relevant process will take place only after the approval of the ERN by the Board and follows the formal designation of each of the Affiliated Partners by its national authorities.

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 organisation 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 honour 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 organisation 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.

Orphanet database: an internationally recognised database for rare diseases and orphan drugs.

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 1a – Operational Criteria for Networks

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 (Annex I). 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 for Networks consists of **nine** 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; and Implementing Decision 2014/287/EU and Implementing Decision 2019/1269/EU and, amending Implementing Decision 2014/287/EU and Implementing Decision 2020/534/EU;
- **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.

Regarding the Evidence, where applicable (i.e. if evidence is subjected to documentation review) it is mentioned where or how the evidence should be provided: 1. **Application form: the evidence should be provided on the Application form; 2. **Supporting documentation**: Network must have ready at the time the application is submitted all supporting documentation listed in the List of Supporting Documentation for Networks; 3. **Upon request**: in addition to the required documentation on the List of Supporting documentation, assessors may request additional documentation; 4. **Optional**: the documentation should be provided when possible.*

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 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). 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.

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

In addition to the above, some measures have been categorised 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**.

Summary Table - Operational Criteria for the Network

Operational Criteria to Assess Compliance with EU Legislation

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.	3.1.1	There is one designated representative for each applicant member of the Network.
		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 Network has established mechanisms to involve patient representatives in the overall governance of the ERN.
		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.
		3.1.7	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.

PATIENT CARE			
No.	**Criteria**	**No.**	**Measure(s)**
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 specialised 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. Through collaboration with patients and/or patient organisations, the information is adapted to the specific needs of patients and families.
		4.2.2	The Network collaborates with patient associations to improve the safety and quality of care, based on the expressed needs and expectations of patients.
		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 e.g. patient surveys or assessments of patients' needs. The Network undertakes actions to fulfil unmet patient' needs, where appropriate.

MULTIDISCIPLINARY APPROACH			
No.	**Criteria**	**No.**	**Measure(s)**
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.
GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL			
No.	**Criteria**	**No.**	**Measure(s)**
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	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.

CONTRIBUTION TO RESEARCH			
No.	**Criteria**	**No.**	**Measure(s)**
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 organisations 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.
CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT			
No.	**Criteria**	**No.**	**Measure(s)**
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.
NETWORKING AND COLLABORATION			
No.	**Criteria**	**No.**	**Measure(s)**
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, best practices and clinical expertise within and outside of the Network, including other Networks and Centres of Expertise and non-expert healthcare professionals. other Networks and Centres of Expertise.
		9.1.2	The Network develops a communication plan and establishes communication tools to support collaboration with other organisations.
		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.

1. ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK

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. The 10 members include Healthcare Providersapproved as "full members" by the European Reference Network Board of Member States. Potential Affiliated Partners will not be considered as applicant Healthcare Providers.

Evidence

- List of Applicant Healthcare Providers and their Member States (Application form)

Method of Assessment

- Eligibility Check
- Documentation Review

2. HIGHLY SPECIALISED HEALTHCARE

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 have 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. 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.[1]

Evidence

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

Method of Assessment

- Eligibility Check
- Documentation Review

2.1.2 MEASURE

[1] Strategic Conclusions of the ERN Board of Member States (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)

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)

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 a multidisciplinary approach and well planned organisation of services over time is required.

The criteria for expertise and specialisation should be explicit and supported by documented clinical and scientific evidence. Factors that should be considered are: 1. diagnosis and/or treatment requires special competence, resources and a concentration of knowledge;
2 . potential for increased cost efficiency and quality of care; 3. the disorder, condition, and/or treatment has a low prevalence or incidence; 4. centralisation of service and collaboration across the Network will improve conditions for research and development, ensure availability, and improve continuity of care.

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 (Application form)
- Number of scientific publications, research projects, and clinical trials on the Network's area of expertise (Supporting documentation)

Method of Assessment

- Eligibility Check
- Documentation Review

2.1.3 MEASURE

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 at least three objectives from the list laid down in the Directive, and demonstrate that it has the necessary competencies to pursue them effectively.

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 organisations, 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 Board of Member States (BoMS) and revised every three to five years.

Evidence

- Mission and Vision Statement (Supporting documentation)
- Initial Strategic Plan (Supporting documentation)

Method of Assessment

- Documentation Review

3. GOVERANCE AND COORDINATION

3.1 CRITERIA

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

3.1.1 MEASURE

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

Guideline

Each applicant Member's representative is selected from among the health care professionals belonging to the staff of the Healthcare Provider. 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 the 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 (Application form)
- Organogram showing representation, membership and structure of the Network (Supporting documentation)

- Written Statements of Members Role and Responsibilities (Supporting documentation)
- 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 (Supporting documentation)

Method of Assessment

- Documentation Review

3.1.3 MEASURE

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 rules and procedures state that the Board of Directors should review and update its policies and/or rules of procedure on an annual basis.

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

Evidence

- Board policies or rules of procedure (upon request)
- Information Posted on the Network Website

Method of Assessment

- Documentation Review
- Onsite Audit

3.1.4 MEASURE

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 (upon request)

Method of Assessment

- Documentation Review

3.1.5 MEASURE

The Network has established mechanisms to involve patient representatives in the overall governance of the ERN.

Guideline

The Network allows patients and/ or patients organisations to be involved in the overall governance of an ERN to ensure that patient care is needs led. In order to achieve this, the Network implements a framework which directs the ERN board and clinicians to actively ask for the opinions of patient representatives and to demonstrate what has been done to resolve and improve issues raised by the patient representatives. The exact interpretation and implementation of such a framework should be defined by the Network.

The role and responsibilities of patient representatives or patient organisations should be clearly defined and documented in the set of governance policies or rules of procedure.

Evidence

- Board policies or rules of procedure for the role of patient representatives in the ERN governance
- Framework for a role of patient representatives in the ERN governance and/or planned actions and timelines to develop a framework

Method of Assessment

- Documentation review
- Semi-structured interviews

3.1.6 MEASURE

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 in swiftly becoming fully operational in their interaction within the Network.

For Affiliated Partners, i.e. Associated or Collaborative National Centres 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 organisation originates, as well as the regulations set by the Cross-Border Directive and Delegated Acts.

Evidence

- Rules of Procedure and Entrance Pathways for New Members and Affiliated Partners
- Board Policies or Rules of Procedure (upon request; previously required documentation)

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 Coordinator is selected from among the health professionals belonging to the Coordinating Member's staff. 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" (Application form)
- Board Policies or Rules of Procedure (upon request; previously required documentation)

Method of Assessment

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

4. PATIENT CARE

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.

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 tohealthcare 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 organisations to improve access to care and inform patients and families aboutpatient pathways.

Evidence

- Patient Pathways and/or Planned actions and timelines to establish pathways (Supporting documentation)

Method of Assessment

- Documentation Review

4.1.2 MEASURE

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 tele-expertise. Telemedicine involves the use of ICT to provide a healthcare service directly to a patient. Tele-expertise 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

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

The Network promotes the safe use of highly specialised 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 specialised diagnostic technologies within its area of expertise

Evidence

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

Method of Assessment

- Documentation Review

4.1.5 MEASURE

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 organisations 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 of Quality indicator for transitions of care or planned actions to develop quality indicator

Method of Assessment

- Documentation Review
- On site Visit (Tracer Methodology)

4.2 CRITERIA

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

4.2.1 MEASURE

The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families. Through collaboration with patients and/ or patient organisations, the information is adapted to the specific needs of patients and families.

Guideline

In collaboration with patient organisations, 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. 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, Website (Supporting documentation)

Method of Assessment

- Semi-structured Interview with Network Coordinator
- Documentation Review

4.2.2 MEASURE

The Network collaborates with patient associations to improve the safety and quality of care based on the expressed needs and expectations of patients.

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

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, breaches in continuity of care, and publicly release figures every year within the Network's area of expertise and disseminates this information to patients and families.

Evidence

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

Method of Assessment

- Documentation Review

4.2.4 MEASURE

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

The Network collaborates with its Members to establish a standardised common tool for measuring patient experience e.g. patient surveys or assessments of patients' needs. The Network undertakes actions to fulfil unmet patient' needs, where appropriate.

Guideline

The Network defines a plan to develop a common tool, e.g. patient surveys, for gathering and analysing data across its Members and support benchmarking of patient experience information. In addition, the Network defines a framework to act upon gathered unmet patient needs, where possible.

Evidence

- Patient Experience Survey(s)/assessment of patients' needs and/or planned activities and timelines to establish a commontool (Supporting documentation)
- Planned activities and timelines to develop a framework to undertake actions to fulfil unmet patient' needs (Supporting documentation)

Method of Assessment

- Documentation Review

5. MULTIDISCIPLINARY APPROACH

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

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 and/or planned activities and timelines for developing clinical guidelines (Supporting documentation)

Method of Assessment

- Documentation Review
- Semi-structured Interview

5.1.2 MEASURE

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 and 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 organisations, 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 depending on their area of expertise.

Evidence

- Guides/Recommendations on Multidisciplinary Teams (Supporting documentation)
- Written Agreements and/or Letters of Intent (upon request)

Method of Assessment

- Documentation Review

5.1.3 MEASURE

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.

Evidence

- Documented Process for Offering Multidisciplinary advice (upon request)

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

6. GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL

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

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 (upon request)

Method of Assessment

- Documentation Review

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

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 organisations 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 specialised 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

6.3 CRITERIA

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

6.3.1 MEASURE

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 (Supporting documentation; previously required documentation)
- 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

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 ethic 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. 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

- Rules and procedures to ensure transparency and adhere to ethic requirements and/or planned activities and timelines for developing rules and procedures

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

Method of Assessment

- Documentation Review
- Semi-structured interview with Network Coordinator

6.3.3 MEASURE

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 for cross-border pathways. 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 (Supporting documentation)

Method of Assessment

- Documentation Review

6.3.4 MEASURE

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 (upon request)
- Examples of guidelines and pathways where implementation is to be monitored (upon

request)

Method of Assessment

- Documentation Review

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

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 (Supporting documentation)
- Sample of Quarterly Reports (upon request)

Method of Assessment

- Documentation Review

6.4.2 MEASURE

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

Guideline

The Quality, Patient Safety, and Evaluation Framework describes 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) (Supporting documentation)
- Policies and Standard Operating Procedures

Method of Assessment

- Documentation Review
- Semi-structured Interview with Network Coordinator

7. CONTRIBUTION TO RESEARCH

7.1 CRITERIA

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

7.1.1 MEASURE

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, 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 (upon request)

Method of Assessment

- Documentation Review

7.1.2 MEASURE

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 is 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 (Supporting documentation)
- Examples of how the Network supports collaborative research and facilitates translation of research into care

Method of Assessment

- Documentation Review
- Semi-structured interviews

7.1.2 MEASURE

The Network keeps its Members, partners, and patient organisations 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 EuropeanUnion. 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 (upon request)
- Annual Report on Research Projects and Clinical Trials and/or planned actions and timelines to develop the Report (Supporting documentation)

Method of Assessment

- Documentation Review

7.1.2 MEASURE

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 organisations 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 (upon request)
- 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

8. CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT

8.1 CRITERIA

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

8.1.1 MEASURE

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 (Supporting documentation)

Method of Assessment

- Documentation Review
- Semi-structured Interview with Network Coordinator

8.1.2 MEASURE

The Network facilitates and supports the development and use of standardised 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 for developing and/or promoting the use of standardised continuous education training programmes and tools (upon request)
- Examples of standard programmes and tools used and/or planned activities and timelines (upon request)

Method of Assessment

- Documentation Review

8.1.3 MEASURE

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 for education and training is adapted to the learner and 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 (optional)

Method of Assessment

- Documentation Review

9. NETWORKING AND COLLABORATION

9.1 CRITERIA

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

9.1.1 MEASURE

The Network exchanges and disseminates knowledge, best practices and clinical expertise within and outside of the Network, including other Networks and Centres of Expertise and non-expert healthcare providers.

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.

Establishing collaborations with learned societies, patient organisations, 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 or 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 (upon request)
- Tools used and best practices shared within/outside the Network and/or planned activities and timelines
- Examples to date of collaborations with other Networks and National Centres, where applicable

Method of Assessment

- Documentation Review
- Semi-structured Interviews

9.1.2 MEASURE

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

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.

The Network should develop an action plan with specific timelines for setting up communication tools and methodologies. The collaboration with other organisations 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.

Evidence

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

Method of Assessment

- Semi-structure Interviews
- Documentation Review

9.1.3 MEASURE

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. 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 under-pinning 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 designationof 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 New Members and Affiliated Partners (Supporting documentation; previously required documentation)

Method of Assessment

- Documentation Review

Annex 1b - Operational Criteria for Healthcare Providers

Background

PURPOSE OF THE OPERATIONAL CRITERIA

The central component of the assessment programme is the Operational Criteria for 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 (Annex II). The purpose of the operational criteriais to provide a common framework to assess Healthcare Providers' compliance with this legislation.

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

DESCRIPTION OF THE OPERATIONAL CRITERIA

The Operational Criteria for Healthcare Providers consist of **two** sections. The first section covers general criteria that are common to all specialised healthcare providers (e.g. organisation and management, research and training, and information systems).

The second section consists of specific criteria with regards to the condition(s) or disease(s) covered by the Network. The Healthcare Provider must adapt the requirements in these criteria related to competency and expertise, qualifications of the healthcare professionals, composition of the multidisciplinary team, and access to specialised resources (facilities, equipment and diagnostic services) specific to the Network's area of expertise based on recognised sources, and/or expert consensus. The Healthcare Provider should follow these requirements as defined by the Network.

For each criterion, the following elements are included:

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

- **Method of Assessment:** how the evidence will be collected and evaluated to determine compliance with the measure.
  Regarding the Evidence, where applicable (i.e. if evidence is subjected to documentation review) it is mentioned where or how the evidence should be provided: 1.* ***Application form**: the evidence should be provided on the Application form; 2.* ***Supporting documentation****: the Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in the List of Supporting Documentation for Healthcare Providers. This documentation is provided with a number that corresponds to the numbering tin the self-assessment online tool); 3.* ***Upon request****: in addition to the required documentation on the List of Supporting documentation, assessors may request additional documentation; 4.* ***Optional****: the documentation should be provided when possible*

For the general criteria, most measures must be in place at the Healthcare Provider level but some measures need to be covered at the organisational level, for instance certain policies and procedures. In this case, these measures are marked with the following symbol:

For the specific criteria, all measures must be in place at the Healthcare Provider level.

EVIDENCE OF COMPLIANCE

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

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

Summary Table: Operational Criteria for the Assessment of Health Care Providers

Operational Criteria to Assess Compliance with EU Legislation

1.General criteria and conditions for applicants for membership of a Network			
1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE			
No.	**Criteria**	**No.**	**Measure(s)**
1.1	The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.	1.1.1	The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.
		1.1.2	The Healthcare Provider has processes in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.
		1.1.3	The Healthcare Provider has patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages available.
		1.1.4	The Healthcare Provider provides patients and their families with written information about the facility, the organisation, and its specific area of expertise.
		1.1.5	The Healthcare Provider gives patients and their families written information about their rights and responsibilities.
		1.1.6	There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.
1.2	The Healthcare Provider provides patients with clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients.	1.2.1	There is clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients. Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.

1.3	The Healthcare Provider regularly collects information on patient care experience within the Network's area of expertise and uses this information to make ongoing improvements.	1.3.1	The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.
1.4	The Healthcare Provider protects the privacy and confidentiality of patient health information.	1.4.1	The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.
1.5	Patient informed consent to share personal health information complies with the requirements set out in Article 2(e) of the Directive 2014/286/EU.	1.5.1	If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.
1.6	The Healthcare Provider maintains transparency by providing information to patients and the general public about clinical outcomes, treatment options, and quality and safety standards that are in place.	1.6.1	The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.
		1.6.2	All data sources are accessible to patients in an anonymised format, including claims data, patient registry data, clinical data, and patient-reported outcomes.
		1.6.3	The Healthcare Provider provides every patient with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.
		1.6.4	The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.
1.7	The Healthcare Provider is transparent about all possibleconflicts of interest related to treatment and/or research activities.	1.7.1	The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.
2.ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY			
No.	**Criteria**	**No.**	**Measure(s)**
2.1	The organisation follows a documented set of organisation and management rules and procedures for services provided within the Network's area of expertise.	2.1.1	The Healthcare Provider has management and staff and/or clinician roles and responsibilities specific to the area of expertise clearly defined in an organisation chart.
		2.1.2	The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.
		2.1.3	The Healthcare provider has policies and procedures for managing cross-

			border patients within the Network's area of expertise.
2.2	The Healthcare Provider has information about any tariffs that may be in place for the reimbursement of care, including how these are calculated, transparently available and provides patients and their families with access to this information, upon request.	2.2.1	The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits, upon request.
2.3	The Healthcare Provider has a business continuity plan.	2.3.1	The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.
2.4	The Healthcare Provider establishes procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.	2.4.1	The Healthcare Provider has procedures in place for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admittedwithout delay to a suitable hospital ward service area, where necessary.
		2.4.2	When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.
2.5	The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.	2.5.1	The Healthcare Provider ensures that treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.
2.6	The Healthcare Provider has policies and procedures in place to communicate with clinicians post discharge, including cross-border.	2.6.1	The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.
		2.6.2	Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.
3.RESEARCH, EDUCATION AND TRAINING			
No.	**Criteria**	**No.**	**Measure(s)**
3.1	The Healthcare Provider participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.	3.1.1	The Healthcare Provider delivers university, post-graduate, or specialised levelof education and training in the Network's area of expertise.
		3.1.2	The Healthcare Provider has a defined set of objectives for its education and training activities.

		3.1.3	The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.
		3.1.4	Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.
		3.1.5	The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.
3.2	The Healthcare Provider has the capacity to carry out research activities and demonstrated research experience.	3.2.1	The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.
		3.2.2	The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.
		3.2.3	The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.
		3.2.4	There is a procedure to review the ethical implications of research activities.
		3.2.5	The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.
		3.2.6	The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.
4.EXPERTISE, INFORMATION SYSTEMS, AND eHealth TOOLS			
No.	**Criteria**	**No.**	**Measure(s)**
4.1	The Healthcare Provider is able to exchange expertise with other providers and provide support to them.	4.1.1	The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.
		4.1.2	The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.
4.2	The Healthcare Provider safeguards the use of medical data within the Network's area of expertise.	4.2.1	The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the Delegated Decision 2014/286/EU.

4.3	The Healthcare Provider fosters the use of telemedicine and other eHealth tools within and outside its facility.	4.3.1	To support the use of telemedicine and other eHealth tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations. The Healthcare Provider maintains a documented list of available and used eHealth technology.
4.4	The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.	4.4.1	The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).
5.QUALITY AND SAFETY			
No.	**Criteria**	**No.**	**Measure(s)**
5.1	The Healthcare Provider regularly monitors the quality and safety of the care it provides to patients with rare or low prevalence complex diseases or conditions.	5.1.1	The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.
		5.1.2	The Healthcare Provider regularly collects and monitors process and outcome Indicators and has procedures in place to monitor and maintain data quality.
		5.1.3	The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise.
		5.1.4	There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements.
		5.1.5	The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.
5.2	The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.	5.2.1	There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.
5.3	The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.	5.3.1	The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure.
		5.3.2	The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.
		5.3.3	The Healthcare Provider regularly reviews their clinical practice guidelines to ensure they reflect current research and best practice information.

Specific operational criteria and conditions for applicant providers with regard to the area of expertise, disease or condition of the Networks they wish to Join			
6.COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE			
No.	**Criteria**	**No.**	**Measure(s)**
6.1	The Healthcare Provider maintains its competence in the Network's area of expertise.	6.1.1	The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.
		6.1.2	To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.
6.2	The Healthcare Provider demonstrates good clinical care and outcomes.	6.2.1	The Healthcare Provider provides evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.
		6.2.2	The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.
7.HUMAN RESOURCES			
No.	**Criteria**	**No.**	**Measure(s)**
7.1	The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.	7.1.1	The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.
		7.1.2	The Healthcare Provider has a sufficient number of staff with the necessary qualifications to perform the specialised function.
		7.1.3	Each Healthcare Provider core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.
		7.1.4	The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialised tasks.
8.ORGANISATION OF PATIENT CARE			
No.	**Criteria**	**No.**	**Measure(s)**
8.1	The Healthcare Provider delivers comprehensive care by a multidisciplinary and specialised care team.	8.1.1	The Healthcare Provider documents the characteristics of the multidisciplinary team.

		8.1.2	There is a designated leader and chair of the Healthcare Providers' multidisciplinary team.
		8.1.3	The Healthcare Provider has documented procedures in place to support the organisation and functioning of the Healthcare Providers' multidisciplinary care team.
		8.1.4	There are regular structured meetings between Healthcare Providers' multidisciplinary team members.
		8.1.5	Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.
		8.1.6	The Healthcare Providers' multidisciplinary team evaluates its performance on an annual basis.
9.FACILITIES AND EQUIPMENT			
No.	**Criteria**	**No.**	**Measure(s)**
9.1	The Healthcare Provider has the necessary facilities and equipment to attend to patients specific to the area of expertise, disease, or condition as defined by the Network.	9.1.1	The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.
		9.1.2	The Healthcare Provider has access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.
		9.1.3	The Healthcare Provider has access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.
		9.1.4	Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.

1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

1.1 CRITERIA

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

1.1.1 MEASURE

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

Guideline

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

Evidence

- Mission or Core Values (Supporting documentation, 1a)
- Patient Information and Education materials (Supporting documentation, 1a)

Method of Assessment

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

1.1.2 MEASURE

The Healthcare Provider has processes in place to assist patients and their families in knowing who is providing their care,and the role of each person on the multidisciplinary care team.

Guideline

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

Evidence

- Examples of Patients' Notes
- Clinical audits and/or chart reviews

Method of Assessment

- Onsite Audit (Tracer Methodology)

1.1.3 MEASURE

The Healthcare provider has patient education materials appropriate for readers of varying literacy levels and for speakers ofdifferent native languages available.

Guideline

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

Evidence

- Patient Information and Education Materials (Supporting documentation, 1a; previously required documentation)

Method of Assessment

- Onsite Audit (Documentation Review)

1.1.4 MEASURE

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

Guideline

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

Evidence

- Patient Information and Education Materials (Supporting documentation, 1a; previously required documentation)

Method of Assessment

- Documentation Review

1.1.5 MEASURE

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

Guideline

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

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

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

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

Evidence

- Written material describing patient and family rights and responsibilities (Supporting documentation, 1a)

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

1.1.6 MEASURE

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

Guideline

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

Evidence

- Organisation Policy and Process on Disclosure

Method of Assessment

- Onsite Audit (Documentation Review)

1.2 CRITERIA

The Healthcare Provider provides patients with clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients.

1.2.1 MEASURE

There is clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients. Patients and their families are given information about how to file a complaint, report violationsof their rights, and raise concerns about their care and/or safety.

Guideline

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

There is a procedure to investigate and respond to complaints and claims that patients' rights have been violated, and respond to patient and their family concerns in a timely way. The

Healthcare Provider can demonstrate evidence of proactive remedial actions to a complaint or concern.. Standards for response times are clearly defined, documented, and followed.

Evidence

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

Method of Assessment

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

1.3 CRITERIA

The Healthcare Provider regularly collects information on patient care experience within the Network's area of expertise and uses this information to make ongoing improvements.

1.3.1 MEASURE

The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.

Guideline

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

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

Evidence

- Patient Experience Survey (Supporting documentation, 1c)
- Sample Patient Experience Reports (Supporting documentation, 1c)
- Action Plan for Improvement (upon request)

Method of Assessment

- Documentation Review

1.4 CRITERIA

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

1.4.1 MEASURE

The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.

Guideline

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

Evidence

- Confidentiality and Privacy Policies and Procedures (upon request)
- Privacy and Record Keeping Audits

Method of Assessment

- Documentation Review
- Onsite Audit

1.5 CRITERIA

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

1.5.1 MEASURE

If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The informed consent is documented in the patient's medical record.

Guideline

Informed consent is given freely, unambiguously and explicitly by the patient or their legal

representative after being informed of the purpose, nature, significance and implications of the use of their personal health information. The given consent should be duly documented.

Evidence

- Informed Consent Policy and Procedure (Supporting documentation, 1e)
- Informed Consent Forms
- Medical Record Audit or Chart Review

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

1.6 CRITERIA

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

1.6.1 MEASURE

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

Guideline

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

Evidence

- Patient Information and Education Material (Supporting documentation, 1a; previously required documentation)

Method of Assessment

- Documentation Review

1.6.2 MEASURE

All data sources are accessible to patients in an anonymised format, including claims data, patient registry data, clinical data, and patient-reported outcomes.

Guideline

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

Evidence

- Policies and procedures for accessing information (upon request)

Method of Assessment

- Documentation Review

1.6.3 MEASURE

The Healthcare Provider provides every patient with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.

Guideline

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

Evidence

- Informed Consent Policy and Procedure (Supporting documentation 1e; previously required documentation)
- Patient Information and Education Material (Supporting documentation 1a; previously required documentation)

Method of Assessment

- Documentation Review

1.6.4 MEASURE

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

Guideline

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

Evidence

- Patient Information and Education Material or Videos (Supporting documentation 1a; previously required documentation)

Method of Assessment

- Documentation Review

1.7 CRITERIA

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

1.7.1 MEASURE

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

Guideline

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

Evidence

- Conflict of Interest Policy (Supporting documentation, 1g)

Method of Assessment

- Documentation Review

2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY

2.1 CRITERIA

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

2.1.1 MEASURE

The Healthcare Provider has management and staff and/or clinician roles and responsibilities specific to the area of expertiseare clearly defined in an organisation chart.

Guideline

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

Evidence

- Organisation chart (Supporting documentation, 2a)

Method of Assessment

- Documentation Review

2.1.2 MEASURE

The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.

Guideline

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

Evidence

- Policies and Procedures or planned actions and timelines to develop policies and procedures (upon request)
- Schedule for reviewing policies and procedures (upon request)

Method of Assessment

- Documentation Review

2.1.3 MEASURE

The Healthcare Provider has policies and procedures for managing cross-border patients within the Network's area of expertise.

Guideline

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

Evidence

- Policies and Procedures for Managing Cross-border Patients or planned actions and timelines for developing policies and procedures (Supporting documentation, 2a)

Method of Assessment

- Documentation Review

2.2 CRITERIA

The Healthcare Provider has information about any tariffs that maybe in place for the reimbursement of care, including how these are calculated, transparently available and provides patients and their families with access to this information, upon request.

2.2.1 MEASURE

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

Guideline

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

are those set out in the legislation of the Member State of treatment and as described in the Directive 2011/24 and Social Security Regulation 883.

Evidence

- Patient Information and Education Materials (Supporting documentation, 1a; previously required documentation)

Method of Assessment

- Documentation Review

2.3 CRITERIA

The Healthcare Provider has a business continuity plan.

2.3.1 MEASURE

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

Guideline

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

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

The Healthcare Provider collects and analyses data as a part of its facilities management programs to support planning for replacing or upgrading medical technology, equipment, and systems, and reducing risks in the environment specific to the Network's area of expertise. Clinical leads or experts may work with regional hospitals to develop succession plans.

Succession planning increases the availability of experienced and capable providers that are prepared to assume these roles as they become available.

Evidence

- Business continuity plan (Supporting documentation, 2c)

Method of Assessment

- Documentation Review

2.4 CRITERIA

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

2.4.1 MEASURE

The Healthcare Provider has procedures in place for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.

Guideline

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

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

Evidence

- Emergency and After Hour Procedures
- Referral Protocols
- Patient Information and Education Materials (Supporting documentation, 1a; previously required documentation)

Method of Assessment

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

2.4.2 MEASURE

When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.

Guideline

There are documented procedures and/or formal agreements between the Healthcare Provider,

i.e. centre of expertise, and other highly specialised providers and/or services such as proton therapy, special radiotherapy, burn care, hyperbaric chambers, etc. necessary for diagnosing and managing patients across the disease trajectory.

Evidence

- Formal Agreements between Healthcare Providers and/or Procedures (upon request)

Method of Assessment

- Documentation Review

2.5 CRITERIA

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

2.5.1 MEASURE

The Healthcare Provider ensures that treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.

Guideline

Examples of dedicated, easily accessible and appropriate facilities are surgery theatres, intensive care units, isolation units, emergency wards, laboratories, etc.

Evidence

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

Method of Assessment

- Onsite Audit (Tour of Facility or Unit)

2.6 CRITERIA

The Healthcare Provider has policies and procedures in place to communicate with clinicians post discharge, including cross-border.

2.6.1 MEASURE

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

Guideline

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

Evidence

- Discharge procedure (Supporting documentation, 2f)
- Discharge Template (Supporting documentation, 2f)

Method of Assessment

- Documentation Review
- Onsite Audit (Tracer Methodology)

2.6.2 MEASURE

Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.

Guideline

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

The Healthcare Provider provides and maintains a list with eHealth tools available and a notification of whether these tools are used in practice or not.

Evidence

- List of available and used eHealth technology (Supporting documentation)
- Technologies Used for the sharing of information post discharge

Method of Assessment

- Documentation review
- Semi-structured Interview with Healthcare Provider Representative

3. RESEARCH, EDUCATION AND TRAINING

3.1 CRITERIA

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

3.1.1 MEASURE

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

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

3.1.2 MEASURE

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

Guideline

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

Evidence

- List of teaching objectives (Supporting documentation, 3a)

Method of Assessment

- Documentation Review

3.1.3 MEASURE

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

Guideline

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

Evidence

- List of Teaching Staff and Qualifications (Supporting documentation, 3a)
- Description of Site Resources to Support Education and Training

Method of Assessment

- Documentation Review
- On Site Audit and Tour

3.1.4 MEASURE

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

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

3.1.5 MEASURE

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

Guideline

The effectiveness of education and training activities may be measured by satisfaction, acquired knowledge or skills, and/or demonstrated competence. Where possible, the Healthcare Provider is accredited and/or certified for its teaching and training activities. Compliance with set standards for education and training protects the integrity of the learning experience and ensures that education and training providers are credible and competent.

Evidence

- List of Measures and results over the last three years (upon request)
- Accreditation or Certification (upon request)

Method of Assessment

- Documentation Review

3.2 CRITERIA

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

3.2.1 MEASURE

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

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

- On Site Audit and Tour

3.2.2 MEASURE

The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.

Guideline

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

Evidence

- List of grants and research projects over the last 5 years (Supporting documentation, 3b)

Method of Assessment

- Documentation Review

3.2.3 MEASURE

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

Guideline

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

Evidence

- Standard Operating Procedures (SOPs) (Supporting documentation, 3b)

Method of Assessment

- Documentation Review

3.2.4 MEASURE

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

Guideline

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

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

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

Evidence

- Defined criteria for ethics approval
- Research Policy and Procedure (Supporting documentation, 3b)
- Research Ethics Board or Committee Terms of Reference and Meeting Minutes

Method of Assessment

- Onsite Audit
- Documentation Review

3.2.5 MEASURE

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

Guideline

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

Evidence

- Demonstration of Information System Used to Collect Data

Method of Assessment

- Onsite Audit (Documentation Review)

3.2.6 MEASURE

The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

4. EXPERTISE, INFORMATION SYSTEMS, AND EHEALTH TOOLS

4.1 CRITERIA

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

4.1.1 MEASURE

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

Guideline

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

Evidence

- Advisory Service
- Procedures and Strategies to Disseminate Knowledge

Method of Assessment

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

4.1.2 MEASURE

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

Guideline

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

Evidence

- Policies and procedures for clinical documentation (upon request)
- Patient Database

Method of Assessment

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

4.2 CRITERIA

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

4.2.1 MEASURE

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

Guideline

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

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

Evidence

- Policies and Procedures (upon request)

Method of Assessment

- Documentation Review

4.3 CRITERIA

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

4.3.1 MEASURE

To support the use of telemedicine and other eHealth tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations. The Healthcare Provider maintains a documented list of available and used eHealth technology.

Guideline

The Healthcare Provider participates in activities to advance best practice in the use of telemedicine to support the care to patients within the Network's area of expertise. Where possible, the Healthcare Provider uses telemedicine technology to facilitate consultations between centres within different domains specific to the area of expertise. The Healthcare Provider provides and maintains a list with eHealth tools available and a notification of whether these tools are used in practice or not. When using telemedicine and other eHealth tools, the Healthcare Provider follows set Standard Operating Procedures and protocols. The minimum interoperability requirements include the technical specifications to support: transmission speed and bandwidth; image storage, retrieval and transmission; physical location of the equipment and room requirements.

Evidence

- List of available and used eHealth technology (same documentation as required for Measure 2.6.2)
- Telemedicine Standard Operating Procedures and Protocols, where possible
- Description of Telemedicine Activities

Method of Assessment

- Documentation Review
- Onsite Audit

4.4 CRITERIA

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

4.4.1 MEASURE

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

Guideline

This coding system is in line with nationally and internationally recognised systems, when appropriate. This may include the International Classification of Diseases and Complementary Codes and/or Orphanet Classification. Given that systems are not yet available within all countries, evidence may include an agreement amongst all Healthcare Providers within the Network on the use of the most appropriate coding system.

Evidence

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

Method of Assessment

- Onsite Audit (Semi-structured Interview)

5. QUALITY AND SAFETY

5.1 CRITERIA

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

5.1.1 MEASURE

The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.

Guideline

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

Evidence

- Quality Assurance or Management System
- Quality Improvement Plan (Supporting documentation, 5a)
- List of audits, including their findings and status of recommendations, completed in the past year within the Network's area of expertise
- Description of Process Improvements (upon request)

Method of Assessment

- Documentation Review
- Onsite Audit (Semi-structured Interview)

5.1.2 MEASURE

The Healthcare Provider regularly collects and monitors process and outcome indicators and has procedures in place to monitor and maintain data quality.

Guideline

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

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

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

Evidence

- Current Structure, Process or Outcome Indicators (Dashboard) and their definitions or planned actions and timelines for their development (Supporting documentation, 5a)
- Patient Reported Outcome Measures or planned actions and timelines for their development (upon request)
- Sample Indicator Report that includes quarterly or biannual data over the past year, as appropriate (optional)
- Data Quality Procedures

Method of Assessment

- Documentation Review
- Onsite Audit

5.1.3 MEASURE

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

Guideline

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

Evidence

- Patient Safety Plan (Supporting documentation, 5a)
- Patient Safety Reports
- Patient Safety and Quality Committee Minutes

Method of Assessment

- Documentation Review
- Onsite Audit (observation of patient safety reports and minutes)

5.1.4 MEASURE

There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements.

Guideline

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

Evidence

- Detailed Example of Root Cause Analysis and Description of Process Improvement methods (5a)

Method of Assessment

- Documentation Review
- Onsite Audit

5.1.5 MEASURE

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

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

5.2 CRITERIA

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

5.2.1 MEASURE

There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.

Guideline

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

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

Evidence

- Mechanisms used to review and share best practice information
- List of standardised procedures and protocols (upon request)

Method of Assessment

- Semi-structured Interviews
- Documentation Review

5.3 CRITERIA

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

5.3.1 MEASURE

The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure.

Guideline

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. Guidelines may be developed and/or selected by the Network a committee, council, or individual who makes recommendations.

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

Evidence

- Procedure for developing/selecting and updating clinical practice guidelines
- Methods used to obtain patient and their family input
- List and examples of Clinical Practice Guidelines or Clinical Decision Support tools (Supporting documentation, 5c)

Method of Assessment

- Documentation Review
- Onsite Audit (semi-structured interview)

5.3.2 MEASURE

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

Guideline

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

Evidence

- Implementation of clinical practice guidelines

Method of Assessment

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

5.3.3 MEASURE

The Healthcare Provider regularly reviews their clinical practice guidelines to ensure they reflect current research and best practice information.

Guideline

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

Evidence

- Procedure for developing/selecting and updating clinical practice guidelines (upon request; previously required documentation)

Method of Assessment

- Documentation Review

6. COMPENTENCE, EXPERIENCE, AND OUTCOMES OF CARE

6.1 CRITERIA

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

6.1.1 MEASURE

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

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review and Onsite Audit (documentation review)

6.1.2 MEASURE

To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

- On-site Audit

6.2 CRITERIA

The Healthcare Provider demonstrates good clinical care and outcomes.

6.2.1 MEASURE

The Healthcare Provider provides evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.

Guideline

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

Evidence

- Documentation and description of treatment protocols used and the evidence to support their use (upon request)
- Anonymised Registry of Visited/Treated Patients

Method of Assessment

- Documentation Review
- On-site Audit

6.2.2 MEASURE

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

Guideline

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

Evidence

- Performance and outcome indicators, data definitions, data collection methods, and interpretation
- Last two years of published data, where possible (optional)

Method of Assessment

- Documentation Review

7. HUMAN RESOURCES

7.1 CRITERIA

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

7.1.1 MEASURE

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

Guideline

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

Evidence

- List of professionals and their qualifications (Application form)

Method of Assessment

- Documentation Review

7.1.2 MEASURE

The Healthcare Provider has a sufficient number of staff with the necessary qualifications to perform the specialised function.

Guideline

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

Evidence

- List of professionals and their qualifications (Application form)
- Description of functional and operational structure of human resources (upon request)

Method of Assessment

- Documentation Review

7.1.3 MEASURE

Each Healthcare Provider core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.

Guideline

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

Evidence

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

Method of Assessment

- Documentation Review

7.1.4 MEASURE

The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialised tasks.

Guideline

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

Evidence

- Human Resource Records (upon request)
- Competency Assessments completed in the last two years, as applicable (optional)

Method of Assessment

- Documentation Review

8. ORGANISATION OF PATIENT CARE

8.1 CRITERIA

The Healthcare Provider delivers comprehensive care is delivered by a multidisciplinary and specialised care team.

8.1.1 MEASURE

The Healthcare Provider documents the characteristics of the multidisciplinary team.

Guideline

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

Evidence

- Description of the multidisciplinary team (Application form)
- Sample job profile

Method of Assessment

- Documentation Review and Onsite Audit (Documentation Review)

8.1.2 MEASURE

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

Guideline

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

Evidence

- Terms of Reference (upon request)

Method of Assessment

- Documentation Review

8.1.3 MEASURE

The Healthcare Provider has documented procedures to support the organisation and functioning of the Healthcare Providers' multidisciplinary care team.

Guideline

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

Evidence

- Documented Procedures

Method of Assessment

- Onsite Audit

8.1.4 MEASURE

There are regular structured meetings between multidisciplinary team members.

Guideline

All team members have dedicated time included in their job to attend team meetings. Core team members are present for all cases where there input is needed. Extended members and non- members may attend for those cases that are relevant to them. The team leader ensures that there is adequate representation at each meeting to make safe recommendations about patients. A register of attendance for all meetings should be maintained.

Evidence

- Meeting Minutes

Method of Assessment

- Onsite Audit

8.1.5 MEASURE

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

Guideline

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

Evidence

- Operational Policy and Procedures
- Patient Records

Method of Assessment

- Onsite Audit - Tracer Methodology

8.1.6 MEASURE

The Healthcare Providers' multidisciplinary team evaluates its performance on an annual basis.

Guideline

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

Evidence

- Policies and procedures (upon request)

Method of Assessment

- Documentation Review

9. FACILITIES AND EQUIPMENT

9.1 CRITERIA

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

9.1.1 MEASURE

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

Guideline

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

Evidence

- Available facilities and equipment (Application form)

Method of Assessment

- Documentation Review
- Onsite Audit

9.1.2 MEASURE

The Healthcare Provider has access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.

Guideline

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

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

Evidence

- List of laboratory Services available (Application form)
- Activity and Number of Samples or Tests Performed

Method of Assessment

- Documentation Review
- Onsite Audit (Facility Tour)

9.1.3 MEASURE

The Healthcare provider has access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.

Guideline

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

Evidence

- Diagnostic Technologies available (Application form)

Method of Assessment

- Documentation Review
- Onsite Audit (Facility Tour)

9.1.4 MEASURE

Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.

Guideline

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

Evidence

- Specialised Technologies available (Application form)

Method of Assessment

- Documentation Review

Glossary of Terms

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

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

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

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 inclinical 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 2a - Instructions for Self-Assessment for Networks

Introduction

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex I (b), the application to establish a European Reference Network must include this self-assessment questionnaire for Networks. This provides networks with the opportunity to evaluate themselves against the specific legislated criteria and conditions to fulfil as detailed in the **Operational Criteria for Networks** document before submitting their application to the European Commission. In addition, it provides a mechanism for both the Independent Assessment Body (IAB) and the Network to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

Description of the self-assessment tool

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

- Establishment of a European Reference Network
- Highly Specialised Healthcare
- Governance and Coordination
- Patient Care
- Multidisciplinary Approach
- Good Practice, Outcomes Measures, and Quality Control
- Contribution to Research
- Continuous Education, Training, and Development
- Networking and Collaboration

These nine (9) sections are based on the requirements set out in the Delegated Decision 2014/286/E Annex I. Each section includes multiple items to help the Network evaluate its readiness to submit a Network Application, see ***example of the self-assessment checklist tool*** below. These items are based on those Operational Criteria that the European Commission and IAB will use to assess compliance with the legislation. Note that a complete self-assessment must accompany the Application Form for the application to be considered.

Instructions for completing the self-assessment

1. Establish a team consisting of the designated Network Coordinator and representation from each ofthe potential Healthcare Providers and/or rare or low prevalence complex disease or condition thematic areas.

The team should be given sufficient time to complete the self-assessment. Completion of the self-assessment is estimated to take approximately three to four meetings with time allocated between meetings, pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointedto organise the group, assign tasks, and coordinate the self-assessment effort. As the self-assessment will be filled for submission in the online application, it is advised that the team uses a paper form to collect the information agreed during the preparatory process.

2. Read and review the Operational Criteria in their entirety before beginning the self-assessment process. If possible, make copies and send them to team members before the first meeting.

3. Discuss each individual element in the Self-Assessment Checklist and evaluate the Network's progress in implementing it. As necessary, verify the level of implementation with other individuals outside of the team. Document this information in the "Comments" section of the checklist. This "Comments" section is **mandatory** for each Measure of the Operational Criteria, to briefly explain each rating provided. The applicant must reference any supporting documentation, as required.

4. Once consensus is reached, complete the table below by marking the box that most appropriately captures the current status of compliance with the criterion, using the following rating scale and scoring guide:

Rating	Guidelines
0: No activity / Not Implemented	***All Criteria:*** **this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	***All Criteria:*** **this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance.** *This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	***All Criteria:*** **this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • A single negative observation may not prevent a score of "fully implemented". • 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.

5. Repeat the process for each element. Once complete, tally up the Network's score for each sectionusing the template provided in the sample of the ***Scoring table*** below. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

6. Use this information to develop an Action Plan to improve readiness to submit the application andcomplete the independent assessment process.

7. Prior to finalising and submitting the self-assessment, a process to validate the results internally should be followed. The purpose of the internal validation is to:
    - Provide a level of quality assurance;
    - Confirm that the self-assessments are accurate and therefore can be shared externally;
    - Identify any inconsistency in practice across the Network; and
    - Identify areas of best practice that could be shared across the Network.

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

- The process is fair and robust;
- The process is agreed to by all Healthcare Providers;
- Accountability for the self-assessment is agreed to by the Chief Executive Officer of the Healthcare Provider; and
- The process includes patient and family involvement.

At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.

8. Complete and sign *the Checklist and Declarations Forms for CEOs and HCP representatives (see Technical Toolbox Annex 12a and Annex 12b)*.

9. Submit the completed Self-Assessment along with the Application Form ***on or before the deadline*** for submitting applications in response to the Call for Interest. The Network must have ready at the time the application is submitted all supporting documentation listed in ***List of Supporting Documentation for Networks*** below. These documents should be made available to the IAB, at their request.

The self-assessment checklist tool for European Reference Networks (this is a sample only)

I. ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK					
1.1 The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.					
Measurement Elements	**0**	**1**	**2**	**Comments**	*
1.1.1 The Network is comprised of a minimum of 10 Members across 8 Member States.	☐	☐	☐		
II. HIGHLY SPECIALISED HEALTHCARE					
1.2 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.					
Measurement Elements	**0**	**1**	**2**	**Comments**	*
1.2.1 The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.	☐	☐	☐		
1.2.2 The Network's area of expertise is highly specialised and well defined and the expected gains of centralising care for these patientscan be demonstrated.	☐	☐	☐		
1.2.3 The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.	☐	☐	☐		**X**

III. GOVERNANCE AND COORDINATION					
1.3 The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.					
Measurement Elements	**0**	**1**	**2**	**Comments**	*
1.3.1 There is one designated representative for each applicant member of the Network.	☐	☐	☐		**X**
1.3.2 The Network is governed by a Board composed of one representative from each Member in the European Reference Network.	☐	☐	☐		**X**
1.3.3 The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.	☐	☐	☐		

** The Symbol 📄 indicates the requirement to have ready at the time of application a specific document as evidence of compliance. These documents are to be submitted at the request of the IAB. See **List of Supporting Documentation for Networks** below for the full list of supporting documentation required.*

LIST OF SUPPORTING DOCUMENTATION FOR NETWORKS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- **Measure 2.1.3** Mision, Vision, Initial Strategic Plan
- **Measure 3.1.1** Network Organogram and Written Statements of Members' Role and Responsibilities
- **Measure 3.1.2** Board Terms of Reference
- **Measure 9.1.2** Communication Strategy and Plan
- **Measure 9.1.3** Collaboration Strategy with Affiliated Partners

ATTACHMENT B — PATIENT EMPOWERMENT

- **Measure 4.2.1** Sample of information provided to patients and families, i.e. Brochures, Web-site
- **Measure 4.2.5** Patient Experience Survey(s) and/or planned activities and timelines to establisha common tool

ATTACHMENT C – ORGANISATION OF CARE

- **Measure 4.1.1** Patient Pathways and/or Planned Actions and Timelines
- **Measure 5.1.2** Guides/Recommendations on Multidisciplinary Teams
- **Measure 6.3.1** Clinical Guidelines and/or planned activities and timelines for developingGuidelines
- **Measure 6.3.2** Policy on the declaration and management of conflict of interest regardingclinical guidelines, patient pathways, and clinical decision making tools
- **Measure 6.3.3** Cross Border Pathways and/or planned actions and timelines to develop crossborder pathways

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM

- **Measure 4.1.4** List of Diagnostic Technologies and Services Certified or Accredited throughNational, European, and/or International Programs provided by Network Members
- **Measure 4.2.3** Published Annual Reports and/or Planned actions and Timelines for PatientSafety Data Collection and Reporting
- **Measure 6.4.1** List of performance and outcome indicators and their definitions
- **Measure 6.4.2** Quality and Safety Framework (including Adverse Events Reporting System)

ATTACHMENT E- RESEARCH AND TRAINING

- **Measure 7.1.2** Strategic Research Plan
- **Measure 7.1.3** Annual Report on Research Projects and Clinical Trials and/or planned actionsand timelines to develop the Report
- **Measure 8.1.1** Annual Education Work plan

Scoring table (this is a sample only)

SELF ASSESSMENT SCORING TABLE			
Establishment of a European Reference Network			
Total Score out of a Possible 2	0	Percent of Total	%
Highly Specialised Healthcare			
Total Score out of a Possible 6	0	Percent of Total	%
Governance and Coordination			
Total Score out of a Possible 14	0	Percent of Total	%
Patient Care			
Total Score out of a Possible 20	0	Percent of Total	%
Multidisciplinary Approach			
Total Score out of a Possible 6	0	Percent of Total	%
Good Practice, Outcomes Measures, and Quality Control			
Total Score out of a Possible 18	0	Percent of Total	%
Contribution to Research			
Total Score out of a Possible 8	0	Percent of Total	%
Continuous Education, Training, and Development			
Total Score out of a Possible 6	0	Percent of Total	%
Networking and Collaboration			
Total Score out of a Possible 6	0	Percent of Total	%
Overall			
Grand Total out of a Possible 86	**0**	**Percent of Total**	**%**

Annex 2b - Instructions for Self-Assessment for Healthcare Providers

Introduction

In accordance with the requirements outlined in Implementing Decision 2014/287/EU Annex II (b), the application to join a Network must include this self-assessment questionnaire Healthcare Providers. This provides Healthcare Providers with the opportunity to evaluate themselves against the criteria and conditions to fulfil as detailed in the **Operational Criteria for Healthcare Providers** document. In addition, it provides a mechanism for both the Independent Assessment Body and the Healthcare Provider to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

Instructions and Recommendations for Completing the Self-Assessment

1. Establish a multidisciplinary team consisting of the Healthcare Provider's Representative and care provider representation. The team should discuss and agree on the self-assessment information to be include in the IT form. This exercise as a team increases the value of the process and the accuracy of the information. It is estimated to take approximately three to four meetings, with time allocated between meetings pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointed to organise the group, assign tasks, and coordinate the self-assessment effort. As the self-assessment will be filled for submission in the online application, it is advised that the teamuses a paper form to collect the information agreed during the preparatory process.

2. Read and review the Operational Criteria in its entirety before beginning the Self-Assessment process. If possible, make copies and send them to team members before the first meeting.

3. Discuss each individual element in the Self-Assessment Checklist and evaluate the progress in implementing it. As necessary, verify the level of implementation with other individuals outside of the team. Document this information in the "Comments" section of the checklist. This "Comments" section is **mandatory** for each Measure of the Operational Criteria, to briefly explain each rating provided. The applicant must reference any supporting documentation, as required.

4. Once consensus is reached, complete the table below by marking the box that most appropriatelycaptures the current status of compliance with the criterion, using following rating

scale and scoring guide:

Rating	Guidelines
0: No activity / Not Implemented	*All Criteria:* this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance. *This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).* <u>Considerations</u>: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	*All Criteria:* this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance. *This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).* <u>Considerations</u>: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	*All Criteria:* this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to support compliance. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* <u>Considerations</u>: • A single negative observation may not prevent a score of "fully implemented". • 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.

5. Repeat the process for each element. Once complete, tally up the score for each section using the template provided in the sample of the **scoring table** below. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

6. Use this information to develop an Action Plan to improve readiness to submit the application and complete the independent assessment process.

7. Prior to finalising and submitting the self-assessment, a process to validate the results internally should be followed.
   The purpose of the internal validation is to:
   - Provide a level of quality assurance;
   - Confirm that the self-assessments are accurate and therefore can be shared externally;
   - At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.

8. Complete the self-assessment online form.

9. Submit the completed Self-Assessment along with the Application Form ***on or before the deadline*** for submitting applications in response to the Call for Interest. The Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in the ***List of Supporting Documentation for Healthcare Providers*** below. These documents should be made available to the BoN, IAB, or EC, at their request.

THE SELF-ASSESSMENT CHECKLIST TOOL FOR HEALTHCARE PROVIDERS

Criteria and conditions for Healthcare Providers

I. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE					
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences arerespected.					
1.1.1 The Healthcare Provider's commitment to patient-centered care is formally and consistently communicated with patients and their families.	☐	☐	☐		**X**
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	☐	☐	☐		
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	☐	☐	☐		
1.1.4The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.	☐	☐	☐		
1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.	☐	☐	☐		
1.1.5 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.	☐	☐	☐		

* The Symbol 🗏 indicates the requirement to have ready at the time of application a specific document as evidence of compliance. These documents are tobe submitted at the request of the IAB. See the list of supporting documentation for all documentation required.

LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE (English Summary of all A measures)

- **Measure 1.1.1** Mission and/or Core Values **(1a)***
- **Measure 2.1.1** Organization chart **(2a)* Measure 1.7.1** Conflict of Interest Policy **(1g)*Measure 2.3.1** Business continuity plan **(2c)***

ATTACHMENT B – PATIENT EMPOWERMENT (English Summary of all B measures)

- **Measure 1.1.3** Sample of Patient Information and Education Materials already produced by the Healthcare Provider **(1a)***
  Measure 1.1.5 Written Material Describing Patient and Family Rights and Responsibilities **(1a)* Measure 1.3.1** Patient Experience Survey and Sample Patient Experience Reports **(1c)***
- **Measure 1.5.1** Examples of Informed Consent Policy and Procedures used by the Healthcare Provider **(**English translation of one sample + documents in original language**)** (1e)*

ATTACHMENT C – ORGANISATION OF CARE (English Summary of all C measures)

- **Measure 2.1.3** Existing Policies and Procedures for Managing Cross Border Patients or plannedactions and timelines for developing policies and procedures **(2a)***
- **Measure 2.6.1** Discharge procedure and Discharge Template **(2f)***
- **Measure 5.3.1** List and examples of Clinical Practice Guidelines or Clinical Decision Support tools developed or adopted by the Healthcare Provider related with its area of expertise **(5c)***

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM (English Summary of all D measures)

- **Measure 2.5.1** Third party reports issued by local or national bodies or external accreditation or certification bodies and/or inspections on the quality care environments **(2c)***
- **Measure 5.1.1** Quality Improvement Plan (**5a)***
- **Measure 5.1.2** Current Structure, Process or Outcome Indicators (Dashboard) and their definitions or planned actions and timelines for their development **(5a)***
- **Measure 5.1.3** Patient Safety Plan **(5a)***
- **Measure 5.1.4** Examples of methodologies used for adverse events analysis (Root CauseAnalysis, etc.) and Description of Process Improvement methods **(5a)***

ATTACHMENT E – RESEARCH AND TRAINING (English Summary of all E measures)

- **Measure 3.1.2** List of training objectives **(3a)***
- **Measure 3.1.3** List of Teaching Staff and Qualifications **(3a)***
- **Measure 3.2.2** List of grants and research projects over the last 5 years **(3b)***
- **Measure 3.2.3** List of Standard Operating Procedures (SOPs) that govern research activities **(3b)*Measure 3.2.4** Research Policy and Procedure **(3b)***

*** Please note the numbers in () correspond to the numbering in the** self-assessment online tool

Scoring table (this is a sample only)

GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30	**0**	Percent of Total	**0%**

Organisation, Management, and Business Continuity			
Total Score out of a Possible 20	**0**	Percent of Total	**0%**
Research, Education and Training			
Total Score out of a Possible 24	**0**	Percent of Total	**0%**
Expertise, Information Systems, and eHealth Tools			
Total Score out of a Possible 12	**0**	Percent of Total	**0%**
Quality and Safety			
Total Score out of a Possible 18	**0**	Percent of Total	**0%**
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
Human Resources			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
Organisation of Patient Care			
Total Score out of a Possible 12	**0**	Percent of Total	**0%**
Facilities and Equipment			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
OVERALL			
Subtotal Score for General Criteria	**0**	Percent of Total	**0%**
Subtotal Score for Specific Criteria	**0**	Percent of Total	**0%**
GRAND TOTAL SCORE out of a Possible 140	**0**	Percent of Total	**0%**

Annex 3 - Instructions for Application

DG SANTE document on instructions for online application.

Annex 4 – Instructions for Monitoring Application Status

DG SANTE document on instructions for monitoring online application status.

Annex 5 – Instructions regarding Specific criteria per Network

Excel file with specifications for the Specific criteria per ERN.

Annex 6 - Interview Guide for Completing Virtual Interviews

As a complement to the documentation review, the assessors also complete virtual interviews with the Healthcare Provider Representatives within approximately 5 working days of the completion of the documentation review. The documentation review and the virtual interview will only be completed if the Applicant was "Deemed Eligible" and received a positive final opinion by the Board of the Network.

Purpose

The purpose of the documentation review and virtual interviews is to:

- Verify that the process used to complete the self-assessment was robust;
- Verify that self-assessments have been completed in a similar manner across Healthcare Provider Applicants (in case of Network proposal);
- Verify that there is sufficient evidence provided; and
- Rate compliance with the operational criteria.

During the virtual interview, the assessors have an opportunity to **ask questions and/or request clarifications on the information submitted by the Applicant**. The assessors use this additional information to rate compliance against the Operational Criteria for the Network/ Healthcare Provider and/or confirm previous ratings based on the documentation review.

Virtual Interview Date

The Virtual Interview will be coordinated by the Assessment Coordinator. The Assessment Coordinator will send out an email with three dates and times that the Network Coordinator or Healthcare Provider Representative(s), in the case of a Healthcare Provider applying to an existing Network, may pick from. If these dates and times do not work for the site, the Applicant(s) must inform the Assessment Coordinator.

Conference Call Requirements

The Network Coordinator will liaise with the Healthcare Provider Representatives to determine which of the three dates would work best and confirm the participants on the call. Once complete, the Network Coordinator is responsible for informing the Assessment Coordinator.

OR:

The Healthcare Provider Representative and/or sub-Representative should determine which of the three dates would work best and confirm the participants on the call. Once complete, the Applicant is responsible for informing the Assessment Coordinator.

Once this information is received, the Assessment Coordinator will arrange for the conference call/virtual interview and send out call instructions. The Applicant should communicate call instructions, including what to do if the assessor team or participants experience call difficulties or cannot access the conference call line. A

cancellation of this call, once the date and time of the call have been agreed to, will be considered an incomplete application. In this instance, the Applicant cannot proceed to the next stage of the assessment.

Agenda

The agenda is sent out by the Assessment Coordinator at least 1 week prior to the virtual interview. The agenda provides a guide for the call; however, the assessment team may decide to touch on additional topics pending the discussion and/or information provided by the call participants during the call. A sample agenda and list of topics that may be covered are provided below:

Item	Topic	Owner	**Time** (minutes)
1.	Welcome and Introductions	Assessor Team Leader	5
2.	Introductory Remarks - Network coordinator OR Representative and/or Sub-representative • Overview of Governance Structure • Status of Network Objectives and Timelines • Successes? Challenges and Barriers?	Network coordinator /Applicant HCP	10
3.	General topics to be covered • Transfer of Knowledge re: innovative medicine? • Dissemination of best practice information? Methods to share expertise? Information & Communication Tools (ICT) tools used? • Collaboration with patient organizations? Access and use of patient experience information? • Contribution to research? • Network Collaborations?	Assessor Team/All Participants	60
4.	Topic Areas Requiring Further Clarification and/or Evidence (To be determined)	Assessor Team	60
5.	Additional information Healthcare Providers would like to share	Network coordinator /Healthcare Provider Representatives	10
6.	Next Steps	Assessment Coordinator	5

During the interactive dialogue between the assessors and the participants, questions or specific statements about the Operational Criteria are clarified and/or answered.

Length of Call

Virtual interviews are conducted using a web-based conferencing system and are about two to three hours in length.

Attendees

The Network coordinator /Healthcare Provider Representatives must be present throughout the virtual interview.

The Applicant may invite key stakeholders, as appropriate, pending the topics to be covered during the call. In addition, the Assessor Team Leader may request, prior to the call, certain additional individuals be present based on the results of the documentation review.

The Assessor Team Leader will chair the meeting and the Assessment Coordinator will record the minutes of the call.

Recording the Call

Recording of the conference call is prohibited.

Additional Evidence

Additional evidence requested during the call must be submitted within 72 hours after receiving a written request from the Applicant on behalf of the Assessor Team Leader following the call.

Outcome of the Call

Pending the outcome of the documentation review and the virtual interview, a decision will be made as to whether or not the Applicant can proceed to the on-site audits (if selected for on-site audits).

Conducting Effective Virtual Interviews

Checklist for the Assessment Coordinator and Assessors

Before the Virtual Interview

- Provide sufficient notice to the Applicant and Assessor Team on meeting date and time so that they can make arrangements to attend.
- Confirm the number of participants and who will be participating prior to the call.
- Convene a pre-teleconference call between the Assessment Coordinator and the Assessors to complete the following:
    - Review the purpose of the interview, guidelines for conducting the interview and the role and responsibilities of the Assessment Coordinator and Assessors during the call
    - Review and confirm the topics to be covered and the list of interview questions
    - Confirm the flow of events during the call, e.g. who will ask what questions
- Prepare an interview package that includes a short biography of each assessor, the agenda, and topics to be covered during the call and send to the Applicant for distribution prior to the call.

During the Virtual Interview

- Test the technology 15 minutes prior to the call.
- Welcome the participants to the call; have all participants introduce themselves; and provide a brief overview of the purpose of the call and agenda. Ask participants at the outset to keep responses as brief as possible.
- Actively listen to the Applicant(s) response to each question. Take notes while the applicant(s) is speaking to ensure there is an accurate record of the response to the question.
- Maintain a relaxed, positive, and encouraging atmosphere throughout the call.
- Ask questions and provide time for the Applicant(s) to prepare their response; do not be afraid of silence. If the Applicant(s) appears to be struggling with the response, re-word the question to help explain what is being asked.
- If the participants appear to be off track or if the assessors would like to gather more information in response to the questions, use probing questions to generate specific responses.
- Manage time effectively; keep track of time and the amount of time spent on each question.
- Provide sufficient time at the end of the interview to allow Applicant(s) to provide any additional information they feel is relevant.
- Explain the next steps and timeline. Thank the Applicant(s) for participating.

After the Interview

- Reserve time following the virtual interview to discuss the information gathered during the call amongst the Assessment Coordinator and Assessors.
- Based on the results of the interview, confirm the ratings for each measure in the Operational Criteria using the *Checklist for Independent Assessors in* ***Annex E***.Tally the scores and compare them against the threshold set in the *Assessment Manual and Technical Toolbox*. Determine if the Applicant(s) can proceed to the on-site audits.

Annex 7 - On-site Audit Checklist for Networks and Healthcare Providers

The following is a list of activities that the *Network Coordinator or Healthcare Representative* needs to complete in preparation for the on-site audit.

Steps	Tasks
Logistics	❒ Provide meeting space for Assessors' initial planning session, including access to printer, paper, shredder, extension cords for laptops, contact information while onsite, etc. ❒ Provide meeting space, telephone and/or teleconference access for Assessors to conduct information exchanges during the day, according to the schedule ❒ Arrange for large meeting space for the General Debriefing ❒ Provide access to an LCD projector and screen for the General Debriefing ❒ Invite key stakeholders to the General Debriefing (e.g. Healthcare Providers, healthcare professionals, management, and Board members) ❒ Arrange for Assessors to have refreshments and a light lunch throughout the day ❒ Provide hotel suggestions and any transportation information to Assessors ❒ Prepare to discuss logistics during teleconferences with the Assessment Coordinator and Assessors
Preparation	❒ Communicate information to the Healthcare Providers on the on-site audit, the services(s) and sites to be visited, as well as the Assessor activities ❒ Inform board members and Healthcare Provider Representatives of when on-site audit will take place and confirm their participation as per the schedule activities ❒ For the duration of the on-site audit, assign an individual to accompany the Assessor and help in navigating and travelling throughout the site and in each service area, and connect the Assessor to key healthcare professionals ❒ Prepare a list of current patients, as well as access to the patient records ❒ Plan for interpreters, if needed ❒ Ensure that operational documentation is available on-site in its normal site(e.g. strategic, operational plans, clinical practice guidelines, etc.) ❒ Arrange for Network Coordinator or Healthcare Provider Representative to prepare a 10-15 minute overview
Survey schedule	❒ Review draft schedule ❒ Discuss the list of service(s), site(s), draft schedule and associated survey activities with the assessment coordinator ❒ Agree on date for submission of any changes to the draft schedule with the Assessment Coordinator ❒ Send draft of survey schedule to the Assessment Coordinator, who will forward to Assessor Team Leader for feedback and finalisation ❒ Receive suggestions and feedback from the Assessment Coordinator and Assessor Team Leader

	❒ Finalise schedule
Preparation for pre-survey teleconference	❒ Contact the Assessment Coordinator to do the following: • discuss pre-survey preparation • discuss finalisation of survey schedule • confirm on-site audit activities • discuss and confirm agenda items for pre-survey teleconference • address any particular issues if necessary
Pre-survey conference	❒ Participate in pre-survey teleconference with Assessment Coordinator and Assessors ❒ Discuss and confirm final survey schedule with Assessors ❒ Receive and respond to questions Assessors may have ❒ Discuss logistical arrangements with the Assessors, including: • hotel accommodations available in the area • travel suggestions • Assessor team's expected time of arrival directions to the hotel and Healthcare Provider

Tip(s): *It is recommended that the Network Coordinator and/or Healthcare Provider Representative completes the checklist before the on-site audit. Healthcare Providers are encouraged to involve patients and/or their national authorities in the on-site audit.*

Annex 8 - Instructions for Reviewing Application and Report Decisions (online)

DG SANTE document on instructions for reviewing online application and report decisions.

Annex 9 - Decision Guidelines for the Approval of a Network or Healthcare Provider

Recommendation by the Independent Assessment Body (IAB)

For a Network to obtain a positive assessment, the following conditions must be met:

- An overall compliance rate of 50% of the maximum score
- A rating of "1" for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.
- There should be no measurement elements under any theme rated as "0".
- A minimum of 10 HCP from 8 Member States in a Network must receive a positive assessment against the healthcare provider Decision Guidelines.

If the Network is unable to meet **all** of the above conditions, this will result in a negative assessment forboth the Network and the Healthcare Provider.

For Healthcare Provider(s) to obtain a positive assessment, the following conditions must be met:

- An overall compliance rate of 70% of the maximum score of the HCP general and specific operational criteria.
- Each theme under the General Criteria must achieve 70% compliance against the maximum score.
- Each theme under the Specific Criteria must achieve 80% compliance against the maximum score.
- There should be no measurement elements under any theme rated as "0".
- A rating of "1" for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.

If the Healthcare Provider is unable to meet **all** of the above conditions, this will result in a negative assessment. Only Healthcare Providers with a positive assessment can progress to the next stage.

Approval of Applicants by the Board of Member States (BoMS)

The Board of Member States (BoMS) reviews all positive assessment reports and recommendations from the IAB. In accordance with the Implementing Decision 2014/287/EU, Article 6, the Board of Member States will decide whether or not to approve proposals for a European Reference Network, their membership, and termination of an ERN. Rules of procedure to support Board decision-making are defined by the BoMS.

Toolbox items

Annex 10 - Checklist and Template Letter of Member State Endorsement for Healthcare Providers

GUIDANCE

Endorsement of a healthcare provider by the National Authority of its own Member State is mandatory to initiate the application process. Each healthcare provider that applies to become a member of a new/existing ERN must have a written statement from its National Authority (NA) or Member State (MS) certifying that participation in the new or existing ERN is in accordance with the Member State's national legislation.

Prior to completing the template of the Letter of endorsement for the healthcare provider, the representative of the national authority is asked to complete the checklist below.
This checklist serves several purposes:

- Standardisation of the endorsement process across Member States. Adhering to this checklist will support equal treatment of applicants to the ERNs, regardless of geographical location
- Efficiency of the technical assessment process:
    - Member States can play an important role in managing expectations of applicants with regards to their role and obligations when becoming a member of an ERN. Applicants that are not fully aware of the tasks and responsibilities now have the opportunity to refrain from applying and save the resources that would be spend on their application during the technical assessment
    - A general check (or 'pre-assessment') of the compliance of the applicant with the operational criteria for healthcare provider will provide insight for the applicant whether it is likely that the application will be successful or not. If not, resources that would be spend on the application are saved

The checklist is part of the endorsement letter. The representative of the national authority checks all the boxes, signs the checklist and sends it together with the filled out and signed letter of endorsement back to the health care provider.

If the representative of the national authority cannot check all the boxes, the representative of the national authority should reconsider endorsing the concerning health care provider.

Applications without the signed checklist or written endorsement statement or with an endorsement not signed by the officially nominated National Authority will be considered incomplete and will be ineligible to proceed to the technical assessment.

Endorsement Checklist for the Member State

Please check the boxes that apply:

O I have checked that there are no limitations or exclusions regarding my Member State for this call;

O I confirm that the healthcare provider is aware of the content of the healthcare provider's membership application (Annex II, Implementing decision 2014/287/EU);

O I have read and understand the operational (general and specific) criteria that a healthcare provider must meet to become a member of an ERN;

O I conform that there has been contact between the healthcare provider and the ERN about a potential application;

O I have discussed the general criteria with the institutions' CEO and healthcare provider representative;

O I have discussed the specific criteria for the relevant ERN with the institutions' CEO and healthcare provider representative;

Based on the above checklist, I, undersigned, confirm that the healthcare provider is aware of – and in compliance with the operational criteria, conditions and obligations necessary to become and stay a valuable member of the ERN.

<Place> , <Date>

<Signature of Representative>

<Insert Name of Representative of the National Authority>

Template Letter of Endorsement for Healthcare Providers

<Date>

<Contact Person>

<Address>

SUBJECT: Healthcare Provider National
Endorsement

Dear Sir/Madam,

I, **<Insert National Authority>** as nominated by the **< Insert competent National Body on ERNS (if different than National Authority) >** certify that **<Insert Healthcare Provider's Name>** *participation in the call for membership to existing European Reference Networks* ***<NAME OF ERN>*** **OR** *participation in the proposal to establish a European Reference Network* launched by the European Commission is in accordance with the Member State's national legislation.

Sincerely,

<Signature of Representative>

<Insert Name of Representative of the National Authority>

Annex 11a - Application Checklist for Networks

The Network must complete the following steps before submitting their proposal to the European Commission.

Checklist:

- ❒ The Network has a Network Coordinating Member
- ❒ The Network has a *Network Coordinator* from the Coordinating Member
- ❒ The Network has a Board with representation from each Healthcare Provider
- ❒ The *Network Coordinator* chairs the meetings of the Board of the Network
- ❒ The Network includes a minimum of 10 Healthcare Providers from 8 Member States
- ❒ The Network provides highly specialised healthcare for **rare or complex disease(s), condition(s) or highly specialised intervention(**s) All Healthcare Providers provide highly specialised healthcare for the same **rare or complex disease(s), condition(s) or highly specialised intervention(**s) or group of **rare or complex disease(s), condition(s) or highly specialised intervention(**s)
- ❒ The Network is pursuing at minimum three objectives from Article 12(2) of Directive 2011/24/EU
- ❒ The Network and all Healthcare Providers have completed the application forms and self- assessments with supporting documentation
- ❒ Each Healthcare Provider provided a written statement of endorsement and a signed endorsement checklist from its Member State
- ❒ Each Healthcare Provider provided a signed checklist and declaration form from the CEO
- ❒ Each Healthcare Provider provided a signed checklist and declaration form from the Healthcare Provider representative

Annex 11b - Application Checklist for Healthcare Providers

The Healthcare Providers must complete the following steps before submitting their proposal to the European Commission.

Checklist:

- ❒ The Healthcare Provider has an identified representative
- ❒ The Healthcare Provider has a representative on the Board of the Network
- ❒ The Healthcare Provider completed the application form for Healthcare Providers
- ❒ The Healthcare Provider obtained a written statement of endorsement and a signed endorsement checklist from its Member State
- ❒ The Healthcare Provider provided a signed checklist and declaration form from the CEO
- ❒ The Healthcare Provider provided a signed checklist and declaration form from the Healthcare Provider representative
- ❒ The Healthcare Provider completed the self-assessment for Healthcare Providers with supporting documentation

Annex 12a – Checklist and Declaration Form for the Chief Executive Officer (CEO)

Application for Healthcare Provider Membership in a European Reference Network: Agreement and Signature

GUIDANCE

A signed declaration from the organisation's CEO is mandatory in the application process for healthcare providers. Each healthcare provider that applies to become a member of a new/existing ERN must have a written statement from the CEO of their organisation certifying that the participation of the healthcare provider in the ERN is supported by the management of the organisation with the necessary means to carry out the activities related to the Network goals.

Prior to completing this declaration, the CEO of the organisation is asked to complete the checklist below. This checklist serves several purposes:

- Standardiation of the endorsement process across Member States. Adhering to this checklist will support equal treatment of applicants to the ERNs, regardless of geographical location
- Efficiency of the technical assessment process:
    - Member States can play an important role in managing expectations of applicants with regards to their role and obligations when becoming a member of an ERN. Applicants that are not fully aware of the tasks and responsibilities now have the opportunity to refrain from applying and save the resources that would be spend on their application during the technical assessment
    - A general check (or 'pre-assessment') of the compliance of the applicant with the operational criteria for healthcare provider will provide insight for the applicant whether it is likely that the application will be successful or not. If not, resources that would be spend on the application are saved

The checklist is part of the declaration form. The CEO checks all the boxes, signs the checklist and sends it together with the filled out and signed declaration form back to the health care provider.

If the CEO cannot check all the boxes, the CEO should reconsider signing the declaration form.

Applications without the signed checklist or with a declaration form not signed by the CEO will be considered incomplete and will be ineligible to proceed to the technical assessment.

Checklist and Declaration for the CEO

Having read the call for interest for healthcare providers to join the existing European Reference Networks (ERN) or to create a new ERN for rare or low prevalence, complex disease(s) or condition(s), and the accompanied application document:

I, undersigned, confirm that:

I have read and understand the conditions, tasks and obligations of a healthcare provider wanting to become and stay an ERN-member;

O I confirm that the healthcare provider is aware of the content of the healthcare provider's membership application (Annex II, Implementing decision 2014/287/EU);

O I have read and understand the operational (general and specific) criteria that an healthcare provider must meet to become a member of an ERN;

O I have discussed the general criteria with the healthcare provider representative and the representative of the national authority;

O I have discussed the specific for the relevant ERN with the healthcare provider representative and the representative of the national authority;

O The healthcare provider applicant will be supported by the management of this institution with the necessary means to carry out the activities related to the Network goals. This support includes the recognition of the time devoted by the healthcare professionals to fulfil those activities as part of their standard working time;

O The healthcare provider applicant will be supported by the management of this institution with the necessary resources and documentation required by the applicant during the assessment process, i.e.:

- accreditation certificates and documentation (if applicable)
- organisational scheme
- strategic policy plan
- training plan
- business continuity plan

Please indicate the name of the network(s) that the Healthcare Provider wishes to join:

Network		Network		Network	
ERN BOND	☐	ERN-RND	☐	ERN ITHACA	☐
ERN CRANIO	☐	ERN-Skin	☐	ERN MetabERN	☐
ENDO-ERN	☐	ERN EURACAN	☐	ERN PaedCan	☐
ERN EpiCare	☐	ERN EuroBloodNet	☐	ERN RARE-LIVER	☐
ERKNet	☐	ERN eUROGEN	☐	ERN ReCONNET	☐
ERN-EYE	☐	ERN EURO-NMD	☐	ERN RITA	☐
ERNICA	☐	ERN GENTURIS	☐	ERN TRANSPLANT-CHILD	☐
ERN-LUNG	☐	ERN GUARD-HEART	☐	VASCERN	☐

Please complete the below in BLOCK CAPITALS:

This form must be printed, signed and uploaded to <u>all</u> membership applications via the SANTE Data CollectionPlatform

Name of Healthcare Provider as per application form	
Country of Healthcare Provider as per application form	
CEO	
Title, Name and Surname	
Signature	
Date	

Annex 12b – Checklist and Declaration Form for the Healthcare Provider Representative

Application for Healthcare Provider membership in a European Reference Network: Agreement and Signature

GUIDANCE

A signed declaration from the healthcare provider representative is mandatory in the application process. Each healthcare provider that applies to become a member of a new/existing ERN must have a written statement from its representative certifying that he or she will commit to fulfil the tasks and responsibilities as member of the ERN in accordance with the rules established by the Board of the Network and to provide all the necessary information requested by the ERN Coordinator and the European Commission in order to fulfil the assessment, monitoring and evaluation requirements of the Quality Improvement System of the Network.

Prior to completing this declaration, the healthcare provider representative is asked to complete the checklist below. This checklist serves several purposes:

- Standardisation of the endorsement process across Member States. Adhering to this checklist will support equal treatment of applicants to the ERNs, regardless of geographical location
- Efficiency of the technical assessment process:
  - Member States can play an important role in managing expectations of applicants with regards to their role and obligations when becoming a member of an ERN. Applicants that are not fully aware of the tasks and responsibilities now have the opportunity to refrain from applying and save the resources that would be spend on their application during the technical assessment
  - A general check (or 'pre-assessment') of the compliance of the applicant with the operational criteria for healthcare provider will provide insight for the applicant whether it is likely that the application will be successful or not. If not, resources that would be spend on the application are saved

The checklist is part of the declaration form. The healthcare provider representative checks all the boxes, signs the checklist and sends it in together with the filled out and signed declaration form.

If the healthcare provider representative cannot check all the boxes, the healthcare provider representative should reconsider signing the declaration form.

Applications without the signed checklist or with a declaration form not signed by the healthcare provider representative will be considered incomplete and will be ineligible to proceed to the technical assessment.

Checklist and Declaration for the Healthcare Provider Representative

Having read the call for interest for healthcare providers creating a new European Reference Network (ERN) OR joining an existing ERN for rare or low prevalence, complex disease(s) or condition(s), and the accompanied application document:

I, undersigned, confirm that

- O I have read and understand the conditions and obligations of a healthcare provider wanting to become and stay an ERN-member;
- O I am aware of the content of the healthcare provider's membership application (Annex II, Implementing decision 2014/287/EU);
- O I have read and understand the operational (general and specific) criteria that a healthcare provider must meet to become a member of an ERN;
- O I have discussed the general criteria with the organisation's CEO and the representative of the national authority;
- O I have discussed the specific criteria for the relevant ERN with the CEO of my institution and the representative of the national authority;
- O I will commit to fulfil the tasks and responsibilities as member of the ERN in accordance with the rules established by the Board of the Network and to provide all the necessary information requested by the ERN Coordinator and the European Commission in order to fulfil the assessment, monitoring and evaluation requirements of the Network.

  Among other tasks, ERN members are required to:

  - ✓ Undergo extensive assessment that includes a number of decision moments;
  - ✓ Provide raw data on all required monitoring indicators
  - ✓ Undergo regular evaluation, at least every 5 years
  - ✓ Actively participate in the network;
  - ✓ Continue to meet (specific) criteria of a network;
  - ✓ use the CPMS system;;

  In principle, no financial compensation from European Commission, only for network coordinator.

I understand that the lack of compliance with these commitments could imply the termination of the membership to the Network.

Please indicate the name of the network(s) that the Healthcare Provider wishes to join:

Network		Network		Network	
ERN BOND	☐	ERN-RND	☐	ERN ITHACA	☐
ERN CRANIO	☐	ERN-Skin	☐	ERN MetabERN	☐
ENDO-ERN	☐	ERN EURACAN	☐	ERN PaedCan	☐
ERN EpiCare	☐	ERN EuroBloodNet	☐	ERN RARE-LIVER	☐
ERKNet	☐	ERN eUROGEN	☐	ERN ReCONNET	☐
ERN-EYE	☐	ERN EURO-NMD	☐	ERN RITA	☐
ERNICA	☐	ERN GENTURIS	☐	ERN TRANSPLANT-CHILD	☐
ERN-LUNG	☐	ERN GUARD-HEART	☐	VASCERN	☐

Please complete the below in BLOCK CAPITALS:

Name of Healthcare Provider as per application form		
Country of Healthcare Provider as per application form		
	HCP Representative	**Sub Representative**
Title, Name and Surname		
Signature		
Date		

This form must be printed, signed and uploaded to <u>all</u> membership applications via the SANTE Data CollectionPlatform

Annex 13 - Template Business Continuity Plan

A Business Continuity Plan (BCP) outlines how a business will continue operating during an unplanned disruption in service, both during short- and long-term outages. Documents that could be useful to carry out a BCP: impact and risk assessment, business impact analysis, employee contact list, recovery priorities, emergency operations centre locations, alternate site transformation information, alternate site resources, vital records, vendor lists, IT system reports and resources, recovery task list, and office recovery plans.

Developing a BCP is usually an organisation-wide exercise and will therefore probably be available at the board of the organisation (or the quality management division). In case the organisation or the Healthcare Provider doesn't have a business continuity plan yet, a list of subjects that need to be covered by an BCP, is given below:

Content of a Business Continuity Plan

1. **Risk Analysis and Prevention Strategies**

Clinical Risks and Prevention Strategies
- Potential risk areas
- Risk prevention strategies

IT Risks and Prevention Strategies
Including data storage and accessibility of Electronic Health Records
- Potential risk areas
- Risk prevention strategies

Operational & Financial Risks and Prevention Strategies
- Potential risk areas
- Risk prevention strategies

2. **Prioritisation of Essential Functions for Recovery**

Determine the priority for each business function and the acceptable downtime for each critical function. Completing a Business Impact Analysis (BIA) will help in this process.

3. **Determining Essential Resources**

Determine what essential resources are needed for each function in terms of: people, places and things (e.g. equipment, supplies, vendors, and IT applications and services).

4. **Emergency Relocation Strategy**

Identify the minimum alternate site requirements needed to resume operations if forced to relocate. Other plans and arrangements include: plans for administrative chain of command and communication during relocation, possibilities to consolidate operations with another site, partnerships with other practices not in the immediate vicinity for relocation or using their supplies in an emergency, storing backup supplies elsewhere, etc.

5. **Recovery Strategy and Tasks**

Procedure during: disaster occurrence (declare disaster and make decisions to activate the rest of the recovery plan), activation of business continuity plan (relocate business operations), alternate site operation (phase continues until primary facility is restored), and transition to primary site (phase continues until business operations are back to the original business site).

6. **Records Backup and Restoration Plan**

Address disruptions/disasters that would affect all records vital to the continuation of business operations, plans to maintain, control and periodically check essential records by IT-teams and disaster recovery teams, and address activities to back up and store most critical files at an offsite location.

7. **Recovery Teams and Procedures**

List of activities, tasks and delegates to perform in order to recover normal and critical business operations. Describe each strategy by enumerating a specific set of recovery activities, tasks and responsibilities.

Make sure when providing this document for Application and/or Audit: the anonymise the personal information.

Annex 14 - On-site Audit Schedule Template

Name of the Network

Schedule

Date

(Example with 2 Assessors and 3 sites)

Name of Assessor 1	Name of Assessor 2
Operational Criteria for the Network and Operational Criteria for Healthcare Providers: Site 1: Coordinating Member on behalf of the Network	
Operational Criteria for Healthcare Providers: Site 2	**Operational Criteria for Healthcare Providers:** Site 3

Day 1: [Date]

Day 1	Name of Assessor 1	Name of Assessor 2
13:00-16:00	**Planning Day** (Assessors only)**:** • Organisational charts (Network and Healthcare Providers) • Annual reports and strategic plans (Network and Healthcare Providers) • Assessor ratings and notes from documentation review and virtual interviews, and copies of the application forms and self-assessments – should the preliminary report beavailable and have been sent to Network Coordinator • Reports from other assessment bodies (if used for evidence of general criteria ofHealthcare Providers) • Examples of published research, clinical protocols, guidelines in use on site • Schedule for reviewing and planning on-site audit activities Note: Documentation may be made available in electronic format	

Day 2: Date (Site 1: Coordinating Member)

Day 2	Name of Assessor 1	Name of Assessor 2

8:00-8:15	**Introductory Meeting (Network):** • Welcome and Introductions • Objectives of the Onsite Audit
8:15-12:00	**Group Discussion (Network Leaders):** • Overview of the Network and key successes and challenges • Review of preliminary report from documentation review and virtual interviews • Governance structure (Board of the Network and composition) • Area of expertise and range of services • Network objectives and timelines • Network contributions (clinical practice guidelines, education and training, and researchactivities) • Quality improvement initiatives, patient registry and performance indicators **Focus Group (Network Collaborators):** • Patient organisations and/or patient representatives • Other Healthcare Providers involved in the continuum of care, specific to the patientpopulation • Academics • Other stakeholders from the community, as appropriate **On-Site Documentation Review (Assessors Only):** • Terms of reference and meeting minutes for the Network and the Board • Sample of recent publications • Sample of education and training materials for the team • Clinical practice guidelines • Quality improvement plan, proposed indicator data collection, patient registry (actual andplanned)
12:00-13:00	**Lunch and Assessor information exchange**
13:00-15:30	**Group Discussion (Multidisciplinary Team):** • Overview of the programme- key successes and challenges • Roles and responsibilities as a coordinating member within the Network • Contributions of the Coordinating Member (clinical practice guidelines, education andtraining, and research activities) • Patient care pathways: patient involvement, patient safety, clinical outcomes **On-Site Documentation Review (Assessors Only):** • Sample of personnel files, job descriptions, and training and competency assessments • Sample of representative patient files/chart audits • Quality improvement plan and indicator data collection

Day 2	Name of Assessor 1 Name of Assessor 2
8:00-12:00	**Tour of the Site (Assessors and Network Coordinator):** • Follow the care path of the patient (implement patient tracer methodology)
12:00-13:00	**Lunch and Assessor information exchange**
13:00-15:30	**Documentation review and/or additional interviews required to validate Assessor ratings andcomments**
15:30-16:00	**Review and debrief with the Network Coordinator and MDT**
16:00-17:00	**Assessor information exchange and report writing**

Day 3: Date (Sites 2 and 3: Healthcare Providers)

	Name of Assessor 1 (Site 2)	Name of Assessor 2 (Site 3)
8:00-12:00	**Group Discussion with Multidisciplinary Team(Healthcare Provider):** • Welcome and introductions • Objectives of the site audit • Review of preliminary report • Overview of the role and its participation inNetwork, and key successes and challenges • Validation of general criteria • Evidence of specific criteria as defined bynetwork • Objectives, action plan specific to healthcareprovider and its role in the network **On-Site Documentation Review (AssessorsOnly):** • Sample of personnel files, job descriptions,and training and competency assessments • Sample of representative patient files • Quality improvement plan and indicator datacollection	**Group Discussion with Multidisciplinary Team(Healthcare Provider):** • Welcome and introductions • Objectives of the site audit • Review of preliminary report • Overview of the role and its participation inNetwork, and key successes and challenges • Validation of general criteria • Evidence of specific criteria as defined bynetwork • Objectives, action plan specific to healthcareprovider and its role in the network **On-Site Documentation Review (AssessorsOnly):** • Sample of personnel files, job descriptions,and training and competency assessments • Sample of representative patient files • Quality improvement plan and indicator datacollection **Tour of the Environment of Care (Assessors**

	Tour of the Environment of Care (Assessors andHealthcare Provider Representative): • Follow the path of the patient (tracer) • Care Protocols, clinical decision tools at thepoint of care	**andHealthcare Provider Representative):** • Follow the path of the patient (tracer) • Care protocols, clinical decision tools at thepoint of care
12:00-13:00	**Lunch and Assessor information exchange (teleconference)**	
13:00-15:00	**Documentation review and/or additional interviews required to validate Assessor ratings andcomments**	
15:00-17:00	**Debrief with the Healthcare Provider Representative and Multidisciplinary Team**	

Annex 15 - Instructions and Scoring Table for Peer Reviewing Specific Criteria HCP

Online document on the ERN Coordinators group proposal for assessing the Applicant Healthcare Providers in the new call.

Annex 16 - Sample Conflict of Interest and Confidentiality Statement

CONFLICT OF INTEREST STATEMENT

Statement of Policy

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

- Current or past employment as faculty, staff, or consultant to the applicant;
- Current or past discussion of employment or negotiation of employment with the applicant;
- Attendance as a student at the institution;
- Involvement of a close family member as an employee, patient and/or family member of a patient; or
- Any reason that hinders the individual in making an unbiased decision.

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

Potential Conflict of Interest Statement

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

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

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

Signature: _____
Print Name: _____
Date: _____

CONFIDENTIALITY AGREEMENT

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

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

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

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

Signature: _____
Print Name: _____
Date: _____

Annex 17 - Eligibility Checklist for Networks and Healthcare Provider Applicants

Procedure for Determining Eligibility

Who is responsible for determining eligibility?

In accordance with the Implementing Decision 2014/287/EU Article 4 (2) and Article 4 (3), both the European Commission (EC) and the Independent Assessment Body (IAB) are responsible for determining eligibility.

The eligibility process should begin ***within approximately 5 working days*** of receiving a completed proposal. Eligibility decisions are to be made, as much as possible, from current information submitted on the application form.

Eligibility Checklist for Networks

*All potential applicants must meet **all** eligibility criteria based on information detailed in the application form and approved by the European Commission and Independent Assessment Body.*

I. Network Applicant Information

Name of the Proposed Network	
Name and Address of the Network Coordinating Member	
Surname and First Name of Network Coordinator and Credentials	
Contact Information of the Network Coordinator	Telephone Number:
	Email Address:

II. Eligibility Criteria for Networks

PART A: TO BE COMPLETED BY THE EUROPEAN COMMISSION

Criteria	**Yes**	**No**	**Supporting Documentation***
1. The Proposed Network includes a minimum of 10 Members across 8 Member States.* *(The Network must fulfil both (a) and (b) to meet this requirement)*	☐	☐	1. Section 5 – ERN Application Form: List of Healthcare Providers and Member States
a. Minimum of 10 Members	☐	☐	
b. 8 Member States Represented	☐	☐	

2. The content of the application fulfills the requirements set out in Annex I to the Implementing Decision 2014/287/EU. * *(The Network must fulfil (a), (b), (c) to meet this requirement)*	☐	☐	1. Section 1 – ERN Application Form: Network's Name 2. Section 2 – ERN Application Form: Healthcare Provider acting as the Network Coordinator 3. Section 4 – ERN Application Form: Network Coordinator and Contact Details
a. Name of Proposed Network indicated.	☐	☐	
b. Name of Coordinating Member indicated.	☐	☐	
c. Name and contact details of Coordinator included.	☐	☐	
***PART B*: TO BE COMPLETED BY THE INDEPENDENT ASSESSMENT BODY**			
3. The Network fulfils the requirement to provide highly specialised healthcare for one or more rare or low prevalence complex diseases or conditions. ***(The Network must fulfil (a), (b), (c) and (d) to meet this requirement)*	☐	☐	
a. The rare or low prevalence complex disease(s) or condition(s) is listed and described. **	☐	☐	1. Section 6a – ERN Application Form: Main thematic grouping(s) covered by Network 2. Section 6b – ERN Application Form: Sub-thematic areas of expertise 3. Section 6h – ERN Application Form: Rationale for thematic and sub thematic groupings
b. There is a need for highly specialised healthcare. ** • Disease/condition complex to diagnose and treat? • Diagnosis/treatment is resource demanding? • Advanced/highly specialised equipment and facilities are needed?	☐	☐	1. Section 6d – ERN Application Form: Key diagnostic tests and highly specialized interventions 2. Section 6e – ERN Application Form: Key treatments, resources, or procedures 3. Section 6g – ERN Application Form: Description of disease(s)/condition(s) and challenges 4. Section 8 – ERN Application Form: Specialised equipment, infrastructure, and information technology

c. There is a need for a particular concentration of expertise and resources. ** • Diagnosis/treatment requires special competence? • Diagnosis/treatment requires concentration of knowledge? • Diagnosis/treatment has low prevalence/incidence?	☐	☐	1. Section 8d – ERN Application Form: Core and extended multidisciplinary team 2. Section 8g – ERN Application Form: Human Resources and professional qualifications 3. Section 8h – ERN Application Form: Rational for requirements 4. Section 6a & 6b – ERN Application Form: Incidence/prevalence
d. Based on high-quality, accessible and cost-effective healthcare. ** • Assessment of clinical risk/patient safety is available? • Risk/benefit analysis is available? • Expected gains of centralizing care for these patients are clearly defined?	☐	☐	1. Section 6h – ERN Application Form: Benefits and added value
4. There is a clearly defined governance and coordination structure. **	☐	☐	1. Section 2, 4 – ERN Application Form: One Coordinating Member and Network Coordinator 2. Section 7a, 7b – ERN Application Form: Network Board and organization flow chart
5. The Proposed Network has a clearly defined set of objectives. ** *(The Network must have a minimum of <u>three</u> objectives to meet this requirement.)*	☐	☐	1. Section 6f – ERN Application Form: Network objectives
6. The information contained in the Application is complete. ** ***(****The Network must fulfil (a), (b), (c) to meet this requirement)*	☐	☐	1. Application Form 2. Self-Assessment Questionnaire 3. Supporting documentation attached
a. The Application Form includes is complete.	☐	☐	
b. The Self-Assessment Questionnaire is complete.	☐	☐	
c. All required supporting documentation attached	☐	☐	

Note: All application forms must include supporting documentation to confirm applicant eligibility. See page 23 of the Independent Assessment Body ERN Assessment Manual: Description and Procedures for supporting documents to be uploaded at the time of Application
**To be completed by the European Commission and verified by the Independent Assessment Body.*
***To be completed by the Independent Assessment Body only.*

III. Status of Application

Verified by the European Commission (Part A) ☐ Verified by the Independent Assessment Body (Part B) ☐
Application Approved: Pending Review by the IAB ☐ Yes ☐ No ☐

IV. Statement of Eligibility (To be completed by the IAB)

This Applicant is **[**☐ **eligible** / ☐ **ineligible]** for the technical assessment of the criteria and conditions set out in Annex I of the Delegated Decision 2014/286/EU.

Comments by the Reviewer (To be completed by the IAB)

Signature of Reviewer:	Date:

Eligibility Checklist for Healthcare Provider Applicants

All potential applicants must meet <u>all</u> eligibility criteria based on information detailed in the application form and supporting documentation approved by the European Commission and Independent Assessment Body.

I. Healthcare Provider Applicant Information

Name of Proposed/Existing Network	
Name of the Healthcare Provider	
Surname and First Name of Healthcare Provider Representative	
Type of Facility: ☐ Hospital ☐ Healthcare Centre ☐ Clinic ☐ Other [Please Specify]:	

II. Eligibility Criteria for Healthcare Provider Applicants

<u>PART A</u>: TO BE COMPLETED BY THE EUROPEAN COMMISSION

Criteria	Yes	No	Supporting Documentation*
1. The content of the application fulfills the requirements set out in Annex I to the Implementing Decision 2014/287/EU. ***(****The Healthcare Provider must fulfil (a) and (b) to meet this requirement)****	☐	☐	
a. Name of Relevant Network indicated.	☐	☐	1. Section 1 – Member Application Form: Network name
b. Name and Contact Details of the Healthcare Provider's Representative included	☐	☐	2. Section 4,5 – Member Application Form: Name and Contact Details of the Healthcare Provider's Representative

2. There is a written statement from the Healthcare Provider's Member State certifying that its participation in the proposed/existing Network is in accordance with national legislation. *	☐	☐	1. Supporting Documentation – Written Statement of Certification
PART B: TO BE COMPLETED BY THE INDEPENDENT ASSESSMENT BODY			
3. The Healthcare Provider has the same area of expertise as the proposed/existing Network. **	☐	☐	1. Section 7 – Membership Application Form: Diseases/conditions and highly specialized interventions covered by the Healthcare Provider 2. Section 8 – Membership Application Form: Healthcare Provider contribution to patient care 3. Section 9a & 9b – Membership Application Form: Types of services and treatments/interventions
4. There is a sufficient number of healthcare providers with the necessary qualifications to perform the specialized function. ** • Critical competencies are well defined?	☐	☐	1. Section 12 – Membership Application Form: List of healthcare professionals and their qualifications.
5. The information contained in the Application is complete. **	☐	☐	1. Completed Application Form 2. Completed Self-Assessment Questionnaire 3. All required supporting documentation attached

Note: All application forms must include supporting documentation to confirm applicant eligibility. See page 23 of the Independent Assessment Body ERN Assessment Manual: Description and Procedures for supporting documents to be uploaded at the time of Application

***To be completed by the European Commission and verified by the Independent Assessment Body.*

****To be completed by the Independent Assessment Body only.*

III. Status of Application

Verified by the European Commission (Part A) ☐ Verified by the Independent Assessment Body (Part B) ☐

Application Approved: Pending Review by the IAB ☐ Yes ☐ No ☐

IV. Statement of Eligibility (To be completed by the IAB)

This Applicant is **[☐ eligible** / **☐ ineligible]** for the technical assessment of the criteria and conditions set out in Annex II of the Delegated Decision 2014/286/EU.

Comments by the Reviewer (To be completed by the IAB)

Signature of Reviewer:	Date:

Annex 18 - Self-assessment Checklist for Independent Assessors

Instructions for Self-Assessment for Networks

Introduction

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex I (b), the application to establish a European Reference Network must include this self-assessment questionnaire for Networks. This provides networks with the opportunity to evaluate themselves against the specific legislated criteria and conditions before submitting their application to the European Commission. In addition, it provides a mechanism for both the Independent Assessment Body (IAB) and the Network to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

Description of the self-assessment tool

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

- Establishment of a European Reference Network
- Highly Specialised Healthcare
- Governance and Coordination
- Patient Care
- Multidisciplinary Approach
- Good Practice, Outcomes Measures, and Quality Control
- Contribution to Research
- Continuous Education, Training, and Development
- Networking and Collaboration

These nine (9) sections are based on the requirements set out in the Delegated Decision 2014/286/E Annex I. Each section includes multiple items to help the Network evaluate its readiness to submit a Network Application, see ***example of the self-assessment checklist tool***. These items are based on those Operational Criteria that the European Commission and IAB will use to assess compliance with the legislation. Note that a complete self-assessment must accompany the Application Form for the application to be considered.

Instructions for completing the self-assessment

10. Establish a team consisting of the designated Network Coordinator and representation from each ofthe potential Healthcare Providers and/or rare or low prevalence complex disease or condition thematic areas.

    The team should be given sufficient time to complete the self-assessment. Completion of the self-assessment is estimated to take approximately three to four meetings with time allocated between meetings, pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointedto organise the group, assign tasks, and coordinate the self-assessment effort. As the self-assessment will be filled for submission in the online application, it is advised that the team uses a paper form to collect the information agreed during the preparatory process.

11. Read and review the Operational Criteria in their entirety before beginning the self-assessmentprocess. If possible, make copies and send them to team members before the first meeting.

12. Discuss each individual element in the Self-Assessment Checklist and evaluate the Network's progress in implementing it. As necessary, verify the level of implementation with other individualsoutside of the team. Document this information in the "Comments" section of the checklist. This "Comments" section is mandatory for each Measure of the Operational Criteria, to briefly explain each rating provided. The applicant must reference any supporting documentation, as required.

13. Once consensus is reached, complete the table by marking the box that most appropriatelycaptures the current status of compliance with the criterion, using the following rating scale and scoring guide:

Rating	Guidelines
0: No activity / Not Implemented	***All Criteria:*** **this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	***All Criteria:*** **this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance.** *This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	***All Criteria:*** **this rating is used if the answer is "yes" or "always" to the specific measure and/or** **when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • A single negative observation may not prevent a score of "fully implemented". • 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.

14. Repeat the process for each element. Once complete, tally up the Network's score for each sectionusing the template provided in the sample of the ***Scoring table***. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

15. Use this information to develop an Action Plan to improve readiness to submit the application and complete the independent assessment process.

16. Prior to finalising and submitting the self-assessment, a process to validate the results internally should be followed. The purpose of the internal validation is to:
    - Provide a level of quality assurance;
    - Confirm that the self-assessments are accurate and therefore can be shared externally;
    - Identify any inconsistency in practice across the Network; and

- Identify areas of best practice that could be shared across the Network.

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

- The process is fair and robust;
- The process is agreed to by all Healthcare Providers;
- Accountability for the self-assessment is agreed to by the Chief Executive Officer of the Healthcare Provider; and
- The process includes patient and family involvement.

At the conclusion of the internal validation, the self-assessment team should check and record anychanges in the self-assessment.

17. Complete and sign the *Declarations Forms for CEOs and HCP representatives (see Technical Toolbox)*.

18. Submit the completed Self-Assessment along with the Application Form ***on or before the deadline*** for submitting applications in response to the Call for Interest. The Network must have ready at the time the application is submitted all supporting documentation listed in ***List of Supporting Documentation for Networks*** below. These documents should be made available to the IAB, at their request.

THE ASSESSOR CHECKLIST FOR NETWORKS (Note: This Section is a sample only)

Criteria and conditions to be fulfilled by the European Reference Network[2]

ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK					
1.1 The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.					
Measurement Elements	0	1	2	**What to look for?**	**Assessor Comments**
1.1.1 The Network is comprised of a minimum of 10 Members across 8 Member States.	☐	☐	☐	List of Applicant Healthcare Providers and their Member States	
HIGHLY SPECIALISED HEALTHCARE					
1.2 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.					
Measurement Elements	**0**	**1**	**2**	**What to look for?**	**Assessor Comments**
1.2.1 The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.	☐	☐	☐	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	
1.2.2 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.	☐	☐	☐	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	

[2] Commission Delegated Decision (2014/286/EU) – Annex I

				on the Network's area of expertise	
.3 The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.	☐	☐	☐	Mission and Vision Statement Initial Strategic Plan	
GOVERNANCE AND COORDINATION					
1.3 The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.					
Measurement Elements	**0**	**1**	**2**	**What to look for?**	**Assessor Comments**
.1 There is one designated representative for each applicant member of the Network.	☐	☐	☐	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	
.2 The Network is governed by a Board composed of one representative from each Member in the European Reference Network.	☐	☐	☐	Board Terms of Reference	
.3 The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.	☐	☐	☐	Board policies or rules of procedure Information Posted on the Network Website	

LIST OF SUPPORTING DOCUMENTATION FOR NETWORKS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- **Measure 2.1.3** Mision, Vision, Initial Strategic Plan
- **Measure 3.1.1** Network Organogram and Written Statements of Members' Role andResponsibilities
- **Measure 3.1.2** Board Terms of Reference
- **Measure 9.1.2** Communication Strategy and Plan
- **Measure 9.1.3** Collaboration Strategy with Affiliated Partners

ATTACHMENT B — PATIENT EMPOWERMENT

- **Measure 4.2.1** Sample of information provided to patients and families, i.e. Brochures, Web-site
- **Measure 4.2.5** Patient Experience Survey(s) and/or planned activities and timelines to establisha common tool

ATTACHMENT C – ORGANISATION OF CARE

- **Measure 4.1.1** Patient Pathways and/or Planned Actions and Timelines
- **Measure 5.1.2** Guides/Recommendations on Multidisciplinary Teams
- **Measure 6.3.1** Clinical Guidelines and/or planned activities and timelines for developingGuidelines
- **Measure 6.3.2** Policy on the declaration and management of conflict of interest regardingclinical guidelines, patient pathways, and clinical decision making tools
- **Measure 6.3.3** Cross Border Pathways and/or planned actions and timelines to develop crossborder pathways

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM

- **Measure 4.1.4** List of Diagnostic Technologies and Services Certified or Accredited throughNational, European, and/or International Programs provided by Network Members
- **Measure 4.2.3** Published Annual Reports and/or Planned actions and Timelines for PatientSafety Data Collection and Reporting
- **Measure 6.4.1** List of performance and outcome indicators and their definitions
- **Measure 6.4.2** Quality and Safety Framework (including Adverse Events Reporting System)

ATTACHMENT E- RESEARCH AND TRAINING

- **Measure 7.1.2** Strategic Research Plan
- **Measure 7.1.3** Annual Report on Research Projects and Clinical Trials and/or planned actionsand timelines to develop the Report
- **Measure 8.1.1** Annual Education Work plan

Scoring table (this is a sample only)

SELF ASSESSMENT SCORING TABLE			
Establishment of a European Reference Network			
Total Score out of a Possible 2	0	Percent of Total	%
Highly Specialised Healthcare			
Total Score out of a Possible 6	0	Percent of Total	%
Governance and Coordination			
Total Score out of a Possible 14	0	Percent of Total	%
Patient Care			
Total Score out of a Possible 20	0	Percent of Total	%
Multidisciplinary Approach			
Total Score out of a Possible 6	0	Percent of Total	%
Good Practice, Outcomes Measures, and Quality Control			
Total Score out of a Possible 18	0	Percent of Total	%
Contribution to Research			
Total Score out of a Possible 8	0	Percent of Total	%
Continuous Education, Training, and Development			
Total Score out of a Possible 6	0	Percent of Total	%
Networking and Collaboration			
Total Score out of a Possible 6	0	Percent of Total	%
Overall			
Grand Total out of a Possible 86	**0**	Percent of Total	**%**

Preliminary Assessment Summary Form *(THIS IS A SAMPLE ONLY)*

TO BE COMPLETED BY THE PERSON LEADING THE ASSESSMENT (following the Documentation Review)					
Person Leading the Assessment					
Name:					
Assessor 2:					
Name:					
Assessment Purpose					
Assessment Type	Initial Approval				
Preliminary Assessment					
Date:					
Preliminary Results	GRAND TOTAL SCORE	**0**	Percent of Total	**0%**	
Notes Relevant to the Preliminary Assessment (if any)					
Recommendation of the Assessment Team:					
Proceed to the On-site Audit **Negative Assessment**					
Signature of the Assessor Team Leader					
Signature:					
Declaration					
The findings have been explained to the Network and/or Healthcare Provider Representative and understood.					
Signature:		Name:		Date:	

Final Assessment Summary Form *(THIS IS A SAMPLE ONLY)*

TO BE COMPLETED BY THE PERSON LEADING THE ASSESSMENT	
Person Leading the Assessment	
Name:	
Assessor 2:	
Name:	
Assessment Purpose	
Assessment Type	Initial Approval
Assessment	
Date:	
Outcome	Full Compliance with the Operational Criteria Partial Compliance with the Operational Criteria Not Compliant with the Operational Criteria
Notes Relevant to the Assessment (if any)	
Recommendation of the Assessment Team:	
Positive Assessment **Negative Assessment**	
Signature of the Assessor Team Leader	
Signature:	
Declaration	
The findings have been explained to the Network and/or Healthcare Provider Representative and understood.	

Signature:		Name:		Date:	

Instructions for Self-Assessment for Healthcare Providers

Introduction

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex II (b), the membership application to join a Network must be submitted in response to a call for interest published by the Commission and must include the completed application form with the self- assessment questionnaire and supporting documentation.

The self-assessment provides Healthcare Providers with the opportunity to evaluate themselves against the criteria and conditions to fulfil as detailed in the **Operational Criteria for the Assessment of Healthcare Providers** document, before submitting their application to the European Commission.

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

INSTRUCTIONS AND RECOMMENDATIONS FOR COMPLETING THE SELF-ASSESSMENT

1. Establish a multidisciplinary team consisting of the Healthcare Provider's Representative and care provider representation. The team should discuss and agree on the self-assessment information to be include in the IT form. This exercise as a team increases the value of the process and the accuracy of the information. It is estimated to take approximately three to four meetings, with time allocated between meetings pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointed to organize the group, assign tasks, and coordinate the self-assessment effort.

2. As the self-assessment will be filled for submission in the online application, it is advised that the team uses a paper form to collect the information agreed during the preparatory process.

3. Read and review the Operational Criteria in its entirety before beginning the Self-Assessment process. If possible, make copies and send them to team members before the first meeting.

4. Discuss each individual element in the Self-Assessment Checklist and evaluate the progress in implementing it. As necessary, verify the level of implementation with other individuals outsideof the team. Document this information in the "Comments" section of the checklist. This "Comments" section is mandatory for each Measure of the Operational Criteria, to briefly explain each rating provided. The applicant must reference any supporting documentation, as required.

5. Once consensus is reached, complete the table by marking the box that most appropriately captures the current status of compliance with the criterion, using following rating scale and scoring guide:

Rating	Guidelines
0: No activity / Not Implemented	***All Criteria:*** **this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	***All Criteria:*** **this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance.** *This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	***All Criteria:*** **this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • A single negative observation may not prevent a score of "fully met". • 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

6. Repeat the process for each element. Once complete, tally up the score for each section using the template provided in the sample of the **scoring table**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

7. Use this information to develop an Action Plan to improve readiness to submit the application and complete the independent assessment process.

8. Prior to finalizing and submitting the self-assessment, a process to validate the results internally should be followed.

   The purpose of the internal validation is to:

   - Provide a level of quality assurance;
   - Confirm that the self-assessments are accurate and therefore can be shared externally;

   At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.

9. Complete the self-assessment online form.

10. Submit the completed Self-Assessment along with the Application Form ***on or before the deadline*** for submitting applications in response to the Call for Interest. The Healthcare Provider must have ready at the time the application is submitted all supporting documentation listed in the ***List of Supporting Documentation for Networks***. These documents should be made available to the BoN, IAB, or EC, at their request.

THE ASSESSOR CHECKLIST TOOL FOR HEALTHCARE PROVIDERS *(**NOTE:** THIS SECTION IS A SAMPLE ONLY)*

Criteria and conditions for applicants for membership of a Network[3]

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE					
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.					
Measurement Elements	0	1	2	**What to look for?**	**Assessor Comments**
..1 The Healthcare Provider's commitment to patient-centered care is formally and consistently communicated with patients and their families.	☐	☐	☐	Mission or Core Values Patient Brochures and Information	
..2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	☐	☐	☐	Examples of Patients' Notes Clinical audits and/or chart reviews	
..3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	☐	☐	☐	Patient Education Materials	
..4The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.	☐	☐	☐	Patient Brochures and Information	
..5 The Healthcare Provider gives patients and their families' written information about their rights and responsibilities.	☐	☐	☐	Written Material Describing Patient and Family Rights	
..6 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.	☐	☐	☐	Organization Policy and Process on Disclosure	

[3] Commission Delegated Decision (2014/286/EU) – Annex II

LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE (English Summary of all A measures)

- **Measure 1.1.1** Mission and/or Core Values **(1a)***
- **Measure 2.1.1** Organization chart **(2a)* Measure 1.7.1** Conflict of Interest Policy **(1g)*Measure 2.3.1** Business continuity plan **(2c)***

ATTACHMENT B – PATIENT EMPOWERMENT (English Summary of all B measures)

- **Measure 1.1.3** Sample of Patient Information and Education Materials already produced by the Healthcare Provider **(1a)***
  Measure 1.1.5 Written Material Describing Patient and Family Rights and Responsibilities **(1a)***
  Measure 1.3.1 Patient Experience Survey and Sample Patient Experience Reports **(1c)***
- **Measure 1.5.1** Examples of Informed Consent Policy and Procedures used by the Healthcare Provider **(**English translation of one sample + documents in original language**)** (1e)*

ATTACHMENT C – ORGANISATION OF CARE (English Summary of all C measures)

- **Measure 2.1.3** Existing Policies and Procedures for Managing Cross Border Patients or plannedactions and timelines for developing policies and procedures **(2a)***
- **Measure 2.6.1** Discharge procedure and Discharge Template **(2f)***
- **Measure 5.3.1** List and examples of Clinical Practice Guidelines or Clinical Decision Support tools developedor adopted by the Healthcare Provider related with its area of expertise **(5c)***

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM (English Summary of all D measures)

- **Measure 2.5.1** Third party reports issued by local or national bodies or external accreditation or certification bodies and/or inspections on the quality care environments **(2c)***
- **Measure 5.1.1** Quality Improvement Plan (**5a)***
- **Measure 5.1.2** Current Structure, Process or Outcome Indicators (Dashboard) and their definitions or planned actions and timelines for their development **(5a)***
- **Measure 5.1.3** Patient Safety Plan **(5a)***
- **Measure 5.1.4** Examples of methodologies used for adverse events analysis (Root CauseAnalysis, etc.) and Description of Process Improvement methods **(5a)***

ATTACHMENT E – RESEARCH AND TRAINING (English Summary of all E measures)

- **Measure 3.1.2** List of training objectives **(3a)***
- **Measure 3.1.3** List of Teaching Staff and Qualifications **(3a)***
- **Measure 3.2.2** List of grants and research projects over the last 5 years **(3b)***
- **Measure 3.2.3** List of Standard Operating Procedures (SOPs) that govern research activities **(3b)***
  Measure 3.2.4 Research Policy and Procedure **(3b)***

** Please note the numbers in () correspond to the numbering in the **self-assessment online tool***

Scoring Table (this is an example only)

Self-Assessment Scoring Table			
GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30	**0**	Percent of Total	**0%**
Organisation, Management, and Business Continuity			
Total Score out of a Possible 20	**0**	Percent of Total	**0%**
Research, Education and Training			
Total Score out of a Possible 24	**0**	Percent of Total	**0%**
Expertise, Information Systems, and E-health Tools			
Total Score out of a Possible 12	**0**	Percent of Total	**0%**
Quality and Safety			
Total Score out of a Possible 18	**0**	Percent of Total	**0%**
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
Human Resources			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
Organization of Patient Care			
Total Score out of a Possible 12	**0**	Percent of Total	**0%**
Facilities and Equipment			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
OVERALL			
Subtotal Score for General Criteria	**0**	Percent of Total	**0%**
Subtotal Score for Specific Criteria	**0**	Percent of Total	**0%**
GRAND TOTAL SCORE out of a Possible 140	**0**	Percent of Total	**0%**

Preliminary Assessment Summary Form *(THIS IS A SAMPLE ONLY)*

TO BE COMPLETED BY THE PERSON LEADING THE ASSESSMENT (following the Documentation Review)				
Person Leading the Assessment				
Name:				
Assessor 2:				
Name:				
Assessment Purpose				
Assessment Type	Initial Approval			
Preliminary Assessment				
Date:				
Preliminary Results	GRAND TOTAL SCORE	**0**	Percent of Total	**0%**
Notes Relevant to the Preliminary Assessment (if any)				
Recommendation of the Assessment Team:				
Proceed to the On-site Audit **Negative Assessment**				
Signature of the Assessor Team Leader				
Signature:				
Declaration				
The findings have been explained to the Network and/or Healthcare Provider Representative and understood.				

Signature:		Name:		Date:	

Final Assessment Summary Form *(THIS IS A SAMPLE ONLY)*

TO BE COMPLETED BY THE PERSON LEADING THE ASSESSMENT					
Person Leading the Assessment					
Name:					
Assessor 2:					
Name:					
Assessment Purpose					
Assessment Type	Initial Approval				
Assessment					
Date:					
Outcome	Full Compliance with the Operational Criteria Partial Compliance with the Operational Criteria Not Compliant with the Operational Criteria				
Notes Relevant to the Assessment (if any)					
Recommendation of the Assessment Team:					
Positive Assessment **Negative Assessment**					
Signature of the Assessor Team Leader					
Signature:					
Declaration					
The findings have been explained to the Network and/or Healthcare Provider Representative and understood.					
Signature:		Name:		Date:	

Annex 19 - Assessment tool for Independent Assessors (Excel)

Excel file for the Independent Assessment Body (IAB) to fill in and score the assessment of Applicants.

Annex 20- Patient Tracer Method and Guide for Assessors

For Use During the On-Site Audit Only

Description: Care and treatment provided to a patient with a rare or low prevalence complex disease or condition from the first encounter with a Healthcare Provider through the completion of the last encounter related to that specific disease or condition.

Note: The Patient Tracer tool is intended to be a guideline for Assessors only. Assessors may not necessarily ask every question or may ask additional questions during the on-site audit.

Patient Referral

- How is the patient referred to the Healthcare Provider?
- Who are the sources of referral?
- Was a specific referral pathway applied?
- What works well, and what could be improved?
- How are cross border referrals managed?

Planning & Coordination of Care

- Is there a designate Provider or Care Coordinator assigned to each patient?
- Is each patient reviewed by the multidisciplinary team? What is the process for this review and composition of the team?
- Who leads the coordination of care within the Healthcare Provider? Local area? Is a shared care approach used?
- How are health and social service needs coordinated?

Effective Care and Treatment

- What care and treatments are delivered to patients?
- How easy is it to access treatments and medications?
- What specific clinical practice guidelines or cross border patient pathways are followed?
- How is patient information outcomes of treatment documented? Is standardised information and coding system used?

Diagnosis and Early Intervention

- What diagnostic tests are completed? Is there a process to access timely diagnostic tests?
- Was a specific diagnosis pathway followed?
- How long did the patient have to wait for a final diagnosis following the onset of symptoms?
- How many doctors did the patient see before being diagnosed?
- What is the process for managing undiagnosed patients?

Patient Empowerment

- What information, education, and support are available to patients and their families?
- What format is the information provided?
- How are patient/family informed of research?
- How are patients /families involved in the planning of service?
- Is there a process for patients to file a complaint? Are unanticipated outcomes of treatment disclosed?
- Is there a process to obtain informed consent from patients?

Transition/Discharge and Follow-Up

- What information is provided to patients/ families at end of service or transition?
- Is there a process to follow-up with patients after transition or end of service?
- Are discharge summaries standardised?
- What tools/technologies are used to share information and/or follow-up with patients in their local area?
- How is the transition from children to adult services arranged?

Key Activities During the On-site Audit for the Patient Tracer
(to be completed by the Assessor)

1. Review the files of current patients within the Network's area of expertise.
2. Select up to three (3) patient files based the following criteria:
    a. Representative of patients served by the multidisciplinary team.
    b. Case complexity.
3. Become familiar with each file:
    a. Patient's medical history.
    b. Care and treatment received.
    c. Providers involved in service delivery.
4. Plan the tracer by making a list of:
    a. The healthcare professionals to talk to.
    b. The questions to ask and issues to address.
    c. Any documentation or additional files to review, including files of recently discharged patients, if applicable.
5. Carry out the tracer.

One on One Interview: Clinical Leader

1. Select the most appropriate clinical leader.
2. Focus your questions on:
    a. The patient care processes and procedures.
    b. Systems issues involving the multidisciplinary team.

Discussion with the Multidisciplinary Team

1. Based on the information contained in the patient file, speak to staff and care providers in the care area. This discussion is repeated in every service area/sector.
2. Focus your questions on:
    a. The processes of patient care (vs. individual practice).
    b. Systems issues or challenges that may be affecting patient care.
    c. Fully understanding a process or line of questioning before moving on to the next issue.

Notes and Observations

Include:

- Additional questions
- Points of clarification/requests for additional documentation
- Similarities, inconsistencies, or points for follow-u

Annex 21 - Assessor Core Competencies

Purpose of the Task

Assessors are peer reviewers who assess compliance against the Operational Criteria to determine if the Applicant(s) fulfil the criteria and conditions of the Delegated Decision 2014/286/EU.

Required Qualifications

The Assessors are senior healthcare professionals with one or more of the following qualifications:

ASSESSOR	REQUIRED QUALIFICATIONS
Team Leader	A senior healthcare professional with a relevant university degree specialised in the area of quality, healthcare, public health administration of healthcare management, and a minimum of 10 years of professional experience. Experience in the area of audits and certification, accreditation, or licensing of healthcare providers at national level should be included.
Team Member	A university degree in quality, healthcare, public health administration, or healthcare management and at least 10 years of professional experience in the area of audits and certification, accreditation or licensing of healthcare providers at national level. And / Or A university degree in medicine and master and/or medical specialty in healthcare or public health with at least 10 years of relevant professional experience in healthcare quality and in particular in the field of accreditation, certification, licensing or external assessment or evaluation of healthcare providers. And / Or A university degree and a master degree in the area of healthcare or public health with at least 5 years of professional experience in performing quality assurance reviews or audits, evaluation of clinical information and documentation including medical record reviews or peer review reports and writing of clinical and quality performance reports.

Additional Requirements

Assessors should also have a combination of the following:

- Knowledge of the European healthcare system and regulations;
- Experience providing care to patients and their families with rare or low prevalence complex diseases or conditions;
- Working knowledge of English;
- C2 level of English (Team Leader Only); and
- Excellent writing skills.

The assessor team must be able to carry out services in any of the other EU official languages, if requested.

General Core Competencies

Assessors must also demonstrate a combination of soft skills related to adaptability, analytical thinking, patient focus, communication, organisation and teamwork. The table below provides a description of each of these requirements.

COMPETENCY	DEFINITION
Adaptability	• Willing and able to adapt to change. • Adjusts own behaviours to work efficiently and effectively in different situations and environments. • Demonstrates flexibility in meeting workload and demands.
Analytical Thinking	• Skilled at developing strategies to obtain complete/detailed information such as developing question lines and interview techniques. • Applies an effective range of data collection techniques, including observing, interviewing, probing, listening and reviewing documentation. • Able to identify root causes, causal links and patterns. • Able to consider issues in a way that encompasses the interactions of all system components. • Assesses situations in an objective and rigorous manner.
Patient Focus	• Strives to provide service excellence to patients. • Able to establish positive rapport with patients. • Understands and consistently applies the principles of patient focused care

Communication	• Uses active listening techniques. • Responds openly and effectively to others. • Delivers information clearly; objectively explains positive and negative findings. • Adapts communication style and uses language appropriate to audience and situation. • Shows tact and sensitivity in all interactions. • Writes concisely and accurately.
Organisation	• Prepares in advance. • Adheres to established schedules and confirmed plans.
Teamwork	• Able to work cooperatively with others. • Able to work to resolve and reduce potential for conflicts. • Willing to assist colleagues if needed.

Team leaders are also expected to have additional soft skills related to management and conflict resolution. See table below for a description of these additional requirements.

COMPETENCY	DEFINITION
Conflict resolution	• Able to manage and/or resolve conflicts within the Assessor Team or during the on-site audit. • Able to manage conflicting needs, as applicable, and develop creative solutions to problems.
Management	• Sets a positive tone for the assessment and on-site audit. • Able to mobilise team members, as necessary, to complete tasks. • Able to coordinate a smooth and seamless series of on-site audits.

Annex 22a – Assessment Report Template for Networks

Network Assessment Report

Prepared for:

[*Name of the Network*]

On-site Audit Dates:

[*Start Date – End Date*]

An initiative of the

Confidentiality Statement

The results of the assessment of [*name of the Network*] are documented in the attached report which was prepared by the Independent Assessment Body.

This report is based on information obtained from the Network and Healthcare Providers through the application forms, self-assessments, supporting documentation, virtual interviews and the on-site audit. The Independent Assessment Body relies on the accuracy of this information to prepare the report.

This confidential report is intended for the Network and Healthcare Providers, the European Commission, and the Board of Member States. Any alteration of this report is strictly prohibited.

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Introduction

The assessment model for the European Reference Networks (ERNs) is a voluntary process that fosters a culture of quality improvement and offers a peer review assessment of highly specialised healthcare providers. The assessment process provides a standardised method for forming and evaluating ERNs under the regulatory framework of the Commission Delegated and Implementing Decisions of 10 March 2014. It includes a comprehensive assessment of the Applicant through documentation review (application forms, self-assessments and supporting documentation), virtual interviews, and on-site audits.

Assessment Summary

[Network Name]

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

Coordinating Member

[Name and Address of Coordinating Member]

Healthcare Providers

The Network is composed of the following Healthcare Providers:

- [List name of each Healthcare Provider and Member State*]

*Selected for the On-site Audit.

Assessor Team

The following assessor team completed the technical assessment:

[List assessors and organisation affiliation]

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

*Team Leader

Results Overview

Assessor's Commentary

The assessor team provided the following overall comments regarding the Network and Healthcare Providers.

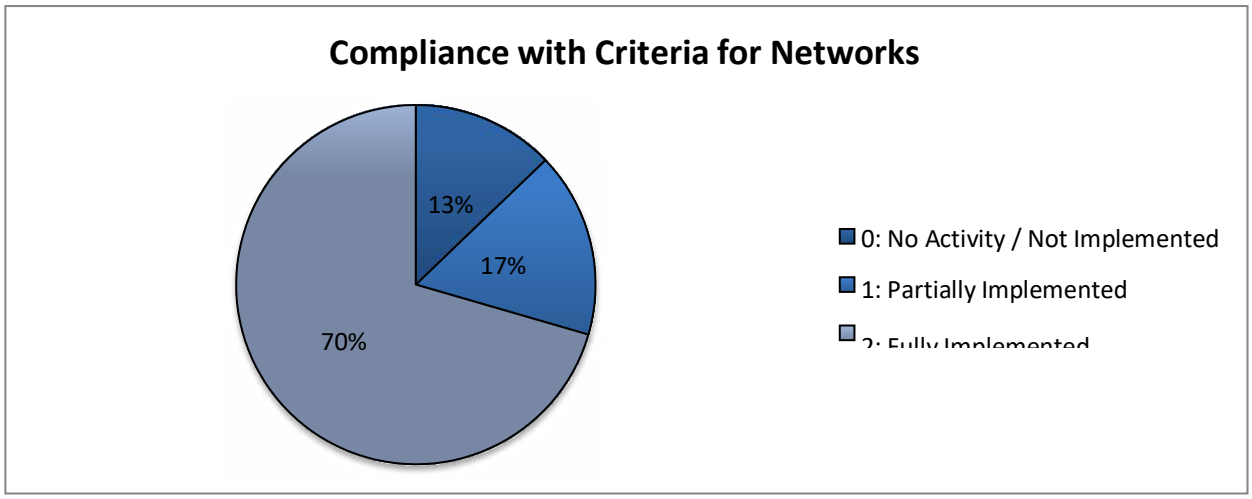
Objectives of the Network: [assessor comments]

Successes and Challenges: [assessor comments]

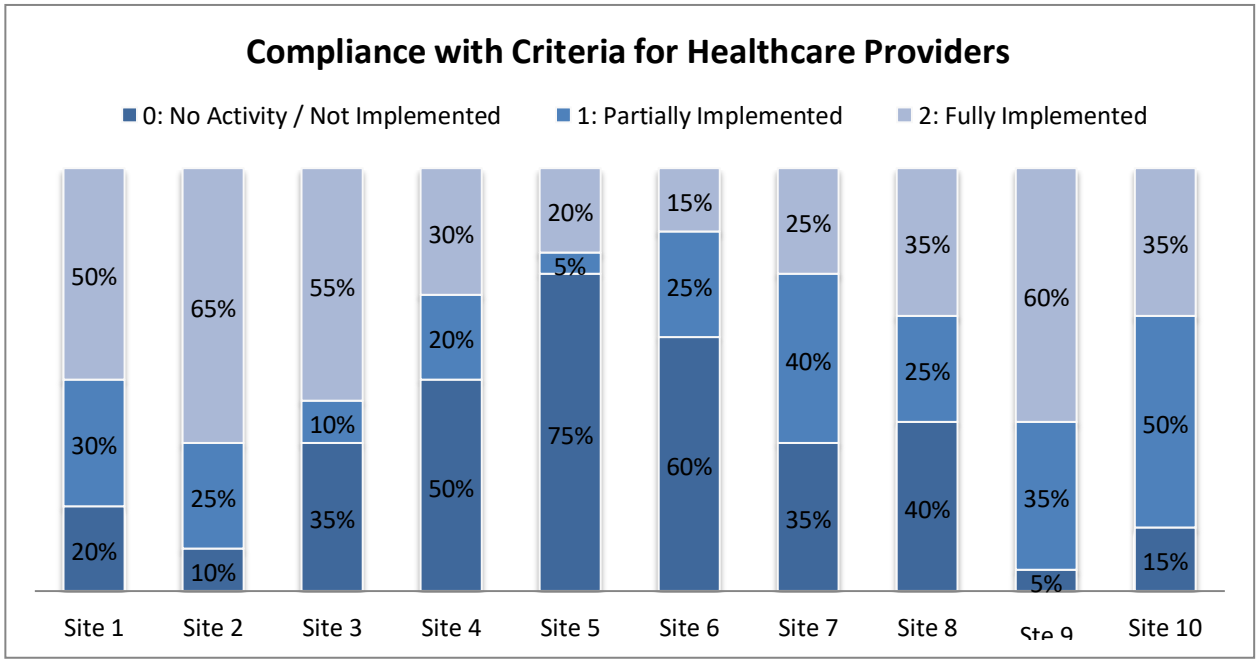
Response to Previous Recommendations (if applicable): [assessor comments]

Overall Compliance with the Operational Criteria

Based on the assessment of compliance against the Operational Criteria for Networks, the following graph represents the overall distribution of the ratings for the Network. Please see *Appendix A* for more information on the rating scale used by the assessors.



Compliance was also assessed for each Healthcare Provider in the Network against the Operational Criteria for Healthcare Providers. The following graph represents the distribution of the assessor ratings against the criteria for each Healthcare Provider.



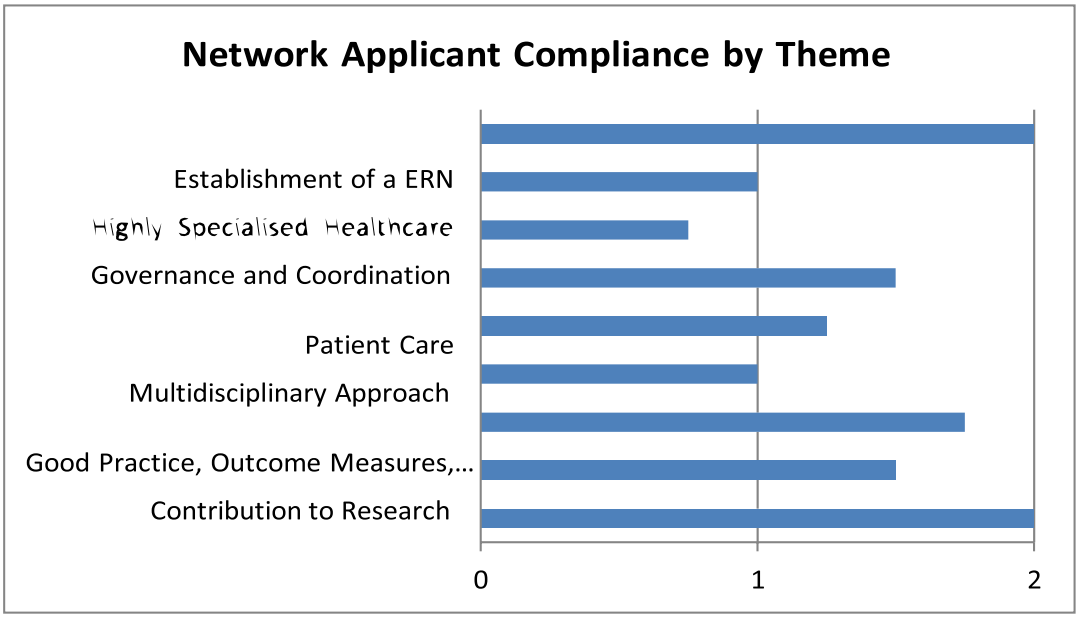
Overview by Themes

Network Results

The Operational Criteria for the Network are grouped into the following nine themes:

1. Establishment of a European Reference Network
2. Highly Specialised Healthcare
3. Governance and Coordination
4. Patient Care
5. Multidisciplinary Approach
6. Good Practice, Outcome Measures, and Quality Control
7. Contribution to Research
8. Continuous Education, Training, and Development
9. Networking and Collaboration

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision (2014/286/EU). The following graph represents the Network's average rating for each theme.



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

The following tables show the Network's compliance with the measures in each theme. Based on the assessors' findings, areas of strength and challenges are also highlighted.

Governance and Coordination *(EXAMPLE ONLY)*	Assessor Rating
1.3.1 There is one designated representative for each applicant member of the Network.	2
1.3.2 The Network is governed by a Board composed of one representative from each Member in the European Reference Network.	1
Average Rating	**2.4**

Strengths: [assessor comments]

Challenges: [assessor comments]

Patient Care *(EXAMPLE ONLY)*	Assessor Rating
2.1.1 The Network works with its Members to establish clear patient pathways based on the needs of patients, clinical evidence, and best use of resources.	2
2.1.2 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.	1
Average Rating	**2.4**

Strengths: [assessor comments]

Challenges: [assessor comments]

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

Healthcare Providers' Results

The Operational Criteria for the Healthcare Providers are grouped into the following nine themes:

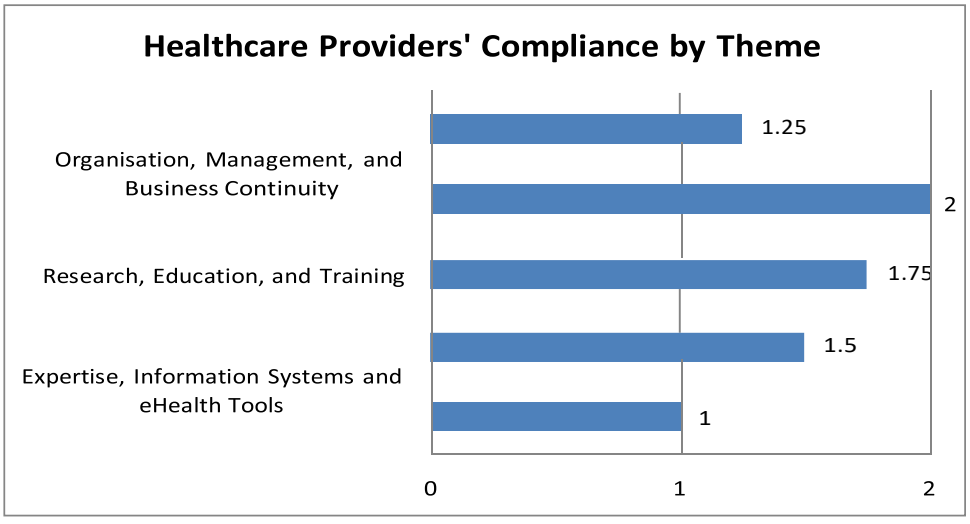
General Criteria and Conditions:

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

Specific Criteria and Conditions:

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

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision (2014/286/EU). The following graph represents the average rating of all the Healthcare Providers in each theme.



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

The following tables show the average rating of all the Healthcare Providers with the measures in each theme. Strengths and challenges are also noted in each area.

Patient Empowerment and Patient-Centred Care	Assessor Rating
1.1.1 The Healthcare Provider's commitment to patient-centered care is formally and consistently communicated with patients and their families.	1
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	2
[…]	
Average Rating	**1.6**

Strengths: [assessor comments]

Challenges: [assessor comments]

Organisation, Management, and Business Continuity	Assessor Rating
2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.	1
[…]	
Average Rating	**…**

Strengths: [assessor comments]

Challenges: [assessor comments]

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

Detailed Results and Recommendations

The following tables show the Network's compliance with each criterion in the Operational Criteria and the Assessor recommendations.

Criterion	Assessor Average Rating	Assessor Recommendations
1.1	2	
1.2	1	
2.1	0	
2.2	2	
[…]		

Final Outcome of the Assessment

Scoring Table			
Establishment of a European Reference Network			
Total Score out of a Possible 2	**0**	Percent of Total	**%**
Highly Specialised Healthcare			
Total Score out of a Possible 6	**0**	Percent of Total	**%**
Governance and Coordination			
Total Score out of a Possible 14	**0**	Percent of Total	**%**
Patient Care			
Total Score out of a Possible 20	**0**	Percent of Total	**%**
Multidisciplinary Approach			
Total Score out of a Possible 6	**0**	Percent of Total	**%**
Good Practice, Outcomes Measures, and Quality Control			
Total Score out of a Possible 18	**0**	Percent of Total	**%**
Contribution to Research			
Total Score out of a Possible 8	**0**	Percent of Total	**%**
Continuous Education, Training, and Development			
Total Score out of a Possible 6	**0**	Percent of Total	**%**
Networking and Collaboration			
Total Score out of a Possible 6	**0**	Percent of Total	**%**
Overall			
Grand Total out of a Possible 86	**0**	Percent of Total	**%**

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

Healthcare Provider	Outcome of the Assessment
1. <Insert HCP Name>	Positive/Negative Assessment
2.	Positive/Negative Assessment
3.	Positive/Negative Assessment
4.	Positive/Negative Assessment
5.	Positive/Negative Assessment
6.	Positive/Negative Assessment
…..	Positive/Negative Assessment

Based on the overall score and detailed findings in this report, the Network has achieved a:

POSITIVE ASSESSMENT

NEGATIVE ASSESSMENT

Next Steps

Congratulations on reaching this important milestone in the assessment process for European Reference Networks (ERNs). Your ongoing efforts to incorporate the Operational Criteria for the Network and Healthcare Providers into how you deliver patient care have been, and will continue to be, of great benefit to the Network, Healthcare Providers, healthcare professionals, patients, and families.

The Network and Healthcare Providers are encouraged to follow-up on the recommendations in this report, as appropriate. The following is a summary of the next steps:

- Review the assessment report and notify the Assessment Coordinator of any requests for amendments
- Once the Assessment Coordinator receives confirmation from the *Network Coordinator* that the reports have been reviewed and confirmed, the assessment reports will be sent to the European Commission. Once received, they will be forwarded to the Board o Member States for review
- The Board of Member States will issue the final approval for ERNs based on the assessment results

If you have any questions, please contact the Assessment Coordinator..

Assessor Team Leader					
Signature:		Name:		Date:	
Assessment Coordinator					
Signature:		Name:		Date:	

Appendix A: Rating Scale and Scoring guide

The following rating scale is used by the assessors to evaluate compliance with the operational criteria for Network and Healthcare Providers. The same rating scale is used by the applicant for the self-assessments.

Rating	Guidelines
0: No activity / Not Implemented	**All Criteria: this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance.** This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable). Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	**All Criteria: this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance.** This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable). Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	**All Criteria: this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to support compliance**. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable). Considerations: • A single negative observation may not prevent a score of "fully implemented". • 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.

Annex 22b – Assessment Report Template for Healthcare Providers

Share. *Care*. Cure

Healthcare Provider's Assessment Report

Prepared for:

[*Healthcare Provider's Name*]

Confidentiality Statement

The results of the assessment of [*name of the Healthcare Provider*] are documented in the attached report which was prepared by the Independent Assessment Body.

This report is based on information obtained from the Healthcare Provider through the application forms, self-assessments, supporting documentation, virtual interviews and the on-site audit. The Independent Assessment Body relies on the accuracy of this information to prepare the report.

This confidential report is intended for the Network and Healthcare Providers, the European Commission, and the Board of Member States. Any alteration of this report is strictly prohibited.

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Introduction

The assessment model for the European Reference Networks (ERNs) is a voluntary process that fosters a culture of quality improvement and offers a peer review assessment of highly specialised healthcare providers. The assessment process provides a standardised method for forming and evaluating ERNs under the regulatory framework of the Commission Delegated and Implementing Decisions of 10 March 2014 and amendment of the Implementing Decision of 19 July 2019. It includes a comprehensive assessment of the Applicant through documentation review (application forms, self-assessments and supporting documentation), virtual interviews, and on-site audits.

Assessment Summary

[Healthcare Provider's Name]

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

Network

[Name of the Network]

Representative and Sub-representative Name and/or Applicant Name

[Name and Address of applicant Member]

Assessor Team

The following assessor team completed the technical assessment:

[List assessors and organisation affiliation]

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

*Team Leader

Results Overview

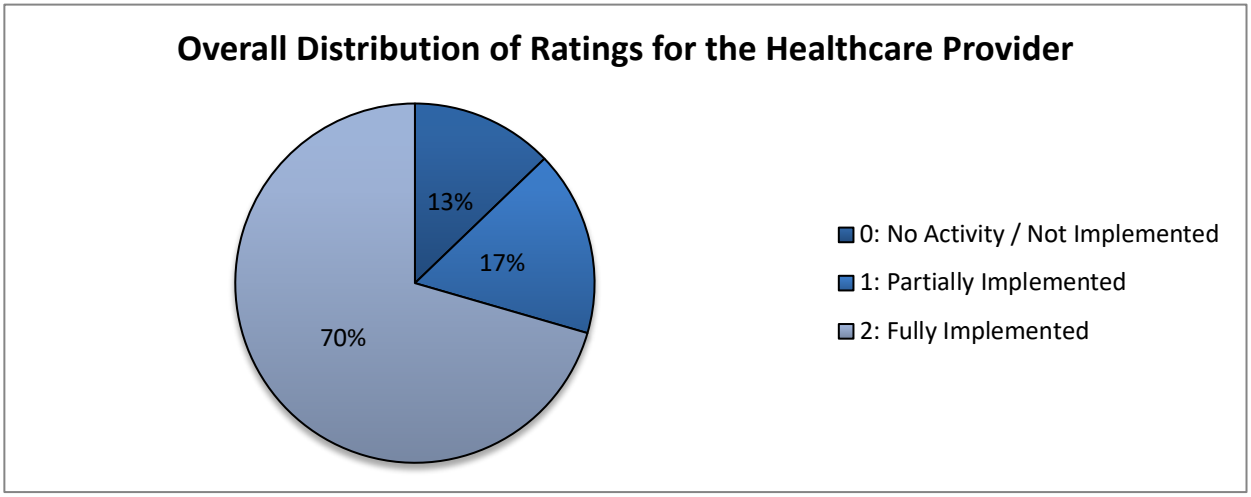
Assessor's Commentary

The assessor team provided the following overall comments regarding the Healthcare Provider.

- **Main discrepancies between the self-scoring of the applicant and the assessor team judgement** [assessor comments]
- **Comments on the Board of the Network (BoN) opinion:** [assessor comments]
- **Successes and Challenges:** [assessor comments]
- **Response to Previous Recommendations (if applicable):** [assessor comments]

Overall Compliance with Operational Criteria

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



Overview by Themes

The Operational Criteria for the Healthcare Providers are grouped into the following nine themes:

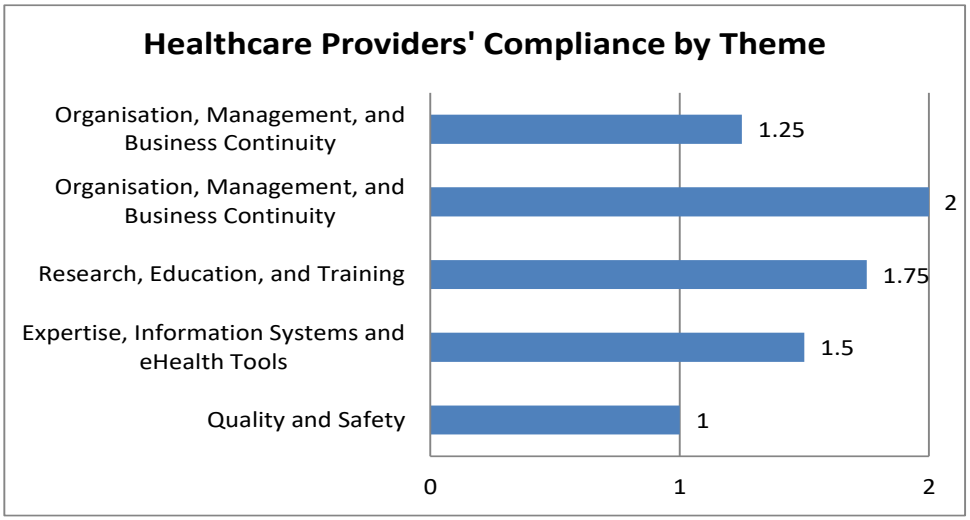
General Criteria and Conditions:

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

Specific Criteria and Conditions:

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

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision. The following graph represents the Healthcare Provider's overall compliance with the Operational Criteria by theme.



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

The following tables show the Healthcare Provider's compliance with the measures in each theme. Based on the assessors' findings, areas of strength and challenges are also highlighted.

Patient Empowerment and Patient-Centred Care	Assessor Rating
1.1.1 The Healthcare Provider's commitment to patient-centered care is formally and consistently communicated with patients and their families.	1.7
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	1.5
[…]	
Average Rating	1.6

Strengths: [assessor comments]

Challenges: [assessor comments]

Organisation, Management, and Business Continuity	Assessor Rating
2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.	1
[…]	
Average Rating	…

Strengths: [assessor comments]

Challenges: [assessor comments]

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

Detailed Results and Recommendations

The following tables show the Healthcare Provider's compliance with each criterion in the Operational Criteria and the Assessor recommendations.

Criterion	Assessor Average Rating	Assessor Recommendations
1.1	2	
1.2	1	
2.1	0	
2.2	2	
[…]		

Final Outcome of the Assessment

Scoring Table			
GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centered Care			
Total Score out of a Possible 30	0	Percent of Total	0%
Organisation, Management, and Business Continuity			
Total Score out of a Possible 20	0	Percent of Total	0%
Research, Education and Training			
Total Score out of a Possible 24	0	Percent of Total	0%
Expertise, Information Systems, and E-health Tools			
Total Score out of a Possible 12	0	Percent of Total	0%
Quality and Safety			
Total Score out of a Possible 18	0	Percent of Total	0%
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8	0	Percent of Total	0%
Human Resources			
Total Score out of a Possible 8	0	Percent of Total	0%
Organization of Patient Care			
Total Score out of a Possible 12	0	Percent of Total	0%

Facilities and Equipment			
Total Score out of a Possible 8	**0**	Percent of Total	**0%**
OVERALL			
Subtotal Score for General Criteria	**0**	Percent of Total	**0%**
Subtotal Score for Specific Criteria	**0**	Percent of Total	**0%**
GRAND TOTAL SCORE out of a Possible 140	**0**	Percent of Total	**0%**

Based on the overall score and detailed findings in this report, the Healthcare Provider has achieved a:

POSITIVE ASSESSMENT

NEGATIVE ASSESSMENT

Next Steps

Congratulations on reaching this important milestone in the assessment process for European Reference Networks (ERNs). Your ongoing efforts to incorporate the Operational Criteria into how you deliver patient care have been, and will continue to be, of great benefit to the Network, other Healthcare Providers, healthcare professionals, patients, and families.

The Healthcare Provider is encouraged to follow-up on the recommendations in this report, as appropriate. The following is a summary of the next steps:

a. Review the assessment report and notify the Assessment Coordinator of any requests for amendments
b. Once the Assessment Coordinator receives confirmation from the *Applicant* that the reports have been reviewed and confirmed, the assessment reports will be uploaded in the system of the European Commission. Once received, they will be forwarded to the Board of Member States for review.
c. The Board of Member States will issue the final approval for ERNs based on the assessment results, the Applicant will be informed about the results through the online tool.

If you have any questions, please contact the Assessment Coordinator.

Team Leader					
Signature:		Name:		Date:	
Assessment Coordinator					
Signature:		Name:		Date:	

Appendix A: Rating Scale and scoring guide

The following rating scale and scoring guide is used by the assessors to evaluate compliance with the Operational Criteria for Networks and Healthcare Providers. The same rating scale is used by the applicant for the self-assessments.

Rating	Guidelines
0: No activity / Not Implemented	***All Criteria:*** **this rating is used if the answer is "rarely" or "never" to the specific measure and/or when there is no action plan in place or there is insufficient evidence to support compliance.** *This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance is not appropriate for the purpose or not complete. • An action plan is developed but is not implemented. • When there are multiple requirements in one measure, 49% or fewer are present.
1: Partially Implemented	***All Criteria:*** **this rating is used if the answer is "usually" or "sometimes" to the specific measure and/or when there is an action plan in place or there is some evidence to support compliance.** *This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).* Considerations: • Evidence of compliance cannot be found in all areas/departments in which the requirement is applicable (such as inpatients but not outpatients, surgery but not day surgery, sedating areas except dental). • An action plan is developed and implemented but does not seem to be sustainable. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully Implemented	***All Criteria:*** **this rating is used if the answer is "yes" or "always" to the specific measure and/or when there is sufficient evidence to support compliance**. *This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).* Considerations: • A single negative observation may not prevent a score of "fully implemented". • 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.