European Reference Networks

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ERN Assessment Manual for Applicants

7. Self-Assessment Checklist for Networks in Active PDF

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An initiative of the

European Commission

Version 1.1 April 2016

Preamble

This document contains the Self-Assessment Checklist for Networks in Active PDF. It is part of series of *__nine__* documents that include the following:

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

SELF-ASSESSMENT CHECKLIST 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 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 the supporting documentation required in the assessment manual (See page 23 of the *ERN Assessment Manual for Applicants*).

The self-assessment 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, the self-assessment provides a mechanism for both the Independent Assessment Body 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:

1. Establishment of a European Reference Network
2. Highly Specialised Healthcare
3. Governance and Coordination
4. Patient Care
5. Multidisciplinary Approach
6. Good Practice, Outcomes Measures, and Quality Control
7. Contribution to Research
8. Continuous Education, Training, and Development
9. 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. These items are based on those Operational Criteria that the European Commission and Independent Assessment Body will use to assess compliance with the legislation. Note that a complete self-assessment must accompany the Application Form for the application to be considered.

INSTRUCTIONS FOR COMPLETING THE SELF-ASSESSMENT

1. Establish a team consisting of the designated Network Coordinator and representation from each of the 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. Because the implementation of a Network can be complex, completing the self-assessment as a team increases the value of the process and accuracy of the information. 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 appointed to organize the group, assign tasks, and coordinate the self-assessment effort.

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.

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 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).
1: Partially Implemented	*All Criteria:* this rating is used when there is an action plan in place or there is some evidence to support compliance. This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).
2: Fully Implemented	*All Criteria:* this rating is used when there is sufficient evidence to support compliance. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).

5. Repeat the process for each element. Once complete, tally up the Network's score for each section using the template provided in **Appendix A**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.

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

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

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

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

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

8. Complete and sign the *Declaration Form* in **Appendix C** of the self-assessment.

9. Submit the completed Self-Assessment along with the Application Form ***on or before the deadline*** for submitting applications in response to the call for interest. The Network <u>must</u> have ready at the time the application is submitted all supporting documentation listed in **Appendix B**. These documents should be made available to the IAB, at their request.

THE SELF-ASSESSMENT CHECKLIST TOOL
FOR EUROPEAN REFERENCE NETWORKS

1. 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.			
Measure Elements	**Rating (0 or 1 or 2)**	**Comments**	**▤** *
1.1.1 The Network is comprised of a minimum of 10 Members across 8 Member States.			

2. HIGHLY SPECIALISED HEALTHCARE

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.

Measure Elements	Rating (0 or 1 or 2)	Comments	🗎 *
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.			

3. GOVERNANCE AND COORDINATION

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
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 Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.			
3.1.6 The Network has a defined strategy for integrating new Members approved by the ERN Board of Member States and Affiliated Partners designated by the Competent National Authorities.			
3.1.7 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.			

4. Patient Care			
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.			
Measure Elements	**Rating (0 or 1 or 2)**	**Comments**	📋*
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 and share pertinent data within its area of expertise.			
4.1.3 The Network facilitates the transfer of knowledge on safe, evidence-based, effective and innovative medicine.			

| 4.1.4 The Network promotes the safe use of highly specialized diagnostic techniques and services and the application of recognized international quality standards, certification, and accreditation schemes. | | | 📄 |
| 4.1.5 The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable. | | | |

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
4.2.1 The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families.			📄
4.2.2 The Network collaborates with patient associations to improve the safety and quality of care.			

4.2.3 The Network disseminates information on patient safety standards and safety measures to patients and families to reduce or prevent errors.			📄
4.2.4 The Network provides accessible means for patients and families to report possible safety incidents or adverse events and express their views about the care received and their experience, including safety concerns.			
4.2.5 The Network collaborates with its Members to establish a standardised common tool for measuring patient experience.			📄

5. Multidisciplinary approach

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
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.			

6. Good Practice, Outcome Measures, and Quality Control

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
6.1.1 The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network.			
6.1.2 Representatives from each Member meet periodically to review and share best practices, and discuss new evidence-based treatments, therapies, and health care technologies.			

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
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.			
Measure Elements	**Rating (0 or 1 or 2)**	**Comments**	🗎*
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.			
Measure Elements	**Rating (0 or 1 or 2)**	**Comments**	📄*
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.			📄

7. Contribution to Research

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📄*
7.1.1 The Network identifies where there are research gaps and carries out activities to fulfil these gaps.			
7.1.2 The Network promotes and supports collaborative research amongst its Members, Affiliated Partners, and relevant patient, professional and research organisations.			📄
7.1.3 The Network keeps its Members, partners, and patient organizations informed about new research projects and clinical trials.			📄

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

8. Continuous education, training, and development

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

Measure Elements	Rating (0 or 1 or 2)	Comments	🗎*
8.1.1 The Members work together to identify and fulfil education, training, an3 d 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.			

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

Measure Elements	Rating (0 or 1 or 2)	Comments	📰*
9.1.1 The Network exchanges and disseminates knowledge and best practices with other Networks and Centres of Expertise.			
9.1.2 The Network develops a communication plan and establishes communication tools to support collaboration with other organizations.			📰
9.1.3 The Network collaborates with Affiliated Partners, i.e. Associated National Centres, Collaborative National Centres or National Coordination Hubs, chosen by Member States.			📰

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

APPENDIX A: SCORING TABLE

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

APPENDIX B: 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 9.1.2** 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 establish a 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 developing Guidelines
- **Measure 6.3.2** Policy on the declaration and management of conflict of interest regarding clinical guidelines, patient pathways, and clinical decision making tools
- **Measure 6.3.3** Cross Border Pathways and/or planned actions and timelines to develop cross border pathways

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM

- **Measure 4.1.4** List of Diagnostic Technologies and Services Certified or Accredited through National, European, and/or International Programs provided by Network Members
- **Measure 4.2.3** Published Annual Reports and/or Planned actions and Timelines for Patient Safety 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 actions and timelines to develop the Report
- **Measure 8.1.1** Annual Education Work plan

APPENDIX C: DECLARATION FORM

TO BE COMPLETED BY THE PERSON LEADING THE SELF-ASSESSMENT	
Person Leading the Self-Assessment	
Name:	
Title:	
Contact Email:	
Assessment Purpose	
Application Type	Initial Approval Network and/or Healthcare Provider Renewal
Self Assessment	
Date:	
Outcome	Full Compliance with the Operational Criteria Partial Compliance with the Operational Criteria Not Yet Compliant with the Operational Criteria
Notes Relevant to the Self-Assessment (if any)	
Signature of the Network Coordinator	
Signature:	
Declaration	

I confirm that this self-assessment is an accurate and true reflection of the compliance status of the Network against the Operational Criteria and that all supporting documentation listed in **Appendix B** are prepared and ready for submission, at the IAB's request.

Signature:		Name:		Date:	