



European
Reference
Networks

Share. Care. Cure.

ERN Assessment Manual for Applicants

2. Technical Toolbox for Applicants



An initiative of the



History of changes

Version	Date	Change	Page
1.0	16.03.2016	<ul style="list-style-type: none">▪ Initial version	
1.1	21.04.2016	<ul style="list-style-type: none">▪ Typos correction▪ Deleted Annexe II▪ Page renumbering▪ Updated version of Appendix B and Appendix C Version 1.0 (pp. 38 & 39). Version 1.1 (pp. 20 & 21)	20 & 21 38 & 39

Preamble

This manual was designed to provide Network and Healthcare Provider Applicants with information and guidance on how to submit a proposal and complete the assessment and approval process for European Reference Networks. It is part of **series of nine** documents that include the following:

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

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

Technical Toolbox

The following tools are shared with the Network Coordinator and Healthcare Provider Representatives to support the application process and provide information about the assessment process for European Reference Networks.

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Application Forms for Networks and Healthcare Providers are available in the participant portal of the call for ERN and in the Europa webpage: http://ec.europa.eu/health/ern/implementation/call/more_info_en.htm



Annex I – Operational Criteria for Networks and Healthcare Providers

(Note: The full document is available under separate cover)

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Annex III – Application Checklist for the Networks and Healthcare Providers



APPLICATION CHECKLIST FOR THE NETWORK AND HEALTHCARE PROVIDERS

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

Network 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 from its Member State

Healthcare Provider 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 from its Member State
- The Healthcare Provider completed the self-assessment for Healthcare Providers with supporting documentation

Annex IV – Self-Assessment for Networks and Healthcare Providers



SELF-ASSESSMENT CHECKLIST FOR NETWORKS (**NOTE:** THIS SECTION IS A
SAMPLE ONLY - SELF ASSESSMENT CHECKLIST PROVIDED UNDER SEPARATE COVER
IN ACTIVE PDF FORM)

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:

- 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. 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 must have ready at the time the application is submitted all supporting documentation listed in **Appendix B**. These documents should be made available to the IAB, at their request.

THE SELF-ASSESSMENT CHECKLIST TOOL FOR EUROPEAN REFERENCE NETWORKS

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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
1.2.3 The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		X

1.3.2 The Network is governed by a Board composed of one representative from each Member in the European Reference Network.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* 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 **Appendix B** for the full list of supporting documentation required.

APPENDIX A: 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	%

APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR NETWORKS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- **Measure 1.2.3** Mission, Vision, Initial Strategic Plan
- **Measure 1.3.1** Network Organogram and Written Statements of Members' Role and Responsibilities
- **Measure 1.3.2** Board Terms of Reference
- **Measure 7.1.2** Communication Strategy and Plan
- **Measure 7.1.3** Collaboration Strategy with Affiliated Partners

ATTACHMENT B —PATIENT EMPOWERMENT

- **Measure 2.2.1** Sample of information provided to patients and families, i.e. Brochures, Web-site
- **Measure 2.2.5** Patient Experience Survey(s) and/or planned activities and timelines to establish a common tool

ATTACHMENT C – ORGANISATION OF CARE

- **Measure 2.1.1** Patient Pathways and/or Planned Actions and Timelines
- **Measure 3.1.2** Guides/Recommendations on Multidisciplinary Teams
- **Measure 4.3.1** Clinical Guidelines and/or planned activities and timelines for developing Guidelines
- **Measure 4.3.2** Policy on the declaration and management of conflict of interest regarding clinical guidelines, patient pathways, and clinical decision making tools
- **Measure 4.3.3** Cross Border Pathways and/or planned actions and timelines to develop cross border pathways

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM

- **Measure 2.1.4** List of Diagnostic Technologies and Services Certified or Accredited through National, European, and/or International Programs provided by Network Members
- **Measure 2.2.3** Published Annual Reports and/or Planned actions and Timelines for Patient Safety Data Collection and Reporting
- **Measure 4.4.1** List of performance and outcome indicators and their definitions
- **Measure 4.4.2** Quality and Safety Framework (including Adverse Events Reporting System)

ATTACHMENT E- RESEARCH AND TRAINING

- **Measure 5.1.2** Strategic Research Plan
- **Measure 5.1.3** Annual Report on Research Projects and Clinical Trials and/or planned actions and timelines to develop the Report
- **Measure 6.1.1** Annual Education Work plan

APPENDIX C: DECLARATION FORM *(THIS IS A SAMPLE ONLY)*

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

INTRODUCTION

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

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

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

DESCRIPTION OF THE SELF-ASSESSMENT TOOL

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

General criteria and conditions for Healthcare Providers¹

- Patient Empowerment and Patient Centred Care
- Organisation, Management, and Business Continuity
- Research, Education, and Training
- Expertise, Information Systems, and e-Health Tools
- Quality and Safety

Specific criteria and conditions for Healthcare Providers with regard to the area of expertise, disease or condition²

- Competence, Experience, and Outcomes of Care
- Human Resources
- Organisation of Patient Care
- Facilities and Equipment

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

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

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

INSTRUCTIONS FOR COMPLETING THE SELF-ASSESSMENT

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

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

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

Rating	Guidelines
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 score for each section using the template provided in **Appendix A**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.
6. Use this information to develop an Action Plan to improve readiness to submit the application and complete the assessment process.
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;
 - Identify any inconsistency in practice across the Network; and
 - Identify areas of best practice that could be shared across the Network.


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

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

THE SELF-ASSESSMENT CHECKLIST TOOL FOR HEALTHCARE PROVIDERS

Criteria and conditions for Healthcare Providers³

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 are respected.					
Measurement Elements	0	1	2	Comments	 *
1.1.1 The Healthcare Provider's commitment to patient-centered care is formally and consistently communicated with patients and their families.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
1.1.4 The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
1.1.5 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* 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 **Appendix B** for the full list of supporting documentation required.

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

APPENDIX A: SCORING TABLE *(THIS IS A SAMPLE 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%

APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- **Measure 1.1.1** Mission and/or Core Values ([English_Summary](#))
- **Measure 2.1.1** Organization chart ([English_Summary](#))
- **Measure 1.7.1** Conflict of Interest Policy ([English_Summary](#))
- **Measure 2.3.1** Business continuity plan ([English_Summary](#))

ATTACHMENT B – PATIENT EMPOWERMENT ([English_Summary of all B measures](#))

- **Measure 1.1.3** Sample of Patient Education Materials
- **Measure 1.1.5** Written Material Describing Patient and Family Rights and Responsibilities
- **Measure 1.3.1** Patient Experience Survey and Sample Patient Experience Reports
- **Measure 1.5.1** Informed Consent Policy and Procedure ([English translation of one sample + documents in original language](#))

ATTACHMENT C – ORGANISATION OF CARE ([English_Summary of all C measures](#))

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

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM ([English_Summary of all D measures](#))

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

ATTACHMENT E – RESEARCH AND TRAINING ([English_Summary of all E measures](#))

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

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 Healthcare Provider Representative		
Signature:		
Declaration of the Network Coordinator		
<p>I confirm that this self-assessment is an accurate and true reflection of the compliance status of the Healthcare Provider against the Operational Criteria and that all supporting documentation listed in Appendix B are prepared and ready for submission, at the IAB's request.</p>		
Signature:	Name:	Date:



Annex V – Interview Guide for Completing Virtual Interviews with Applicants

As a complement to the documentation review, the assessors also complete virtual interviews with the Network Coordinator and 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*” based on the results of the eligibility check.

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, as applicable;
- 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 Networks and Healthcare Providers 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. Once this information is received, the Assessment Coordinator will arrange for the conference call/virtual interview and send out call instructions. The Network Coordinator 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 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 <ul style="list-style-type: none">• Overview of Governance Structure• Status of Network Objectives and Timelines• Successes? Challenges and Barriers?	Network Coordinator/Board Member(s)	10
3.	General topics to be covered <ul style="list-style-type: none">• Transfer of Knowledge re: innovative medicine?• Dissemination of best practice information? Methods to share expertise? Information and Communication Tools (ICT) 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 the Network or 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 and the Healthcare Provider Representatives must be present throughout the virtual interview. One or two members of the Network's Board may also be asked to attend for a portion of the interview.

The Applicant may invite key stakeholders, as appropriate, pending the topics to be covered during the call. In addition, the Assessment 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 Assessment Coordinator 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. The Assessment Coordinator will inform the Applicant directly of the outcome of this stage of the assessment.

Annex VI - 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
<p align="center">Operational Criteria for the Network and Operational Criteria for Healthcare Providers:</p> <p align="center">Site 1: Coordinating Member on behalf of the Network</p>	
<p>Operational Criteria for Healthcare Providers:</p> <p>Site 2</p>	<p>Operational Criteria for Healthcare Providers:</p> <p>Site 3</p>

Day 1: [Date]

Day 1	Name of Assessor 1	Name of Assessor 2
<p>1300-1600</p>	<p>Planning Day (Assessors only):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Organisational charts (Network and Healthcare Providers) <input type="checkbox"/> Annual reports and strategic plans (Network and Healthcare Providers) <input type="checkbox"/> Assessor ratings and notes from documentation review and virtual interviews, and copies of the application forms and self-assessments – should the preliminary report be available and have been sent to Network Coordinator <input type="checkbox"/> Reports from other assessment bodies (if used for evidence of general criteria of Healthcare Providers) <input type="checkbox"/> Examples of published research, clinical protocols, guidelines in use on site, <input type="checkbox"/> Schedule for reviewing and planning on-site audit activities <p><u>Note:</u> Documentation may be made available in electronic format</p>	

Day 2: Date (Site 1: Coordinating Member)

Day 2	Name of Assessor 1	Name of Assessor 2
8:00-8:15	<p>Introductory Meeting (Network):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Welcome and Introductions <input type="checkbox"/> Objectives of the Onsite Audit 	
8:15-12:00	<p>Group Discussion (Network Leaders):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Overview of the Network and key successes and challenges <input type="checkbox"/> Review of preliminary report from documentation review and virtual interviews <input type="checkbox"/> Governance structure (Board of the Network and composition) <input type="checkbox"/> Area of expertise and range of services <input type="checkbox"/> Network objectives and timelines <input type="checkbox"/> Network contributions (clinical practice guidelines, education and training, and research activities) <input type="checkbox"/> Quality improvement initiatives, patient registry and performance indicators <p>Focus Group (Network Collaborators):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient organisations and/or patient representatives <input type="checkbox"/> Other Healthcare Providers involved in the continuum of care, specific to the patient population <input type="checkbox"/> Academics <input type="checkbox"/> Other stakeholders from the community, as appropriate <p>On-Site Documentation Review (Assessors Only):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Terms of reference and meeting minutes for the Network and the Board <input type="checkbox"/> Sample of recent publications <input type="checkbox"/> Sample of education and training materials for the team <input type="checkbox"/> Clinical practice guidelines <input type="checkbox"/> Quality improvement plan, proposed indicator data collection, patient registry (actual and planned) 	
12:00-13:00	<p>Lunch and Assessor information exchange</p>	
13:00-15:30	<p>Group Discussion (Multidisciplinary Team):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Overview of the programme- key successes and challenges <input type="checkbox"/> Roles and responsibilities as a coordinating member within the Network <input type="checkbox"/> Contributions of the Coordinating Member (clinical practice guidelines, education and training, and research activities) <input type="checkbox"/> Patient care pathways: patient involvement, patient safety, clinical outcomes <p>On-Site Documentation Review (Assessors Only):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Sample of personnel files, job descriptions, and training and competency assessments <input type="checkbox"/> Sample of representative patient files/chart audits <input type="checkbox"/> 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 <i>Network Coordinator</i>): <input type="checkbox"/> 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 and comments	
1530--1600	Review and debrief with the <i>Network Coordinator and MDT</i>	
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	<p>Group Discussion with Multidisciplinary Team (Healthcare Provider):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Welcome and introductions <input type="checkbox"/> Objectives of the site audit <input type="checkbox"/> Review of preliminary report <input type="checkbox"/> Overview of the role and its participation in Network, and key successes and challenges <input type="checkbox"/> Validation of general criteria <input type="checkbox"/> Evidence of specific criteria as defined by network <input type="checkbox"/> Objectives, action plan specific to healthcare provider and its role in the network <p>On-Site Documentation Review (Assessors Only):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Sample of personnel files, job descriptions, and training and competency assessments <input type="checkbox"/> Sample of representative patient files <input type="checkbox"/> Quality improvement plan and indicator data collection <p>Tour of the Environment of Care (Assessors and Healthcare Provider Representative):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Follow the path of the patient (tracer) <input type="checkbox"/> Care Protocols, clinical decision tools at the point of care 	<p>Group Discussion with Multidisciplinary Team (Healthcare Provider):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Welcome and introductions <input type="checkbox"/> Objectives of the site audit <input type="checkbox"/> Review of preliminary report <input type="checkbox"/> Overview of the role and its participation in Network, and key successes and challenges <input type="checkbox"/> Validation of general criteria <input type="checkbox"/> Evidence of specific criteria as defined by network <input type="checkbox"/> Objectives, action plan specific to healthcare provider and its role in the network <p>On-Site Documentation Review (Assessors Only):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Sample of personnel files, job descriptions, and training and competency assessments <input type="checkbox"/> Sample of representative patient files <input type="checkbox"/> Quality improvement plan and indicator data collection <p>Tour of the Environment of Care (Assessors and Healthcare Provider Representative):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Follow the path of the patient (tracer) <input type="checkbox"/> Care protocols, clinical decision tools at the point of care <input type="checkbox"/>
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 and comments	
15:00-17:00	Debrief with the Healthcare Provider Representative and Multidisciplinary Team	

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

Steps	Tasks
Logistics	<ul style="list-style-type: none"> <li data-bbox="477 510 1442 611">❑ Provide meeting space for Assessors' initial planning session, including access to printer, paper, shredder, extension cords for laptops, contact information while onsite, etc. <li data-bbox="477 653 1442 753">❑ Provide meeting space, telephone and/or teleconference access for Assessors to conduct information exchanges during the day, according to the schedule <li data-bbox="477 795 1224 827">❑ Arrange for large meeting space for the General Debriefing <li data-bbox="477 869 1390 900">❑ Provide access to an LCD projector and screen for the General Debriefing <li data-bbox="477 942 1430 1003">❑ Invite key stakeholders to the General Debriefing (e.g. Healthcare Providers, healthcare professionals, management, and Board members) <li data-bbox="477 1045 1433 1106">❑ Arrange for Assessors to have refreshments and a light lunch throughout the day <li data-bbox="477 1148 1409 1180">❑ Provide hotel suggestions and any transportation information to Assessors <li data-bbox="477 1222 1377 1283">❑ Prepare to discuss logistics during teleconferences with the Assessment Coordinator and Assessors
Preparation	<ul style="list-style-type: none"> <li data-bbox="477 1329 1419 1390">❑ 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 <li data-bbox="477 1432 1398 1533">❑ Inform board members and Healthcare Provider Representatives of when on-site audit will take place and confirm their participation as per the schedule activities <li data-bbox="477 1575 1419 1675">❑ 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 <li data-bbox="477 1717 1386 1749">❑ Prepare a list of current patients, as well as access to the patient records <li data-bbox="477 1791 891 1822">❑ Plan for interpreters, if needed <li data-bbox="477 1864 1425 1896">❑ Ensure that operational documentation is available on-site in its normal site

Steps	Tasks
	<p>(e.g. strategic, operational plans, clinical practice guidelines, etc.)</p> <ul style="list-style-type: none"> ❑ Arrange for Network Coordinator or Healthcare Provider Representative to prepare a 10-15 minute overview
Survey Schedule	<ul style="list-style-type: none"> ❑ 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	<ul style="list-style-type: none"> ❑ Contact the Assessment Coordinator to do the following: <ul style="list-style-type: none"> • 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 teleconference	<ul style="list-style-type: none"> ❑ 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: <ul style="list-style-type: none"> • hotel accommodations available in the area • travel suggestions • Assessor team’s expected time of arrival • directions to the hotel and Healthcare Provider



European
Reference
Networks

Annex VIII – Assessment Report Template for Networks

Share. Care. Cure.

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.

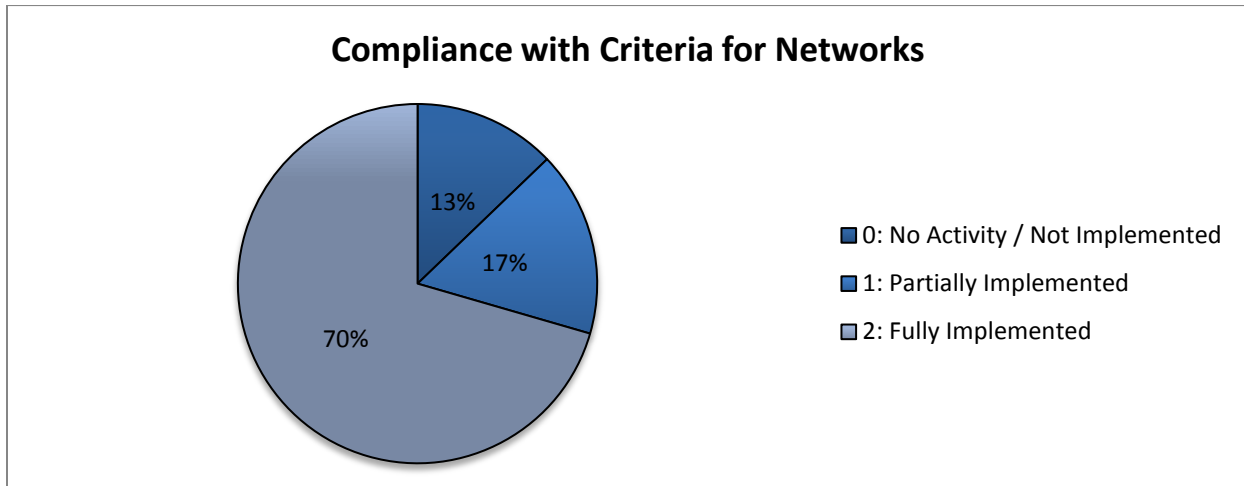
Objectives of the Network: [assessor comments]

Successes and Challenges: [assessor comments]

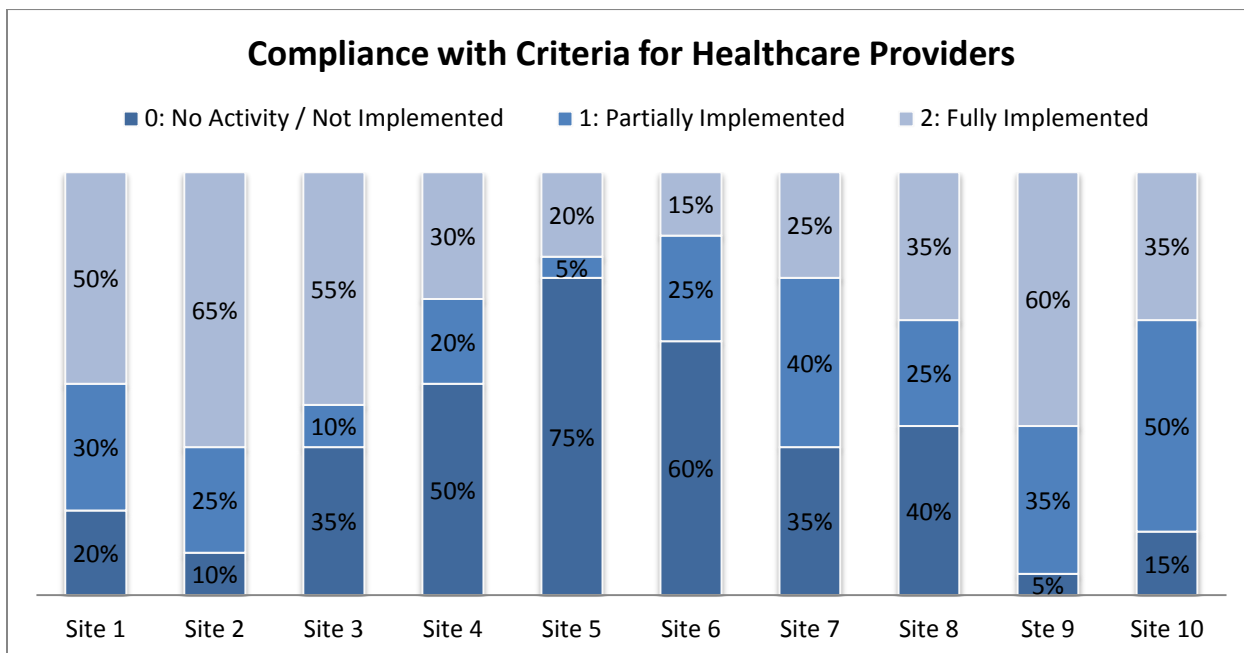
Response to Previous Recommendations (if applicable): [assessor comments]

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.



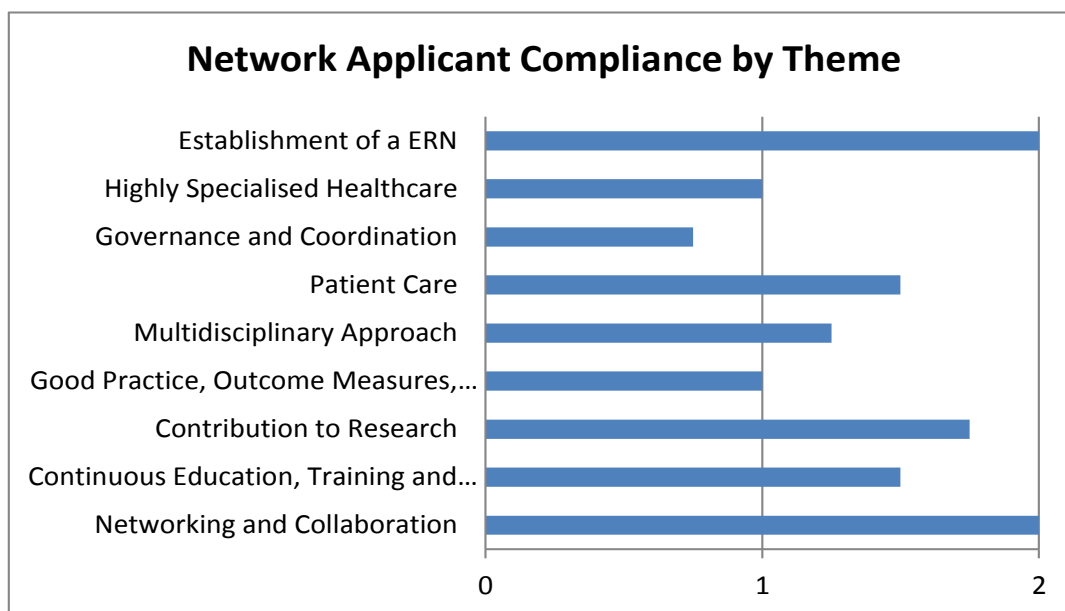
Overview by Themes

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:

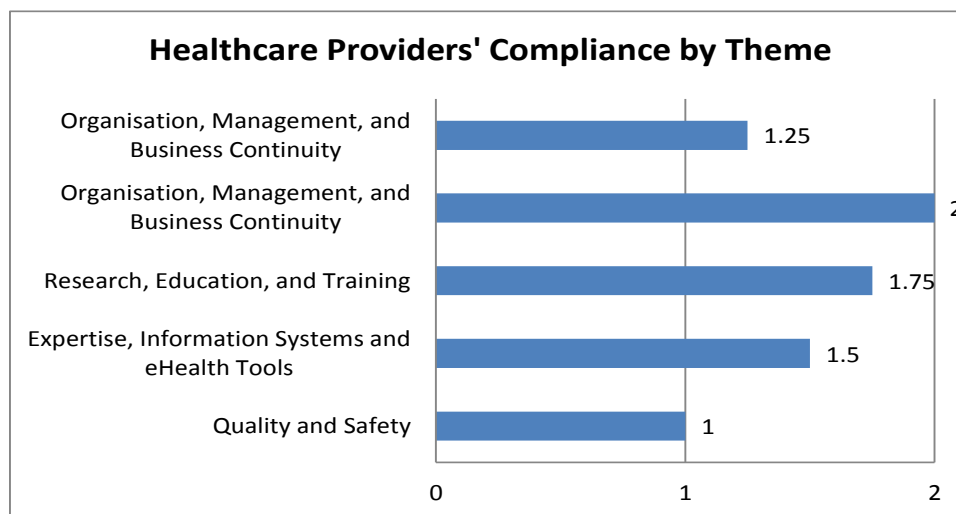
General Criteria and Conditions:

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 of 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

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 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).



European
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Annex IX – Assessment Report Template for Healthcare Providers

Share. Care. Cure.

Healthcare Provider's Assessment Report

Prepared for:

[Healthcare Provider's Name]

An initiative of the



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. 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]

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 Healthcare Provider.

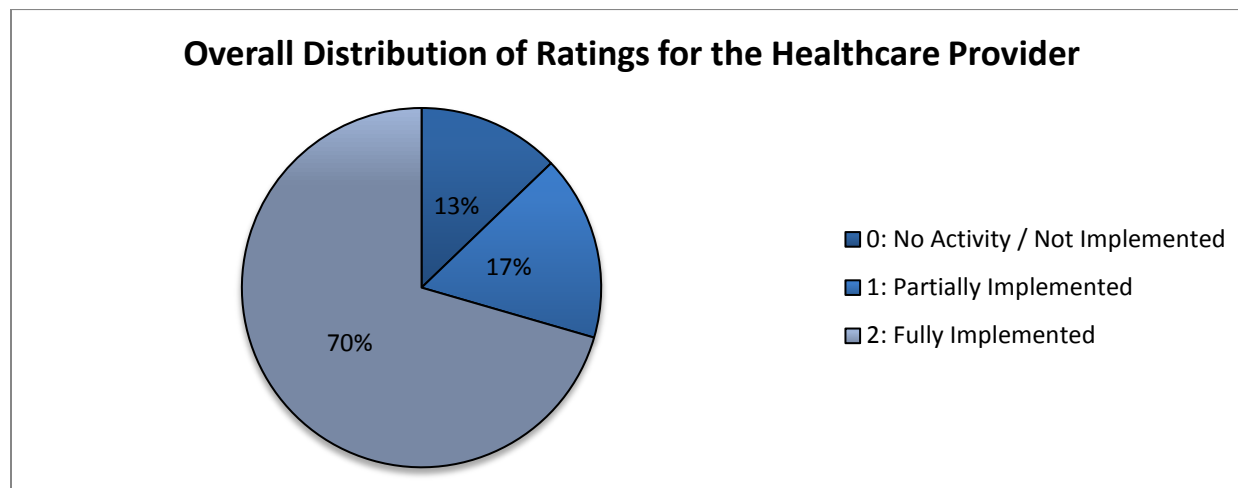
Role within the Network: [assessor comments]

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:

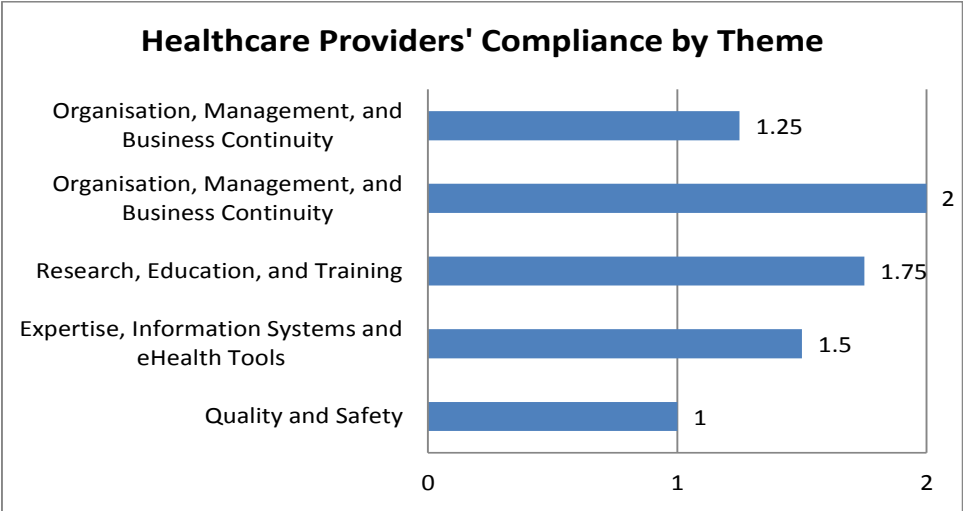
General Criteria and Conditions:

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 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%

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:

- 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 of 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.

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

Appendix A: Rating Scale

The following rating scale 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 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).

Annex X – Decision Guidelines for the Approval of a European Reference Network or Member



Recommendation by the Independent Assessment Body (IAB)

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

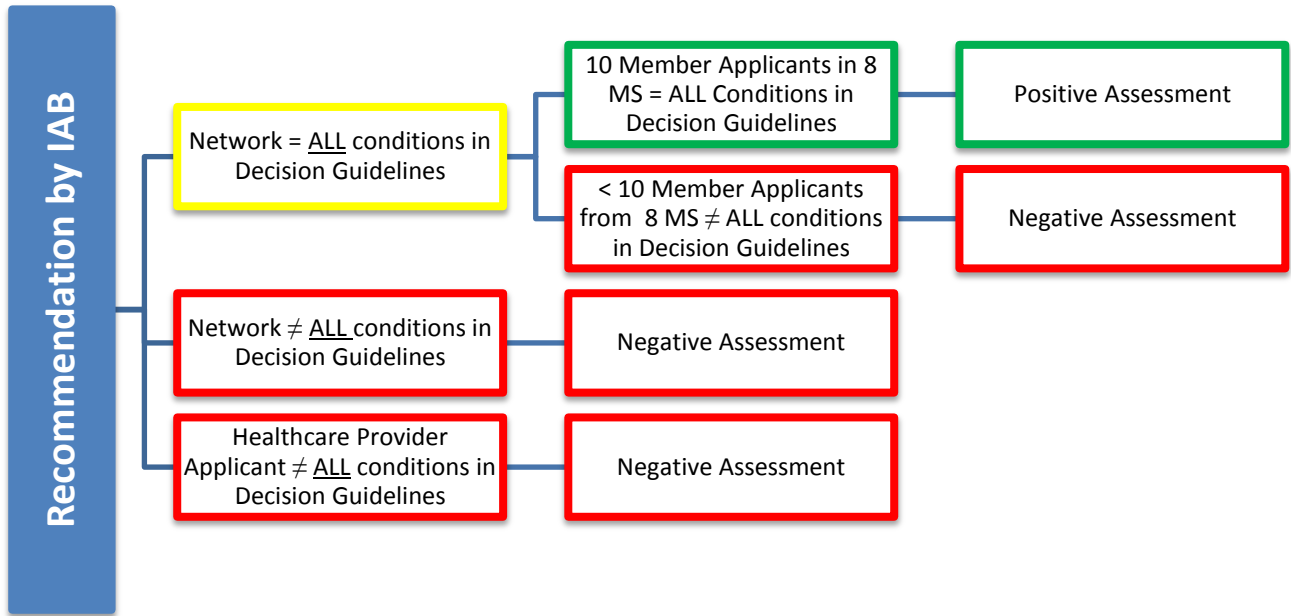
- An **overall compliance rate of 50% of the maximum score**
- A rating of “1” for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.
- There should be **no measurement elements under any theme rated as “0”**.
- **A minimum 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 for both 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 and their respective Network Applicants with a positive assessment can progress to the next stage as illustrated in the diagram below.



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.



European
Reference
Networks

ANNEX XI - SAMPLE LETTER OF ENDORSEMENT FOR HEALTHCARE PROVIDERS

<Date>

Contact Person
European Commission
<Address>

RE: Healthcare Provider National Endorsement

Dear Sir/Madam,

I, **<Insert National Authority>** certify that **<Insert Healthcare Provider's Name>** participation in the proposal to establish a European Reference Network is in accordance with the Member State's national legislation.

Sincerely,

<Signature of Representative>

<Insert Name of Representative of the National Authority>