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How to Perform a Self-Assessment and Prepare a Strong Application

Second EC European Reference Network Conference, Lisbon

Dr. Louise Clement and Paula Greco

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Partnership for Assessment of Clinical Excellence in European Reference Network (PACE-ERN)

Note: This document has been developed in the frame of a service contract signed between EURORDIS as contractor and Consumers, Health, Agriculture and Food Executive Agency (Chafea) as contracting authority. The opinions expressed in this document are those of the contractor only and do not represent European Commission's or Chafea 's official position.

Objectives

- Overview of the Assessment Process and Tools
- Description of the Operational Criteria
- Description of the Self-Assessment

Assessment Manuals and Technical Toolboxes



AMT for Applicants (Sample)

4. Stage 2: Application Process

At the second stage of the assessment programme, healthcare providers interested in forming a European Reference Network (ERN) or joining an existing ERN are invited to respond within **3 months following the posting** of the call for interest by the European Commission (EC). To be considered for the establishment of an ERN, a minimum of 10 Applicant Healthcare Providers from a minimum of 8 Member States (MS) are needed to participate in the application in line with the Commission Implementing Decision, Article 2 (2014/287/EU). The following diagram summarises the key steps of this stage in the assessment programme.



4.1 Completing the Application Forms for Networks and Applicant Healthcare Providers

4.1.1 Description

All Networks and Applicant Healthcare Providers are required to complete application forms. Two separate application forms are available under the documents section in the call for interest: one for the establishment of an ERN and a separate form for Applicant Healthcare Providers. The application forms for the Network and the Applicant Healthcare Providers should be combined into one file for submission to the European Commission. Application forms include a description of the Network and Applicant Healthcare Providers, area of expertise and scope of services, epidemiology of the disease(s) or condition(s), the added value of the Network, and common objectives in line with Annexes I and II in the Commission Implementing Decision (2014/287/EU).

4.1.2 Instructions for Network and Applicant Healthcare Providers

The Network must first complete **one** Application Form for Networks and circulate the completed form to the Applicant Healthcare Providers. As a next step, **each** Applicant Healthcare Provider (including the Coordinating Member for the Network) must complete the Application Form for Applicant Healthcare Providers and provide a written statement of support from its Member State. Once complete, the applications forms for the Applicant Healthcare Providers should be integrated into the application form for the Network.

Tip(s):

It is recommended that the Coordinator of the Network liaise with each Applicant Healthcare Provider Representative to complete the application form on behalf of the Network. In parallel, each Applicant Healthcare Provider liaises as needed to complete the Application Form for Applicant Healthcare Providers on behalf of the Applicant Healthcare Provider.

Tool(s):

Annex II includes a copy of the Application Forms for both the Network and Applicant Healthcare Providers.

4.2 Self-Assessment for Networks and Applicant Healthcare Providers

4.2.1 Description

As part of the application form and process, the Network and Applicant Healthcare Providers are required to complete a self-assessment against the Operational Criteria in accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex I (b). There are 2 self-assessment tools: **one** for the Network and **one** for the Applicant Healthcare Provider. The self-assessment is available under the documents section in the call for interest.

The self-assessment is a valuable step that can be addressed before the call for ERNs where both the Network and Applicant Healthcare Providers have the opportunity to assess themselves against the specific legislated criteria and conditions before submitting their application to the European Commission (EC). The self-assessment tool is available at the EUROPA website. The self-assessment offers guidance on the type of information required to demonstrate compliance with the requirements.

Once the call for ERNs is launched, the same self-assessment tool is used as the main mechanism for the Independent Assessment Body (IAB) to assess the compliance against the Operational Criteria. The information submitted through the self-assessment will help support a thorough documentation review and plan the on-site visit.

Roles and responsibilities

Key participants in preparing and submitting the application:

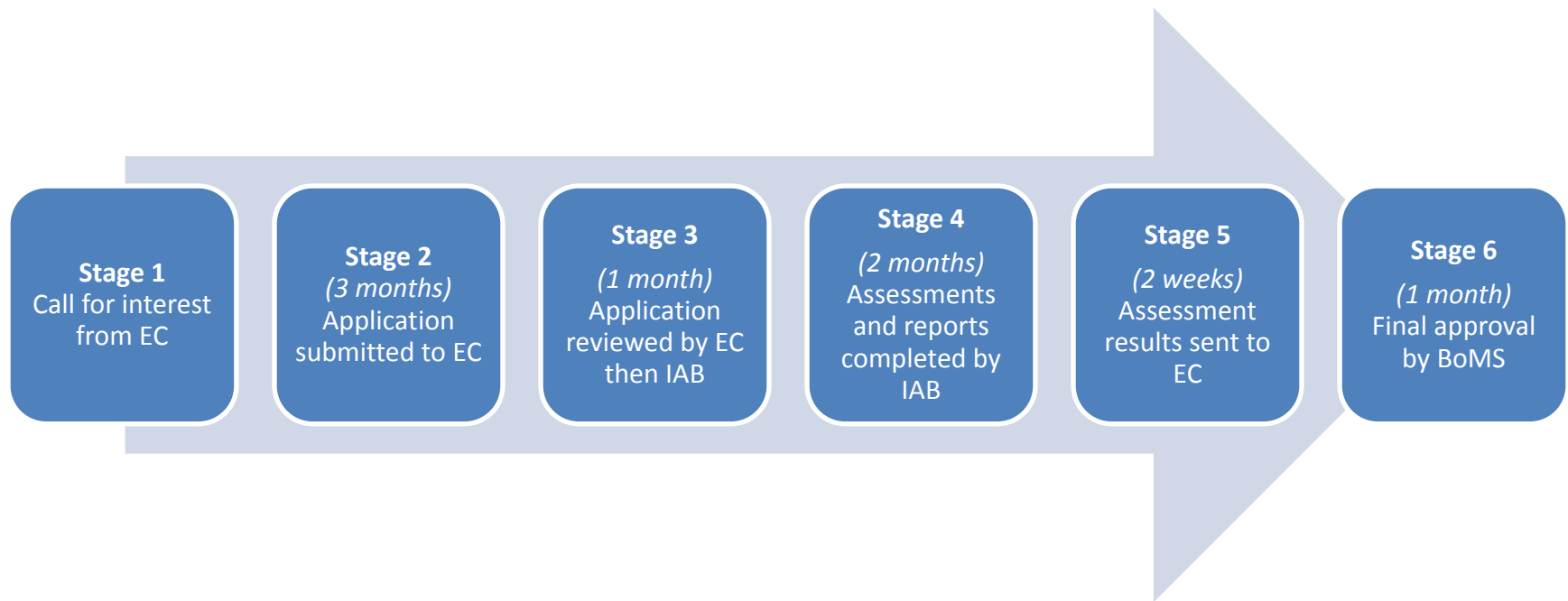
- Designate a Network Coordinator and Healthcare Provider Representatives
- Define how participants will work together



Assessment Process for Networks and Healthcare Provider Applicants

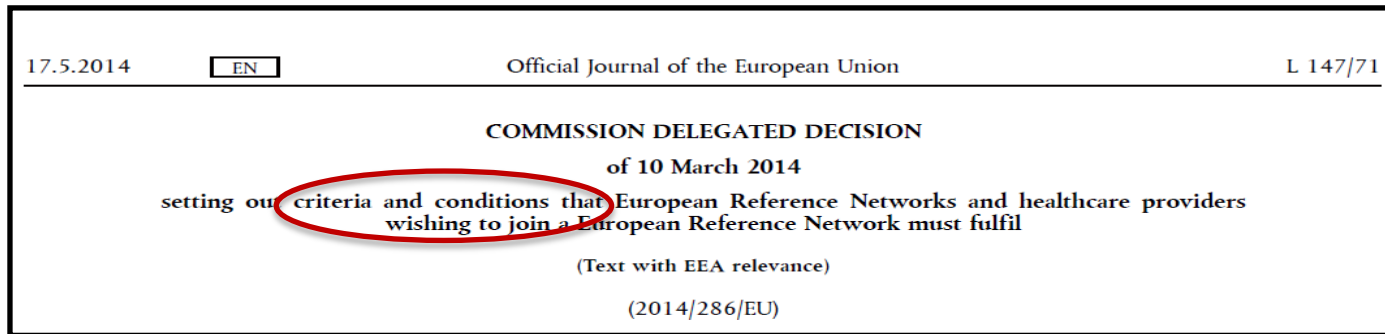
Overview of the Process

- Objectives of Process
- Six-Stage Process & 6-8 month Timeline
- Tool: Operational Criteria



Operational Criteria

Foundation: Commission Delegated Decision 2014/286/EU



Source Documents:

- Mapping Exercise:
 - Literature Review
 - Exhaustive Review (European and international)
 - On-site visits (x10 MS)
 - Written consultation questionnaire (30MS)
- Other literature and good practice documents

Operational Criteria

- Designed based on the following key principles:
 - To be *objective*
 - To be *measurable*
 - To be *specific and clear*
 - To be *achievable*
 - To improve *patient and family experience*
 - To encourage continuous *quality improvement*
- Consist of **two** sections: one for Proposed ERNs and one for Member Applicants

Operational Criteria


Organisation of the Operational Criteria

Networks

General Criteria and Conditions to be fulfilled:

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

Defined in the Network proposal and fulfillment assessed for each applicant healthcare provider. Based on the evidence and consensus of the scientific, technical and professional community



Healthcare Providers

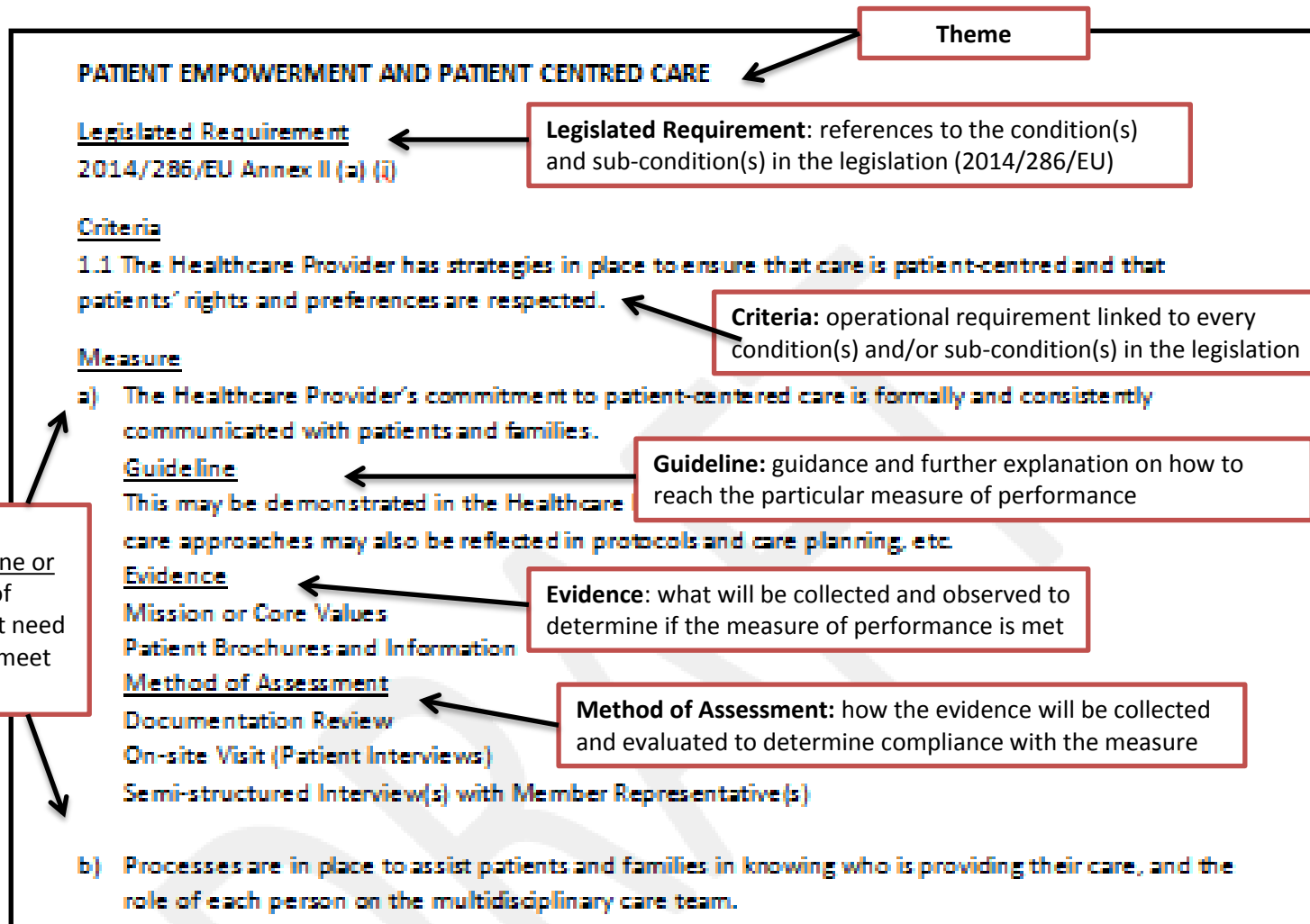
General Criteria and Conditions to be fulfilled:

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

Specific Criteria and Conditions to be fulfilled:

1. Competence, Experience and Outcomes of Care
2. Human Resources
3. Organisation of Patient Care
4. Facilities and Equipment

Operational Criteria Format



Operational Criteria (SAMPLE)

General Criteria and Conditions to be fulfilled by Networks:

GOVERNANCE AND COORDINATION

Criteria

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

Measure

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

Guideline

The Coordinating Member should be chosen on the basis of proven ability to coordinate and lead a Network as well as the medically relevant activities in the field of expertise. The best Coordinating Member may not necessarily be the best center of expertise or the one with the largest volume of patients, rather the one that has the capacity to fulfil all the key functions of coordination and to develop, promote, and expand the Network, as necessary. The Coordinator is selected from among the health professionals belonging to the Coordinating Member. The Coordinator, assisted by the Board, supports and facilitates coordination within the Network and with other Healthcare Providers. The Coordinator chairs the meetings of the Board and represents the Network. The Coordinator may also be supported by a Steering or Coordination Committee.

Evidence

Name of Coordinating Member and Network “Coordinator”; Rationale for selecting the designated Coordinating Member; Documented role and responsibilities of the Coordinating Member and “Coordinator”; Terms of Reference for the Steering or Coordination Committee, as applicable

Operational Criteria (SAMPLE)

General Criteria and Conditions to be fulfilled by Healthcare Providers:

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

Legislated Requirement

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

Criteria

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

Measure

- a) The Healthcare Provider provides patients and their families with written information specific to the area of expertise, disease, or condition.

Guideline

The information should include, at a minimum, the following: services offered; the nature of the disease, treatment and possible complications, rights and obligations, how to access the center; information about the staff and collaborating consultants; other members in the Network, and local and national patient support organizations.

Evidence

Patient Brochures and Information

Operational Criteria (SAMPLE)

General Criteria and Conditions to be fulfilled by Healthcare Providers:

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

Measure

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

Guideline

Patient and 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; maintain cultural practices; pursue spiritual beliefs; live at risk; and to be free from abuse, exploitation, and discrimination.

Patients and families should be given information about their rights and responsibilities at the earliest possible point in their trajectory of care. Information is adapted to meet diverse needs such as language, culture, level of education, lifestyles, and physical or mental disability.

Evidence

Written Material Describing Patient and Family Rights

Operational Criteria (SAMPLE)

Specific Criteria and Conditions to be fulfilled by Healthcare Providers:

COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

Legislated Requirement

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

Criteria

1.1 The Healthcare Provider maintains its competence in the Network's area of expertise and demonstrates good clinical care and outcomes.

Measure

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

Guideline

This includes, as an example, volume of activity such as number of prevalent and incident cases, number of referrals, and accumulated experience such as the number of published reports, peer-reviewed publications, grants, training activities, participation in projects, and clinical trials.

Evidence

Dashboard of Patient Activity Measures

Operational Criteria (SAMPLE)

Specific Criteria and Conditions to be fulfilled by Healthcare Providers:

Measure

- b) To maintain its competency and expertise, the Healthcare Provider defines the minimum/optimal number of patients to be served and/or procedures to be completed per year according to professional/technical standards or recommendations.

Guideline

The Healthcare Provider documents the minimum/optimal number of patients to be served and/or procedures to be completed per year. Competency may be systematically self-defined based on published evidence or the consensus of experts with validation from national or international experts.

Evidence

Policy, guideline or standard

Evidenced based rationale

Number of patients seen and/or procedures completed per year for the last three years

Stage 1: Call for Interest

Description

- First stage in the assessment process
- Published on the EUROPA website (DG Sante)
- Deadline for submission usually about 3 months
- National Endorsement by the Member State **for each** Healthcare Provider Applicant



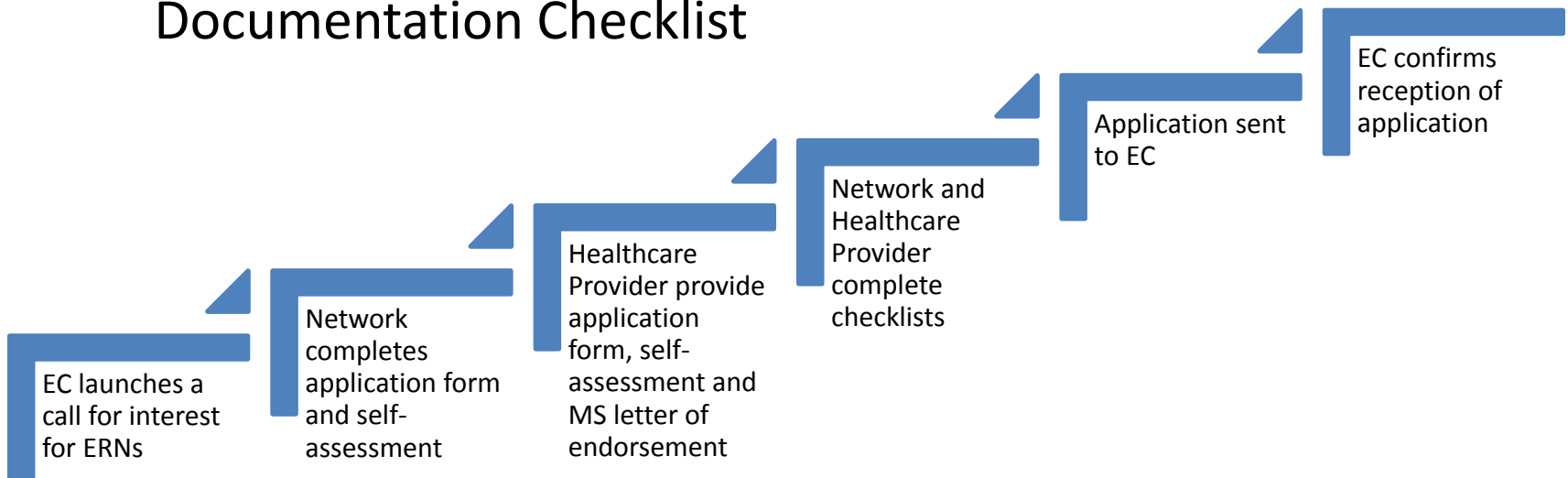
Define and agree on the specific disease(s) or condition(s) covered by the Network.

Set up regular teleconferences to coordinate the application activities and exchange information.

Stage 2: Application Process

Description

- Network should first review and define specific criteria
- Complete the Application Forms
- Complete the Self-Assessment and gather the evidence
- **Tools**: Application Forms, Self-Assessments, Documentation Checklist



Application Forms

- Two separate application forms for Networks and Healthcare Providers

Annex D – Application forms for the Network and Healthcare Provider Applicants



APPLICATION TO ESTABLISH A EUROPEAN REFERENCE NETWORK

Instructions

Please complete one Network Application Form in response to the call for interest for European Reference Networks. Each Healthcare Provider Applicant within the Proposed Network must also complete the Application Form for Healthcare Provider Applicants and provide a written statement of support from its Member State.

Each application must be accompanied by a completed Self-Assessment with the Supporting Documentation. Please refer to the Application Checklist for the Network and Healthcare Provider Applicants to ensure that all the necessary steps have been completed prior to the submission of the application to the European Commission.

EUROPEAN REFERENCE NETWORK APPLICATION FORM

EUROPEAN REFERENCE NETWORK INFORMATION

1. Network's Name:

2. Healthcare Provider Applicant acting as the Network Coordinating Member:

Name:

Address:

3. Individual acting as the Network Coordinator (must be from the Coordinating Member):

First Name: Last Name:

Title:

Tel: Email:

APPLICATION FORM FOR HEALTHCARE PROVIDER APPLICANTS

HEALTHCARE PROVIDER APPLICANT INFORMATION

1. Network's Name:

2. Healthcare Provider Applicant:

Name:

Address:

3. Chief Executive Officer of the Healthcare Provider Applicant:

First Name: Last Name:

Tel: Email:

4. Individual acting as the Lead or Representative for the Healthcare Provider Applicant:

First Name: Last Name:

Title:

Tel: Email:

5. Representative who will participate as a member of the Board of the Network:

First Name: Last Name:

Title:

Tel: Email:

6. Does the Healthcare Provider Applicant participate in a national or regional assessment programme?

Yes, at the national level

Yes, at the regional level

No

Not applicable

If yes, please describe:

Application Forms

- Application Forms include:
 - Description of the Network and Healthcare Provider, i.e. area of expertise, scope of services
 - Description of the disease(s) or condition(s)
 - Added-Value and objectives of the Network
- Combine application forms into one file for submission



First, complete the Network Application and circulate to each Healthcare Provider.

Second, each Healthcare Provider should complete the Form.

Third, the Coordinator should review all the Forms to ensure consistency.

The Self-Assessment

1. Create your team.
2. Considering the Network's vision, purpose, and objectives, review the Operational Criteria by theme.
3. Discuss each individual element of the criteria and evidence required.
4. Assess and rate against established criteria.
5. Prior to finalizing the self-assessment, validate the results internally to ensure consistency and completeness.

The Self-Assessment

Rating Scale

Comments

THE SELF-ASSESSMENT CHECKLIST TOOL FOR EUROPEAN REFERENCE NETWORKS



Operational Criteria

Documentation Required

I. GOVERNANCE AND COORDINATION						
1.1 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 aftercare, and follow-up.						
Measurement Elements	0	1	2	Comments		
a) The disease(s) or condition(s) are defined within a 'manual' or 'designation or licensing list'.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
b) The Network's area of expertise is well defined and the expected gains of centralising care for these	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
c) The objectives of the Network and its activities within Member States are clearly defined within the national specification (the mission and/or vision statement).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		X	
d) The Network has a well-defined strategic plan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		X	
e) The strategic plan is developed with input from patients, families and patient associations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
1.2 The Network has a clear governance and coordination structure that includes mechanisms to support oversight and assessment.						
Measurement Elements	0	1	2	Comments		
a) There is one representative and a designated lead from each member of the Network.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
b) The Network is governed by a Board of Directors composed of one representative from each Member in the Network.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		X	
c) The role and responsibilities of the Board are clearly defined and documented in a set of governance policies and by-laws.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
d) The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

The Self-Assessment

APPENDIX A: SCORING TABLE *(THIS IS A SAMPLE ONLY)*

Self Assessment Scoring Table			
Governance and Coordination			
Total Score out of a Possible 18		Percent of Total	%
Patient Care			
Total Score out of a Possible 18		Percent of Total	%
Multidisciplinary Approach			
Total Score out of a Possible 8		Percent of Total	%
Good Practice, Outcomes Measures, and Quality Control			
Total Score out of a Possible 12		Percent of Total	%
Contribution to Research			
Total Score out of a Possible 12		Percent of Total	%
Continuous Education, Training, and Development			
Total Score out of a Possible 4		Percent of Total	%
Networking and Collaboration			
Total Score out of a Possible 14		Percent of Total	%
Overall			
Grand Total out of a Possible 88		Percent of Total	%

APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR NETWORKS**

- Attachment A - Strategic Plan
- Attachment B - List of Board Policies and Bylaws
- Attachment C - Sample Referral Pathway
- Attachment D - List of Clinical Practice Guidelines
- Attachment E - Dashboard of Process and Outcome Measures
- Attachment F - Quality and Patient Safety Assessment Framework

***Please note that this is only a sample for display only. A comprehensive list of supporting documentation will be developed once the operational criteria have been finalized.*

DRAFT

Application Checklist



APPLICATION CHECKLIST FOR NETWORK AND HEALTHCARE PROVIDER APPLICANTS

The Network (EMN) and Healthcare Provider Applicants must complete the following steps before submitting their application 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 Applicant
- The Network Coordinator chairs the meetings of the Board of the Network
- The Network includes a minimum of 10 Healthcare Provider Applicants from 5 Member States
- The Network provides highly specialized healthcare for rare or low prevalence complex diseases or conditions
- All Healthcare Provider Applicants provide highly specialized healthcare for the same rare or low prevalence complex disease/condition or group of rare or low prevalence complex diseases/conditions
- The Network is pursuing at minimum three objectives from Article 12(2) of Directive 2011/24/EU
- The Network and all Healthcare Provider Applicants have completed the application forms and self-assessments with supporting documentation
- Each Healthcare Provider Applicant provided a written statement of support from its Member State

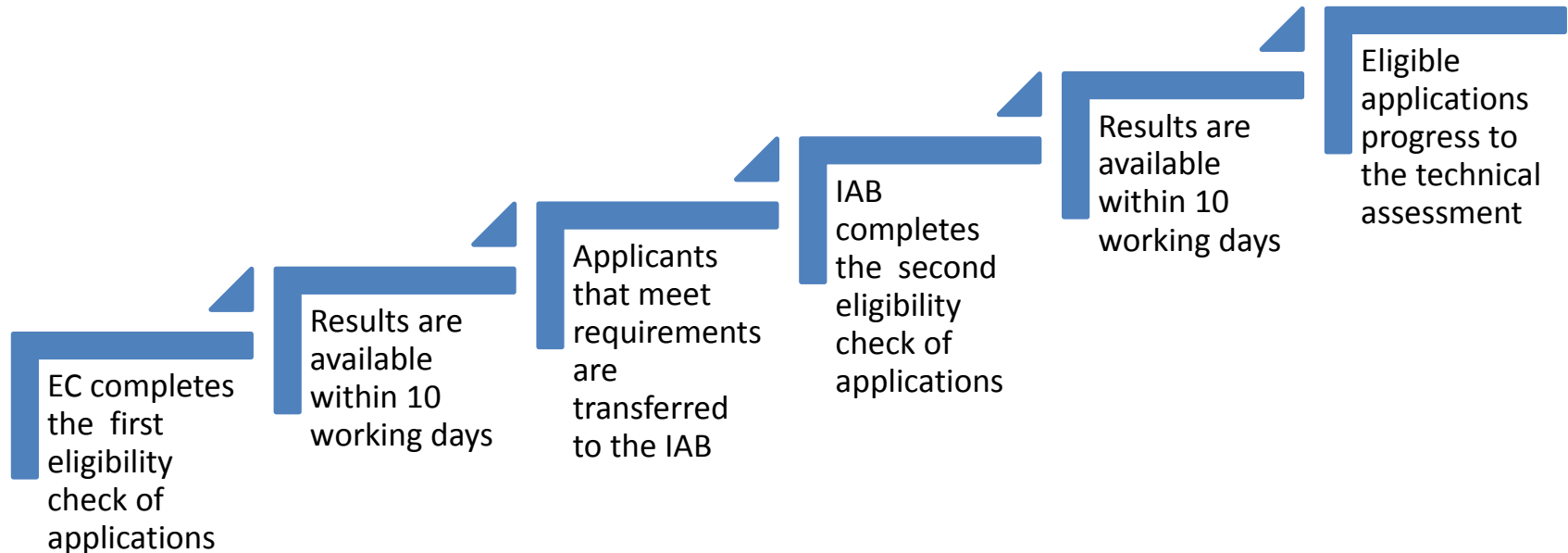
Healthcare Provider Applicant Checklist:

- The Healthcare Provider Applicant has an identified representative
- The Healthcare Provider Applicant has a representative on the Board of the Network
- The Healthcare Provider Applicant completed the application form for Healthcare Provider Applicants
- The Healthcare Provider Applicant obtained a written statement of support from its Member State
- The Healthcare Provider Applicant completed the self-assessment for Healthcare Provider Applicants with supporting documentation

Stage 3: Determining Eligibility for the Assessment

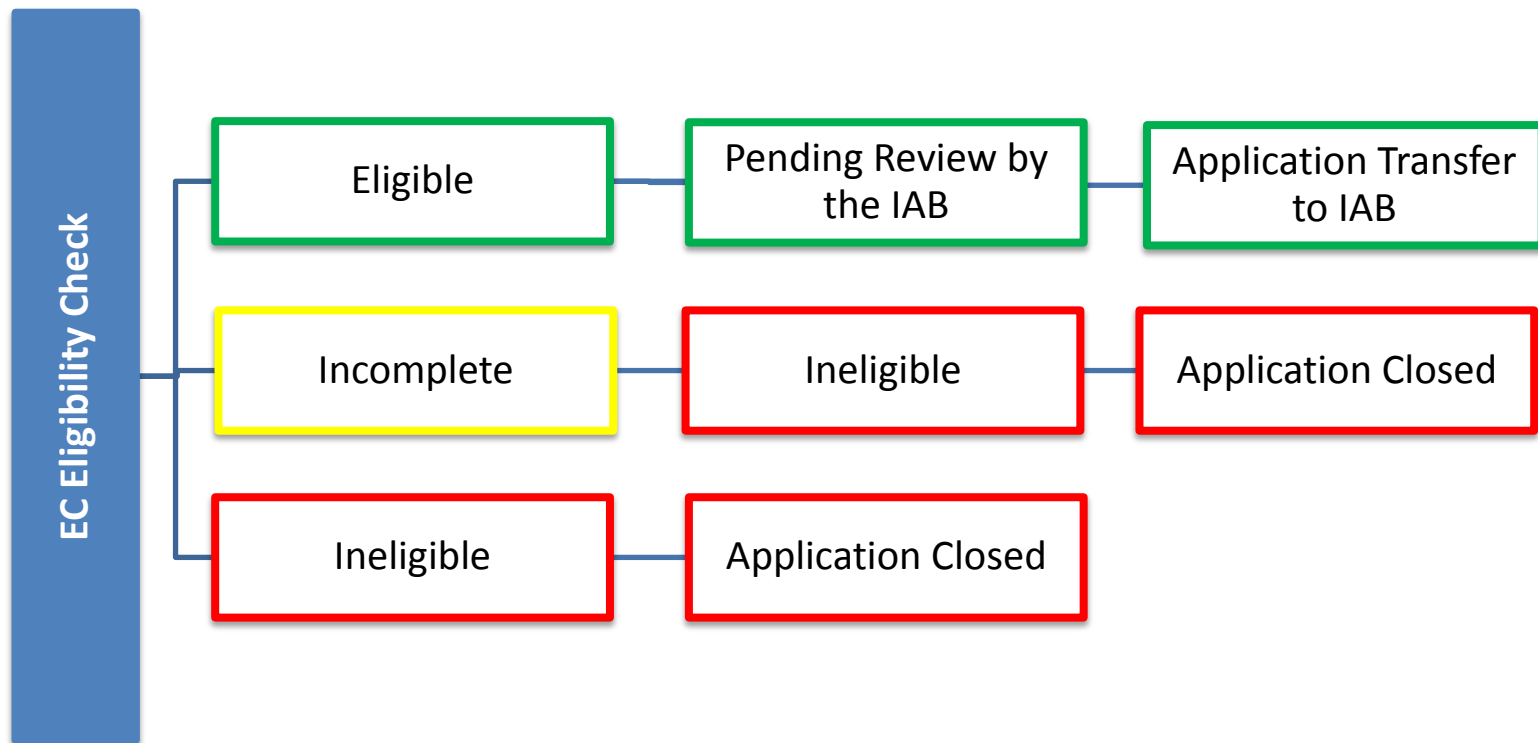
Description

- Completed by both the EC then IAB
- EC: Structural validation
- IAB: Content verification



Stage 3: Determining Eligibility for the Assessment *(continued)*

Validation of the Application by the EC *(1st Decision Point)*



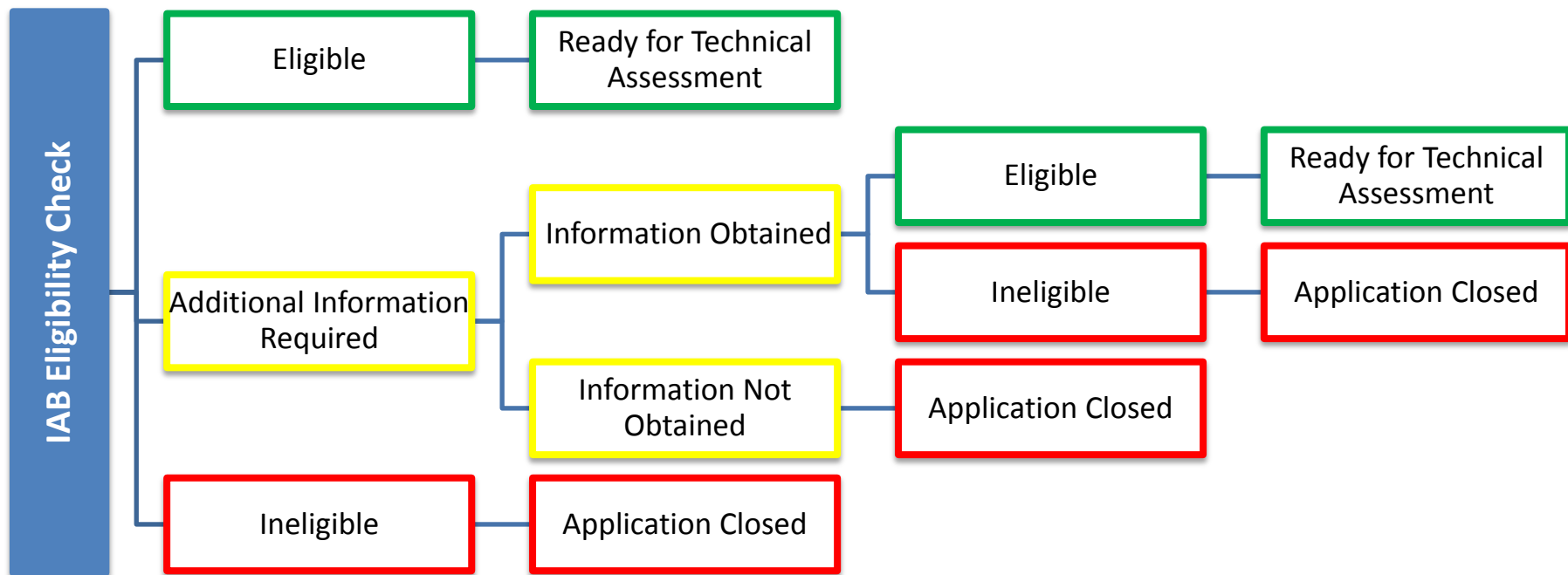
Stage 3: Determining Eligibility for the Assessment *(continued)*

Validation of the Application by the EC *(1st Decision Point)*

- The proposed ERN includes a minimum of 10 Member Applicants from 8 Member States
- The Network and all Healthcare Providers have completed the application forms and self-assessments with all supporting documentation
- Each Healthcare Provider has a written statement of endorsement from its Member State

Stage 3: Determining Eligibility for the Assessment *(continued)*

Verification of the Application by the IAB *(2nd Decision Point)*



Stage 3: Determining Eligibility for the Assessment *(continued)*

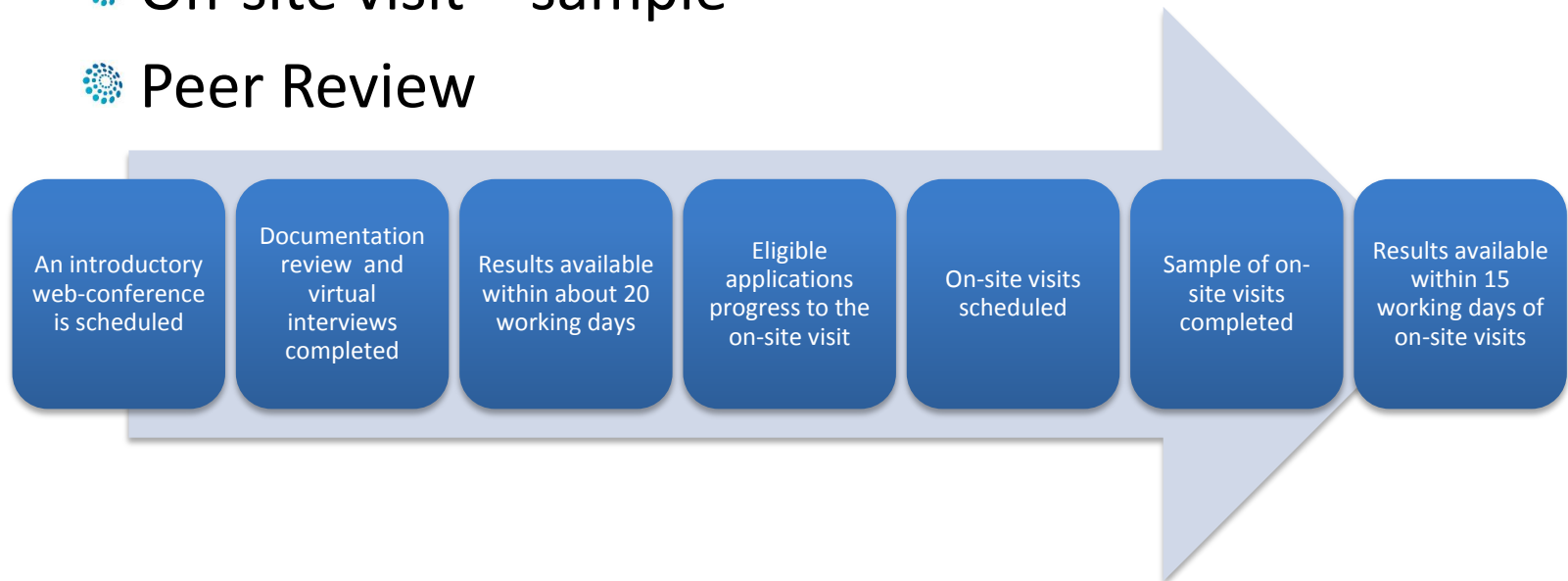
Verification of the Application by the IAB *(2nd Decision Point)*

- The content of the application for Networks fulfills the requirements of Annex I
- The content of the application for each Healthcare Providers fulfills the requirements of Annex II
- The Network fulfills the requirement to provide highly specialised healthcare
- All Healthcare Providers share the same area of expertise related to specialised healthcare for rare or low prevalence complex diseases or conditions

Stage 4: Technical Assessment

Three components:

- Documentation review of Network and all Healthcare Providers
- Virtual interview with Network Coordinator and Members
- On-site visit – sample
- Peer Review



Stage 4: Technical Assessment

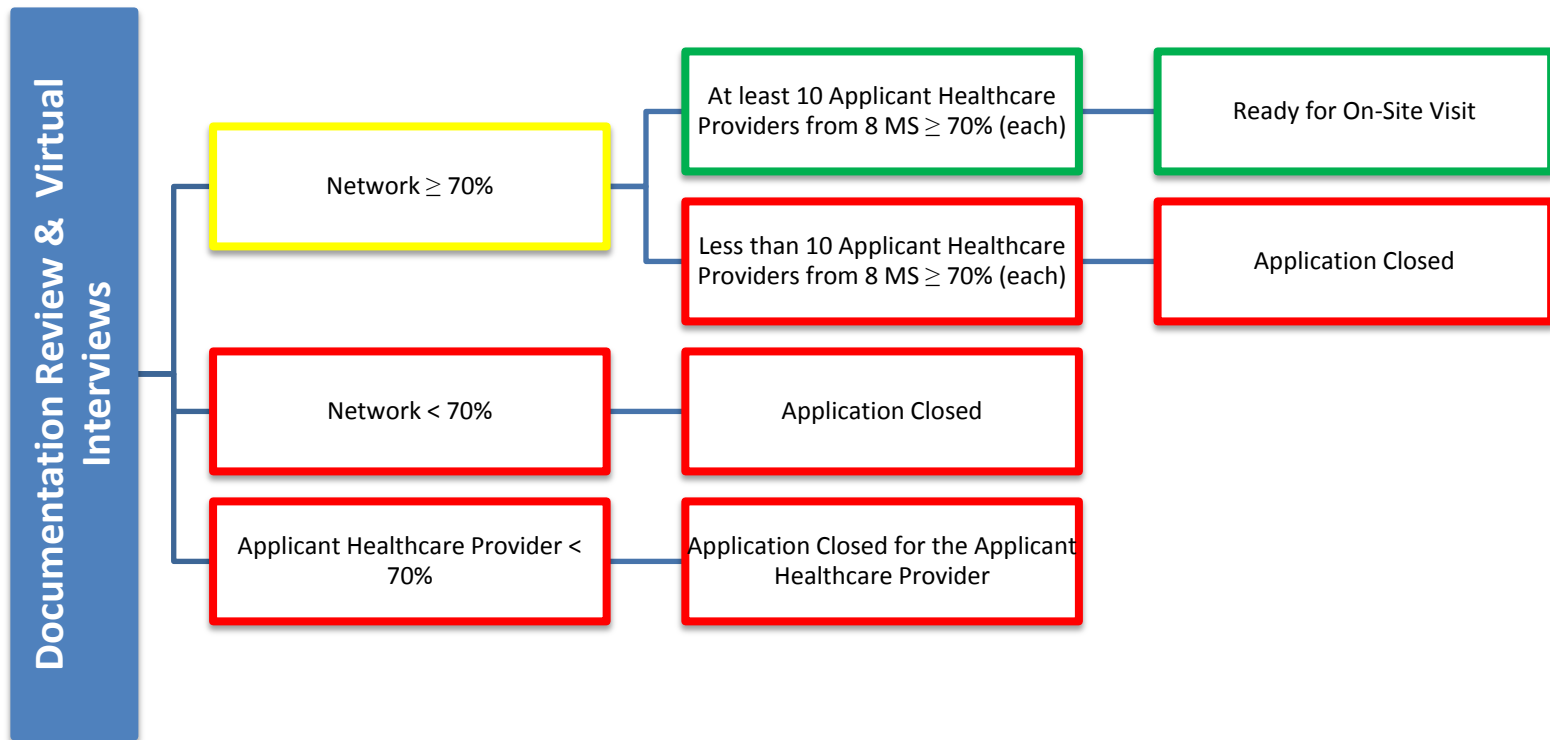
Documentation Review and Virtual Interviews completed by the IAB Assessors

- Validate process used to complete self-assessment to ensure rigor
- Verify self-assessments completed in similar manner across Healthcare Providers
- Verify sufficient evidence
- Rate compliance

Tools: Guidelines for Conducting Virtual Interviews

Stage 4: Technical Assessment

Documentation Review and Virtual Interviews (3rd Decision Point)



Stage 4: Technical Assessment

(continued)

On-Site Visits (*4th Decision Point*)

- Assessor Activities (documentation review, chart audits, interviews with multidisciplinary team members, patient tracer)
- Tools:** On-Site Visit Checklist and Template, *Patient Tracer Method*

Stage 4: Technical Assessment

(continued)

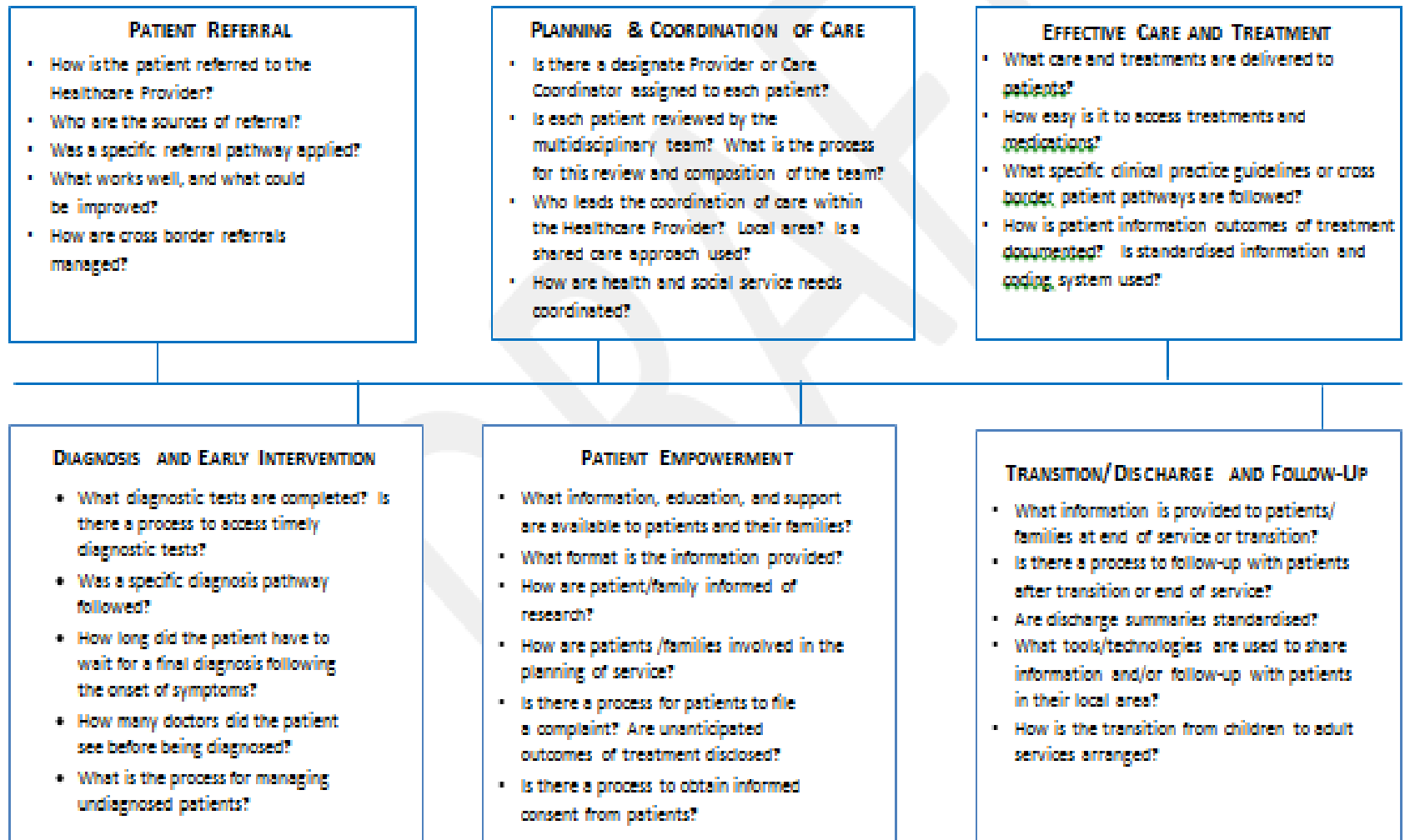
Sampling Methodology

- Specific role within the Network
- Highest and lowest compliance rate of the Operational Criteria based on the documentation review and virtual interviews
- Highest and lowest patient volume

Additional Criteria (random)

- Geographic representation
- Disease grouping representation

Patient Tracer



Onsite Visit Checklist



European
Reference
Networks

Annex J - On-Site Visit Checklist for Network and Healthcare Provider Applicants

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

Steps	Tasks
Logistics	<ul style="list-style-type: none"> <input type="checkbox"/> Provide meeting space for assessors' initial planning session, including access to printer, paper, shredder, extension cords for laptops, contact information while onsite, etc. <input type="checkbox"/> Provide meeting space, telephone and/or teleconference access for assessors to conduct information exchanges during the day, according to the schedule <input type="checkbox"/> Arrange for large meeting space for the General Debriefing <input type="checkbox"/> Provide access to an LCD projector and screen for the General Debriefing <input type="checkbox"/> Invite all stakeholders to the General Debriefing (e.g. Healthcare Provider Applicants, healthcare professionals, management, and Board members) <input type="checkbox"/> Arrange for assessors to have refreshments and a light lunch throughout the day <input type="checkbox"/> Provide hotel suggestions and any transportation information to assessors <input type="checkbox"/> Prepare to discuss logistics during teleconferences with the assessment coordinator and assessors
Preparation	<ul style="list-style-type: none"> <input type="checkbox"/> Communicate information to the Healthcare Provider Applicants on the on-site visit, the service(s) and location to be visited, as well as the assessor activities <input type="checkbox"/> Inform Board members and network collaborators of when on-site visit will take place and confirm their participation as per the schedule activities <input type="checkbox"/> For the duration of the on-site visit, assign a lead person to accompany the assessor and help in navigating and traveling throughout the site and in each service area, and connect the assessor to key healthcare professionals <input type="checkbox"/> Prepare a list of current patients, as well as access to the patient records <input type="checkbox"/> Provide assessors with a list of committee/programme meetings that are occurring at the time of the on-site visit

Stage 4: Technical Assessment

(continued)

Assessment Results

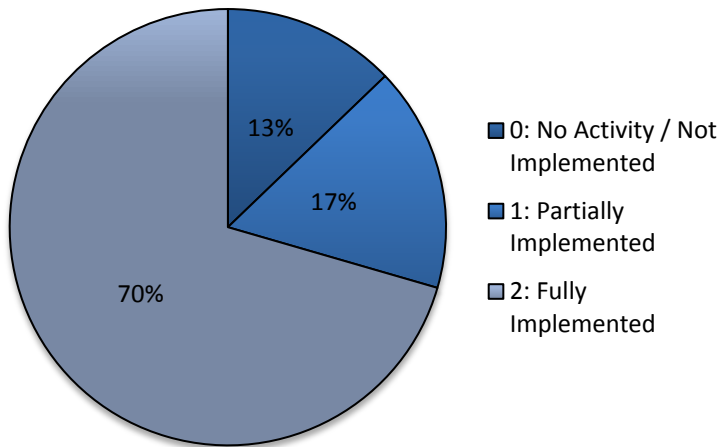
- 🌀 Assessment Reports for Network and Healthcare Providers
- 🌀 Applicant Submission of Comments
- 🌀 **Tools**: Report Templates for Networks and Healthcare Provider Applicants

Stage 4: Technical Assessment

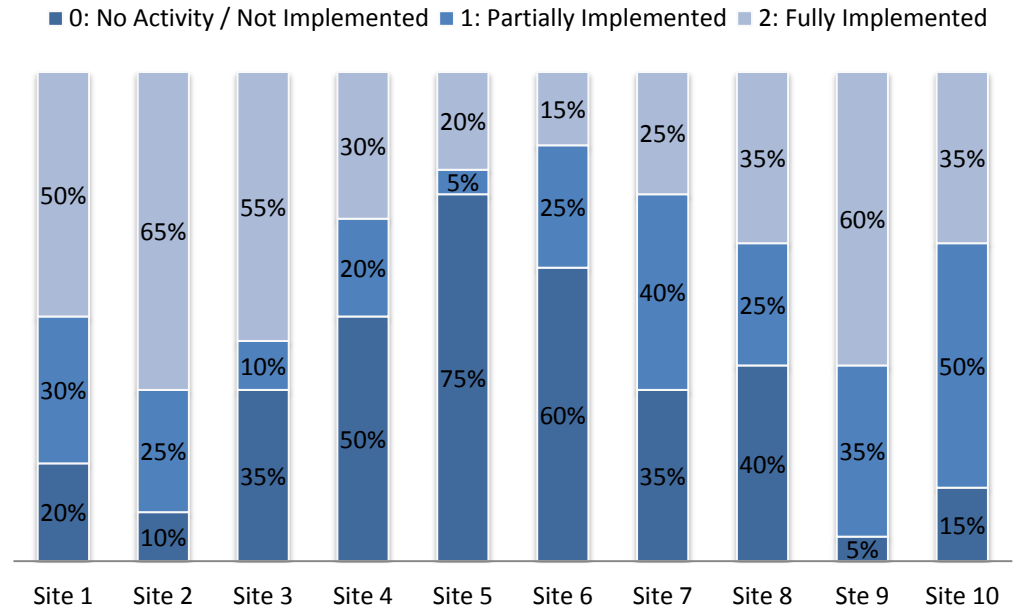
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Assessment Reports (Sample)

Compliance with Criteria for Networks



Compliance with Criteria for Healthcare Providers

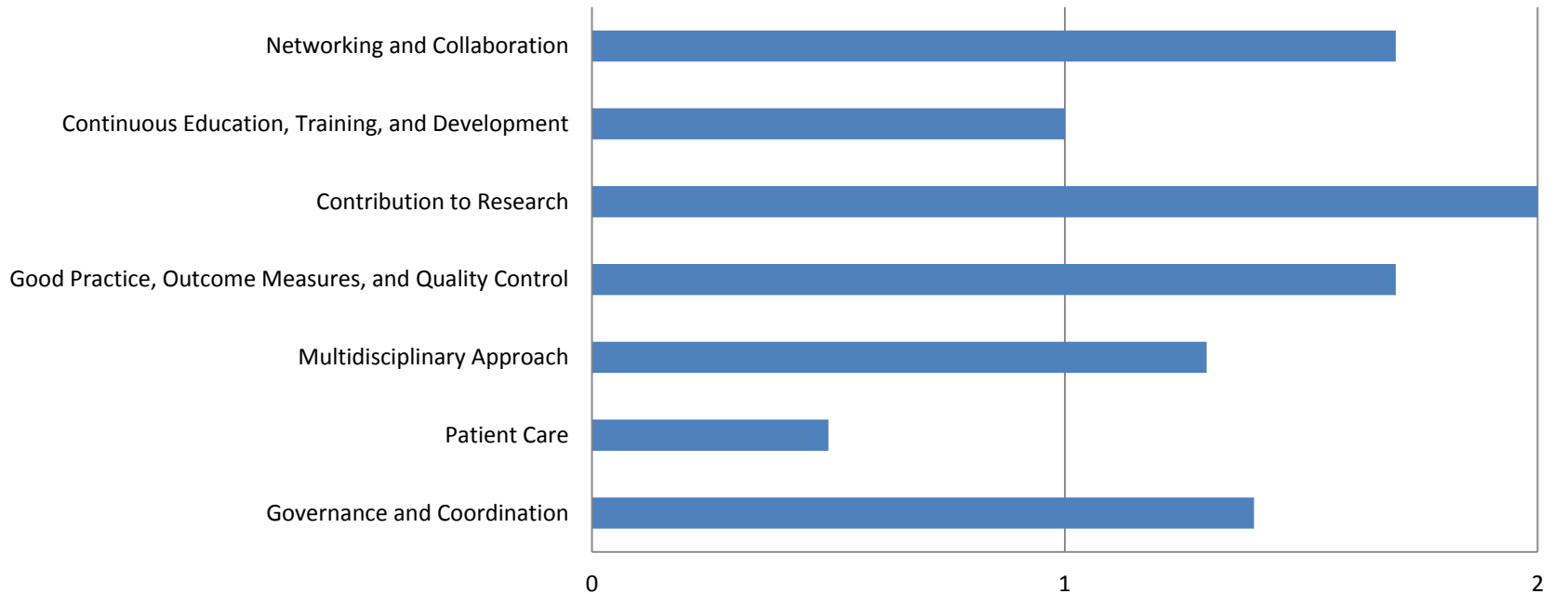


Stage 4: Technical Assessment

(continued)

Assessment Reports (Sample)

Network Compliance by Theme



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

Approval of Network and Healthcare Provider Applicants

Proposed decision guidelines:

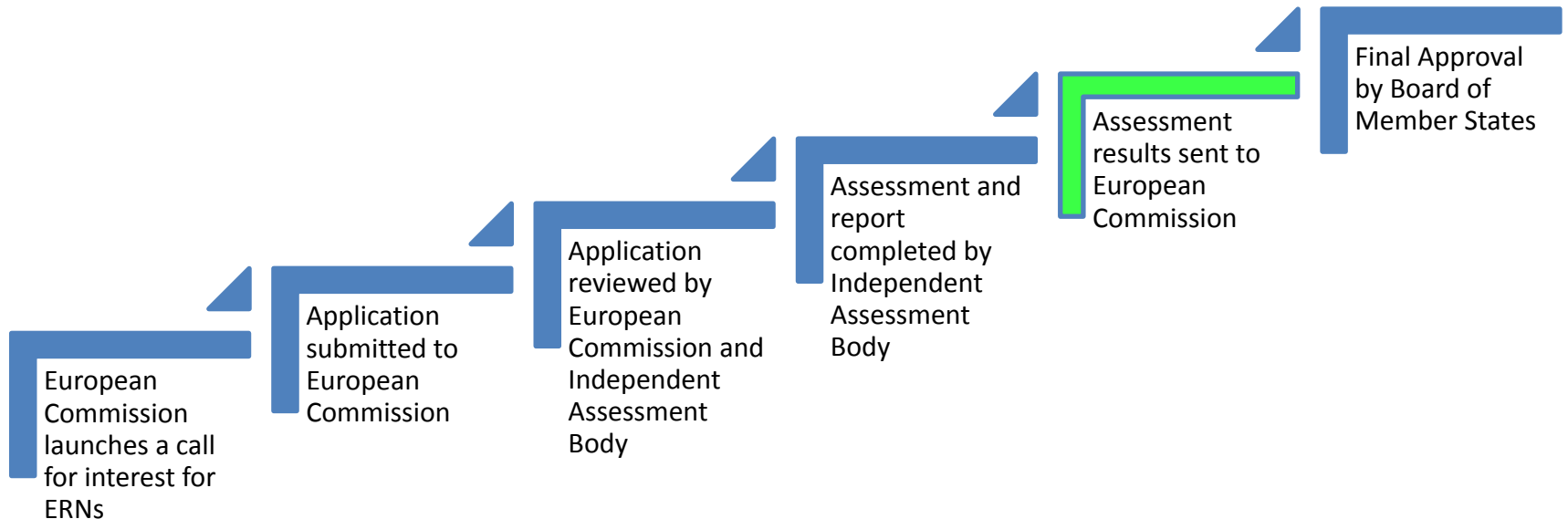
- Overall compliance rate of $\geq 70\%$ of the total maximum score
- For each theme, at least 70% compliance against the maximum score
- There should be no criteria under any theme rated as “0”.
- A rating of “1” for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place. There should be no more than 2 criteria in any theme rated as “1”.
- All core measurement elements must achieve a rating of 2.

Tool: Decision Guidelines

Stage 5: Assessment Results Submitted

Description:

- Transfer of Application Forms, Self-Assessment Forms and Positive Assessment Reports
- Review by Board of Member States

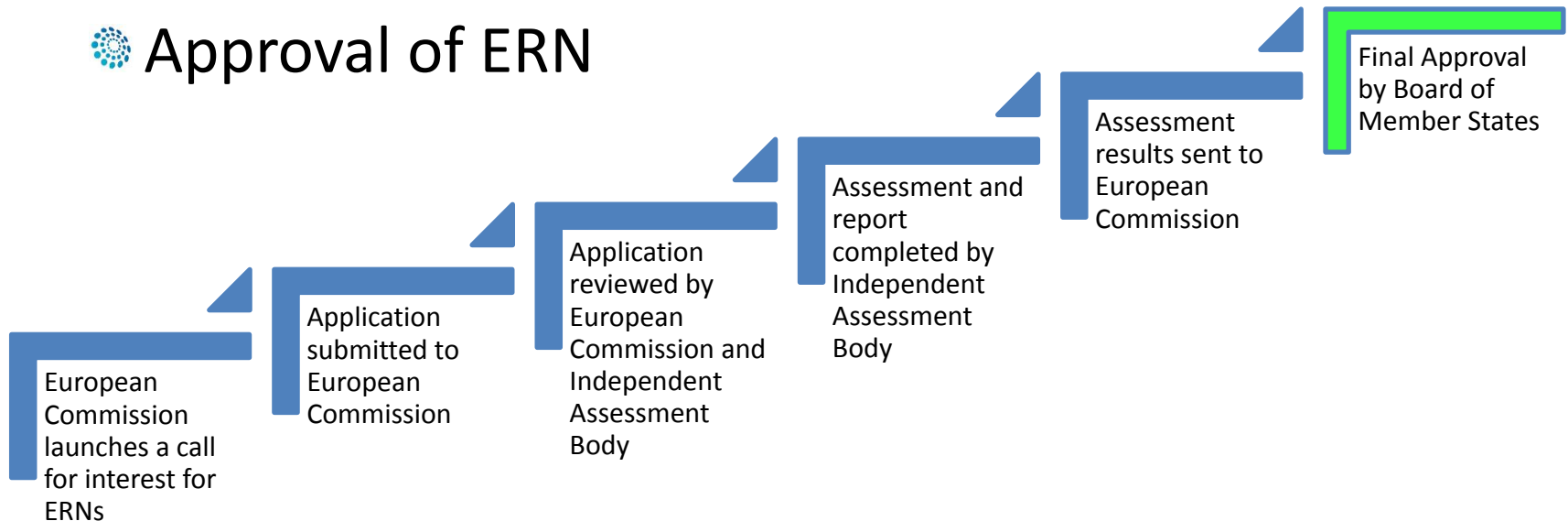


Stage 6: Final Approval

Description: (5th Decision Point)

- Board of Member States reviews the recommendation by the Independent Assessment Body

Approval of ERN



Summary of Key Points

Getting Ready.....

- Define your purpose and disease(s) or condition(s) based on supporting evidence
- Clear and well-defined governance and coordination structure
- Identify three objectives: actions, expected impacts, timelines
- As a Network, agree on the specific criteria thresholds for Healthcare Providers





Thank you!



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