ERN Minimum Requirements

Minimum requirements:
- 10 Healthcare Provider Applicants from 8 Member States
- Member State Endorsement

Network application:
- One Network Application (x1)
- Application for each Healthcare Provider (minimum of x10)
ERN Assessment Scheme

Member State

- MS Health System
- Hospital
- Endorsement by MS

Balanced Assessment

- Existing assessment of highly specialised care

European Union

- Assessment of Healthcare Provider
- Assessment for Network
- Decision Guidelines

Approval
Mapping Exercise

Highly Specialised Healthcare, Centres and Networks:

- Multidisciplinary approach is consistently present
- Greater inclusion of the patient voice seen as an improvement opportunity
- Diversity of experience with variable involvement of local care systems
- Focus on raising awareness, referral pathways and addressing delays in diagnosis
- Shared ambition to establish common, well-defined clinical data
- Sustainability of expertise and services provision is a priority

Existing national or regional healthcare assessment programmes:

- Consistent themes, but diversity of structure, process and monitoring
- Shared approach to defined clinical areas of concern and conditions through available evidence or consensus
- Variability in the maturity of assessment programmes
- Technical quality of the assessment process is valued by clinicians and support improvement
## Foundation for Assessment Process

<table>
<thead>
<tr>
<th>Technical quality as a foundation for assessment proposal:</th>
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<tbody>
<tr>
<td>- <strong>Self-assessment with external validation</strong> optimise efficacy and improve the quality of the services</td>
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<tr>
<td>- Effective assessment programme must involve <strong>multiple methods</strong> to assess quality</td>
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<td>- <strong>Patient involvement</strong> in the process of assessment improves the relevance of the assessment to patient care</td>
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<td>- <strong>Quality improvement framework</strong> supports sustainability</td>
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</table>
Assessment Manuals and Technical Toolboxes
Assessment Manuals and Technical Toolboxes

*(continued)*

<table>
<thead>
<tr>
<th>Common content</th>
<th>Additional items in EC and IAB manual</th>
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<tbody>
<tr>
<td><strong>Content for Applicants:</strong></td>
<td><strong>Content for EC and IAB:</strong></td>
</tr>
<tr>
<td>• Operational Criteria</td>
<td>• Same Content as Applicant Manual</td>
</tr>
<tr>
<td>• Overview of Six-Stage Process</td>
<td>• Instructions or Procedures from the EC &amp; IAB’s perspective</td>
</tr>
<tr>
<td>• Descriptions and Timelines</td>
<td>• Additional Sections:</td>
</tr>
<tr>
<td>• Instructions</td>
<td>• Conflicts of Interest</td>
</tr>
<tr>
<td>• Tips</td>
<td>• Eligibility Procedures and Checklist</td>
</tr>
<tr>
<td>• Tools</td>
<td>• Assessor Application and Selection Process</td>
</tr>
<tr>
<td>• References to EC Directives</td>
<td>• Assessor Training and Competency Review</td>
</tr>
<tr>
<td>• Glossary</td>
<td>• Assessor Checklists and Procedures</td>
</tr>
<tr>
<td></td>
<td>• Additional Technical Tools</td>
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</table>
## Operational Criteria (content)

### Organisation of the Operational Criteria

<table>
<thead>
<tr>
<th>Networks</th>
<th>Healthcare Providers</th>
</tr>
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<tbody>
<tr>
<td><strong>General</strong> Criteria and Conditions to be fulfilled:</td>
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<tr>
<td>1. Highly Specialised Healthcare</td>
<td><strong>General</strong> Criteria and Conditions to be fulfilled:</td>
</tr>
<tr>
<td>2. Governance and Coordination</td>
<td>1. Patient Empowerment and Patient-Centred Care</td>
</tr>
<tr>
<td>3. Patient Care</td>
<td>2. Organisation, Management, and Business Continuity</td>
</tr>
<tr>
<td>5. Good Practice, Outcome Measures, and Quality Control</td>
<td>4. Expertise, Information Systems, and e-Health Tools</td>
</tr>
<tr>
<td>6. Contribution to Research</td>
<td>5. Quality and Safety</td>
</tr>
<tr>
<td>7. Continuous Education, Training, and Development</td>
<td><strong>Specific</strong> Criteria and Conditions to be fulfilled:</td>
</tr>
</tbody>
</table>

**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

**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

*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.*
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’s commitment to patient-centered care is formally and consistently communicated with patients and families.

Guideline
This may be demonstrated in the Healthcare Provider’s mission and/or core values. Patient centered care approaches may also be reflected in protocols and care planning, etc.

Evidence
Mission or Core Values
Patient Brochures and Information
Method of Assessment
Documentation Review
On-site Visit (Patient Interviews)
Semi-structured Interview(s) with Member Representative(s)

b) Processes are in place to assist patients and families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.
Roles and responsibilities

Key participants in assessment of applications:

- Applicant – Network and Healthcare Providers
- Assessors – Independent Assessment Body(s)
- Member States
- European Commission
- Board of Member States
Assessment Programme for Networks and Healthcare Provider Applicants

- Operational Criteria
- Six-Stage Process
- Tools

Stage 1: Call for interest from EC
Stage 2: Application submitted to EC
Stage 3: Application reviewed by EC then IAB
Stage 4: Assessments and reports completed by IAB
Stage 5: Assessment results sent to EC
Stage 6: Final approval by BoMS
Stage 1: Call for Interest

**Stage 1:**

- First call for expressions of interest published
- Network defines area of expertise
- National endorsement of Healthcare Provider by the Member State

- Application submitted to European Commission
- Application reviewed by European Commission and Independent Assessment Body
- Assessment and report completed by Independent Assessment Body
- Assessment results sent to European Commission
- Final Approval by Board of Member States
Stage 2: Application Process

Stage 2:
- Complete application form for the Network and Healthcare Providers
- Complete self-assessment checklist with supporting documentation
Stage 3: Determining Eligibility for the Assessment

Stage 3:
- Structural validation - minimum requirements, completed assessment and endorsement
- Content verification - full application and highly specialised healthcare

European Commission launches a call for interest for ERNs
Application submitted to European Commission
Application reviewed by European Commission and Independent Assessment Body
Assessment and report completed by Independent Assessment Body
Assessment results sent to European Commission
Final Approval by Board of Member States
Stage 4: Technical Assessment

Stage 4:
- Documentation review for Network and all Healthcare Providers
- Virtual interview with Network Coordinator and Healthcare Provider
- On-site visit – sample
Stage 5: Assessment Results Submitted

Stage 5:
- Transfer of Application Forms, Self-Assessment Forms and Assessment Reports to European Commission
- Independent Assessment Body’s Recommendation
Stage 6: Final Approval

Stage 6:

- Board of Member States reviews the assessment reports and recommendation by the Independent Assessment Body
- Approval of ERN
Overview of technical assessment

Application
- Network and HCP application forms
- Self-assessment and supporting documentation for Network and HCP

Assessment
- Vision and purpose
- Objectives and goals
- Experience and functionality

Method
- Documentation review
- Virtual interview of network coordinator and HCP applicants
- On-site visit – sample
- Decision guidelines

Evidence
- Vision statement and mission
- Strategic plan
- Work plan and progress report regarding themes in operational criteria
Technical Tools

- Self-Assessment Checklist
- Application Form
- Applicant Checklist
- Schedule template
- Operational Criteria
- Patient Tracer Method and Guide for Assessors
- Virtual Interview Guide
- Assessment report template
- Decision guidelines
- On-site visit checklist
- Eligibility checklist
Thank you ... more to come tomorrow!