



Enrique Terol
Anna Carta
DG SANTE
Directorate B
European Commission

The European Reference Networks call for proposal Part 2



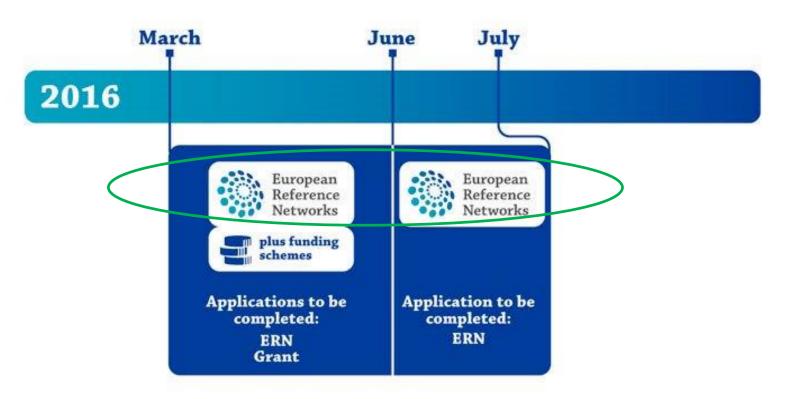
Brussels, 7 April 2016





Presentation blocks

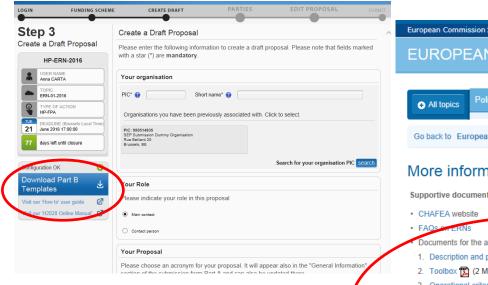
- Manuals and tools (Anna)
- Applications' documents active pdf (Enrique)

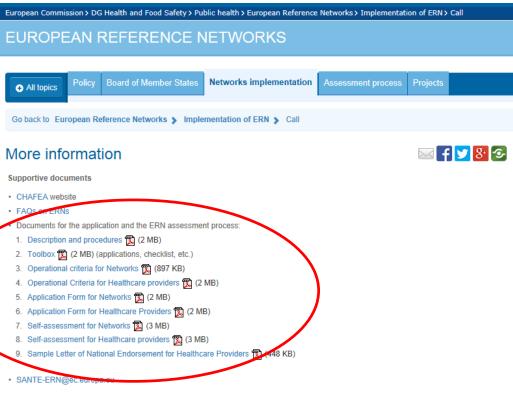






Where and what?





DG SANTE together with CHAFEA is organising an info day in Brussels on the 7 April 2016 to explain the call for ERN to the interested

Health and Consumers

stakeholder and to answer your questions on this call.

Info day



The 9 documents

- 1. Description and Procedures
- 2. Technical Toolbox for Applicants
- 3. Operational Criteria for the Assessment of Networks
- 4. Operational Criteria for the Assessment of HealthCare Providers
- 5. Network Application Form in Active PDF
- 6. Membership Application Form in Active PDF

5 application forms

- 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

4 informative and guiding



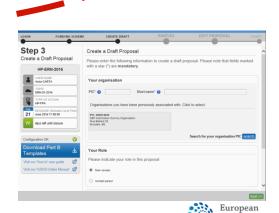
Who's applying?

The Healthcare Provider Representative:

- 1. Membership Application Form
- 2. Self-Assessment Checklist for Healthcare Providers
- 3. National Endorsement for Healthcare Providers

The Network coordinator:

- 1. Network <u>Application Form</u>
- 2. <u>Self-Assessment</u> Checklist for Networks









DOCUMENTS TO BE UPLOADED AT THE TIME OF APPLICATION

	ONE NETWORK	APPLICATION	FORM
--	-------------	-------------	-------------

- ONE MEMBERSHIP APPLICATION FORM FOR EACH HEALTHCARE PROVIDER (INCLUDING THE
 - COORDINATING MEMBER)
- ONE NETWORK SELF-ASSESSMENT
- ONE SELF-ASSESSMENT PER HEALTHCARE PROVIDER
- ONE LETTER OF ENDORSEMENT FOR EACH HEALTHCARE PROVIDER (INCLUDING THE COORDINATING MEMBER)

<u>ALL</u> OTHER SUPPORTING DOCUMENTATION LISTED IN **ANNEX IX, APPENDIX B** OF THE SELF-ASSESSMENT SHOULD BE SUBMITTED DIRECTLY TO THE IAB, AT ITS REQUEST.







1. <u>Description and Procedures</u>

This documents provide Network and HCPs applicants with an overview of the **whole European Reference Network Process**.

- Roles and Responsibility
- Assessment Process for the Applicant
- Publication of the Call for Interest
- Preparing the Proposal for a European Reference Network
- Completing the Application
- Submitting the Application Forms, Self-Assessments and Supporting
- Assessment of the Proposal
- Approval of Members to Existing ERNs
- Loss of Membership or Termination of a Network
- Guidelines for the Use of Logo
- Glossary of Terms









2. Technical Toolbox for Applicants



It includes **all documents** related with the call and the evaluation of the applications.

It is mainly addressed to the Network coordinators and the Healthcare Providers representatives.

- ✓ Annex I Operational Criteria
- ✓ Annex II Application Forms
- ✓ Annex III Application Checklist
- ✓ Annex IV Self-Assessment
- ✓ Annex XI Sample Letter National Endorsement (Healthcare Providers)





Tools for the assessment

Annex V to X

Interview Guide Virtual Interviews

On-site Audit Schedule Template

On-site Audit Checklist

 Assessment Report Templates for Networks and HCP

 Decision Guidelines for the Approval

Technical Tools



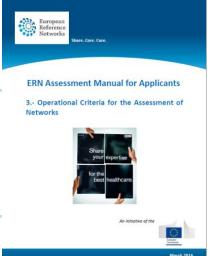






3. <u>Operational Criteria for the Assessment of</u> Networks

The <u>operational criteria</u> are link to the Commission Delegated Decision 2014/286/EU.



Purpose of the operational criteria:

To provide a common framework to assess Networks' and Healthcare Providers' compliance with this legislation.





The **Operational Criteria for Networks** consists of **9 subsections** or themes.

Each theme includes one or more criterion that the Network must comply with.



CORE MEASURES

Network Applicants must ensure that they are in compliance with these requirements by either having it in place or addressed within a detailed and well-defined implementation strategy within one year of the formal establishment of the Network.

REMAINING MEASURES

a clearly **defined action plan** and set **timelines** for achievement of the measure will be accepted initially as evidence.







The first theme structure

1. ESTABLISHMENT OF A EUROPEAN REFERENCE NETWORK

Legislated Requirement

2014/287/EU Chapter II Article 2.2

1.1 CRITERIA

The Network meets the minimum requirement for Healthcare Provider membership and their location to be recognised as a European Reference Network.



1.1.1 MEASURE

The Network is comprised of a minimum of 10 Members across 8 Member States.

Guideline

The combined scope of all Members should cover the full range of services throughout the trajectory of care needed for patients living with a rare or low prevalence complex disease or condition specific to the Network's area of expertise. Other Healthcare Providers may become Affiliated Partners in order to have access to good practice guidelines for diagnosis, care and treatment; and involvement in research activities. The 10 members include Healthcare Providers approved as "full members" by the European Reference Network Board of Member States. Potential Affiliated Partners will not be considered as applicant Healthcare Providers. The addition of Affiliated Partners will take place only after the approval of the ERN by the Board and following the formal designation of each of the Affiliated Partners by its national authorities.

Evidence

List of Applicant Healthcare Providers and their Member States

Method of Assessment

- Eligibility Check
- Documentation Review







4. <u>Operational Criteria for the Assessment of HealthCare Providers</u>

The Operational Criteria for Healthcare Providers consist of **two** sections.

- 1. General criteria
- 2. Specific criteria

The first section covers **general criteria** that are <u>common to all specialised healthcare providers</u> (e.g. organisation and management, research and training, and information systems).

The results of **other accreditation and/or certification schemes** may be accepted as evidence of compliance only if they are formally recognized by the national authority and have been completed within the last 4 years.





Specific criteria

The second section consists of **specific criteria** with regards to the condition(s) or disease(s) covered by the Network.

For the specific criteria the requirements are defined by the Network. As evidence, the Healthcare Provider must demonstrate compliance with these requirements.

- 6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE
- 7. HUMAN RESOURCES
- 8. ORGANIZATION OF PATIENT CARE
- 9. FACILITIES AND EQUIPMENT





Operational Criteria



Organisation of the Operational Criteria

Networks	Healthcare Providers
General Criteria and Conditions to be fulfilled:1. Establishment of a European Reference	·
Network 2. Highly Specialised Healthcare 3. Governance and Coordination 4. Patient Care 5. Multidisciplinary Approach	Centred Care 2. Organisation, Management, and Business Continuity 3. Research, Education and Training 4. Expertise, Information Systems, and e-
 Good Practice, Outcome Measures, an Quality Control Contribution to Research Continuous Education, Training, and Development Networking and Collaboration 	 Health Tools Quality and Safety Specific Criteria and Conditions to be fulfilled: Competence, Experience and Outcomes
Defined in the Network application proposal and fulfillment assessed for each applicant healthcare provider. Based on the evidence and consensus of the	of Care 2. Human Resources 3. Organisation of Patient Care 4. Facilities and Equipment
scientific, technical and professional community	Health and Ref



5. Network Application Form in Active PDF

Application should include:

Description of the Network and Healthcare Provider:

- Description of the governance
- Thematic area of expertise (diseases and conditions)
- Epidemiology, volume cases
- Scope and type of services.
- Expected added-value and objectives of the Network
- Specific criteria to be fulfilled by all Members





<u>First</u>, complete the Network Application and circulate to each Healthcare Provider.

<u>Second</u>, each Healthcare Provider should complete the Form.

<u>Third</u>, the Coordinator should review all the Forms to ensure consistency.





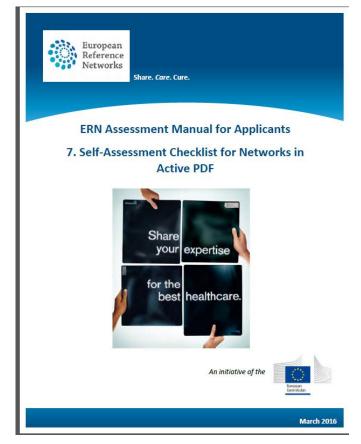
6. Membership Application Form in Active PDF







7. Self-Assessment Checklist for Networks in Active PDF

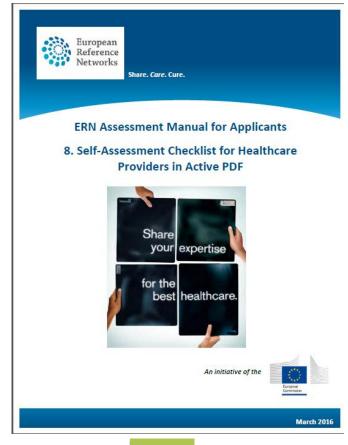








8. Self-Assessment Checklist for Healthcare Providers in Active PDF







THE SELF-ASSESSMENT CHECKLIST TOOL FOR HEALTHCARE PROVIDERS

Criteria and conditions for Healthcare Providers³

I. PATIENT EMPOWERMENT AND PATIENT CENTRED CAR	E							
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences respected.								
Measurement Elements	0	1	2	Comments				
1.1.1 The Healthcare Provider's commitment to patient-centered is formally and consistently communicated with patients and thei families.	_							
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 multidisciplinary care team.								
1.1.3 Patient education materials appropriate for readers of varyi literacy levels and for speakers of different native languages are available.	ing							
1.1.4The Healthcare Provider provides patients and their families written information about the facility, the organization, and its sp area of expertise.					X			
1.1.5 The Healthcare Provider gives patients and their families wr information about their rights and responsibilities.	itten							
1.1.5 There is a policy and procedure in place to disclose unanticipoutcomes and complications to patients and their families, as appropriate.	pated				(x)			

Symbol \square indicates the requirement to prepare or collect a specific document as evidence of compliance. The document should be ready to submission at the IAB's request





9. Sample Letter of National Endorsement for Healthcare Providers









Minimum thresholds to meet: Network

- An overall compliance rate of 50% of the maximum score.
- 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.







Minimum thresholds to meet: HCP

- 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".







Thank you!







http://ec.europa.eu/health/ern/policy/index_en.htm



SANTE-ERN@ec.europa.eu
Enrique.terol@ec.europa.eu
Anna.carta@ec.europa.eu



