

European Reference Networks

*Directive of patients' rights in cross-border
healthcare*



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**EUCERD JOINT ACTION WP7
WORKSHOP**
Madrid 9 May 2015



Legal acts on ERN



17.5.2014

EN

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What

COMMISSION DELEGATED DECISION

of 10 March 2014

setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

(Text with EEA relevance)

(2014/286/EU)

17.5.2014

EN

Official Journal of the European Union

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COMMISSION IMPLEMENTING DECISION

of 10 March 2014

setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

(Text with EEA relevance)

(2014/287/EU)

How

Entry into force 27 May 2014

Health and
Consumers

Preparation of proposals & self assessment



6 sets of Criteria for Networks



5 sets of general criteria for members



2 sets of specific criteria for members



Key elements of the Networks

- ✓ *Patient centered and clinically lead*
- ✓ *10 Members in at least 8 Countries*
- ✓ *Strong independent (3rd party) assessment*
- ✓ *Fulfillment of Network and Members criteria*
- ✓ *Endorsement and approval by National Authorities (grouping and strategic value)*

Networks criteria and capacities




- ✓ knowledge and **expertise to diagnose, follow up and manage patients**
- ✓ Evidence of **good outcomes**
- ✓ **multi-disciplinary** approach
- ✓ capacity to **produce good practice guidelines and to implement outcome measures and quality control**
- ✓ **Research, teaching and training**
- ✓ collaborate with **other centers of expertise and networks**

Member's general criteria



1. **Set of horizontal criteria and conditions** to be fulfilled by all healthcare providers regardless of the field of expertise

5 groups
22 criteria



- a) patients empowerment and centred care**
- b) organisational, management and business continuity**
- c) research and training capacity**
- d) exchange of expertise, information systems and e-health tools**
- e) expertise, good practice, quality, patients safety and evaluation**

Member's specific criteria



Set of specific criteria and conditions may vary depending on the scope of the concrete area of expertise

- ✓ **documented competence, experience and activity**
- ✓ **provide evidence of good clinical care and outcomes**
- ✓ **characteristics of human resources**
- ✓ **organisation and functioning : multidisciplinary healthcare team**
- ✓ **specific equipment within the centre or easily accessible**
- ✓ **communication / interaction at a distance capacity**

Based on the evidence and consensus of the scientific, technical and professional community

Bottom up proposals



How to assess and approve the Networks?



Key role of Member States

- ✓ **Recognition of centers at national level.** (important differences) MS with systems in place (minority)
- ✓ **Endorsement** of applications
- ✓ **Board of Member States**
- ✓ **Approval** of Networks (once positively assessed)



Board of Member States

❑ **Responsible of:**

- ✓ Approval of Networks and Membership
- ✓ Termination of Networks
- ✓ Loss of Membership

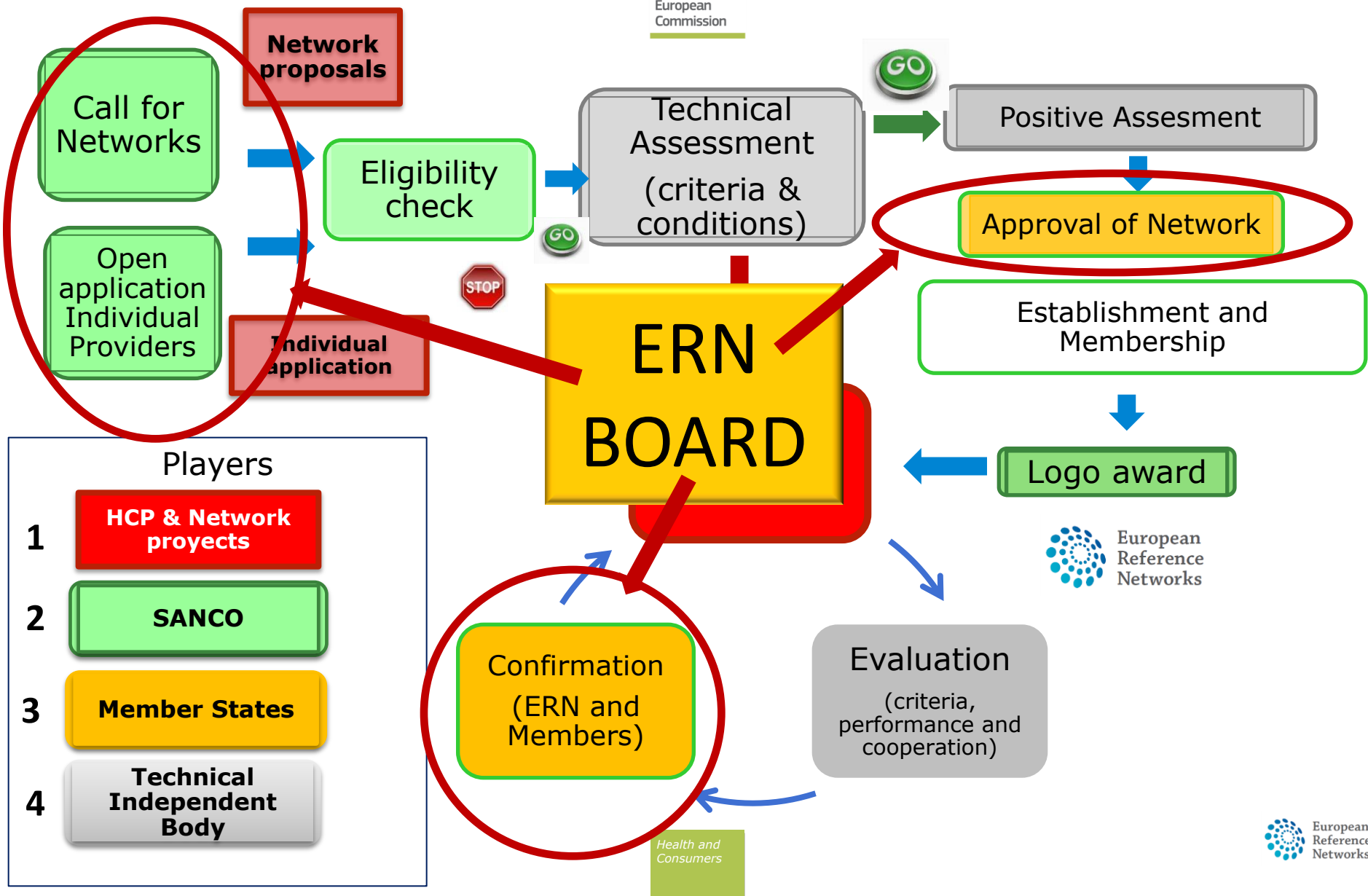


❑ **Constitution: 5 December 2014**

- ✓ Minutes and rules approved and made public (DG SANTE website)
- ✓ Voting rules
- ✓ Co-Chair Member States elected: Till Voigtländer (Austria)

❑ **3 meetings in 2015 (June, October, December)**

ERN Scenario



Assessment Manual and tool box

- ❑ **Competitive call:** Consortium PACE-ERN (EURORDYS HOPE & Accreditation Europe (Canada);



- ❑ **Deliverables (work ongoing)**

- ✓ *Legal criteria into operational criteria.*
- ✓ *Tools and guidance for the call and the assessment process*
- ✓ *Tools and guidance for the networks proposals (self assessment, how to prepare the proposal , etc)*



WVP
1

Mapping Exercise
Literature Review
National models Review
On-site visits (x10 MS)

WVP
2

Methods, guide and
flowchart of the
assessment process

WVP
3

Operational Criteria
Assessment
Networks &
Healthcare Providers

WVP
4

Manual of
Assessment and
Technical Toolbox

WVP
5

Technical support:
Development and follow up
Workshops Independent
Assessment Bodies

WP6

Dissemination:
website scheme,
elements and
electronic documents

WP7: Steering Committee



Elements of the assessment process :

- Applications and self assessment desktop review
- On-site survey (sample)
- Eligibility check and assessment report
- Quality check and appeal process

Material for the support toolbox:

- Criteria, processes, guidelines and application forms, e.g.: self-assessment tools
- Guidelines for applicants for submission applications
- Guideline for independent assessment bodies

Mapping Exercise

Literature Review (1)



Preliminary Results:

- ✓ *EU pioneer in the field*
- ✓ *Heterogeneity in language & variability in assessment methods*
- ✓ *National endorsement & alignment with Delegated decision*
- ✓ *International collaborations*
- ✓ *Patient engagement*

Learning Opportunities:

- ✓ *Network Pilots (funded by EU)*
- ✓ *Informal European networks*
- ✓ *Mature networks for common diseases and injuries*

Preliminary Results:

- ✓ *2/3 responses from Members States*
- ✓ *Support for the ERNs*
- ✓ *Key Considerations*
 - **Standardisation across Europe**
 - **Integration of existing assessment programs**
- ✓ *Challenges with ERN Themes*
 - **Patient information transfer**
 - **Interoperability e.g.: eHealth**
 - **Coordination of care**
 - **Demonstration of good treatment outcomes**

Methods

- ✓ 10 Member State site visits

Visited: Denmark, France, Germany, Netherlands, Spain, Sweden, Poland, United Kingdom

Pending: Lithuania, Italy (tbc), Czech Republic (tbc)

- ✓ National authorities
- ✓ Clinician's experience

Topics covered:

- ✓ Highly specialised services, rare disease programmes and cancer networks
- ✓ Designation, accreditation, certification, licensing and commissioning processes
- ✓ Clinical experiences of the application and evaluation process
- ✓ National experience of assessment process

Diversity and different level of maturity of systems in place

Independent Assessment Bodies



- ❑ *Institutions/entities with solid background in the field of HCP accreditation/certification*
- ❑ *Perform the assessment of Networks proposals*
- ❑ *Use of a common Assessment Manual*
- ❑ *Competitive Framework Contract:*
 - ✓ *June: Tender call*
 - ✓ *March - June 2016: Assessment process*
 - ✓ *June - July 2016: feedback to ERN Board of MS*

Other upcoming actions

ERN IT PLATFORM:



- ✓ Feasibility of the setup of a comprehensive IT platform
- ✓ CEF proposal

ERN services study:

- ✓ Services typology of a ERN, resources and cost drivers



- ☐ *Webpage*
- ☐ *Conference on ERN October 2015 (Lisbon)*
- ☐ *Ads in Scientific journals (more than 30)*
- ☐ *Meetings with stakeholders and participation in conferences*
- ☐ *Discussions with advisory groups to the commission*



Second Conference ERN 2015; Lisbon 8-9 October 2015

400 participants

- ✓ **8 October: Plenary season:** *High-level table; call & assessment; lesson learned from pilot experiences; producing knowledge and measuring outcomes; national models & experiences*
- ✓ **9 October: Workshops:** *Preparation of Networks proposals, Good clinical practices & guidelines; IT, research and networking elements;*
- ✓ **8-9 October: Showroom:** *space for informational material and small stand for Networks*

Active participation of CEGRD, National authorities, pilot networks, stakeholders

Meetings with stakeholders and national authorities

✓ **Healthcare providers, pilot networks, workshops, advisory groups:**

- Rare skin diseases (genodermatosis)
- Expornet (rare paediatric cancers)
- Gynecological rare disorders
- Rare adult cancers
- Rare Immunologic/allergic disorders
- Rare haematological disorders
- Rare neurological disorders (refractory epilepsy)
- Rare severe respiratory diseases (ECMO)
- Rare endocrine/diabetes in children
- Rare hepatic / transplant in children
- Genetic testing
- Rare urological diseases
- Rare best practices
- Eucerd JA Rare Diseases workshops



Network proposals: Preparatory and strategic activities

- ✓ ***Strengthening the network value and capacities:***
 - ❑ Multidisciplinary
 - ❑ Avoid fragmentation: Grouping of diseases
 - ❑ Identify mature and clear EU added value type of diseases
 - ❑ Discuss and *Identify other players, partners and members*

- ✓ ***Liaison with MS authorities*** (contact with ERN board representative at national level and discuss !!)

- ✓ ***Define the services of the Network***

Network proposals: Preparatory and strategic activities (2)

- ✓ Agree on the **specific criteria for each area of expertise**
- ✓ **Self-assessment exercise** (*Network and members*)
- ✓ Define **Pathways** models, referral criteria, clinical decision tools
- ✓ **Information** system/indicators

Challenges



- ***Engagement of providers and national authorities***
- ***Attract and approve the right Networks and Centers***
- **Being able to produce evidence of its value:**
 - *Clinical outcomes,*
 - *Better access to care*
 - *efficiency*
- ***Sustainability***

Call for Networks proposals

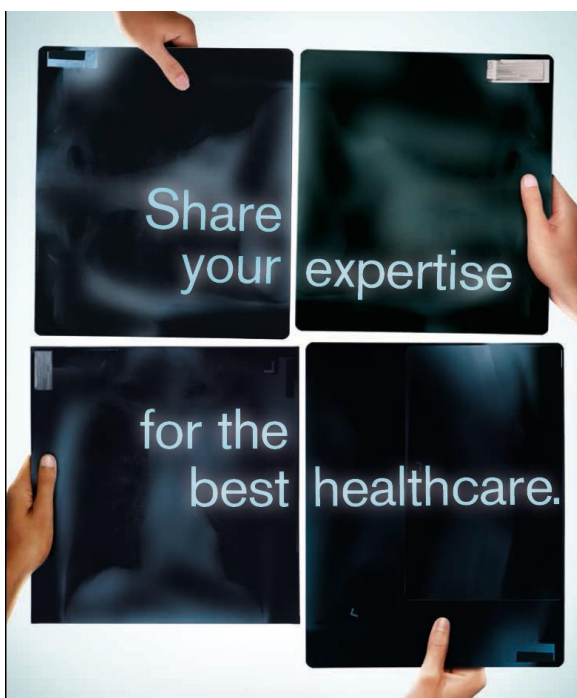


Timeline:

- ✓ ***ERN workshop (EUCERD + DG SANTE): July 2015***
- ✓ ***Preparatory conference; Lisbon October 2015***
- ✓ ***Call: December 2015***
- ✓ ***Assessment of proposals April -June 2016.***
- ✓ ***Approval of + proposals by Board of MS July 2016***
- ✓ ***Establishment of Networks July-September 2016***



Thank you!



Imagine if the **best specialists** from across Europe could join their efforts to tackle **medical conditions** that require **highly specialised healthcare** and a concentration of knowledge and resources.

That's the purpose of **the European Reference Networks** and it's becoming a reality.

Share and enhance your expertise. Talk with your colleagues. Join a **Network proposal** in early 2015.

More information at ec.europa.eu/join-ern

Share. Care. Cure.

Supported by the



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