



European Reference Networks

Criteria for Networks and Providers Implementation Framework

Directive of patients' rights in cross-border healthcare



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Overview

✓ **Context , scope and objectives**

✓ **Legal measures:**

Criteria for networks and providers

Assessment and establishment

✓ **Timeline for the implementation**

Key issues addressed by the Directive



Directive 2011/24/EU of patients' rights in cross-border healthcare



- Right to **choose and be reimbursed for healthcare provided** by public or private providers located in the EU
- More **transparency about their rights**, treatment options or , the quality and safety levels of healthcare providers
- Strong focus on **cooperation among Member States**

Entry into force at National level 25 October 2013

Cooperation between MS: Article 12 European Reference Networks

Networks of healthcare providers aiming at
Improving quality and safety and access to highly specialised healthcare

- ✓ Patients affected by **rare or low prevalence and complex diseases**
- ✓ Added **value** at EU level
- ✓ Need of **cooperation**:
 - Scarcity knowledge / need education
 - Complexity / high cost
- ✓ **multidisciplinary approach** (different specialities/areas of knowledge)

Consultation & decision process



2011 - 2014

Looking at best practices: MS and Centres visits

Public Consultation

Advise from

- EUCERD
- EPAAC
- PARENT

Cross-border Healthcare Expert Group

Technical Brainstorming & workshops

Scientific societies
Patients associations

Reports and technical papers

SANCO

Delegated Decision

Implementing Decision

criteria and conditions for providers & Networks

Exchange of information and expertise for ERN

criteria for establishing and evaluating ERN

enter into force **27 May 2014**

Legal acts on ERN



EUROPEAN
COMMISSION

HOW


Brussels, 10.3.2014
C(2014) 1408 final

COMMISSION DELEGATED DECISION

of 10.3.2014

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)



EUROPEAN
COMMISSION

What

Brussels, 10.3.2014
C(2014) 1411 final

COMMISSION IMPLEMENTING DECISION

of 10.3.2014

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)

Entry into force 27 May 2014



6 sets of Criteria for Networks



5 sets of general criteria for members

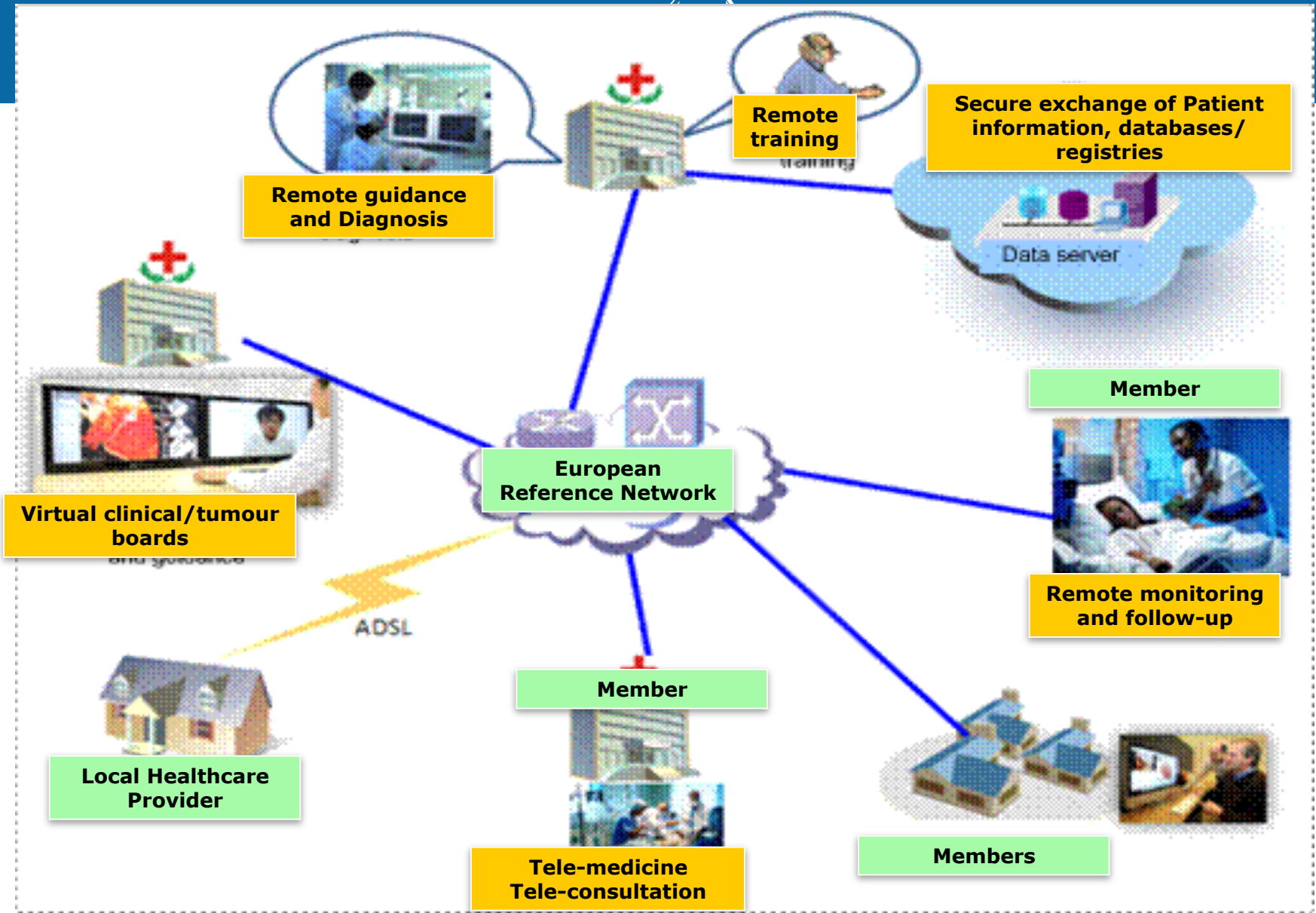


2 sets of specific criteria for members



European Reference Networks: **networking dimension**

- *Key issues:*
 - **Exchange of expertise** and clinical data through the network and across the EU
 - Swift and smooth **contact between providers and between patients and providers at a distance**
 - **Collaborative/cooperative actions and systems**
- ***Networking activities** and availability of specific network tools -It solutions- are the basis for this project.*

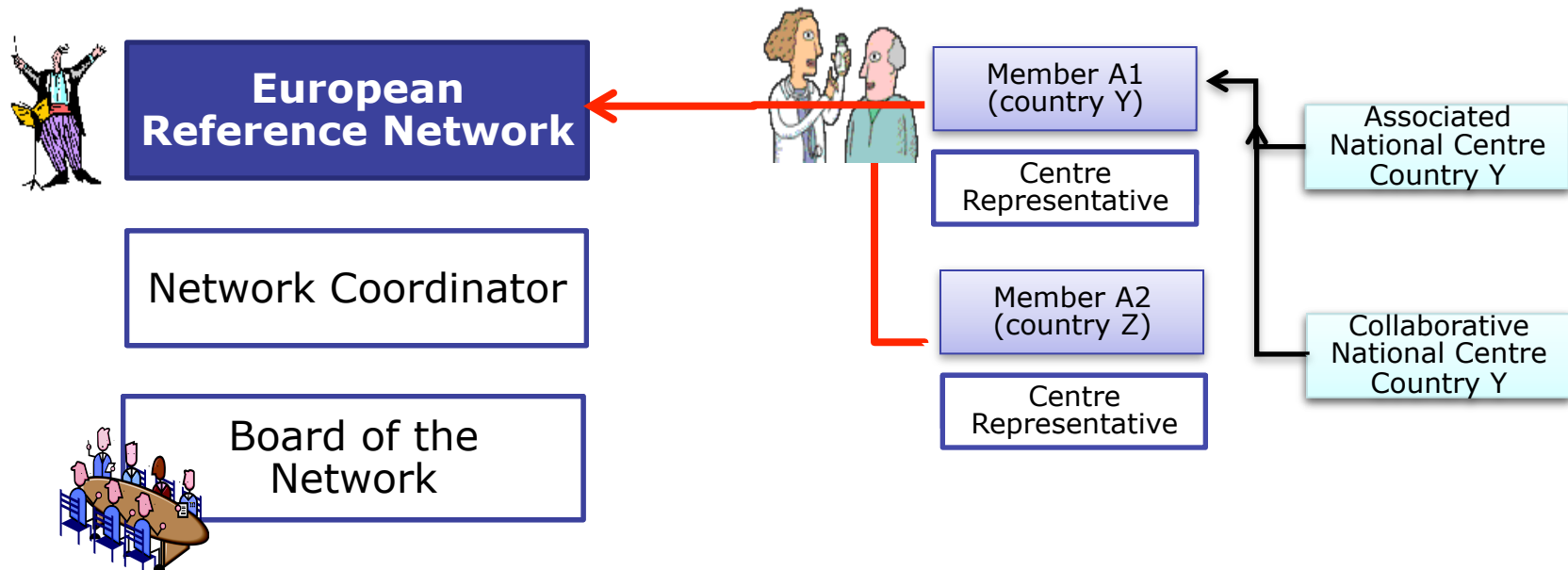


Networking elements , communication and eHealth solutions

Governance / coordination Networks



- ✓ **Transparent and effective** coordination & governance (adequate structures and elements)
- ✓ **Networks can be flexible** & have different architectures and internal relations **but there are key organizational features.**





Key issues

- ✓ *Principal **constituents** of the European Reference networks*
- ✓ *Work based in **cooperation amongst themselves** in a dedicated field of expertise*
- ✓ *In **accordance with legislation** of their Member States*
- ✓ ***Fulfilment of the criteria** provided in the delegated decision*
- ✓ *Full responsibilities, tasks and participation in all the technical and **governance bodies of the ERN***
- ✓ *Acting as a **hub (interconnector)** between the nat. healthcare providers and the ERN*

All Members in an ERN must have in common:

(a) the expertise they specialise in

(b) certain treatment(s) offered or

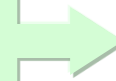
(c) disease (s) or health condition(s) they focus on.





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**



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

- ✓ **document 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



Main principles agreed with Member States

- 1. Clear and solid eligibility criteria of the Networks**
- 2. Key role of Member States: endorsement and approval**
- 3. Participation: voluntary and commitment with the rules**
- 4. Transparency and efficiency of the process**
- 5. Based on a strong independent technical assessment**

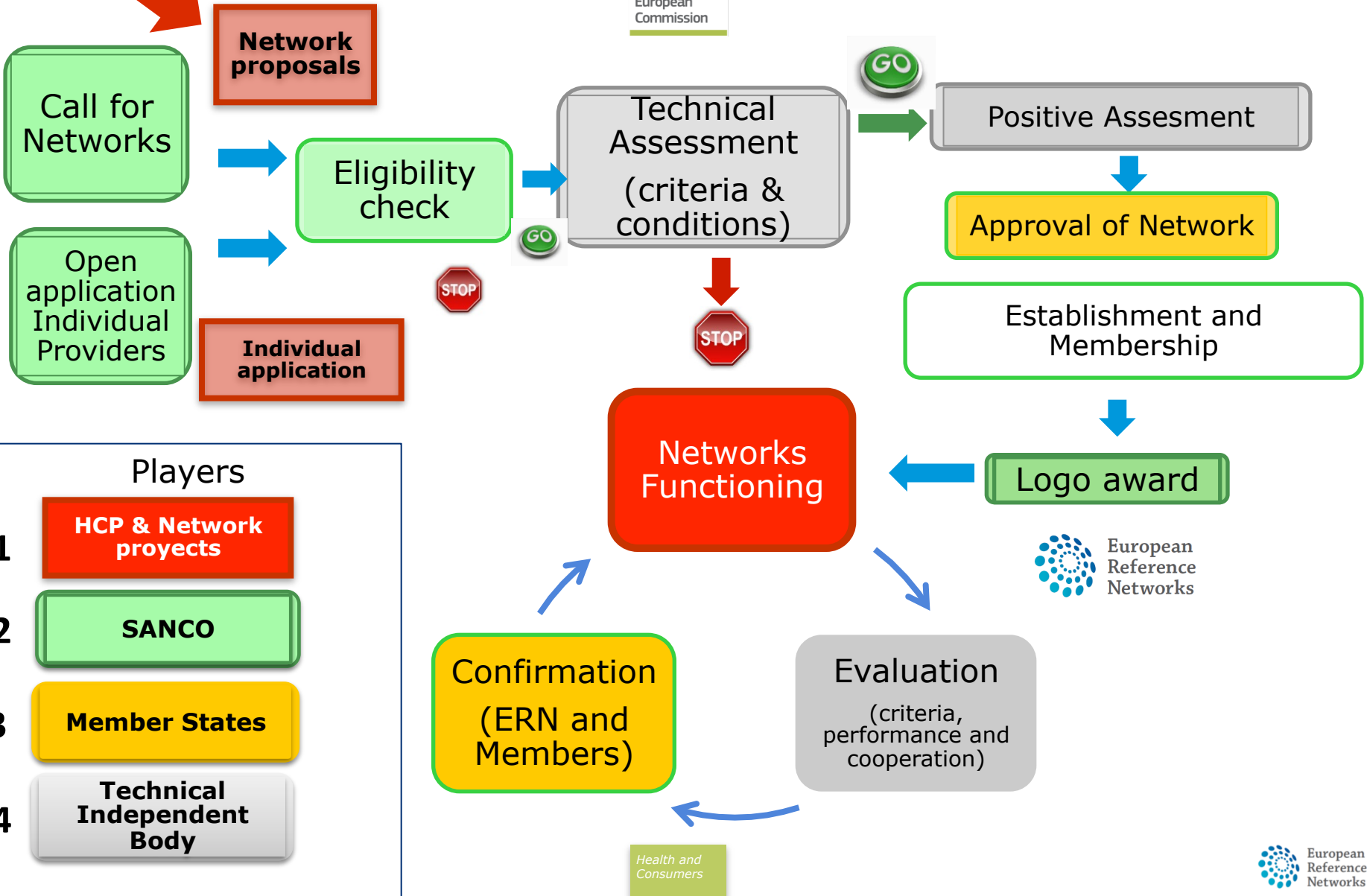


institutions or entities with a solid background

- ***External and independent***
- ***Experience & knowledge on healthcare systems***
- ***Capacity and knowledge to develop methodology (manual and procedures) based on the criteria established in the legal acts***
- ***Capacity to conduct and carry out assessment (pre) and evaluation (post) of the Networks and healthcare providers***

Competitive Call

ERN Scenario



- Players**
- 1 **HCP & Network projects**
 - 2 **SANCO**
 - 3 **Member States**
 - 4 **Technical Independent Body**



ERN IMPLEMENTATION: the way forward

- **Communication and awareness activities**



- **Preparation of the Assessment Manual and toolkit**

Call for tender n° X concerning the development of a manual and toolbox for the assessment of European Reference Networks: July 2014

- **Framework contract for independent assessment bodies: November 2014**



ERN IMPLEMENTATION: the way forward

Cross-sectorial cooperation and funding sources

- ✓ Public health program 2014-2020: studies & project grants to approved ERN
- ✓ RTD horizon 2020 : 2016 research on networks organizational models
- ✓ Connecting European Facilities (CEF): the eHealth dimension
- ✓ Structural funds (cross border cooperation)
- ✓ Social funds (training and better skills)

ERN tentative timeline & milestones



May
2014



**Entry into force
legal acts**

July
2014



**Call for
Assessment
Manual**

II quarter
2015



**Call for selection
independent
body(ies)**

IV quarter
2015

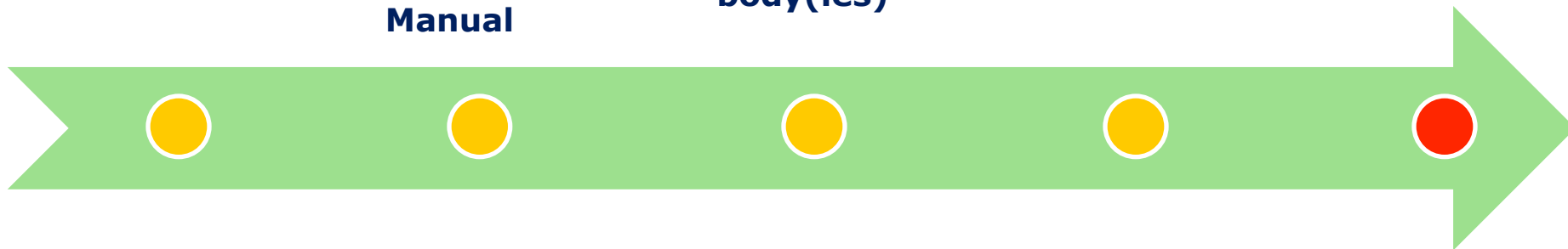


**Call for
Networks**

II quarter
2016



**Establishment
of Networks**





❑ 2014-2015: Preparation of Network Proposals

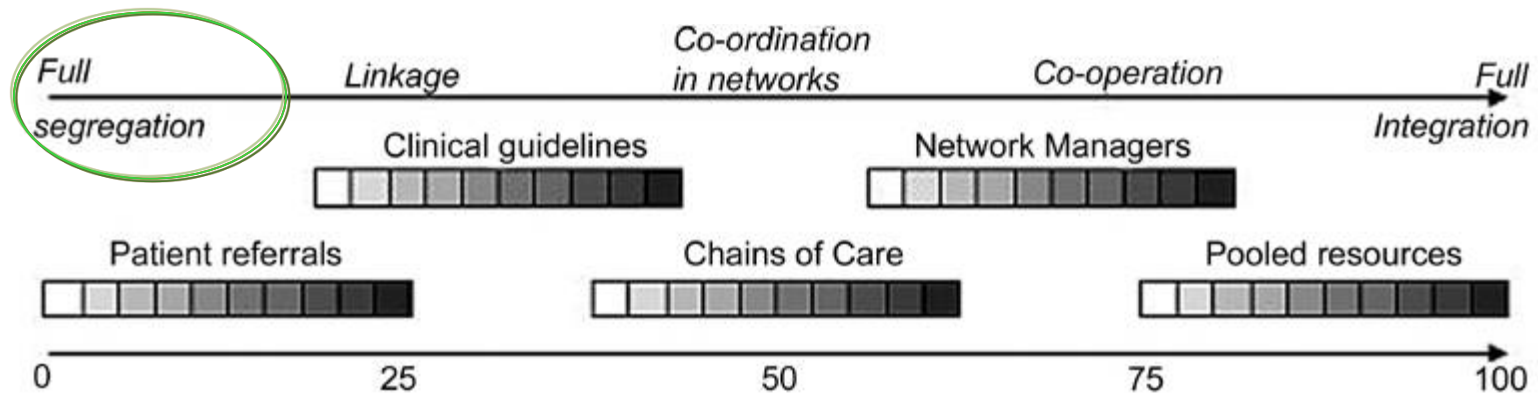
- ✓ Identify clusters of diseases (scope of ERN)
- ✓ Identify qualified healthcare providers and informal networks
- ✓ Establish synergies

❑ 2015: Guidelines and technical documents for the Network proposals

❑ 2015: Call for Networks

- ✓ Complete Network and individuals proposals and documentation
- ✓ Self-assessment

Don't forget that this will be a long journey



Int J Integr Care. 2005 Jul-Sep; 5: e01.

Published online 31 August 2005.

Evaluating integrated health care: a model for measurement

Bengt Ahgren and Runo Axelsson, PhD, Professor of Health Management

Thank you!



European Reference Networks

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