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### Implementation of European Reference Networks







## The road to ERNs







Background, policy and legal base



#### **Chapter IV Cooperation between MS Article 12 European Reference Networks**

#### Networks of healthcare providers aiming at

of the costs. stions open to you, are, and whether a

Improving quality and safety and access to highly specialised healthcare

 ✓ Patients affected by rare or low prevalence and complex diseases

 multidisciplinary approach (different specialities/areas of knowledge) Added value at EU level

Need of cooperation:

- Scarcity knowledge
- Need education
- Complexity / high cost
- Effectiveness in the use

of resources





Background, policy and legal base

## European Reference Networks (ERN): aim of Article

**12:** (Directive Patient's Rights to Cross border Healthcare )

Support the development of ERN

Commission

**Member States** 





## Legal acts on ERN



17.5.2014 Official Journal of the European Union L 147/71 COMMISSION DELEGATED DECISION of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wiching to join a European Reference Network must fulfil (Text with EEA relevance) (2014/286/EU) 17.5.2014 Official Journal of the European Union L 147/79 EN COMMISSION IMPLEMENTING DECISION of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their HOW Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (Text with EEA relevance) (2014/287/EU) Entry into force 27 May 2014





Background, policy and legal base

## **Key features 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)





#### Implementation process



# How to assess and approve the Networks?







Implementation process

## **Players**

#### Healthcare providers

Member States

Commission

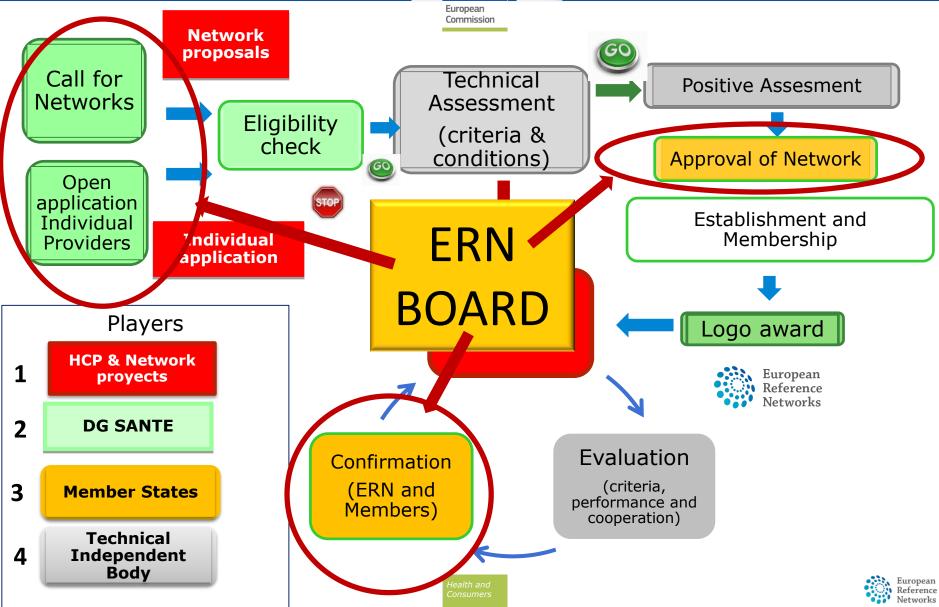
Assessment process and Assessment Bodies





#### **ERN Scenario**







- Executive Body
- 5 meetings so far (December 2014 March 2016)
- Strong commitment of MS
- Strategic paper on approval criteria of the Board
- Definition of national processes (mostly developed or final steps)



### Strategic role ERN Board of MS





 Integrative approach of ERN: Strong message on fragmentation overlapping (already having an impact on the potential candidates)

- ✓ Issues under discussion
  - o Common template endorsement of HCP
  - o ERN relation with Industry conflict of interest
  - o Criteria/processes to designate affiliated partners
  - o ERN IT platform and CEF







#### **Assessment Manual and tool box**

- Application forms
- Operational criteria
- Guidance & tools for applicants and assessment bodies

#### **Independent Assessment Bodies**

- solid background in assessment/certification Healthcare providers
- Task: to perform the assessment of Networks proposals
- Contracted trough a competitive Call





## Study ERN services

- The role of ERNs in specific <u>patient cases;</u>
- <u>Draft catalogue of services</u> to be provided by ERN;
- ERN services <u>cost drivers</u> and structure
- Workshops with clinical experts, potential networks and national authorities

European Commission

www.pwc.com/pt

Study on the services to be provided by the European Reference Networks and its members – Cataolgue of Services

CRAFEA – Consumers, Health, Agriculture and Food Executive Agency

24 of February , 2018 Advisory Service





#### Health Programme – <u>Work Programme 2016</u>

• Approved ERNs (eligibility criteria)

Funding

- **Call for Grants** jointly with the ERN Call for interest
- Patient registries projects
- For **technical assistance** for the assessment of applications
- **3rd ERN Conference** (February 2017) Kick off meeting approved ERN

#### **Connecting European Facilities: IT Platform**



## Timeline



#### ERN Approval

- 1. Call
- 2. Assessment for ERN

#### Positive assessment

- 3. Approval of the Board
- 4. ERN established

#### Grant

- 1. Eligible for funding
- 2. Evaluation of the grant proposal
- 3. Positive evaluation Framework Partnership Agreement (FPA)
- 4. Eligible for <u>Specific Grant Agreement (SGA</u>) February 2017

#### 16 March 2016

October 2016?

November 2016

November 2016







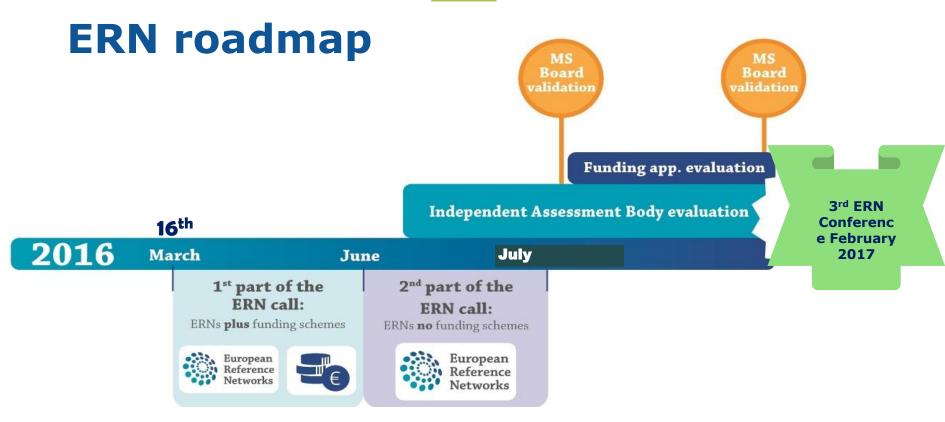
## **Call for ERN**

## 16 March - 21 June 2016











## Communication & awareness activities









- ✓ More than **50 interested groups** or pilot networks identified
- 12 14 mature and broad thematic networks potential applications
- ✓ Dynamic interaction of stakeholders with MS and Commission
- Interaction among professionals of the same thematic diseases groups
- Active implication of EU patients and professional/scientific societies
- Close cooperation between Board of MS and Commission
- Cooperation and support of the RD Joint Action to the ERN implementation













http://ec.europa.eu/health/ern/policy/index\_en.htm



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