The European Reference Networks call for proposal

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European Reference Networks

Info Day

Brussels, 7 April 2016

Health and Consumers

European Commission

Agenda

09:30	Walk in, registration and coffee
10:00	1.- Welcome (**Xavier Monne Prats, Director General, DG SANTE**) Introduction of the day: the agenda (**Tapani Piha, Head of Unit B3, DG SANTE**)
10:05	**PART 1: The European Reference network call for proposals – (*Enrique Terol, DG SANTE*)** • Structure of the call for interest for ERN • The ERNs application, assessment and approval process • Q&A
10:50	**PART 2 : The European Reference network call for proposals – (*Enrique Terol, Anna Carta, DG SANTE*)** • The ERNs application forms and documents • Q&A
11:50	**Break**
12:00	**PART 3: The call for grants for ERN of the Health Programme:** • The Call for Mono-beneficiary Grant projects (*Vera Zazvonov, Hristina Mileva - CHAFEA*) ○ Framework Partnership Agreements (FPA) and Specific Grant Agreements (SGA). • The online application process (SEP) (Charalampos Xenogiannis/Davis Baird) • Q&A
13:15	END OF THE MEETING

PART 1: The European Reference network call for proposals – (Enrique Terol, DG SANTE)

- ✓ *Background information*
- ✓ *Call for interest for ERN and call for grants*
- ✓ *The ERNs application, assessment and approval process*
- ✓ *Strategic issues*

Q&A

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Background information

The road to ERNs

Scope and Context

Background, policy and legal base

European Commission

Chapter IV 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**

✓**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**

Legal acts on ERN

European

What

17.5.2014 EN 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 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 L 147/79

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

European Commission

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)*

Funding

Health Programme – Work Programme 2016

- Approved ERNs (eligibility criteria)
  - **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

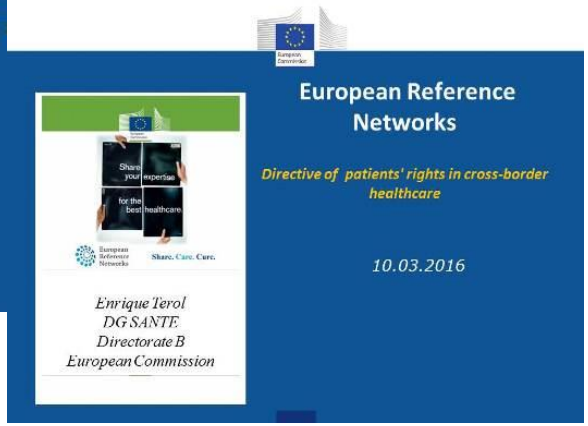
Communication & awareness activities

European Commission

Info Day

ERN Info day 7th April

Third European Union Action Programme in the field of Health - National Focal Points Meeting 18th March



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Call for ERN

16 March - 21 June 2016

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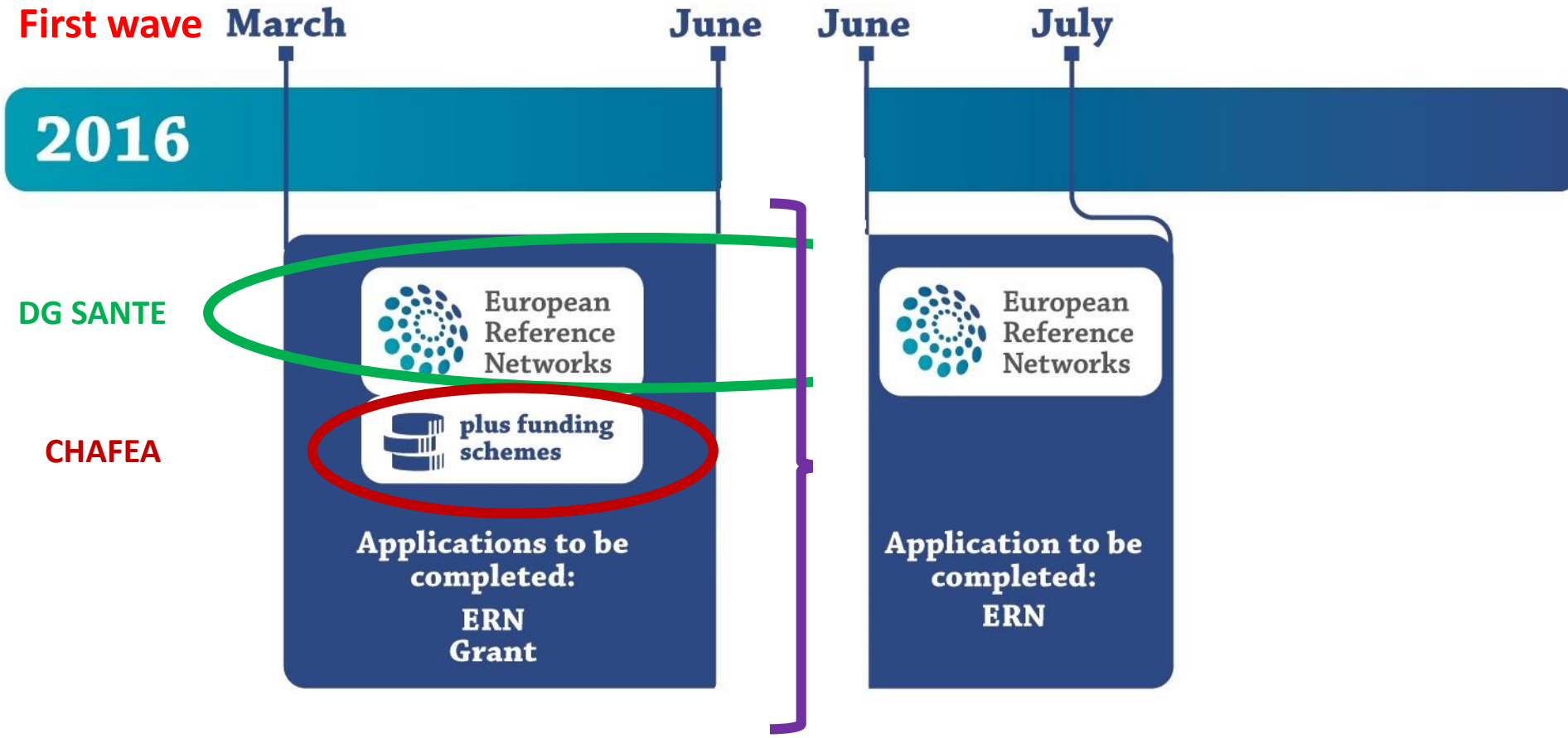
The call for ERNs: a two steps process



Why two calls (for ERN & for Grants) at the same time ?

- To reduce the paperwork
- To speed up the process

- *Call for ERN interest will have two waves*
- *First wave: ERN application + Grants*
- *Second wave: only ERN application (not eligible for grants)*

Timeline

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ERN Approval

1. *Call* — ***16 March – 21 June2016***
2. *Assessment for ERN*

Positive assessment

3. *Approval of the Board* — ***October/November 2016***
4. *ERN established* — ***November/December 2016***

Grant

1. *Eligible for funding* — ***November 2016***
2. *Evaluation of the grant proposal*
3. *Positive evaluation Framework - Partnership Agreement (FPA)*
4. *Eligible for Specific Grant Agreement (SGA)* ***February 2017***

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How to assess and approve the Networks?

European Reference Networks

Players

Healthcare providers

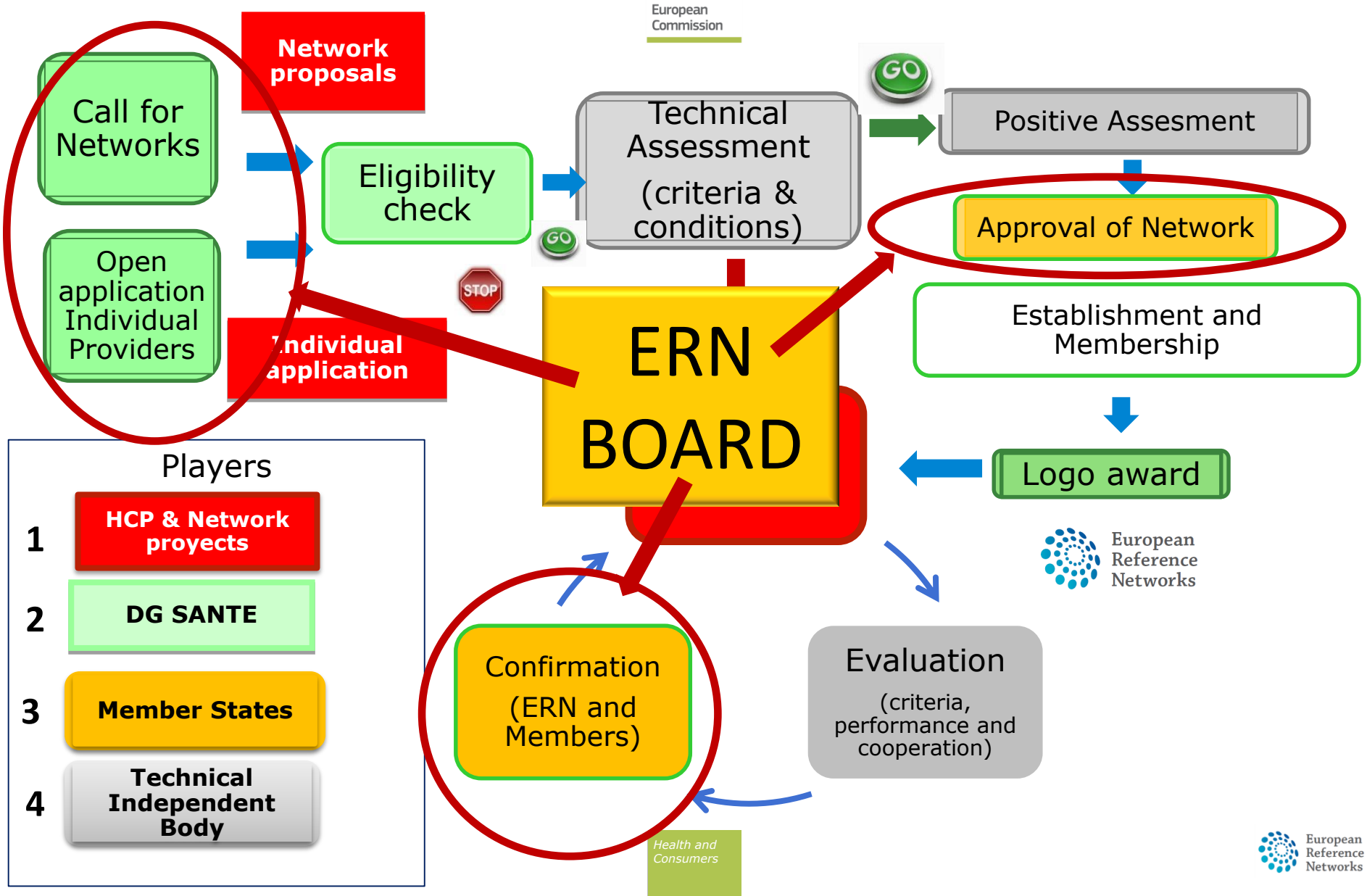
Member States

Commission

Assessment process and Assessment Bodies

ERN Scenario

Implementation process



The Board of MS

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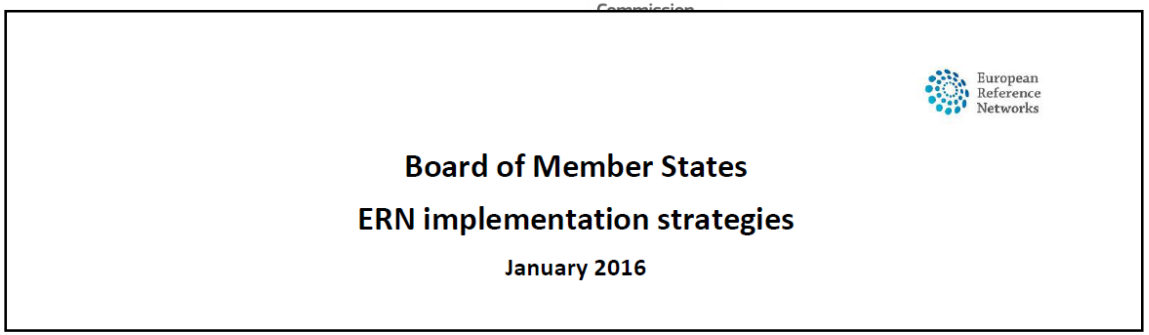
28 EU MS & EEA: Chaired by AT

- ✓ Approval of Networks & Members
- ✓ Termination of Networks
- ✓ Loss of Membership

- ***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*

Strategic criteria of the ERN Board


European Reference Networks

Board of Member States

ERN implementation strategies

January 2016

- *To avoid **fragmentation, overlapping and too limited scope** of the Network proposals*
- ***Avoid competition and promote cooperation** between similar interested groups in a common thematic field*
- ***Connect / assure the connection of member states** where there is no member of a Network (affiliated partners)*

The ERN Board has the capacity to
define and apply their strategic criteria in the final process of Network approval

Strategic role
ERN Board of MS

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

Orphanet journal of Rare Diseases

POSITION STATEMENT

Position statement on the role of healthcare professionals, patient organizations and industry in European Reference Networks

Abstract

BioMed Central

Assessment elements

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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*

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Strategic issues

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Network proposals: Preparatory and strategic activities

- ✓ ***Strengthening the network value and capacities:***
  - ❑ Multidisciplinarity
  - ❑ 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 Nework***

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Network proposals: Preparatory and strategic activities

- ✓ Agree on the **specific criteria for each area of expertise**
- ✓ ***Self-assessment exercise*** *(Network and members): decision of participation as members or later in agreement with the MS as Affiliated Partners*
- ✓ *Define **Pathways** models, referral criteria, clinical decision tools*
- ✓ ***Information** system/indicators*

Strategic issues

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Value and content

What: *epidemiology, thematic group of diseases, type of services*

Why: *demonstration of added value and technical reasons*

Who: *type of players (heterogeneity, consortiums, subareas of specialization, etc)*

How: *Criteria to be fulfilled* ***a)*** *as Network* ***b)*** *as member*

- *Assessment of Networks proposals will focus on how well the proposal is envisaged and defined*
- *(Networks are "in general" not set up so far)*

Networks Governance

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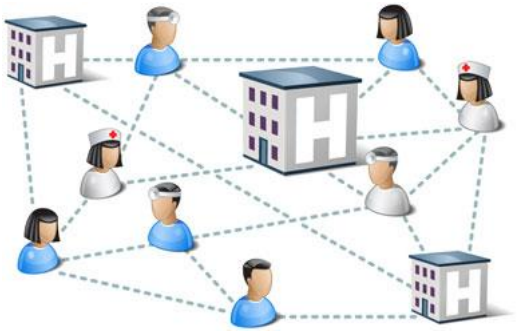
- ✓ ***Transparent and effective*** *coordination & governance*
- ✓ ***Flexibility*** *and* ***key organizational features.***

European Reference Network



Board of the Network

Network Coordinator

Centre Representative

Centre Representative

Collaborative National Centre

Associated National Centre

Scientific Societies

Patients Organisations

Academy

Other stakeholders

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About numbers …

- ***Minimum number** of HCP in an ERN is 10 from 8 Member States.*

- ***Optimal number** of HCP in an ERN:*
  - **To define the right 'size' of an ERN we need to focus on the "manageability " and functions of the network:**

    - All HCP members (full members) sit on the ERN Board. Too big, the board is unmanageable.
    - Be well connected to the majority, if ALL Member State
    - Scope and structure of ERN: ‘Grouped disease' network of 'sub-grouped or individual' networks…

- ***Maximum number of HCP in an ERN** : There is no upper limit*

Preparing an application …

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- ***Who decides who's in or out …***
  - Clinical community to discuss between themselves and decide …
  - MS to decide the endorsement
- ***Do you have to be in it to win it …***
  - Not every hospital needs to take part in an application, as centres can join approved ERNs anytime over the first 5 years.
  - What is important to select the strongest group of core healthcare providers to have the strongest application

How are thinks going?

- ✓ *More than **50 interested groups** or pilot networks identified*
- ✓ ***20-22** potential networks 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***

Potential Networks proposals (06.04.16)

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Broad thematic proposals (13)

- Rare auto-immune and auto inflammatory diseases
- Rare Bone Diseases
- Rare Cancers and Tumours Paedriatic
- Rare Eye Diseases
- Rare hepatic diseases
- Rare hereditary metabolic disorders
- Rare malformations and developmental anomalies and rare intellectual disabilities
- Rare neuromuscular diseases
- Rare pulmonary diseases
- Rare renal diseases
- Rare skin disorders
- Rare urogenital diseases
- Transplantation in children

Still initial or unclear proposals (3)

- Rare gynaecological and obstetric diseases
- Rare connective tissue and musculoskeletal diseases
- Rare Cancers and Tumours Adults

Two or more tentative proposals (5)

- Rare endocrine diseases
- Rare Vascular diseases
- Rare Cardiac Diseases
- Rare haematological diseases
- Rare neurological diseases

No known proposals

- Rare craniofacial anomalies and ENT (ear, nose and throat) disorders
- Rare gastronintestinal diseases

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Support for preparing your application !!!

FAQ

Info Day

ERN Info day
7th April

Partners search

Consumers, Health, Agriculture, and Food Executive Agency
Chafea

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Thank you!

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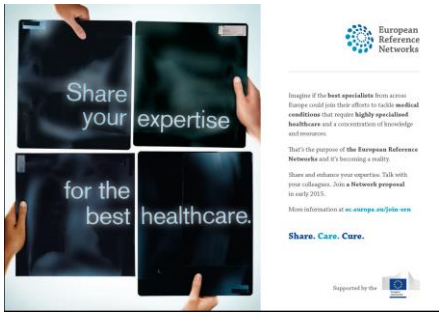

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