

European Reference Networks (ERNs)

Towards a ERN on Rare Multi-Systemic Vascular Diseases

**Filière de Santé Maladies Rares FAVA-Multi
French Healthcare Network on Rare Multi-
Systemic Vascular Diseases**

Symposium Ghent – March, 8th 2016

ERN Call for interest *(European Commission, DG Health)*

- **Call March 2016 (?)**
 - 3 months to answer
 - establish ERNs by Oct 2016
- **Possibility for Centres of Reference to join established ERNs : call every year**
 - ERN : open a clear procedure for associated/
collaborative members
- **Further ERNs calls next years**

ERNs aim to...

- Link and pool **existing highly specialised healthcare providers** across the EU
 - Institutionalize EU experts cooperation
 - concrete projects: communication, telemedicine, teaching, research, information dissemination and evaluation
 - overcome the challenges of rarity
- Facilitate access to diagnosis and treatment in **rare or low prevalence complex diseases or conditions**
 - centralising: knowledge, experience, medical research, training, resources
 - Reduce inequalities of treatment within the EU

Principles

- **Networking : key element**
 - expertise travelling rather than the patient
 - fluid exchange of information and knowledge
 - use of e-tools
- **Patient-centered**
- **a “home” for each patients, including undiagnosed**
 - very rare / less visible RDs to be integrated within ERNs
- **Open to affiliated Centers**
 - entrance pathways once ERNs established
 - concrete cooperation plan

Members & Grouping of RD

- **≥ 10 Healthcare providers**
 - **from 8 EU countries**
- Countries :
 - 28 EU Member States
 - EEA : Norway, Liechtenstein
- **Grouping of Rare Diseases to create a logical and feasible number of ERNs: 22 thematic groups**
 - « Rare Multi-Systemic Vascular Diseases »
 - « Rare Connective tissues and Musculoskeletal Diseases »

Sharing practices

ERN on Rare and Undiagnosed Skin Disorders

5 disease groups + subgroups on high level patient management and research

- Epidermolysis Bullosa with EB-Clinet, a clinical network of EB centres and experts
- Ichthyosis & Palmoplantar Keratoderma
- Ectodermal Dysplasia including Incontinentia Pigmenti and Skin Fragility Disorders
- Connective Tissue Disorders
- Cutaneous Mosaic Disorders - Nevi & Nevoid Skin Disorders

5 transversal groups

- Teaching & training
 - Deep phenotyping
 - Outcome measures
 - e-health
 - Website based on the Genodermatoses Network and Geneskin, online database
- inclusive approach: invitation to other involved to join

Legislative background ERN

follow at least 3 of the following objectives

(a) to help realise the potential of **European cooperation regarding highly specialised healthcare** for patients and for healthcare systems by **exploiting innovations** in medical science and health technologies;

(b) to contribute to the **pooling of knowledge** regarding sickness prevention;

(c) to **facilitate improvements** in diagnosis and the delivery of high-quality, accessible and cost effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;

(d) to **maximise the cost-effective use of resources** by concentrating them where appropriate;

(e) to **reinforce research, epidemiological surveillance like registries and provide training** for health professionals;

(f) to **facilitate mobility of expertise**, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;

(g) to encourage the **development of quality and safety benchmarks** and to help develop and spread **best practice** within and outside the network;

(h) to **help Member States** with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

Criteria

Each criteria shall be implemented through measures, checked by evidences

Organisation of the Operational Criteria

Networks

General Criteria and Conditions to be fulfilled:

1. Highly Specialised Healthcare
2. Governance and Coordination
3. Patient Care
4. Multidisciplinary Approach
5. Good Practice, Outcome Measures, and Quality Control
6. Contribution to Research
7. Continuous Education, Training, and Development
8. Networking and Collaboration

Defined in the Network proposal and fulfillment assessed for each applicant healthcare provider. Based on the evidence and consensus of the scientific, technical and professional community



Healthcare Providers

General Criteria and Conditions to be fulfilled:

1. Patient Empowerment and Patient-Centred Care
2. Organisation, Management, and Business Continuity
3. Research, Education and Training
4. Expertise, Information Systems, and e-Health Tools
5. Quality and Safety

Specific Criteria and Conditions to be fulfilled:

1. Competence, Experience and Outcomes of Care
2. Human Resources
3. Organisation of Patient Care
4. Facilities and Equipment

General Criteria & conditions for ERNs

Each criteria : implemented through measures, checked by evidences

ESTABLISHMENT OF A ERN

- minimum of **10** Members across **8 Member States**

HIGHLY SPECIALISED HEALTHCARE

- for one or more rare or low prevalence complex diseases or conditions

GOVERNANCE AND COORDINATION

- clear **governance and coordination structure**, mechanisms to support oversight and evaluation

PATIENT CARE

- **good quality and safe** patient care
- empowers and **involves patients**

MULTIDISCIPLINARY APPROACH to care

GOOD PRACTICE, OUTCOME MEASURES, AND QUALITY CONTROL

- **specialised** clinical expertise and produces good **practice guidelines**
- **collaborates** with its Members and other relevant partners to bring healthcare within its area of expertise closer to its patients
- develops and/or implements **clinical guidelines** and cross border patient pathways.
- **quality controls and monitors** clinical outcome measures

CONTRIBUTION TO RESEARCH

- evidence of **ongoing research**

CONTINUOUS EDUCATION, TRAINING, AND DEVELOPMENT

- continuous **education, training,** and development activities

NETWORKING AND COLLABORATION

- **collaborates** closely with other Centres and Networks

General Criteria & conditions for HCPs

Each criteria : implemented through measures, checked by evidences

PATIENT EMPOWERMENT PATIENT CENTERED CARE

- care is **patient-centred** and **patients' rights and preferences** are respected
- provides patients with **clear and transparent information** about the **complaints procedures and remedies**
- **collects patient care experience** and uses this information to make on-going **improvements**
- protects the **privacy and confidentiality** of patient
- **Patient informed consent** Article 2(e) of the Directive 2014/286/EU
- maintains **transparency**, (patients and general public) about **clinical outcomes, treatment options, and quality and safety standards** that are in place

ORGANISATION, MANAGEMENT, BUSINESS CONTINUITY

- **rules and procedures for services provided**
- **shares information** with patients and their families about reimbursement
- a **business continuity plan**
- **procedures and/or inter-agency or shared care agreements** to support ease of access and coordination with other resources
- **good general facilities**
- policies and procedures in place to **communicate with clinicians** post discharge
- **education and training activities**
- **research activities** and experience

General Criteria & conditions for HCPs

*Each criteria : implemented through measures,
checked by evidences*

EXPERTISE, INFORMATION SYSTEMS, e-HEALTH TOOLS

- exchange expertise
- safeguards the use of medical data
- use of **telemedicine and other e-health tools** within and outside its facility
- **coding and information system** is in line with nationally and internationally recognised systems

QUALITY AND SAFETY

- monitors the **quality and safety of the care**
- **commitment to using best practice knowledge** and evidence based health technologies and treatments
- develops and/or uses **clinical practice guidelines**

Criteria

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Specific Criteria for HCPs

COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

- maintains its **competence** in the Network's area of expertise
- **good clinical care and outcomes**

HUMAN RESOURCES

- team of **trained professionals**

ORGANIZATION OF PATIENT CARE

- **multidisciplinary and specialised** care team

FACILITIES AND EQUIPMENT

- necessary **facilities and equipment** to attend to patients specific to the area of expertise, disease, or condition as defined by the Network

Funding issues

- **No funding** in the ERN call
- **Some exclusivity accessing sources of funding (H2020)?**
- **Secure ERN IT platform** by EU:
 - a shared intranet by all networks
 - specific intranet platforms for each ERN
- **3rd EU Health Programme, Work Programme 2016**
 - ERNs coordination and projects (not clinical)
 - RD registries (3 or 4) by established ERNs

Patient organisations (PO)

- Not ERNs members
- ERNs includes patients representatives (national PO)
- **“EPAGs - EURORDIS Patients Advisory Groups”**
 - 1 group / ERN
 - elected patient representatives
 - will ensure that the patient voice is heard throughout the ERN development process

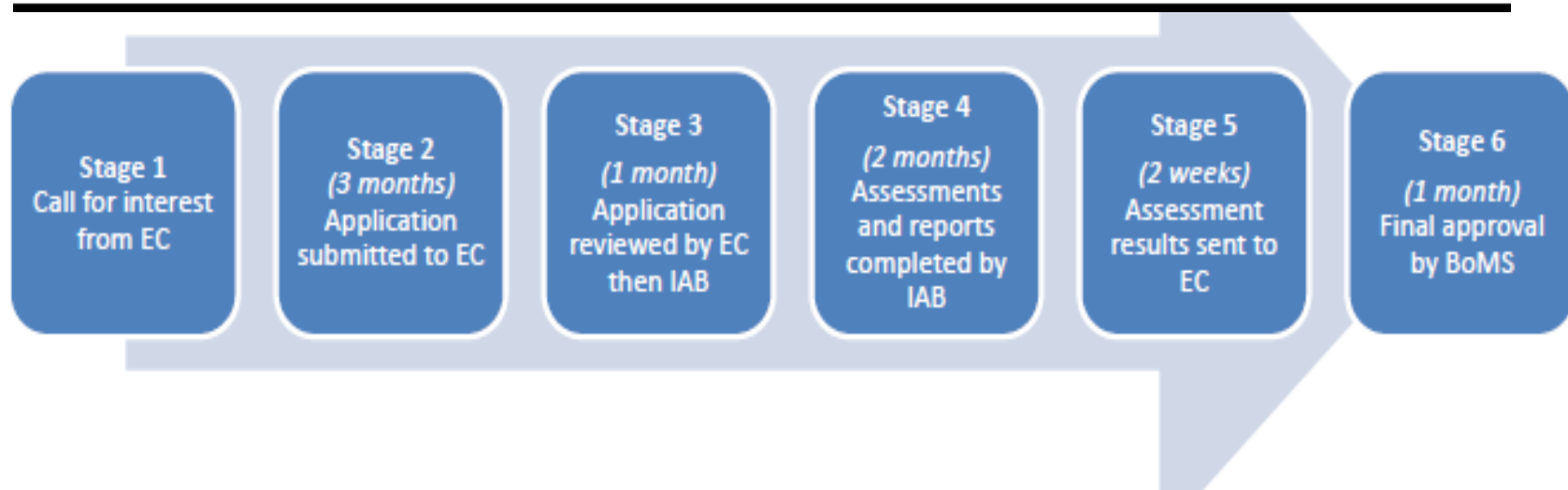
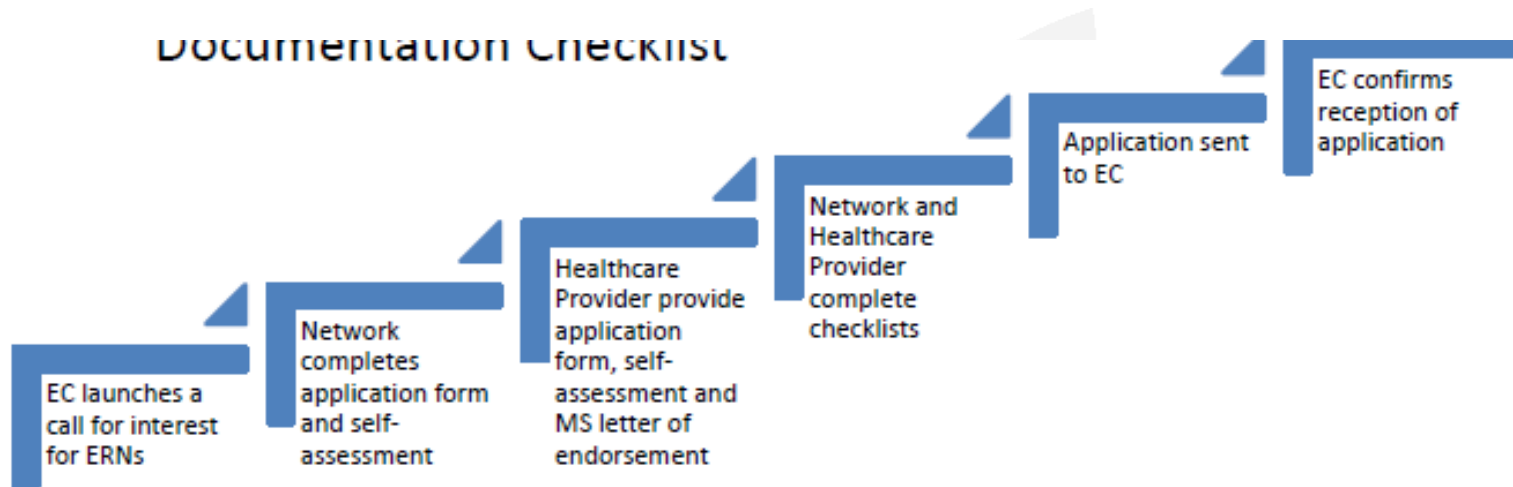
Challenges

- **Network :**
 - avoid fragmentation and duplication of efforts
- **Centres of expertise :**
 - *validated* by national governments
 - Important work
 - Application form
 - Supportive documents
 - Self-assessments
- **1st ERNs:**
 - Test
 - 2-3 to 10 ERNs ?



Application, Assessment

Documentation Checklist



Application process

- 1 / Declaration of interest
- 2 / **Validation by Member State**
 - Board of Member States representative(s)
- 3 / Fill-in applications forms:
 - Network and HCPs

ERN on Rare Multi-Systemic Vascular Diseases

- Manifestation of interest from CE in Belgium, Spain, Italy, Netherlands, France, Hungary, Germany, UK
- Call to EU partners HHT network launched
- Diseases included:
Marfan and related disorders, TAA, EDS, HHT, lymphatic ?

Thank you for your attention

Q&A session

**Contact us to build together the ERN on Rare
Multi-Systemic Vascular Diseases**

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