Overview of Assessment Process

Yann Le Cam and Matt Johnson, EURORDIS

Council of European Federation, 29 October 2015

Objectives

Build capacity of the members of the Council of European Federations on the ERNs:

- ✓ Overview of Assessment Process
- ✓ Description of the Assessment Manual and Toolbox
- ✓ Understanding of the Operational Criteria
- ✓ Overview of the Decision Points and Guidelines

Overall Assessment Process

ERN Minimum Requirements

Minimum requirements:

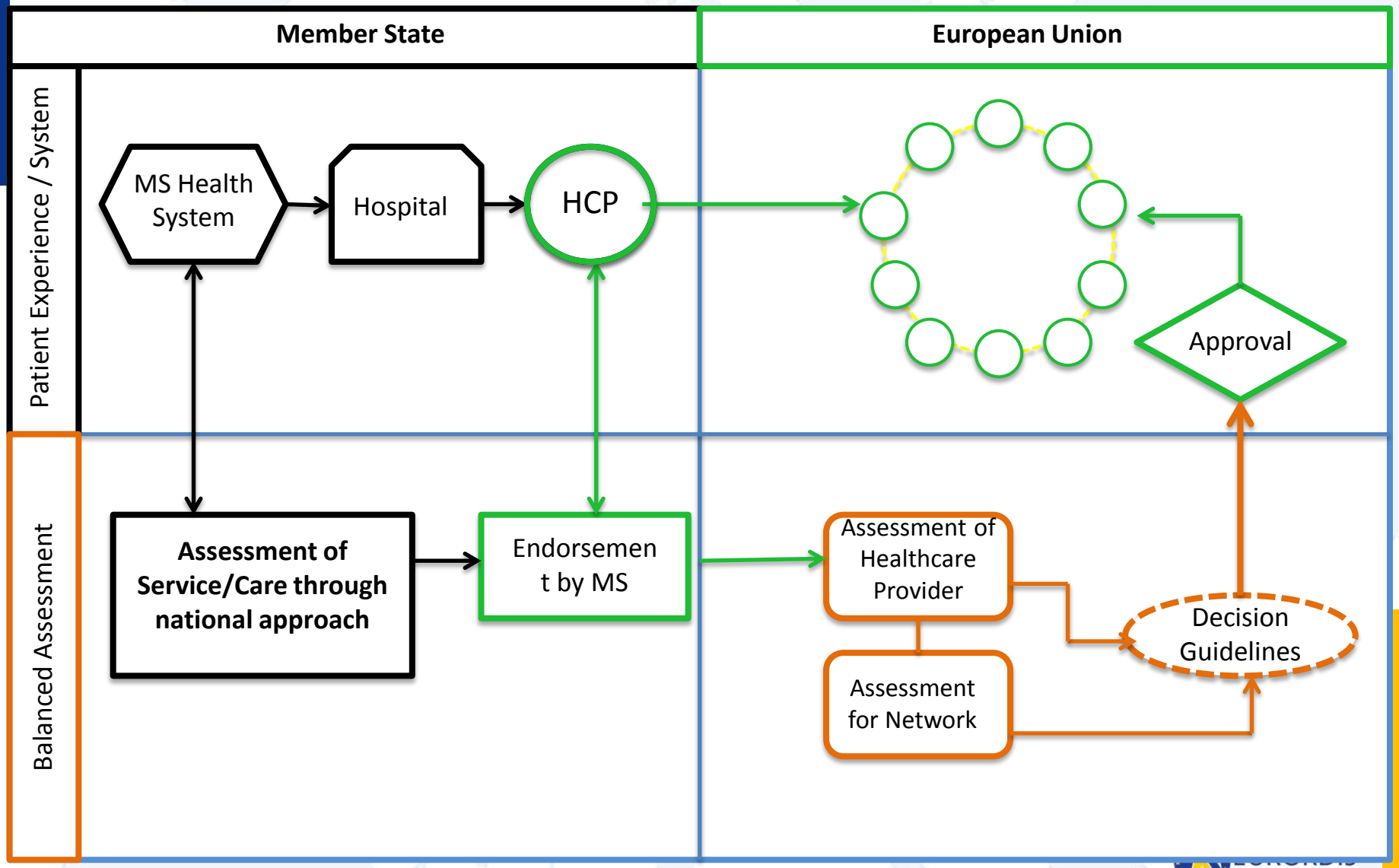
- 10 Member Applicants from 8 Member States
- Member State Endorsement

Proposed Network application:

- One Network Application (x1)
- Application for each Healthcare Provider Member (minimum of x10)

Source: EC ERN Plenary Workshop Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

ERN Assessment Scheme

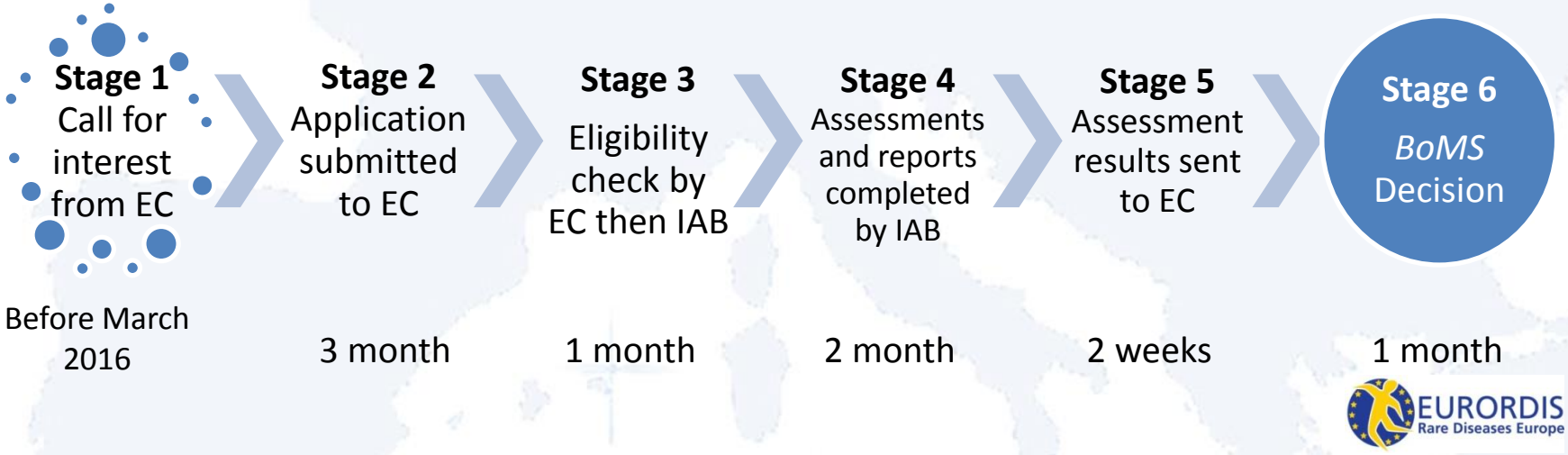


Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Assessment Process for ERN Applications

Description of the Assessment Process

- EC ERN Implementation Decision sets out the legal steps of the assessment process
- 6 Stage Process & provisional timescale of 6-8 month

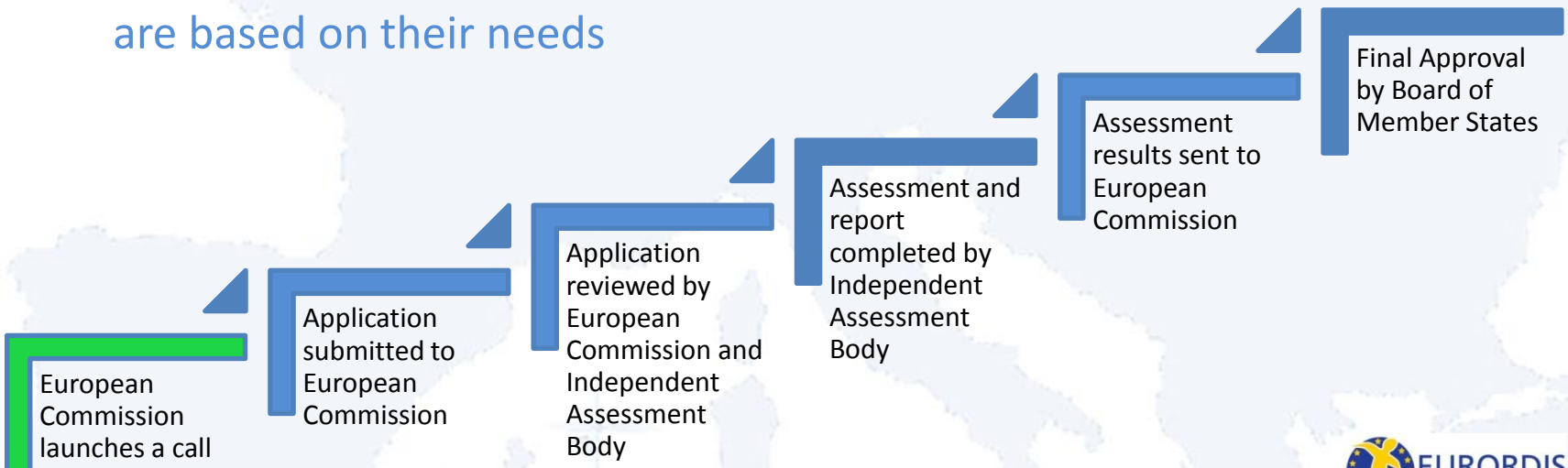


Stage 1: Call for Interest

Call for Interest:

- 1st stage of the Assessment Process
- 3 months for applicants from 1st Call to submission of application
- ALL Healthcare Provider must have National Endorsement by their Member State
- Applicant need to define the scope of diseases covered by the Network and the threshold for expertise

❖ Advocacy activity – Patient Organisations should engage with potential Applicants to ensure the Network disease scope and services covered are based on their needs



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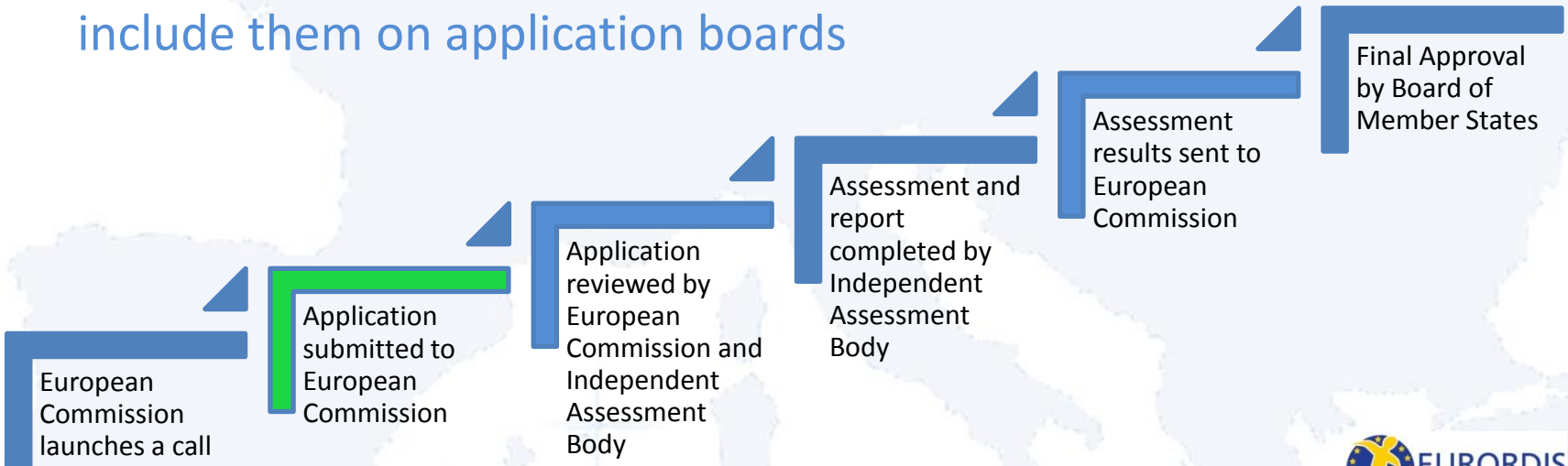
Stage 2: Application Process

Development of the Application(s)

- Network should first review and define specific criteria
- Complete the Application Forms and collect supporting evidence
- Complete an internal peer review using the Self-Assessment forms

❖ Advocacy activity: Patient Organisations should ensure clinical leads include them on application boards

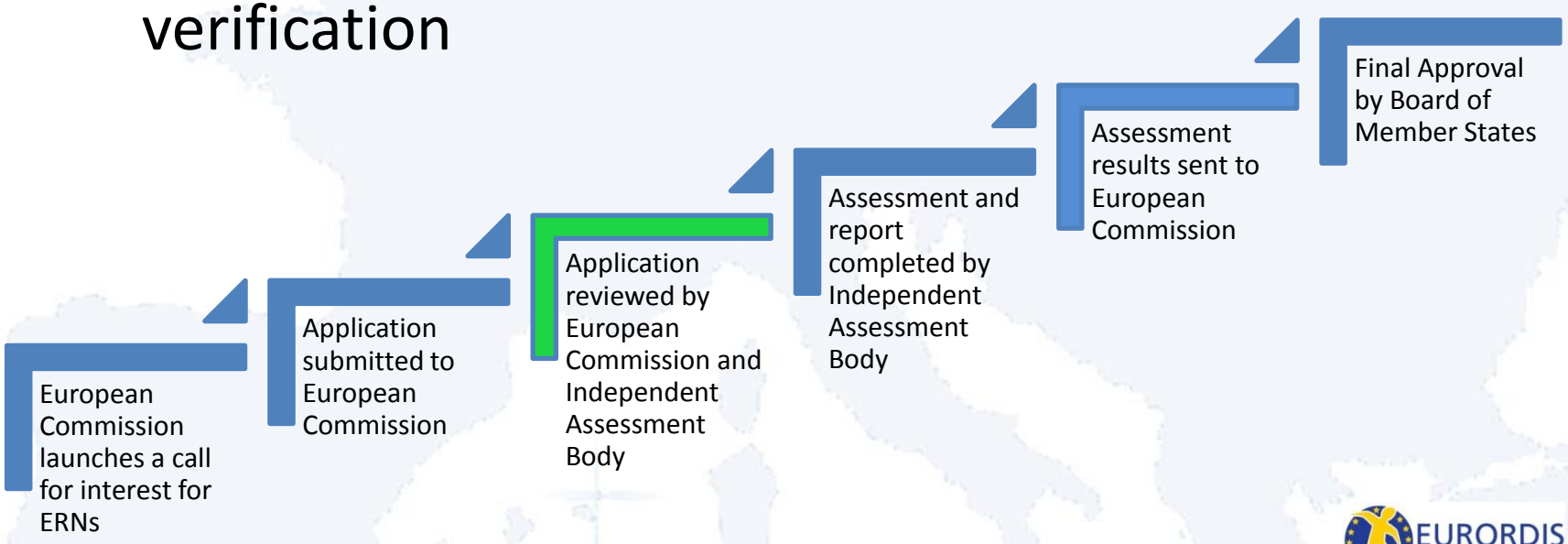


Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Stage 3: Determining Eligibility for the Assessment

Description

- Completed by both the EC then IAB
- European Commission: Structural validation
- Independent Assessment Body: Content verification

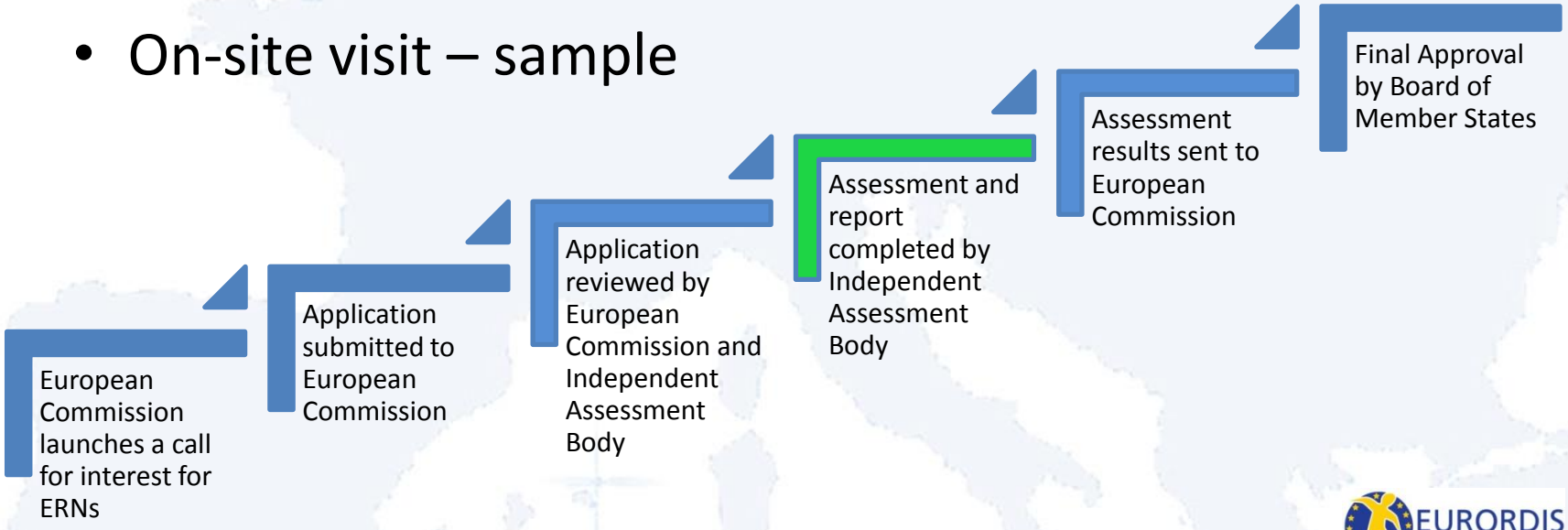


Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Stage 4: Technical Assessment

Three components:

- Documentation review of Network and all Healthcare Providers
- Virtual interview with Network Coordinator and Members
- On-site visit – sample



Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Stage 4: Technical Assessment

The site visit sampling methodology is defined in the AMT for IAB as:

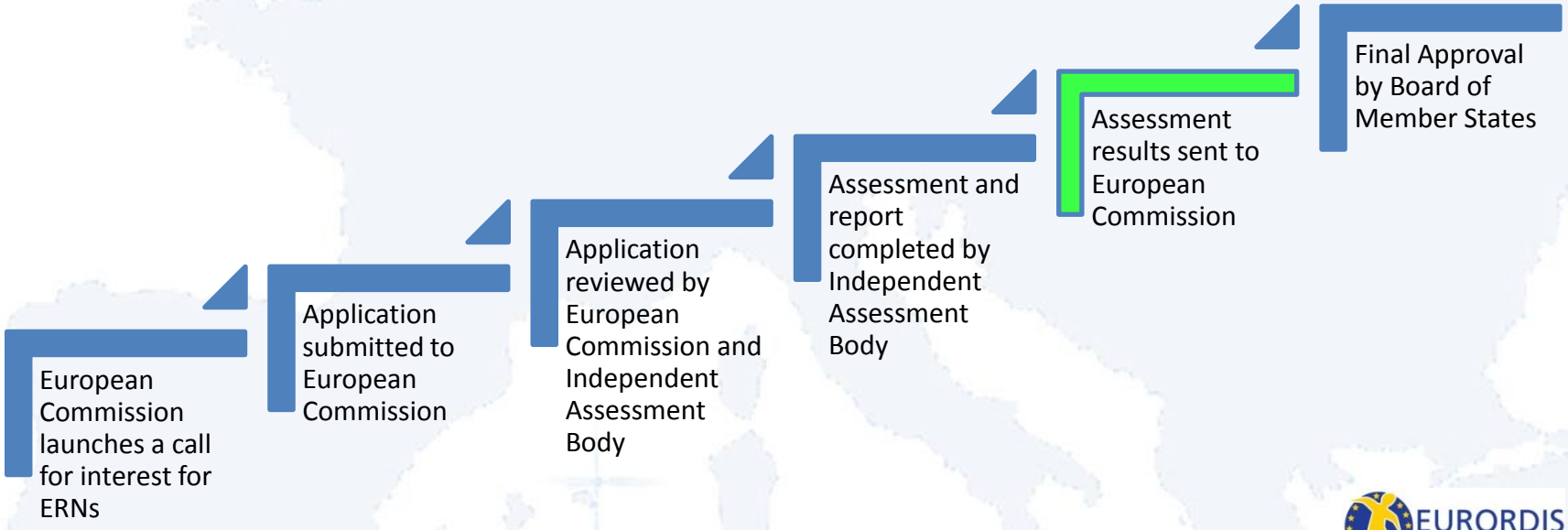
- Specific role within the Network
- Highest and lowest compliance rate of the Operational Criteria based on the documentation review and virtual interviews
- Highest and lowest patient volume
- Geographic representation
- Disease grouping representation

Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Stage 5: Assessment Results Submitted

Description:

- Transfer of Application Forms, Self-Assessment Forms and Positive Assessment Reports
- Review by Board of Member States

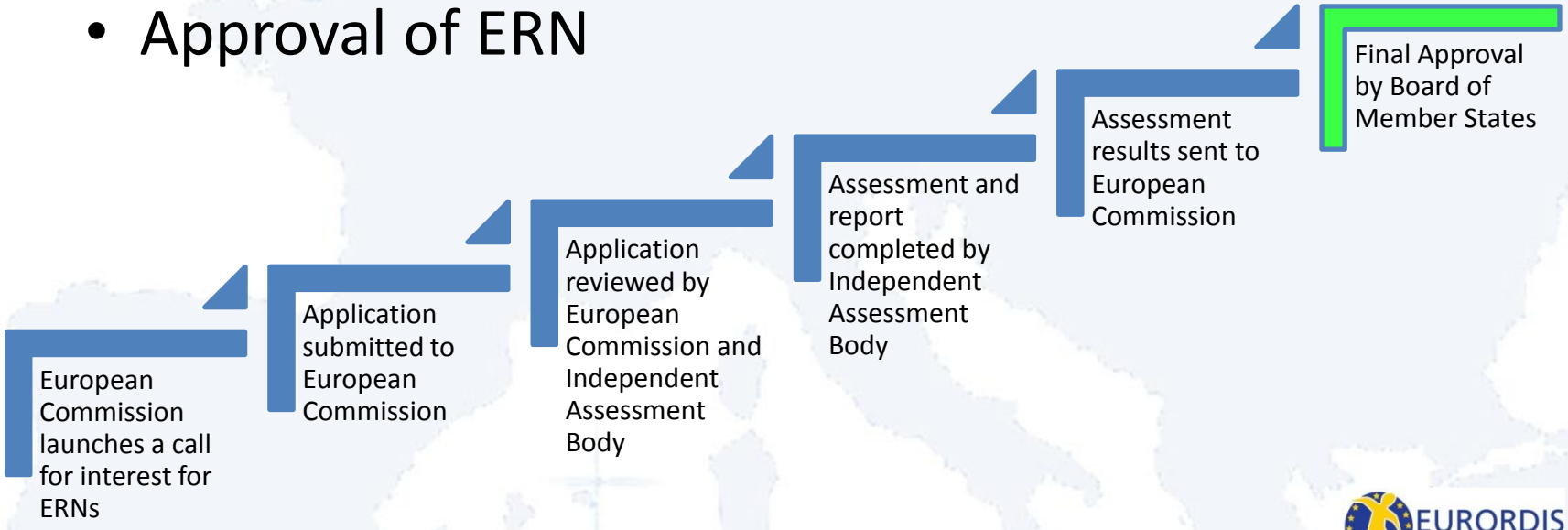


Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Stage 6: Final Approval

Description: (*5th Decision Point)*

- Board of Member States reviews the recommendation by the Independent Assessment Body
- Approval of ERN



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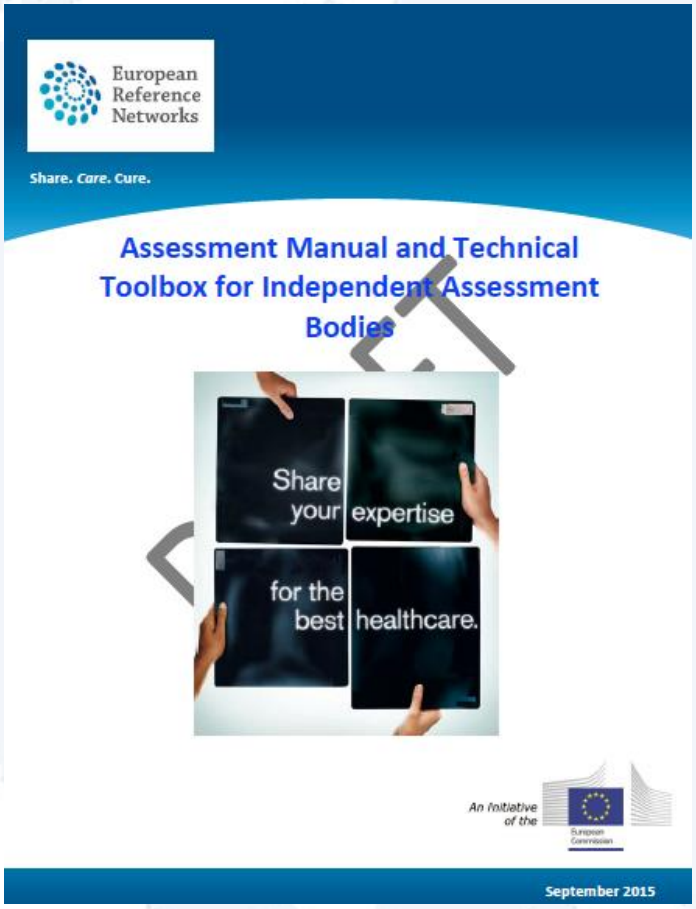
Assessment Manual & Technical Toolbox

Assessment Manuals and Technical Toolboxes

http://ec.europa.eu/health/ern/docs/assessment_manual_applicants_en.pdf



http://ec.europa.eu/health/ern/docs/assessment_manual_iab_en.pdf

EURORDIS Rare Diseases Europe

Assessment Manuals and Technical Toolboxes

Common content

Additional items in EC and IAB manual

Content for Applicants:

- Operational Criteria
- Overview of Six-Stage Process
- Descriptions and Timelines
- Instructions
- Tips
- Tools
- References to EC Directives
- Glossary

Content for EC and IAB:

- Same Content as Applicant Manual
- Instructions or Procedures from the EC & IAB's perspective
- Additional Sections:
  - Conflicts of Interest
  - Eligibility Procedures and Checklist
  - Assessor Application and Selection Process
  - Assessor Training and Competency Review
  - Assessor Checklists and Procedures
  - Additional Technical Tools

Operational Criteria

Legal Foundation for Operational Criteria

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [1], and in particular point (a) of Article 12(4) thereof,

Whereas:

(1) Article 12 of Directive 2011/24/EU provides that the Commission is to support the Member States in the development of European Reference Networks ('Networks') between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases [2]. For the purposes of this, the Commission shall adopt a list of specific criteria and conditions that must be fulfilled by European Reference Networks and healthcare providers wishing to join and become a Member of a Network ('Member'). The Networks should improve access to diagnosis, treatment and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.

Operational Criteria

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:

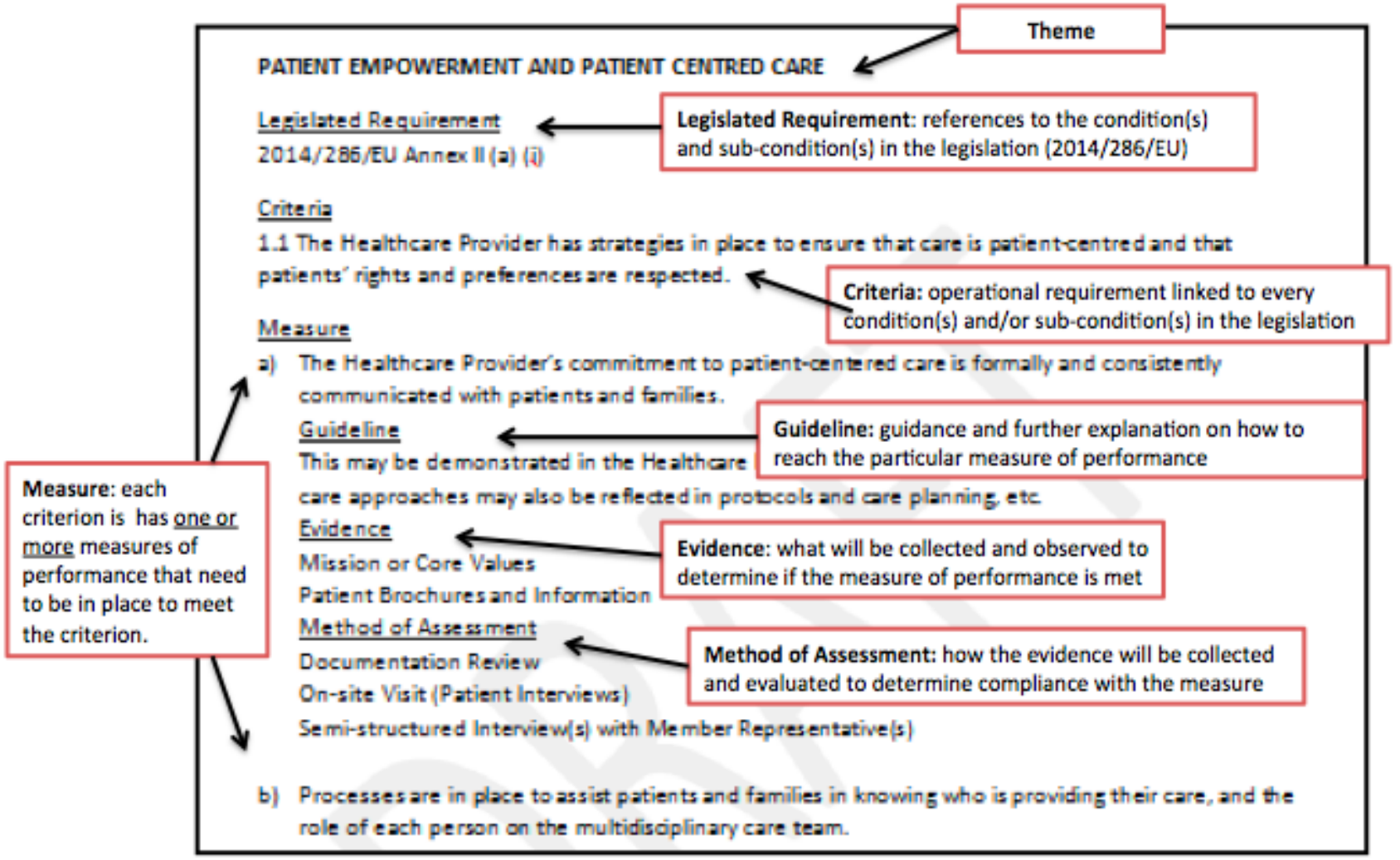
1. Patient Empowerment and Patient-Centred Care
2. Organisation, Management, and Business Continuity
3. Research, Education and Training
4. Expertise, Information Systems, and e-Health Tools
5. Quality and Safety

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

Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Operational Criteria Format



Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Operational Criteria (SAMPLE)

General Criteria and Conditions to be fulfilled by Networks:

GOVERNANCE AND COORDINATION

Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Criteria

1.2 The Network has a clear governance and coordination structure that includes mechanisms to support oversight and evaluation.

Measure

a) There is one Member within the Network designated as the Coordinating Member. One person is appointed by the Coordinating Member to act as the "Coordinator" of the Network.

Guideline

The Coordinating Member should be chosen on the basis of proven ability to coordinate and lead a Network as well as the medically relevant activities in the field of expertise. The best Coordinating Member may not necessarily be the best center of expertise or the one with the largest volume of patients, rather the one that has the capacity to fulfil all the key functions of coordination and to develop, promote, and expand the Network, as necessary. The Coordinator is selected from among the health professionals belonging to the Coordinating Member. The Coordinator, assisted by the Board, supports and facilitates coordination within the Network and with other Healthcare Providers. The Coordinator chairs the meetings of the Board and represents the Network. The Coordinator may also be supported by a Steering or Coordination Committee.

Evidence

Name of Coordinating Member and Network "Coordinator"; Rationale for selecting the designated Coordinating Member; Documented role and responsibilities of the Coordinating Member and "Coordinator"; Terms of Reference for the Steering or Coordination Committee, as applicable

Operational Criteria (SAMPLE)

General Criteria and Conditions to be fulfilled by Healthcare Providers:

PATIENT EMPOWERMENT AND PATIENT CENTRED CARE

Legislated Requirement

2014/286/EU Annex II (a) (i)

Criteria

1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.

Measure

a) The Healthcare Provider provides patients and their families with written information specific to the area of expertise, disease, or condition.

Guideline

The information should include, at a minimum, the following: services offered; the nature of the disease, treatment and possible complications, rights and obligations, how to access the center; information about the staff and collaborating consultants; other members in the Network, and local and national patient support organizations.

Evidence

Patient Brochures and Information

Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Operational Criteria (SAMPLE)

Specific Criteria and Conditions to be fulfilled by Healthcare Providers:

COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

Legislated Requirement

2014/286/EU Annex II 2 (a) (i-ii)

Criteria

1.1 The Healthcare Provider maintains its competence in the Network's area of expertise and demonstrates good clinical care and outcomes.

Measure

a) The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.

Guideline

This includes, as an example, volume of activity such as number of prevalent and incident cases, number of referrals, and accumulated experience such as the number of published reports, peer-reviewed publications, grants, training activities, participation in projects, and clinical trials.

Evidence

Dashboard of Patient Activity Measures

Source: EC ERN Plenary Workshop, Lisbon – http://ec.europa.eu/health/ern/events/ev_20151008_en.htm

Decision Point & Guidelines

Proposed Decision Guidelines

6.4.3 Decision Guidelines

In addition to being an objective, measurable, and consistent approach, the technical assessment helps applicants assess their current performance and identify where improvements are needed in providing care to patients with rare or low prevalence complex diseases or conditions.

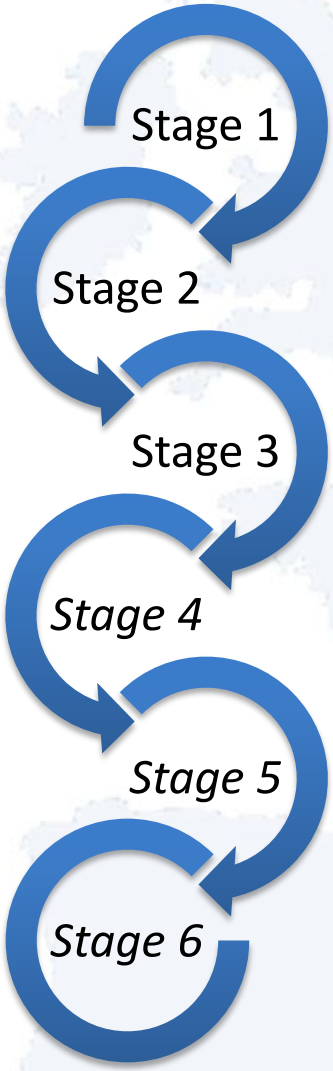
For an applicant to obtain a positive assessment, the following conditions must be met:

- An overall compliance rate of 70% of the maximum score ("X" number of criteria X a maximum rating of 2 = "X").
- Each theme must also achieve 70% compliance against the maximum score.
- All core measurement elements must achieve a rating of 2.
- There should be no criteria under any theme rated as "0".
- A rating of "1" for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place. There should be no more than 2 criteria in any theme rated as "1".

If the Applicant is unable to meet **all** of the above conditions, this will result in a negative assessment.

Source: EC ERN'S AMT for Applicants – http://ec.europa.eu/health/ern/docs/assessment_manual_iab_en.pdf

Decision Points



- **Pre-assessment Decision Point - National endorsement** of Healthcare Provider to take part in Network application by Member States
- No Decision
- **1st & 2nd Decision Point - Eligibility check**
  - **Structural validation** by European Commission - Minimum requirements, completed application forms and endorsements for ALL Healthcare Provider
  - **Content verification** by Independent Assessment Body - Expertise, full application completed, meetings the requirements to provide highly specialised healthcare
- **4th Decision Point - Technical assessment** against operational criteria
- *No Decision*
- **5th Decision Point - Approval** by Board of Member States

Source: EC ERN'S AMT for IAB – http://ec.europa.eu/health/ern/docs/assessment_manual_iab_en.pdf

Constrains & Flexibility

- Recommendation on Rare Disease Groupings is “strongly indicative”– avoiding fragmentation and overlap in applications
- Defining scope of network applications
- Network defining specific criteria – expertise, resources, equipment
- Visability of interested partners and applications
- Variability in maturity of national assessment process and defining experts
- No definition yet of Collaborative and National Associated Centres
- Developing strategic direction across Europe
- Timescale for new grouping of networks
- No date for second call for ERN Applications
- Funding
- Framework of partnership with pharma & biotech

EUCERD Rare Disease Groupings

Rare immunological and auto-inflammatory diseases	Rare craniofacial anomalies and ENT (ear, nose and throat) disorders
Rare bone diseases	Rare Hepatic diseases
Rare cancers* and tumours	Rare hereditary metabolic disorders
Rare cardiac diseases	Rare multi-systemic vascular diseases
Rare connective tissue and musculoskeletal diseases	Rare neurological diseases
Rare malformations and developmental anomalies and rare intellectual disabilities	Rare neuromuscular diseases
Rare endocrine diseases	Rare pulmonary diseases
Rare eye diseases	Rare renal diseases
Rare gastro-intestinal diseases	Rare skin disorders
Rare gynecological and obstetric diseases	Rare urogenital diseases
Rare hematological diseases	

Source: http://ec.europa.eu/health/rare_diseases/docs/20150610_erns_eucerdaddendum_en.pdf

03/11/2015

European Federations & Networks strategic activities?

1. Identifying the right expertise, centres, healthcare providers and engage with potential clinical leaders or ERN leader and Member State lead
2. Advocate for patient representative to be included in the preparation of the application (selection od clinical networks, choice of CoE, self assessment of CoE and ERN) as much as in the decision making processes and national advisory board
3. Work with applicant to shape the scope and expansion plan of the network
4. Advocate population needs and priority areas to Member State lead to inform the strategic direction
5. Promote interested experts and clinicians to raise the profile of the rare disease with Member State lead and to encourage their expert and clinical counterparts to also raise the profile of their interest to develop an application
6. Advocate for centres to be identify as Collaborative or National Associate Centres and National Hubs in your respective Member State

EURORDIS strategic activities?

1. PACE-ERN + Assessment Manual & Tools final + Translation in French & German + Training of Independent Assessment Bodies + Project Management
2. Advocate for a) Call in May b) Announcement of year 2nd Call c) Funding attached to ERNs from 2017 as glue money for ERN coordination
3. Work through the Joint Action RD-Action to support matchmaking between clinical leaders, to inform and build capacities of potential ERN leaders, etc
4. Prepare sessions for ECRD 2016, EMM 2016 and content for National Conferences (part of Joint Action WP2)
5. Develop guidance to members of CEF and future patient representatives in ERN on where and how to engage in ERN: based on previous guidance developed by CEF + on CEG-RD Recommendation + Assessment Criteria
6. Organise the democratic representation of PLWRDs per rare disease grouping (afternoon session)
7. Organise the support and tools to enable information sharing, experience exchanges, collective intelligence, co-elaboration: staff team support, communication (RareConnect), Webinars, Training or F2F Sessions…

EURORDIS Rare Diseases Europe

Questions?

- Assessment Process
- Assessment Manual & Technical Toolbox
- Operational Criteria
- Decision Point and Guidelines
- European Networks & Federation strategic activities
- EURORDIS' Strategic Activities

Thank you

Daniel -Sanfilippo syndrome

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