European Reference Networks (ERNs)

Q & A for Researchers

European Reference Networks (ERNs) have been the focus of much discussion at European events, including the two conferences organised by DG Health and Food Safety which took place in Brussels on June 23rd 2014 and Lisbon October 8th and 9th 2015.

The information below is a compilation of basic information about ERNs along with several frequently asked questions raised by researchers during the period ERNs have been developing, divided into topics:

1. Timing
2. Researches involvement in ERNs
3. Groupings of diseases
4. Funding
5. Quality of Expertise
6. Clarification of impact of ERNs
7. Incentive for clinical researchers
8. Existing legislation

For further information:

European Commission webpage:
http://ec.europa.eu/health/ern/implementation/faq_en.htm

This Q&A has been developed based on a EURORDIS document:
http://www.eurordis.org/sites/default/files/ERN%20Q%26A%20Final..pdf?platform=hootsuite
and on our own experience and knowledge acquired by attending conferences and reviewing all the published policy documents about ERNs.

Once the specific procedure for Spain is defined by the MSSSI and in place, CIBERER will forward you the information. For more details please contact CIBERER's Scientific Management Department: gestores@ciberer.es

Basic information about ERNs

1) What is an ERN?

A network connecting health care providers and centres of expertise granting highly specialised healthcare, for the purpose of improving access to diagnosis, treatment and the provision of high-quality healthcare for patients with conditions requiring a particular concentration of resources or expertise no matter where they are in Europe. For clinicians already participating in networks, the ERN will represent the formalisation of their networking structures/practices in highly specialized healthcare. For those without specialized networking communities at present, ERNs will promote expertise and support health care providers in order to bring local, regional and national provision of healthcare closer to the patients.

2) How many centres from each country might participate in an ERN?

- To be eligible for application, a proposed network has to consist at least of 10 HCP out of 8 Member States. The Commission Implementing Decision provides the minimum but not the maximum of possible HCP. This will be agreed by the proposing network along with their considerations of the governance of the network. The possibility to include more than one centre of expertise of a member state by endorsement is in the responsibility of the Member State.
- When considering the number of centres to network in any given ERN, it is important to remember that as per the Acts, one representative from each member will need to serve on the Board of that ERN - the larger the Board, the more challenging the governance.

3) How to proceed to become an ERN?

Before starting to set up an ERN, the following suggestions might be helpful:

- Review the information on the Commission webpage which includes the current framework, the legislative proposal and many frequently asked questions (FAQ).
- Contact your national representatives in the ERN Board of Member States. They will provide you with more specific information on the national endorsement process.
- Conceive a one page document with your network proposal and share it with the national and European medical societies as well as your national representatives.
- Address a wide scope in your network proposal referring to thematic groups. An example of such possible groupings can be found in the Rare Disease European Reference Networks: Addemdum to EUCERD Recommendation of January 2013.

4) How do you become a member of an ERN?

The directive 2011/24/EU is intended to provide a legal framework within the European Union (EU) to facilitate cross-border care. Article 12 requires the European Commission to support the Member States in the establishment of the ERN. The process regarding how to become a

member of an ERN is clearly defined in the Implementing Acts: a healthcare provider (HCP) wishing to become a member of an ERN will have to pass an assessment process based on the criteria in Delegated Decision (2014/286/EU) Annex II and on the Implementing Decision (2014/287/EU). This assessment will comprise several steps:

- the formal support/endorsement by the Member State in which the HCP is based (for further information an interested HCP should approach the relevant MS representative on the Board of Member States (BoMS)(where you can find the contact of the Spanish representatives) of ERNs and ensure they understand and abide by the agreed national process for endorsing HCPs (More information).
- Spain has a clear policy and criteria regarding the designation or identification of National Centres of Expertise, known as Reference Centres, Services and Units (CSUR) of the Spanish National Health System (NHS) (More information).
- After passing an eligibility check by the Commission, and a technical assessment by the independent assessment bodies, composed of documentation review, teleconferences and on-site visits will follow (see point 6).
- The final approval of the proposed ERN will take place by the Board of Member States.

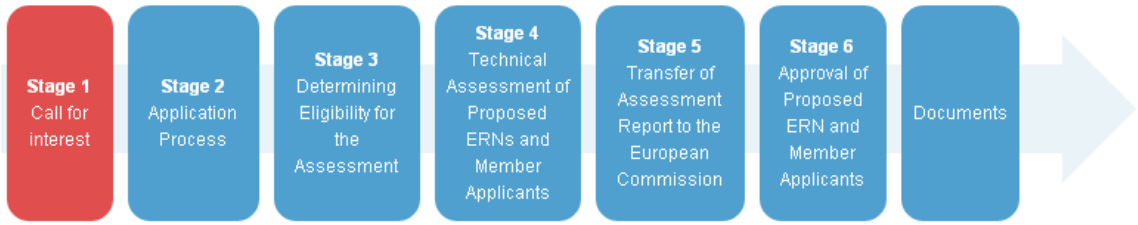
5) How will coordination of an ERN be decided?

- The Acts state that the ERNs will be governed by a Board of each network, composed of representatives of each member HCP. One of these HCPs has to be designated as the coordinator of the proposed network and a single individual from this HCP will be named network coordinator.
- More details are (will be) found in the Assessment Manual and Toolkit.

6) How will applications be assessed?

The applications will go through three different stages - the eligibility check by the Commission and the independent assessment bodies, the technical assessment by the independent assessment bodies and the approval by the Board of Member States. For the application, each applicant member will have to secure the endorsement of its Member State. An Assessment Manual and Tool-Kit for applicant members will describe the assessment procedure.

Assessment process



http://ec.europa.eu/health/ern/assessment/index_en.htm

Frequent Questions and Answers for Researchers

1. Timing

- **What is the schedule for the first ERN call?**

The European Commission ERN Delegated Acts require the first call to have been launched by 27 May 2016. **It is expected that the first call will be launched in spring 2016, possibly in March.** There will be 3 months to develop a proposal.

- **How many calls will there be for ERNs?**

The 1st call will take place in 2016. After consulting the Member States, the Commission shall decide on the appropriate timing for the publication of subsequent calls for interest.
It is expected that there will be other future calls for ERN applications. The timing of these future calls has not yet been published. However, the possibility to join an already existing ERN should always be opened, provided that the Centre applying fulfils all the necessary requirements.

2. Researchers involvement in ERNs

- **Can clinical researchers be involved before the formation of ERNs?**

Clinical researchers can prepare an application to help shape the scope of rare disease ERNs and potential services provided by successful ERNs. One criterion to be fulfilled by ERNs is that the Network must:

a) identify and fill research gaps;
b) promote collaborative research within the Network;
c) reinforce research and epidemiological surveillance, through setting up of shared registries.

So it is been established as a formal requirement in the legislation, as set out the Commission Delegated Decision (setting out criteria and conditions that the ERNs and healthcare providers wishing to join an ERN must fulfil).

It´s also important to highlight that the ERNs members must be healthcare providers, that being the reason why we only refer to "clinical" researchers.

- **What is the role of clinical researchers in each ERN?**

The Networks should improve access to diagnosis, treatment and the provision of high-quality healthcare to patients who have the 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.

In order to promote participation of clinical researchers in each ERN, CIBERER wants to facilitate and support research groups to participate in the ERN application process.

- **In the implementing decision specific mention to collaborative/associated members of ERNs is made- what are these and can other research centres get involved?**

Collaborative and associated members are centres which can also become part of an ERN. There is no definition of these centres in the European Commission ERN Delegated Acts and they are not assessed as part of an ERN application. Only Healthcare providers that have been identified as experts according to the Member State legislation can formally sit on the Network's Board and be assessed against this EC legislation. It is the responsibility of Member States to identify and define the role and function of collaborative and associated centres in an ERN.

3. Groupings of diseases

- **How do multi-disciplinary diseases fit into one ERN?**

It is expected that multisystem rare diseases will be supported in a number of relevant ERNs, with these networks working together to meet the needs of rare disease patients. The important aspect is to ensure that, by working with ERN applicants, the scope of an ERN application includes these diseases. Different ERNs are expected to work together for the benefit of patients living with a multisystem condition or disease.

It is unfeasible to create a separate ERN for every one of the over 6000 rare diseases that exist; ERNs will therefore be organised according to disease groupings. This grouping of rare diseases in the thematic networks is set out in the Addendum to de EU Committee of Experts on Rare Disease Recommendations on ERNs, establishing 21 ERN groupings, as the only way to ensure all rare diseases have a 'home' within an ERN.

4. Funding

- **Is there funding available to support ERNs?**

Presently there is no confirmed funding for ERNs, however it is expected that there will be grants available to support the ERNs over the first five years. In addition, it is considered that ERNs will be in a strong position to secure research grants and other funding due to the fact that they will have been successfully awarded a European Commission ERN status following a formal assessment process.

Regarding funds for the implementation of the ERN IT platform, the Connecting European Facilities (CEF) 2015 work plan (see pages 35-39 of the annex) has been amended and now includes a specific budget line to develop a centralised ERN IT platform.

5. Quality of expertise

- **One major concern is that the quality of Centres of Expertise (CoE) is too broad. Before a CoE or a** healthcare provider **(HCP) joins an ERNs, it is necessary to establish criteria to make sure that all CoEs meet standards. Who is it that decides these standards and how?**

It is each Member State's responsibility to assess the quality of their CoE and HCP and endorse their participation in an ERN application, according to their respective national legislation. Member States are at various stages of developing legislation to designate or assess their CoE and HCP before the first call is launched.

The information on highly specialised providers, centres of expertise (reference), National networks and European Reference Networks from Spain is available on:
http://ec.europa.eu/health/ern/docs/national_spain_en.pdf

As part of the assessment process for ERN applications, the European Commission will assess the quality of each CoE and HCP against the Delegated Decision's general and specific conditions/criteria. This will ensure that CoE and HCP participating in an application meet clear and robust quality criteria both at a national and EU level.

In addition, during the application process, the ERN itself will define the threshold or required level of disease-specific expertise or competency that CoE and HCP will need to meet to become an ERN member. The ERN will have to validate their application upon receiving evidence that the required level of expertise is met.

All **applicants** wishing to join a Network shall comply the following criteria and conditions, specifically with regard to research capacity: having research capacity and demonstrated research experience or production in the area of expertise of the Network, at national and international level.(The Assessment Manual - **Operational Criteria for the Assessment of Healthcare Providers** (Draft December 2015 - See page 23).

Specifically to fulfil the requirement regarding "make contribution to research", the **Network** itself must: identify and fill research gaps; promote collaborative research within the Network; and reinforce research and epidemiological surveillance, through setting up of shared registries. (The Assessment Manual - **Operational Criteria for the Assessment of Networks** **(**Draft December 2015 - See pages 29-31).

Finally, each CoE within a network are required to probe that the centre continues to meet the required competency as defined by the legislation, throughout the 5 years that networks will be approved for operation.

- **How will compliance to the requirements of the ERNS be regulated to ensure that standards are maintained? What sanctions will there be for CoE which do not continue to meet the required standards?**

ERN applications will need to demonstrate compliance with the conditions and criteria in the Delegated Decision. If a network application does not meet some of these conditions and criteria it will need to include a plan detailing action to be taken in order to achieve compliance within the first five years. This will be monitored by the Network's Board. At the end of the five years, these networks will be evaluated by the European Commission for a renewal of their ERN designation.

If one or more HCP or CoE, at any point during the five year period, ceases to comply with the conditions and criteria set out in the Delegated Decision, they are required under the legislation to inform the Network's Board, whose members should then report this to the Board of Member States.

- **Which bodies will endorse an ERN in Member States?**

Each Member State has a designated representative on the Board of Member States (BoMS). The BoMS oversees and approves ERN applications following an assessment by the European Commission's Independent Assessment Bodies. These representatives are working with their respective Member States to ensure that the endorsement process in established in their Member State.

- **If a centre is not endorsed for its participation in a Network by its MS authorities what are the options to participate in ERNs?**

The MS has the full capacity and responsibility on the endorsement process and the EU legislation does not provide a legal base related with this matter.

6. Incentive for clinical researchers

- **How could interest a clinician or clinical researcher to take part in these networks?**

ERN applications require strong cooperation between clinicians as this will reflect their ability to provide a functional and operational ERN if an application is successful. The strongest applications in the first call will be those where there is a well-developed network of clinicians who can demonstrate their cooperation in order to make their network functional.

There is significant interest from the clinical community to take part in these networks. Since an ERN application has a minimum requirement of 10 healthcare providers from 8 Member States, it is important to reach out to clinicians in your Member State and across the EU to work together in order to ensure that this minimum requirement is met and that HCP are endorsed by their respective Member State.

There are significant benefits and opportunities in the creation of an ERN, to which clinicians will respond positively to, including:

- Connecting up scattered expertise to increase understanding of rare diseases' natural history and improve diagnosis and outcome to treatment.
- Increased critical mass for research and ability to successfully secure research grants.
- Improved access to high quality diagnosis and healthcare, reducing care inequalities.
- Share knowledge and have access to eHealth/IT platforms support.
- Reduce ineffective treatment and inappropriate use of scarce resources.
- Maximise integration and interoperability of EU and national strategic projects.
- Provide a clear interface for industry, attracting investment opportunities and economic growth.

There will be different infrastructures to support successful ERN applications, which will support the sustainably of networks in the long term. It is likely that ERNs will be able to apply for other EU project and research grants to support the actions aimed at the improvement of diagnosis and quality of healthcare. For example, in the H2020 Call 2.1.4.2., Rare diseases - Support for new registries are a set priority, as key instruments to develop clinical research in the field of rare diseases and improve patient care and healthcare planning. This call specifies that **only approved ERNs are eligible to be co-funded.**

- **How can clinicians contact with other CoE in the field interested in taking part in the ERN Call?**

Continuing the work of the previous Joint Action to support the field as the first Call for European Reference Networks (ERNs), the new Joint Action for Rare Diseases launched an informal Rare Disease ERN "matchmaker" exercise to facilitate discussions and collaboration between experts willing to join an ERN. The aim this informal "matchmaker" tool is facilitate to those groups planning to lead a network finding colleagues and consortia that might be interested in applying to set-up or join an ERN in the same thematic group of disease field and vice versa, encouraging discussions and collaboration between specialists and increasing transparency. For more information visit: http://www.rd-action.eu/european-reference-networks-erns/

7. Existing legislation

- **How does national and EU legislation align?**

The mapping report of the current state of the art on national assessment systems, completed in the development of the European Commission's Assessment Manual and Technical Toolbox of ERN applications, shows that whilst there is variation in the procedures MS employ to assess their respective HCP and CoE, the aspects they all take into account are in line with the European Commission's Delegated Decision. The European Commission Manual and Technical Toolbox also outline the conditions and criteria a network and its HCPs are required to meet to be awarded the ERN designation.

Spain is one of the few MS which has a clear policy and criteria regarding the designation or identification of National Centres of Expertise, known as Reference Centres, Services and Units (CSUR) of the Spanish National Health System (NHS) (More information).