

Frequently asked questions (FAQs)

Procedural aspects of establishing ERNs

What is an ERN?

A network connecting health care providers and centres of expertise of 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 who network widely already, the ERN will represent the formalisation of their networking structures/practices in highly specialized healthcare. For those without specialist 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.

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 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 be composed of 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 Members States of ERNs and ensure they understand and abide by the agreed national process for endorsing HCPs (see webpage (http://ec.europa.eu/health/ern/policy/index_en.htm)).
- After passing an eligibility check a technical assessment composed of documentation review, teleconferences and on-site visits will follow.
- The final approval of the proposed ERN will take place by the Board of Member States.

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.

Can there be more than one network coordinator in a proposed ERN?

No, according to the delegated decision only one coordinator of the network will be chosen from among the health professionals belonging to the staff of the coordinating member, who will chair the meetings of the Board and represent the network.

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.

How will applications be assessed?

The applications will have to pass three steps – 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 State. For the application, each applicant member will have to secure the endorsement of their Member State. An Assessment Manual and Tool-Kit for applicant members will describe the assessment.

When will the Manual become available?

The Assessment Manual and Tool-Kit is expected to be published in 2015.

What is the role of the Board of MS?

The Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs). The BoMS consists of representatives from across the EU Member States and European Economic Area (EEA). The Board's main roles and responsibilities are to:

- Develop and maintain rules of procedure for the Board of Member States (functioning and decision-making process);
- Review the assessment reports and recommendations from the Independent Assessment Body (IAB);
- Give final approval of applications for ERNs;
- Approve proposals to add one or more members to an existing ERN;
- Approve the termination of an ERN; and
- Decide on the loss of membership of one or more members of an existing ERN.

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.

Will all members of a network need to submit membership applications?

Yes, each applicant member will need to submit an application in addition to the application of the proposed network as a whole.

Some existing networks involve scores of partners across many countries – should coordinators of an ERN invite all these centres to join a proposal?

Coordinators will need to think carefully about possible memberships of HCPs especially considering the efficient governance of proposed networks. In these considerations they will have to include the eligibility check criteria for each applicant member of the proposed network. Alternative means of affiliation (such as Associated and Collaborating National Providers) may be of use here.

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.

If a centre does not meet the Criteria defined in the Delegated Act Annex II, what are the options to participate in ERNs?

For centres which will *not* meet the criteria but nonetheless could contribute to an ERN, the MS where the centre is located might take a strategic decision on the convenience to designate it as an Associated National Centre or a Collaborating National Centre

What are the criteria for Associated National Centres and Collaborating National Centres?

At present, there are no specific criteria for each of these forms of affiliation to an ERN (note not membership of). As formulated in the Delegated Decision "proposed networks must collaborate with Associated National Centres and Collaborative National Centres chosen by Member States with no Member in a given Network, particularly if the objectives of the Network are among those listed in Article 12 (2) (f) and (h) of the directive. The ERN should facilitate mobility of expertise virtually or physically and develop, share and spread information, knowledge and best practice and foster developments of the diagnosis and treatment of rare diseases, within and outside the networks. Further they should 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."

Operations of ERNs

What is the difference between ERNs and HCPs/Centres of Expertise? How do they relate to each other?

The ERN is a network composed of at least 10 healthcare providers from at least 8 different Member States with at least 3 out of 8 objectives defined in the Cross-Border Healthcare Directive. The main goal is to support cooperation in healthcare where expertise is scarce and to facilitate access to high-quality diagnosis and medical care in this field. The Network will operate at the European level and will be formally approved by the Board of Member States. It is for each National Authority to decide on the role and organisation at National level of their healthcare providers or centres of expertise. It would be advised that the HCPs/CEs endorsed and approved as member of an ERNs would act as the 'nodes' around which the ERN is centred and will continue to provide care for their patients with RD nationally, as they do at present .

What are the roles of healthcare providers/CEs in ERNs?

- An ERN is centred around highly specialised healthcare, first and foremost, and is expected to demonstrate:
 - knowledge and expertise to diagnose, follow up and manage patients with complex diseases or conditions which necessitate highly specialized healthcare

- evidence of good outcomes
 - a multi-disciplinary approach to care
 - capacity to produce good practice guidelines and to implement outcome measures and quality control
 - research, teaching and training
 - collaboration with other centers of expertise and networks
- In addition the Delegated Decision (Annex II) stipulates criteria for all ERN members to meet, with regards to:
 - patient empowerment and patient-centred care
 - organisation, management and business continuity
 - research and training capacity
 - exchange of expertise, information systems and e-health tools
 - expertise, good practices, quality, patient safety and evaluation

What formalised structure will ERNs assume?

Health care provider applicants will be approved member of a European Reference Network which will have an institutional value. Networks' Members should be licensed to use the 'European Reference Network' logo. The logo, owned by the European Union, should constitute the visual identity of the Networks and their Members.

Will ERNs be able to involve experts from outside of the EEA e.g. Serbia or Israel? How might these countries participate?

In addition to the EU 28, the three EEA countries are eligible and indeed have the right to participate in the Board of MS for ERNs. The policy and legal documents state that members of ERNs are expected to collaborate with others centres and networks; however, it is not possible to include them as formal members as they cannot be included in any formal EU assessment of the centres and networks. Therefore, external participation and contributions are encouraged, but cannot be formalised.

How will be the disease-specific operational ('vertical' criteria of the Delegated Acts Annex II) defined for each ERN?

The Commission will approve in consultation with an Assessment Manual and Toolbox including a set of *operational* criteria according to those established in the legal base. Those criteria will apply to healthcare providers or networks in a *generic* way. There is the necessity for the Criteria to be transparent, measurable, objective and comparable to all kind of settings in highly specialised healthcare. There are the set of horizontal criteria and conditions on patient empowerment and centred care, organisational, management and business continuity, research and training capacity, exchange of expertise, information systems and e-health tools and expertise, good practice, quality, patient safety and evaluation to be fulfilled by all healthcare providers regardless of the field of expertise.

Further there are a set of specific criteria and conditions that may vary depending on the scope of the concrete area of expertise where the proposed Network has to propose and document its specific

criteria on the required competence, experience and activity of all possible members of the Network including the provision of evidence of good clinical care and outcomes in its field, describe the characteristics of human resources important for this thematic group of diseases, show the organisation and functioning in a multidisciplinary healthcare team, describe the specific equipment within the centre or easily accessible show communication strategies / interactions at a distance capacity for cross border health care. Those criteria would be used to assess the level of fulfilment of each of the applicant healthcare providers.

Thematic scope of the ERNs by disease area and respective specialisms

The Commission Implementing Decision on ERN states that in order to guarantee that the Network has genuine European Union added value and is big enough to enable the sharing of expertise and to improve access to care for patients across the Union, only applications from the minimum required numbers of healthcare providers and Member States, submitted in line with the call of interest, should be approved. It might be difficult to reach the required minimum number of healthcare providers or Member States for some rare diseases or conditions due to a lack of expertise. It would therefore be a good idea to group healthcare providers that focus on related rare diseases or conditions in a thematic Network. Networks could also include providers of high technology services which usually require very high capital investment, such as laboratories, radiology services or nuclear medicine services.

Moreover, the Commission Expert Group on Rare Diseases has adopted an Addendum to the EUCERD Recommendations on Rare Disease ERNs. This Addendum espouses a model for grouping RD to enable all RD to 'find a home' within a manageable number of overarching ERNs.

Many clinical experts currently participate in disease-specific networks (for instance 'pilot' networks, established by EC funding in the past) or in networks dedicated to a relatively small number of diseases: is it possible for such networks to simply 'transform' into ERNs, retaining their current scope?

In principle, no, this is not the aim of ERNs which represent a collaboration in healthcare. Many former networks were collaborating in different fields of research. The goals and criteria established in the legal acts are mandatory and therefore the current pilot networks or groups wishing to apply as a Network proposal shall assess themselves and reach an agreement on how to fulfil those criteria. It would be advisable for the current narrow disease-specific networks to expand their focus and increase their networking associations in order to better reach the goals and minimum number of participants.

Would a HCP be able to join an ERN if it does not possess expertise in *all* the diseases that could fall under the thematic scope or grouping of a Network proposal?

Yes a HCP could join a proposed ERN even though it does not possess expertise in all diseases under the scope of the proposed network.

Who decides which category diseases fall 'under'?

It will be for the healthcare providers and stakeholders preparing a Network proposal to decide on this very important issue, to argue and defend its proposed ERN scope. The recommendation issued by the

Commission Expert Group on Rare Diseases on a model of grouping should give an orientation of what is intended, which means several disease entities are grouped together. Examining who takes care of a patient at present could be a useful way of approaching this. The specialists themselves are best-placed to determine which ERN grouping their disease falls under as this is something best addressed at the grass-roots level by those expert in the diseases. However, a mapping of some sort may be advisable during the ERN proposal preparation stage, in order to assess the sort of disease coverage desired by that ERN at the end of the strategic plan for ensuring comprehensive coverage of RD to address patient needs.

Why does the model for grouping RD for the purposes of ERNs not refer to specific procedures or specialities like by instance surgery , laboratory etc.?

Multidisciplinary is the cornerstone of the Networks. Networks are not intended as a cooperation limited to one speciality but as a multidisciplinary approach to the diseases, including the participation of all possible healthcare professionals involved and all necessary procedures or techniques related to the diagnosis or treatment of the diseases covered by the ERN.

The model for grouping ERNs seems to be that a single network must care for both paediatric and adult patients – what if existing groups are only geared towards paediatric patients at present?

The proposed model of grouping serves as an orientation. It is acknowledged that it will be difficult to incorporate adult services into existing paediatric-focused highly specialised services: it will depend on how the networks will convey and argue their choice of specific criteria and conditions which may vary depending on the scope of the concrete area of expertise. Perhaps a stepwise development could be expected, of integrating adult care with paediatric care. The primary goal of the proposed scheme is inclusivity at the European level. Such inclusivity should also relate to the ages of patients as referred to in the Addendum to the EUCERD Recommendation of January 2013 adopted in June 2015. It is expected from the proposed network to have a business plan to improve over time and address the areas which are not incorporated at present.

How might cross-talk across ERNs be ensured?

The Commission should facilitate the exchange of information and expertise on establishing and evaluating the Networks. It should produce general information on the Networks and their Members and ensure the technical documentation and manuals on establishing and evaluating the Networks and their Members are available to the public. It may offer to the Networks and their Members the use of specific communication media and tools. Conferences and expert meetings should be organised to provide a forum for technical and scientific debate among Networks.

The added-value of ERNs

What will be the added-value of RD ERNs to those already running successful, disease-focused networks?

ERNs will provide for the first time a unique opportunity to work together in healthcare. The main goal is to support cooperation in healthcare where expertise is scarce and to facilitate access to high-quality diagnosis and medical care including the European added value by working cross border in this field. Proposed networks have to define how they want to communicate with each other (i.e. access to shared communication tools and assets to support e-health and teleconsultations) and what services they will offer such as sharing diagnostic tools etc. between collaborators within a single ERN.