NHS England

European Reference Networks

Guidance on the recognition of Healthcare Providers and UK Oversight of Applications

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The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.

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1 Introduction

The UK is a recognised leader in research on rare diseases, their treatment and care for those affected. The diagnosis, treatment and management of rare diseases require the highest level of partnership working to remove unnecessary barriers. We want to encourage and develop collaboration at all levels and wherever possible to build upon the best research, diagnosis and service provision that already takes place in the UK and elsewhere.

The establishment of European Reference Networks (ERN) supports these objectives. They encompass the principles of better access for patients to highly specialised, safe care of the highest quality, support European co-operation on highly specialised healthcare, knowledge pooling, improving diagnosis and care in medical domains where expertise is rare. This type of collaboration can maximise the speed and scale of adoption and spread of innovations in medical science and health technologies. ERN can also be focal points for medical training and research, information dissemination and evaluation.

Article 12 of the 2011 *EU Directive on the application of patients' rights in cross-border healthcare* describes ERN as centres of expertise, in particular in the area of rare diseases complex diseases and conditions, led by healthcare providers in the Member States.

ERN must meet least three 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.

The purpose is not necessarily to create new care centres but to link existing ones, and/or recognise existing networks. Before networks can be given the stamp of approval by the Commission, each healthcare provider in the network needs to have the support of their Member State to establish, or participate in, ERN. The process for the UK is set out in this document.

1.1 Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it.

Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

2 Approval of a UK healthcare provider to join a European Reference Network

The UK Strategy for Rare Diseases was published in 2013 and sets out the five areas where all four UK countries agreed to take action. These were:

1. Empowering those affected by rare diseases.
2. Identifying and preventing rare diseases.
3. Diagnosis and early intervention.
4. Coordination of care.
5. The role of research.

Effective engagement with ERN, either as a leader or collaborator, should help the UK deliver on these commitments. It should also enhance the role of the UK as a European and global leader in the field of rare diseases, in research, technology adoption and improving patient services.

The European Commission has set in place an approval system for both ERN establishment and assessment of applications from individual healthcare providers wishing to be members of an ERN. Only healthcare providers approved by their Member State as eligible to lead or join an ERN will be considered by the Board of Member States for European Reference Networks.

The UK operates as a single entity in matters relating to the European Union. Healthcare services and their provision are the individual responsibility of each UK country, and the definition of a recognised healthcare provider reflects their commissioning practices in each country. Applicants must meet the specific criteria for the country where they provide services, set by NHS England, NHS Scotland, NHS Wales and the Department of Health, Social Services and Public Safety in Northern Ireland.

There are no limits to how many UK healthcare providers can be part of the same ERN. However, the approval processes for the UK and the EU are designed to identify and address any duplication of proposals. Discussions with prospective partners to agree clarity of purpose and defined objectives should be completed prior to the application process being started.

3 Individual country recognised healthcare provider criteria

The following describes the requirements for each country that need to be met for UK healthcare providers to be eligible to join an ERN.

3.1 England

- Each healthcare provider must have a contract with NHS England for the service in question and must meet the requirements of the relevant NHS England service specification(s). Exceptionally, where the provider does not have a contract with NHS England (for example in the case of some private providers), a determination will be made as to whether the provider meets the requirements of the relevant NHS England service specification.

In addition, where genetic services are provided, the following requirements must be met:

- Each healthcare provider will be expected to adhere to applicable national standards, e.g. NICE quality standards and follow applicable NICE guidance for specific clinical conditions e.g. for genetic testing of cancer and for diagnostic services when available. Providers will be expected to use standardised test, gene and mutation nomenclature in accordance with current professional guidelines, HGVS recommendations, UKGTN listings and future National Laboratory Medicine Catalogue entries, as required in the UK Strategy for Rare Diseases (England).
- Providers will need to be compliant with European requirements including OECD Guidelines for Quality Assurance in Molecular Genetic testing and the In Vitro Diagnostic Medical Devices Directive. Providers will also be expected to meet the requirements set out in the NHS England Pathology Quality Assurance Review.
- Healthcare providers must be compliant with the relevant Best Practice Guidelines of the Association for Clinical Genetic Science, British Society for Genomic Medicine, the Royal College of Pathology and applicable guidelines from other Royal Colleges.
- All Statutory Regulated healthcare scientists, registered with the Health & Care Professions Council must have the necessary training, qualifications, experience and competence to perform their roles and undertake relevant continuing professional development or further

registration requirements as appropriate to the level of staff. Those staff not subject to statutory regulation must be working towards accredited voluntary registration arrangements with the Academy for Healthcare Science and demonstrate that they have undergone appropriate education and training for the role being performed.

- Providers must be compliant with NHS England guidance on Information Governance and the IG Toolkit Laboratory provision at UK Healthcare. Provider sites must meet NIB standard requirements and be responsible for the security of and access to, electronic data as outlined in the Data Protection Act.
- Healthcare providers must be CQC service regulated for all the services offered and meet MHRA and HTA regulatory requirements and their laboratories must be UKAS accredited to BSI Standard 15189:2012.
- Providers must have a robust quality management system in place. All the quality standards, policies and procedures that laboratories implement must be consistent with national, professional and regulatory guidelines and national benchmarking.
- Providers must apply internal quality control procedures to all results prior to reporting to ensure that they are accurate and fit for purpose and validated against known datasets where clinically appropriate.
- Providers must participate in relevant external quality assurance assessment schemes where they exist (e.g. UK and/or European National External Quality Assurance Schemes). In the absence of an appropriate external quality assurance schemes they must ensure that there is appropriate assurance of the test results and reports.
- Healthcare providers must participate in the NHS England Medical Genetics CRG (E01) quality dashboard monitoring including any relevant extension of KPIs for their laboratories.

3.2 Northern Ireland

- The service targets patients in Northern Ireland with a condition which meets the EU definition of a rare disease which is one that affects 5 people or fewer per 10000 of

population. It is recognised that such services in NI may already be linked to services in Great Britain or the Republic of Ireland.

- The service promotes and works toward the goals for 'Transforming Your Care' a patient-centre approach to health care in Northern Ireland; Quality 2020; a 10 year strategy to protect and improve quality in Health and Social Care; Making life better; a whole system framework for Public Health 2013-2023; and the Department of Health, Social Services and Public Safety's strategies for 'Living with Long-term Conditions' and 'Physical and Sensory disability'.
- The service meets national standards which apply to Northern Ireland e.g. NICE guidelines or guidelines in use in other parts of the UK e.g. NHS England guidelines for the management of lysosomal storage disorders (http://www.england.nhs.uk/wp-content/uploads/2013/06/e06-lyso-stor-dis-child.pdf).
- The service meets patient safety requirements as set out in individual plans and strategies pertinent to the services being represented.
- Laboratories used by the provider should be CPA accredited, take part in appropriate NEQAS schemes and follow best practice guidelines.
- If the condition is genetic, laboratory providers should also be compliant with the relevant best practice guidelines such as Best Practice Guidelines of the Association for Clinical Genetic Science, British Society for Genomic Medicine, the Royal College of Pathology and applicable guidelines from other Royal Colleges.
- The service can be funded through existing resources.

3.3 Scotland

- The service meets NHS Scotland quality ambitions on patient safety, equity of access and timeliness, and is of proven effectiveness.
- The service is for a condition requiring diagnosis and/or treatment that is rare and/or unpredictable - usually involving a low incidence and a prevalence of no more than 500 patients in Scotland (one year period prevalence).
- The service is person centred and meets a recognised need for all residents of Scotland within a clearly defined clinical area.
- Provision requires a highly skilled multidisciplinary team and/or specialist equipment and facilities that can be provided clinically and cost effectively in one, or only a few, locations.
- The service requires scarce clinical skills.
- There is a clear clinical pathway for the service including criteria for referring patients and a co-ordination strategy for conditions that are provided by more than one clinical specialty.
- The target patient group or subset is distinct for clinical reasons.
- There will be significant benefits from involvement in a European Reference Network, which might include: improved clinical quality, focused clinical expertise, and/or more efficient use of NHS resources.

3.4 Wales

- The service is in line with NHS Wales ambitions as identified in the Rare Disease Delivery Plan for Wales.
- There will be significant benefits from involvement in a European Reference Network, which might include improved clinical quality, focused clinical expertise, more efficient use of NHS resources and benefits of European collaboration.

- There is a clear clinical pathway for the service including criteria for referring patients and a co-ordination strategy for conditions that are provided by more than one clinical specialty.
- Any healthcare provider will be expected to adhere to all applicable regulatory and national standards including accreditation. Healthcare providers must be HIW service regulated for all the services offered. The service must have clear links with the All Wales Medical Genetic service.
- The service is fully endorsed by the hosting organisation and can identify sustainable funding.

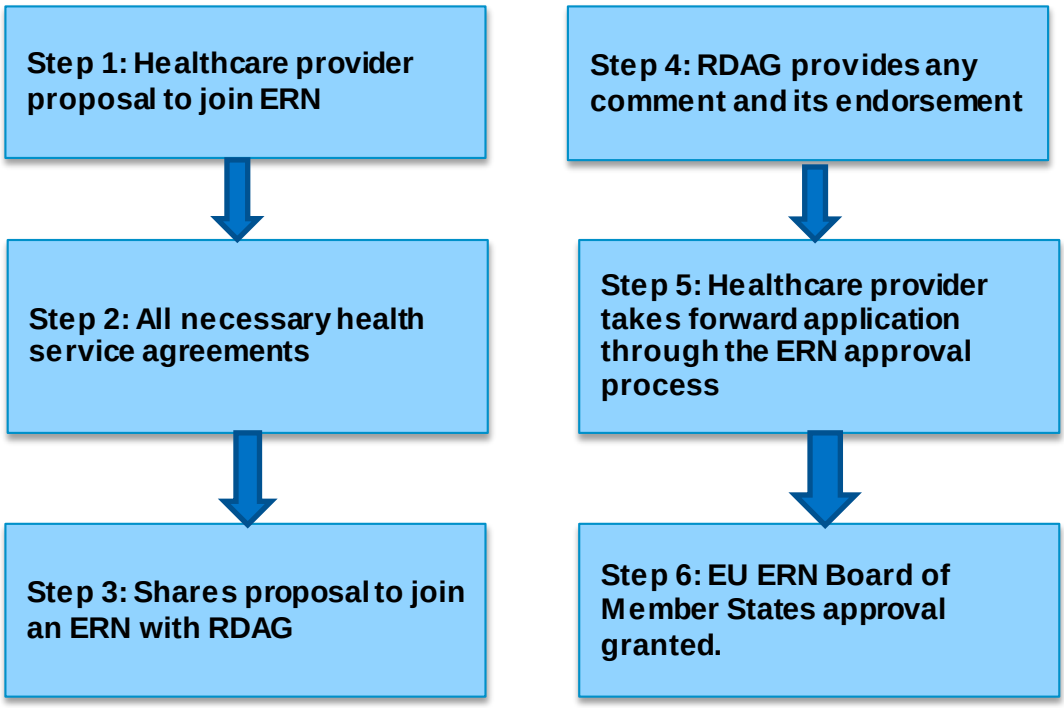
4 UK oversight of ERN applications

To ensure there is oversight at a UK level, it has been agreed that applications from recognised healthcare providers will be endorsed by the Rare Diseases Advisory Group (RDAG), which is led by NHS England with representation from across the UK.

RDAG makes recommendations to NHS England and the devolved administrations of NHS Scotland, NHS Wales and NHS Northern Ireland on developing and implementing the strategy for rare diseases and highly specialised services. The membership of the Group is broad and includes representatives from Royal Colleges, commissioners, patient and public voice representation and professionals such as a geneticist and an ethicist. There is also representation from the four UK health departments. RDAG will be open to public scrutiny and accountability by having its agendas and minutes published on the NHS England website, and by having an independent patient and public voice included in the membership.

All four countries want to ensure that engagement with ERN is led by recognised healthcare providers and driven by a "from the bottom up" approach to the process. It is the decision of the healthcare provider whether or not to apply for membership of an ERN – as long as they meet the relevant national criteria.

However, the added dimension of RDAG oversight means that ERN activity in the UK will be monitored, albeit in a light touch way. This should help avoid duplication and promote collaboration. It is the intention to keep the process as simple as possible. If a recognised healthcare provider intends to join or lead an ERN, they will notify RDAG as part of the process. RDAG will provide any comments it may wish to make e.g. knowledge of similar network activity already underway and provide an endorsement of the application. RDAG will also notify the UK representative on the ERN Board of Member States of RDAG's endorsement of the healthcare provider's application.


Step 1: Healthcare provider proposal to join ERN
Step 2: All necessary health service agreements
Step 3: Shares proposal to join an ERN with RDAG
Step 4: RDAG provides any comment and its endorsement
Step 5: Healthcare provider takes forward application through the ERN approval process
Step 6: EU ERN Board of Member States approval granted.

5 Contacts and further information

Healthcare providers should use the template at Annex 1 to notify RDAG of their intention to join an ERN. The template should be completed and sent to ERN.application@nhs.net
This address should also be used for any queries about the notification process or the healthcare provider recognition criteria.

It is important to stress that this guidance is meant to support the initial process of healthcare provider recognition and UK oversight of ERN participation activity. For information on the submission, assessment and approval of ERN membership applications, visit http://ec.europa.eu/health/ern/policy/index_en.htm.

6 Annex 1 Notification form for the Rare Diseases Advisory Group

Name of healthcare provider	
Name of NHS Trust	
Name of European Reference Network	
Role	**Lead** ☐ **Member**[1] ☐
Will you be joining an existing network?	
Do you intend to collaborate in establishing a new network?	
Are there any other UK Approved Healthcare Providers (AHP) involved?	
Please list the other UK Healthcare Providers/AHP	
Purpose of joining the ERN	
Objectives	

[1] Delete as appropriate

Outcomes	
Has the allocation of resources been agreed at the appropriate local level?	

European reference networks

Supporting Notes for the completion of *Notification form for the Rare Diseases Advisory Group*

(Annex 1 to *Guidance on the recognition of healthcare providers and UK oversight of applications*)

7 Purpose of this document

This document provides advice to healthcare providers on completing the *Notification form for the Rare Diseases Advisory Group* (Notification form), which is Annex 1 to *Guidance on the recognition of healthcare providers and UK oversight of applications* (Guidance).

Before completing the Notification form, healthcare providers should obtain agreement and approval from their relevant national NHS body (NHS England, NHS Scotland, NHS Wales or Health and Social Care in Northern Ireland). To obtain this approval, healthcare providers will need to demonstrate that they meet the individual country recognised healthcare provider criteria in section 3 of the Guidance. Only once healthcare providers have obtained approval from their relevant NHS body should the Notification form be completed. It is advisable for healthcare providers to share a copy of this completed form with their relevant NHS body for comment prior to submitting the form.

Advice on the information required for each section of the Notification form is below. Once compete, the form should be submitted to the Rare Diseases Advisory Group at ERN.application@nhs.net. Any queries about the completion of the Notification form should be sent to the same email address.

8 Name of healthcare provider

This section should state the full legal name of the healthcare provider.

9 Name of NHS Trust

This section should state the full name of the relevant NHS Trust.

10 Name of European Reference Network

If the healthcare provider is proposing to establish a new ERN, the proposed name of the ERN should be stated.

If the healthcare provider is seeking to join an existing ERN, this section should state the full name of the ERN.

11 Role

This section should indicate whether the healthcare provider is proposing to lead the relevant ERN or join as a member. The words 'Lead' or 'Member' should be deleted as appropriate. Note: the 'Lead' healthcare provider is referred to as the 'Coordinating Member' in EU documentation.

12 Existing or proposed membership of ERN

The healthcare provider should have in-principle agreement with the proposed members of the ERN on the purpose and objectives of the ERN before submitting this form.

If the intention is to establish an ERN, this section should detail the proposed membership, noting that each ERN *must* have at least ten healthcare providers from eight Member States.

If the intention is to establish an ERN or join an existing ERN, information on any proposed or existing UK members of the ERN should be included, be they collaborating partners or others.

This section should also state if you intend to be an Affiliated Partner.

13 Purpose of joining the ERN

This section should detail why the healthcare provider would like to establish or join the ERN, including any special expertise of the healthcare provider, the expected contribution of the healthcare provider to the work of the ERN and the expected benefits to UK patients.

If the healthcare provider is proposing the establishment of a new ERN, this section should also explain why a new ERN is needed to carry out this work, including how the proposed ERN will differ from existing ERNs and how it will collaborate with existing ERNs to achieve the overall objectives of the ERN programme.

14 Objectives

If the healthcare provider is proposing the establishment of a new ERN, this section should detail the objectives of that ERN and how they meet the requirements of Art 12(2) of Directive 2011/24/EU, which are replicated in section 1 of the Guidance.

If the healthcare provider is seeking to join an existing ERN, this section should detail how its contribution will further the specific objectives of that ERN and support better care for UK patients.

15 Outcomes

If the healthcare provider is proposing the establishment of a new ERN, this section should detail the expected outcomes or outputs of that ERN. It should also specify any deliverables. For example, if the proposed ERN expects to produce good practice guidelines on a particular topic, or establish a new training programme, this should be detailed here.

16 Resources

This section should detail the resources available to the healthcare provider to fulfil its role as lead or member of the ERN. Resources should be agreed at the local level prior to the completion of this form.