ANNEX
Description of an Associated National Center

Name of the Associated National Center[1]: Click or tap here to enter text.

A) Definition

Choose the type of institution: Choose an item.

B) Minimum recommended criteria

Please note that as indicated in the Statement of the ERN Board of Member States on the definition and minimum recommended criteria for Associated National Centres and Coordination Hubs adopted in the Board meeting of 10 October 2017[2], "*despite the mandatory requirement for some specific expertise within the thematic area covered by the respective network, Associated National Centres are not requested to meet these criteria to the same degree that is expected for full membership*".

1. General criteria

Please tick the box in case the Associated National Center fulfils the criteria. Also, note that the at a later stage Networks might request from the Associated National Center further information in this respect.

These general criteria are valid for clinics and departments/clinical units; they may also be applied for diagnostic laboratories and other diagnostic institutions, where applicable.

1.1. Evidence of a clear and well-defined organization (governance, management, definition of one representative as contact person): ☐

1.2. Measures in place related to respect patients' rights and to ensure patient-centred care, including:
- Informed consent procedures: ☐
- Personal data protection: ☐
- Complaint procedures: ☐

1.3. Measures in place related to patient safety. This includes, inter alia:
- Infections control: ☐
- Safe surgery: ☐
- Medication safety: ☐

[1] Associated National Centre as described in the ERN Board of Member States Statement of 10 October 2017:

Associated National Centre is an Affiliated Partner **with a special link to a given Network** (see recital 4 of Commission Delegated Decision 2014/286/EU of 10 March 2014).
As recalled by the Board Statement of 10 October 2017, an Associated National Centre is "a healthcare provider with at least some special expertise matching the global thematic domain of a given reference network that concentrates primarily on the provision of healthcare directly related to the activities and services of this specific network, including any type of diagnostic contribution supporting this provision of healthcare. Associated National Centres can therefore comprise any of the following institutions:
- Clinics and departments/clinical units providing direct outpatient and/or inpatient services to patients;
- Medical and genetic diagnostic laboratories;
- Pathological laboratories;
- Specific facilities for instrument-based diagnostics".

[2] https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf

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2. Specific criteria in relation with the area of expertise of the related network

You might consider using as reference the table the European Commission has published[3] on specific criteria established by each Network in their application to the 2016 call.

The assignment of these specific criteria to clinics and departments/clinical units, and/or diagnostic and histopathological laboratories and other diagnostic institutions is indicated in bold capital letters at each criterion or its bullet points.

2.1. Dedication for, general knowledge of and some special expertise in the thematic area of the ERN

Description, how the Healthcare Provider monitors and documents its patient activity, as well as its experience, specific to the Network's area of expertise.
This includes the description of:

- The volume of clinical activities (e. g. the number of patients seen per year and/or procedures completed, both as absolute numbers and in relation to the estimated number of patients within the country suffering from those diseases covered by the Healthcare Provider's and the Network's area of expertise, and the number of second opinions within the last three years) **[CLINICAL INSTITUTIONS]**:
  Click or tap here to enter text.

- The volume of diagnostic activities (e. g. the number of samples and tissue specimens processed, as well as the number of diagnostic assays and/or histological assessments and/or instrument-based diagnostic assessments performed within the last three years) **[DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

- The accumulated experience (e.g. the number of published reports and peer-reviewed publications in the thematic domain of the ERN over the last three years) **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

2.2. Availability of human resources and organization of care

2.2.1. Description, how the Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care. This includes the description of:

- The type and number of professionals, including their specific qualifications and skills **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

- The specialized functions covered by the different professionals within the team (like, for instance, diagnosis, treatment, information, observation, nursing,

[3] https://ec.europa.eu/health/sites/health/files/ern/docs/specificcriteria_en.xlsx

rehabilitation, etc.) **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**:
Click or tap here to enter text.

- The specific knowledge and experience with the diagnosis and treatment of children (when applicable) **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

*2.2.2. Description of the established clinical practice and to which extent the Healthcare Provider is capable to provide a multidisciplinary approach **[CLINICAL INSTITUTIONS]**. This includes, for example:*

- The willingness and capacity to follow best practices guidelines and established treatment protocols recommended and/or developed by the related network (if available): ☐

- The description of the locally available multidisciplinary team in the area or subarea of expertise of the related ERN and its degree of conformity with the recommended structure of the multidisciplinary team in this area as defined by the given network:
  Click or tap here to enter text.

2.3. Equipment and facilities (including cooperating facilities)

*2.3.1. Description, which kind of equipment and facilities the Healthcare Provider has available (either within the centre or with guaranteed easy access to in a collaborating unit) necessary to provide good quality patient care **[CLINICAL INSTITUTIONS]**.*
Click or tap here to enter text.

- Equipment and facilities may include radiotherapy laboratories or hemodynamic facilities, day hospitals, hospitalization units, nurseries, operation theatre, and other tools for supporting the diagnosis.
  Click or tap here to enter text.

2.3.2. Depending on whether the Healthcare Provider is a clinical or a laboratory institution, description, in which way and to which extent the Healthcare Provider collaborates with or offers itself a specialized laboratory and/or histopathological service capable of carrying out the analyses required to diagnose the rare or low prevalence complex disease(s) or condition(s) covered by the HCP. This may include access to or provision of microbiological, virological, biochemical, haematological, histopathological and blood bank services, as appropriate. The description may also include, for example:

- In which way these laboratories are able to analyse blood cells, biopsy tissue, and plasma and urine samples, as applicable **[BOTH CLINICAL AND DIAGNOSTIC LABORATORY INSTITUTIONS]**:
  Click or tap here to enter text.

- Whether access to or provision of these diagnostic services includes biochemical analysis of specific enzyme functions and genetic testing (where necessary) **[BOTH CLINICAL AND DIAGNOSTIC LABORATORY INSTITUTIONS]**:
  Click or tap here to enter text.

- How these laboratories ensure the specific quality control related to their diagnostic services **[BOTH CLINICAL AND DIAGNOSTIC LABORATORY INSTITUTIONS]**:
  Click or tap here to enter text.

- Whether or not the laboratories and/or histopathological services participate in external quality control schemes and/or whether they are certified or accredited **[BOTH CLINICAL AND DIAGNOSTIC LABORATORY INSTITUTIONS]**:
  Click or tap here to enter text.

- In which way the laboratories and/or histopathological services participate in clinical trials and research projects and how they are involved in the publication of the data generated **[DIAGNOSTIC LABORATORY INSTITUTIONS]**:
  Click or tap here to enter text.

Clinics and departments/clinical units should maintain a comprehensive list of collaborating laboratories and diagnostic services including the responsible diagnostic specialists and their qualifications. Special attention should be given to whether the service is certified and/or accredited, and whether it participates in external quality control schemes on a regular basis.

2.3.3. Depending on whether the Healthcare Provider is a clinical or an instrument-based diagnostic institution, description, in which way and to which extent the Healthcare Provider collaborates with facilities/institutions providing a range of diagnostic technologies, or offers this range of technologies itself, required to diagnose the rare or low prevalence complex disease(s) or condition(s).

- Equipment and facilities may include ultrasound, electrophysiology, computed tomography (CT), and magnetic resonance imaging (MRI) **[BOTH CLINICAL AND INSTRUMENT-BASED DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

The description may also include, for example:

- Whether the diagnostic services are certified or accredited **[BOTH CLINICAL AND INSTRUMENT-BASED DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

- In which way the diagnostic services participate in clinical trials and research projects and how they are involved in the publication of the data generated **[INSTRUMENT-BASED DIAGNOSTIC INSTITUTIONS]**:
  Click or tap here to enter text.

2.3.4. Description, in which way and to which extent the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with the related ERN (where applicable) ***[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]****.*
Click or tap here to enter text.

- This may include the technical capacity to handle, store, print, and transmit secure information in biomedical imaging.
  ☐
- It also includes the technical capacity to handle, store and safely ship clinical samples (e.g. blood, plasma and urine samples, as well as tissue specimens.
  ☐
- It further includes a confirmation that the Healthcare Provider is capable to follow set standards for exchanging medical information with outside facilities.
  ☐
- If the Healthcare Provider currently has no technical capacity to electronically process and transfer biomedical images, it has to identify and describe other ways of sharing this information suitable for the ERN.
  Click or tap here to enter text.

2.4. Processing of patient data, coding and participation in patient registries [CLINICAL AND DIAGNOSTIC INSTITUTIONS]

2.4.1. Description of the information and coding system used by the Healthcare Provider. This may include, for example:

- The coding system used to identify the rare or low prevalence complex disease(s) or condition(s) covered by the thematic domain of the related ERN is in accordance with the with the approach established by the network.
  ☐
- The explicit willingness to introduce such systems, if the Healthcare Provider currently has no appropriate information and/or coding system available.
  ☐

2.4.2. Description of the capacity to keep accurate records of clinical information and to collect all required information for patient registries in the area of expertise of the related ERN, respecting the data protection laws in force in the Member States.
Click or tap here to enter text.