

ANNEX

Description of an Associated National Centre

Name of the Associated National Centre¹:

A) Definition

Choose the type of institution²:

1. General criteria

Please tick the box in case the Associated National Center fulfils the criteria. Also, note that 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 other diagnostic institutions, where applicable.

1.1. Evidence of a clear and well-defined organization³ (governance), management), definition of one representative as contact person:

1.2. Measures in place related to respecting patients' rights and ensuring 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 As per the cover note of the WG ELSI of October 2025, a unanimous position of the WG was that any institution joining as an affiliated partner should be part of an institution providing clinical care. This is particularly relevant to institutions titled medical and genetic diagnostic laboratories, pathological laboratories and specific facilities for instrument-based diagnostics.

³ This may include, for example, an organization chart defining management and staff and/or clinical roles and responsibilities specific to the area of expertise and/or a set of policies and procedures addressing aspects of management and activities or services.

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

You might consider using as reference the table the European Commission has published⁴ on specific criteria established by each Network in their application to the 2016 call.

The assignment of these specific criteria relates to clinics and departments/clinical units, and/or other diagnostic institutions. Other diagnostic institutions may comprise medical and genetic diagnostic laboratories, pathological laboratories and specific facilities for instrument-based diagnostics.

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 thematic area of expertise.

This includes the description of:

- The main thematic groups⁵ and sub thematic areas for which special expertise is provided in the thematic area of the ERN:

- 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):

⁴ https://health.ec.europa.eu/document/download/58334bff-3a15-46a0-8523-dc483b28a918_en?filename=specificcriteria_en.xlsx

⁵ This should utilize the main thematic groups and sub thematic areas, including corresponding Orphacode(s) for sub thematic areas, where available, as listed in the specific criteria established by each Network in their application to the 2016 call. Document available here: [here: here: https://health.ec.europa.eu/document/download/58334bff-3a15-46a0-8523-dc483b28a918_en?filename=specificcriteria_en.xlsx](https://health.ec.europa.eu/document/download/58334bff-3a15-46a0-8523-dc483b28a918_en?filename=specificcriteria_en.xlsx)

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- 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:

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.

- Equipment and facilities may include radiotherapy laboratories or hemodynamic facilities, day hospitals, hospitalization units, nurseries, operation theatre, imaging facilities, genetic diagnostics, metabolic screening and other tools for supporting the diagnosis:

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- Technical capacity to handle, store and safely ship clinical samples (e.g. blood, plasma and urine samples, as well as tissue specimens).
- 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.

2.4. Processing of patient data, coding and participation in patient registries

*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 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.

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