ERN board of Member States

Statement adopted by the Board of Member States on the definition and minimum recommended criteria for Associated National Centres and Coordination Hubs designated by Member States and their link to European Reference Networks

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1 Introduction

The following document is the result of a one-year reflection process of the Board of Member States on a more detailed definition and characterization of Associated National Centres and Coordination Hubs (The expression "Affiliated Partner" is used in this statement for ease of reading when referring to Associated National Centres and Coordination Hubs) to be designated by their Member States, and on the procedures to be developed and implemented in order to integrate these new partners into European Reference Networks (ERNs). A third type included in the concept of affiliated partners, the Collaborative National Centres, is not part of this strategic document. Their more detailed definition and characterization will be described in a separate strategic document that will be developed and published as soon as the necessary conceptual framework is established.

Focussing on Associated National Centres and Coordination Hubs, this document shall serve as a strategic guidance document addressing the needs of the key stakeholders in the establishment and operation of ERNs, including Member States, coordinators and full members of those networks, as well as new healthcare providers and other institutions interested in joining an ERN as Associated National Centre or Coordination Hub.

In particular, it shall:

- Provide a common understanding of Associated National Centres and Coordination Hubs among the Member States and among the coordinators and full members of ERNs;
- Support Member States in the concrete identification, internal evaluation and designation of healthcare providers (HCPs) or other institutions as Associated National Centres and Coordination Hubs prior to their affiliation to and integration into ERNs;
- Provide interested HCPs and other Member State institutions, as well as coordinators and full members of networks, with clear criteria and instructions about the identification, designation and affiliation procedures necessary and relevant when linking/integrating these two subtypes of affiliated partners to the networks.

Accordingly, the document covers seven main areas:

- The description of the legal background;
- The description of the principles governing the affiliation process;
- The extended definition of the two subtypes of affiliated partners (including the provision of generic examples to better illustrate the different categories and their characteristics);
- The definition of a set of minimum recommended criteria for each of these subtypes;
- The description of the tasks, rights and obligations of the affiliated partners;
- The description of the intended timelines of the affiliation process;
- The termination of the affiliation.

The document is based on the previous work of the Working Group on Affiliated Partners of the Board, in particular the “Statement adopted by the ERN BoMS on affiliated partners”, published May 20, 2016 [1], and an internal roadmap outlining the general principles and the intended

[1] https://ec.europa.eu/health/sites/health/files/ern/docs/boms_strategicview_affiliatedpartners_en.pdf

timeline of the affiliation process that was approved by the Board in its meeting on December 15, 2016[2].

The Board of Member States finally emphasises the fact that – in contrast to the operational criteria in force for full members of ERNs – the minimum recommended criteria for Associated National Centres and Coordination Hubs provided in this document are not linked to any kind of predefined threshold levels at the European level. Instead, the minimum criteria are designed as a conceptual framework and guideline only delineating the areas and the content to be covered in the description of the level of expertise and capacities of any HCP or other institution wishing to join a network.

The final definition of concrete national threshold levels and other requisites such as inclusion and/or exclusion criteria for any candidate remain in the exclusive competence of the respective Member State, depending on a variety of factors including the size of the country and the number of expected patients, the organization of the national healthcare system and the definition of national priorities and possible strategic developments.

2 Legal background

Commission Delegated Decision 2014/286/EU [3]:

Recital 14 of the 2014 Commission Delegated Decision states that "*Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given Network, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing in the provision of healthcare or as Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care. Member States may also wish to designate a national coordination hub with all types of Networks. That might help Member States to pursue Article 12(3)(a) of Directive 2011/24/EU particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU. The Coordinator should facilitate the cooperation with these healthcare providers linked to a Network. Those healthcare providers shall support the objectives and respect the rules of the Network and share the work related with the cooperation activities of the Network*."

Moreover, in ANNEX I of the above mentioned Delegated Decision, where the criteria and conditions to be fulfilled by the networks are listed, criteria 7.c says that "*the Networks must …collaborate with Associated National Centres and Collaborative National Centres chosen by Member States with no Member of a given Network, particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU*."

[2] https://ec.europa.eu/health/sites/health/files/ern/docs/ev_20161215_mi.pdf

[3] Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (OJ L 147, 17.5.2014, p.71)

Commission Implementing Decision 2014/287/EU[4]

Recital 7 of the 2014 Implementing Decision states that "*Member States none of whose healthcare providers are Members of a Network should designate collaborative and associated national centres to encourage them to cooperate with the relevant Network*".

3 General principles for the affiliation process of Healthcare Providers to the ERNs

The process to link and integrate any subtype of affiliated partner into European Reference Networks has been developed based on the following considerations and general principles[5]:

- **Priority to identify and select affiliated partners for Member States with no full member in a given ERN**

  In order for ERNs to deliver genuine added value to all European Union Member States, the current legal framework foresees for Member States which do not have representation from a member within an approved ERN to participate through healthcare providers that are designated by their Member State as "*associated*" and or "*collaborative national centres*". Member States may also wish to designate a national coordination hub with all types of Networks (Statement on affiliated partners adopted by the ERN BoMS on 20 May 2016).

- **Inclusiveness of the affiliation process**

  Member States can decide and select which ERNs they would like to be engaged with. In the event that they wish to join an ERN for which they do not have a healthcare provider fulfilling all the necessary criteria to be approved as a full member of the network, they are encouraged to designate appropriate affiliated partners, starting with Associated National Centres and Coordination Hubs, based on the tailored definition of these two subtypes as provided in chapter 4 of this document. This will ensure a high level of inclusion and broaden geographical coverage. Of note, identification and selection of affiliated partners remains in the exclusive competence of the Member States taking into account their individual situation and planning.

- **Assurance of a fruitful relationship between the affiliated partners and ERNs: a "win-win" situation**

  As the main aim of ERNs is to pool and disseminate expertise for the benefit of patients and Member States, it is a clear goal from the outset that the relationship between the affiliated partners and ERNs should be a situation of mutual benefit for both parties (i.e. on a 'give and take' relationship and to avoid unidirectional dependency).

[4] Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p.79)

[5] Of note, this chapter addresses the general strategic principles for the affiliation process of all three possible types of affiliated partners. Due to their general nature, these principles are valid for Associated National Centres and Coordination Hubs, as well as Collaborative National Centres, even if the latter are otherwise not part of this document.

This implies that, on the one hand, each ERN must develop a clear policy objective for the active engagement and participation of affiliated partners, underpinned by transparent rules and strategies that describe how affiliated partners can interact, participate and contribute to the specific ERN. On the other hand, the affiliated partners have to specify their objectives for their enrolment in a given ERN, as well as the possible areas for collaboration with this ERN, based on their area of expertise, capacity and needs.

- **Development of bilateral cooperation agreements between affiliated partners and related ERNs**

  Prior to formalising the enrolment of an affiliated partner in a specific ERN, a bilateral cooperation agreement between the two parties in the sense of a work plan-agreement should be developed, defining the rules of engagement, the areas of collaboration and the methods and objectives used to measure and evaluate the activities performed. In particular, this work plan-agreement should foster the commitment and active involvement of affiliated partners in developing clinical guidelines, in research and training, in registering data in common registries, in clinical trials, and in the provision of healthcare, proportionate to their capacity. Importantly, this also includes the participation of the affiliated partners in the network monitoring system and quality standards of the respective network. the bilateral cooperation agreements should be in accordance with the legal framework of the Member State from which the organisation originates, as well as with the rules set by the Cross-border Healthcare Directive[6] and the 2014 Commission Delegated and Implementing Decisions. The Board of Member States should have full access to this bilateral agreement as soon as its negotiation is finalised.

- **Consensus to allow newly established ERNs a period of initial operational preparation prior to the first enrolment of affiliated partners**

  Established ERNs will be required to be in a position to accept applications for affiliated partners designated by the Member States, starting with Associated National Centres and Coordination Hubs, within a prudent time from their official launch (the timeline for the first and successive calls for Affiliated partners will be established in due time in a separated document by the BoMS). This preparation period is needed so that the established ERNs can develop a clear strategy which includes detailed pathways regarding the integration and participation of affiliated partners in the networks. These strategies will need to be presented to, discussed with and approved by the Board of Member States prior to implementation.

- **Open time frame for the further enrolment of affiliated partners**

  The affiliation process is an open procedure allowing Member States to identify and designate affiliated partners on a national level at any time. The subsequent integration of affiliated partners into ERNs should take place at regular time intervals, following a similar procedure and time line as envisaged for new full members wishing to join existing networks.

  The inclusion of further new affiliated partners (after the enrolment of the first group) should be planned and operated in tandem with the inclusion of new full members. This will help to harmonize the process as well as allow for the upward mobility of affiliated partners that apply

[6] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p.45)

for and are assessed to have reached the levels required to approve their transition to full membership.

4 Definition of Associated National Centres and Coordination Hubs and of the related Minimum Recommended Criteria for their identification and evaluation in Member States

As described in section 2, the ERN legal framework foresees the designation of Affiliated Partners in order to achieve the widest possible geographical coverage, exchange of knowledge and best practice throughout Europe.

Associated National Centres, Collaborative National Centres and Coordination Hubs are characterized by different specifications, necessitating the definition of individual sets of minimum criteria for each subtype of affiliated partnership. While the following sub-chapters focus on the detailed specifications of Associated National Centres and Coordination Hubs, respectively, the detailed specifications of Collaborative National Centres will be provided at a later stage in a separate document. In order to better illustrate the interdependence between the definition of the role and tasks of the respective affiliated partner within the network and the Member State on the one hand, and the related minimum criteria on the other hand, both, the definitions and the minimum recommended criteria are presented block by block, first for Associated National Centres, followed by Coordination Hubs.

4.1 Associated National Centres

A) Definition

According to Recital 14 of the 2014 Commission Delegated Decision, Associated National Centres focus "*in the provision of healthcare*" and feature a specific link to an individual network. Thus, an Associated National Centre is defined as 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.

B) Minimum recommended criteria

Since Associated National Centres will mainly constitute Healthcare Providers that offer clinical services directly to patients in a similar way as compared to full members of a European Reference Network, the Board decided that the minimum recommended criteria for this subtype should be linked to a certain level to the operational criteria defined for full member applicants and therefore be elaborated based on selected general and specific criteria extracted and adapted from the respective document (e.g. the "ERN Assessment Manual for Applicants: document 4 – Operational Criteria for the Assessment of Healthcare Providers", published March 2016).

In this context, it is important to note that 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. On the other hand, the Board of Member States strongly supports the view that, depending on the further increase in expertise and/or capacities, enrolment as associated partner to a given network might eventually pave the way to full membership for clinics and departments/clinical units offering direct services to patients. This does not include laboratories and mere facilities for instrument-based diagnostics.

Like in the original document for full member applicants, the criteria for Associated National Centres are subdivided into general criteria, reflecting common best practice in all Member States that should be fulfilled by any Healthcare Provider applying to be designated as Associated National Centre, and specific criteria tailored to the thematic domain and its particular characteristics and requirements of the related network.

1. General criteria

Important information: 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

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

Important information: 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]**;
- 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]**;
- 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]**.

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]**;
- The specialized functions covered by the different professionals within the team (like, for instance, diagnosis, treatment, information, observation, nursing, rehabilitation, etc.) **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**;
- The specific knowledge and experience with the diagnosis and treatment of children (when applicable) **[BOTH CLINICAL AND DIAGNOSTIC INSTITUTIONS]**.

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.

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]**.

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

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]**;
- 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]**;
- How these laboratories ensure the specific quality control related to their diagnostic services **[BOTH CLINICAL AND DIAGNOSTIC LABORATORY INSTITUTIONS]**;
- 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]**;
- 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]**.

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]**.

The description may also include, for example:

- Whether the diagnostic services are certified or accredited **[BOTH CLINICAL AND INSTRUMENT-BASED DIAGNOSTIC INSTITUTIONS]**;
- 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]**.

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]**.

- 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.

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 confirmation that the information system operated by the Healthcare Provider warrants interoperability with the information platform of the related ERN;
- 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.

While the minimum recommended criteria define the minimum level of information necessary to illustrate the level of expertise, the human resources and the medical, as well as technical capacities of Associated National Centres, the Board of Member States recommends clinics and departments/clinical units applying to be designated as Associated National Centre to complete the Membership Application Form for full members as exhaustively as possible (and independent of any threshold levels in force for full members) in order to provide the best possible overview of their individual strengths and weaknesses. This will help in the negotiation for an appropriate agreement of engagement (see chapter 2) and will establish a baseline for the planned evaluations of the operating partnership.

4.2 National Coordination Hubs

A) Definition

Complementing the set of institutions with an official link to reference networks, Recital 14 defines National Coordination Hubs as an option for Member States to link "*with all types of Networks*". Thus, National Coordination Hubs comprise any type of institution with the appropriate knowledge and the legal and organizational capacity to link the national healthcare system to a number or all

European Reference Networks. National Coordination Hubs function as interfaces between the national healthcare system and those networks where a given Member State is neither represented by a full member nor by an Associated National Centre. National Coordination Hubs do not need any specific medical expertise or knowledge and their composition might range from:

- A major national healthcare provider offering the necessary organisational support (such as management, infrastructure and resources) to specialised units that can join different ERNs and that operate within its organisational structure;
- A network of healthcare providers coordinated at national level;
- A non-hospital-based, specifically assigned institution as contact and coordination point, linking ERNs with the national healthcare system, like, for instance, an administrative authority such as a national and/or regional ministry of health or other health authority, or a national or regional focal contact point such as those established by the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

B) Minimum recommended criteria

With the broad range of non-specialized institutions eligible as National Coordination Hub, the minimum recommended criteria applicable to all are confined to general aspects only.

General criteria

1. Evidence of a clear and well-defined organization (governance, management, definition of one representative as contact person).
2. Listing of the different ERNs the coordination hub should be linked to.
3. Description of the capacity and the ways to link the different ERNs with the national healthcare system.

Member States interested in adopting the first model outlined above (i.e. a major national healthcare provider offering the necessary organisational support [such as management, infrastructure and resources] to specialised units that can join different ERNs and that operate within its organisational structure), should consider to additionally apply a set of minimum criteria that mirror the minimum recommended criteria for Associated National Centres comprising clinics and departments/clinical units providing direct outpatient and/or inpatient services to patients (as outlined in pages 5-8 of this document). In this particular instance, the recommended general criteria would apply for the general hospital setting while the specific criteria would apply to the specific specialised units according to the respective network's area of expertise.

5 Tasks, rights and obligations of the Affiliated Partners

The Associated National Centres and Coordination Hubs should:

1. Support the ERN objectives established in Article 12 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
2. Fulfil the Minimum Recommended Criteria described in point 4 of this statement.
3. Respect the rules of the Network to which the Affiliated Partner will be linked and participate and share the tasks and work related with the cooperation activities of the Network.

4. Act as a hub-node at national level in the area of expertise of the ERN to which the Affiliated partner is linked including the referral of patients to the ERN Clinical Patient Management System.
5. Contribute through their relation with the ERNs to pool and disseminate expertise for the benefit of patients and Member States.
6. Follow the rules and strategies established in an ERN-Affiliated partner bilateral cooperation agreement that should describe how affiliated partners interact, participate and contribute to the specific ERN.

6 Timeline for the affiliation process

The timeline for the affiliation process foresees two subsequent steps for newly established ERNs:

1. Development of an affiliation strategy (by ERNs and Member States) and identification of affiliated partners (by Member States)

2. Integration of affiliated partners identified and designated on the national level into their respective ERNs

Collectively, the affiliation process should be executed in an as flexible as possible manner with regard to the exact timing of affiliation for each Member State in order to account for any kind of country-specific factors and conditions, in particular for the time required to identify and designate the different subtypes of affiliated partners in each Member State.

The timing of the affiliation process will be agreed by the ERN BoMS and will be established in a separated document and updated periodically.

In the event of a disagreement on the integration of a concrete, nationally designated affiliated partner into an ERN between the Member State and the coordinator of the given Network, the Board of Member States on ERN should be contacted by both parties and provided with all necessary information on the nationally designated candidate in question, as well as the reasons identified by the ERN why it might not be advisable to include this specific candidate into the network. Based on the information and evidence provided, the Board will take the final decision on the inclusion or non-inclusion of this candidate into the network.

7 Termination of the affiliation

Comparable to the situation of full members, certain rules and procedures, as well as reporting requirements apply for the termination of an affiliated membership.

An affiliated partner may lose its affiliated membership in one (Associated and Collaborative National Centres, as well as National Coordination Hubs) or several Networks (National Coordination Hubs) for a number of reasons including:

- Voluntary withdrawal

- Decision of the national authority of the Affiliated Partner
- Lack of fulfilment of essential parts of the work plan-agreement with a given ERN.
- Termination of the ERN where the centre is affiliated.
- If a healthcare provider from the same Member State is approved as full member of the same ERN where the centre was affiliated.

The ERN BoMS should, prior to the designation of affiliated partners, approve the additional document stablishing the detailed **Rules and procedures regarding the Termination Process of an affiliated partner.**