ERN Strategy for the Integration of Affiliated Partners

(Associated National Centres and National Coordination Hubs)

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1 Introduction

The European Reference Networks (ERNs) Coordinators Group produced this guidance document (strategy) to indicate how Affiliated Partners[1] (APs) of ERNs can collaborate with the ERNs. The document is addressed to all the 24 ERNs and individual ERNs, who are free to amend it as they see fit and to tailor it to meet the specific needs of their medical domain and the AP which has been designated by the competent Member State.

2 Definitions of Affiliated Partners

Current ERN system does not cover the whole EU and EEA area and therefore questions regarding the accessibility of the ERNs in countries with no member in a given Network may arise. The addition of the APs will therefore increase the accessibility of the ERNs to patients in a more equitable way. Identification and selection of APs falls under the exclusive competence of the Member States taking into account their individual situation and planning.

There are **two types** of APs that the Member States are currently designating:

- **Associated National Centres**[2] for those ERNs where an EU Member State is not yet represented by a full member in the respective ERN. It establishes a link with one specific ERN.
- **A national Coordination Hub**[3] establishes at once a link with more than one Network in which a given Member State is neither represented by a full member nor by an

1 Recital 14 and point (7)(c) of Annex I of Delegated Decision 2014/286/EU 12 of the 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). https://ec.europa.eu/health/sites/health/files/ern/docs/ern_delegateddecision_20140310_en.pdf

2 For definitions of Affiliated Partners see the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU and the Board Statement of 10 October 2017: https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf

An **Associated National Centres** 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 Centre. National Coordination Hubs may especially represent a useful solution for those Member States with very small populations that need to establish such links with many ERNs at once.

3 ERN Policy Statement

It is anticipated that in most cases APs do not have the same levels of expertise and resources as the current full members of the ERN. Indeed, it would be difficult notably for healthcare providers from a Member State with a very small population to see the same volume of patients with a particular rare disease or complex condition. However, the ERNs look forward to collaborating with the designated APs.

The APs may request highly specialised advice from the ERNs on patients with rare diseases or low prevalence complex conditions, thereby expanding the geographical coverage of the ERNs to all EU and EEA Member States. Thus the ERNs hope that, over time, equity of access to their services will be achieved through collaboration with the APs.

ERNs anticipate that through such collaborations, specialised knowledge will transfer from the current ERN healthcare providers and their clinical teams to the healthcare professionals in the APs, thereby raising their levels of expertise over time. **ERNs welcome such interactions.**

4 Tasks of the Affiliated Partners

The ERN Board of Member States (BoMS) has identified a number of tasks for the APs when working with the ERNs:

- Support the ERN objectives established in Article 12 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[4].
- Fulfil the Minimum Recommended Criteria described in point 4 the Board Statement of 2017.
- Respect the rules of the Network to which the AP will be linked and participate and share the tasks related to the cooperative activities of the Network.
- Act as a hub-node at national level in the area of expertise of the ERN to which the AP is linked, including the referral of patients to the ERN Clinical Patient Management System.
- Contribute through their relation with the ERNs to pool and disseminate expertise for the benefit of patients and Member States and patient organisations involved.
- Follow the rules and strategies established in an ERN-AP bilateral cooperation agreement that should describe how affiliated partners interact, participate and contribute to the specific ERN.

The rules for the termination of an AP have been described by the BoMS in their document published in June 2018[5]. The AP is aware of this document and will comply with the rules described by the BoMS.

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[3] **National Coordination Hub** is a healthcare provider that can 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.

[5] https://ec.europa.eu/health/sites/health/files/ern/docs/2018_rulestermination_ap_en.pdf

5 ERN engagement with APs

The Coordinators are expected to receive and process the designation letters received from the Member States.

Once a particular ERN has been notified by the Member State as to which Affiliated Partners have been chosen to collaborate with that ERN, the following activities can be anticipated:

1. An introductory videoconference will be arranged between the AP organisation and the ERN Coordinator, ERN manager and other members of the ERN as deemed appropriate by the Coordinator. During this meeting the general objectives and activities of the ERN will be explained in further detail as well as the principles of the governance. The extent of participation of the AP in individual ERN activities will be discussed and agreed upon. Any questions will be answered either during the meeting or followed up through an exchange of emails.
2. Coordinators may also want to assess whether they would need any further information from the designated AP, and if so, request that information from them.[6]
3. The ERN Structure and governance documents (the Network Agreement and any supporting documents) will be sent in advance of the aforementioned introductory meeting. The AP will be asked to read the governance documents and respect the rules of the ERN.
4. Following the introductory Videoconference, the ERN will prepare a draft Bilateral Cooperation Agreement which will be sent to the AP for their consideration. When finalised, this agreement will be signed by the ERN Coordinator and the legal signatory for the AP healthcare provider in order to ensure that **the required level of resources is available to deliver the Bilateral Cooperation Agreement**. A copy of the Agreement will be sent to the Commission's functional mailbox (SANTE-ERN-AFFILIATED-PARTNERS@ec.europa.eu).The ERN Team will save all signed agreements in a space dedicated to Affiliated Partners within the ERN Collaborative Platform (ECP) so as to provide all Board members with access to them.
5. Once an agreement has been signed by the ERN and the AP and the Commission has been informed (as described in point 4) **the AP will be granted access to the Clinical Patient Management System (CPMS)**. CPMS is a web-based platform, patient information can be uploaded and shared among centres securely and effectively in accordance with all current legal requirements for data protection.
6. The Member State having designated the AP will provide clarity to the ERN in a written statement on how the process of referring patients to the ERN will work in their country.

[6] As stated by the Board on 10 October 2017, "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 shall 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". Therefore, in case a Coordinator has reasons to doubt about the designation of an Affiliated Partner, he/she is invited to **promptly inform the designating Member States**, and if no agreement is found, to **alert the ERN Team**, so that the issue can be raised with the ERN Board of Member States.

This should take account of the fact that ERNs are intended to provide assistance for those patients whose rare or low prevalence complex conditions that cannot easily be dealt with at a national level.

7. APs should act as entry points to ERNs for patients, improving accessibility for patients to the ERNs across the EU. Where cases cannot easily be dealt with at national level they can be considered for referral to the ERN. If there is more than one AP in a given country, the APs will cooperate at national level.
8. The process of designation of an AP by a Member State should include ensuring that the AP has sufficient organisational capacity and resources to actively engage with the ERN.
9. While the APs are welcome to participate in various ERN activities, they will not have voting rights on the ERN Board, in which only full members are represented.
10. The ERN Strategy for the Integration of Affiliated Partners are to be presented and approved by the Board of Member States.