



Dear Colleagues,

We would like to share information with you about the designation of affiliated partners of European Reference Networks (ERNs).

EpiCARE is a European Reference Network for Rare and Complex Epilepsies and connects 28 expert centres in 13 European countries with the aim of aiding the diagnosis and treatment of rare epilepsy patients by utilizing e-tools and cross-country e-consultancy.

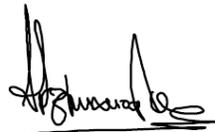
European member states *without* EpiCARE centres can nominate affiliated partners to join the network. Please find information below about process itself.

We hope you find the information useful. Should you have further questions about ERNs and their work or the designation of affiliated centres, please don't hesitate to contact us.

Yours sincerely,



Professor J Helen Cross OBE
ERN EpiCARE Coordinator (2017-2019)
Email: h.cross@ucl.ac.uk



Professor Alexis Arzimanoglou
ERN EpiCARE Coordinator
Email: aarzimanoglou@orange.fr



Q&As on the designation of Affiliated Partners

1. Which types of Affiliated Partners do exist?

There are two types of Affiliated Partners that may be designated at this stage:

- (a) **Associated National Centres** which establish a link with one specific Network and, as defined in the 2017 Board Statement, are healthcare providers "*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: (i) clinics and departments/clinical units providing direct outpatient and/or inpatient services to patients; (ii) medical and genetic diagnostic laboratories; (iii) pathological laboratories; (iv) specific facilities for instrument-based diagnostics*".
- (b) **National Coordination Hubs** which establish at once a link with more than one Network and, as defined in the 2017 Board Statement, 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: (i) a major national healthcare provider [...]; (ii) a network of healthcare providers coordinated at national level; (iii) a non-hospital based, specifically assigned institution as contact and coordination point linking the ERNs with the national system [...]*" such as the National Contact Points created by the 2011 Cross Border Healthcare Directive.

2. What is the expected role of the Affiliated Partners?

Affiliated Partners are **not members of the Networks**. They are expected to **establish a link** to the Networks for those countries which do not have a member in a specific ERN thus **addressing the concerns related to the geographic coverage of the Networks**.

Our understanding is that, while not having the level of expertise that would make them qualify for membership, the Affiliated Partners will contribute to the Networks' activities and benefit from their expertise, **facilitating the sharing of knowledge across the EU**. Most importantly,



Affiliated Partners should act as **entry points to ERNs for patients, improving the accessibility for patients across the EU**. For that reason, the Affiliated Partners shall participate in the CPMS virtual consultation panels for those patients that they have referred to the Networks and may also attend some other virtual panels for their own learning purposes or to fill any knowledge gap, due to their specific expertise (e.g. in case of laboratories).

3. Can an Affiliated Partner become an ERN member?

Affiliated Partners may at a later stage, if they are healthcare providers and develop the required expertise, **become ERN members**. This would only happen **in compliance with the procedures for membership** applicable to any healthcare provider and **NOT automatically or with a special procedure**.

4. What happens if a healthcare provider is approved as member in a Network having already an Affiliated Partner from the same Member State?

An Affiliated Partner will **lose its partnership** *i.a.* if a healthcare provider from the same Member State joins the Network as a member.

5. What are the essentials of the designation of an Affiliated Partner?

- (a) the designation is the **responsibility of the Member State**. The **National Competent Authority** shall therefore **sign** the designation letter;
- (b) the **healthcare provider** designated as Affiliated Partner must be **clearly identified**;
- (c) the **Network** with which the Affiliated Partner establishes the link must be **clearly identified**;
- (d) the Member State must **clarify** whether the Affiliated Partner will be a **Associated National Center or a National Coordination Hub**; the **information on the healthcare provider** must be provided so as to allow the Coordinator to integrate the Affiliated Partner in the activities of the Network.

6. How will Member States designate Affiliated Partners?

The ERN Team has prepared **templates for the designation**, including a **designation letter** and an **informative annex**. There is one template for each subtype of Affiliated Partner (Associated National Centre and National Coordination Hub). The designation letter includes information on the Affiliated Partner and the Network(s) which they wish to establish a link with and the annex gives a description of the designated Affiliated Partner, highlighting how the Affiliated Partner complies with the set of minimum recommended criteria identified in the 2017 Board Statement. At the same time, as stated by the Board in that document, *“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.***” As for National Coordination Hubs, the Board noted in the same document that “*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.***”

In this context, various Member States asked the Commission to publish the **Network specific criteria** to be complied with by the healthcare providers wishing to join a Network as **members**, established by each Network in their application to the 2016 Call. The respective table can be found at this link:

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

The Member States remain, of course, **free to use or not the templates.**

The designation letters shall be **signed by the National Competent Authority.**

Member States have been invited to send accompanying documents in English.

The Networks might **request further information** from the designated Affiliated Partners at a later stage them, if needed.

7. Can the healthcare provider sign the designation letter while the Member State signs an endorsement letter?

No, the designation letter must be signed by the **National Competent Authority.**

8. What is the difference between the designation of an Associated National Center and the designation of a National Coordination Hub?

As seen in question 0, the two types of Affiliated Partners are very different:

- the **Associated National Centre** establishes a **link with a specific Network only** while the **National Coordination Hub** establishes **at once a link with more than one Network**;
- **Associated National Centres** must be “(i) **clinics and departments/clinical units providing direct outpatient and/or inpatient services to patients**; (ii) **medical and genetic diagnostic laboratories**; (iii) **pathological laboratories**; (iv) **specific facilities for instrument-based diagnostics**” while the composition of **National Coordination Hubs** “*might range from: (i) a major **national healthcare provider** [...]; (ii) a **network of healthcare providers** coordinated at national level; (iii) a **non-hospital based, specifically assigned institution** as contact and coordination point linking the ERNs with the national system [...]*”;
- the **Associated National Centre** is a healthcare provider “*with at least some **special expertise** matching the global thematic domain of a given reference network*” while the **National Coordination Hubs** “*do not need any specific medical expertise or knowledge*” and are called to “*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";

As a consequence, when designating an **Associated National Centre** a Member State must provide **detailed information on its activities and expertise**, while when designating a **National Coordination Hub** it would be sufficient to provide **information on the organisational capacity only**.

9. Can the same healthcare provider be designated as Associated National Center in various ERNs? What is then the difference with a National Coordination Hub?

The same way as a healthcare provider can be member of various ERNs, it can also become **Associated National Center in various ERNs**. The differences with a National Coordination Hub, as seen in questions 0 and 8, will be:

- related to the **role** that an Associated National Center will have to play compared to the National Coordination Hub and to the **institutions** which can be chosen as Associated National Centres or National Coordination Hubs (see questions 0 and 8);
- related to the **competences** that are required (special expertise in the area of work of the Network for the Associated National Center vs organisational capacity for the National Coordination Hub);
- related to the **process** (a specific designation letter for each designation in each Network for an Associated National Center one single designation letter for a National Coordination Hub).

10. Can a Member State designate a National Coordination Hub also for those Networks for which it has already designated an Associated National Center?

No, as stated in the 2017 Board Statement, a National Coordination Hub "*functions as interface 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*".

11. Can a healthcare provider fulfilling the criteria for membership be designated at this stage as Affiliated Partner?

Yes, a healthcare provider fulfilling the criteria for membership can be designated at this stage as Affiliated Partner and may **become a member at a later stage** (see question 3).

12. Can a healthcare provider be designated as Associated National Center in the same Network where it is already a member (on different areas of activity)?

No, if a healthcare provider is already a member of a Network, it cannot become Associated National Center in the same Network.



13. Can a Member State designate more than one Affiliated Partners in the same ERN?

Yes, this is allowed. Considerations related to the manageability and sustainability of the Networks should however be taken into account by the Member States.

14. To whom the designation needs to be sent by the designating Member State?

The designation letter shall be sent to the **Commission's functional mailbox** SANTE-ERN-AFFILIATED-PARTNERS@ec.europa.eu and to the **Coordinator of the Network** that this Affiliated Partner shall join (with Project Managers in copy).

To simplify the process:

- the Member States do not need to send the letters for information to the Board. The ERN Team will regularly send the Board an updated list of designated Affiliated Partners (per Member State of designation and per ERN) and also save designation letters in the space dedicated to the Board within the [ERN Collaborative Platform](#) (ECP) so as to provide all Board members with access to them.
- the ERN Team will regularly send the Coordinators an updated list of designated Affiliated Partners (per Member State of designation and per ERN): this will help the Coordinators check that they have received all the designation letters related to the Network. It will also save designation letters in the space dedicated to the Coordinators within the [ERN Collaborative Platform](#) (ECP) so as to allow the Coordinators to see which designation letters have already been checked by the ERN Team.

15. What is the deadline for the designation exercise?

As agreed at the November 2018 Board meeting, the deadline for the designation (initially set for December 2018) was extended until the **launch of the next Call for new Members** joining existing Networks.

16. What are the Coordinators expected to do within the process of designation of Affiliated Partners?

First, the Coordinators are expected to **receive and process the designation letters** (see below).

Second, as per the 2017 Board Statement, the Coordinators are expected to 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";*
- "a **clear strategy** which includes detailed pathways regarding the integration and participation of affiliated partners in the networks".* The strategies will need to be presented to, discussed with and approved by the Board of Member States prior to implementation. The initial deadline was end of February 2019. However, this has to be



adjusted to the ongoing designation process and the new deadline for designation (see above).

The Coordinators have been invited to **coordinate the preparation of these documents** among themselves to avoid duplication of efforts and ensure cross-ERN consistency on the issues covered and on the level of details.

17. What are the Coordinators expected to do after receiving the designations letters?

The Coordinators are invited to **establish contacts with the designated Affiliated Partners and the designating Member States.**

They may also want to **assess whether they would need any further information** from the designated Affiliated Partner, and if so, request that information from them.

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.

18. Where can the Board Statements related to Affiliated Partners be found?

The documents agreed by the Board can be found at the following links:

- 2016 Statement on Affiliated Partners
https://ec.europa.eu/health/sites/health/files/ern/docs/boms_strategicview_affiliatedpartners_en.pdf
- 2017 Statement on the definition and minimum recommended criteria for Affiliated Partners
https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf;
- 2018 Statement on the timeline for designation of Affiliated Partners
https://ec.europa.eu/health/sites/health/files/ern/docs/2018_statementtimeline_ap_en.pdf;



Great Ormond Street 
Hospital for Children
NHS Foundation Trust



- 2018 Rules for termination of Affiliated Partners
https://ec.europa.eu/health/sites/health/files/ern/docs/2018_rulestermination_ap_en.pdf.