

ERN GUARD-Heart Strategy for Integration of Affiliated Partners (Associated National Centres and National Coordination Hubs)

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EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



Authors: Arthur A.M. Wilde, Ahmad S. Amin, Nynke Hofman

1. INTRODUCTION

The European Reference Networks (ERNs) Coordinators Group (ERN CG) produced a guidance document (strategy) in May 2019, addressed to all 24 ERNs, to indicate how Affiliated Partners¹ (APs) of ERNs can collaborate with the ERNs. This document has been developed based on the ERN CG guidance document and has been adapted to meet the specific needs of ERN GUARD-Heart, the ERN for rare or low prevalence and complex diseases of the heart. By pooling knowledge and expertise and working in multidisciplinary expert teams, members of the ERN GUARD-Heart aim to provide better, safer, more efficient healthcare to all European patients with rare or low-prevalence diseases and complex conditions of the heart on the basis of the best evidence and value available.

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 Centres¹** 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 Hub²** which 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 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. DESIGNATION OF AFFILIATED PARTNERS

It was initially anticipated that in most cases APs would not have the same levels of expertise and resources as the current full members of the ERN. Indeed, it would be particularly difficult for healthcare providers from a Member State with a lower than average population to see the same volume of patients with a particular rare disease or complex condition. However, some Member States decided to give letters of approval to HCPs for AP status whilst appreciating

¹ For definitions of Affiliated Partners see 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.

² **National Coordination Hubs** is a healthcare provider that has 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.

that the same HCP intended to apply to the call (closed on 30 November 2019) to become a full member. When a full member joins a specific ERN after the call, any APs from the same Member State will lose their AP status and leave that ERN. It is expected to take at least until the beginning of 2021 before the new full members will actually join the ERNs; therefore, in practice, some APs may have about a year to work with the ERNs before any change in their status takes effect. ERN GUARD-Heart will work actively with all APs during this period regardless of any potential change in status in the future and they will all be treated equally by the ERN.

A total of 9 Associated National Centres (ANCs) across a total of 7 EU Member States (Austria, Croatia, Estonia, Hungary, Lithuania, Slovakia, and Slovenia) were designated to work with ERN GUARD-Heart, alongside the appointment of two National Coordination Hubs (HUBs) (Luxembourg and Malta). Prior to the designation of the APs, ERN GUARD-Heart comprised of 24 HCPs in a total of 12 Member States (Belgium, Germany, Denmark, Finland, France, Italy, The Netherlands, Romania, Czech Republic, Spain, Sweden, and The United Kingdom). The addition of the APs increased this coverage to 35 HCPs in 21 countries.

4. ERN GUARD-HEART POLICY STATEMENT ON AFFILIATED PARTNERS

The mission of ERN GUARD-Heart is to facilitate access to highly specialised diagnosis and treatment of rare and complex heart diseases in adult and paediatric patients across the European Union (EU) using the Clinical Patient Management System (CPMS). CPMS is a secure IT tool for virtual exchange of patient data and clinical advice. By using CPMS, healthcare professionals across Europe can request advice from expert multidisciplinary teams based on the best evidence and value available. This advice can now be transferred more quickly to countries that have designated APs to work with the ERNs, thereby expanding the geographical coverage of the ERNs. Thus all the ERNs hope that, over time, equity of access to their services will be achieved through collaboration with the APs.

ERN GUARD-Heart anticipates that, through such active collaboration at European level, highly specialized knowledge will transfer from the current full members and their multidisciplinary teams to the healthcare professionals and their teams in the APs, thereby raising their levels of expertise over time. However, it is also now clear that some of the APs working with ERN GUARD-Heart are already expert teams in specialist HCPs likely to succeed in the call and become full members. This presents a valuable opportunity for the ERN to add new experts and their multidisciplinary teams who will be able to contribute their expertise to the panel discussions. The numbers of patients and procedures will also be counted in the ERN monitoring system. ERN GUARD-Heart welcomes collaboration with all the APs and will work actively with them on an equal expert knowledge basis.

Based on the legislation, APs do not have voting rights on the ERN GUARD-Heart Board of the Network and this point is included in ERN GUARD-Heart's governance documents. APs have access to the ERN GUARD-Heart governance documents and are respectfully asked to comply with them.

5. ERN GUARD-Heart Affiliated Partners

ERN GUARD-Heart has the following 11 APs (including of 9 ANCs and 2 HUBs):

- **Austria:** Medical University Innsbruck.

- **Austria:** Medical University of Vienna.
- **Croatia:** University Hospital Centre Zagreb, Department of Cardiac Surgery.
- **Estonia:** Tartu University Hospital.
- **Hungary:** Albert Szent-Györgyi Health Centre - University of Szeged.
- **Lithuania:** Hospital of Lithuanian University of Health Sciences Kauno Klinikos.
- **Lithuania:** Vilnius University Hospital Santaros Klinikos.
- **Luxembourg:** Centre Hospitalier du Luxembourg.
- **Malta:** Mater Dei Hospital.
- **Slovenia:** University Medical Center Ljubljana.
- **Slovakia:** Grown-up Congenital Heart Diseases Center Bratislava.

The APs were invited to a face-to-face welcome introductory meeting with the ERN GUARD-Heart Coordinator and the project management team on 2 September 2019 in Paris, France. A bilateral agreement (using the revised template provided by the European Commission in September 2019) will be signed by all the ERN GUARD-Heart APs. The areas the AP wants to actively collaborate on depends on their area(s) of expertise, and this is expressed by each AP in its bilateral agreement with the ERN GUARD-Heart. The bilateral agreements will be reviewed by the ERN GUARD-Heart Board of the Network.

6. 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 healthcare³.
- 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 2018⁴. The AP is aware of this document and will comply with the rules described by the BoMS.

³ 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).

⁴ https://ec.europa.eu/health/sites/health/files/ern/docs/2018_rulestermination_ap_en.pdf

7. 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. A first introductory conference was arranged on 2 September 2019 in Paris between the APs and ERN GUARD-Heart Coordinator and project managers. During this meeting the general objectives and activities of the ERN GUARD-Heart were explained in detail as well as the principles of the governance. A second introductory (video) conference will be arranged between all APs and the ERN GUARD-Heart Coordinator and project managers. During this meeting the general objectives and activities of ERN GUARD-Heart will be explained in further detail as well as the principles of the governance. The extent of participation of the APs in individual ERN activities will be discussed and agreed upon. Any questions will be answered either during future meetings 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 APs, and if so, request that information from them.⁵
3. ERN GUARD-Heart 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 (video) conference, the ERN GUARD-Heart will prepare a draft Bilateral Cooperation Agreement which will be sent to the APs 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 GUARD-Heart 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.

⁵ 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. They will actively receive the notes of the board meetings.
10. The ERN Strategy for the Integration of Affiliated Partners are to be presented and approved by the Board of Member States.