

ERN eUROGEN STRATEGY FOR THE INTEGRATION OF AFFILIATED PARTNERS:

Associated National Centres & National Coordination Hubs

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EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

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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 eUROGEN, the ERN for rare urogenital diseases and complex conditions, comprising teams of highly specialized urogenital surgeons, working with multidisciplinary expert teams and dedicated to dealing with patients during their whole life span from paediatric, adult and urogenital cancer patients. The high level of expertise of the surgeons is rare and it is critical to transfer this high level of knowledge and skills to the next generation of urogenital surgeons.

2. DEFINITIONS OF AFFILIATED PARTNERS (APS)

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

The process of designation ended when the new call opened on 30 September 2019. There are **two types** of APs that the Member States have designated:

- **Associated National Centers²** 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 Hub³** 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 represent a useful solution especially for those Member States with small populations that need to establish such links with many ERNs at once.

3. DESIGNATION OF APS BY MEMBER STATES

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

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 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.

3 A **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.



particular rare disease or complex condition. However, some Member States decided to give letters of approval to HCPs for AP status whilst appreciating that the same HCP intended to apply to the call to become a full member. When a full member joins an ERN network after the call, any APs from the same country will lose their AP status and leave the network. It is expected to take at least until the beginning of 2021 before the new full members⁴ will actually join the ERNs; therefore, in practice, APs will have about a year to work with the ERNs before any change in their status takes effect. When a full member joins an ERN network following the 2019 call, any APs from the same country are expected to develop an intensive, formal collaboration (for example, as may be described in their National Plans for rare diseases), although they would no longer be a formal AP of the ERN. ERN eUROGEN 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 11 Associated National Centers (ANCs) across a total of three countries (Austria, Spain, and Latvia) were designated to work with ERN eUROGEN, alongside the appointment of four National Coordination Hubs (HUBs) (Hungary, Luxembourg, Malta and Slovenia). Prior to the designation of the APs, ERN eUROGEN comprised 29 HCPs in a total of 11 countries (Belgium, Germany, Denmark, France, Italy, Lithuania, The Netherlands, Poland, Portugal, Sweden, and The United Kingdom) and thus the addition of the APs increased this coverage to 44 HCPs in 18 countries. As a result of the 2019 call for full members, if all applicants are successful coverage could potentially increase to 65 HCPs in 21 countries (the new three countries being Czech Republic, Finland, and Croatia). Therefore, following the AP process and the new call by the European Commission (EC) in 2019 for new members to join existing ERNs, the following eight countries would still not be connected to ERN eUROGEN: Bulgaria, Cyprus, Estonia, Greece, Ireland, Norway, Romania and Slovakia.

4. ERN EUROGEN POLICY STATEMENT

The top priority for ERN eUROGEN is to provide highly specialized advice on diagnosis and surgical treatment options using the Clinical Patient Management System (CPMS), the secure IT tool for virtual exchange of clinical advice. By using CPMS, healthcare professionals across Europe can request **advice from surgeons, urologists and expert multidisciplinary teams working with the surgeons** who are currently performing the highest volumes of rare and the most complex urogenital surgical procedures in Europe. 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 eUROGEN anticipates that, through such active collaboration at European level, highly specialized knowledge will transfer at pace from the current full members and their clinical 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 eUROGEN are already expert teams in specialist HCPs likely to succeed in the call and become full members. This presents a valuable opportunity for the network in terms of the addition of new experts and their multidisciplinary teams who are able to contribute their considerable expertise to the panel discussions. Their numbers of patients and surgical

⁴ The new call closed on 30 November 2019. This resulted in 841 applications from highly specialized units in HCPs to become members of the 24 ERNs. 31 applications are for ERN eUROGEN although this number will not be confirmed until the EC has performed the eligibility check to ensure that all the correct paperwork is included.



procedures will also be counted in the ERN monitoring system. **ERN eUROGEN 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 Board of Networks and this point is included in ERN eUROGEN's governance documents. APs are sent ERN eUROGEN's governance documents and are respectfully asked to comply with them.

5. ERN EUROGEN'S APS

As of the time of writing this document, ERN eUROGEN has 16 Affiliated Partners; comprised of 12 ANCs and four HUBs. The table below shows the Member States from which ERN eUROGEN has received designated APs, the names of the centers, whether contact has been established with them and a welcome introductory WebEx has been held, whether they have returned a signed bilateral agreement (using the revised template provided by the EC in September 2019), and which boxes they have ticked on the aforementioned bilateral agreement (indicating which areas of activity the AP wants to actively collaborate on). All but two of the APs that have returned bilateral agreements have indicated they will work with ERN eUROGEN on all possible areas of activity. The bilateral agreements with the APs will be reviewed by the ERN eUROGEN Board of the Network (BoN) on an annual basis.

	Member State	Center	Welcome WebEX Held	Bilateral Agreement Returned	Boxes Ticked on Bilateral Agreement
Associated National Centres (ANCs)	Austria (AT)	Krankenhaus der Barmherzigen Schwestern Linz	Yes	Yes	All
	Croatia (HR)	University Hospital Centre Sestre Milosrdnice, Zagreb	Awaiting	-	-
	Spain (ES)	Hospital Universitario 12 de Octubre, Barcelona	No response to contact	-	-
		Hospital Universitario Cruces, Barakaldo	Yes	Awaiting	-
		Hospital General Universitario Gregorio Marañón, Madrid	No response to contact	-	-
		Hospital Universitario La Paz, Madrid	Yes	Yes	All
		Marqués de Valdecilla University Hospital, Santander	No response to contact	-	-
Hospital de la Santa Creu i Sant Pau y Fundació Puigvert, Barcelona	Yes	Yes	All		



		Hospital Sant Joan de Déu, Barcelona	Yes	Yes	All
		Vall d'Hebron University Hospital, Barcelona	Yes	Yes	All
		Complex Public Hospital Virgen del Rocío Regional, Seville	Yes	Yes	All
	Latvia (LV)	Children's Clinical University Hospital, Riga	Yes	Yes	All
National Coordination Hubs (HUBs)	Hungary (HU)	Semmelweis University, Budapest	Yes	Yes	Did not tick: developing patient information dissemination; integration strategy
	Luxembourg (LU)	Centre Hospitalier de Luxembourg, Luxembourg City	Awaiting	Yes	None - will check
	Malta (MT)	Mater Dei Hospital, Msida	Yes (+ site visit)	Yes	All
	Slovenia (SI)	University Medical Center, Ljubljana	Yes	Awaiting	-

6. TASKS OF THE AFFILIATED PARTNERS

The Board of Member States representatives for ERNs (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 healthcare⁵.
- Fulfil the Minimum Recommended Criteria as described in point 4 the Board Statement of 2017.
- Respect the rules of the Network to which the AP will be linked and participate in 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 the patients, Member States, and patient organizations involved.
- Follow the rules and strategies established in an ERN-AP bilateral cooperation agreement that should describe how APs 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 2018⁶. The AP should be aware of this document and will comply with the rules described by the BoMS.

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



7. ERN ENGAGEMENT WITH APS

The ERN 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 APs have been chosen to collaborate with that ERN, the following activities can be anticipated:

- An introductory videoconference will be arranged between the AP organization and ERN eUROGEN's Coordinator, Centre Manager and other members of the ERN as deemed appropriate by the Coordinator. During this meeting the general objectives and activities of ERN eUROGEN will be explained in further detail, as well as the principles of the governance. The extent of participation of the AP in ERN eUROGEN's activities will be discussed and agreed upon (e.g. whether the AP will include patients in the possible ERN eUROGEN registry and whether the AP can provide monitoring data). Any questions will be answered either during the meeting or followed up through an exchange of emails. In return, collaboration with ERN eUROGEN gives access to the leading, highly specialized urogenital surgeons in Europe, the opportunity to have panel discussions (clinicians and trainees), and the potential to participate in other areas of activity (e.g. training and education, research, development of clinical guidelines etc.).
- 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. For example, ERN eUROGEN includes paediatric and adult highly specialized urogenital surgery and therefore it is optimal for the ERN to connect to both paediatric and adult services which may not always be located in the same healthcare provider in some countries.
- The ERN Structure and governance documents (the Network Agreement and any supporting documents) will be sent to the AP. The AP will be asked to read the governance documents and respect the rules of the ERN.
- Following the introductory videoconference, ERN eUROGEN will prepare a draft Bilateral Cooperation Agreement which will be sent to the AP for their consideration. When finalized, this agreement will be signed by the legal signatory for the AP healthcare provider and the ERN eUROGEN Coordinator 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. ERN eUROGEN decided that a timeline would not be insisted upon for the various activities in order to allow the relationship with the individual AP to develop gradually. The intensity of the activity will, to a large extent, depend upon the time the AP clinician has available to engage in ERN activities.

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.



- Once an agreement has been signed by ERN eUROGEN and the AP and the EC has been informed (as described in point 4) **the AP will be granted access by the EC to the Clinical Patient Management System (CPMS)**. CPMS is a web-based platform where patient information can be uploaded and shared among centers securely and effectively in accordance with all current legal requirements for data protection. The EC is expected to grant **access to CPMS for the APs by the end of January 2020**.
- The Member State, having designated the AP, will provide clarity to ERN eUROGEN in a written statement on how the process of referring patients to ERN eUROGEN will work in their country. This should take account of the fact that ERN eUROGEN is intended to provide assistance for those patients whose rare urogenital disease or low prevalence complex urogenital conditions cannot easily be dealt with at a national level.
- 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 ERN eUROGEN. If there is more than one AP in a given country, the APs will cooperate at national level.
- The process of designation of an AP by a Member State should include ensuring that the AP has sufficient organizational capacity and resources to actively engage with ERN eUROGEN.
- While the APs are welcome to participate in various ERN eUROGEN activities, they will not have voting rights on the ERN eUROGEN Board (only full members and patient representatives have voting rights).
- This ERN eUROGEN Strategy for the Integration of Affiliated Partners will be presented to the Board of Member States for ERNs for approval.
- The ERN Strategy for the Integration of Affiliated Partners will be presented and approved by the Board of Member States.

8. NATIONAL COORDINATION HUBS

ERN eUROGEN has received designations for HUBs from Malta, Luxembourg, Hungary and Slovenia. In these countries, one healthcare provider has been selected to form links with more than one ERN in a so called “hub and spoke model”. The Maltese HUB is establishing a link with 24 ERNs, Luxembourg with 23 ERNs, Slovenia with 9 ERNs and Hungary with 8.

To support the integration of the new HUBs, ERN eUROGEN organized a visit with ERN BOND to Mater Dei Hospital in Malta, the National Coordination Hub for the ERNs, for meetings on 28 November 2019 on behalf of the ERN network. The focus was to, firstly explain the philosophy and aims behind the creation of the ERNs, and secondly to introduce the CPMS and how it can be utilized for virtual case discussions with the Maltese clinicians.

Visits to the other HUBs will be arranged in the near future in collaboration with other representatives from other ERNs. The visit to Malta will be evaluated and any improvements implemented for the following HUB visits.



European Reference Networks

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