

Document version: Revised template, October 2025

## Template<sup>1</sup> for ERN Bilateral Cooperation Agreement with Associated National Centres and National Coordination Hubs

In accordance with the Statement of the ERN Board of Member States on the definition and minimum recommended criteria for Associated National Centres and National Coordination Hubs adopted in the Board meeting of 10 October 2017 and the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU<sup>2</sup>, I the undersigned (**add name of person and role in institution**) as authorised representative of (**add name of institution that the agreement is being signed with**) has received, read, understood and endorse the governance documents of ERN (add name of ERN: .....).

### Information on the Affiliated Partner (AP):

Healthcare Provider's name (native language) <sup>3</sup> :	Click or tap here to enter text.	
Healthcare Provider's name (English) <sup>4</sup> :	Click or tap here to enter text.	
Address:	Click or tap here to enter text.	
Website:	Click or tap here to enter text.	
Chief Executive Officer of the Healthcare Provider:	Name: Click or tap here to enter text.	
	Tel.: Click or tap here to enter text.	E-mail: Click or tap here to enter text.
Representatives <sup>5</sup> of the Healthcare Provider (contact persons) for the ERN:	Names: Click or tap here to enter text.	
	Tels.: Click or tap here to enter text.	E-mails: Click or tap here to enter text.

<sup>1</sup> This document is a template. All activities, indicators objectives, and timelines can therefore be modified following agreement by the signatory parties.

<sup>2</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1269&from=EN>

<sup>3</sup> Official name recognised by the national authority.

<sup>4</sup> Official name recognised by the national authority.

<sup>5</sup> Please provide the details for two representatives of the Healthcare Provider.

<b>ERN activity and related indicators</b>	<b>Objectives for the AP</b>	<b>ERN Coordination Team</b>	<b>Timeline</b> (to be agreed by AP and ERN Coordination)
<b>A. GENERAL ORGANIZATION &amp; COOPERATION</b>			
(i) ERN Governance documents: Terms of Reference and Terms of Engagement	AP has read and endorsed the ERN governance documents	ERN coordination team has provided governance documents and additional information specifically detailing what input is expected by the AP, together with all related documentation as requested by the AP	Upon signature of this agreement
(ii) Internal organization of the AP and Integration plan	The AP provides to the ERN coordination a description of its internal organization, identification of clinical specialists, available resources, needs for future improvement and information about on-site competencies in the corresponding disease area	ERN coordination team discusses with the medical representatives of the AP the content, steps and timelines of an integration plan	Suggested timeline 3-6 months
<b>B. PATIENT CARE</b>			
(i) Fields of Expertise	The AP defines its domains of expertise in the corresponding area of diseases, informs the ERN coordination and designates experts	ERN coordination team appropriately promotes the expertise that the AP can provide and makes sure the experts are invited to contribute whenever needed	Suggested timeline 3-6 months
(ii) Capacity for Case Management outside of scope of expertise	The AP provides to the ERN Coordination a description of its capacity for case management outside of scope of expertise on site or at national level	ERN coordination team provides to the AP all necessary information about case management practices that patients followed by the AP medical team can benefit from	Suggested timeline 3-6 months
(iii) CPMS 2.0 use training	AP to identify staff to be trained in use of CPMS2.0, including informed consent and data protection rules. The AP is joint	ERN coordination team will arrange CPMS training and support	Suggested timeline 0-6 months

	controller for the patients it enrolls in CPMS		
(iv) Referral of patients to the CPMS2.0	<p>AP is ready to regularly upload clinical cases for panel review and provide expertise to panel reviews when needed</p> <p>It provides to the ERN Coordination Team an estimation of the number of patients to be uploaded per year, based on its experience with rare diseases that are treated annually in that centre</p>	ERN coordination team monitors the use of CPMS by the AP and, whenever needed, envisages ways to improve the services provided	Suggested timeline 3-6 months
<p><b>C. REGISTRIES AND ERN ACTIVITIES</b></p> <p><i>Regarding registries: when, for any reason, the Data Sharing Agreement cannot be signed, the Affiliated Partner has the obligation to keep a local registry, reflecting all data elements included in the central registry. After a maximum of 12 months, the Affiliated Partner must ensure that this data is transferred to the ERN registry system.</i></p>			
(i) Registries	APs sign the Data Sharing Agreement and prepare for inputting medical information into the ERN registry system	ERN coordination team to provide the Data Sharing Agreement and support and training, if necessary, on how to use the registry	Suggested timeline 3-6 months
(ii) Registries	APs ready to regularly input medical information of all pertinent patients into the ERNs registry system	ERN coordination team to annually monitor enrichment of the Registry and propose improvements when necessary	Suggested timeline 3-12 months
(iii) ERN Working Groups and Meetings	<p>AP will actively participate in regular ERN meetings and Working Groups.</p> <p>Contribution to WGs is detailed and agreed as per the Terms of Reference and Terms of Engagement of the ERN</p>	<p>ERN coordination team to notify APs of meeting schedules and provide guidance (and training/support if needed)</p> <p>ERN coordination team regularly monitors participation of the AP to ERN activities and, when needed, discusses proposals for improvement</p>	Suggested timeline 3-6 months

<b>D. CLINICAL PRACTICE GUIDELINES &amp; CLINICAL DECISION SUPPORT TOOLS</b>			
(i) Identification of expertise for Clinical Practice Guidelines and Clinical Decision Support Tools	AP to identify individuals with reference to disease area and level of expertise who could work with ERN on Clinical Practice Guidelines and Clinical Decision Support Tools	ERN coordination team to inform and discuss with AP on expertise requirements for Clinical Practice Guidelines and Clinical Decision Support Tools	Suggested timeline 3-6 months
(ii) Development of Clinical Practice Guidelines and Clinical Decision Support Tools	If expertise identified, AP regularly contributes to the development of the Clinical Practice Guidelines and Clinical Decision Support Tools	<p>ERN coordination team actively incorporates the APs on guideline and recommendations development, with reference to its domains and levels of expertise.</p> <p>This also includes, when needed, training on literature review procedures, analysis of available data and writing of recommendations, if available in the ERN.</p> <p>ERN coordination team monitors involvement of AP in Clinical Practice Guidelines and Clinical Decision Support Tools</p>	<i>Provided expertise identified:</i> Suggested timeline 6-12 months
(iii) Dissemination of Clinical Practice Guidelines and Clinical Decision Support Tools	<p>The AP disseminates the Clinical Practice Guidelines and Clinical Decision Support Tools within the healthcare provider and stakeholders at national level. AP shares feedback on implementation or not to the ERN coordination.</p> <p>The AP contributes to a medically sound translation in the</p>	<p>ERN coordination team supports the AP in all efforts to disseminate Clinical Practice Guidelines and Clinical Decision Support Tools.</p> <p>Difficulties encountered for implementation are monitored and reported to the BoMs</p>	Suggested timeline 3-6 months

	national language of the Clinical Practice Guidelines and Clinical Decision Support Tools		
(iv) Patient Leaflets	The AP contributes to the development of patient leaflets related to its field of expertise, contributes to the translation of all patient leaflets produced by the ERN into a national language and facilitates their dissemination to patients and caregivers	ERN coordination team facilitates the contribution of the AP to those Patient Leaflets relevant to its domain of expertise. Once translated patient leaflets become available on the ERN website, acknowledging the contribution of the AP	Suggested timeline 6-12 months
<b>E. TRAINING &amp; EDUCATION</b>			
(i) Dissemination of educational and training activities: Webinars, Workshops, etc	APs to promote and facilitate the participation to all national stakeholders the educational activities developed by the ERN	ERN coordination team to ensure all training and educational activities are open and disseminated to APs	Suggested timeline 0-3 months
(i) Participation and involvement in educational and training activities: Webinars, Workshops, etc	APs participate in the training and educational activities of the ERN.  APs provide input, in the respective expertise areas, to educational webinars, workshops and other educational activities organized by the ERN	ERN coordination team, after concertation with the AP representative, includes in the integration plan the educational activities the AP is expected to provide input	Suggested timeline 6-12 months
(ii) Learning from use cases	The AP facilitates, for educational purposes, the participation of its early- and mid-career clinicians to Case Discussions	ERN coordination team ensures that early- and mid-career clinicians and other staff working for the AP receive regular and direct information on Case Discussions and monitors participation, if available in the ERN.	Suggested timeline 3-6 months
<b>F. MEDICAL DEVELOPMENTS &amp; COLLECTION AND ANALYSIS OF DATA</b>			

(i) Reinforce collection and analysis of data	Depending on its area and level of expertise, the AP collaborates on activities, such as collection and analysis of data and relevant document preparations	ERN coordination team ensures that the AP is informed about collection and analysis of data activities and encourages participation in document preparations. ERN coordination team monitors the contribution of the AP to collection and analysis of data activities and includes proposals for improvement in the integration plan	Suggested timeline 6-12 months
(ii) Scientific Publications	Depending on its area and level of expertise, the AP publishes in peer reviewed journals (national or international) the most pertinent results of its collection and analysis of data activities. The estimated number of publications in a 5yrs period is included in the ERN governance documents	ERN coordination team regularly informs the AP about scientific publications in preparation that benefit from its input, considering the areas of excellence and monitors contribution to peer reviewed publications	Suggested timeline 6-12 months
<b>G. HORIZONTAL COMMUNICATION &amp; DISSEMINATION</b>			
(i) HCP & ERN webpages	The AP contributes to the development and regular update of an ERN specific webpage in the HCPs website. This webpage includes all relevant information on services it can provide to patients with rare diseases or complex conditions	ERN coordination team includes in all distribution lists the contacts provided by the AP. The ERN coordination ensures the dissemination of all types of Newsletters. ERN coordination team monitors the presentation and updates of the ERN activities on the AP's local webpage	Suggested timeline 3-6 months
(ii) Development of communication and dissemination strategy	APs contribute to the development of a communication and dissemination strategy aiming to inform other national HCPs and	ERN coordination team invites the AP to contribute to the development of communication strategies and activities and monitors the response	Suggested timeline 3-6 months

	stakeholders about the ERN activities		
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The implementation of this bilateral cooperation agreement by the Affiliated Partner is important. As per the ERN Board of Member State Statement 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 of 2017: “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 signed bilateral cooperation agreement will be uploaded in the HCP ERN Application Tool and is therefore made available to the concerned ERN Coordinator, the concerned Board of Member State and DG SANTE.

**Signed on (add date):** [Click or tap to enter a date.](#)

**[Signature]**  
**Chief Executive Officer  
of the Healthcare Provider**

**[Signatures]**  
**Representatives of the  
Healthcare Provider**

**[Signature]**  
**ERN Coordinator**