

## Ministère des Affaires Sociales et de la Santé, France

1. Respondent Profile	
1.1 Please indicate the type of organisation on behalf of which you are responding to this consultation:	Public authorities and government-appointed bodies responsible or involved in the definition of criteria and the establishment and evaluation of centres of reference/excellence (e.g. highly specialised healthcare, specialised commissioning services)
Please indicate level:	National level
Please indicate for what the administration is responsible:	
1.1.1. Other (please specify):	
1.2 Please indicate the name of your organisation or centre:	Ministère des Affaires Sociales et de la Santé
1.3 Please indicate the country where your organisation/centre is located/has its headquarters or main representative office in Europe:	FR
1.4 Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) and accessing country (Croatia) in which your organisation conducts business/is represented:	1
1.5 If need be, can we contact you by e-mail to obtain further information on your submission?	Yes
1.5.1 Please provide an e-mail address where we can contact you:	romann.datus@sante.gouv.fr

1.6 Please provide us with a contact person (incl jobtitle and daytime phone number):

Romann DATUS Délégation aux Affaires Européennes et Internationales (DAEI) Chargé de Mission "Santé Communautaire" +33-1-40-56-75-67

1.7 Please provide additional contact details if needed:

## 2. Involvement of your organisation in the matter of centres of excellence/reference (COE) and healthcare networks in highly specialised healthcare (HSHC).

2.1 How would you describe your organisation's knowledge of CoE and HSHC?

Very high

2.1.1 Space for further comments:

La France dispose d'une expérience en matière de coordination de réseaux d'acteurs destinés à aider les professionnels. Voir lien : [http://circulaire.legifrance.gouv.fr/pdf/2012/06/cir\\_35428.pdf](http://circulaire.legifrance.gouv.fr/pdf/2012/06/cir_35428.pdf)

<p>2.2. What aspects or domains related to the topic of CoE and HSHC would correspond to your organisation's key knowledge? (cross any that applies)</p>	<p>Highly specialised healthcare provision  Costs and economic evaluation  Priorities, description and characteristics of CoE and HSHC  Ethical analysis  Management and organisational aspects of highly specialized healthcare  Social aspects  Professional performance, clinical practice, quality and safety of specialized healthcare  Legal aspects  Assessment/evaluation/certification of clinical practice and healthcare providers  Information system, coding  Engineering/e-health</p>
<p>2.2.1. Space for further comments:</p>	<p>La France a développé un plan "Maladies rares" depuis plusieurs années. En 2012 a adopté une doctrine relative aux Centres de référence.</p>
<p>2.3 Is highly specialised healthcare a priority in your organisation's strategies and work plans?</p>	<p>Very high</p>
<p>2.3.1 Space for further comments:</p>	
<p>2.4. What specific field of healthcare services/specialities are most relevant for your centre/organisation's field of work?</p>	<p>High tech diagnostic and treatment services (radiology, nuclear medicine, electrophysiology, radiotherapy etc.)</p>
<p>Please specify:</p>	<p>All the options in point 2.4 have been marked.</p>

2.5. Has your organisation/centre been directly involved in the design or assessment of professional standards and criteria related with highly specialised healthcare?	Frequently
2.5.1 Please describe your role in such actions/projects:	l'action du Ministère des AS et de la Santé est large et complète. Elle concerne, en effet, les différentes étapes que sont: - la conception des politiques; - la mise en oeuvre; - l'évaluation
2.6. Has your organisation been involved in projects/activities supported by the Commission in relation with HSHC or professional and technical criteria/standards in highly specialised healthcare?	Yes
2.7. Do you have concrete examples based on your own organisation's experience or could you provide us with references or links to documents related with professional criteria and standards in highly specialised healthcare/CoE or HSHC (e.g. quality criteria, guidelines, consensus documents)?	Yes
2.7.1 Space for further comments:	Voir question 2.1.1 sur la doctrine de 2012 sur les centres de référence.
2.13. What is the scope of the network?	
2.14. Which kind of network?	
2.14.1 Space for further comments:	
2.15. Would you be interested in applying to the process to be considered Centre of Excellence of the future European Reference Network? (1 = not interested at all, 5 = very interested)	
2.15.1 Space for further comments:	

### 3. Proposed criteria for ERN (scope, general and specific criteria)

#### 3.1 Criteria related with diseases or conditions in order to be considered under the scope of the ERN

3.1.1. Need of highly specialised healthcare	5
3.1.1.1. Complexity of the diagnosis and treatment	5
3.1.1.2. High cost of treatment and resources	4
3.1.1.3. Need of advanced/highly specialised medical equipment or infrastructures	4
3.1.2. Need of particular concentration of expertise and resources	5
3.1.2.1. Rare expertise/need of concentration of cases	5
3.1.2.2. Low prevalence/incidence/number of cases	5
3.1.2.3. Evaluated experiences of Member States	5
3.1.3. Based on high-quality, accessible and cost-effective healthcare	5
3.1.3.1. Evidence of the safety and favourable risk-benefit analysis	5
3.1.3.2. Feasibility and evidence of the value and potential positive outcome (clinical)	5

3.1.4. Do you recommend any additional criteria or option that would effectively address the issue?	Yes
3.1.4.1 Explain your proposal in free text:	- Complexité des cas à traiter est un critère importante, à côté de la rareté des cas. - L'expertise spécialisée doit être multidisciplinaire. Voir réponse en papier.
3.1.5. Would you prioritise or suggest any concrete disease or group of diseases to be addressed by the future ERN according to the above criteria?	Yes
3.1.5.1 Explain your proposal in free text:	Maladies rares et certains cancers constituent des domaines dans lesquels les RER sont très attendus et les plus faciles à imaginer. (voir plus de détails dans la réponse en papier).

### 3.2. General criteria of the centres wishing to join a European Reference Network

3.2.1. Organisation and management	5
3.2.2. Patients empowerment and centered care	4
3.2.3. Patient care, clinical tools and health technology assessment	4
3.2.4. Quality, patient safety and evaluation framework policies	5
3.2.5. Business continuity, contingency planning and response capacity	5
3.2.6. Information systems, technology and e-health tools and applications	5
3.2.7. Overall framework and capacity for research and training	4

3.2.8. Specific commitment of the management/direction of the centre/hospital to ensure a full and active participation in the ERN	5
3.2.9. Do you recommend any additional option that would effectively address the issue?	No
3.2.9.1. Space for further comments:	Pour les autorités françaises il importe que le centre de référence adhère à sa dimension européenne et qu'il informe les autorités nationales de sa démarche, dans une logique de cohérence.

### 3.3. Specific criteria regarding the areas of expertise

3.3.1. Competence, experience and good outcomes and care	5
3.3.2. Specific resources and organisation:	4
3.3.2.1. Human resources	4
3.3.2.2. Team/centre organisation	5
3.3.2.3. Structural conditions	4
3.3.2.4. Specific equipment	4
3.3.2.5. Presence and coordination with other required complementary units or services	5
3.3.3. Patient care pathways, protocols and clinical guidelines in the field of expertise	4
3.3.4. External coordination, care management and follow-up of patients	5

3.3.5. Research, training, health technology assessment in the field of expertise	5
3.3.6. Specific information systems	5
3.3.7. Do you recommend any additional criteria or option that would effectively address the issue?	No
3.3.7.1. Space for further comments:	c