

Veneto Region Coordinating Centre for Rare Diseases (VRCCRD), Italy

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:	Regional 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:	Veneto Region Coordinating Centre for Rare Diseases (VRCCRD)
1.3 Please indicate the country where your organisation/centre is located/has its headquarters or main representative office in Europe:	IT
1.4 Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) and accession 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:	facchin@pediatria.unipd.it
1.6 Please provide us with a contact person (incl jobtitle and daytime phone number):	Prof. Paola Facchin +39 0498215700

1.7 Please provide additional contact details if needed:

+39 0498215695

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:

Since 2002 Veneto Region has officially identified CoE, per groups of RD (21). CCRD monitor their activities and carries out health statistics analyses to identify RD pts aggregations and outcomes

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)

Highly specialised healthcare provision
Costs and economic evaluation
Priorities, description and characteristics of CoE and HSHC
Management and organisational aspects of highly specialized healthcare
Professional performance, clinical practice, quality and safety of specialized healthcare
Assessment/evaluation/certification of clinical practice and healthcare providers
Information system, coding
Engineering/e-health

2.2.1. Space for further comments:

VRCCRD is directly in charge of: selecting CoE, monitoring activities, providing information through a helpline, collaborating with patients' org. for aspects related to the RD care network functioning

2.3 Is highly specialised healthcare a priority in your organisation's strategies and work plans?	Very high
2.3.1 Space for further comments:	CoE delivering HSHC are the core of the RD regional care network, but VR-RDCC is responsible for the whole RD care network, made of other services delivering rehabilitation, palliative care, social care
2.4. What specific field of healthcare services/specialities are most relevant for your centre/organisation's field of work?	Other
Please specify:	All the above mentioned, in terms of coordination
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:	CoE selection process carried out by VRCCRD has been extended to other Regions, to enlarge referral dimension of CoE (interregional). Common interregional protocols and care pathways have been defined
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?	No
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:

Official acts:

<http://bur.regione.veneto.it/BurvServices/Pubblica/DettaglioDgr.aspx?id=198613&highlight=true> DGR 2046/2007 All.A: technical report on methods used for the selection of interregional

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	4
3.1.2.1. Rare expertise/need of concentration of cases	4

3.1.2.2. Low prevalence/incidence/number of cases	3
3.1.2.3. Evaluated experiences of Member States	4
3.1.3. Based on high-quality, accessible and cost-effective healthcare	4
3.1.3.1. Evidence of the safety and favourable risk-benefit analysis	4
3.1.3.2. Feasibility and evidence of the value and potential positive outcome (clinical)	4
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:	ERN organized per groups of RD with common diagnostic and/or care problems
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:	Added value of networks for undiagnosed patients (see UnRareNet project: An Italian multicenter collaborative research network for rare undiagnosed patients).

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

3.2.1. Organisation and management	4
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	4
3.2.5. Business continuity, contingency planning and response capacity	3
3.2.6. Information systems, technology and e-health tools and applications	5
3.2.7. Overall framework and capacity for research and training	5
3.2.8. Specific commitment of the management/direction of the centre/hospital to ensure a full and active participation in the ERN	4
3.2.9. Do you recommend any additional option that would effectively address the issue?	Yes
3.2.9.1. Space for further comments:	Involvement of Regional Health Authorities, through regional/interregional coordinating Centres, where established per Law, as they are formally in charge to support and monitor CoE RDrelated activities

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:	5
3.3.2.1. Human resources	4
3.3.2.2. Team/centre organisation	4
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	4
3.3.5. Research, training, health technology assessment in the field of expertise	4
3.3.6. Specific information systems	5
3.3.7. Do you recommend any additional criteria or option that would effectively address the issue?	Yes
3.3.7.1. Space for further comments:	IS connecting CoE with the other nodes of the care network; teleconsultation; outcomes objectively pre-evaluated by the competent Regional Health Authorities