



**EUCERD RECOMMENDATIONS**  
**on**  
**RARE DISEASE EUROPEAN**  
**REFERENCE NETWORKS (RD**  
**ERNS)**

**31 January 2013**

# **EUCERD RECOMMENDATIONS ON RARE DISEASE EUROPEAN REFERENCE NETWORKS (RD ERNS)**

## **INTRODUCTION**

### **1. BACKGROUND TO THE RECOMMENDATIONS**

The specificities of rare diseases — great heterogeneity of diseases and of expression of diseases without predominant symptoms, a limited number of patients and a scarcity of relevant knowledge and expertise — single them out as a unique domain of very high added value of action at Community level. This is acknowledged and described in the *Council Recommendation on an action in the field of rare diseases (2009/C 151/02)* adopted on 8 June 2009.

This added value can especially be achieved through gathering national expertise on rare diseases which is scattered throughout the Member States and organising the collaboration between centres of expertise (CEs), healthcare providers, laboratories, patients and individual experts within Member States and between Member States to offer optimal cross-border services to all EU citizens.

The EUCERD has already adopted a set of recommendations on quality criteria for CEs in Member States (see bibliography in Appendix). CEs are the future nodes of European Reference Networks (ERNs). CEs have to work with other healthcare providers, laboratories and other experts who are the closest competent point of care for patients to ensure that:

- Expertise travels rather than patients themselves when appropriate: through the national healthcare systems there can be very different structures organised by regions, treatments, development and adoption of e-tools for tele-expertise and tele-consultation;
- Exchange of data, biological samples, radiological images, other diagnostic procedures and all offers of materials, occurs appropriately when needed to improve diagnosis and care, to improve knowledge and contribute to the development of new therapies.

The analysis of the previous and current pilot European Reference Networks (ERNs) funded by DG Sanco or by DG Research during the EU programme 2008-2013, shows that the most valuable services developed by these networks are:

- Shared databases/registries/biobanks at the disposal of the research community;

- Shared tools for tele-expertise at the disposal of the medical community;
- Common production of guidelines/best standards of diagnosis and care and information packages, training tools and training sessions covering both the medical and the social dimension of care.

Core to the move from the pilot ERNs to RD ERNs under the terms of the *Cross-Border Healthcare Directive* is the possibility to embed RD ERNs in the healthcare systems of the EU so that the sustainability of such networking is ensured and no longer driven by short-term projects.

Further consideration may need to be given to the various different possible network structures to be considered depending on the outcomes of the deliberation of the Cross-Border Healthcare Expert Group:

- i) Horizontal – CEs at the same level such as the expert centres across the different member states
- ii) Vertical – the different “points of care” of a healthcare pathway from primary care through to the CE providing the expertise
- iii) Diagonal – when different specialties such as social, rehabilitative, psychological, physiotherapists etc, work together.

## **2. SCOPE OF THESE RECOMMENDATIONS**

The general concept and the method of implementing ERNs are defined in *Article 12 of the Cross-Border Healthcare Directive (Directive 2011/24/EU)*.

These recommendations will help focus on the specificities of rare diseases and the criteria for the establishment and evaluation of ERNs within the field of rare diseases (RD ERNs), as well as the exchange and dissemination of information.

The document is based on iterative review and discussion at workshops and EUCERD meetings. This included initial discussion by EUCERD at their meeting in January 2012, followed by the EURORDIS position paper and informal RD ERN workshop and EUCERD plenary discussion in June 2012. This in turn was followed by the RD ERN workshop in September 2012, which produced a working draft of the final recommendations for review by the MS members of EUCERD ahead of the EUCERD meeting in November 2012. The recommendations were rediscussed at the EUCERD meeting in November 2012, then amended according to these discussions. The amended version was then sent to all members for their final input before the document was finalised taking into account these final comments and then presented to the members for adoption. The present recommendations were adopted unanimously by the EUCERD on the 31 January 2013 at their 7<sup>th</sup> meeting.

These recommendations are designed to be complementary to the advice of the Cross-Border Healthcare Expert Group on ERNs and develop the specific vision of RD ERNs. Therefore, generic issues are not addressed and the following recommendations focus on the networking dimensions specific for RD, assuming that MS have established and designated national CEs, or will do so in the framework of their national plan or strategy for RD. EUCERD and the EUCERD Joint Action will continue to stimulate the establishment of CEs in countries where there are none and identify where there is the need for improved capacity building in this area. Therefore it excludes recommendations on the care pathway dimension that is linked to the functioning of CEs, not of RD ERNs. Due to the parallel discussions of the Cross-Border Healthcare Expert Group, EUCERD may need to revisit these recommendations at a later date as the conclusions of the Cross-Border Healthcare Expert Group become established. In addition, work of other groups (for example conclusions on RD registry platform development) may need to be taken into account as plans for RD ERNs evolve.

### **3. TARGET GROUPS FOR THESE RECOMMENDATIONS**

Member States, European Commission, other EC initiatives (e.g. other projects and joint actions, Cross-Border Healthcare Expert Group, EUnetHTA, EPAAC), Centres of expertise in the field of rare diseases healthcare providers, RD experts and existing RD network co-ordinators and partners, patient organisations

## RECOMMENDATIONS OF THE EUCERD TO THE EUROPEAN COMMISSION AND THE MEMBER STATES

### MISSION, VISION AND SCOPE

**1. The overall vision of RD ERNs is that they will provide the framework for healthcare pathways for RD patients through a high level of integrated expertise.** RD ERNs will enable networking of centres on a European level, and promote that the appropriate healthcare professionals have access to the tools and guidelines provided by the RD ERN and to the knowledge of the networks. This will cover in a step-wise approach all rare disease patients, including those in the process of seeking a diagnosis or in whom a final diagnosis is not yet confirmed.

**2. Nationally designated centres of expertise (CE) are the core participants in RD ERNs.** In the context of rare diseases, such centres should be compliant with the *EUCERD recommendations for quality criteria for CE in rare diseases* and *Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*.

**3. An RD ERN needs to be flexible enough to accommodate working with different national CE structures.** Depending on the national healthcare system, CEs can be very different structures organised by regions, treatments, or diagnostic procedures, offering services in one location or through an established network.

**4. An RD ERN should cover essential core tools and activities.** The detailed scope of each RD ERN will vary between medical areas. However, some core components of an RD ERN can be identified, and the tools required to facilitate the delivery of some of these transversal components could be shared between different RD ERNs to allow interoperability. The core components of a RD ERN should include:

#### ***i. Disease Registries***

At a minimum, the primary purpose of data collection for an RD ERN should be to obtain clinical information from the patient and to interchange this information between professionals who care for the patients to improve the diagnosis and the delivery of clinical care. Also, the system should be used to assess the quality of care and the results of the healthcare provided in the CE. An RD ERN registry should integrate and harmonise existing resources where necessary, and possible, rather than duplicate effort. Such resources should use international terminologies to support interoperability as part of the global RD efforts on data sharing.

***ii. Quality assurance mechanisms for laboratory testing***

RD ERNs should promote the use of laboratory testing facilities which participate in quality assurance programmes in collaboration with, for example EuroGentest, EMQN. Supporting the establishment of quality assurance schemes for the methods applied in a very limited number of centres should be within the scope of RD ERNs.

***iii. Mechanism for information flow for good practice guidelines/best standards of diagnosis and care amongst MS***

It is the mission of the RD ERNs to develop good practice guidelines for patients' care. Good practice guidelines for RD generated by particular CEs in an RD ERN or by a network should be shared within an ERN and more broadly, as applicable. RD ERNs should have a mechanism whereby this information can be shared between MS for implementation as applicable within their specific healthcare setting.

***iv. Training and education tools***

RD ERNs should secure resources for training and education purposes that will promote good practice, with the aim of raising standards of care, diagnosis and treatment of patients within each network.

***v. Mechanisms for evaluation and clear indicators of performance***

The groups providing evaluation of RD ERNs should be multi-stakeholder and include patient organisations. Indicators should cover processes, outcomes (many of which will be able to be measured utilising the output of the registries) and impact such as, for example, through the utilisation of patient reported outcomes.

***vi. Communications infrastructure to ensure visibility of the RD ERNs and their processes and accessibility***

RD ERNs will establish and maintain their own web sites and their visibility will also be assured via the Orphanet database and the national help lines.

***vii. Cross-border referral mechanisms***

RD ERNs will provide a resource for the operation of the cross-border mechanisms under both Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and Regulation EC 883/2004 on the coordination of social security schemes, for example by highlighting the availability of relevant CEs and facilities and the mechanisms by which access to them are available.

***viii. Telemedicine core***

In all of these areas where disease specific resources and tools have already been generated and demonstrated to be of high quality (e.g. by previous

networks), RD ERNs should be required to utilize these in order to maximise the value of previous investments to support tele-consultations, training and education.

**5. An RD ERN will provide to the MS, guidance, definitions and mechanisms to ensure transparent and seamless healthcare pathways for the following:**

i) Patients with either

- A clear and confirmed diagnosis with or without a CE covering this diagnosis in their country,
- A suspicion of diagnosis with or without a CE in their country, and
- An unclear diagnosis

ii) CEs when

- A patient requires expertise from a suitable CE outside their country
- Support, training and consultation is required

All decisions on individual patients using these pathways should be the responsibility of the national health authorities. The national health authorities should take into account the pathways defined by the RD ERNs, in recognition that they represent the highest level of expertise available at one point in time.

**6. A particular problem in the field of rare diseases is that for some patients a complete diagnosis is not possible even with the highest levels of medical knowledge.** The concept of an RD ERN sharing, improving and providing the highest levels of medical knowledge at the European level provides a unique opportunity to reduce the uncertainties for the patients with an unclear diagnosis. Therefore, patients who may have a rare disease but who have an unclear diagnosis require a pathway into the most appropriate RD ERN or RD ERNs to have the best possible chance of achieving a precise diagnosis and to access appropriate care once a diagnosis is achieved. **Models to provide such a mechanism for patients with an unclear diagnosis should be further explored.**

**7. An RD ERN should have the capacity to follow patients with an unclear diagnosis and manage their care according to medical need.** For this purpose, RD ERNs might require access to research expertise, though any diagnoses achieved in a research setting would need to be confirmed in a laboratory testing facility thereafter. Due to fast advancing technologies, the RD field is frequently on the border between research and care. Therefore, RD ERNs will need to address how to deal with

increasing capacity following research advances. MS will need to agree on the procedure for following these patients.

## **GOVERNANCE**

**8. As with all ERNs, RD ERNs should have robust and clearly defined governance, with oversight structures and clear and comparable methods for evaluation.** Due to the specific role of patient organisations in RDs, RD ERNs should take into account the views of patient organisations. Patient organisations should play an integral role, especially in the evaluation of RD ERNs where patient organisations exist and where MS recognise that they have the capacity to do so.

**9. RD ERNs require strong leadership and the co-ordinating site(s) should be chosen preferably on the basis of proven ability to coordinate a network and its shared tools as well as to lead the medically relevant activities in the disease field.** The best coordinating partner is not automatically the best centre of expertise or the one with the largest number of patients, rather the one that has the capacity to fulfil all the key functions of coordination and to expand the network as necessary.

## **COMPOSITION OF RD ERNs**

**10. All RD ERNs will be required to deliver added value in at least three of the objectives listed in Article 12 of the Directive on patients' rights in cross-border healthcare.** RD ERNs will be composed of existing CEs but they will need to collaborate with each other, as well as with patient groups, health and social care providers, relevant research groups and diagnostic laboratories. Because of the specificities of rare diseases — great heterogeneity of diseases and of expression of diseases without predominant symptoms, a limited number of patients and a scarcity of relevant knowledge and expertise — sharing knowledge between different healthcare providers is an overarching goal of an RD ERN. It also has to promote access to centres not fulfilling the EUCERD quality criteria or not nationally designated, as well as individual healthcare professionals to the tools and guidelines provided by the RD ERN and to the knowledge of the network.

**11. Therefore, different forms of affiliation to an RD ERN (association, collaboration) should be allowed to ensure inclusivity.** Existing sources of information (Orphanet, pilot ERNs, EUCERD, help lines, information from patient organisations) will contribute to identify key experts who can play a valuable role in RD ERNs. In smaller countries for example, where there may be no or limited number of CEs, we recommend that other healthcare providers can become affiliated members of an RD ERN in order to have access to the good practice guidelines for care, treatment and diagnosis. Such affiliated members should adhere

to the agreed clinical guidelines for onward referrals, and would be required to attend network-training meetings and contribute to the overall data collection of the network. This will allow an RD ERN to reach out to as many MS as possible. **Within the on-going national planning for rare diseases (national plans or strategies for rare diseases), there should be a framework to promote and support the common process for designation of national CEs or experts who may be affiliated in the future RD ERNs.**

## **FUNDING AND EVALUATION**

**12. Funding mechanisms for RD ERNs need to be adequate and long-term.** Sustainable and long-term funding processes are needed, as RD ERNs are likely to remain necessary for the foreseeable future. Based on satisfactory evaluation against agreed indicators, funding should be for at least 5-year periods.

**13. The funding for RD ERNs should include support for co-ordination and networking.** The financial system of the CEs and affiliated centres in delivering healthcare are the competence of the MS. However, there are specific costs for networking, which should be part of a sustainable funding support mechanism from EC funds. Such funds should be available for:

- Co-ordinator time
- Project management
- Registry and data collection co-ordination
- IT, web site and communication platform
- Support for network meetings within an RD ERN and between RD ERNs, training and education packages both online and face to face
- Networking activities with other RD ERNs
- Board activities with their bureau
- Evaluation of the RD ERNs

**14. Funding for core network activities should be proportional to the number of targeted patients, the number of centres integrated, and the number of diseases covered in terms of information to be produced and disseminated.**

## **DESIGNATION OF RD ERNs**

**15. Ahead of the designation process for RD ERNs, consideration should be given to the possible economies of scale of developing shared platforms across RD ERNs such as core components for registries and data collection, quality assurance etc. (as listed in recommendation 4).**

**16. A clear process for the designation of RD ERNs should be established.** Criteria for the evaluation of prospective RD ERNs should include their inclusiveness and plans for expansion, excellence of the network, leadership qualities of the proposed co-ordinator(s), and numbers of MS involved, amongst others.

**17. A step-wise strategy for RD ERN designation should be delineated so that all patients with a rare disease will have access to an appropriate RD ERN in a defined period of time.**

**18. As it will only be possible to establish a limited number of RD ERNs at the beginning of the process, it is recommended to give priority to RD ERNs which meet the following 4 priority criteria** as a robust starting point: 1. Preferably existing formal or informal networks of experts that have reached maturity and have the scope to expand; 2. There are patient registries established and willing to interoperate; 3. There are existing networks of patient groups; and 4. There are sufficient existing activities of research output. When the priority criteria are established in the delegated act of the Cross-Border Healthcare Directive, these should be followed. Each thematic RD ERN would still need to expand over the course of its first five years of designation to include other centres, expert groups, patient groups and ultimately diseases.

**19. Based around the concept of medical specialties and body systems, diagnostic and therapeutic areas can be identified each covering a wide range of rare diseases.** Comparison of the systems in place in MS with well developed services for rare diseases shows that the number of diagnostic and systemic areas which might cover the majority of diagnoses could be approximately 20-30. By the end of the Health for Growth Programme (in 2020), the 20 to 30 RD ERNs should be established and covering a wide range of RD. These first established RD ERNs will be the ones meeting the “priority criteria” as defined above and will then progressively expand in order to cover all RDs by the end of the two next EU Public Health Programmes (by 2025), through integration of appropriate centres and expertise.

**20. A formal system for networking across all RD ERNs and sharing expertise should be defined and implemented.** Good practice and common methodologies on the common areas of RD ERN work should be shared (e.g. registry development, utilisation and sharing of data and banked tissue resources, good practice guidelines etc.). For future RD ERNs, as high quality systems to implement common tools are defined, the utilisation of these standards and methodologies should be a condition for designation.

**21. Working groups should be established as necessary to help oversee the establishment and implementation of the RD ERNs within the scope of *Article 12 of the Cross-Border Healthcare Directive (Directive 2011/24/EU)*. These working groups may act under the auspices of the EUCERD in order to guarantee that progress in RD ERN developments will be aligned with other ongoing RD initiatives.**

## **APPENDIX**

### **EXTRACTS OF RELEVANT EUROPEAN TEXTS**

#### **Directive (EC 2011/24/EU) of the European Parliament and of the Council on the application of patients' rights in cross-border health care**

(...)

(54) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases. This Directive should therefore give incentives to Member States to reinforce the continued development of European reference networks. European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive support from the Commission.

(...)

#### **Article 12**

##### ***European reference networks***

1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.
2. European reference networks shall have at least three of the following objectives:
  - a) to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;

- b) to contribute to the pooling of knowledge regarding sickness prevention;
- c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;
- d) to maximise the cost-effective use of resources by concentrating them where appropriate;
- e) to reinforce research, epidemiological surveillance like registries and provide training for health professionals;
- f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;
- g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;
- h) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

3. Member States are encouraged to facilitate the development of the European reference networks:

- a) by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;
- b) by fostering the participation of healthcare providers and centres of expertise in the European reference networks.

4. For the purposes of paragraph 1, the Commission shall:

- a) adopt a list of specific criteria and conditions that the European reference networks must fulfil and the conditions and criteria required from healthcare providers wishing to join the European reference network. These criteria and conditions shall ensure, inter alia, that European reference networks:

- i. have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;
- ii. follow a multi-disciplinary approach;
- iii. offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;
- iv. make a contribution to research;
- v. organise teaching and training activities; and
- vi. collaborate closely with other centres of expertise and networks at national and international level;
  - b) develop and publish criteria for establishing and evaluating European reference networks;
  - c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and their evaluation.

5. The Commission shall adopt the measures referred to in paragraph 4(a) by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19. The measures referred to in points (b) and (c) of paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

6. Measures adopted pursuant to this Article shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

### **Article 13**

#### **Rare diseases**

The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

- a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;
- b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No

883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

**Council Recommendation (2009/C 151/02) of 8 June 2009 on an action in the field of rare diseases**

(...)

(13) In July 2004, a Commission High-Level Group on Health Services and Medical Care was established to bring together experts from all Member States to work on practical aspects of collaboration between national health systems in the EU. One of this High-Level Group's working groups is focusing on European Reference Networks (ERNs) for rare diseases. Some criteria and principles for ERNs have been developed, including their role in tackling rare diseases. ERNs could also serve as research and knowledge centres, treating patients from other Member States and ensuring the availability of subsequent treatment facilities where necessary.

(14) The Community added value of ERNs is particularly high for rare diseases by reason of the rarity of these conditions, which implies both a limited number of patients and a scarcity of expertise within a single country. Gathering expertise at European level is therefore paramount in order to ensure equal access to accurate information, appropriate and timely diagnosis and high quality care for rare disease patients.

(15) In December 2006 an expert group of the European Union Rare Diseases Task Force issued a report 'Contribution to policy shaping: for a European collaboration on health services and medical care in the field of rare diseases' to the High-Level Group on Health Services and Medical Care. The expert group report outlines, inter alia, the importance of identifying centres of expertise and the roles that such centres should fulfil. It is also agreed that, in principle and where possible, expertise should travel rather than patients themselves. Some measures called for in the report are included in this recommendation.

(16) Cooperation and knowledge sharing between centres of expertise has proven to be a very efficient approach to dealing with rare diseases in Europe.

(17) The centres of expertise could follow a multidisciplinary approach to care, in order to address the complex and diverse conditions implied by rare diseases.

#### **IV. CENTRES OF EXPERTISE AND EUROPEAN REFERENCE NETWORKS FOR RARE DISEASES**

11. Identify appropriate centres of expertise throughout their national territory by the end of 2013, and consider supporting their creation.
12. Foster the participation of centres of expertise in European reference networks respecting the national competences and rules with regard to their authorisation or recognition.
13. Organise healthcare pathways for patients suffering from rare diseases through the establishment of cooperation with relevant experts and exchange of professionals and expertise within the country or from abroad when necessary.
14. Support the use of information and communication technologies such as telemedicine where it is necessary to ensure distant access to the specific healthcare needed.
15. Include, in their plans or strategies, the necessary conditions for the diffusion and mobility of expertise and knowledge in order to facilitate the treatment of patients in their proximity.
16. Encourage centres of expertise to be based on a multidisciplinary approach to care when addressing rare diseases.

#### **V. GATHERING THE EXPERTISE ON RARE DISEASES AT EUROPEAN LEVEL**

17. Gather national expertise on rare diseases and support the pooling of that expertise with European counterparts in order to support:
  - a) the sharing of best practices on diagnostic tools and medical care as well as education and social care in the field of rare diseases;
  - b) adequate education and training for all health professionals to make them aware of the existence of these diseases and of resources available for their care;
  - c) the development of medical training in fields relevant to the diagnosis and management of rare diseases, such as genetics, immunology, neurology, oncology or paediatrics;
  - d) the development of European guidelines on diagnostic tests or population screening, while respecting national decisions and competences;
  - e) the sharing of Member States' assessment reports on the therapeutic or clinical added value of orphan drugs at Community level where the relevant knowledge and expertise is gathered, in order to minimise delays in access to orphan drugs for rare disease patients.

## KEY DOCUMENTS

- **Directive (EC 2011/24/EU) of the European Parliament and of the Council on the application of patients' rights in cross-border health care**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

- **EUCERD Recommendations on Quality Criteria for Centres of Expertise for Rare Diseases in Member States (24 October 2012)**

<http://www.eucerd.eu/upload/file/EUCERDRecommendationCE.pdf>

- **EURORDIS Position Paper – European Reference Networks for Rare Diseases (May 2012)**

<http://www.eurordis.org/publication/european-reference-networks-rare-diseases>

- **EUCERD Report: Preliminary analysis of the experiences and outcomes of ERNs for rare diseases (May 2011)**

<http://www.eucerd.eu/upload/file/Reports/ERN2011Analysis.pdf>

- **Commission Communication, Rare Diseases Europe's Challenge**

[http://ec.europa.eu/health/ph\\_threats/non\\_com/docs/rare\\_com\\_en.pdf](http://ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf)

- **Council Recommendation (2009/C 151/02) of 8 June on an action in the field of rare diseases**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF>

- **Work of the High Level Group on Health Services and Medical Care during 2005**

[http://ec.europa.eu/health/archive/ph\\_overview/co\\_operation/mobility/docs/highlevel\\_2005\\_013\\_en.pdf](http://ec.europa.eu/health/archive/ph_overview/co_operation/mobility/docs/highlevel_2005_013_en.pdf)

- **RDTF Report: Overview of Current Centres of Reference on rare diseases in the EU (September 2005)**

<http://www.eucerd.eu/upload/file/Publication/RDTFECR2005.pdf>

- **RDTF Report: Centres of Reference for Rare Diseases in Europe – State-of-the-art in 2006 and Recommendations of the Rare Diseases Task Force (September 2006)**

<http://www.eucerd.eu/upload/file/Publication/RDTFECR2006.pdf>

- **RDTF Report: European Reference Networks in the field of Rare Diseases: State of the art and Future Directions (July 2008)**

<http://www.eucerd.eu/upload/file/Publication/RDTFERN2008.pdf>

- **EUCERD Workshop Report: Centres of expertise and European Reference Networks for Rare Diseases (8-9/12/2010)**

<http://www.eucerd.eu/upload/file/WorkshopReport/EUCERDWorkshopReportCECERN.pdf>

- **EUCERD Workshop Report: National centres of expertise for rare diseases and networking between centres of expertise for rare diseases (21-22/03/2011)**

<http://www.eucerd.eu/upload/file/EUCERDReport220311.pdf>

- **Eurordis Declaration of Common Principles on Centres of Expertise and European Reference Networks for Rare Diseases, 15 November 2008**

<http://www.eurordis.org/publication/centres-expertise-european-reference-networks-rare-diseases>