

"European Research Projects on Rare Diseases driven by Young Investigators"

Submission deadline for pre-proposals: January 31, 2012

[Link to pre-proposal template](#)

Link to electronic proposal submission
(Available from second week of January)

[Link to guidelines for applicants](#)

For further information, please visit us on the website <http://www.e-rare.eu>
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Call text

1. MOTIVATION AND AIM OF THE CALL	2
2. TOPICS OF THE CALL	3
3. ELIGIBILITY CRITERIA FOR YOUNG INVESTIGATORS	3
3.1. DEFINITION OF A COMPETITIVE CANDIDATE FOR THE E-RARE-2 JTC FOR YOUNG INVESTIGATORS (JTC 2012)	3
3.2. WHO CAN APPLY?	4
3.3. DEFINITION OF YOUNG INVESTIGATOR	4
3.4. COMMITMENT OF THE HOST INSTITUTION	4
3.5. ELIGIBILITY OF INSTITUTIONS	4
4. SUBMISSION OF JOINT PROPOSALS	5
4.1. FURTHER INFORMATION	6
5. EVALUATION	6
5.1. MANAGEMENT BOARDS	6
5.2. EVALUATION CRITERIA	7
5.3. ELIGIBILITY CHECK OF PRE-PROPOSALS AND FIRST STEP PEER REVIEW	7
5.4. EVALUATION OF FULL PROPOSALS WITH RIGHT TO REPLY (REBUTTAL STAGE)	8
5.5. FUNDING DECISION	8
6. FINANCIAL AND LEGAL ISSUES	9
6.1. FUNDING MODEL	9
6.2. FUNDING CONTRACTS	9
6.3. RESEARCH CONSORTIUM AGREEMENT AND OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS	9
7. RESPONSIBILITIES, REPORTING REQUIREMENTS AND DISSEMINATION	10
8. CONTACT AND FURTHER INFORMATION	10
ANNEX I. NATIONAL/REGIONAL CONTACT DETAILS	11
ANNEX II. INDICATIVE FUNDING COMMITMENTS OF THE PARTICIPATING ORGANIZATIONS OF THE E-RARE-2 JTC 2012	12
ANNEX III. ELIGIBILITY OF BENEFICIARY INSTITUTIONS FOR THE PARTICIPATING ORGANISATIONS OF THE E-RARE-2 JTC 2012	13

1. MOTIVATION AND AIM OF THE CALL

There are at least 6000 to 7000 distinct rare diseases, the great majority being of genetic origin. Although individually rare, taken together rare diseases affect at least 26-30 million people in Europe. Moreover, they represent a major issue in health care: a large number of these diseases lead to a significant decrease of life expectancy and most of them cause chronic illnesses with a large impact on quality of life and the health care system.

Therefore, research on rare diseases is needed to provide knowledge for prevention, diagnosis and better care of patients. Yet, research is hampered by lack of resources at several levels: (1) Few scientists work on one specific disease, (2) There are few patients per disease and they are scattered over a large geographic area, causing difficulties to gather the necessary cohorts, (3) Existing databases and material collections are usually local, small, and not accessible or standardized, (4) Diseases often have complex clinical phenotypes and require interdisciplinary cooperation for research, hence, interdisciplinary approaches to treatment.

The specificities of rare diseases - limited number of patients, scarcity of relevant knowledge and expertise, and fragmentation of research - single them out as a distinctive domain of very high European added value. Rare diseases are therefore a prime example of a research area that can strongly benefit from collaboration/coordination on a transnational scale.

In this context, the ERA-Net “E-Rare-2” for research programmes on rare diseases aims at fostering the coordination of the research efforts of European countries in the field of rare diseases.

The aim of the call **“European Research Projects on Rare Diseases driven by Young Investigators”** is to provide to **young, independent investigators the opportunity of building transnational collaborations in the field of rare disease research**. The transnational project should be based on complementarities and sharing of expertise, demonstrating a clear added value of the cooperation and impact of the expected results on patients affected by rare diseases.

The following parties,

- The Austrian Science Fund (FWF), Austria
- The Research Foundation Flanders (FWO), Belgium, Flanders
- The French National Research Agency (ANR), France
- The Federal Ministry of Education and Research (BMBF), Germany
- The Chief Scientist Office of the Ministry of Health (CSO/MOH), Israel
- The National Centre for Research and Development (NCBiR), Poland
- Foundation for Science and Technology (FCT), Portugal
- The Institute of Health Carlos III (ISCIII), Spain
- The Netherlands Organization for Health Research and Development (ZonMw), The Netherlands

have decided to open the fourth E-Rare Joint Transnational Call (JTC 2012). This call will fund multilateral research projects on rare diseases driven by young investigators. The call is being opened simultaneously by the partners in their respective countries.

2. TOPICS OF THE CALL

Projects shall involve a group of rare diseases or a single rare disease following the European definition i.e. a disease affecting not more than five in 10.000 persons in the European Community. **Rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases are excluded from the scope of this call.**

Transnational research proposals must cover at least one of the following areas, which are equal in relevance for this call:

a) Collaborative research using patient databases and corresponding collections of biological material that would generally not be possible at a national scale. This research must have clear potential for clinical/public health or socio-economic application and well-defined scientific objectives e.g.:

- Definition of new nosological entities, epidemiological studies, genotype/phenotype correlations, natural history of diseases;
- Characterization of the genetic/molecular basis of specific diseases

b) Research on rare diseases including genetic, epigenetic, and pathophysiological studies, using innovative and shared resources, technologies (OMICS, new generation sequencing, etc.) and expertise. The clinical relevance of this research must be clearly demonstrated.

c) Research on development of applications for diagnosis and therapies for rare diseases. This may include identification, characterization and/or validation of (bio)-markers for diagnosis and prognosis, development of innovative screening systems and diagnostic tools, the generation of relevant cellular and/or animal models, and preclinical studies using pharmacological, gene or cell therapies.

d) Patient oriented research in the area of social and human sciences - e.g. psychological, psychosocial and behavioral research - as well as health services research and health economy research in the field of rare disorders.

Interventional clinical trials are excluded from the scope of the call.

Project proposals must clearly demonstrate the potential health impact as well as the added-value of transnational collaboration: gathering a critical mass of patients/biological material, sharing of resources (models, databases, diagnosis etc.), harmonization of data, sharing of specific know-how and/or innovative technologies, etc.

3. ELIGIBILITY CRITERIA FOR YOUNG INVESTIGATORS

3.1. Definition of a competitive candidate for the E-Rare-2 Joint Transnational Call for Young Investigators (JTC 2012)

Applicants must have the necessary qualifications (postdoctoral experience) and the required infrastructure to perform the project. It is essential that applicants have published excellent work in international scientific journals or have made recognized contributions in the scientific community to the development of a particular field. Candidates must prove that they are scientifically independent, for example that they lead or have led a research group or project.

3.2. Who can apply?

With the support of the host institution, successful principle investigators (PI's) will be expected to lead their individual teams and be strongly engaged in running the call grant, which will enable them to establish or consolidate their independent research activity.

All principal investigators, including the coordinator of such consortium must be "young investigators" (for detailed definition see below).

3.3. Definition of Young Investigator

The young investigator must have been awarded his/her first PhD/MD or equivalent doctoral degree, at least 2 and up to 10 years prior pre-proposal submission deadline of the E-Rare-2 JTC 2012. Extensions to this period may be allowed in case of eligible career breaks, which **must be properly documented**. Eligible career breaks are:

- For maternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by 18 months for each child born before or after the PhD/MD award.
- For paternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by the actual amount of paternity leave taken for each child born before or after the PhD/MD award.
- For long term illness (over ninety days), clinical qualification or national service the effective elapsed time since the award of the first PhD/MD will be considered reduced by the documented amount of leave taken for each event which occurred after the PhD/MD award.

Eligible events that take place within the extension of the eligibility window may lead to further extensions.

The cumulative eligibility period should not in any case surpass 14 years and 6 months following the award of the first PhD/MD.

No allowance will be made for principal investigators working part-time.

3.4. Commitment of the Host Institution

A grant is awarded to the applicant legal entity - the host institution - that engages and hosts the PI for at least the duration of the grant.

The host institution must provide a commitment letter offering access to reasonable space and facilities for conducting the research for the PI to direct independently the research and manage its funding for the duration of the project.

3.5. Eligibility of institutions

Joint research proposals may be submitted by applicants belonging to one of the following categories (according to country/regional regulations):

- Academia (research teams working in universities, other higher education institutions or research institutes)

- Clinical/public health sector (research teams working in hospitals/public health and/or other health care settings and health organizations)
- Enterprise (all sizes of private companies). Nevertheless, enterprises cannot be project coordinators. Small and medium-size enterprises (SMEs) are eligible when allowed by national/regional regulations.

➤ Please note that the inclusion of a non-eligible partner in a proposal **leads to the rejection of the entire proposal without further review**. Whilst applications will be submitted jointly by research groups from several countries, individual groups will be funded by the individual funding organization of their country/region that is participating in the E-Rare-2 JTC 2012. The applications are therefore subjected to **eligibility criteria of individual funding organizations**. Applicants are strongly advised to contact their corresponding national/regional representative and confirm eligibility with their respective funding organizations in advance of submitting an application (see national/regional contact details and Annex).

Only transnational projects will be funded. Each consortium submitting a proposal must involve a **minimum of three** and a maximum of six research groups from **at least three different countries** participating to the call (see list above).

Research groups from countries whose funding organizations are not partner in this E-Rare-2 call **may participate in projects if they are able to secure their own funding**, nevertheless the overall maximum number of research groups in a given consortium should be maintained at 6. They must state clearly in the proposal if these funds are already secured or if not, how they plan to obtain funding in advance of the project start. It will be required to document the availability of their funds before October 1, 2012.

The number of participants and their research contribution should be appropriate for the aims of the transnational research project and reasonably balanced in terms of national participation. The latter means that **there must not be more than two research groups from one country in one project proposal**. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

Special attention will be given to the quality of patient's recruitment, biometric/statistical methods, phenotyping and collection of biological resources with regards to the objectives of the transnational project. For linkage analysis, sufficient genealogical information should be given in the application.

Each transnational proposal must nominate a project consortium coordinator among the project partner principal investigators. The coordinator must be a project partner from an E-Rare-2 JTC 2012 funding country/region. The project coordinator will represent the consortium externally and towards the Joint Call Secretariat (**JCS**) and Call Steering Committee (**CSC**), and will be responsible for its internal scientific management (such as controlling, reporting, intellectual property rights issues and contact with the JCS). Each project partner will be represented by one (and only one) principal investigator. Within a joint proposal, each project partner principal investigator will be the contact person for the relevant country/regional funding organization.

The duration of the projects can be up to 3 years. Nevertheless, a partner can receive funding for less than 3 years according to E-Rare-2 JTC 2012 funding organizations eligibility criteria and regulations.

4. SUBMISSION OF JOINT PROPOSALS

There will be a **two-stage submission procedure for joint applications**: pre-proposals and full proposals. In both cases, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted to the JCS by one spokesperson, the coordinator.

Joint **pre-proposals** (in English) must be received by the JCS in an electronic version no later than **31 January 2012 at 12:00 CET**. The pre-proposals should strictly follow the "Guidelines for applicants".

The decision on selection of applications for invitation to full proposal will be communicated by the start of April 2012.

Please note that **joint full proposals will be accepted only from those applicants explicitly invited by the JCS to submit them**. Full proposals (in English) must be received by the JCS in an electronic version no later than **24 May 2012 at 12:00 CET**.

The information given in the pre-proposal is binding. Thus, any fundamental changes between the pre- and full proposals, e.g. composition of the consortia, objectives of the project, must be communicated to the JCS with detailed justification and will only be allowed by the CSC under exceptional circumstances.

The selection on full proposals will be communicated to applicants as soon as possible and before the end of October 2012.

Further information on how to submit pre-proposals and full proposals electronically will be made available through the E-Rare website (www.e-rare.eu) and in the "Guidelines for applicants". The forms that have to be used for submission of pre-proposals and full proposals are available on the E-Rare website. **Applicants should take note of individual national/regional rules, and should contact their national/regional contact person for any questions (see "contact information" section).**

For applicants from some countries/regions it might be necessary to submit the proposals and/or other information directly to the country/regional funding organizations. Therefore, applicants are strongly advised to check their national/regional funding organizations for more details (see country/regional contact details and "Guidelines for applicants").

4.1. Further information

If you need additional information, please contact the JCS or your national/regional funding agency representative (see contact information below). For further details please refer to the "Guidelines for applicants" 2012 or visit the E-Rare website at www.e-rare.eu.

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5. EVALUATION

5.1. Management boards

Two boards, the Call Steering Committee (**CSC**) and the Scientific Evaluation Committee (**SEC**), will manage the evaluation process of the call with support of the Joint Call Secretariat (**JCS**) (set up at The Institute of Health Carlos III, Spain ISCIII). The process includes the evaluation procedure of pre- and full-proposals and the final selection and award of research projects.

- **The Call Steering Committee (CSC)** is composed of a single representative from each country/region funding organization. The CSC will supervise the progress of the call and the evaluation of proposals. The CSC will make the final funding recommendation to the national/regional funding organizations on the proposals to be funded, based on the final ranking list provided by the SEC. All decisions concerning the call procedures will be taken by the CSC.

- **The Scientific Evaluation Committee (SEC)** is a panel of internationally recognized scientific experts responsible for the evaluation of submitted proposals. SEC members will not submit or participate in proposals within this call, and must sign a confidentiality form and a statement to confirm that they do not have any conflicts of interest. The SEC will nominate external peer reviewers.

5.2. Evaluation criteria

Pre-proposals and full proposals will be assessed according to specific evaluation criteria (see below), using a common evaluation form. A scoring system from 0 to 5 will be used to evaluate the proposal's performance with respect to the different evaluation criteria.

5.2.1 Scoring system

- 0: fails or missing/incomplete information;
- 1: poor;
- 2: fair;
- 3: good;
- 4: very good;
- 5: excellent

5.2.2 Evaluation criteria

- Scientific quality of the proposal (innovative potential, adequate methodology)
- Feasibility of the project (adequate requested resources, time schedule)
- Scientific qualification of the applicants (quality of previous scientific work, integration in the international scientific community, potential for future scientific development)
- Level of collaborative interaction between the groups and added value of the transnational consortium
- Potential of the expected results for future clinical, public health and/or other socio-economic health relevant applications (impact)

5.3. Eligibility check of pre-proposals and first step peer review

5.3.1 Eligibility check

The JCS will assess all pre-proposals to ensure that they meet the call's formal criteria (definition of young investigator; date of submission; number and country distribution of participating research groups; inclusion of all necessary information in English, page length of each section). The JCS will forward the proposals to the CSC members, who will perform a formal check for compliance to country/region rules.

Please note that proposals not meeting the formal criteria or the national/regional eligibility criteria and requirements **will be declined without further review.**

5.3.2 Peer review of pre-proposals

Proposals passing formal checks (call secretariat and country/region) will be forwarded to the SEC members for a first evaluation (see evaluation criteria above). The SEC will meet to establish a ranking of the proposals. The CSC will meet to decide how many proposals according to the ranking list will be accepted for the full proposal submission based on the SEC recommendations.

5.4. Evaluation of full proposals with right to reply (rebuttal stage)

5.4.1 Formal criteria check

The JCS will check the full proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals before sending them to the external reviewers.

5.4.2 External reviewer's evaluation

Each proposal will be allocated to at least two external reviewers who fit the profile of the application.

5.4.3 Rebuttal stage

Before the SEC members see the reviews from external reviewers, each project coordinator will be provided with the opportunity of studying the assessments and commenting on the arguments and evaluations of the external reviewers, which remain anonymous. This stage allows applicants to comment on factual errors or misunderstandings that may have been committed by the external reviewers while assessing their proposal and to reply to reviewers' questions. However, issues which are not related with reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage.

The applicants will have up to one week (around mid-July) for this **optional** response to the reviewers' comments.

5.4.4 SEC evaluation

The JCS will send full proposals, reviews and rebuttals to the SEC members. The SEC will meet to discuss each proposal and, after consideration of the evaluation criteria, external reviews, rebuttals and their own discussions, the SEC will make a classification of the proposals and rank proposals recommended for funding.

5.5. Funding decision

Based on the proposals' ranking established by the SEC and on available funding the CSC will suggest the projects to be funded to the national/regional funding agencies. Based on these

recommendations, final decisions will be made by the national/regional funding agencies and will be subject to budgetary considerations.

The Joint Call Secretariat will communicate to all project coordinators the final decisions together with the review from the SEC.

6. FINANCIAL AND LEGAL ISSUES

6.1. Funding model

The E-Rare-2 JTC 2012 Funding Partners have agreed to launch a joint call using the “virtual common pot” funding mode. This means that national/regional funding will be made available through national/regional funding organizations according to national/regional funding regulations. Each country/region funds only its national/regional component of the transnational research project. The funding rate within the call will be variable up to a maximum of 100% of the funds requested, according to national/regional rules. Prior to submitting a proposal, applicants should verify their eligibility and the rate of financial support with their national/regional funding organization, and are recommended to contact their national/regional contact person (see national/regional contact details).

Funding is granted for a maximum of three years according to national regulations. Eligible costs may vary according to the corresponding national/regional funding agency regulations. Each applicant is subject to the rules and regulations of their respective national/regional funding agency.

6.2. Funding contracts

Each project includes several consortium members called research partners and one project coordinator. Each research partner (including the project coordinator) will have a separate funding contract/letter of grant according to national/regional regulations with the appropriate national/regional funding institutions.

Changes to the composition of research consortia or in budget cannot occur during the contract/letter of grant, unless there is a good justification. Any minor change has to be well justified and the relevant funding organizations will decide upon the proper action to be taken. However, in case of major changes, an independent expert can be consulted to help with the final decision of the funding organizations. The research partners shall inform the JCS and the funding bodies of that project of any event that might affect the implementation of the project.

6.3. Research consortium agreement and ownership of intellectual property rights

The project consortium partners must sign a consortium agreement (CA) for cooperation addressing the issues given in “Guidelines for Applicants” on consortium agreements (available on the E-Rare-2 website). The research consortium is strongly encouraged to sign this CA before the official project start date, and in any case the CA has to be signed no later than six months after the official project start date. Upon request, this consortium agreement must be made available to the concerned E-Rare-2 JTC 2012 funding organizations.

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the E-Rare-2 Joint Transnational Call will be owned by the researchers' organisations according to national rules on IPR. If several participants have jointly carried out work generating new IPR, they shall agree amongst themselves (consortium agreement) as to the allocation of ownership of IPR, taking into

account their contributions to the creation of those IPR as well as the European guidelines on IPR issues.

The results of the research project and IPR created should be actively exploited and made available for use, whether for commercial gain or not, in order for public benefit to be obtained from the knowledge created.

The funding partners shall have the right to use documents, information and results submitted by the research partners and/or to use the information and results for their own purposes, provided that the owner's rights are kept and taking care to specify their origin.

7. RESPONSIBILITIES, REPORTING REQUIREMENTS AND DISSEMINATION

The coordinators of all the funded projects must submit **brief annual scientific project reports and a final scientific project report** (within six months of the end of the project) to the JCS. All reports must be in English and use a common report form that will be provided. The research partners are jointly responsible for delivery of the reports, and the JCS will only accept reports delivered on behalf of the consortium, via the project coordinator.

If required, each participant should submit financial and scientific reports to their **national/regional funding organisations**, according to national/regional regulations. The progress and final results of each individual contract/letter of grant will be monitored by the respective national/regional funding organisations.

Funding recipients must ensure that all outcomes (publications, etc.) of transnational E-Rare-2 projects include a proper acknowledgement of ERA-Net E-Rare-2 and the respective national/regional funding partner organisations.

The coordinators and/or national group leaders might be asked to present the results of their projects at an **intermediate and/or a final status symposium** organized by the JCS.

8. CONTACT AND FURTHER INFORMATION

The JCS 2012 is set up at *Institute of Health Carlos III*, Madrid, Spain to assist the CSC and the national/regional funding bodies during the implementation of the call and the follow-up phase until the funded research projects have ended. The JCS 2012 will be responsible for the administrative management of the call. It will be the primary point of contact referring to the call procedures between the research consortia, the funding organizations (CSC) and the peer reviewers. The project coordinator will be the person contacted by the JCS focus call during the application procedure, so he/she must forward this information to the other participants.

Further information on the E-Rare-2 Project, the Call and the follow-up is available at the E-Rare-2 website (www.e-rare.eu). **It is advised to contact the national/regional contact person for any questions regarding the Call (please see national/regional contact details below).**

ANNEX I. National/Regional contact details

Country/Region	Institution	Website	National Contact
Austria	FWF	www.fwf.ac.at	Stephanie Resch Phone: +43(1) 505 67 40-8201; Email: stephanie.resch@fwf.ac.at Iris Fortmann Phone: +43(1) 505 67 40-8211; Email: iris.fortmann@fwf.ac.at
Belgium (Flanders)	FWO	www.fwo.be	Olivier Boehme Phone: 00 32 2 550 15 45; Email: Olivier.Boehme@fwo.be
France	ANR	www.agence-nationale-recherche.fr	Natalia Martín Health and Biology Department Agence Nationale de la Recherche-ANR- 7 rue de Watt- 75013 Paris, France Phone: (33) (0) 1 73 548133; Email: natalia.martin@agencerecherche.fr
Germany	BMBF/PT-DLR	www.gesundheitsforschung-bmbf.de	Project Management Agency of the German Aerospace Centre (PT-DLR) -Health Research- Heinrich-Konen-Strasse 1, 53227 Bonn Phone: 0049 0 228/3821-1210; Telefax: 0049 0 228/3821-1257 Email: gesundheitsforschung@dlr.de
Israel	CSO/MOH	www.health.gov.il	Zelina Ben-Gershon Phone: +972 2 5681209, +972 506-242-117 Email: zelina.bengershon@moh.health.gov.il ; zelinabg@gmail.com
Poland	NCBiR	www.en.ncbir.pl/	Marcin Chmielewski National Centre for Research and Development. Poland (NCBiR) Phone: +48 222442858 ext: 109; Email: m.chmielewski@ncbir.pl
Portugal	FCT	www.fct.pt	Anabela Isidro E-mail : Anabela.Isidro@fct.pt ; Phone: +351 21 391 1552 Foundation for Science and Technology (FCT)
Spain	ISCIII	www.isciii.es	Ignacio Baanante Phone: +34 91 82 22576; Email: ibaanante@isciii.es Subdirección General de Evaluación y Fomento de la Investigación
The Netherlands	ZonMw	www.zonmw.nl	Sonja van Weely The Netherlands organisation for health research and development Phone +31-70-349 5220/5211 Email: weely@zonmw.nl

ANNEX II. Indicative funding commitments of the participating organization of the E-Rare- 2 JTC 2012

Country/ Region	Institution	Envisioned amount of funding (M€ for 3 years)	Anticipated Number of Fundable Research groups
Austria	The Austrian Science Fund (FWF)	1	~4
Belgium (Flanders)	Research Foundation Flanders (FWO)	0,2	1
France	French National Research Agency (ANR)	1	~6-8
Germany	German Federal Ministry of Education and Research (BMBF)	3	12-15
Israel	Chief Scientist Office, Ministry of Health (CSO/MOH)	0.18	3
Poland	The National Centre for Research and Development (NCBiR)	1,0	3-5
Portugal	Foundation for Science and Technology (FCT)	0,2	1-2
Spain	ISCIII Instituto de Salud Carlos III	0,5	3-5
The Netherlands	The Netherlands Organization for Health Research and Development (ZonMW)	0.7	3-4

ANNEX III. Eligibility of beneficiary institutions for the participating organizations of the E-Rare-2 JTC 2012

Country/Region	Institution	Eligible Beneficiary Institution		
		Academia	Clinical/ public health	Company
Austria	The Austrian Science Fund (FWF)	Yes ⁽¹⁾	Yes ⁽¹⁾	Yes ⁽¹⁾
Belgium (Flanders)	Research Foundation Flanders (FWO)	Yes	Yes ⁽²⁻³⁾	No
France	French National Research Agency (ANR)	Yes	Yes	Yes ⁽²⁾
Germany	German Federal Ministry for Education and research (BMBF)	Yes	Yes	Yes ⁽²⁾
Israel	Chief Scientist Office, Ministry of Health (CSO/MOH)	Yes	Yes	No
Poland	The National Centre for Research and Development (NCBiR)	Yes	Yes	Yes
Portugal	Foundation for Science and Technology (FCT)	Yes	Yes	Yes
Spain	Institute of Health Carlos III (ISCIII)	No	Yes	No
The Netherlands	The Netherlands Organization for Health Research and Development (ZonMw)	Yes ⁽⁴⁾	Yes ⁽⁴⁾	Yes ⁽⁴⁾

Please note that the information on this table is only indicative

- (1) Applications for projects from Austria may only be submitted by single natural persons. Affirmation of the research institution (academia, clinical/public health, enterprise) of the applicant is mandatory.
- (2) The eligibility of companies and institutions is subjected to different conditions in each country/region. Further details regarding the eligible beneficiaries and other national eligibility criteria and requirements are available on the "guidelines for applicants" and the E-Rare-2 website (www.e-rare.eu).
- (3) Only clinics associated with universities are eligible for the FWO
- (4) For universities, research institutes affiliated to universities, university medical centers, research hospitals and for health promoting institutes and knowledge institutes the several ZonMw grant terms and conditions (as of 1 January 2009) apply. Companies are not eligible for funding of ZonMw in this call, however co-financing by companies or in kind contribution of companies is possible.

Applicants are encouraged to contact their national/regional contact points for further information.