



European Joint Programme on Rare Diseases (EJP RD)

Call for Proposals 2019

"Transnational research projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases"

Call Text

Submission deadline for pre-proposals: February 15, 2019

Submission deadline for full proposals: June 11, 2019

The links to pre-proposal template, electronic proposal submission, guidelines for applicants can be found at the EJP RD website: www.ejprarediseases.org

or contact the Joint Call Secretariat at DLR-PT, Germany:

E-Mail: EJPRD2019@dlr.de

or individually:

Katarzyna Saedler
katarzyna.saedler@dlr.de
+49 (0)228 3821 1947

Michaela Fersch
michaela.fersch@dlr.de
+49 (0)228 3821 1268

Ralph Schuster
ralph.schuster@dlr.de
+49 (0)228 3821 1233



DLR Projektträger



1. MOTIVATION

There are at least 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 have an early or very early onset and/or lead to a significant decrease of life expectancy. Moreover, 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 any given specific disease, (2) There are few patients per disease and they are scattered over large geographic areas, causing difficulties to assemble the necessary cohorts, (3) Existing databases and bio-material collections are usually local, small, and not accessible or standardised, (4) The complex clinical phenotypes of these diseases require interdisciplinary cooperation to improve research and treatment.

The specificities of rare diseases - limited number of patients per disease, 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 necessitates collaboration/coordination on a transnational scale.

In this context, the ERA-Net E-Rare has successfully implemented ten Joint Transnational Calls for rare disease research projects since 2006. This effort is now continued in the frame of the **European Joint Programme on Rare Diseases (EJP RD)** that has been established to further help in coordinating the research efforts of European, Associated and non-European countries in the field of rare diseases and implement the objectives of the International Rare Disease Research Consortium (IRDiRC).

The following funding organisations:

- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research - FNRS (F.R.S.-FNRS), Belgium, Wallonia*
- Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG), Canada
- Fonds de recherche du Québec-Santé (FRQS), Québec (Canada)
- Ministry of Education, Youth and Sports (MEYS), Czech Republic
- Ministry of Social Affairs of Estonia (MoSAE), Estonia
- Academy of Finland (AKA), Finland
- French National Research Agency (ANR), France
- French Foundation for Rare Diseases (FFRD), France
- Federal Ministry of Education and Research (BMBF), Germany*
- German Research Foundation (DFG), Germany
- General Secretariat for Research and Technology (GSRT), Greece
- National Research, Development and Innovation Office (NKFIH), Hungary
- Health Research Board (HRB), Ireland

* Decision pending



- Chief Scientist Office of the Ministry of Health (CSO-MOH), Israel
- Italian Ministry of Health (MoH-IT), Italy*
- Ministry of Education, Universities and Research (MIUR), Italy
- Regional Foundation for Biomedical Research (FRRB), Lombardy (Italy)*
- Tuscany Region (RT/TuscReg), Tuscany (Italy)
- Research Council of Lithuania (RCL), Lithuania
- National Research Fund (FNR), Luxembourg
- National Centre for Research and Development (NCBR), Poland
- The Foundation for Science and Technology (FCT), Portugal
- Slovak Academy of Sciences (SAS), Slovakia
- National Institute of Health Carlos III (ISCIII), Spain
- Swedish Research Council (SRC), Sweden
- Vinnova, Sweden
- Swiss National Science Foundation (SNSF), Switzerland
- Netherlands Organization for Health Research and Development (ZonMw), The Netherlands
- The Scientific and Technological Research Council of Turkey (TUBITAK), Turkey
- The French National Institute of Health and Medical Research (INSERM), France (will provide dedicated funding only to Patient Advocacy Organisations)

have decided to open the first **EJP RD Joint Transnational Call (JTC 2019)** for funding multilateral research projects on rare diseases **together with the European Commission (EC) under the EJP-COFUND mechanism**. The call is being opened simultaneously by the above-mentioned funding organisations in their respective countries/regions.

2. AIM OF THE CALL

The aim of the call is to enable scientists in different countries to build an effective collaboration on a common interdisciplinary research project based on complementarities and sharing of expertise, with a clear benefit for patients.

Topic: Research projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases.

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

- a. Research to accelerate diagnosis, e.g.:
 - New schemes for finding diagnosis for undiagnosed patients;
 - Improved annotation and interpretation of variants and development of diagnostic tests for the more prevalent variants;
 - Novel modalities of functional analysis of candidate variants through in vitro, cell, tissue or animal studies.
 - -omic or multi-omic integrated approaches for discovery of disease causes and mechanisms including development of relevant bioinformatic tools;



- b. Research to explore disease progression and mechanisms, e.g.:
- Natural history studies and patient registries (also for clinical trial readiness). Whenever possible these should include development and use of patient reported outcome measures. In addition, the exploration of the use of standardized M-Health-based surveillance instruments and of patient entered data to gather information for natural history studies is welcome;
 - Identification of clinical biomarkers, clinical outcome measures and surrogate endpoints;
 - Identification of novel pathophysiological pathways in appropriate disease models that effectively mimic the human condition.

Furthermore, **additional elements need to be considered in the application:**

- The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and has to be part of the proposal;
- For natural history studies and patient registries: strategies and timelines for patient recruitment, retention, assessment, and analysis must be included. Data supporting the proposed recruitment numbers is mandatory. The study design and objectives should take into consideration what information regarding the rare disease population would be needed in order to pursue clinical trials or other health care related studies in that rare disease. There always need to be clear research questions that are addressed in the study/registry. Clear plans for sustainability of the resources must be described. Consideration of common data elements as outlined in the recent publication "Set of Common Data Elements for RD Registration" (http://www.erare.eu/sites/default/files/SetCommonData-EU%20RD%20Platform_CDS%20_final.pdf) is highly recommended;
- Integration of appropriate bioinformatics and statistical skills should constitute, whenever justified, an integral part of the proposal, and the relevant personnel should be clearly specified;
- The new research data resulting from the project should be treated permissible according to the FAIR¹ principles, and deposited and shared, according to the national/regional rules of the countries involved. It is strongly advised to make data accessible through RD-Connect (<http://rd-connect.eu/> - connecting databases, patient registries, biobanks and clinical bioinformatics data into a central resource for researchers worldwide) and through Elixir (<https://www.elixir-europe.org/platforms/data/elixir-deposition-databases> - compiling a list of resources for the deposition of experimental, biomolecular data). To make

¹ FAIR: Findable, Accessible, Interoperable, Reusable (for more information: see "The FAIR Guiding Principles for scientific data management and stewardship" (<https://www.nature.com/articles/sdata201618>))



research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy for the proposed full project is mandatory in the full proposal stage. Some countries involved in EJP RD JTC 2019 will also ask for a data management plan (DMP) at national level at the stage of full proposal or after granting of the project.

- To ensure that the needs and priorities of rare disease patients are adequately addressed, they or their representatives should be appropriately involved in all projects wherever relevant. For examples, inclusion and involvement of patient representatives includes but is not restricted to natural history studies / registries where patients should be involved in the governance of the registry. Please consult the INVOLVE website for information on various ways to involve patients: <http://www.invo.org.uk/resource-centre/resource-for-researchers/>. For additional guidance and practical advice on patient involvement in research studies, please consult also the JPND guidelines: <http://www.neurodegenerationresearch.eu/wp-content/uploads/2013/11/JPND-guide-for-Patient-and-Public-Involvement.pdf>.

The following approaches and topics are excluded from the scope of this call:

- a. Approaches concerning rare infectious diseases or rare cancers;
- b. Approaches concerning rare adverse drug events/medical complications in treatments of common diseases;
- c. Studies that focus on pre-clinical therapy development and/or validation in vitro, cellular or animal models. These will be addressed in future calls;
- d. Interventional clinical trials;
- e. Rare neurodegenerative diseases which are within the main focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND; <http://www.neurodegenerationresearch.eu/>). These concern: Alzheimer's disease and other dementias; Parkinson's disease (PD) and PD-related disorders; Prion disease; Motor Neuron Diseases; Huntington's disease; Spinal Muscular Atrophy and dominant forms of Spinocerebellar Ataxia. Interested researchers should refer to the relevant JPND calls. Not excluded through this specification are childhood dementias/neurodegenerative diseases.

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, EC associated states and Canada. Applicants are encouraged to assemble groups of rare diseases based on solid criteria and commonalities if this leverages added value in sharing resources or expertise and has the capacity to elucidate common disease mechanisms and therapeutic targets.

The research projects submitted within this call must be based on novel ideas stemming from consolidated previous results or preliminary data and must be clearly endowed with benefit for the patients, i.e. studies allowing a rapid implementation into public health-related decisions or into the clinics. To achieve this goal, the necessary expertise and resources should be brought together from academia,



clinical/public health sector, patients and private companies whenever relevant. The research teams within a consortium should include investigators from complementary scientific disciplines, research areas and expertise necessary to achieve the proposed objectives.

The research proposals must demonstrate complementary and synergistic interaction among the partner teams. There should be clear added value in the transnational collaboration over the individual projects, in terms of:

- Gathering a critical mass of subjects/patients and or subjects/patients databases and corresponding biological materials that would not be possible otherwise;
- Sharing of resources (biobanks, models, databases, diagnostic tools, etc.), of specific know-how and/or innovative technologies including “-omics”, and of expertise. The projects should clearly demonstrate the potential health impact.

The use of **existing European health research infrastructures** and/or **IRDiRC recognized resources** is strongly encouraged when appropriate, e.g. research infrastructures established as an European Research Infrastructure Consortium (ERIC) or identified on the roadmap of the European Strategy Forum on Research Infrastructures (ESFRI). Projects are invited to identify the existing European research data infrastructures that may be used and how these may be mobilised, in particular for long-term data curation and preservation (in accordance with EU and IRDiRC recommendations (www.irdirc.org)).

The following ESFRI European Research Infrastructures and European/international projects or their results were identified as potentially useful for this kind of studies:

- Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) - <http://bbmri-eric.eu/about>
- The European Life Sciences Infrastructure for Biological Information (ELIXIR) - <http://www.elixir-europe.org/>
- European Infrastructure for Phenotyping, Archiving and Distribution of Mouse Models (INFRAFRONTIER) - <https://www.infracontier.eu/>
- Integrated Structural Biology Infrastructure for Europe (INSTRUCT) - <http://www.structuralbiology.eu/>
- Clinical Research Infrastructure Network (ECRIN): <http://www.ecrin.org/>
- European Infrastructure for Translational Medicine (EATRIS): www.eatris.eu
- European high-capacity screening network (EU-OPENSREEN) <https://www.eu-openscreen.eu/>
- An integrated platform connecting databases, registries, biobanks and clinical bioinformatics for rare disease research (RD-Connect) - <http://rd-connect.eu/>
- Matchmaker Exchange - federated platform to facilitate the matching of cases with similar phenotypic and genotypic profiles - <https://www.matchmakerexchange.org/>
- IRDiRC recognized resources - <http://www.irdirc.org/activities/irdirc-recognized-resources/>



- Orphanet Rare Disease Ontology - <http://www.orphadata.org/cgi-bin/index.php>
- Human Phenotype Ontology - <https://hpo.jax.org/app/>
- Horizon 2020 FAIR Data Management Plan - Annex 1 in http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
- Recommendations for Improving the Quality of Rare Disease Registries - <https://www.mdpi.com/1660-4601/15/8/1644/htm>

The aim of the call is in compliance with the vision and goals set by the International Rare Diseases Research Consortium (IRDiRC) which fosters international collaboration in rare diseases research.

The IRDiRC vision: **Enable all people living with a rare disease to receive an accurate diagnosis, care, and available therapy within one year of coming to medical attention.**

In order to work towards this vision, IRDiRC has set three goals for the next decade:

Goal 1: All patients coming to medical attention with a suspected rare disease will be diagnosed within one year if their disorder is known in the medical literature; all currently undiagnosable individuals will enter a globally coordinated diagnostic and research pipeline

Goal 2: 1000 new therapies for rare diseases will be approved, the majority of which will focus on diseases without approved options

Goal 3: Methodologies will be developed to assess the impact of diagnoses and therapies on rare disease patients.

For more information see IRDiRC website: <http://www.irdirc.org/>

3. 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 DLR-PT, Germany). SEC and CSC members are not allowed to submit or participate in proposals within this call. 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 organisation. 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 organisations 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 recognised, independent, scientific experts responsible for the evaluation of submitted proposals. SEC members must sign a confidentiality agreement and a statement to confirm that they do not have any conflicts of interest.



4. APPLICATIONS

Joint research proposals may be submitted by partners 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 organisations)
- enterprise (all sizes of private companies). Participation of small and medium-size enterprises (SMEs) is encouraged when allowed by national/regional regulations
- patient advocacy organisations (PAOs - see more information below and refer to the INSERM contact point)

Please note that the inclusion of a non-eligible research partner (principle investigator) in a proposal **leads to the rejection of the entire proposal without further review**. Whilst applications will be submitted jointly by applicants from several countries/regions, individual groups will be funded by the individual funding organisation of their country/region that is participating in the EJP RD JTC 2019. The applications are therefore subjected to **eligibility criteria of individual funding organisations**. Applicants are **strongly advised** to contact their corresponding national/regional representative and enquire about / confirm their eligibility with their respective funding organisations in advance of submitting an application (see national/regional contact details). **The adherence to the national/regional regulations in the “Guidelines for applicants” document is mandatory.**

Only transnational projects will be funded. Each consortium submitting a proposal must involve a **minimum of four eligible** and a **maximum of six eligible research partners** from **at least four different countries** participating to the call (see list above). No more than two eligible research partners from the same country participating in the call will be accepted in one consortium.

The Joint Call Secretariat and national/regional funding organisations will perform cross-checks in parallel submissions to other joint transnational calls (e.g. NEURON, JPND, EuroNanoMed, ERA PerMed and others) and national calls. Applicants shall avoid applying for same research activities to different calls. Double funding is not allowed.

The consortium coordinator must always be eligible to receive funding from the funding organisations participating in the call and cannot be a partner that joins only with their own funding. Only groups that contribute substantially to at least one of the work packages are considered as partners and should be indicated in the project.

Applicants are encouraged to **include research partners from participating countries usually underrepresented in projects (Czech Republic, Slovakia, Estonia, Hungary, Lithuania, Poland, and Turkey)**. If they include such research partners, the maximum number of research partners can be increased to **eight** (see tables below).

Consortia are also encouraged to include **Early Career Scientists as principal investigators** in their proposal. For further information on the definition see 6.8. Early career PIs must prove that they are scientifically excellent and independent, for



example that they lead or have led a research group or project. They also must clearly be eligible according to national/regional funding regulations. **Early Career Scientists** should be clearly identified in the proposal and their CV.

Additional research partners that secure their **own funding** may join consortia. However, their number is **limited to two** and depends on the number of research partners requesting funding (see table below). These additional research partners can only come from countries that are not involved in the EJP RD JTC 2019 funding or are not eligible for the respective funding organization due to national/regional rules. These research partners 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, as well as what the concrete amount of contributed funding will be. It will be required to document the availability of their funds before October 1, 2019. In the (pre)proposal form these research partners are mentioned in the category «Associated research partners not asking for funding».

Number of research partners requesting national/regional funding	Possible number of additional research partners with own funding
4	2
5	
6	
7 (only possible with inclusion of 1 partner from usually underrepresented countries)	1
8 (only possible with inclusion of 2 partners from usually underrepresented countries)	0

To collect the necessary patient data and/or samples for the proposed study, a consortium may need to collaborate with other institutions. If the unique role of those institutions is providing patients data and/or samples for the study only, they will not be considered as research partners of the consortium but can be included otherwise, e.g. via cooperation agreements or subcontracting.

In addition, the inclusion of **patient advocacy organizations (PAO)** in the proposal is highly encouraged. These can be involved in all levels of the proposed work including helping to develop the research question or patient centred tools, advising on prioritisation, being involved in advisory groups, being a member of the consortium steering group or the governance group of a registry, carrying out the research and disseminating the research findings. Therefore PAOs are also eligible to receive funding for their activities. If PAO involvement is not deemed appropriate within a specific research study, this should be explained and justified. The included PAO(s) will not be counted as a national/regional principal investigator partner and therefore their inclusion does not influence the maximum number of research partners as described above. For further information see 6.3.

Each transnational proposal must nominate a **project consortium coordinator** among the project partner principal investigators. The coordinator must be a research partner from an EJP RD JTC 2019 funding country/region. The project coordinator will represent the consortium externally and towards the JCS and CSC, and will be responsible for its internal scientific management (such as controlling, reporting,



intellectual property rights issues and contact with the JCS). This workload should be taken into account in the estimation of the budget of the coordinator. Each project partner will be represented by a single principal investigator. Within a joint proposal, the principal investigator of each project partner will be the contact person for the relevant country/regional funding organisation.

Consortia of projects funded in previous Joint Transnational Calls of the ERA-Net E-Rare can apply for funding for an extension of their cooperation. These consortia must clearly demonstrate the success of the current project and innovative scientific aims for their future collaboration. Their applications will compete on the same terms as the applications for new research projects.

The duration of the projects can be up to 3 years. Nevertheless, a partner can receive funding for less than 3 years according to EJP RD JTC 2019 funding organisations eligibility criteria and regulations.

4.1 Submission of joint proposals

There will be a **two-stage submission procedure for joint applications**: pre-proposals and then 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 uploading it on the electronic submission system by the coordinator.

Joint **pre-proposals** (in English) must be received by the JCS in an electronic version no later than **February 15, 2019 at 05 p.m. Central European Time (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 in the first week of May 2019.

Please note that **joint full proposals will be accepted only from those applicants who were 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 **June 11, 2019 at 05 p.m. Central European Summer Time (CEST)**.

In general, no fundamental changes between the pre- and full proposals concerning the composition of the consortia, objectives of the project or requested budget will be accepted. The CSC, however, may allow such changes in case of widening as described below and in more detail in 6.2 and in other exceptional cases, if detailed justification is provided to the JCS. Exceptional cases could be e.g. moving of a partner or health issues of a partner.

The EJP RD is aware of the importance of international collaboration and capacity building, especially in the countries/regions presenting lower success rate. Thus, if a country, involved in EJP RD JTC 2019, is insufficiently represented in the pre-proposals that are invited to write a full proposal (after the first evaluation by the Scientific Evaluation Committee), the funding organisation in this country/region may be given an opportunity to propose research teams that could be of added value for the projects to be evaluated in the 2nd stage and/or the coordinator/partners of the



EJP RD JTC 2019: Call Text
project(s) invited to the 2nd stage of evaluation can inquire themselves to find suitable partners from among listed countries (see section 6.2 for details).

The selection of full proposals will be communicated to applicants as soon as possible in October/November 2019.

Further information on how to submit pre-proposals and full proposals electronically will be made available through the EJP RD website (www.ejprarediseases.org) 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 EJP RD 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).

In addition to the submission through the electronic submission system, applicants from some countries/regions might also have to submit the proposals and/or other information directly to the country/regional funding organisations (see "Guidelines for applicants").

4.1 Further information

Applicants must contact their corresponding national/regional representative and enquire about / confirm eligibility with their respective funding organisations in advance of submitting a pre-proposal (see national/regional contact details and Annex). If you need additional information, please contact the JCS. **The adherence to the national/regional regulations in the "Guidelines for applicants" document is mandatory.**

5. EVALUATION

5.1 Evaluation criteria

Pre-proposals and full proposals will be assessed according to specific evaluation criteria that are in line with Horizon 2020 rules (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.

Scoring system:

0: Failure: The proposal fails to address the criterion in question, or cannot be judged because of missing or incomplete information.

1: Poor: The proposal shows serious weaknesses in relation to the criterion in question.

2: Fair: The proposal generally addresses the criterion, but there are significant weaknesses that need corrections.

3: Good: The proposal addresses the criterion in question well but certain improvements are necessary.

4: Very good: The proposal addresses the criterion very well, but small improvements are possible.

5: Excellent: The proposal successfully addresses all aspects of the criterion in question.



Evaluation criteria:

1. Excellence
 - a. Clarity and pertinence of the objectives;
 - b. Credibility of the proposed approach and methodology;
 - c. Soundness of the concept;
 - d. Innovative potential;
 - e. Feasibility of the project (adequate requested resources, time schedule, access to patients or patient's data and/or material);
 - f. Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific technical expertise).

2. Impact
 - a. Potential of the expected results for future clinical, public health and/or other socio-economic health relevant applications, including patients' needs;
 - b. 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.;
 - c. Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data. A data management strategy in the full proposal is mandatory;
 - d. Involvement of patient organisations and patient representatives (when appropriate/applicable/available);
 - e. Involvement of industry (when appropriate/applicable/available);
 - f. Inclusion of Early Career Scientists as Principal Investigators.

3. Quality and efficiency of the implementation
 - a. Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks, resources and time-frame;
 - b. Complementarity of the participants within the consortium;
 - c. Appropriateness of the management structures and procedures, including risk management, contingency plans and innovation management;
 - d. Concept for sustainability of infrastructures or resources initiated by the project;
 - e. Budget and cost-effectiveness of the project (rational distribution of resources in relation to project's activities, partners' responsibilities and time frame).



Sub-criteria 2a and 2b will be prioritized for assessing the impact of proposals (pre- and full proposal stage).

Sub-criteria 2c, 3c, 3d and 3e will be taken into account only for the full proposal evaluation step.

Evaluation scores will be awarded for the 3 main criteria, and not singularly for the different aspects listed below the criteria. Each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 12. The maximum score that can be reached from all three criteria together is 15 points.

5.2 Eligibility check of pre-proposals and first step peer review

Eligibility check

The JCS will check all pre-proposals to ensure that they meet the call's formal criteria (date of submission; number and country distribution of participating research partners; 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 check for compliance to country/regional/PAOs eligibility rules as described in the "Guidelines for applicants".

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

Peer review of pre-proposals

Pre-proposals passing the eligibility check (call secretariat and country/region/PAO) will be forwarded to the SEC members for a first evaluation (see evaluation criteria above). The SEC members will perform the assessment of the pre-proposals and fill the evaluation forms with scores and comments for each criterion. Each pre-proposal will be assessed by 2 SEC members. The SEC members will meet to discuss further and establish a ranking of the pre-proposals. The CSC will meet to decide which pre-proposals will be accepted for the full proposal submission based on the SEC recommendations. The summary review report and potential recommendations of the SEC will be forwarded to all applicants.

At this stage research teams of underrepresented countries may join successful pre-proposals (see 6.2 for more details).

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

Formal criteria check

The JCS will check the full proposals to ensure that they meet the call's formal criteria.

External reviewer's evaluation



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

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. The scores will not be given at this stage. This step 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. It is in the best interest of the applicants to submit this rebuttal.

The applicants will have up to one week (in the final week of July 2019) for this **optional** response to the reviewers' comments.

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 assign final scores, make a classification of the proposals and rank proposals recommended for funding. The final summary review report prepared by the SEC members will be sent to all applicants.

Ethical evaluation

Full proposals will also be remotely evaluated by independent experts in ethics. These experts will report on the feasibility of a given proposal to comply with the ethical requirements. If necessary, it will list those tasks that need to be done and documents that need to be submitted by the given evaluated consortium in order to receive the approval for funding from the ethical point of view. Only those proposals approved by both, the scientific and ethical evaluations (complying with all central Horizon 2020 and regional/national ethical requirements), will be funded.

5.3 Funding decision

Based on the ranking list established by the SEC and on available funding the CSC will suggest the projects to be funded to the national/regional funding organisations. Based on these recommendations, final decisions will be made by the national/regional funding organisations and will be subject to budgetary considerations.

If necessary, the CSC will determine a priority order for proposals, which have been awarded the same score within a ranked list. The following criteria will be applied successively for every group of *ex aequo* proposals requiring prioritization, starting with the highest scored group, and continuing in descending order:

- Availability of national/regional funding;
- Maximization of use of national/regional funding;
- Proposals with participation of underrepresented countries;



- Proposals that address diseases not otherwise covered by more highly-ranked proposals.

The Joint Call Secretariat will communicate to all project coordinators the final decisions together with the consensus report of the evaluation from the SEC.

6. FINANCIAL AND LEGAL ISSUES

6.1 Funding model

The EJP RD JTC 2019 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 organisations according to national/regional funding regulations. In addition, the EC will also provide funding that will maximize the number of selected projects that can be funded in rank order. Funding from the EC will be distributed through the national/regional funding agencies.

Each country/region funds only its national/regional component of the transnational research project. Eligible costs and funding rates may vary according to the corresponding national/regional funding organisation regulations. Prior to submitting a proposal, applicants should enquire about / verify their eligibility and financial support and thus must contact their national/regional contact person (see national/regional contact details). Funding is initially granted for a maximum of three years according to national/regional regulations. It may be possible that cost neutral extensions can be granted depending on regional/national regulations and agreement by the CSC and EJP RD governing board.

6.2 Opening of pre-proposals after the first evaluation round for involvement of researchers from countries/regions involved in the EJP RD JTC 2019 but insufficiently represented in full proposals

If a country/region, involved in the EJP RD JTC 2019, is insufficiently represented in the pre-proposals invited to the full proposal stage (after the first evaluation by the SEC), an opportunity will be given to involve a research team from that country/region with added value for the projects to be evaluated in the 2nd stage. This inclusion will not be considered as a fundamental change between pre- and full proposal (see 4.2 page 8). The decision which countries/regions are considered as insufficiently represented will be taken by the CSC.

How does it work?

Step 1. A list of countries/regions eligible for this “widening procedure” will be published on the EJP RD website after completion of the 1st stage of evaluation or sent to the coordinators that are invited to write a full proposal (2nd stage).

Step 2. Two inclusion options will be available:

- The concerned national/regional funding agency(ies) may investigate whether there is/are national/regional team(s) that could provide additional expertise to projects. A list of such teams will be sent to the Joint Call secretariat. The Joint Call Secretariat will contact the coordinator(s) of projects invited to the 2nd stage of evaluation and propose them to consider



the addition of such a new research team. In any case, the final decision to take a new research team on board will be taken by the project consortium;

- The coordinator/partners of the project(s) invited to the 2nd stage of evaluation can inquire themselves to find suitable partners from among listed countries/regions. Again, the decision on taking on board a new team will be taken by the project consortium.

The rules concerning the maximum number of research partners in a consortium and the maximum of two research partners per country/region within a consortium still have to be respected. Furthermore, the new research partner should be eligible for the national/regional funding agency. For this purpose, national funding agencies from insufficiently represented countries may indicate that only national research partners that were already involved in pre-proposals passing the eligibility check (and thus are considered eligible) are allowed to be included thanks to the “widening principle”.

IMPORTANT: Inclusion of new research teams is not mandatory. The new teams included should bring an added value and expertise to the projects.

6.3 Involvement of Patient Advocacy Organisations (PAOs)

In general, eligible participating patient advocacy groups are defined as private not-for-profit organisations which are patient focused, where patients and/or carers and/or family members of patients represent a majority of members in governing bodies and are financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies). The specific funding for involvement PAOs is limited to max 50.000 € for 3 years per project regardless of the number of participating PAOs. This funding will be administered centrally by INSERM (France) and will therefore be subject to specific rules as described in the “Guidelines for applicants” document which also defines the eligibility criteria in more detail. Besides this funding, PAOs can also be involved through national/regional funding or subcontracting depending on the proposed tasks and national/regional funding rules.

Please note that the section on involvement of PAOs within the proposals will also be evaluated to ensure that this has been appropriately and adequately considered and addressed. Already from an early stage in the development of the proposal the applicants are encouraged to consult relevant disease-specific patient organisations when possible and/or alliance organisations of rare disease patient organisations. If PAO involvement is not deemed appropriate within a specific research study, this should be explained and justified.

6.4 Funding contracts

Each project includes several partners (one of which is the project coordinator) as beneficiaries. Each 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 organizations.

Changes to the composition of research consortia or in budget cannot occur within the contract/letter of grant, unless there is a good justification. Any minor changes have to be well justified and the relevant funding organisations 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 organisations. The research partners shall inform the JCS and the respective funding bodies of any event that might affect the implementation of the project.

6.5 Research consortium agreement and ownership of intellectual property rights

The project consortium partners have to sign a consortium agreement (CA) for cooperation. For reference see the DESCA 2020 Model Consortium Agreement (<http://www.desca-2020.eu/>). It is recommended that the research consortium signs the CA before the official project start date, and in any case the CA should be signed early during the lifetime of the project. Please note that national/regional regulations may apply concerning the requirement for a CA (please contact your national/regional contact point or check the country-specific information in the guidelines). Upon request, this consortium agreement must be made available to the concerned EJP RD JTC 2019 funding organisations.

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the EJP RD JTC 2019 will be owned by the projects beneficiaries' organisations according to national/regional 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 relevant 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.

6.6 IRDiRC policies and guidelines

The project partners **are expected to follow IRDiRC policies and guidelines**. For more information see <http://www.irdirc.org/>.

6.7 Respect of relevant European and international standards

The submitted proposals have to respect relevant European and international standards like:

- The new EC Regulation (EC 2016/679) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. This Regulation applies in all Member States from May 25, 2018 and thus also for the EJP RD JTC 2019 granted projects (<https://publications.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/language-en>).



- The EC Directive 2010/63/EU on the protection of animals used for scientific purposes (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063>)
- European Research Council Guidelines on Implementation of Open Access to Scientific Publications and Research Data (referred to in http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/open-access_en.htm)
- To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy is mandatory in the full proposal. For an example of questions for a data management strategy, see Annex 1 in http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf.

A data management strategy/plan should include information on:

- the handling of research data during & after the end of the project;
- what data will be collected, processed and/or generated and/or reused;
- which methodology & standards will be applied;
- whether data will be shared/made open access;
- how data will be curated & preserved (including after the end of the project).

Some funding parties involved in EJP RD JTC 2019 may ask for a data management plan (DMP) at national level at the stage of full proposal or after granting of the project.

- General ethical and legal requirements: Ethics is an integral part of research. Please be aware that regulations and ethical issues vary across different countries and should be considered from the outset. The EJP RD expects applications to fulfil ethical and legal requirements. Among other things, special attention will be paid to potential ethical issues (e.g. research on humans or animals; privacy of data and biomaterials; informed consent; etc.). Only projects that fulfil the legal and ethical international/EU and national and institutional standards will be funded.

6.8 Definition of Early Career Scientists

Early Career Scientists are defined in analogy to the regulations of the European Research Council (ERC) criteria for starting grants. In short, this means having been awarded his/her first doctoral degree at least 2 and up to 7 years prior to the pre-proposal submission deadline. Extensions to this definition period are allowed in case of reasonably justified career breaks, which must be properly documented. Acceptable career breaks are leaves of absence for maternal or paternal breaks as well as long-term sick leave and compulsory military service.

For medical doctors (or applicants holding a degree in medicine), a medical doctor degree is not considered by itself as equivalent to a PhD award. To be considered an **Early Career Scientist**, medical doctors (or applicants holding a degree in medicine) need to provide the certificates of both a medical doctor degree and a PhD or proof of an appointment that requires doctoral equivalency (e.g. post-doctoral fellowship, professorship appointment). In these cases, the certified date of the medical doctor degree completion plus two years is the time reference for calculation of the definition time-window (i.e. 4 - 9 years past the medical doctor



degree). For medical doctors who have been awarded both an MD and a PhD, the date of the earliest degree that makes the applicant eligible takes precedence in the calculation of the eligibility time-window (2 - 7 years after PhD or 4 - 9 years past the medical doctor). For clinical training, an extension will be given by the documented amount of clinical training actually received by the Principal Investigator after the award of the first eligible degree, and by up to 4 years maximum. **Please note that national/regional time limits might differ.** Therefore please refer to national guidelines and contact your national/regional funder.

7. RESPONSIBILITIES, REPORTING REQUIREMENTS AND DISSEMINATION

The **coordinators** of all funded projects must submit **brief annual scientific project reports** (due on the 28th of February of the following year) **and a final scientific project report** (due within six months of the end of the project) in the form of an online questionnaire. This monitoring will be under the responsibility of CS0-MOH, Israel (contact: Irit Allon, irit.allon@moh.health.gov.il) and FNRS, Belgium (contact: Florence Quist, florence.quist@frs-fnrs.be), which is responsible for the online monitoring system for the funded projects. All reports must be in English and use a common electronic reporting form that will be provided. The research partners are jointly responsible for delivery of the reports, and only reports delivered on behalf of the consortium, via the project coordinator, will be accepted.

If required, each beneficiary 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.

The coordinators and/or national/regional PIs will be asked to present the results of their projects at an **intermediate final status symposium** organized by EJP RD. The presence of at least one representative (coordinator or PI) per project will be mandatory. Therefore, **the coordinator and respective PIs are responsible to foresee the expenses related to these events in the budget of the project.**

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results if this is compliant with national/regional funding regulations.

Beneficiaries must ensure that all outcomes (publications, etc.) of transnational EJP RD projects include a proper acknowledgement of EJP RD and the respective national/regional funding partner organisations. This includes the display of the EJP RD logo when possible.

Beneficiaries must also include credits according to national/regional rules, where applicable.

In addition, unless the EC requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

- display the EU emblem and
- include the following text:
"This project has received funding from the European Union's Horizon 2020 research and innovation programme under the EJP RD COFUND-EJP N° 825575".



- When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of the obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not however give it the right to exclusive use.

Moreover, the beneficiary may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

8. CONTACT AND FURTHER INFORMATION

The JCS is set up at DLR-PT to assist the CSC and the national/regional funding bodies during the implementation of the call. The JCS will be responsible for the administrative management of the call. It will be the primary contact point between the research consortia, the funding organisations (CSC) and the peer reviewers with regard to call procedures. The project coordinator will be the person contacted by the JCS during the application procedure, so he/she must forward the information to the other participants. CSO-MOH, Israel, will be responsible for the monitoring phase until the funded research projects have ended.

Further information on the EJP RD, the call and the follow-up is available at the EJP RD website (www.ejprarediseases.org). It is strongly advised to contact the national/regional contact person for any questions regarding the Call (please see national/regional contact details below).



ANNEX I

Country/Region	Institution	Website	National/regional contact
Austria	FWF	www.fwf.ac.at	Stephanie Resch Phone: +43 (1) 505 67 40-8201 Email: stephanie.resch@fwf.ac.at Anita Stürtz Phone: +43 (1) 505 67 40-8206 E-mail: anita.stuertz@fwf.ac.at
Belgium/Flanders	FWO	www.fwo.be	Alain Deleener Phone: +32 2 550 15 95 Email: eranel@fwo.be Toon Monbaliu Phone: +32 2 550 15 70 Email: eranel@fwo.be
Belgium/French speaking community	FNRS	www.frs-fnrs.be/	Florence Quist Phone: +32 2 504 93 51 Email: florence.quist@frs-fnrs.be Joël Groeneveld Phone: +32 2 504 92 70 E-mail: joel.groeneveld@frs-fnrs.be
Canada	CIHR-IG	www.cihr-irsc.gc.ca	Ilana Gombos Phone: +1 613 952 0819 Email: ilana.gombos@cihr-irsc.gc.ca
Canada (Québec)	FRQS	www.frqs.gouv.qc.ca	Fonds de recherche du Québec-Santé (FRQS) Maxime Beaudoin Phone: +1 514 873 2114, ext 1369 Email: maxime.beaudoin@frq.gouv.qc.ca
Czech Republic	MEYS	www.msmt.cz	Ministry of Education Youth and Sports Daniel Hanšpach (MSMT) Phone: +420 234 811 360 E-mail: Daniel.Hanspach@msmt.cz



Country/Region	Institution	Website	National/regional contact
Estonia	MoSAE	https://www.sm.ee/en	<p>Ministry of Social Affairs (MoSAE)</p> <p>Heli Paluste Phone : +372 626 9127 E-mail: Heli.Paluste@sm.ee</p> <p>Angela Ivask Phone : +372 626 9735 E-mail: Angela.Ivask@sm.ee</p>
Finland	AKA	www.aka.fi	<p>Heikki Vilen Phone: +358 29 5335 135 Email: heikki.vilen@aka.fi</p>
France	ANR	www.agence-nationale-recherche.fr	<p>Florence Guillot Phone: + 33) (0)1 78 09 80 01 Email: E- RareCalls@agencerecherche.fr</p> <p>Agence Nationale de la Recherche – ANR Health & Biology Department 50 Avenue Daumesnil 75012 Paris, France</p>
France	FFRD	https://fondation-maladiesrares.org/eng/	<p>Ingrid Zwaenepoel Phone : + 33 (0) 1 58 14 22 85 Diana Désir-Parseille Phone : + 33 (0) 1 58 14 22 81 Email: aap-bio@fondation-maladiesrares.com</p> <p>Fondation Maladies Rares Plateforme Maladies rares 96 rue Didot - 75014 Paris, France</p>
Germany	BMBF/ PT-DLR	www.gesundheitsforschung-bmbf.de	<p>Katarzyna Saedler Phone: +49 (0)228 3821 1947 Email: Katarzyna.Saedler@dlr.de</p> <p>Michaela Fersch Phone: +49 (0)228 3821 1268 Email: Michaela.Fersch@dlr.de</p> <p>Ralph Schuster Phone: +49 (0)228 3821 1233 Email: Ralph.Schuster@dlr.de</p> <p>Project Management Agency of the German Aerospace Centre (PT-DLR) -Health Research-</p>



Country/Region	Institution	Website	National/regional contact
Germany	DFG	www.dfg.de	Dr. Katja Großmann Email: katja.grossmann@dfg.de Phone: +49 (0) 228 885 2565 Fax: +49 (0) 228) 885 2777 Kennedyallee 40 53175 Bonn
Greece	GSRT	www.gsrt.gr	Sofia DIMITROPOULOU Phone: +30 2107 458 187 Email: s.dimitropoulou@gsrt.gr Ministry of Education, Research & Religious Affairs General Secretariat for Research & Technology International S&T Cooperation Directorate Division of Bilateral & Multilateral Relations
Hungary	NKFIH	www.nkfi.gov.hu	National Research, Development and Innovation Office Department of Research and Development Előd Nemerkenyi Phone: +36 1 8963987 Email: elod.nemerkenyi@nkfi.gov.hu Gábor Tóth Phone: +36 1 8961727 Email gabor.toth@nkfi.gov.hu
Ireland	HRB	https://www.hrb.ie/	Annalisa Montesanti Phone +353-1-2345208 Email amontesanti@hrb.ie Health Research Board Research Strategy and Funding
Israel	CSO-MOH	www.health.gov.il	Irit Allon Phone: +972-2-5082167 Email: Irit.allon@moh.health.gov.il
Italy	MoH-It	www.salute.gov.it	Dr. Giselda Scalera Phone: +39 065994 2596 Email: g.scalera@sanita.it research.EU.dgric@sanita.it Head Office 5 (Health Research IRCCS), Directorate General for Research and Innovation in Healthcare Ministry of Health, Viale Giorgio Ribotta, 5 -00144 Rome, Italy



Country/Region	Institution	Website	National/regional contact
Italy	MIUR	http://www.ricercainter nazionale.miur.it/	Aldo Covello aldo.covello@miur.it - +39 06.5849.6465 Valeria Cardia valeria.cardia@miur.it - +39 06.5849.7333
Italy	FRRB	www.frrb.it	Fondazione Regionale per la Ricerca Biomedica Address: Via Taramelli 12, 20124 – Milano Tel: +39 02 67650174 Miss Paola Bello Mrs. Carmen De Francesco Dr. Paola Larghi, PhD Email : bandi@frrb.it
Italy	RT/TuscReg	www.regione.toscana.it	Donatella Tanini Phone:+39 055 4383256 Teresa Vieri Phone:+39 055 4383289 Email: ejprare@regione.toscana.it Office for Legal advice and administrative support to health research, Directorate for citizenship right and social cohesion Tuscany Region
Lithuania	RCL	www.lmt.lt	Dr. Živilė Ruželė Phone: +370 676 14383 Email: zivile.ruzele@lmt.lt Chief Officer International Programmes Unit Research Foundation Research Council of Lithuania Gedimino ave. 3, LT-01 103 Vilnius, Lithuania
Luxembourg	FNR	www.fnr.lu	Dr. Sean Sapcariu Phone: +352 261 925 33 Email: sean.sapcariu@fnr.lu Luxembourg National Research Fund 2, avenue de l'Université L-4365 Esch-sur-Alzette



Country/Region	Institution	Website	National/regional contact
Poland	NCBR	www.ncbr.gov.pl/en/	Marcin Chmielewski Department for International Cooperation, Nowogrodzka Str. 47a, 00-695 Warsaw, Poland, Phone: +48 22 39 07 109 Email: marcin.chmielewski@ncbr.gov.pl
Portugal	FCT	https://www.fct.pt/index.phtml.en	Anabela Isidro Phone: +351 213 911 552 Email: anabela.isidro@fct.pt Rita Cavaleiro Phone: +351 213 911 541 Email: rita.cavaleiro@fct.pt
Slovakia	SAS	https://www.sav.sk/?&lang_change=en	Zuzana Cernakova, PhD. International Cooperation Dpt., SAS Phone: +421257510118 Email: cernakova@up.upsav.sk Jan Barancik, PhD. Head, International Cooperation Dpt. Phone: +421257510137 Email: barancik@up.upsav.sk
Spain	ISCIII	www.isciii.es	María Druet SG de Programas Internacionales de Investigación Phone: +34 9182 22530 E-mail: mdruet@isciii.es
Sweden	SRC	www.vr.se	Malin Eklund Swedish Research Council Department of Research policy Phone: +46 (0)76 526 72 56 E-mail : malin.eklund@vr.se
Sweden	Vinnova	www.vinnova.se	Frida Lundmark Division of health Vinnova, Sweden's innovation agency Phone: +46-8- 473 30 74 E-mail : frida.lundmark@vinnova.se
Switzerland	SNSF	www.snf.ch	Christoph Meier Division Biology and Medicine Swiss National Science Foundation Phone: +41 31 308 23 62 Email: christoph.meier@snf.ch



Country/Region	Institution	Website	National/regional contact
The Netherlands	ZonMw	www.zonmw.nl	Harald Moonen Phone: +31-(0)70 349 53 49 Email: moonen@zonmw.nl Sonja van Weely Email: weely@zonmw.nl The Netherlands Organization for Health Research and Development (ZonMw)
Turkey	TUBITAK	www.tubitak.gov.tr	Jale Şahin Phone: +90- 312- 298 17 96 Email: jale.sahin@tubitak.gov.tr The Scientific and Technological Research Council of Turkey (TUBITAK) International Cooperation Department Division of Bilateral and Multilateral Relations
Multinational, for funding of PAO	INSERM	www.inserm.fr	Daria Julkowska Email: daria.julkowska@inserm.fr

Please note that the information on this table is only indicative

(1) The eligibility of companies and institutions is subjected to different conditions in each country/region. Further details regarding the eligible beneficiaries and other national/regional eligibility criteria and requirements are available on the "Guidelines for applicants" and the EJP RD website (www.ejprarediseases.org).

(2) Only clinics associated with Flemish universities are eligible for the FWO.

(3) Applications for projects from FWF (Austria) may only be submitted by single natural persons. Affirmation of the research institution (academia, clinical/public health, enterprise) of the applicant is mandatory.

(4) Research Hospital: Istituti di ricovero e cura a carattere scientifico (IRCCS). Only IRCCS (The Italian Scientific Institutes for Health Research and Health Care). The list of the IRCCS by Region and City is available here: <http://www.salute.gov.it/ricercaSanitaria/paginaInternaMenuRicercaSanitaria.jsp?id=1064&menu=strumentieservizi>.

(5) 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 July 2013) apply. Companies are eligible for funding of ZonMw in this call under strict conditions (see the separate document on Guidelines). Co-financing by companies or in kind contribution of companies is encouraged.

(6) The institution must belong to the French speaking community.



(7) Clinical studies can be funded as long as they are addressing scientific questions without any link to industry of private sector.

(8) Schools of public health are eligible if they are linked or associated with an institution from the French speaking community.

(9) SNSF has formal and material eligibility criteria. Applicants must show that they have successfully carried out research work for several years, and must be capable of running a project under their sole responsibility and leading the project team engaged for the (sub) project. Proposals that are manifestly inadequate to be forwarded to external experts for review or show obvious substantial insufficiencies in any of the SNSF scientific assessment criteria are rejected and not forwarded to external review.

(10) For some non-university academic institutions a duty to cooperate with university institutions may exist. See guideline 55.01 (http://www.dfg.de/formulare/55_01/)

(11) Only non-profit clinics and institutions are eligible.

(12) Academic institutions are eligible if there is another Spanish beneficiary in the consortium from a Hospital or health care setting belonging to the National Health System or from Health Research Institutes (IIS) or from CIBER/CIBERNED. The last two could only participate as coordinators of the EJP RD project.

(13) Public health care institutions: University hospitals, other public hospitals.

(14) SME (in collaboration with Lithuanian research and education institutions and health care institutions) meeting special criteria. More information will be available at the national call and national contact point.

(15) This is not a comprehensive list of requirements for the Lithuanian participants. All national rules are presented in the Lithuanian language in the call text and Rules for Financing (Lietuvos mokslo tarybos mokslo ir skaidos projektų konkursinio finansavimo bendrosios taisyklės).

(16) Specific information regarding the eligibility of Clinical/public health institutions are specified in the document "Avviso integrativo nazionale".

(17) To be eligible for FNR funding, beneficiaries must be accredited by the Ministry for Research. See website for more details (<https://www.fnr.lu/fnr-beneficiaries/>).

(18) Only Patient Organisations are eligible for funding.

(19) According to national regulation see www.vr.se and approved administrative organisations.

(20) It is COMPULSORY that at least one IRCCS (public or private) or ASST is partner of the project proposal. Other types of organisation are eligible ONLY in partnership with them. All Partners, to be eligible, must be located in Lombardy Region.

Applicants need to contact their national/regional contact points for further information and refer to the national/regional information in the "Guidelines for applicants" document