# 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
- 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 FAIR[1] 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

[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)

resources for the deposition of experimental, biomolecular data). To make 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 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.infrafrontier.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-OPENSCREEN) 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<br>(only possible with inclusion of 1 partner from usually underrepresented countries) | 1 |
| 8<br>(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 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.ejpraretdiseases.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<br>Phone: +43 (1) 505 67 40-8201<br>Email: stephanie.resch@fwf.ac.at<br><br>Anita Stürtz<br>Phone: +43 (1) 505 67 40-8206<br>E-mail: anita.stuertz@fwf.ac.at |
| Belgium/Flanders | FWO | www.fwo.be | Alain Deleener<br>Phone: +32 2 550 15 95<br>Email: eranet@fwo.be<br><br>Toon Monbaliu<br>Phone: +32 2 550 15 70<br>Email: eranet@fwo.be |
| Belgium/French speaking community | FNRS | www.frs-fnrs.be/ | Florence Quist<br>Phone: +32 2 504 93 51<br>Email: florence.quist@frs-fnrs.be<br><br>Joël Groeneveld<br>Phone: +32 2 504 92 70<br>E-mail: joel.groeneveld@frs-fnrs.be |
| Canada | CIHR-IG | www.cihr-irsc.gc.ca | Ilana Gombos<br>Phone: +1 613 952 0819<br>Email: ilana.gombos@cihr-irsc.gc.ca |
| Canada (Québec) | FRQS | www.frqs.gouv.qc.ca | Fonds de recherche du Québec-Santé (FRQS)<br><br>Maxime Beaudoin<br>Phone: +1 514 873 2114, ext 1369<br>Email:<br>maxime.beaudoin@frq.gouv.qc.ca |
| Czech Republic | MEYS | www.msmt.cz | Ministry of Education Youth and Sports<br>Daniel Hanšpach (MSMT)<br>Phone: +420 234 811 360<br>E-mail: Daniel.Hanspach@msmt.cz |

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

| Country/Region | Institution | Website | National/regional contact |
|---|---|---|---|
| Germany | DFG | www.dfg.de | Dr. Katja Großmann<br>Email: katja.grossmann@dfg.de<br>Phone: +49 (0) 228 885 2565<br>Fax: +49 (0) 228) 885 2777<br>Kennedyallee 40<br>53175 Bonn |
| Greece | GSRT | www.gsrt.gr | Sofia DIMITROPOULOU<br>Phone: +30 2107 458 187<br>Email: s.dimitropoulou@gsrt.gr<br>Ministry of Education, Research & Religious Affairs<br>General Secretariat for Research & Technology<br>International S&T Cooperation Directorate Division of Bilateral & Multilateral Relations |
| Hungary | NKFIH | www.nkfih.gov.hu | National Research, Development and Innovation Office<br>Department of Research and Development<br><br>Előd Nemerkényi<br>Phone: +36 1 8963987<br>Email: elod.nemerkenyi@nkfih.gov.hu<br><br>Gábor Tóth<br>Phone: +36 1 8961727<br>Email gabor.toth@nkfih.gov.hu |
| Ireland | HRB | https://www.hrb.ie/ | Annalisa Montesanti<br>Phone +353-1-2345208<br>Email amontesanti@hrb.ie<br><br>Health Research Board<br>Research Strategy and Funding |
| Israel | CSO-MOH | www.health.gov.il | Irit Allon<br>Phone: +972-2-5082167<br>Email: Irit.allon@moh.health.gov.il |
| Italy | MoH-It | www.salute.gov.it | Dr.Giselda Scalera<br>Phone: +39 065994 2596<br>Email: g.scalera@sanita.it<br>research.EU.dgric@sanita.it<br><br>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.ricercainternazionale.miur.it/ | Aldo Covello<br>aldo.covello@miur.it - +39 06.5849.6465<br>Valeria Cardia<br>valeria.cardia@miur.it - +39 06.5849.7333 |
| Italy | FRRB | www.frrb.it | Fondazione Regionale per la Ricerca Biomedica<br>Address: Via Taramelli 12,<br>20124 – Milano<br>Tel: +39 02 67650174<br><br>Miss Paola Bello<br>Mrs. Carmen De Francesco<br>Dr. Paola Larghi, PhD<br>Email : bandi@frrb.it |
| Italy | RT/TuscReg | www.regione.toscana.it | Donatella Tanini<br>Phone:+39 055 4383256<br><br>Teresa Vieri<br>Phone:+39 055 4383289<br>Email: ejprare@regione.toscana.it<br>Office for Legal advice and administrative support to health research, Directorate for citizenship right and social cohesion<br>Tuscany Region |
| Lithuania | RCL | www.lmt.lt | Dr. Živilė Ruželė<br>Phone: +370 676 14383<br>Email: zivile.ruzele@lmt.lt<br><br>Chief Officer<br>International Programmes Unit<br>Research Foundation<br>Research Council of Lithuania<br>Gedimino ave. 3, LT-01103 Vilnius, Lithuania |
| Luxembourg | FNR | www.fnr.lu | Dr. Sean Sapcariu<br>Phone: +352 261 925 33<br>Email: sean.sapcariu@fnr.lu<br><br>Luxembourg National Research Fund<br>2, avenue de l'Université<br>L-4365 Esch-sur-Alzette |

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

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

## ANNEX II. Indicative funding commitments of the participating organisations of the EJP RD JTC 2019

| Country/Region | Institution | Envisioned amount of funding (M€ for 3 years) | Anticipated number of fundable research partners |
|---|---|---|---|
| Austria | FWF | 0.6 | 2 |
| Belgium/Flanders | FWO | 0.7 | 2-3 |
| Belgium/French speaking community | F.R.S.-FNRS | 0.24 | 1 |
| Canada | CIHR-IG [2] | 1.0 | 3 |
| Canada | FRQS | 0.36 | 1-2 |
| Czech Republic | MEYS | 0.6 | 2-3 |
| Estonia | MoSAE | 0.075 | 1 |
| Finland | AKA | 0.6 | 2-3 |
| France | ANR | 3.0 | 10 |
| France | FFRD | 0.1 | tbd |
| Germany | BMBF | 3.0 | 10-15 |
| Germany | DFG | 3.0 | tbd |
| Greece | GSRT | 1.0 | 4-5 |
| Hungary | NKFIH | 0.2 | 1-2 |
| Israel | CSO/MOH | 0.3 | 2 |
| Ireland | HRB | 0.37 | 2 |
| Italy | MoH-IT | 2.0 | 8-12 |
| Italy | MIUR | 0.4 | 3 |
| Italy | FRRB | 1.3 | 4-6 |
| Italy | RT/TuscReg | 0.3 | 2-3 |
| Lithuania | RCL | 0.1 | 1 |

[2] CIHR-IG will fund to a maximum of $1.35 million Canadian over three years (currently equivalent to 1 Mio €) to support operational research costs only. The Canadian amount will not be adjusted to reflect conversion rate changes.

| Country/Region | Institution | Envisioned amount of funding (M€ for 3 years) | Anticipated number of fundable research partners |
|---|---|---|---|
| Luxembourg | FNR | 0.3 | 2 |
| Poland | NCBR | 0.6 | 1-3 |
| Portugal | FCT | 0.3 | 1-2 |
| Slovakia | SAS | 0.12 | 1 |
| Spain | ISCIII | 0.5 | 3-5 |
| Switzerland | SNSF[3] | 0.84 | 3-4 |
| Sweden | SRC | 1.5 | 3-5 |
| Sweden | Vinnova | 1.0 | 3-5 |
| The Netherlands | ZonMw[4] | 1.8 | 7-9 |
| Turkey | TUBITAK | 1.0 | 7-8 |
| Multinational* | INSERM | 0.5 | tbc |

[3] SNSF has earmarked a budget of 1.0 million Swiss Francs over three years (currently equivalent to 0.84 Mio €).
[4] Maximum funding of 250,000 € for Dutch participation per project

## ANNEX III. Eligibility of beneficiary institutions for the participating organisations of the EJP RD JTC 2019

| Country/Region | Institution | Eligible beneficiary institution | | |
|---|---|---|---|---|
| | | Academia | Clinical/public health | Company |
| Austria | FWF | Yes (3) | Yes (3) | Yes (3) |
| Belgium (Flanders) | FWO | Yes | Yes (1,2) | No |
| Belgium (French-speaking community) | F.R.S.-FNRS | Yes (6) | Yes (7,8) | No |
| Canada | CIHR-IG | Yes | Yes | No |
| Canada | FRQS | Yes | Yes | No |
| Czech Republic | MEYS | Yes | Yes | No |
| Estonia | MoSAE | Yes | Yes | No |
| Finland | AKA | Yes | Yes | Yes |
| France | ANR | Yes | Yes | Yes (1) |
| France | FFRD | Yes | Yes | No |
| Germany | DFG | Yes (10) | Yes (11) | No |
| Germany | BMBF | Yes | Yes | Yes (1) |
| Greece | GSRT | Yes | Yes | Yes(1) |
| Hungary | NKFIH | Yes | Yes | No |
| Ireland | HRB | Yes | Yes | No |
| Israel | CSO-MOH | Yes | Yes | No |
| Italy | MoH-IT | No | Yes (4) | No |
| Italy | MIUR | Yes | TBD (16) | Yes |
| Italy | FRRB | Yes(20) | Yes | No |
| Italy | RT/TuscReg | No | Yes | No |
| Lithuania | RCL(15) | Yes | Yes(13) | Yes(14) |
| Luxembourg | FNR | Yes(17) | Yes(17) | No |

| | | | | |
|---|---|---|---|---|
| Poland | NCBR | Yes | Yes | Yes |
| Portugal | FCT | Yes | Yes | Yes |
| Slovakia | SAS | Yes | No | Yes (1) |
| Spain | ISCIII | Yes (12) | Yes | No |
| Sweden | SRC | Yes (19) | Yes(19) | No |
| Sweden | Vinnova | Yes | Yes | Yes |
| Switzerland | SNSF | Yes (9) | Yes (9) | No |
| The Netherlands | ZonMw | Yes | Yes | Yes(5) |
| Turkey | TUBITAK | Yes | Yes | Yes (1) |
| Multinational(18) | INSERM | Patient Organisations | | |

**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 sklaidos 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.

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**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**

# 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"

# Guidelines for applicants

**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. BACKGROUND

The E-Rare ERA-Net 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)**. Under this umbrella, the funding organisations mentioned in the call text 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.

## 2. REGISTRATION

Research consortia who intend to submit a transnational project proposal should register at the electronic proposal system **as soon as possible** via the link: https://ptoutline.eu/app/ejprd19

The system will be opened in the first week of January 2019 at the latest. To register, please fill in the data sheet in the system. The same data sheet can be used for the final electronic proposal submission. **Please note that additional information will be required to be completed in the online system.** This includes: general project information, lay summary, suggestion of reviewers, personal/institutional information per partner, budget items requested per partner. **Please plan for sufficient time to complete this information.**

## 3. PROPOSAL SUBMISSION

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 research consortium, and must be submitted to the JCS by uploading it on the electronic submission system by one spokesperson, 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)**.

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)**.

Please note that project coordinators will be provided with the opportunity of studying the assessments of external reviewers and commenting on their evaluations of full proposals (for details see point *5.3.3. Rebuttal stage* in the "Call text"). The applicants will have up to one week **(between third and fourth week of July)** for this **optional response to the reviewers' comments.**

Please note that a signed paper version of your proposal will not be solicited. However, both the electronic pre-proposals and full proposals need to be signed (electronic signature or a scan of the paper containing the signature will be accepted).

Please take into account that the online data entry may be overloaded on the days of the deadlines. It is therefore recommended to transfer all mandatory data in good time.

## 4. PRE-PROPOSAL STRUCTURE

One joint pre-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. Only transnational projects will be funded (please see consortium requirements described in the "Call text").

Please note that only the **pre-proposal template** provided on the EJP RD web page (www.ejprarediseases.org) will be accepted. The pre-proposal document must respect the format (DIN-A4, Arial 11, single-spaced) and the length indicated. **Pre-proposals exceeding these limitations will be rejected.**

Pre-proposals must include the following information:

1. Project title and project acronym
2. Name and full affiliation of the project coordinator designated by the consortium to act as its representative
3. Names and full affiliations of the principal investigators participating in the joint transnational project
4. Duration of the project (months)
5. Total funding applied for (€)
6. Budget from associated research partners (in cash or in kind) (€)
7. Keywords and medical domain
8. Lay summary (max. 1600 characters including spaces)
9. Description of the project (once converted into Pdf document: max. 5 pages DIN-A4, Arial 11, single-spaced, and margins of 1.27 cm). The summary must contain:
    - Background and present state of the art in the research field and preliminary results obtained by the consortium members;
    - Description of the working program including the objectives, the rationale and the methodology, highlighting the novelty, originality and feasibility of the project as well as main hypothesis(es), sample size calculation (if applicable) and items for description of a natural history cohort/registry study (if applicable);
    - Description how the new research data in this project will be findable, accessible, interoperable and re-usable (what data will be collected, processed and/or generated and/or reused; which methodology & standards will be applied; will the data be shared/made open access; how will the data be curated & preserved);
    - Unmet medical and patient need that is addressed by the proposed work and the potential health impact that the results of your proposed work will have;
    - Added value of the proposed transnational collaboration;
    - Description of patient organizations within the proposal, including their role and contribution.

*If the application concerns a request for extension of a project funded in previous E-Rare calls, add 1 page describing the scientific results achieved in that project so far.*

10. Diagrams of the work plan, timeline, work flow and interconnections of work packages (Gantt chart, Pert or similar, max. 1 page)
11. In addition, two more sections can be added to the pre-proposal (optional):
    - a page of diagrams, figures, etc. to support the work plan description (max. 1 page)
    - a list of references (no page limit)
12. Budget plan of the project (template of the requested budget table is present in the application form)
13. Brief CV for each principal investigator including a description of the main domain of research and a list of the 5 most relevant publications within the last five years regarding the proposal (once converted into Pdf document: max. 1 page DIN-A4; Arial 11, single-spaced, margins of 1.27 cm per principal investigator). Dates/requirements for the identification of early career scientists (not included in page limit).
14. Date and signature of the coordinator.

## 5. FULL PROPOSAL STRUCTURE

The information given in the pre-proposal is binding. Thus, any fundamental changes between the pre- and full proposals, e.g. composition of the consortium, objectives of the project, must be communicated to the JCS with detailed justification and will only be allowed by the Call Steering Committee (CSC) under exceptional circumstances[1].

Please note that only the **full-proposal template** provided on the EJP RD web page (www.ejprareddiseases.org) will be accepted. The proposal document must respect the format and the length indicated. **Full-proposals exceeding these limitations will be rejected.**

**Full proposals must include the following information (can be subject to change in final full proposal form):**

- Project title and acronym
- Name and full affiliation of the project coordinator
- Names and full affiliations of each principal investigator and other personnel participating in the transnational project
- Duration of project
- Total project cost and total budget requested
- Funding from associated research partners
- Scientific summary (max. ½ page)
- Keywords and medical domain (5 to 7)
- Background and present state of the art in the research field (max. 2 pages)

[1] One of the exceptional circumstances may be that a preproposal has been opened for a research team from a country that joins EJPRD JTC 2019, but was not represented in the chosen preproposals to be elaborated into a full proposal (See "6.2. Opening of pre-proposals after the first evaluation round for involvement of researchers from countries joining EJPRD JTC 2019 but not represented in full proposals" in the Call text).

- Preliminary / previous results obtained by the consortium members (if the application concerns a request for extension of a project funded in a previous E-Rare Joint Transnational Call, please describe the scientific results achieved in that project so far, including: publications, collaboration, impact on clinical and public health applications and relevance to patients' needs.) (max. 2 pages, only if applicable)
- Work plan (aims, methodology, involvement of participants clearly defining the responsibilities and workloads [expressed in person months] of each participating research partner, time plan, project coordination and management; max. 15 pages. *The references to be included in the work plan are not included in the page limit of 15 pages.*
- Added value of the proposed transnational project collaboration (max. 1 page)
- Unmet medical and patients' need that are addressed by the proposed work and the potential health impact that the results of your proposed work will have (max ½ page)
- Translatability of the project results: Description of the potential of the expected results for commercial exploitation and for future clinical, public health and/or other socio-economic health relevant applications (including description of the exploitation strategy for project results focussing on the next steps in the therapy development process (e.g. regulatory advice, orphan designation, cooperation with industry partners, business development concept etc.)) (max. ½ page)
- Description of patents and present / future position with regard to intellectual property rights, both within and outside the consortium (e.g. any barriers to sharing materials or translating the results into clinical application) (max. ½ page)
- Description of ongoing or submitted research grants of each participating partner related to the present topic (indicating funding sources [include at least: ID number, amount and duration of funded project; funding agency] and possible overlaps with the project proposed) (max. ½ page per research partner)
- Ethical and legal issues (max.4 pages)
- Concept for sustainability of infrastructures initiated by the project (e.g. registries, cohorts, biobanks, databases, etc.) and their possible interaction with European Infrastructure Initiatives (where applicable, e.g. BBMRI, ECRIN, ELIXIR, EU-Openscreen, INFRAFRONTIER, INSTRUCT, RD-Connect, etc.) (max. 1 page)
- Data management strategy (mandatory): description how the new research data in this project will be findable, accessible, interoperable and re-usable: 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) (max 2 pages)[2]

[2] For more information on preparing a data management strategy, please consult Annex 1 of http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf and http://www.snf.ch/en/theSNSF/research-policies/open_research_data/Pages/data-management-plan-dmp-guidelines-for-researchers.aspx

- Description of participation/engagement of Industry within the proposal, including their role and contribution (max. 1/2 page, only if applicable)
- Description of participation/engagement of patient organizations within the proposal, including their role and contribution (max. 1 page, only if applicable)
- Scientific justifications of requested budget (rational distribution of resources in relation to project's activities, partners responsibilities and time frame; when applicable specifying co-funding from other sources necessary for the project (max. ½ page per partner)
- Financial plan for each consortium member
- Brief CVs for each participating principal investigator with a list of up to five relevant publications within the last five years demonstrating the competence to carry out the project (max. 1 page each). Dates/requirements for the identification of early career scientists (not included in page limit)
- When requested by a national's eligibility criteria, additional information must be provided. The information provided will be checked by the corresponding national organisation

Applicants are invited to **name potential experts** suited for the evaluation of their full proposals. These experts should not have any conflict of interest (e.g. co-publication in the past three years or current close collaboration) with the partners involved, otherwise they will not be considered. Experts not suited due to conflict of interest (e.g. direct competition) could be also named in the electronic proposal submission system form.

## 6. PLEASE NOTE

Some advice to succeed with your proposal:

- **Read several times the Call text**, including the aim of the Call JTC 2019 and the evaluation criteria
- Make sure that your proposal falls into the **scope of the call**
- Make sure that your proposal fulfills the **eligibility criteria of the joint call**
- Make sure that all consortium members have understood the **national eligibility criteria and requirements (Annex 2) and that they fulfill these criteria**
- Make sure that all consortium members **contacted their national representative** and confirmed eligibility with their respective funding organisations in advance of submitting an application (see **Annex 2**)
- Prepare your proposal in advance
- Enter the requested information on the submission site as soon as possible
- Use the proposal templates provided on the EJP RD web site (www.ejprarediseases.org)
- Respect the length limitations of each section in the proposals

Only the pre-proposal and full proposal templates provided on the EJP RD web page (www.ejprarediseases.org) will be accepted. Proposals exceeding the length limitations of each section **will be discarded without further review.**

Please note that proposals not meeting the formal criteria or the national eligibility criteria and requirements **will be declined without further review.**
Applicants are advised to read the national eligibility criteria and requirements and confirm eligibility with their respective funding organisations in advance of submitting an application (Annex 2).

## 7. PROJECT START AND CONSORTIUM AGREEMENT

Consortium members of projects selected for funding **must fix a common project start date**, which would be the reference date for yearly and final reports and extensions. This common project start date must appear in the Consortium Agreement. It is expected that project funding will start in the first half of 2020.

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 partners sign this 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.

The purpose of this CA shall be:

- to underpin the research partners' collaboration and provide the research partners with mutual assurance on project management structures and procedures, and their rights and obligations towards one another;
- to assure the CSC that the research consortium has a satisfactory decision making capability and is able to work together in a synergistic manner.

The following subjects (as a minimum) should be addressed by the CA:

- purpose of and definitions used in the CA
- names of organisations involved
- common start date of the research project
- organisation and management of the project
- role and responsibilities of the research consortium coordinator and the research partners: person in charge, their obligations and key tasks, conditions for their change
- deliverables (transnational reports and if relevant requirements for national reports where coordination is required)
- resources and funding
- confidentiality and publishing
- Intellectual Property Rights (how this issue will be handled between research partners)
- decision making within the consortium
- handling of internal disputes
- the liabilities of the research partners towards one another (including the handling of default of contract).

## ANNEX I: OVERHEADS IN EACH COUNTRY/REGION

| COUNTRY/REGION | FUNDING AGENCY | OVERHEADS |
|---|---|---|
| Austria | FWF | Overheads are not eligible costs for FWF |
| Belgium/Flanders | FWO | Determining the overhead amount depends on the FWO funding channel in which the project fits, being fundamental (FO) or strategic (SBO) research; see Annex 2: National/regional regulations for Belgium, FWO.<br><br>For FO projects:<br>A mandatory 6% overhead cost has to be included in the requested funding of max. 350.000 EUR. This overhead cost of 6% on the applied for budget needs to be inserted in the 'overhead' category.<br>A practical example: if 350.000 EUR is requested by a researcher in total, 6% of this amount has to be inserted as overhead (21.000 EUR), which means only 329.000 EUR is effectively available for other cost categories (personnel, consumables, equipment).<br><br>For SBO projects:<br>The specific SBO overhead regulations apply:<br>https://www.fwo.be/media/652551/Cost-model-SBO-and-TBM-2017.pdf |
| Belgium/French speaking community | F.R.S.-FNRS | Overheads are not eligible costs for FNRS |
| Canada | CIHR-IG | Overheads are not eligible costs for CIHR |
| Canada | FRQS | Overheads are not eligible costs for FRQS |
| Czech Republic | MEYS | Eligible costs for a Czech participant involved in a project consortium are defined by § 2 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds and on Amendment to Some Related Acts. The maximum indirect costs set for the present call are 25 % (flat rate) of direct costs without the sub-contracting. |
| Estonia | MoSAE | Overheads are eligible and the maximum amount is 20% of the direct cost of the project |

| COUNTRY/REGION | FUNDING AGENCY | OVERHEADS |
|---|---|---|
| Finland | AKA | According to Academy guidelines for full cost model. Draft the application so that the Academy's contribution to funding comes to no more than 70% of the estimated total project costs. |
| France | ANR | Please note that the ANR cost category corresponding to «overheads» is « *frais généraux* ». Eligible overhead rates vary depending on the types of partners applying for funding. Please refer to ANR's financial regulations ("Règlement financier ANR" section 3.1.1) for full details http://www.agence-nationale-recherche.fr/financer-votre-projet/reglement-financier/. |
| France | FFRD | Overheads are not eligible costs for FFRD |
| Germany | BMBF | Overheads refer to "Gemeinkosten" (applicable for Helmholtz-centres and Fraunhofer-Society) as well as "Projektpauschale" (applicable for universities and university hospitals). The "Projektpauschale" generally will amount to 20% of the applied total project expenditure. For further information on the "Projektpauschale" please refer to https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=179 (Pos. 0865) or contact the German national contact point for this EJP RD call. |
| Germany | DFG | The "Programmpauschale" generally will amount to 22% of the applied total project expenditure. See www.dfg.de for further details. |
| Greece | GSRT | 15% calculated on the basis of the personnel budget of the partner. |
| Hungary | NKFIH | 20% of the eligible direct costs of the project. Applicants should consult the regulations in the latest NKFIH NN call (currently NN_18) for details. |
| Israel | CSO/MOH | 10% of the entire project |
| Ireland | HRB | In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for laboratory or clinically-based research and 25% of Total Direct Modified Costs if desk-based research. |
| Italy | MoH-IT | Up to 10% of the direct cost of the project, intended to cover the general cost of the institution that hosts the research team and which cannot be used by the research team |
| Italy | MIUR | Overheads (*Spese generali*) are eligible costs and they are calculated as a percentage of the personnel cost. This percentage must be calculated on the basis of the general accounts of the beneficiary and, in no case, can be higher than 50% of the personnel costs. |

| COUNTRY/REGION | FUNDING AGENCY | OVERHEADS |
|---|---|---|
| | | Costs for travels, coordination and dissemination of the results are to be included in the overheads. |
| Italy | FRRB | Up to 20% flat rate calculated on direct costs – Subcontracting costs excluded from this calculation. |
| Italy | Tuscany Region | Up to 10% of the direct cost of the project, intended to cover the general cost of the institution that hosts the research team. |
| Lithuania | RCL | Up to 30 % from the listed direct costs (personnel, travel, consumables, subcontracting, contractual research, consultancy), unless otherwise specified in the documents of the programme or in the call for proposal. Exceptional cases may include additional indirect costs for the operation of scientific equipment. |
| Luxembourg | FNR | Overhead expenses may include, but are limited up to 25%, accounting, advertising, depreciation, indirect labour, insurance, interest, legal fees, rent, repairs, supplies, taxes, telephone, travel and utilities. Overhead costs may not include depreciation costs of large equipment having been completely funded by FNR in other previous programmes. |
| Poland | NCBR | That costs cannot account for more than 25% of eligible project costs, and are counted as a multiplication by percentage given above and the rest of direct costs, excluding subcontracting. |
| Portugal | FCT | When there is indirect costs allocation, these shall be calculated on a simplified costs base, by means of the application of a fixed rate of 25% of direct eligible costs with exclusion of subcontracting and resources made provided by third parties. |
| Slovakia | SAS | Up to 20% of the direct costs (excluding subcontracting) |
| Spain | ISCIII | Up to 21% of the direct costs. |
| Switzerland | SNSF | Overhead costs may not be included in the Swiss project budget. Overhead contributions, calculated on the basis of the total research funding given to a particular institution through all SNSF funding instruments, are paid directly to the applicant's institution on a yearly basis. |
| Sweden | SRC | The grant can be used to cover any type of project-related costs, for example salaries (including salary of PI, corresponding to the level of activity in the project), travel (including visits to, and stays at, research facilities), publication costs, minor equipment and depreciations, etc. The grant may not be used for scholarships. For details follow the link |

| COUNTRY/REGION | FUNDING AGENCY | OVERHEADS |
|---|---|---|
| | | General conditions for grant applications: https://www.vr.se/english/calls-and-decisions/grant-terms-and-conditions/general-grant-tc.html |
| Sweden | Vinnova | Eligible costs for companies can be funded up to the levels presented in table 1 in this document: https://www.vinnova.se/contentassets/03d3665164c14b46a854b76bfb3c6055/stodnivaer-statligt-stod.pdf.<br>Projects should be applicable under the categories industrial research or experimental development.<br><br>Public sector, academia and research institutes may receive funding of up to 100% of eligible costs provided that the project is part of their non-economic activities.<br><br>Economic activities mean offering goods or services on a market. If a participant from academia, research institutes, health care or non-profit organisations conducts both economic and non-economic activities the costs and funding for the two types of activities are required to be kept separate. If the accounting is not separate, the organisation will be considered to be a company.<br>https://www.vinnova.se/globalassets/dokument/general-terms-and-conditions-2018.pdf |
| The Netherlands | ZonMw | Overheads are not eligible costs for ZonMw. |
| Turkey | TUBITAK | Overheads are eligible costs and subjected to the terms and conditions stated in ARDEB 1001 Programme. |
| Multinational, for funding of PAO | INSERM | Overheads cost category corresponding to « *frais généraux* » are limited to 15% of total grant amount (that is 15% * 50 000 € = 7500 €). |

## ANNEX II: NATIONAL/REGIONAL REGULATIONS

**It is strongly advised that all applicants contact their EJP RD National/Regional Contact Point in good time before the submission of a proposal**

**AUSTRIA, FWF**

| | |
|---|---|
| **Country** | Austria |
| **Funding organisation** | Fonds zur Förderung der Wissenschaftlichen Forschung (FWF) / Austrian Science Fund<br>http://www.fwf.ac.at |
| **National contact person** | **Stephanie Resch**<br>**Phone:** +43 (1) 505 67 40-8201**, E-mail**: stephanie.resch@fwf.ac.at<br>**Anita Stürtz**<br>**Phone**: +43 (1) 505 67 40-8206**, E-mail**: anita.stuertz@fwf.ac.at |
| **Funding commitment** | 0.6M€ |
| **Anticipated number of fundable research partners** | 2 |
| **Maximum funding per grant awarded to a partner** | For scientists funded by the FWF, the funding is limited to "project-specific costs, i.e. personnel and non-personnel costs that are essential to carry out the project and that go beyond the resources made available from the research institution's infrastructure, according to the general FWF Funding Guidelines published at https://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/Einzelprojekte/p_application-guidelines.pdf<br>The FWF does not finance infrastructure or basic equipment at research institutions. Overheads may not be requested. Subcontracts must be well justified, i.e. must represent the only or the most economical way to have the work performed, please contact the FWF directly for clarification of individual cases.<br>The current FWF salary scale (http://www.fwf.ac.at/en/research-funding/personnel-costs/ indicates the salaries that may be requested. |
| **Eligibility of a partner as a beneficiary institution** | Individual researcher, working in any kind of non-profit organisation: e.g. University, University hospital, Non-university research institute<br>Please refer also to the general FWF Funding Guidelines:<br>http://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/Einzelprojekte/p_application-guidelines.pdf<br>available on:<br>http://www.fwf.ac.at/en/research-funding/application/international-programmes/joint-projects-era-nets/ |
| **Eligibility of costs, types and their caps** | Maximum number of ongoing projects:<br>Stand-Alone Projects (P), International Programmes (I), Clinical Research (KLIF) and Arts-Based Research (PEEK) programmes: |

| | |
|---|---|
| | Starting on August 1st, 2018, each researcher may serve as the principal investigator in a maximum of three projects in the P, I, KLIF and PEEK programmes.<br>Limits on submission of applications:<br>The rule on the maximum number of ongoing projects in the programmes mentioned above leads to limits on the submission of new applications. The number of possible new applications depends on the number of currently ongoing/approved projects in the above mentioned programmes, including pre-proposals for International projects (IK). A maximum of three ongoing/approved projects and new applications is permitted.<br>https://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/project_number_limit.pdf |
| **Submission of the proposal at the national level** | FWF Submission:<br>In addition to the application at the call secretariat administrative data (in accordance with the FWF guidelines for stand-alone projects) must be submitted online to the FWF at https://elane.fwf.ac.at/<br>This is required already at the pre-registration stage via the programme category "IK – International Projects (preproposal)".<br>For the full proposal stage applicants must choose the programme category "I – International Projects". Both steps are mandatory.<br>For submissions to be valid, the cover sheet generated at the end of the online submission process must be printed out and signed. It can then either be sent to the FWF by conventional mail (FWF, Sensengasse 1, 1090 Vienna) or scanned in, given a digital signature and sent to the FWF (office@fwf.ac.at ) as an e-mail attachment.<br>Detailed information may be found under the Internet<br>http://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/Internationale_Programme/i_infosheet-era-net.pdf |
| **Further guidance** | http://www.fwf.ac.at/en/research-funding/application/international-programmes/joint-projects-era-nets/ |

**BELGIUM, FWO**

| | |
|---|---|
| **Country / Region** | Belgium, Flanders |
| **Funding organisation** | Research Foundation - Flanders (FWO)<br>http://www.fwo.be/ |
| **National contact person** | Alain Deleener<br>+32 2 550 15 45<br><br>Toon Monbaliu<br>+32 2 550 15 70<br><br>eranet@fwo.be |
| **Funding commitment** | 0.7M€ |
| **Anticipated number of fundable research partners** | 2-3 |
| **Eligibility of project duration** | Up to 36 months |
| **Eligibility of a partner as a beneficiary institution** | See "Eligibility of principal investigator or other research team member" below. |
| **Eligibility of principal investigator or other research team member** | The FWO participates with two of its project funding channels:<br>➔ Fundamental research (FO)<br>➔ Strategic Basic Research (SBO)<br><br>Dependent on the type of research (fundamental/strategic) that will be performed, researchers applying for FWO funding have to carefully select their funding channel and write their proposal in such a way that it complies with the applicable FWO regulations, for example:<br><br>*FO projects:*<br>Only lowest TRL[3] (TRL 1) will be eligible.<br><br>*SBO projects:* |

[3] Technology Readiness level: https://www.ttopstart.com/news/technology-readiness-levels-a-new-dimension-in-horizon-2020

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| | The valorisation aspect, impact and innovation goals, which, if scientifically successful, can open up prospects for economic or societal applications, have to be clear. These projects imply a TRL-range from 2 to 5.<br><br>Consequently, researchers have to make sure they comply with the eligibility criteria of the funding channel they select.<br>*For 'FO' the 'Research Project' regulations apply: https://www.fwo.be/en/fellowships-funding/research-projects/research-project/*<br><br>*For 'SBO' the 'Regulations Strategic Basic Research' apply: https://www.fwo.be/en/fellowships-funding/research-projects/sbo-projects/regulations-strategic-basic-research-(sbo)/*<br><br>On the basis of the nature of the proposal and the involved researcher(s) the FWO administration will decide on the eligibility of the proposal. Again, it is thus of utmost importance that the proposal complies with the specific regulations and eligibility requirements of the respective funding channel.<br><br>We therefore urge researchers to contact the FWO contact points before submission, in order to verify the researchers' eligibility and avoid the ineligibility of the project proposal/consortium as a whole. |
| **Eligibility of costs, types and their caps** | The max. amount that can be requested per project is 350.000 EUR, overhead included.<br><br>For FO projects:<br>Funding money can be used for staff (temporary; permanent staff cannot be appointed on FWO budget), consumables (incl. travel costs) and equipment. A mandatory 6% overhead cost has to be included in the requested funding. This overhead cost of 6% on the applied for budget needs to be inserted in the 'overhead' category. This is also specified in annex 1: 'Overheads in each country/region'.<br><br>For SBO projects:<br>The specific SBO funding regulations apply:<br>https://www.fwo.be/media/652551/Cost-model-SBO-and-TBM-2017.pdf |
| **Submission of the proposal at the national level** | No |
| **Submission of financial and scientific reports at the national level** | Financial reporting: Yes<br><br>Scientific reporting: depends on the funding channel |

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| | - Fundamental Research (FO): Reporting at ERA-NET level only;<br>- Strategic Basic Research (SBO): Besides the reporting at ERA-NET level, conform the fundamental funding channel, a report at national/regional level is also required, including a valorisation report. |
| **Further guidance** | The FWO administration will contact the applicants after the pre-proposal submission deadline (and possibly also the full proposal, if applicable) in order to verify the choice of funding channel.<br><br>Researchers are obliged to inform their host institution (research coordination units (DOCs)) about their participation, for administrative purposes. The FWO can assist in this matter (e.g. contacts). Additionally, in view of the GDPR regulations, explicit consent will be asked from the researchers, after submission of the project proposal, to deliver some basic information about their participation to the relevant host institutions.<br><br>Interesting links:<br><br>ERA-NET general:<br>https://www.fwo.be/nl/mandaten-financiering/europese-programmas/era-net/<br>https://www.fwo.be/nl/mandaten-financiering/europese-programmas/era-net/oproepen/<br><br>FO regulations:<br>https://www.fwo.be/nl/mandaten-financiering/onderzoeksprojecten/onderzoeksproject/<br><br>SBO regulations:<br>https://www.fwo.be/nl/mandaten-financiering/onderzoeksprojecten/sbo-projecten/ |

**BELGIUM, FNRS**

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| **Country / Region** | Belgium (French Speaking Community) |
| **Funding organisation** | Fund for Scientific Research - FNRS (F.R.S.-FNRS) |
| **National contact person** | Florence Quist<br>Phone: +32 2 504 93 51<br>Email: florence.quist@frs-fnrs.be<br><br>Joël Groeneveld<br>Phone: +32 2 504 92 70<br>E-mail: joel.groeneveld@frs-fnrs.be |
| **Funding commitment** | 240.000 € |
| **Anticipated number of fundable research partners** | 1 |
| **Maximum funding per grant awarded to a partner** | 240.000 € |
| **Eligibility of project duration** | 3 years. If the project involves the recruitment of a PhD student, the project duration of the F.R.S.-FNRS sub-project could be up to 4 years but should remain within the 200.000 € budget maximum (cf. PINT-Multi regulations, art. III.3, second paragraph). |
| **Eligibility of a partner as a beneficiary institution** | All eligibility rules and criteria can be found in the PINT-Multi regulations. It is **strongly advised** to contact the F.R.S.-FNRS prior to submission regarding the eligibility criteria. |
| **Eligibility of principal investigator or other research team member** | All eligibility rules and criteria can be found in the PINT-Multi regulations. It is **strongly advised** to contact the F.R.S.-FNRS prior to submission regarding the eligibility criteria. |
| **Eligibility of costs, types and their caps** | All eligibility rules and criteria can be found in the PINT-Multi regulations. It is **strongly advised** to contact the F.R.S.-FNRS prior to submission regarding the eligibility criteria. |
| **Submission of the proposal at the national level** | Yes |

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| **Submission of other information at the national level** | N/A |
| **Submission of financial and scientific reports at the national level** | Financial reporting must be submitted to the FNRS. |
| **Further guidance** | PINT-MULTI regulations, SEMAPHORE |

**CANADA, CIHR-IG**

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| **Country** | Canada |
| **Funding organisation** | Canadian Institutes of Health Research, Institute of Genetics (CIHR-IG) |
| **National contact person** | Ilana Gombos<br>Phone: 1-613-952-0819<br>Email: ilana.gombos@cihr-irsc.gc.ca<br><br>Etienne Richer<br>Email: Etienne.Richer@cihr-irsc.gc.ca |
| **Funding commitment** | $1.35M CAD<br>$150,000 per year per project.<br>Please note that this is Canadian dollars |
| **Anticipated number of fundable research partners** | 3 projects |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | No |
| **Eligibility of principal investigator or other research team member** | Academia, Clinical, Public Health<br><br>http://www.cihr-irsc.gc.ca/e/22630.html#1-D1-1<br><br>The European definition of an Early Career Scientist will be accepted for Canadian applicants: 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. For further details, please refer to Section 6 of the European Joint Programme on Rare Diseases call. |
| **Eligibility of costs, types and their caps** | http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/FundsUse-UtilisationSubventions_eng.asp |

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| **Submission of the proposal at the national level** | Short application as per CIHR Funding Opportunity (link to follow) |
| **Submission of financial and scientific reports at the national level** | http://www.cihr-irsc.gc.ca/e/22631.html#2-A20 |
| **Further guidance** | CIHR is pleased to be partnering with Muscular Dystrophy Canada (MDC) once again on this call. Of this $ 2,300,000, $ 450,000 is being made available by MDC to fund applications relevant to their mandate. |

**CANADA, FRQS**

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| **Country** | Canada - Québec |
| **Funding organisation** | Fonds de recherche du Québec – Santé (FRQS)<br>http://www.frqs.gouv.qc.ca |
| **National contact persons** | Maxime Beaudoin<br>1+ (514) 873-2114, ext 1369<br>maxime.beaudoin@frq.gouv.qc.ca |
| **Funding commitment** | Minimum of $500,000 (Additional funds from provincial partners maybe available)<br>The maximum amount per grant is $150,000 per year for up to 3 years.<br><br>The maximum amount that can be requested in support of a Canadian component is $150,000 (CAD) per year for up to 3 years from all Canadian funding sources CIHR-IG, FRQS and their funding partners.<br><br>Funds are subject to availability of funds voted annually to FRQS by the National Assembly of Québec and FRQS Board of Directors' approval. |
| **Anticipated number of fundable research partners** | FRQS is providing funding for up to 1 to 2 Quebec teams as outlined in the call text. Canadian funders will be working together to maximize participation from the Canadian research community |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution. Eligibility of principal investigator or other research team member** | Quebec applicants must meet the eligibility criteria for FRQS research grants.<br>Eligible institutions are Quebec Universities or Institutions within Quebec's health and social services network. Further information about eligibility are available on FRQS Common Rules and Regulations (section 2) |
| **Eligibility of costs, types and their caps** | Operational costs (research personnel, consumables, animals)<br>Costs related to scientific and ethical evaluation (clinical research projects)<br>Coordination-related cost (project administration and travel expenses for attending joint meetings)<br>Costs related to knowledge translation and translation<br>Conference attendance (up to **3%** per year of the grant amount as of the second year)<br>Further information about eligible costs is available in section 8 of FRQS Common Rules and Regulations.<br><br>**Note: There is NO support for salaries of investigators.** |

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| | **Overheads means "frais indirects de recherche" and will be managed separately by the FRQS. They should not be included in the requested budget. Please refer to http://www.frqs.gouv.qc.ca/documents/11314/710199/FAQ_FIR_juillet2015.pdf/f8e1a7ea-4543-4462-8a2b-55cb8e2857b6 for further details.**<br><br>**Additional requirement: FRQS applicants invited to submit a rebuttal/modified proposal must also submit a budget to FRQS in Canadian dollars. Specific instructions will be sent to investigators.** |
| **Submission of the proposal at the national level** | A short proposal, including the budget in Canadian dollars will have to be submitted to CIHR via ResearchNet for all Canadian applicants invited to submit a rebuttal/modified proposal. Instructions will be sent via email to those applicants. |
| **Submission of financial and scientific reports at the national level** | Scientific reports according to EJP RD template and requirements only.<br>Annual financial reporting according to FRQS Common Rules and Regulations. |

**CZECH REPUBLIC, MEYS**

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| **Country** | Czech Republic |
| **Funding organisation** | Ministry of Education, Youth and Sports (MEYS)<br>www.msmt.cz |
| **National contact person** | Daniel Hanšpach (MSMT)<br>Phone: +420 234 811 360<br>E-mail: Daniel.Hanspach@msmt.cz |
| **Funding commitment** | 0.6 M€ |
| **Anticipated number of fundable research partners** | (2-3) |
| **Maximum funding per grant awarded to a partner** | No restriction |
| **Eligibility of a partner as a beneficiary institution** | The participants from the Czech Republic in the projects´ consortia must meet the criteria of the **research and knowledge-dissemination organisation** (hereinafter referred to as "research organisation") in accordance with the Framework for State Aid for Research and Development and Innovation (2014/C 198/03). These might be public universities, public research institutes and/or another entities classified as research organisations.<br><br>It is obligatory that the Czech participants involved in the projects´ consortia prove compliance with the eligibility criteria and fulfilment of the conditions set by **§ 18 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds** and on Amendment to Some Related Acts by means of a **Statutory Declaration**. |
| **Eligibility of costs, types and their caps** | Eligible costs<br><br>Eligible costs for a Czech participant involved in a project consortium are defined by **§ 2 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds** and on Amendment to Some Related Acts. The maximum indirect costs set for the present call are **25 % (flat rate)** of direct costs without the sub-contracting.<br><br>The **aid intensity** for activities carried out by a research organisation might be at the level of **100 %** provided that the research organisation complies entirely with requirements stipulated by the Article 2.1.1 "Public funding of non-economic activities" of the Framework for State Aid for Research and Development and Innovation (2014/C 198/03) and proves it by means of the above-mentioned **Statutory Declaration**. |

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| | Should the above-stated criteria not be fulfilled by the Czech participant, funding rates will be adjusted appropriately by the Ministry of Education, Youth and Sports and will reach the level of **100 % for fundamental/basic research** activities, **50 % for applied research** activities and **25 % for experimental development** activities.<br>For further information on the eligibility cost please see http://www.msmt.cz/vyzkum-a-vyvoj-2/e-rare. |
| **Submission of the proposal at the national level** | It is obligatory:<br>- that the Czech participants involved in the projects´ consortia prove compliance with the eligibility criteria and fulfilment of the conditions set by § 18 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds and on Amendment to Some Related Acts by means of a Statutory Declaration.<br>- that each Czech participant in a project consortium is requested to specify the costs related to the envisaged R&D activities in detail by using the Eligible Costs Specification.<br>Template available on websites of the Ministry of Education, Youth and Sports: http://www.msmt.cz/vyzkum-a-vyvoj-2/era-net-cofund.<br><br>All of the requested documentation (i.e. Statutory Declaration and Eligible Costs Specification) shall be sent by each Czech participant in a project consortium to the Ministry of Education, Youth and Sports no later than 6th February 2018, both by electronic correspondence and post.<br>Detail information may be found under the Internet address (http://www.msmt.cz/vyzkum-a-vyvoj-2/era-net-cofund).<br><br>The **electronic version** of requested documentation shall be sent to the address of electronic correspondence Daniel.Hanspach@msmt.cz.<br><br>One **signed and stamped hard copy** (by the statutory representative of research organisation) of requested documentation shall be submitted as well following the instructions stipulated on websites of the Ministry of Education, Youth and Sports: (http://www.msmt.cz/vyzkum-a-vyvoj-2/era-net-cofund). |
| **Further guidance** | http://www.msmt.cz/vyzkum-a-vyvoj-2/e-rare |

**ESTONIA, MoSAE**

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| **Country / Region** | Estonia |
| **Funding organisation** | Ministry of Social Affairs |
| **National contact person** | Heli Paluste<br>Ministry of Social Affairs<br>Head of Health Care Unit<br>Phone : +372 626 9127<br>E-mail: Heli.Paluste@sm.ee<br><br>Angela Ivask<br>Ministry of Social Affairs<br>Scientific Adviser for Health Policy<br>Phone : +372 626 9735<br>E-mail: Angela.Ivask@sm.ee |
| **Funding commitment** | 0.075 M€ |
| **Anticipated number of fundable research partners** | 1 |
| **Maximum funding per grant awarded to a partner** | 0.075 M€ |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution** | Research proposals may be submitted by representatives of Estonian legal persons in private law or in public law that are based and registered in Estonia and:<br>(i) are research and development institutions according to the § 3 (1) of Organisation of Research and Development Act;<br>(ii) are health services providers according to Health Services Organisation Act § 4. |
| **Eligibility of principal investigator or other research team member** | |

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| **Eligibility of costs, types and their caps** | Only costs generated over the lifetime of the project are considered eligible.<br>• Personnel costs incl. taxes can only be paid for the time used to carry out the grant project. Such participation should be clearly identifiable and the salary should take into account the past 12-month average salary of that person. If new staff member will be hired for the project, his salary has to comply with salaries commonly paid for staff carrying out similar work within the institution.<br>• Consumables. Only consumables directly related to the project can be funded.<br>• Subcontracting (≤50% of total costs) includes all external services and need a detailed justification in the application.<br>• Equipment (only depreciation costs)<br>• Travels need to be justified. Travel costs cover expenses for transport, accommodation and for international travels, also daily allowances if relevant;<br>• Fees for participating in scientific forums and conferences<br>• All other costs (≤20% of total costs). Costs which are clearly required for the implementation of the project and respectively identifiable; |
| **Submission of the proposal at the national level** | • All the applicants need to contact Estonian Ministry of Social Affairs (contact e-mail addresses: heli.paluste@sm.ee; angela.ivask@sm.ee or taotlusvoor@sm.ee;) at least two weeks before the call deadline, to confirm their eligibility, to provide a timeline and short description of activities and budget;<br>• Applicants need to ensure that their activity in the project falls under the exception for R&D activities: https://www.hm.ee/sites/default/files/ta_erand_juhend.pdf; |
| **Submission of financial and scientific reports at the national level** | The national partner is expected to provide annual activity report and financial report according to the requirements set by MoSAE in contract that will be signed after the positive funding decision has been made. |
| **Further guidance** | In case of all further questions, please contact:<br>heli.paluste@sm.ee<br>angela.ivask@sm.ee<br>taotlusvoor@sm.ee |

**FINLAND, AKA**

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| **Country** | Finland |
| **Funding organisation** | Academy of Finland (AKA)<br>http://www.aka.fi |
| **National contact person** | Heikki Vilen<br>+358 29 5335 135<br>heikki.vilen@aka.fi |
| **Funding commitment** | 600 000 € |
| **Anticipated number of fundable research partners** | 2-3 Finnish project partners, max. 300 000 € per partner. If there are several Finnish partners in the same consortium, the maximum total commitment from AKA is 300 000 € per consortium. |
| **Eligibility of project duration** | Maximum 3 years |
| **Eligibility of a partner as a beneficiary institution** | Host Institution of PI: University, University hospital, Non-university research institute, Industry |
| **Eligibility of costs, types and their caps** | Personnel, Consumables, Animals, Subcontracts, Equipment, Travel, Overheads<br>Full cost model applies; Requested budget from Academy must be no more than 70% of the full costs of a Finnish PI |
| **Submission of the proposal at the national level** | Only the submission of the joint proposal is required. There is no need to submit any documents directly to AKA. However applicants are requested to contact AKA's contact point (see above) before submitting the proposal. |
| **Submission of financial and scientific reports at the national level** | Yes, according to AKA guidelines |
| **Further guidance** | |

**FRANCE, ANR**

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| **Country** | France |
| **Funding organisation** | French National Research Agency (Agence nationale de la recherche –ANR-)<br>http://www.agence-nationale-recherche.fr |
| **National contact person** | Health & Biology Department<br>Agence Nationale de la Recherche –ANR<br>50 avenue Daumesnil - 75012 Paris, France<br>Florence Guillot<br>Email: **E-RareCalls@agencerecherche.fr**<br>Phone: (33) (0) 1 78 09 80 01 |
| **Funding commitment** | 3 M€ |
| **Anticipated number of fundable research partners** | 10 research partners<br>The ANR has a maximum funding per coordinator/partner for this call: Each research team can be funded with a maximum amount of 300 000 € for a French coordinator and 250 000 € for a French partner. There is a minimum amount per partner: 15 000 € |
| **Eligibility of project duration** | 2-3 years |
| **Eligibility of a partner as a beneficiary institution** | Eligible institutions:<br>- Public research institutes such as EPST, EPIC, universities, university hospitals, non-university research institutes (max. rate of support: 100% of marginal costs)<br>- Enterprises: large & SMEs (max. rate of support: 45% of total costs for SMEs & 30% for larger companies)<br><br>Additional eligibility criteria:<br>- The coordinator (if from a French institution) must belong to a public research organisation.<br>- ANR will avoid double funding and will not finance projects or part of projects that have been funded through other calls. ANR will cross-check the proposals submitted to ANR through the national and international calls for possible demands of double funding. |
| **Eligibility of costs, types and their caps** | Personnel costs for temporary contracts; small equipment; consumables and animal costs; travel; and sub-contracting, if necessary to carry out the proposed activities (sub-contracting costs of max 50% of requested budget per partner).<br>Please note that at ANR « overheads » means «  frais généraux de gestion – frais de structure  », and 8% of the total eligible costs must be applied if the partner belongs to a public research organisation, or 68% of the total personnel costs |

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| | and 7% of other costs if a partner belongs to another category (cf "Règlement financier ANR – section 4.2.3.5) |
| **Submission of the proposal at the national level** | No |
| **Submission of other information at the national level** | Yes. Contacting the ANR national contact point is mandatory. |
| **Submission of financial and scientific reports at the national level** | Yes. Financial reporting is submitted to ANR financial modalities and must be followed according to the contract that will be signed with the future beneficiaries.<br>Scientific reports: individual scientific reports are not required. However, French partners should contribute to the central report to be submitted by the coordinator of the project to EJP RD. This report will be the basis for validation of yearly advancements of the project by ANR. |
| **Further guidance** | Plan d'Action 2018: http://www.agence-nationale-recherche.fr/PA2018#documents<br>Règlement financier: http://www.agence-nationale-recherche.fr/fileadmin/documents/2017/ANR-Reglement-financier-2017.pdf |

**FRANCE, FFRD**

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| **Country / Region** | France |
| **Funding organisation** | French Foundation for Rare Diseases (Fondation maladies rares)<br>https://fondation-maladiesrares.org/eng/ |
| **National contact person** | Fondation Maladies Rares<br>Plateforme Maladies rares<br>96 rue Didot - 75014 Paris, France<br>**aap-bio@fondation-maladiesrares.com**<br>Ingrid Zwaenepoel - Phone : (33) (0) 1 58 14 22 85<br>Diana Désir-Parseille - Phone : (33) (0) 1 58 14 22 81 |
| **Funding commitment** | 100 000€ |
| **Anticipated number of fundable research partners** | TBD as the FFRD will co-finance research projects together with ANR. |
| **Maximum funding per grant awarded to a partner** | No restriction |
| **Eligibility of project duration** | 2-3 years |
| **Eligibility of a partner as a beneficiary institution** | Eligible institutions:<br>- Public research institutes such as EPST, EPIC, universities, university hospitals, non-university research institutes (max. rate of support: 100% of marginal costs) |
| **Eligibility of principal investigator or other research team member** | The coordinator (if from a French institution) must belong to a public research organisation. |
| **Eligibility of costs, types and their caps** | Personnel costs for temporary contracts; small equipment; consumables and animal costs; travel; and sub-contracting, if necessary to carry out the proposed activities.<br>Overheads are not eligible costs. |
| **Submission of the proposal at the national** | No |

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| **Submission of other information at the national level** | No |
| **Submission of financial and scientific reports at the national level** | Yes. Financial reporting is submitted to FFRD financial modalities and must be followed according to the contract that will be signed with the future beneficiaries.<br>Scientific reports: individual scientific reports are not required. However, French partners should contribute to the central report to be submitted by the coordinator of the project. |
| **Further guidance** | |

**GERMANY, BMBF/PT-DLR**

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| **Country** | Germany |
| **Funding organisation** | German Federal Ministry for Education and Research (BMBF)<br>www.gesundheitsforschung-bmbf.de |
| **Management organisation** | German Aerospace Center, DLR Project Management Agency (DLR-PT)<br>www.pt-dlr.de |
| **National contact person** | ***German Aerospace Center***<br>DLR Project Management Agency \| Health \| Division Clinical Research, University Medicine, Digital Health<br>Heinrich-Konen-Straße 1<br>53227 Bonn<br>Germany<br><br>Dr. Katarzyna Saedler<br>Phone: (+49) (0)228 3821-1947<br>E-mail: Katarzyna.Saedler@dlr.de<br><br>Dr. Michaela Fersch<br>Phone: +49 (0)228 3821 1268<br>E-mail: Michaela.Fersch@dlr.de<br><br>Dr. Ralph Schuster<br>Phone: (+49) (228) 3821-1233<br>E-mail: Ralph.Schuster@dlr.de |
| **Funding commitment** | 3 Mio€ |
| **Anticipated number of fundable research partners** | 10-15 partners |
| **Eligibility of project duration** | Maximum 3 years |
| **Eligibility of a partner as a beneficiary institution** | Legal body: university, university hospital, non-university public research institute, industry |

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| **Eligibility of costs, types and their caps** | Personnel, consumables, animals, subcontracts, equipment, travels, documentation according to national regulations.<br>Overheads refer to "Gemeinkosten" (applicable for Helmholtz-centres and Fraunhofer-Society) as well as "Projektpauschale" (applicable for universities and university hospitals). The "Projektpauschale" generally will amount to 20% of the applied total project expenditure. For further information on the "Projektpauschale" please refer to https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=179 (Pos. 0865). |
| **Submission of the proposal at the national level** | No |
| **Submission of other information at the national level** | Yes, for proposal selected for funding |
| **Submission of financial and scientific reports at the national level** | Yes, according to national regulations. |
| **Further guidance** | https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=1750<br>https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=1752 |

**GERMANY, DFG**

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| **Country** | Germany |
| **Funding organisation** | German Research Foundation (DFG)<br>www.dfg.de |
| **National contact person** | ***DFG: Deutsche Forschungsgemeinschaft (DFG)***<br>Kennedyallee 40<br>53175 Bonn<br>Germany<br><br>Dr. Katja Grossmann<br>Tel. +49 (228) 885-2565<br>Fax +49 (228) 885-2777<br>katja.grossmann@dfg.de |
| **Funding commitment** | 3 Mio€ |
| **Anticipated number of fundable research partners** | tbd |
| **Eligibility of project duration** | Maximum 3 years |
| **Eligibility of a partner as a beneficiary institution** | Legal body: university, university hospital, non-university public research institute: Industry is not eligible; some restrictions for non-university public research institutes; for further information see http://www.dfg.de/formulare/55_01/ |
| **Eligibility of costs, types and their caps** | Personnel, consumables, animals, subcontracts, equipment, travels, documentation according to national regulations.<br>Overheads :<br>The "Programmpauschale" will generally amount 22% of the total project expenditure. See www.dfg.de |
| **Submission of the proposal at the national level** | After proposal submission at the EJP RD-portal the proposal will be assigned to DFG and BMBF by the management organisations. Proposals assigned to the DFG will then have to be uploaded at the ELAN-portal of the DFG. |
| **Submission of other information at the national level** | Yes, for proposal selected for funding |
| **Submission of financial and scientific reports at** | Yes, according to national regulations. |

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| **the national level** | |
| **Further guidance** | http://www.dfg.de/en/research_funding/programmes/individual/research_grants/index.html |

**GREECE, GSRT**

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| **Country / Region** | Greece |
| **Funding organisation** | General Secretariat for Research and Technology (GSRT)<br>Directorate for International Scientific &Technological Cooperation<br>www.gsrt.gr |
| **National contact person** | DIMITROPOULOU Sofia<br>s.dimitropoulou@gsrt.gr<br>Tel. 00 30 2131300 187 |
| **Funding commitment** | 1.0 M€ national funding that comes from structural funds and particularly from the Operational Program for Competitiveness, Entrepreneurship and Innovation 2014-2020, Research and Innovation Strategy for Smart Specialization (RIS3).<br>Maximum funding per project<br>200.000 € per project (including indirect costs). Please note that this amount can be increased to 250.000 € per project if the Greek partner assumes project coordination. |
| **Anticipated number of fundable research partners** | 4-5 projects tentatively envisaged to be funded |
| **Eligibility of project duration** | 36 months |
| **National Programme** | **National Research and Innovation Strategy for Smart Specialization 2014-2020**<br>http://www.gsrt.gr/News/Files/New1034/Executive%20Summary-2015-09-17-v04.pdf |
| **Eligibility of a partner as a beneficiary institution** | All legal entities |
| **Eligibility criteria and funding (Legal/administrative/financial conditions)** | ***Research Categories eligible for funding***<br>The aided part of the research should completely fall within one or more of the following categories: industrial research, experimental development and feasibility studies (COMMISSION REGULATION (EU) No 651/2014 article 25).<br>***Eligible applicants***<br>GSRT potentially supports all private and public legal entities namely: private enterprises (such as SMEs, large-companies etc), research organizations, higher education institutions, and other public organizations with R&D activities). **Individuals** |

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| | **<u>are not eligible under this scheme.</u>**<br><br>***Eligible costs***<br>(a) personnel costs: researchers, technicians and other supporting staff to the extent employed on the project.<br>(b) costs on fixed assets i.e. b1) costs of instruments and equipment to the extent and for the period used for the project. Where such instruments and equipment are not used for their full life for the project, only the depreciation costs corresponding to the life of the project, as calculated on the basis of generally accepted accounting principles are considered as eligible and b2) costs for buildings and land, to the extent and for the duration period used for the project. With regard to buildings, only the depreciation costs corresponding to the life of the project, as calculated on the basis of generally accepted accounting principles are considered as eligible. For land, costs of commercial transfer or actually incurred capital costs are eligible.<br>(c) costs of contractual research, knowledge and patents bought or licensed from outside sources at arm's length conditions, as well as costs of consultancy and equivalent services used exclusively for the project.<br>(d) additional general costs and other operating expenses, including costs of materials, supplies, travel expenses, organization of meetings, dissemination/publicity costs, audit costs, incurred directly as a result of the project implementation.<br>(e) indirect costs = flat rate 15% of gross personnel costs excluding VAT. Indirect costs are eligible for all legal entities and include costs that do not incur directly as a result of the project implementation (e. g. administrative and management costs, utility costs).<br><br>**Note**: Please bear in mind that scientific management costs are eligible under category (a) whereas administrative and financial/legal management costs fall under eligible categories (e) or (d)-audit costs only.<br><br>***Aid of intensity***<br>**Public research Institutes and Universities**: the aid intensity can reach 100% for performing non-economic activities in accordance with point 19, article 2.1.1 of the «Framework for State aid for research and development and innovation» (2014/C 198/01)).<br>**Private Sector:** (a) 50% of the eligible costs for industrial research; (b) 25% of the eligible costs for experimental development; (c) 50% of the eligible costs for feasibility studies. |

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| | - The aid intensities for industrial research and experimental development may be increased up to a maximum aid intensity of 80% of the eligible costs as follows:<br>(a) by 10 percentage points for medium-sized enterprises and by 20 percentage points for small enterprises;<br>(b) by 15 percentage points if one of the following conditions is fulfilled:<br>**(i)** the project involves effective collaboration:<br>— between undertakings among which at least one is an SME, or is carried out in at least two Member States, or in a Member State and in a Contracting Party of the EEA Agreement, and no single undertaking bears more than 70 % of the eligible costs, or<br>— between an undertaking and one or more research and knowledge-dissemination organisations, where the latter bear at least 10 % of the eligible costs and have the right to publish their own research results;<br>**(ii)** the results of the project are widely disseminated through conferences, publication, open access repositories, or free or open source software.<br>-The aid intensity for feasibility studies may be increased by 10 percentage points for medium-sized enterprises and by 20 percentage points for small enterprises.<br>***Project Duration***<br>The duration of a funded project must be 24-36 months. Under specific conditions it may be extended further<br>***Submission at the national level is not required at this stage.*** A national call will be published for the submission of the approved, at the transnational level, proposals only.<br>This Annex is for general guidance only. More detailed information (e.g. eligibility criteria, funding rates) can be found at the latest national guide available at the following link:<br>http://www.gsrt.gr/central.aspx?sId=108l334l1106l646l444510&ollD=777&neID=673&neTa=12_20503_1&nclD=0&neHC=0&tbid=0&lrlD=2&oldUllD=al777l0l119l428l1089l0l3&actionID=load |
| **Submission of the proposal at the national level** | After the selection of the projects at European level a national call will be launched for the submission of the approved proposals at national level in order to be funded by GSRT. |
| **Submission of financial and scientific reports at the national level** | Yes, in two phases (interim and final report ) |

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| **Further guidance** | All applicants are strongly encouraged to contact the NCP prior to submission. |

**HUNGARY, NKFIH**

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| **Country** | Hungary |
| **Funding organisation** | National Research, Development and Innovation Office (NKFIH)<br>http://nkfih.gov.hu/; http://nkfih.gov.hu/english/ |
| **National contact person** | National Research, Development and Innovation Office,<br>Kéthly Anna tér 1, Budapest, H-1077, Hungary<br>Dr. Előd Nemerkényi<br>Assistant of International Affairs, Department of Research and Development, NKFIH<br>Phone: +36 1 8963987<br>E-mail: elod.nemerkenyi@nkfih.gov.hu<br>Dr. Gábor Tóth<br>head of department, Department of Research and Development, NKFIH<br>Phone: +36 1 8961727<br>E-mail: gabor.toth@nkfih.gov.hu |
| **Funding commitment** | 200.000€ |
| **Anticipated number of fundable research partners** | 1-2 |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution** | Universities, academic and public research institutions, public health institutions (university or non-university hospitals and clinics) |
| **Eligibility of costs, types and their caps** | 100% of eligible research-related costs for basic (exploratory) research. The maximum indirect costs (overhead) are 20 % of direct costs. The maximum funding of 150.000 € per project includes indirect costs.<br>Detailed list of eligible costs (basically personnel, consumables, animals, equipment, travel, subcontracts, overhead) and guidelines to prepare the budget plan can be found in the call text and guideline of NN_18 call (or the latest relevant NN call for transnational cooperative projects in the year of proposal submission). |
| **Eligibility of principal investigator or other research team member** | The principal investigator must hold a Ph.D., D.Sc., or equivalent degree and be employed by an eligible institution. One researcher can be a principal investigator in maximum two research projects funded by NKFIH (including running OTKA/NKFIH projects). Researchers cannot participate in more than one proposal submitted to the same joint transnational call. |

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| **Submission of the proposal at the national level** | Prior to submission, researchers will provide information to NKFIH, including applicant name and affiliation, as well as an estimation of the requested budget.<br>Upon the EJP RD funding decision an NN-type proposal should be formally submitted to NKFIH in its electronic proposal system (EPR). This is necessary for managing the project by NKFIH. |
| **Submission of financial and scientific reports at the national level** | Required annually |

**ISRAEL, CSO-MOH**

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| **Country** | Israel |
| **Funding organisation** | Chief Scientist office, Ministry of Health (CSO/MOH)<br>http://www.health.gov.il/ |
| **National contact person** | Dr. Irit Allon<br>Phone: +972-2-5082167<br>E-mail: Irit.allon@moh.health.gov.il |
| **Funding commitment** | Up to 300.000 euros |
| **Anticipated number of fundable research partners** | Up to 2 |
| **Maximum funding per grant awarded to a partner** | Up to 140000 euros, additional 20000 euros for project coordination |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution** | **Position in a university, research center or hospital. Research authority must approve position prior to submission.** |
| **Eligibility of principal investigator or other research team member** | PI should hold a Ph.D., M.D., D.M.D., D. Sc or equivalent degree and employed by an eligible institution. Research will not be funded simultaneously by CSO-MOH on more than one grant (ERA-NET or national). Researchers can not apply for more than one grant from any ERA-NET funded by CSO-MOH or submit more than one proposal for any programme. |
| **Eligibility of costs, types and their caps** | Materials and consumables; Travel (up to 10%); No salaries for applicants; No heavy equipment, Institutional overhead 10% |
| **Submission of the proposal at the national level** | Prior to submission, researchers will submit to CSO-MOH an ILabstract approved by their research authority including budget distribution. The ILabstract will contain the project title, acronym and partners and will elaborate the part of the Israeli group in the project. ILabstract is not the abstract of the entire project. No submission of ILabstract can result in declaration of the consortium as ineligible. |
| **Submission of other information at the national level** | If the application involves human or animal experiments, bioethics approvals must be submitted with the application or up to 4 months later. |

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| **Submission of financial and scientific reports at the national level** | Required annually. |
| **Further guidance** | Please see detailed instructions at www.health.gov.il/research-fund |

**IRELAND, HRB**

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| **Country / Region** | Ireland |
| **Funding organisation** | Health Research Board |
| **National contact person** | Dr Annalisa Montesanti<br>Amontesanti@hrb.ie<br>+353-1-2345208 |
| **Funding commitment** | Up to €370,000 in total |
| **Anticipated number of fundable research partners** | Up to two |
| **Maximum funding per grant awarded to a partner** | €370,000 if two partners from Ireland they must split the costs |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution** | Working in a HRB approved Host Institution http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/ |
| **Eligibility of principal investigator or other research team member** | The Lead Applicant must:<br>• Hold a post (permanent or a contract that covers the duration of the award) in a recognised research institution in the Republic of Ireland (the "Host Institution") as an independent investigator, **or**<br>• Be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible, **or**<br>• Be an individual who will be recognised by the Host Institution upon receipt of the HRB ILP award as a contract researcher as defined above. The Lead applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.<br>The Lead Applicant will:<br>i. Show appropriate evidence of expertise matched to the nature and context of the project;<br>ii. Show evidence of achievement as an independent researcher in their chosen research field by:<br>a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs such as published |

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| | book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field.<br>b) Demonstrating record of independence by showing that they have secured at least <u>one</u> peer-reviewed research grant for a research project/s, as either the lead applicant or a co-applicant. Funding received for travel to seminars/conferences and/or small personal bursaries <u>will not</u> be considered in this regard.<br>iii. Show evidence that they possess the capability and authority to mentor, manage and supervise less experienced researchers and to manage relationships with co-applicants, collaborators and the host institution. |
| **Eligibility of costs, types and their caps** | Funding available is inclusive of overheads and pension contributions<br>• Salary related costs<br>• small equipment costs<br>• travel<br>• direct running costs<br>• dissemination and knowledge exchange costs<br>• overheads<br>in accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for **laboratory or clinically-based research** and 25% of Total Direct Modified Costs if **desk-based research.** |
| **Submission of other information at the national level** | Participants from institutions in Ireland in consortia are asked to provide a copy of the submitted proposal to the HRB following submission to the European Portal. In addition applicants will be requested to **clarify deliverables and supplementary budget information** for the partner(s) from Ireland. This will expedite contract negotiations with HRB in the case of successful consortia with applicants from Ireland. A template requesting this further information required from applicants from Ireland will be provided by the HRB. |
| **Submission of financial and scientific reports at the national level** | Annually |
| **Further guidance** | Proposals from Irish institutions that include the following **<u>are not</u>** eligible for funding<br>1. Human Embryonic Stem Cell Research<br>2. Natural history studies and patient registries (also for clinical trial readiness) only with no research question. 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; |

**ITALY, MoH-IT**

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| **Country** | Italy |
| **Funding organisation** | Ministry of Health (Ministero della Salute)<br>www.salute.gov.it |
| **National contact person** | Dr.Giselda Scalera<br>phone: +39 065994 2596<br>Head Office 5 (Health Research IRCCS), Directorate General for Research and Innovation in Healthcare<br>Ministry of Health, Viale Giorgio Ribotta, 5 -00144 Rome, Italy<br><br>g.scalera@sanita.it; research.EU.dgric@sanita.it |
| **National programme** | Framework National Programme "IRCCS Health Research" of the Ministry of Health. |
| **Funding commitment** | About 2 Mio Euro |
| **Anticipated number of fundable project partners** | 8-12 |
| **Maximum funding per grant awarded to a project partner** | ~ 0.25 M€ |
| **Eligibility of project duration** | Max 3 years |
| **Eligibility of a partner as a beneficiary institution** | Scientific Institutes for Research, Hospitalization and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico pubblici e privati, IRCCS). |
| **Eligibility of principal investigator or other research team member** | The simultaneous participation in proposals submitted to different transnational research calls, funded by the Ministero della Salute, is not allowed to Italian Principal Investigators or other research team members.<br>In order to expedite the eligibility check process, the Ministry of Health will grant an eligibility clearance to the applicants prior to the submission of the proposals. **To this end, it is mandatory that the applicants fill out and return a pre-eligibility check form through IRCCS Scientific Directorate using WFR System before submitting their proposals to the Joint Call Secretariat. It is strongly recommended that the form, completed and duly signed, is returned at least 10 working days before the proposal submission deadline.** Applicants will be sent a written notification of their eligibility status. |

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| **Eligibility of costs, types and their caps** | Only costs generated during the lifetime of the project can be eligible. Personnel (only ad hoc contracts/consultants/fellowship, max 50% of the requested fund); travel costs and subsistence allowances (max 10% of the requested fund); equipment (rent/leasing only), consumables (no limit), dissemination of results (publications, meetings/workshops etc.- max 1% of the requested fund); data handling and analysis (no limit); overhead (maximum 10% of the requested fund). (All according to national regulations). Travel expenses and subsistence allowances associated with training activities only linked to the project. |
| **Submission of other information at the national level** | After the joint EJP RD2019 peer review has been completed and the final (scientific) ranking list has been performed and endorsed by the Call Steering Committee, the Ministry of Health will invite the principal investigators of the projects approved for funding to enter the formal national negotiations (according to national regulations). The funding of this projects are under the Ricerca Corrente IRCCS rules. |
| **Submission of financial and scientific reports at the national level** | Submission of annual scientific and financial reports at the national level could be required according to the rules of the Ministry of Health Ricerca Corrente IRCCS. |
| **Further guidance** | Further information on the rules of the Ministry of Health can be found at www.salute.gov.it, on the website page dedicated to the yearly national calls (Bando ricerca finalizzata e giovani Ricercatori and Riecrac Corrente), or requested to the national contact persons. |

**ITALY, MIUR**

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| **Country** | Italy |
| **Funding organisation** | Ministry for Education, Universities and Research (MIUR) |
| **National contact person** | Aldo Covello - aldo.covello@miur.it - +39 06.5849.6465<br>Valeria Cardia - valeria.cardia@miur.it - +39 06.5849.7333 |
| **National programme** | FIRST – Fund for Investments on Scientifics and Technological Research |
| **Funding commitment** | 400.000 € |
| **Anticipated number of fundable project partners** | 3 |
| **Maximum funding per grant awarded to a project partner** | The maximum funding awardable per **project** is 150.000 euro, independently from the number of partners requesting funding to MIUR |
| **Eligibility of project duration** | Up to 36 months |
| **Eligibility of a partner as a beneficiary institution** | The following entities are eligible, providing that they have stable organization in Italy: enterprises, universities, research institutions, research organizations in accordance with EU Reg. n. 651/2014 of the European Commission - June 17, 2014, Hospitals, Health care organisations, Patient associations.<br>Any participant, in order to be eligible, must comply with the eligibility criteria listed in the art. 2.4 of the “Linee guida al DM 593/2016”. |

<table>
<tr><td>Eligibility of principal investigator or other research team member</td><td>No prescriptions</td></tr>
<tr><td>Eligibility of costs, types and their caps</td><td>
All activities classifiable as Basic research, Industrial research and Experimental research are eligible for funding. Furthermore, Basic Research and Industrial research activities must be predominant with respect to Experimental research activities (in terms of costs).<br>
All costs incurred during the lifetime of the project under the following categories are eligible: Personnel, Equipment, Consulting and equivalent services, Consumables and Overheads. Overheads (“Spese generali”) shall be calculated as a percentage of the personnel costs and cannot be higher than 50% of them. Travel expenses, dissemination and coordination costs are to be included in the overheads.<br>
The amount of funding which can be granted to each beneficiary is calculated multiplying the eligible costs for the funding rate listed in the following table:
<table>
<tr><td colspan="2" rowspan="2">Applicant Typology<br>Activity typology</td><td colspan="4">Funding Rates</td></tr>
<tr><td colspan="3">Enterprises and private research bodies (which meets the requirements of research organization under EU Reg. no. 651/2014 of the Commission - June 17, 2014)</td><td>Universities, public research institutions, research organizations (public and private) in accordance with Reg. EU n. 651/2014 of the Commission - June 17, 2014)</td></tr>
<tr><td colspan="2"></td><td>Small Enterprises</td><td>Medium Enterprises</td><td>Large Enterprises</td><td></td></tr>
<tr><td>Basic Research</td><td>grant</td><td>40%</td><td>30%</td><td>20%</td><td>70%</td></tr>
<tr><td>Industrial Research</td><td>grant</td><td>40%</td><td>30%</td><td>20%</td><td>50%</td></tr>
<tr><td>Experimental</td><td>grant</td><td>30%</td><td>20%</td><td>10%</td><td>25%</td></tr>
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| | <table><tr><td>**Research**</td><td></td><td></td><td></td><td></td><td></td></tr></table><br>On request of applicants a pre-payment may be done. The amount of the pre-payment is defined in the "Avviso integrativo nazionale". The remaining part of contribute will be paid in instalments after each financial and progress reporting period. |
| **Submission of other information at the national level** | In addition to the project proposal, which shall be submitted at European level, the Italian participants are requested to submit further documentation to MIUR, through the national web platform, available at the following link: http://banditransnazionali-miur.cineca.it<br><br>**These national additional documents must be submitted by the same deadline established for the pre-proposal phase submission as defined in the international joint call. Any participant who does not submit its national documents by the deadline of the pre-proposal phase, will be considered not eligible for funding.**<br><br>Additional documents will be required at the Full proposal phase.<br><br>It is strongly recommended to contact the National Contact Persons already in early stage of project preparation. |
| **Submission of financial and scientific reports at the national level** | The admission for funding is subject to the adoption of the necessary accounting and administrative measures for the allocation of the resources.<br><br>Funded participants will be requested to submit financial and scientific reports to MIUR. |
| **Further guidance** | The criteria and provisions provided herewith are intended only for informative purposes. The complete list of criteria and provisions legally valid, which must be respected by all the Italian participants, is included in the "Avviso integrativo nazionale", published on the dedicated web page on MIUR website (http://www.ricercainternazionale.miur.it), and in the applicable Italian laws.<br><br>Applicable laws and rules:<br><br>- Decreto legge n. 83/2012<br>- Decreto Ministeriale n. 593 del 26 luglio 2016<br>- Linee guida al D.M. del 26 luglio 2016 n. 593<br>- Procedure operative per il finanziamento dei progetti internazionali ex art. 18 D.M. del 26 luglio 2016 n. 593 |

**ITALY, FRRB**

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| **Country / Region** | Italy |
| **Funding organisation** | Fondazione Regionale per la Ricerca Biomedica - Regional Foundation for Biomedical Research (FRRB) |
| **National contact person** | Fondazione Regionale per la Ricerca Biomedica<br>Via Taramelli 12,<br>20124 – Milano<br>Tel: +39 02 67650174<br><br>Miss Paola Bello<br>Mrs. Carmen De Francesco<br>Dr. Paola Larghi, PhD<br><br>Mail to: bandi@frrb.it |
| **Funding commitment** | € 1.300.000 |
| **Anticipated number of fundable research partners** | 4-6 |
| **Maximum funding per grant awarded to a partner** | € 500,000 per project |
| **Eligibility of project duration** | Max 3 years |
| **Eligibility of a partner as a beneficiary institution** | Public or Private IRCCS (Italian Scientific Institutes for Health Research and Health Care), Public Health Care Providers (ASST), Universities, Research Institutes located in the Lombardy territory.<br>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. MAXIMUM TWO PARTNERS PER PROJECT<br>Enterprises and for profit Organisation are NOT eligible |
| **Eligibility of principal investigator or other research team member** | The Principal Investigator (PI) and all members of the research group must belong to the eligible institutions. |
| **Eligibility of costs, types and their caps** | Direct costs:<br>• Personnel (for public IRCCS and ASST, ONLY temporary contracts) (max 50% of the total direct costs) |

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| | • Consumables, animals purchase, maintenance and breeding;<br>• Subcontracting (max 20% of the total direct costs)<br>• Equipment (on hire or eligible amortization rate);<br>• Travel (max 10% of the total direct costs)<br>• Publications (max 5% of the total direct costs)<br>Indirect costs:<br>• Overheads (20% flat rate calculated on direct costs – Subcontracting costs excluded from this calculation);<br>FRRB will require the submission of a financial audit certificate together with the final financial report. This cost, to be included under the "Subcontracting category" will be eligible up to a maximum of € 8.000.<br><br>Only costs generated over the lifetime of the project will be considered eligible. |
| **Submission of the proposal at the national level** | na |
| **Submission of other information at the national level** | According to internal procedures, Regional Foundation for Biomedical Research (FRRB) will grant an eligibility clearance to the potential applicants prior to the submission of the pre-proposals.<br>The eligibility check will be based on the use of dedicated forms, also available on FRRB institutional web-site to be returned by email to FRRB duly completed and signed by the Principal Investigator at least 10 working days before the pre-proposal submission deadline.<br>Only in case of NON eligibility FRRB will inform the interested PIs.<br>In addition, FRRB provides an excel sheet to be used to help applicants abide by FRRB funding rules (% - for details see below).<br>This form is for internal use only, it does not need to be sent to FRRB. |
| **Submission of financial and scientific reports at the national level** | Submission of annual scientific and financial reports will be requested to Lombardy beneficiaries |
| **Further guidance** | Administrative and financial guidelines will be provided by FRRB in due time to the contact persons of the funded organisations. |

**ITALY, RT/TuscReg**

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| **Country / Region** | Italy |
| **Funding organisation** | Tuscany Region<br>http://www.regione.toscana.it/ |
| **Regional contact person** | Donatella Tanini<br>Phone:+39 055 4383256<br><br>Teresa Vieri<br>Phone:+39 055 4383289<br><br>Email: ejprare@regione.toscana.it<br><br>Office for Legal advice, administrative support to health research<br>Directorate for citizenship right and social cohesion,<br>Tuscany Region |
| **Funding commitment** | Up to 300.000 euros |
| **Anticipated number of fundable research partners** | 2-3 |
| **Maximum funding per grant awarded to a partner** | Up to 300.000 euros |
| **Eligibility of project duration** | Up to 3 years |
| **Eligibility of a partner as a beneficiary institution** | A. Authorities of the Tuscany Health Service-SST (Local Health Authorities, University Hospitals) and the SST bodies that carry out institutional research activities (Fondazione Toscana Gabriele Monasterio and ISPRO Institute for Study, Prevention and Networking Oncology) located in the territory of Tuscany.<br>B. Universities and other research institutes located in the territory of Tuscany.<br><br>**NB**: Institutions referring to point B. are eligible only in partnership with institutions referring to point A. |
| **Eligibility of principal investigator or other research team** | The Principal Investigator must be affiliated to one of the eligible bodies |

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| **member** | |
| **Eligibility of costs, types and their caps** | Only costs generated over the lifetime of the project will be considered eligible.<br>- *Personnel* (ad hoc temporary contracts ONLY)<br>- *Consumables (no limit)*;<br>- *Equipment* (on hire/leasing or eligible amortisation rate ONLY);<br>- *Travel* (up to 10% of the requested fund) Travel expenses and subsistence allowances associated with activities only linked to the project;<br>- *Other direct costs*:<br>◦ dissemination of results (publications, organization of meetings/workshops etc.- up to 5% of the requested fund);<br>◦ data handling and analysis (no limit)<br>• subcontracting (up to 20% of the direct cost of the project)<br>- *Overheads* (Up to 10% of the direct cost of the project excepted subcontracting). |
| **Submission of the proposal at the regional level** | Yes<br>**Tuscany Region will grant an eligibility clearance to the potential applicants prior to the submission of their pre-proposals.** The eligibility check will be performed by Tuscany Region offices after receiving a dedicated form (available on Tuscany Region institutional web-site or on request to ejprare@regione.toscana.it) duly filled and signed by the Tuscan Principal Investigator. **The form should be sent to Tuscany Region (ejprare@regione.toscana.it), at least, 10 working days before the pre-proposal submission deadline.** |
| **Submission of other information at the regional level** | No |
| **Submission of financial and scientific reports at the regional level** | Yes/Submission of intermediate/final scientific and financial reports at the regional level could be required according to regional agreement |
| **Further guidance** | Financial guidelines will be published in due time on Tuscany Region's website. |

**LITHUANIA, RCL**

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| **Country / Region** | Lithuania |
| **Funding organisation** | Lietuvos mokslo taryba (LMT) / Research Council of Lithuania<br>http://www.lmt.lt |
| **National contact person** | **Dr. Živilė Ruželė**<br>**Phone:** (+370) 676 14383**, E-mail**: zivile.ruzele@lmt.lt |
| **Funding commitment** | 0.1M€ |
| **Anticipated number of fundable research partners** | 1 |
| **Maximum funding per grant awarded to a partner** | 100K€ |
| **Eligibility of project duration** | Up to 36 months |
| **Eligibility of a partner as a beneficiary institution** | Eligible for funding institutions are Lithuanian research and higher education institution which is included in the Register of Education and Research institutions and creates conditions for the implementation of the project. Eligible institutions manages the state budget funds allocated to the project following the procedures stated in the legal acts, as well as representing the project partners (if applicable 'project partner' means public or private legal entity that, together with the eligible institution, created the conditions for project implementers for the implementation of the project). Beneficiary institution, if indicated in the call for proposals, may also be the academy of sciences mentioned in the Law on Research and Higher Education of the Republic of Lithuania, or a national, state, or county public library, a state archive, a national or republican museum, a state healthcare institution. |
| **Eligibility of principal investigator or other research team member** | The proposals may be submitted by the project investigator(s) together with the beneficiary institution. A person may submit only one proposal for the same call as a principal investigator or other primary project investigator, unless indicated otherwise in the call for proposal. The principal investigator shall be employed by the beneficiary institution for the duration of the project and his work load must be at least 20 hours multiplied by the duration of the project in months. Hourly rates approved by the Chairman of the Council must be applied for the personnel costs. |
| **Eligibility of costs, types and their caps** | Only costs generated during the lifetime of the project, related to project can be eligible: personnel, travel, consumables, subcontracting, contractual research, consultancy, equipment and instruments, dissemination of results, data handling and analysis, overheads (up to 30 % from the listed direct costs - personnel, travel, consumables, subcontracting, contractual research, consultancy) |

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| **Submission of the proposal at the national level** | no |
| **Submission of financial and scientific reports at the national level** | The annual scientific report shall be submitted after the first (and the second if the project is implemented for longer than 24 months) year of the project implementation. The interim scientific report shall be submitted in the middle of the project implementation period. An interim scientific report shall not be submitted if the project is implemented for a period shorter than 18 months. The final scientific (dissemination) report shall be submitted upon the completion of the project. |
| **Further guidance** | All eligibility rules and criteria can be found in the https://e-tar.lt/portal/en/legalAct/ec3460a004fe11e8b3e7ba9cffd043b1/hRcpszNzmV |

**LUXEMBOURG, FNR**

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| **Country / Region** | Luxembourg |
| **Funding organisation** | Luxembourg National Research Fund - FNR<br>www.fnr.lu |
| **National contact person** | Dr. Sean Sapcariu<br>2, avenue de l'Université<br>L-4365 Esch-sur-Alzette<br>Telephone: +352 261925-33<br>Email: sean.sapcariu@fnr.lu |
| **Funding commitment** | 0,30 M€ |
| **Anticipated number of fundable research partners** | 2 research partners |
| **Maximum funding per grant awarded to a partner** | The maximum funding cannot be larger than the funding commitment of the country |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | Beneficiary institutions must be accredited by the Ministry in charge of public sector research. See website for details (https://www.fnr.lu/fnr-beneficiaries/). |
| **Eligibility of principal investigator or other research team member** | Principle Investigators must follow the following guidelines:<br>(http://storage.fnr.lu/index.php/s/g4OPmRwEYhYwRkZ/download)<br>1. He/she must have a proper employment contract with the eligible beneficiary institution at the starting date of the project.<br>2. The employment contract must last for the full duration of the research project.<br>3. He/she must be an experienced researcher who holds a doctoral degree at the date of the submission of the proposal. |
| **Additional eligibility criteria** | Luxembourgish principal investigators cannot be involved in more than 2 proposals submitted to this call. |
| **Eligibility of costs, types and their caps** | |

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| **Submission of the proposal at the national level** | All joint applications must also be submitted to the FNR by the Luxembourg-based scientist, along with the FNR INTER documents. This must be done no later than 5 days after the lead agency deadline, and must be done via the FNR Online Grant Management System. |
| **Submission of other information at the national level** | The FNR requires the following other documents to be submitted to the FNR's grant management system :<br>- INTER Budget form<br>INTER Project plan, including Gantt Chart |
| **Submission of financial and scientific reports at the national level** | The FNR expects annual reports and a final report for all projects funded through this call. |
| **Further guidance** | https://www.fnr.lu/fnr-international-cooperation/ |

**PORTUGAL, FCT**

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| **Country / Region** | Portugal |
| **Funding organisation** | Foundation for Science and Technology |
| **National contact person** | **Anabela Lopes Isidro, anabela.isidro@fct.pt; +351 21 391 1552; Rita Cavaleiro, Rita.Cavaleiro @fct.pt, +351 21 3911541** |
| **Funding commitment** | 0.3 Mio. € |
| **Anticipated number of fundable research partners** | 1-2 |
| **Maximum funding per grant awarded to a partner** | 3 years |
| **Eligibility of project duration** | **0.250 M€** for a proposal with **Portuguese coordination**;<br>**0.150 M€** for a proposal with **Portuguese participation** |
| **Eligibility of a partner as a beneficiary institution** | Higher education institutions, their institutes and R&D centres; Associate laboratories; State laboratories; Private non-profit institutes whose main objective is to carry out S&T activities; Companies provided that they participate in projects headed by public or private non-profit institutions; Other public and private non-profit institutions which carry out or participate in scientific research activities. |
| **Eligibility of principal investigator or other research team member** | |
| **Eligibility of costs, types and their caps** | Equipment, consumables, human resources, networks & consortium funding, mobility and overheads. |
| **Submission of the proposal at the national level** | Yes. Only for proposals which are selected for funding. |
| **Submission of other information at the national level** | Portuguese teams need to send a statement of commitment to the National Contact Point from FCT, duly signed, dated and stamped by the Head of the Portuguese applicant organisation and by the Principal Investigator, up to 10 days after application submission |
| **Submission of financial and scientific reports at** | Yes. Submission of financial and annual scientific reports at national level is required according with the rules of FCT. |

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| **the national level** | |
| **Further guidance** | https://www.fct.pt/apoios/projectos/regulamentofundosnacionais.phtml.pt |

**POLAND, NCBR**

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| **Country** | Poland |
| **Funding organisation** | National Centre for Research and Development (NCBR)<br>(http://www.ncbr.gov.pl/) |
| **National contact person** | Marcin Chmielewski, Department for International Cooperation, Nowogrodzka Str. 47a, 00-695 Warsaw, Poland,<br>phone: +48 22 39 07 109, e-mail: marcin.chmielewski@ncbr.gov.pl |
| **Funding commitment** | 600 000 EUR |
| **Anticipated number of fundable research groups** | 1-3 |
| **Maximum funding per grant awarded to a project partner** | Up to 200 000 EUR per project, regardless of the number of Polish research groups in the project consortium. |
| **Eligible institutions** | Following entities are eligible to apply:<br>• Micro, Small, Medium and Large Enterprise<br>• Research organizations<br>The organization must conduct its business, R&D or any other activity on the territory of the Republic of Poland, confirmed by an entry into the relevant register, and provide a sufficient guarantee of reliable disbursement of public funds. |
| **Additional eligibility criteria** | All proposals must be aligned with National regulations, inter alia:<br>• The Act of 20 July 2018 on the Law of Higher Education and Science, published in Journal of Laws item 1668, 2018;<br>• The Act of 30 April 2010 on the National Centre for Research and Development, published in Journal of Laws item 1447, 2017 (with amendments);<br>• The Regulation of the Minister of Science and Higher Education of 25 February 2015 on criteria and rules on granting state aid and "de minimis" aid by the National Centre for Research and Development, published in Journal of Laws item 299, 2015. |
| **Eligibility of costs, types and their caps** | The eligible costs shall be the following:<br>1. personnel costs (researchers, technicians and other supporting staff to the extent employed on the research project);<br>2. costs of instruments and equipment, technical knowledge and patents to the extent and for the period used for the research project; if such instruments and equipment are not used for their full life for the research project, only the depreciation costs corresponding to the life of the research project, as calculated on the basis of good accounting practice, shall be considered eligible; |

<table>
<tr><td></td><td>3. costs for buildings and land, to the extent and for the duration used for the research project; with regard to buildings, only the depreciation costs corresponding to the life of the research project, as calculated on the basis of good accounting practice shall be considered eligible; for land, costs of commercial transfer or actually incurred capital costs shall be eligible;<br>4. cost of contractual research, costs of consultancy and equivalent services used exclusively for the research activity; this cost type cannot account for more than 70% of all eligible costs of a project; the subcontracting can be obtained from consortium partner only in justified case, this need will be verified by a national experts panel;<br>5. other operating costs including costs of materials, supplies and similar products incurred directly as a result of the research activity;<br>6. additional overheads incurred indirectly as a result of the research project; that costs cannot account for more than 25% of eligible project costs and are counted as a multiplication by percentage given above and the rest of direct costs, excluding subcontracting (4); It means 6=(1+2+3+5)*25%.</td></tr>
<tr><td>Submission of the proposal at the national level</td><td>Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established</td></tr>
<tr><td>National funding rates</td><td>Funding quota of Polish participants can be up to 100% for universities or research organisations. In the case of enterprises,<br>funding quota will be decided on a case-by-case basis depending on the size of the company, type of research/development,<br>risk associated with the research activities and commercial perspective of exploitation, under the Regulation of the Minister of Science and Higher Education of 25 February 2015 on criteria and rules on granting state aid and “de minimis” aid by the National Centre for Research and Development, published in Journal of Laws item 299, 2015.
<table>
<tr><td></td><td>Large Enterprises</td><td>Medium Enterprises</td><td>Small Enterprises</td><td>Universities and research organizations</td></tr>
<tr><td>Fundamental/ Basic Research</td><td>Not eligible</td><td>Not eligible</td><td>Not eligible</td><td>Not eligible</td></tr>
<tr><td>Industrial/Applied Research</td><td>Up to<br>50+15<br>(max 65 %)</td><td>Up to<br>50+10+15<br>(max 75 %)</td><td>Up to<br>50+20+15<br>(max 80 %)</td><td>Up to<br>100 %</td></tr>
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| Experimental development | Up to 25+15 (max 40 %) | Up to 25+10+15 (max 50 %) | Up to 25+20+15 (max 60 %) | Up to 100 % |

Only Industrial/Applied Research and Experimental Development will be funded. Other type of activities (e.g. coordination, dissemination, management) is not eligible for funding as separate research tasks in the project schedule.

**SLOVAKIA, SAS**

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| **Country** | Slovakia |
| **Funding organisation** | Slovak Academy of Sciences (SAS): https://www.sav.sk/?&lang_change=en |
| **National contact person** | Zuzana Cernakova, PhD.<br>International Cooperation Dpt., SAS<br>Phone: +421257510118<br>Email: cernakova@up.upsav.sk<br><br>Jan Barancik, PhD.<br>Head, International Cooperation Dpt.<br>Phone: +421257510137<br>Email: barancik@up.upsav.sk |
| **Funding commitment** | 120.000 € |
| **Anticipated number of fundable research partners** | 1 |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | Only research Institutes of Slovak Academy of Sciences are eligible organisations for funding (up to 100%). Applicants from other Slovak R&D centres (universities and/or other organisations from Slovakia) have to cover the project costs from their own sources (Letter of Commitment). In addition to this, the teams outside of SAS can be consortium members but not the coordinator of the consortium.<br>Funding of projects is regulated by the SAS Financial Rules for awarding grants for research projects approved by the SAS Presidium on 2 February 2012, updated on 1 July 2018. |

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| **Eligibility of principal investigator or other research team member** | Eligibility of principal investigator or other research team member - Each researcher of the core research team of a project consortium Slovak partner (other than the Principal Investigator) must have a job contract with or a fellowship with such a Slovak project partner, lasting until the end of the project or beyond. The principal Investigator of the research team of a project consortium Slovak partner must be a senior researcher having a job contract with such a project partner, lasting until the end of the granted project or beyond. |
| **Eligibility of costs, types and their caps** | 1. Eligible direct costs<br>1.1 Personal costs<br>- must accurately reflect the work on the project<br>- may be used only to cover the costs (including health and social insurance) related to work agreements performed outside of employment<br>- maximum of 15 % of all direct costs ( ERA.Nets) or<br>- maximum of 30% of all direct costs, if Slovak team is a coordinator of consortium (ERA.Nets)<br>1.2 Material costs and expenditures<br>a. Consumables: minor equipment and instruments, small-scale office and laboratory material (no basic equipment of the workplace; essential computer equipment is exception)<br>b. costs and expenditures for services directly related to the project: contracts, consultations, publication of project results, conference fees<br>c. travel costs and living expenses: limits for travel costs and daily subsistence allowance vary depending on destination country<br>(pursuant to Slovak Act. 283/2002 Col. Of Laws on travel reimbursement)<br>d. capital expenditures: to a maximum of 40% of all direct costs<br>2. Eligible indirect Costs<br>- administration, energy and infrastructure<br>- maximum of 20% of all direct costs |
| **Submission of the proposal at the national level** | National phase – Submission of the proposal at the national level will be carried out once the international evaluation and the ranking list have been performed and endorsed by the Joint Call Steering Committee (CSC) and the Slovak project partner has been informed by the project consortium coordinator and invited by SAS to submit the proposal to it (Formular MVTS). The Presidium of SAS makes the final decision concerning the approval of funding (according to internal rules of SAS) |
| **Submission of financial and scientific reports at the national level** | Yearly financial reports and a scientific report at the end of the project. |

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| **Further guidance** | Further guidance: www.sav.sk; Act No. 133 Act of 19 February 2002 on the Slovak Academy of Sciences; Financial rules for awarding SAS grants for research projects in the framework of ERA.Net Programme for research institutes of SAS; Principles of allocation of funds for the institutes of SAS to support projects in the field of international scientific cooperation<br>For more information please contact the NCP. |

**SPAIN, ISCIII**

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| **Funding organisation** | National Institute of Health Carlos III (ISCIII)<br>www.isciii.es |
| **National Funding Programme** | Acción Estratégica en Salud (AES 2019)<br>http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/fd-financiacion/convocatorias-ayudas-accion-estrategica-salud.shtml |
| **National Contact Point** | Maria Druet<br>Email: mdruet@isciii.es<br>Tel: (+34) 9182 22530 |
| **Initial funding pre-commitment** | 500.000€<br>3-5 projects tentatively envisaged to be funded. |
| **Maximum funding per awarded Spanish project partner** | • Up to 100.000 € per partner (overheads included)<br>• Up to 175.000 € per coordinator (overheads included) |
| **Eligible institutions** | See table below |

| | Coordinator | Partner |
|---|---|---|
| • Hospitals, primary health care or public health settings of the Spanish National Health System (SNS) [1],<br>• Academia or Research Centers[2]<br>• Accredited Health Research Institutes (*Institutos de Investigación Sanitaria acreditados*, IIS)[3] | YES | YES |
| • CIBER or CIBERNED | YES | NO |

[1] These institutions may manage research via a foundation regulated in accordance to the Spanish Act 50/2002, of December 26th (a copy of the foundation's statutes may be submitted)

[2] Please note that these entities can only participate if they apply together with Hospitals, primary health care or public health settings of the Spanish National Health System (SNS), Accredited Health Research Institutes (Institutos de Investigación *Sanitaria* acreditados, IIS) CIBER or CIBERNED in the same proposal. It is not allowed to apply independently, thus there must be two beneficiary Spanish institutions in the same proposal.

[3] Accredited according to the RD 339/2004, of February 27th or RD 279/2016 of June 24th. (These institutions may manage researc via a foundation regulated according to the Spanish Act 50/ 2002, of December 26th)
http://www.eng.isciii.es/ISCIII/es/contenidos/fd-investigacion/fd-institutos-investigacion-sanitaria/listado-de-iis-acreditados

<table>
<tr><td>Additional eligibility criteria</td><td>NOTE:<ul><li>Only one partner per beneficiary institution may be funded within the same proposal</li><li>SMEs and other private companies are encouraged to participate at their own cost, or as subcontractors.</li><li>Only one proposal per partner is allowed</li><li>Researchers with projects granted in an E-RARE call ongoing in 2020 are not eligible for funding by the current call except if the applicant is the coordinator.</li><li>There is no other incompatibility with AES 2019.</li><li>Incompatibilities with any other call are subject to the specification of the relevant call.</li></ul></td></tr>
<tr><td>Eligibility of PI and team members</td><td><ul><li>The Principal Investigator (PI) and all members of the research group must belong to the eligible institution or be affiliated to CIBER, CIBERNED or an IIS.</li><li>Only one proposal per Principal Investigator is allowed. Additional submissions will be declined</li><li>Researchers with an ongoing E-Rare project in 2019 cannot apply to the current call except if the researcher applies as coordinator</li></ul>Excluded personnel as Principal Investigator (PI):<ul><li>Those undergoing a postgraduate training in Health Specialization (MIR, FIR, QIR, BIR, PIR)</li><li>Those undergoing research training (e.g. PhD students, or “Río Hortega” contracts)</li><li>Researchers contracted by a RETIC or a CONSOLIDER</li><li>Those undergoing postdoctoral training (e.g. “Sara Borrell“ or “Juan de la Cierva” contracts)</li></ul></td></tr>
<tr><td>Eligible costs</td><td>
<table>
<tr><th></th><th>Coordinator</th><th>Partner</th></tr>
<tr><td><u>Personnel</u><br>Up to 3-year, full-time or part-time contracts (only for additional personnel)<br>Excluded: Students and fellowships .</td><td>Total cost per annual full-time contract:<ul><li>Technical expert, higher degree: 29.500 €</li><li>Technical expert, medium degree: 24.500 €</li><li>Technical expert, FP II: 20.500 €</li></ul></td><td>Not eligible</td></tr>
<tr><td>Small Equipment</td><td>Up to 40.000 €</td><td>Up to 20.000</td></tr>
<tr><td>Travel and Allowance</td><td>Up to 9.000 €</td><td>Up to 4.500</td></tr>
<tr><td>Consumables</td><td colspan="2">Up to 100% of direct cost</td></tr>
<tr><td>Subcontracting and other services</td><td colspan="2">Up to 50% of total cost<br>Private (bio)companies and SMEs included</td></tr>
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| | Overheads: Up to 21% of direct cost |
| **National phase** | • National applications will be required by ISCIII. Spanish Applicants should periodically check in the web page of ISCIII if they are qualified. ISCIII may not send invitations to the mandatory national phase.<br>• No double funding for the same concepts is allowed.<br>• Due to administrative and legal regulations, the National Institute of Health Carlos III declares September 23rd, 2019, as deadline for the final decision by all relevant funding agencies on a fundable project consortium which includes a Spanish partners to be funded by ISCIII. Any concerned applicant in a proposal for which no final decision in full has been made by such a deadline, will be declared not fundable by ISCIII. |
| **Mandatory acknowledgement** | Any publication, database, product or event protected with IPR or not, resulting from the granted project must acknowledge *"Grant no. XX ,by ISCIII thorough AES 2019 and within the EJP RD Cofund framework"* even after the end of the project |
| **Requirements on data and repositories** | • Researchers funded by ISCIII must make public the human genomic data, as well as relevant data (phenotype and exposition data) generated inside the funded project and will use open access repositories. Researchers must also make public all the necessary information for the interpretation of these genomic data, including lab protocols, data instruments survey tools. Regarding genomic data it is understood: association of complete genomes (GWAS), matrixes of de polymorphism of a single nucleotide (SNP) and sequence of genome, and transcriptomic, metagenomic, epigenomic and gene expression data. The researchers whose projects are funded by ISCIII are recommended to store their scientific data at the" ELIXIR Core Data Resources" or if non European repositories or data bases they must be certified by ELIXIR or the US National Center for Biotechnology Information (NCBI).<br><br>• ISCIII may no fund any project that may require a repository and/or a database without its plan ensuring sustainability and decommissioning after funding end |

**SWITZERLAND, SNSF**

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| **Country** | Switzerland |
| **Funding organisation** | Swiss National Science Foundation: www.snf.ch |
| **National contact person** | Christoph Meier<br>Email: christoph.meier@snf.ch<br>Tel: (+41) 31 308 23 62 |
| **Funding commitment** | 1 Mio Swiss Francs (equivalent to approx. 0.85 Mio €) |
| **Anticipated number of fundable research partners** | 3-4, each Swiss applicants may be partner in only one EJP RD JTC 2019 proposal (Art.7.3, SNSF Regulations on Project Funding). |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | n.a. |
| **Eligibility of principal investigator or other research team member** | Where not otherwise specified, the SNSF Funding Regulations, in particular, the SNSF Regulations on Project Funding apply:<br>• SNSF Funding Regulations<br>• General Implementation Regulations for the Funding Regulations<br>• SNSF Regulations on Project Funding<br>All Swiss partners in EJP RD projects must meet the eligible criteria for applicants in SNSF Project Funding. Swiss partners who have not previously obtained a project grant from division Biology and Medicine must contact the national contact point to confirm their eligibility as an applicant prior to submitting a proposal to the EJP RD JTC 2019.<br>Foreign members of the international consortia applying for funding through the EJP RD JTC 2019 cannot be declared as "project partners" in the sense of Art. 11.2 of the SNSF Funding Regulations and may not receive any funding through the Swiss partner.<br>Article 17 of the SNSF Funding Regulations applies, i.e. EJP RD proposals with overlapping funding periods with ongoing SNSF grants are only allowed if the two research projects are thematically distinct and pursue different goals.<br>Grants given to Swiss partners will be managed according to SNSF Funding Regulations. |

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| | Please note: The SNSF exclusively funds research conducted for non-commercial purposes. Pursuant to the Swiss Research and Innovation Promotion Act (RIPA) and the legal framework of the SNSF, no research grants are awarded if the relevant research is conducted for directly commercial purposes or if the persons involved in the research work do not enjoy full academic freedom. |
| **Eligibility of costs, types and their caps** | For eligible costs, please refer to the SNSF Regulations on Project Funding (Art. 8). Please note: overhead contributions cannot be applied for. Overhead is calculated on the basis of the total SNSF research funding given to a particular institution and is paid separately and in retrospect. |
| **Submission of the proposal at the national level** | Swiss partners are required to submit the pre-proposal and the full proposal to www.mySNF.ch together with the submission of the respective proposals to the EJP RD Joint Call Secretariat. For this, Swiss partners need a personal account on www.mySNF.ch. The SNSF office may ask Swiss partners to submit supplemental information as needed. |
| **Submission of financial and scientific reports at the national level** | Yearly financial reports for the use of SNSF funds and a scientific report at the end of the project. |
| **Further guidance** | Consortia including Swiss partners must submit a data management plan (DMP) which complies with the SNSF policy on open research data. |

**SWEDEN, SRC**

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| **Country** | Sweden |
| **Funding organisation** | Swedish Research Council: www.vr.se |
| **National contact person** | Malin Eklund, malin.eklund@vr.se, +46 (0)76 526 72 56 |
| **Funding commitment** | 15 million SEK (approximately 1.5 Mio €) |
| **Maximum funding for Swedish participation** | For Swedish participation in a consortium, the maximum amount that may be applied for is 450 000 EUR or 600 000 EUR if the consortia contains two Swedish partners. A consortium may include more than one Swedish partner, but the maximum amount for all Swedish participants together may not exceed the amounts given above. |
| **Anticipated number of fundable research partners** | 3-5 |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | Researchers from universities and university colleges (academia), public research institutes, hospitals (for details follow the link below - approved administrating organisations). |
| **Eligibility of principal investigator or other research team member** | Approved administrating organisations: https://www.vr.se/inenglish/researchfunding/applyforgrants/conditionsforapplicationsandgrants/approvedadministratingorganisations.4.4b1cd22413cb479b80537a9.html |
| **Eligibility of costs, types and their caps** | The grant can be used to cover any type of project-related costs, for example salaries (including salary of PI, corresponding to the level of activity in the project), travel (including visits to, and stays at, research facilities), publication costs, minor equipment and depreciations, etc. The grant may not be used for scholarships. (for details follow the link below covering general grant conditions).<br><br>General conditions for grant applications: https://www.vr.se/english/calls-and-decisions/grant-terms-and-conditions/general-grant-tc.html |

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| **Submission of the proposal at the national level** | As a Principal Investigator (PI) of a Swedish partner in a consortium you shall in parallel register corresponding applications (pre-proposal and full proposal) electronically in Prisma, which is the application system used by the Swedish Research Council. For further details see www.vr.se and the instructions for EJP-RD call for proposals on vr.se, |
| **Submission of financial and scientific reports at the national level** | General conditions for grant applications:<br>https://www.vr.se/english/calls-and-decisions/grant-terms-and-conditions/general-grant-tc.html |
| **Further guidance** | General conditions for grant applications:<br>https://www.vr.se/english/calls-and-decisions/grant-terms-and-conditions/general-grant-tc.html<br>and www.vr.se |

**SWEDEN, VINNOVA**

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| **Country** | Sweden |
| **Funding organisation** | Vinnova, Sweden´s innovation agency www.vinnova.se |
| **National contact person** | Frida Lundmark, frida.lundmark@vinnova.se +46-76-527 12 97 |
| **Funding commitment** | 9 million SEK (approximately 1 million €) |
| **Maximum funding for Swedish participation** | For Swedish participation in a consortium, the maximum amount that may be applied for is 450 000 EUR or 600 000 EUR if the consortia contains two Swedish partners. A consortium may include more than one Swedish partner, but the maximum amount for all Swedish participants together may not exceed the amounts given above. |
| **Anticipated number of fundable research partners** | 3-5 |
| **Eligibility of project duration** | 3 years |
| **Eligibility of a partner as a beneficiary institution** | Researchers from universities and university colleges (academia), public research institutes, hospitals (for details follow the link below - approved administrating organisations) as well as industrial partners. |
| **Eligibility of principal investigator or other research team member** | Approved administrating organisations: |
| **Eligibility of costs, types and their caps** | Eligible costs for companies can be funded up to the levels presented in table 1 in this document: https://www.vinnova.se/contentassets/03d3665164c14b46a854b76bfb3c6055/stodnivaer-statligt-stod.pdf. Projects should be applicable under the categories industrial research or experimental development.<br><br>Public sector, academia and research institutes may receive funding of up to 100% of eligible costs provided that the project is part of their non-economic activities.<br><br>*Economic activities mean offering goods or services on a market. If a participant from academia, research institutes,* |

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| | *health care or non-profit organisations conducts both economic and non-economic activities the costs and funding for the two types of activities are required to be kept separate. If the accounting is not separate, the organisation will be considered to be a company.*<br>https://www.vinnova.se/globalassets/dokument/general-terms-and-conditions-2018.pdf |
| **Submission of the proposal at the national level** | As a Principal Investigator (PI) of a Swedish partner in a consortium you shall in parallel register corresponding applications (pre-proposal and full proposal) electronically in the eService portal "Intressentportalen", which is the application system used by Vinnova. For further details, see www.vinnova.se and the instructions for EJP-RD call for proposals on www.vinnova.se. |
| **Submission of financial and scientific reports at the national level** | General conditions for grant applications:<br>https://www.vinnova.se/globalassets/dokument/general-terms-and-conditions-2018.pdf |
| **Further guidance** | General conditions for grant applications:<br>https://www.vinnova.se/globalassets/dokument/general-terms-and-conditions-2018.pdf<br>www.vinnova.se |

**THE NETHERLANDS, ZonMw**

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| **Country** | The Netherlands |
| **Funding organisation** | ZonMw, The Netherlands organisation for health research and development, PO Box 93245, 2509 AE The Netherlands, http://www.zonmw.nl |
| **National contact persons** | Dutch applicants are strongly advised to contact<br><br>Dr. Harald Moonen<br>Phone: +31-(0)70 349 53 49<br>E-mail: moonen@zonmw.nl<br><br>Dr. Sonja van Weely<br>E-mail: weely@zonmw.nl |
| **Funding commitment** | 1.8 M€ maximum |
| **Anticipated number of fundable Dutch project partners** | ~ 7-9 project partners |
| **Maximum funding per grant awarded to a project partner** | Up to 250.000 euro for a project partner for a 3-year project proposal |
| **Maximum funding per grant awarded to a project with two national research partners** | Up to 250.000 euro for a 3-year project proposal. In case a project consists of two Dutch project partners the total amount of the ZonMw funding for the project is still up to 250.000 euro |
| **Eligibility of a partner as a beneficiary institution** | **A.** Dutch universities, research institutes affiliated to universities and university medical centres, settled in The Netherlands<br>**B.** Research hospitals, health promotion institutes and knowledge institutes, settled in The Netherlands<br>**C.** Private companies settled in The Netherlands: up to 20% (incl VAT) of the Dutch budget in the project concerned<br><br>Please note that:<br>• Aid to the organisations in category A does not result in state aid, according to the Framework for State aid for research and development and innovation.<br>• Aid to the organisations in categories B and C is state aid and will be granted under the General Block Exemption Regulation: |

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| | EC REGULATION No 651/2014. The aid intensity depends on the activities, see the EC Regulation for more information.<br>• Max. 1 application as coordinator per person is allowed.<br>• The track record of the PIs is part of the assessment.<br>• Cofinancing by companies (*in cash* or *in kind*) is encouraged. |
| **Eligibility of principal investigator or other research team member** | The principle investigator should have (or get upon granting of the project) an employment contract at the eligible institution for at least the duration of the project; the principle investigator does not need to have a permanent position at the institute. A letter from the department head or other responsible official of the institute has to be submitted at the deadline of application of the full proposal in which information on the employment contract of the principle investigator is indicated. Furthermore, in this letter the department head or other responsible official should also guarantee that the applicant will have the time and facilities to perform the research properly and according to plan. The principle investigator should show strong commitment to (the results of) the project. |
| **Eligibility of costs, types and their caps** | Costs for personnel can be part of the application of the Dutch applicant. Scientific personnel has to be appointed at a scientific institution in The Netherlands. Furthermore, consumables, animals, equipment, travels, costs for dissemination of results (implementation) are eligible (see the ZonMw grant terms and conditions from 1st July 2013: http://www.zonmw.nl/fileadmin/documenten/Corporate/Grant_Terms_and_Conditions_from_1st_July_2013.pdf.<br>In most cases (e.g. in case of university/university medical centers) overhead is not allowed and the salary scales of VSNU (universities; https://www.zonmw.nl/fileadmin/zonmw/documenten/Corporate/Subsidies/Berekening_G_posten_met_sal_peil_01-07-2018_def.pdf ) or NFU (University Medical Centres; https://www.zonmw.nl/fileadmin/documenten/Corporate/Berekening_G_posten_met_sal_peil_01-08-2017_tbv_NFU.pdf). Please use the ZonMw budget formats as basis for the budget calculations. |
| **Eligibility of project duration** | Up to 3 years |
| **National phase** | • Submission of the full proposal to ZonMw will be carried out once the international evaluation and the ranking list have been performed and endorsed by the Call Steering Committee and European Commission. ZonMw will send a letter to invite you to submit the granted full proposal.<br>• The Dutch consortium partners in honoured consortia have to comply with ZonMw procedures for honoured projects (e.g. uploading via MijnZonMw - including the ZonMw budget format, and reporting annually). Scientific personnel has to be appointed at a scientific institution in The Netherlands. Honoured consortia with a Dutch partner have to draw up and sign a Consortium Agreement in which also the intellectual property rights are incorporated.<br>• Before the start of the granted project the Dutch researcher needs to compose a data management plan (DMP) to explain how to make the data collection from the Dutch part of the research project FAIR. ZonMw will send instructions to honoured Dutch researchers. (https://www.zonmw.nl/nl/over-zonmw/toegang-tot-data/). |

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| **Further guidance** | • Collaboration with patient organisations is recommended; see also 6.3 in the Call text.<br>• The ZonMw grant terms and conditions (as of 1st July 2013) apply for Dutch consortium partners (more information: http://www.zonmw.nl/fileadmin/documenten/Corporate/Grant_Terms_and_Conditions_from_1st_July_2013.pdf). |

**TURKEY, TUBITAK**

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| **Country** | Turkey |
| **Funding organisation** | The Scientific and Technological Research Council of Turkey (TUBITAK)<br>http://www.tubitak.gov.tr |
| **National contact person(s)** | Jale SAHIN<br>Phone : +90 312 298 1796<br>E-mail : jale.sahin@tubitak.gov.tr |
| **Funding commitment** | 1 M€ |
| **Anticipated number of fundable research partners** | 7-8 |
| **Maximum funding per grant awarded to a partner** | 720.000 TL + Project Incentive Payment + Overheads |
| **Eligibility of project duration** | Up to 36 months |
| **Eligibility of a partner as a beneficiary institution** | Public and Private Universities in Tukey, University Hospitals in Turkey, Public Research Institutes |
| **Eligibility of principal investigator or other research team member** | Subjected to the terms and conditions of ARDEB 1001 Programme |
| **Eligibility of costs, types and their caps** | Please use the budget form given in the application system (http://uidb-pbs.tubitak.gov.tr) and follow the guidelines found in http://www.tubitak.gov.tr/sites/default/files/263_sayili_bk_islenmis_hali.pdf |
| **Submission of the proposal at the national level** | At both stages of the call, applicants from Turkey must make a national application through TUBITAK UIDB application system: http://uidb-pbs.tubitak.gov.tr/. |
| **Submission of other information at the national level** | Applicants from Turkey must submit necessary documents (Ethics Approval Certificate (https://www.tubitak.gov.tr/sites/default/files/281/ekbn_2018.pdf), Legal Permission Licences (http://tubitak.gov.tr/sites/default/files/yasal_izin_bilgi_notu_16_05_2016.pdf)) at the time of the full proposal submission. |

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| **Submission of financial and scientific reports at the national level** | Submission of the documents are subjected to the terms and conditions stated in ARDEB 1001 Programme |
| **Further guidance** | jale.sahin@tubitak.gov.tr |

**PATIENT ADVOCACY ORGANISATIONS, INSERM**

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| **Country** | Funding of Patient Advocacy Organisations only |
| **Funding organisation** | Institut National de la Santé et de la Recherche Médicale (INSERM) |
| **National contact person** | **Daria Julkowska**<br>**E-mail**: daria.julkowska@inserm.fr |
| **Funding commitment** | 0.5 M€ |
| **Anticipated number of fundable PAO partners** | 10 |
| **Maximum funding per grant awarded to a partner** | 50.000 € per project (if more than one PAO participating the amount should be divided) |
| **Eligibility of a partner as a beneficiary institution** | Patient Advocacy Organisations (PAO) only.<br>**Definition of rare disease patient advocacy organisations:**<br>Patient advocacy organisations are defined as not-for-profit organisations, which are patient focused, and where patients and/or carers and/or family members of patients represent a majority of members in governing bodies. These are:<br>• Umbrella organisations (e.g. representing either European organisations and/or national umbrella organisations for rare diseases);<br>• European rare disease specific organisations (i.e. representing national organisations or individual patients on rare diseases) and<br>• National rare disease specific organisations |
| **Eligibility of costs, types and their caps** | Expenses recognized as eligible are: personnel costs and operating expenses (travels, meeting, conference registration, etc.) but excluding office and IT equipment (workstation, mobile phone, tablets, etc.).<br>Only temporary staff costs are eligible, in proportion to the time spent on the project, with justification in the form of a time sheet.<br>The amount of the grant granted to the PAO in each project is 50 000 €. If several PAOs work in the same project, they share this amount among themselves.<br>Expenditure on general, administrative and / or infrastructure costs is eligible (overheads = frais généraux) is up to 15% of the grant amount.<br>The subcontracting is eligible for up to 50% of the grant.<br>All justifications and supporting documents are auditable by Inserm or by any representative appointed by it during the project and a period of 4 years after its completion. |

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| **Submission of the proposal at the national level** | **<u>Criteria to be fulfilled by PAOs:</u>**<br>The Patient Advocacy Organisations shall fulfil the following criteria:<br>• **Legitimacy**:<br>o Represent rare diseases according to EU prevalence criteria (5/10 000) as defined in the: EU Regulation on Orphan Medicinal Products (1999), Commission Communication on Rare Diseases 2008), Council Recommendation on an Action on Rare Diseases (2009), and Directive on Patients' Rights in Cross-Border HealthCare (2011)<br>o the organisation should be formally established and registered as a not-for-profit organisation in one of the Member States of the EU/EEA/participating in the EJP for RD for more than 1 year<br>• **Mission/objectives**: the organisation shall have its mission/objectives clearly defined and should agree to have it/them published on the EJP RD website.<br>• **Activities**: the organisation shall have, as part of its activities, a specific interest in rare diseases which should be documented (e.g. through a report published on the organisation website).<br>• **Representation**: the organisation shall be representative of rare disease patients within a member state or throughout the EU/EEA.<br>• **Structure**:<br>o the organisation should have governing bodies which includes a majority of rare disease patients or family members of rare disease patients.<br>o Includes in its governing structure a designated representative legally authorised to sign a contract with a public funder/Inserm.<br>• **Accountability:**<br>o With proven activities such as rare disease patient support and/or advocacy activities and/or rare disease research<br>o statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place. In particular, the organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members.<br>o Can demonstrate that its account system is able to trace all costs related to the project and archive these costs for a duration of 5 years after the last payment received from the funder.<br>• **Transparency:**<br>o the organisation shall be financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies) and disclose to the EJP RD its sources of funding both public and |

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| | private by providing the name of the bodies and their individual financial contribution, both in absolute terms and in terms of overall percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. This information shall be communicated to the EJP RD on an annual basis.<br>o The organisation shall publish on its website the registered statutes, sources of funding, and information on their activities.<br>o To facilitate communication, a contact person shall be identified for each organisation. |
| **Further guidance** | daria.julkowska@inserm.fr |

# 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"

# Pre-proposal application form

**CHECKLIST FOR THE COORDINATOR:**

***In order to make sure that your proposal will be eligible to this call, please collect the information required to tick all the sections below before starting to complete this application form.***

☐ I agree that personal data submitted for the consortium members will be used during the whole evaluation and contract negotiation process, in line with GDPR (General Data Protection Regulation).

- **General conditions:**

☐ The project proposal addresses the **AIM/S** of the call

☐ The project proposal meets the **TOPIC/S** included in this call

- **Ethical standards:**

☐ The proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).

- **The composition of the consortium:**

☐ The project proposal involves at least 4 eligible research partners from at least 4 different countries participating in the call.

☐ The project proposal does not include more than two eligible research partners from the same partner country participating in the call.

☐ The consortium coordinator is eligible to receive funding from his/her national funding organisation(s) participating in the call.

☐ There are a maximum of 2 partners who secure their own funding and contribute substantially to the work packages present in the proposal (see table in the Call text for the maximum number of partners).

☐ The project proposal involves a maximum of 6 eligible research partners asking for funding. In case of inclusion of partners from participating underrepresented countries (Czech Republic, Slovakia, Estonia, Hungary, Lithuania, Poland, and Turkey) the project involves a maximum of 8 eligible partners.

☐ There are a maximum of 8 partners in total in the project proposal. This includes the coordinator.

- **Eligibility of consortium partners:**

☐ I have checked that each partner involved in the project proposal is eligible to receive funding by its funding agency. Not eligible partners are aware of the fact that they are not eligible; therefore a signed statement declaring that they will run the project with their own resources is enclosed in the proposal.

☐ I have checked that the applicants have confirmed the eligibility of the pre-proposal with their national/regional Contact Point.

☐ (if applicable) Italian partners applying for funding at the Ministry of Health involved in the proposal have submitted a pre-submission eligibility check form to their national funding organization at least 10 working days before the submission deadline.

☐ (if applicable) Italian partners applying for funding at the Ministry for Education, Universities and Research involved in the proposal have submitted further documentation to MIUR, through the national web platform, available at the following link: http://banditransnazionali-miur.cineca.it, by the day of the pre-proposal submission deadline.

☐ (if applicable) Lombardy partners applying for funding at FRRB involved in the proposal have submitted a pre-submission eligibility check form to their regional funding organisation at least 10 working days before the submission deadline.

☐ (if applicable) Tuscany partners applying for funding at Tuscany Region involved in the proposal have submitted a pre-submission eligibility check form (available on Tuscany Region institutional web-site or on request to ejprare@regione.toscana.it) to their regional funding organisation at least 10 working days before the submission deadline.

☐ (if applicable) Austrian partners have submitted administrative data (in accordance with the FWF guidelines for stand-alone projects) online to the FWF at https://elane.fwf.ac.at/.

☐ (if applicable) Czech partners have submitted all of the requested documentation (i.e. Statutory Declaration and Eligible Costs Specification) to the Ministry of Education, Youth and Sports.

☐ (if applicable) Hungarian partners have submitted mandatory information to NKFIH, including applicant name and affiliation, as well as an estimation of the requested budget.

☐ (if applicable) Swiss partners have submitted the pre-proposal to www.mySNF.ch together with the submission of the respective proposals to the EJPRD Joint Call Secretariat.

☐ (if applicable) Swedish partners have submitted the pre-proposal electronically either in Prisma, which is the application system used by the Swedish Research Council (see www.vr.se) or the eService portal "Intressentportalen", which is the application system used by Vinnova (see www.vinnova.se).

☐ (if applicable) Turkish partners have submitted the pre-proposal to through TUBITAK UIDB application system: http://uidb-pbs.tubitak.gov.tr/.

**Please note:**

- **Proposals that do not meet the national eligibility criteria and requirements will be declined without further review.**
- **All fields must be completed using Arial 11, single-spaced, margins of 1.27 cm. Incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review.**
- **Once completed the pre-proposal must be converted in a single PDF document before being uploaded to the submission website.**
- **In case of inconsistency between the information registered in the submission tool and the information included in the PDF of this application form, the information registered in the submission tool shall prevail.**

**1.a Project Title:**

**1.b Project acronym:**

The application is: ☐ a new proposal
☐ a resubmission from a previous E-Rare call
☐ JTC 2015 ☐ JTC 2016 ☐ JTC 2017 ☐ JTC 2018
☐ a proposal asking for an extension of a previously funded E-Rare project
If so, please state the acronym of the project:

**2. Consortium coordinator:**

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| **Family Name, first Name** | |
| **Institution/Department** | |
| **Department** | |
| **Position** | |
| **Address** | |
| **Zip code, City Country** | |
| **Phone + Fax** | |
| **E-mail address** | |
| **Type of entity** | Academia, Clinical or Public Health, SME or Industry |
| **Type of entity (public/private-for-profit/private-non-for-profit)** | |
| **Early Career Scientist[1] (yes/no)** | |

**3. Project Partners:**

3a. Additional research partners asking for funding:

| No. | Zip code, City, Country | Research Partner (principal investigator) | Institution, Department, full affiliations (address, phone + fax) | Email address | Early Career Scientist* (yes/no) | Type of entity Academia, Clinical or Public Health, SME and Industry | Type of entity (public/private-for-profit/private-non-for-profit) |
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*For definition of Early Career Scientist see 6.8 in Call text

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| 4 | | | | | | | |
| 5 | | | | | | | |
| 6 | | (only possible with inclusion of 1 partner from usually underrepresented countries) | | | | | |
| 7 | | (only possible with inclusion of 2 partners from usually underrepresented countries) | | | | | |

3b. Associated research partners not asking for funding (see table in the Call text for the maximum number of partners):

| No. | Zip code, City, Country | Research Partner (principal investigator) | Institution, Department, full affiliations (address, phone + fax) | Email address | Early Career Scientist (yes/no) | Type of entity Academia, Clinical or Public Health, SME or Industry | Type of entity (public / private-for-profit / private-non-for-profit) |
|---|---|---|---|---|---|---|---|
| 1 | | | | | | | |
| 2 | | | | | | | |

3c. Patient advocacy organisation (PAO) partners asking for funding:

| No. | Zip code, City, Country | Responsible person | Organisation, full affiliations (address, phone + fax) | Email address | Type of entity (public / private-non-for-profit) |
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**4. Duration of the project** (months):
(maximum number of months is 36)

**5. Total funding applied for** € 

**6. Budget from associated research partners (in cash or in kind)**

€

**7. Keywords and medical domain**
please identify between three and seven keywords that represent the scientific content (medical domain, disease, etc.), approach(es), tools (animal models, OMICS, etc.)

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**8. Lay summary** (max. 1600 characters including spaces)

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**9. Description of the project** (once converted into Pdf document: max. 5 pages DIN-A4, Arial 11, single-spaced, and margins of 1.27 cm). Description of the working programme including:

1. Background, present state of the art in the research field and preliminary results obtained by the consortium members;
2. Description of the working program including the objectives, the rationale and the methodology, highlighting the novelty, originality and feasibility of the project
   Please highlight the main hypothesis(es) for the proposed research plan and sample size calculation (if applicable) in separate boxes

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| *main hypothesis(es) for the proposed research plan* |
| *sample size calculation (if applicable)* |
| *name and affiliation of the responsible biostatistics expert (if applicable)* |

If the proposal includes a natural history cohort / registry study, the following items must be addressed:

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| **TYPE OF PROJECT** | *clinical / epidemiological register or cohort study* |
| **PROBANDS (KEY INCLUSION AND EXCLUSION CRITERIA)** | |
| **MAIN OUTCOMES TO BE ANALYSED** | |
| **STATISTICAL ANALYSIS** | *Anonymisation or pseudonymisation of data, statistical details* |
| **SIZE AND DURATION OF REGISTER / COHORT** | *Expected number of patients, duration in months* |
| **CONCEPT FOR SUSTAINABILITY** | |

3. Description how the new research data in this project will be findable, accessible, interoperable and re-usable (what data will be collected, processed and/or generated and/or reused; which methodology & standards will be applied; will the data be shared/made open access; how will the data be curated & preserved);
4. Description of the unmet medical and patient need that is addressed by the proposed work and the potential health impact that the results of your proposed work will have;
5. Added value of the transnational collaboration;
6. Description of patient organizations within the proposal, including their role and contribution.

*If the application concerns a request for extension of a project funded in previous E-Rare calls, please add 1 additional page describing the scientific results achieved in that project so far.*

**10. Diagram** of the work plan that includes timeline, workflow and interconnections of work packages (a Gantt chart, Pert or similar, max. 1 page).

**11. In addition**, two more sections can be added to the pre-proposal (*optional*):

- a page of diagrams, figures, etc. to support the work plan description (max. 1 page)
- a list of references (no page limit) – please use Vancouver Style (see: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15) and include PUBMED IDs

**12. Budget table** (see last page for template)

**13. Brief CV for each principal investigator** (once converted into Pdf document: max. 1 page DIN-A4, Arial 11, single-spaced, margins of 1.27 cm per principal investigator).
Brief CV for each principal investigator including a description of the main domain of research and a list of the 5 most relevant publications within last five years regarding the proposal. Please include dates/requirements for the identification of early career scientists (not included in page limit).

**14. Date and signature of the coordinator**

**12. Budget plan of the project** (only requested budget)

| No. | Project coordinator[4] | Partner 1 | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 (only possible with inclusion of 1 partner from usually underrepresented countries) | Partner 7 (only possible with inclusion of 2 partners from usually underrepresented countries) | Patient advocacy organization(s) |
|---|---|---|---|---|---|---|---|---|---|
| Name (principal investigator) | | | | | | | | | |
| Country | | | | | | | | | |
| Funding organization | | | | | | | | | |
| Personnel € | | | | | | | | | |
| Consumables € | | | | | | | | | |
| Equipment € | | | | | | | | | |
| Travel €[1] | | | | | | | | | |
| Other direct costs €[2] | | | | | | | | | |
| Overheads €[3] | | | | | | | | | |
| Total requested budget € | | | | | | | | | |

national/regional legal framework and funding body regulations. These should be listed in the Partner 1 budget.

**Applicants are encouraged to confirm their eligibility with their national contact points**