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European Joint Programme on Rare Diseases

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Second Public Call documents JTC2020: call text, guidelines for applicants, proposal templates

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The funding of transnational collaborative research is critical to enhance the cooperation between scientists working on rare diseases across Europe and beyond, and thus reduce the fragmentation of research in this field. Therefore, the central Pillar 1 activity is providing financial support to third parties.

The Joint Transnational Calls (JTCs) are implemented using the "virtual common pot" funding mode. This means that national/regional funding will be made available through national/regional funding organisations according to their own regulations. In addition, in the second Joint Transnational Call the EC will also provide funding that will maximize the number of selected projects that can be funded. Each country/region will fund only their own national/regional component of the transnational research project. Funding from the EC will be distributed through the national/regional funding agencies.

The topic of the Joint Transnational Call 2020 is "Pre-clinical research to develop effective therapies for rare diseases"

This deliverable contains the public documents for the JTC2020 that are published on the EJP RD website (http://www.ejprarediseases.org/index.php/open-call-jtc2020/):

- Call text p3
- Guidelines for applicants p26
- Proposal template p108

Call for Proposals 2020
"PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES"

Call Text

Submission deadline for pre-proposals: 2 p.m. (CET), February 18th, 2020

For further information, please visit us on the web:
http://www.ejprarediseases.org/

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1. Background

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).

2. Participating Organisations

A number of national and regional funding organisations will participate in the **EJP RD Joint Transnational Call (JTC) 2020** and will fund multilateral research projects on rare diseases **together with the European Commission (EC) under the EJP-COFUND action**. The call opens simultaneously with the involvement of the following funding organisations in their respective countries/regions:

- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research - FNRS (F.R.S.-FNRS), Belgium, French-speaking community

- 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
- Academy of Finland (AKA), Finland
- French National Research Agency (ANR), France
- French Foundation for Rare Diseases (FFRD), France
- INSERM, France (Patient Advocacy Organisations)
- Federal Ministry of Education and Research (BMBF), Germany
- **Decision Pending:** German Research Foundation (DFG), Germany
- General Secretariat for Research and Technology (GSRT), Ministry of Development & Investments, 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
- Fondazione Regionale per la Ricerca Biomedica (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
- 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

2.1. Management and Evaluation Structures

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**) (ANR, France). 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 that joins the JTC2020. 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 form and a statement to confirm that they do not have any conflicts of interest.

3. 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 future benefit for patients.

Topic: **PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES**

Research proposals must cover <u>at least one</u> of the following areas:

1. Development of novel therapies in a preclinical setting (including small molecules, repurposing drugs, cell and gene advanced therapies) focusing on condition(s) with unmet medical needs
2. Use of disease models suitable for medicinal product's development according to EMA guidelines
3. Development of predictive and pharmacodynamics (PD) biomarkers (with appropriate analytical methods e.g. OMICS) in a preclinical setting (e.g. in the validated model or in pre-collected human samples) for monitoring the efficiency of the therapy. The model chosen must mimic the human diseases and be transposable so that the biomarker identified in animals can be valid for humans
4. Proof of principle studies fostering an early (pre-clinical) stage of drug development (excluding interventional clinical trials of phase 1-4).

The following approaches and topics are <u>excluded</u> from the scope of the call:

a) Therapeutic approaches concerning rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases
b) Interventional clinical trials
c) Surgery or radiation therapies
d) Studies that focus on research to accelerate diagnosis or to set up new registry/cohort studies to explore disease progression and mechanisms as these were the focus of JTC 2019.
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 are: 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.
Childhood dementias/neurodegenerative diseases are not excluded.

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.

It is highly encouraged that the research will focus on diseases without approved treatment options to contribute to the aims of IRDiRC in this area (for information see list of EMA approved orphan medical products).

Translatability into humans should be one of the key focuses of the project, and applicants should demonstrate access to relevant scientific or regulatory expertise (e.g. through innovation task forces or competent national authorities).

Consortia performing preclinical development of therapeutics are strongly advised to engage or consult experts in the various stages of product development, with the aim to establish one or more of the following:

a) **Target validity:** Strong link between target and disease, differentiated efficacy, available and predictive biomarkers.
b) **Right Tissue:** Adequate bioavailability and tissue exposure, definition of pharmacodynamics biomarkers, clear understanding of preclinical pharmacokinetics.
c) **Right safety profile:** Differentiated and clear safety margins (in models), understanding of secondary pharmacology risk which consist in evaluating the potential off-target or unintentional effects of a drug, including understanding of reactive metabolites, genotoxicity, drug–drug interactions, and off-target liability. These studies are important in predicting potential toxicities and demonstrating safety of a therapy.
d) **Right patient:** Identification of the most responsive patient population, with a risk–benefit analysis.

For the development of novel therapies or proof-of-principle studies, the following issues should be addressed in the proposal:

- Orphan drug designation (ODD) planning: has an ODD been granted? If not, the path to ODD development should be described (including target product profile for therapy development).
- Exploration of scale-up feasibility for clinical trials and manufacturing.

- For projects developing a new target (not extensively validated in the literature), target revalidation in preclinical models should be a first step in project.

For validation or development of predictive and pharmacodynamics biomarkers (predictive biomarkers are important to help guide patient selection, pharmacodynamics biomarkers can provide information on the pharmacologic effects of a drug on its target), the following issues should be addressed in the proposal:

- Ensure in the first stage that the biomarker (signature) undergoes analytical validation using high quality samples from an independent collection (different from the collection in which the signal was discovered), which have been collected and stored under quality controlled conditions and following international standards.

Samples used in validation should be sourced from certified biobanks (e.g. http://www.eurobiobank.org/). Upon sample provision biobanks should provide a report including information on:

- Identification and specific properties of the materials
- Relevant quality information of the materials and clinical data
- Method used for identification and characterisation of materials
- Method used for testing of the materials
- Method used for sample collection, preparation, preservation, storage
- Accreditation of the lab performing the analytical validation of the biomarker for the method used (e.g. ISO 17025 or 15189).
- Validation should follow a risk-based approach wherein depending on potential confounding variables such as genetic diversity, multiple biobanks from multiple regions may be utilised. Sample size and number should reflect such risk.

Applicants should **describe and justify the use of any disease models** (animal or otherwise) described in the proposal:

- Describe how the model replicates the pathology or human condition (aetiology, pathophysiology, symptomatology and response to therapeutic intervention),
- Whether the model duplicates aspects of the therapy target including expression, distribution and primary structure, pharmacodynamics, metabolism and other pharmacokinetic aspects,
- If the project involves the use of animals, provide sound scientific justification for their use, explain why there are no realistic alternatives, and demonstrate that the numbers proposed will allow meaningful results to be obtained from the research. Please also specify the sex of the animals, and rationale for the numbers of each sex,
- Describe how the proposed pre-clinical work correlates and aligns with any planned future stages of the research in humans.

Furthermore, the following **additional elements need to be considered in all proposals:**

- The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.
- Appropriate bioinformatics and statistical methods should constitute, whenever justified, an integral part of the proposal, and the relevant personnel should be clearly specified.
- Preliminary data should be described in a manner that would allow a skilled peer to replicate the data, including positive and negative controls, and suitable n values for statistical analysis. All data points should be included in the analysis and presented with error bars where relevant.
- Risk management should be considered including the identification of possible bottlenecks and go/no go contingencies.
- Feasibility of the project given requested resources (budget) and schedule must be demonstrated: timelines should be realistic, and lead times should be accounted for (e.g. regulatory or scientific advice).
- If relevant, the consortium will identify technology transfer officer responsible for intellectual property management. Project plan should include innovation management activities (e.g. ongoing monitoring, expert panels to identify high potential results), and may describe follow-on funding and/or draft study plans past the grant end (e.g. natural history studies with relevant stakeholders including patient groups, or approaching companies for potential in-licensing or co-development).
- Applicants should include information about other ongoing development work on the target/indication, and explain why their approach should be supported.
- Study design and preclinical models (vectors, reagents etc.) may be selected to facilitate approval in human trials and future clinical grade manufacturing.
- To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy for the proposed project is mandatory in the full proposal stage. Some countries involved in this call will also require a data management plan at the full proposal stage or upon granting of the project.
- To ensure that the needs and priorities of rare disease patients are adequately addressed, they or their representatives must be appropriately involved in all projects wherever possible (see section 4.4).

The use of **existing European health research infrastructures** and/or **IRDiRC recognized resources** is strongly encouraged when appropriate: e.g. research infrastructures established as a 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).

The following ESFRI European Research Infrastructures and European/international projects or their results may be of use to consortia:

- BBMRI Biobanking and Biomolecular Resources Research Infrastructure
- ELIXIR The European Life Sciences Infrastructure for Biological Information
- INFRAFRONTIER European Infrastructure for Phenotyping, Archiving and Distribution of Mouse Models
- INSTRUCT Integrated Structural Biology Infrastructure for Europe
- ECRIN European Clinical Research Infrastructure Network
- EATRIS European Infrastructure for Translational Medicine
- EU-OPENSCREEN European high-capacity screening network
- RD-Connect An integrated platform connecting databases, registries, biobanks and clinical bioinformatics for rare disease research
- Matchmaker Exchange A federated platform to facilitate the matching of cases with similar phenotypic and genotypic profiles
- IRDiRC recognized resources
- Orphanet Rare Disease Ontology
- Human Phenotype Ontology
- Horizon 2020 FAIR Data Management Plan Annex 1 in:
- Recommendations for Improving the Quality of Rare Disease Registries

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. For more information, visit the IRDiRC website.

4. Application

4.1. Eligibility

Partners belonging to one of the following categories may request funding under a joint research proposal (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),
- enterprises (all sizes of private companies). Participation of small and medium-sized enterprises (SMEs) is encouraged when allowed by national/regional regulations,
- patient advocacy organisations (PAOs are eligible to obtain funding for their participation in research projects; see section 4.4).

The maximum duration of the project is three years.

4.2. Country and Region-Specific Guidelines

Although applications will be submitted jointly by applicants from several countries, individual groups will be funded by their respective regional/national funding organisation. Applicants therefore must contact their respective funding organisations and confirm eligibility in advance of submitting an application. **The adherence to the national/regional regulations in the "Guidelines for Applicants" document is mandatory.** The inclusion of a non-eligible partner in a proposal will **lead to the rejection of the entire proposal without further review**. If you need additional information, please contact the JCS**.** Note that a parallel proposal submission is required by some regional/national funding organisations.

4.3. Consortium Makeup

Only transnational projects will be funded. Each consortium submitting a proposal must involve **four to six eligible principal investigator partners (referred to as partners below)** from **at least four different participating countries** (see list in section 2). In specific cases this can be increased to eight partners (see below). No more than two eligible partners from the same country can be present in each consortium (further national limits may apply, see "Guidelines for Applicants"). This limit also applies to early career researchers and partners from underrepresented and undersubscribed countries (see below). PAOs requesting funding do not count toward this total.

In order to be considered as an eligible partner, each partner (with their respective research groups) must contribute substantially to at least one of the project work packages. If the only role of a group is to provide patient data or samples for the study, they will not be considered as partners of the consortium, but can be included otherwise, via cooperation agreements or subcontracting.

Consortia may include collaborators that secure their own funding. Collaborators cannot be work package leaders, and their contribution to the research project must be described (where relevant a CV should be included in the proposal). As they do not receive funding as part of this call, they do not count toward the limit of 8 partners requesting research funding. There is no limit on the number of collaborators per country, however, the added value of the collaboration must be clearly described and the number of collaborators must remain manageable within the limits of the project.

Each transnational proposal must nominate a **project consortium coordinator** among the project partner principal investigators. The coordinator must be an eligible project partner from an EJP RD JTC 2020 funding country/region. The project coordinator will represent the consortium externally and to the JCS and CSC, and will be responsible for its internal scientific management (such as controlling, reporting, and intellectual

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

The number of partners can be increased to 8 in two cases:

1. The inclusion of partners from participating countries usually underrepresented in projects (Czech Republic, Slovakia, Hungary, Lithuania, Poland, and Turkey).
2. The inclusion of Early Career Researchers as full partners (see section 4.5).

Double funding of research projects is not permitted. The JCS and national/regional funding organisations will perform cross-checks of submissions against other joint transnational (e.g. NEURON, JPND, EuroNanoMed, ERA PerMed etc.) and national calls. Partners may not apply for funding for the same research activities in different calls.

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 with applications for new research projects.

4.4. Patient Advocacy Organisations and Patient Involvement

Consortia are strongly advised to include patient representatives and patient advocacy organizations (PAOs), which are **eligible to receive funding for their activities**. **If patient involvement is not deemed appropriate within a research project, this should be explained and justified.** The included PAOs will not count towards partner limits, and therefore their inclusion does not influence the partner restriction criteria described above. If there is no PAO for a specific rare disease, the consortia could investigate whether an umbrella PAO or a PAO for a similar rare disease may be involved.

The consortia should clearly present the role and responsibilities of the PAO, how they will operate, at what levels and stages of the research, and provide justifications for allocated resources. PAOs can be involved in all levels of the proposed work, including in project design, by advising on prioritisation, sitting on advisory groups, being a member of the consortium steering group or the governance group of a registry. PAOs may be part of institutional scientific boards to discuss the proposal and subsequent study on issues such as:

- the research idea, for relevance to patient concerns,
- possible outcomes, especially patient reported outcome measures,
- informed consent,

- patient input on appropriate clinical outcome measures,
- possible patient intervention in the project,
- review of the data collected,
- dissemination of research findings.

Consortia should also consider training of PAOs and representatives on biomedical knowledge via the attendance of international congress or via specific programs organized for instance by Eurordis.

For more information on patient-centred care and strategies to involve patient representatives and PAOs in your research project, please consult:

- INVOLVE Briefing Notes for Researchers and cost calculator,
- Recommendations for Successful Patient Involvement in Scientific Research (de Witt et al., 2016),
- Measuring what matters to rare disease patients (Morel & Cano, 2017),
- CIHR's Patient Engagement resources.

From an early stage in proposal development, applicants should consult relevant disease-specific patient organisations when possible and/or alliances of rare disease patient organisations. For information on where to find patient representatives and PAOs willing to be involved in research, please see:

- Orphanet portal for rare diseases and drugs patient organisation directory
- Rare Diseases Europe (EURORDIS)
- European Reference Networks (ERNs)
- European Patient's Academy on Therapeutic Innovation (EUPATI).

Funding for PAOs is limited to a total of 50,000 € over 3 years and per project regardless of the number of participating PAOs (see "Guidelines for Applicants" for eligibility rules). Besides this funding, PAOs can also be involved through national/regional funding or subcontracting depending on the proposed tasks and national/regional funding rules.

4.5. Early Career Researchers

Early Career Researchers (ECRs) are encouraged to join consortia as full research partners and are therefore subject to the same eligibility criteria as other partners. ECRs must demonstrate independence and scientific excellence, and should be clearly identified in the proposal and their CV. Further information including a definition of ECRs according to European Research Council criteria is provided in the "Guidelines for Applicants" (section 3.1). **Please note that national/regional definitions and time limits might differ.** Therefore, please refer to national guidelines and contact your national/regional funder. Please see the "Guidelines for Applicants" document for further information.

5. Registration and Submission

Research consortia who intend to submit a transnational project proposal should **register as soon as possible** via the electronic proposal system: https://ptoutline.eu/app/ejprd20. Please fill in the data sheet in the system. The same data sheet can be used for the submission of pre-proposals and full proposals (if invited).

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

Call Timeline

18th February 2020	Pre-proposal submission deadline
End of April 2020	Invitation to full proposal
16th June 2020	Full proposal submission deadline
28th July 2020	Deadline for rebuttals
November 2020	Notification of funding decision

Full proposals will be accepted only from those applicants who were explicitly invited by the JCS to submit them.

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. In order to make such a change, a detailed justification must be provided to the JCS for consideration by the CSC. One justification can be that because of additional advice gathered on the translatability of the project, additional expertise or resources are needed. However, the national/regional regulations on budget caps will still apply and the budget change needs to be pre-approved by the national/regional funding organisation.

Further information on how to submit pre-proposals and full proposals electronically (including Guidelines for Applicants and submission forms) is available at the EJP RD website (http://www.ejprarediseases.org/).

6. Evaluation Process

At the pre-proposal stage, applicants should focus on presenting the scientific idea/hypothesis and supporting preliminary results. The proposal should describe the project starting from an unmet medical need, and follow through to the expected

end-point of the study (e.g. proof of principle in a preclinical study). Pre-proposals will be evaluated by scientific/clinical experts.

At the full proposal stage, in addition to the scientific content, a full description of patient engagement** (or a justification if this is not applicable), data management, statistical methods, and ethical and legal issues will be required. Applicants should anticipate this requirement, and ensure that they have consulted with relevant experts to verify the feasibility of the project, and that the proposal can be completed within the defined budget (taking into account budget limits listed in the Guidelines for Applicants).

6.1. Evaluation Criteria

Evaluation scores will be awarded according to specific evaluation criteria that are in line with Horizon 2020 rules (see below), using a common evaluation form. Each criterion will be scored out of five, for a maximum overall score of 15 points. The threshold for an individual criterion is three, with an overall threshold of 12 points.

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.

1. **Excellence (0-5)**
   a. Clarity and pertinence of the objectives,
   b. Credibility of the proposed approach and methodology,
   c. Soundness of the concept (supporting data should be robust),
   d. Innovative potential: description of existing development landscape, relationships with technology transfer offices, plan for ongoing development,
   e. Feasibility of the project (adequate requested resources, time schedule, access to and engagement of patients, data, and material, translatability of medicinal products to patient treatment),
   f. Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific technical expertise),
   g. **Active and meaningful participation of PAOs and patient representatives in the project (including where possible in the design and definition of

research priorities, interpretation and implementation of results, their dissemination, and communication).

2. **Impact (0-5)**
   a. *Potential of the expected results for commercial exploitation and for future clinical, public health and/or other socio-economic health relevant applications, and preferably for diseases without approved treatment options,
   b. *Added-value of transnational collaboration: gathering a critical mass of patients/biological material, sharing of expertise and resources (models, databases, diagnosis, etc.), and harmonization of data,
   c. Involvement of industry (when appropriate/applicable/available),
   d. Inclusion of Early Career Researchers as partners,
   e. **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,
   f. **Benefit to patients, their families, and carers developed through the involvement of patient organisations and patient representatives where possible,

3. **Quality and efficiency of the implementation (0-5)**
   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, including the integration of PAOs where possible,
   c. **Appropriateness of the management structures and procedures, including risk management, contingency plans and innovation management,
   d. **Plan 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, partner 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.

6.2. Pre-proposal Review

Eligibility check

The JCS will check all pre-proposals to ensure that they meet the call's formal criteria. The JCS will forward the proposals to the CSC members who will perform a check for compliance to country/regional/PAO eligibility rules. **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 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-proposal to ensure it falls within the scope of the call, 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 then meet to establish a ranking of the pre-proposals. This ranking will be used by the CSC to decide which pre-proposals will be accepted for full proposal submission. The summary review report and eventual recommendations of the SEC will be forwarded to all applicants.

At this stage research teams of underrepresented or undersubscribed countries may join successful pre-proposals (see 3.2 in Guidelines for Applicants for more details).

6.3. Full proposal Review

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

External reviewer evaluation
Each proposal will be allocated to at least two external scientific reviewers with expertise relevant to the application.

Rebuttal stage
Before the SEC members see the reviews from external reviewers, each project coordinator will be provided with the opportunity to read and provide a written response to the evaluations of the external reviewers. The scores will not be given at this stage. This step allows applicants to correct factual errors or misunderstandings in the review, and to reply to reviewers' questions. Issues which are not related with reviewers' comments cannot be addressed and the work plan cannot be modified at this stage.
The applicants will have up to one week (in late July 2020) for this **optional** response to the reviewers' comments.

SEC Meeting Evaluation
Four groups of reviewers will be present at the SEC meeting to evaluate projects:

1. **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 (taking into account patient reviewer comments), 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.

2. **Patient reviewer evaluation**

Proposals will be evaluated by expert patient reviewers according to the evaluation criteria listed above (see section 6.1). These reviewers will be present at the SEC meeting to discuss proposals and provide their feedback on the scores from SEC members for ranking of the proposals.

3. **Statistical evaluation**

Proposals will be evaluated by experts in biostatistics. These reviewers will not provide a score for the proposals, but will be there to assist in evaluating the feasibility of the projects with respect to bio-statistical methods.

4. **Ethical evaluation**

After the second SEC meeting, full proposals will 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 consortium in order to receive approval for funding from an ethics standpoint. 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.

6.4. 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. 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. This will be based on:

- Availability of national funding;
- Maximization of use of national funding;
- Proposals with participation of underrepresented or undersubscribed countries;
- Proposals that address diseases not otherwise covered by more highly-ranked proposals.

The JCS will notify all project coordinators of the final funding decision and disseminate the SEC consensus report.

7. Responsibilities, Reporting Requirements, and Dissemination

The Joint Call Secretariat (JCS) is located at the French National Research Agency (ANR) 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, and peer reviewers with regard to call procedures. **The project coordinator is the point of contact for consortia during the application procedure, and is responsible for forwarding relevant information from the JCS to their consortium members.** CSO-MOH, Israel, will be responsible for the monitoring phase until the funded research projects have ended.

The **coordinators** of all funded projects must submit a **brief annual scientific project report** (due on the 28th of February 2022 and subsequent years) **and a final scientific project report** (due within six months of the end of the project). All reports must be in English and must use the reporting templates provided. The research partners are jointly responsible for delivery of the reports. 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 national/regional group leaders will be asked to present the results of their projects at an **intermediate status symposium** organized by EJP RD. The presence of at least one representative (coordinator and/or partner) per project will be mandatory. Therefore, **the coordinator and respective partners must budget a sufficient amount for the expenses related to these events**.

Please read the "Guidelines for Applicants" document for further information including national/regional information and eligibility requirements.

8. Contact and Further Information

Further information on the EJP RD, the Call, and follow-up is available at the EJP RD website (http://www.ejprarediseases.org/).

Call Contacts

Role	Organisation	Contact Details

Joint Call Secretariat	ANR (France)	EJPRDcall@anr.fr Florence Guillot Phone: +33 (0) 1 78 09 80 01 florence.guillot@agencerecherche.fr Kiri Couchman Phone: +33 (0) 1 78 09 81 29 kiri.couchman@agencerecherche.fr
Multinational, for funding of PAO	INSERM (France)	Coordination EJP RD pao@ejprarediseases.org
Monitoring	CSO-MOH (Israel)	Irit Allon Phone: +972-2-5082167 irit.allon@moh.health.gov.il
	FNRS (Belgium)	Florence Quist Phone: +32 2 504 93 51 florence.quist@frs-fnrs.be

9. National/Regional Contacts

Applicants should refer to the guidelines document for country-specific information including national/regional rules that may apply. Applicants are strongly advised to contact the national/regional contact person to ensure eligibility before submitting their projects.

Country/ Region	Funding Organisation	Contact Details
Austria	Austrian Science Fund (FWF) www.fwf.ac.at	Stephanie Resch Phone: +43 (1) 505 67 40-8201 mailto:stephanie.resch@fwf.ac.at Anita Stürtz Phone: +43 (1) 505 67 40-8206 mailto:anita.stuertz@fwf.ac.at

Belgium: Flanders	Research Foundation Flanders (FWO) www.fwo.be	Alain Deleener Phone: +32 2 550 15 95 mailto:eranet@fwo.be Toon Monbaliu Phone: +32 2 550 15 70 mailto:eranet@fwo.be
Belgium: French-speaking community	Fund for Scientific Research - FNRS (F.R.S.-FNRS) www.frs-fnrs.be/	Florence Quist Phone: +32 2 504 93 51 mailto:florence.quist@frs-fnrs.be Joël Groeneveld Phone: +32 2 504 92 70 mailto:joel.groeneveld@frs-fnrs.be
Canada	Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG) www.cihr-irsc.gc.ca	Jennifer Vineham Phone: +1 613 941-0796 mailto:jennifer.vineham@cihr-irsc.gc.ca
Canada: Québec	Fonds de recherche du Québec-Santé (FRQS) www.frqs.gouv.qc.ca	Maxime Beaudoin Phone: +1 514 873 2114, ext 1369 mailto:maxime.beaudoin@frq.gouv.qc.ca
Czech Republic	Ministry of Education, Youth and Sports (MEYS) www.msmt.cz	Judita Klosaková (MSMT) Phone: +420 234 811 504 mailto:judita.klosakova@msmt.cz
Finland	Academy of Finland (AKA) www.aka.fi	Heikki Vilen Phone: +358 29 5335 135 mailto:heikki.vilen@aka.fi
France	French National Research Agency (ANR) www.agence-nationale-recherche.fr	Florence Guillot Phone: + 33 (0)1 78 09 80 01 Kiri Couchman Phone: + 33 (0)1 78 09 81 29 mailto:EJPRDcall@anr.fr
France	French Foundation for Rare Diseases (FFRD) https://fondationmaladiesrares.org/eng/	Ingrid Zwaenepoel Phone : + 33 (0) 1 58 14 22 85 Diana Désir-Parseille Phone : + 33 (0) 1 58 14 22 81 mailto:aap-bio@fondation-maladiesrares.com
Germany	Federal Ministry of Education and Research (BMBF) / Project	Dr. Katarzyna Saedler Phone: +49 (0)228 3821 1947

	Management Agency of the German Aerospace Centre (BMBF/ PT-DLR) www.gesundheitsforschung-bmbf.de	mailto:Katarzyna.Saedler@dlr.de Dr. Michaela Fersch Phone: +49 (0)228 3821 1268 mailto:Michaela.Fersch@dlr.de Dr. Ralph Schuster Phone: +49 (0)228 3821 1233 mailto:Ralph.Schuster@dlr.de
Germany	German Research Foundation (DFG) www.dfg.de	Dr. Katja Großmann Phone: +49 (0) 228 885 2565 Fax: +49 (0) 228 885 2777 mailto:katja.grossmann@dfg.de
Greece	General Secretariat for Research and Technology (GSRT) www.gsrt.gr	Sofia DIMITROPOULOU Phone: +30 2131300187 mailto:s.dimitropoulou@gsrt.gr
Hungary	National Research, Development and Innovation Office (NKFIH) www.nkfih.gov.hu	Előd Nemerkényi Phone: +36 1 8963987 mailto:elod.nemerkenyi@nkfih.gov.hu Gábor Tóth Phone: +36 1 8961727 mailto:gabor.toth@nkfih.gov.hu
Ireland	Health Research Board (HRB) https://www.hrb.ie/	Louise Drudy mailto:ldrudy@hrb.ie
Israel	Chief Scientist Office of the Ministry of Health (CSO-MOH) www.health.gov.il	Irit Allon Phone: +972-2-5082167 mailto:Irit.allon@moh.health.gov.il
Italy	Italian Ministry of Health (MoH-IT) www.salute.gov.it	Dr. Gaetano Guglielmi Phone : + 39 06 5994 2197 mailto:g.guglielmi@sanita.it mailto:research.EU.dgric@sanita.it Dr. Monica Paganelli Phone : +39 06 5994 2408 mailto:m.paganelli@sanita.it
Italy	Ministry of Education, Universities and Research (MIUR) http://www.ricercainternazionale.miur.it/	Aldo Covello Phone: +39 06.9722.6465 mailto:aldo.covello@miur.it Maria Bianco Phone: +39 06.9722.7146 mailto:maria.bianco@miur.it

Italy: Lombardy	Fondazione Regionale per la Ricerca Biomedica (FRRB) www.frrb.it	Miss Paola Bello Mrs. Carmen De Francesco Dr. Paola Larghi, PhD mailto:bandi@frrb.it
Italy: Tuscany	Tuscany Region (RT/TuscReg) www.regione.toscana.it	Donatella Tanini Phone:+39 055 4383256 Teresa Vieri Phone:+39 055 4383289 mailto:ejprare@regione.toscana.it
Lithuania	Research Council of Lithuania (RCL) www.lmt.lt	Dr. Živilė Ruželė Phone: +370 676 14383 mailto:zivile.ruzele@lmt.lt
Luxembourg	National Research Fund (FNR) www.fnr.lu	Dr. Sean Sapcariu Phone: +352 261 925 33 mailto:sean.sapcariu@fnr.lu
Poland	National Centre for Research and Development (NCBR) www.ncbr.gov.pl/en/	Marcin Chmielewski Phone: +48 22 39 07 109 mailto:marcin.chmielewski@ncbr.gov.pl
Portugal	The Foundation for Science and Technology (FCT) https://www.fct.pt/index.phtml.en	Anabela Isidro Phone: +351 213 911 552 mailto:anabela.isidro@fct.pt Rita Cavaleiro Phone: +351 213 911 541 mailto:rita.cavaleiro@fct.pt
Slovakia	Slovak Academy of Sciences (SAS) https://www.sav.sk/?&lang_change=en	Zuzana Cernakova, PhD. Phone: +421257510118 mailto:cernakova@up.upsav.sk
Spain	National Institute of Health Carlos III (ISCIII) www.isciii.es	María Druet Phone: +34 9182 22530 E-mail: mdruet@isciii.es
Sweden	Swedish Research Council (SRC) www.vr.se	Sverker Lundin Phone: +46 (0) 8 546 12315 E-mail : sverker.lundin@vr.se
Switzerland	Swiss National Science Foundation (SNSF) www.snf.ch	Christoph Meier Phone: +41 31 308 23 62 mailto:christoph.meier@snf.ch

The Netherlands	Netherlands Organization for Health Research and Development (ZonMw) www.zonmw.nl	Harald Moonen Phone: +31-(0)70 349 53 49 mailto:moonen@zonmw.nl Sonja van Weely mailto:weely@zonmw.nl
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK) www.tubitak.gov.tr	Jale şahin Phone: +90- 312- 298 17 96 mailto:jale.sahin@tubitak.gov.tr
Multinational, for funding of PAO	The French National Institute of Health and Medical Research (INSERM) www.inserm.fr	Coordination EJP RD mailto:pao@ejprarediseases.org

Call for Proposals 2020
"PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES"

Guidelines for Applicants

Submission deadline for pre-proposals: February 18th, 2020

For further information, please visit us on the web:
http://www.ejprarediseases.org/

Or contact:

Joint Call Secretariat (ANR, France)
EJPRDcall@anr.fr

Florence Guillot
florence.guillot@agencerecherche.fr
+33 (0) 1 78 09 80 01

Kiri Couchman
kiri.couchman@agencerecherche.fr
+33 (0) 1 78 09 81 29

Table of Content

1. Application Process

1.1. Registration

Research consortia who intend to submit a transnational project proposal should register using the electronic proposal system (we advise as early as possible) via the link: https://ptoutline.eu/app/ejprd20.
To register, please fill in the data sheet in the system. The same data sheet can be used for the final electronic proposal submission.

1.2. Pre- and Full 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 research consortium. The project coordinator must then submit the joint proposal to the Joint Call Secretariat (JCS) via the electronic submission system (https://ptoutline.eu/app/ejprd20). **Proposals must be prepared using the forms provided on the EJP RD web page (www.ejprarediseases.org). Proposals not conforming to the instructions in the form (including length and format) will be rejected.**

There is no need to submit a paper version of the proposal, however, both the electronic pre-proposals and full proposals need to be signed (electronic signature or a scanned copy of the signature page will be accepted).

Joint pre-proposals (in English) must be received by the JCS in an electronic version no later than **February 18th 2020 at 2:00 p.m. Central European Time (CET)**.

Full proposals (in English) must be received by the JCS in an electronic version no later than **June 16th 2020 at 2:00 p.m. Central European Summer Time (CEST)**.

1.3. Rebuttal stage

Please note that project coordinators will be provided with the opportunity to study the assessments of external reviewers and comment on their evaluations of full proposals (for details see section 6.3 in the "Call text" document).

2. Advice for preparing your proposal

Carefully read the "Call Text" and this "Guidelines for Applicants" document, including the call aim and evaluation criteria.

Proposals not conforming to the following may be rejected without review:

- Make sure that your proposal falls into the **scope of the call**
- Make sure that your proposal fulfils the **eligibility criteria of the call**
- Make sure that all consortium members have understood **the national eligibility criteria and requirements** (Annex 1&2) and that they fulfil these criteria
- Make sure that all consortium members **contacted their national representative** and confirmed eligibility with their respective funding agencies in advance of submitting an application (see Annex 1&2)
- Prepare your proposal in advance and enter the requested information on the submission site as soon as possible to **avoid possible overloading on the submission deadlines**
- **Use the proposal forms** provided on the EJP RD website (www.ejprarediseases.org)
- **Respect the length limitations** of each section in the proposals

3. Early Career Researchers (ECRs)

3.1. Definition

Please note that national/regional definitions and time limits might differ. **Therefore, please refer to national guidelines and contact your national/regional funder.** ECRs are otherwise defined as per the regulations of the European Research Council criteria for starting grants. In short, the researcher must have been awarded their **first doctoral degree (PhD) two to seven years prior** to the pre-proposal submission deadline. Extensions to this period are allowed (with documentation) in the case of reasonably justified career breaks: absence for maternal, paternal or long-term sick leave, and compulsory military service.

For medical doctors (or applicants holding a degree in medicine), an MD is not by itself considered equivalent to a PhD award. To be considered an ECR, these applicants must 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 or professorship appointment). MD applicants that do not hold a PhD must have been awarded their **MD four to nine years prior** to the pre-proposal submission deadline. For medical doctors who have been awarded both an MD and a PhD, the date of the earliest degree that makes the applicant eligible will be used to calculate eligibility. Extensions to this period will be given (with documentation) for clinical training periods up to a maximum of four years.

3.2. Eligibility of ECRs

The following dates must be provided by Early Career Researchers so that their eligibility can be evaluated according to their respective regional/national regulations. This information must be present in the CV in the pre- and full proposal forms.

Medical doctors with PhD

Medical Studies:	*indicate dates (start and end) of your studies (year and month)*
End of studies:	*indicate date of your medical certificate*
PhD Time:	*indicate dates (start and end) of your PhD time (year and month)*
PhD:	*indicate date of your PhD certificate*
Appointment:	*indicate dates (start and end) of the appointment that requires doctoral equivalency (e.g. post-doctoral fellowship or professorship appointment), only if applicable*

Medical doctors without PhD

Medical Studies:	*indicate dates (start and end) of your studies (year and month)*
End of studies:	*indicate date of your certificate*
Appointment:	*indicate dates of the appointment that requires doctoral equivalency (e.g. post-doctoral fellowship or professorship appointment)*

Other Early Career Scientists with PhD

Studies:	*indicate dates (start and end) of your studies (year and month)*
End of studies:	*indicate date of your certificate*
PhD Time:	*indicate dates (start and end) of your PhD time (year and month)*
PhD:	*indicate date of your PhD certificate*

Other Early Career Scientists without PhD

Studies:	*indicate dates (start and end) of your studies (year and month)*
End of studies:	*indicate date of your certificate*
Appointment:	*indicate dates of the appointment that requires doctoral equivalency (e.g. post-doctoral fellowship or professorship appointment)*

Reasons for Extensions, if applicable

Clinical Training:	*indicate dates (start and end) of clinical training (year and month);*
Parental leave:	*Women: number of children (1.5 years are given per child; in case of longer maternal leave, please indicate the exact dates); Men: indicate exact dates of paternal leave (per child)*
Career Break:	*indicate dates (year and month) of other career breaks: long-term sick leave, compulsory military service, carer's leave*

4. Financial and Legal Issues

4.1. Funding model and Call governance

The EJP RD JTC 2020 Funding agencies 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 agencies 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 for a maximum of three years. Funding for Patient Advocacy Organisations (PAOs) will be administered by INSERM (France), see Annex 1 for more information and contact points.

The ANR (France) is acting as Joint Call Secretariat (JCS) to assist the Call Steering Committee (CSC), and the national/regional funding agencies during the implementation of the call. CSO-MOH (Israel) and FNRS (Belgium) will be responsible for the follow-up phase until the funded research projects have ended. The JCS will be responsible for the administrative management of the call. It will be the primary point of contact referring to the call procedures between the research consortia, the funding agencies (CSC), and the peer reviewers. The project coordinator will be the point of contact for the JCS during the application procedure, and is responsible for forwarding this information their project partners.

4.2. Widening for the inclusion of underrepresented and undersubscribed countries

For proposals invited to the full proposal stage, there will be a widening step to provide the opportunity to add partners to the project consortium (up to a maximum total of 8, see section 4.3 Consortium Makeup in Call Text). This step will allow for the addition of partners from participating countries that are usually underrepresented in the call, as well as those undersubscribed (countries without any selected applicants for the 2nd stage). This inclusion will not be considered as a fundamental change between pre- and full proposal. **Inclusion of new research teams is not mandatory. The new teams included should bring an added value and expertise to the projects.**

Process:

1. A list of countries eligible for this widening procedure will be published on the EJP RD website after completion of the 1st stage of evaluation and sent to the coordinators who are invited to write a full proposal.
2. Two inclusion options will be available:
   a) The relevant national funding agencies may produce a list of research teams that could provide additional expertise to projects. **For this, the title, pre-proposal abstract, and composition of the consortium will be shared with potentially interested research teams.** The JCS will then provide this list to the coordinators of projects invited to the full proposal stage, and give them the option of adding them to the existing consortium.
   b) The coordinator/partners of projects invited to the 2nd stage of evaluation can inquire themselves about suitable partners from among listed countries. The new prospective partner must then contact their national funding agency to confirm their eligibility.

In all cases, the final decision on whether to take a new research team on board will be taken by the project consortium. The rules concerning the maximum number of partners in a consortium and the maximum of two research teams per country must still be respected. Furthermore, the new research team must be eligible for the national funding agency. For this purpose, national funding agencies from underrepresented or undersubscribed countries may indicate that only national research teams that were already involved in pre-proposals (and thus are eligible) are allowed to make use of this widening step.

4.3. Funding contracts

Each project includes several partners as beneficiaries. Each partner will have a separate funding contract/letter of grant with their respective national/regional funding agency, and according to their regulations.

Changes to the composition of research consortia or budget cannot occur within the contract/letter of grant without thorough justification. Minor changes will be handled by the relevant national/regional funding agency. In the case of major changes, such as a change in consortium structure, an independent expert may be consulted to help with the final decision of the funding agencies. Research partners must inform the JCS and the respective funding agencies of any event that might affect the implementation of the project.

4.4. Project start and consortium agreement

Consortium members of projects selected for funding **must fix a common project start date**, which will be the reference date for yearly and final reports and extensions. This common project start date must appear in the **Consortium Agreement (CA).**

The project consortium partners must sign a CA for cooperation. For reference, applicants may consider modifying the DESCA 2020 Model Consortium Agreement. It is recommended that the CA be signed by all relevant parties before the official project start date. Please note that national/regional regulations may apply concerning the requirement for a CA (please contact your national/regional contact point or check Annex 2). This consortium agreement must be made available on request to the relevant EJP RD JTC 2020 funding agencies.

The purpose of the CA shall be:

- to underpin the collaboration and provide 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 should be addressed by the CA (at minimum):

- 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)

4.5. Ownership of intellectual property rights

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the EJP RD JTC 2020 will be owned by the selected project partner's organisation, according to national/regional rules on IPR. In the case of joint development of intellectual property, consortium partners will resolve this issue internally using their consortium agreement and relevant legal guidelines, and taking into account their relative contributions (this should be described in the consortium agreement).

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 agencies 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.

4.6. IRDiRC policies and guidelines

The project partners **are expected to follow IRDiRC policies and guidelines**.

4.7. European and International standards

The submitted proposals must respect relevant European and international standards including:

- H2020 ethics manual for research projects,
- The Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects,
- The new EC Regulation EC 2016/679 (GDPR) 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 all EJPRD JTC 2020 projects,
- The EC Directive 2010/63/EU on the protection of animals used for scientific purposes,
- European Research Council Guidelines on Implementation of Open Access to Scientific Publications and Research Data,

- To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy is mandatory in the full proposal. Example questions for a data management strategy.

4.8. Publication of Results

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

Funding recipients 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 agencies. This includes the display of the EJP RD logo when possible.

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

1. display the EU emblem and
2. 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 project partners (beneficiaries) may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

5. General Data Protection Regulation

The following Data Privacy Notice applies[1]

By submitting an application to the Co-funded call, applicants consent to the use, processing and retention of their data for the purposes of:

- processing and evaluating the application where processing shall be lawful only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- administering any subsequent funding award;
- managing the Funding Party's relationship with them;
- analysing and evaluating the Co-funded call;

[1] General Data Protection Regulation (GDPR – Regulation (EU) 2016/679)

- reporting to the European Commission/ Research Executive Agency (REA) on the Co-funded call;
- providing aggregate data to national and European surveys and analyses;
- complying with audits that may be initiated by the Funding Parties and the European Commission (or its agencies).

The members of the EJP RD consortia may share an applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

The members of the EJP RD consortia may link the data that applicants provide in the application with national, bibliographic or external research funding data which is available through public subscription based databases (e.g. Scopus, Web of Science, etc.) or other national / open datasets. The members of the EJP RD consortia may also link the data that applicants provide in their application with future data that applicants provide as part of the ongoing management and reporting on a Co-funded call award which may be awarded to them.

Data on Funding Parties including contact details of FC members and NCP/RCP are kept for the purpose of the Co-funded call communication. The information will be published with prior consent of the respective management bodies.

ANNEX 1: Guidelines for Patient Advocacy Organisations

INSERM, France is responsible for administering the funding for all PAOs.

Country	Multinational - Funding of All Patient Advocacy Organisations only
Funding organisation	Institut National de la Santé et de la Recherche Médicale (INSERM)
National contact person	**E-mail**: pao@ejprarediseases.org
Funding commitment	0.7 M€
Overheads	Overheads cost category corresponding to « frais généraux » are limited to 15% of total grant amount (that is 15% * 50 000 € = 7500 €).
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. **Definition of rare disease patient advocacy organisations:** 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: • Umbrella organisations (e.g. representing either European organisations and/or national umbrella organisations for rare diseases); • European rare disease specific organisations (i.e. representing national organisations or individual patients on rare diseases) and • 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.). Only temporary staff costs are eligible, in proportion to the time spent on the project, with justification in the form of a time sheet. 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. Expenditure on general, administrative and / or infrastructure costs is eligible (overheads = frais généraux) is up to 15% of the grant amount. The subcontracting is eligible for up to 50% of the grant. 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.
Submission of the proposal at the national level	**Criteria to be fulfilled by PAOs:** The Patient Advocacy Organisations shall fulfil the following criteria: • **Legitimacy**: 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) • 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 • **Mission/objectives**: the organisation shall have its mission/objectives clearly defined and should agree to have it/them published on the EJP RD website. • **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). • **Representation**: the organisation shall be representative of rare disease patients within a member state or throughout the EU/EEA. • **Structure**: o the organisation should have governing bodies which includes a majority of rare disease patients or family members of rare disease patients. o Includes in its governing structure a designated representative legally authorised to sign a contract with a public funder/Inserm. • **Accountability:** o With proven activities such as rare disease patient support and/or advocacy activities and/or rare disease

	research ○ 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. ○ 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. • **Transparency:** ○ 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 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. ○ The organisation shall publish on its website the registered statutes, sources of funding, and information on their activities. ○ To facilitate communication, a contact person shall be identified for each organisation.
Further guidance	pao@ejprarediseases.org

ANNEX 2: Country and Region-Specific Guidelines

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 http://www.fwf.ac.at
National contact person	**Stephanie Resch** **Phone:** +43 (1) 505 67 40-8201, **E-mail**: stephanie.resch@fwf.ac.at **Anita Stürtz** **Phone**: +43 (1) 505 67 40-8206, **E-mail**: anita.stuertz@fwf.ac.at
Funding commitment	0,6M€
Overheads	Overheads are not eligible costs for FWF.
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 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. 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 Please refer also to the general FWF Funding Guidelines: http://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/Einzelprojekte/p_application-guidelines.pdf available on: http://www.fwf.ac.at/en/research-funding/application/international-programmes/joint-projects-era-nets/

Additional specific rules	Please note that starting on August 1, 2018, the number of ongoing/approved/submitted projects in which one researcher can serve as principal investigator will be limited to three in the Stand-Alone Projects Programme, International Programmes (including ERA-Net projects!), Clinical Research and Arts-Based Research Programmes. Principal investigators who already have three ongoing/approved/submitted projects will not be permitted to submit another application within those programmes until 12 months before the end of one of their ongoing projects. You are strongly advised to contact the national representative in case you may be affected by this regulation. https://www.fwf.ac.at/fileadmin/files/Dokumente/Antragstellung/project_number_limit.pdf
Submission of the proposal at the national level	FWF Submission: 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/ This is required already at the pre-registration stage via the programme category "IK – International Projects (preproposal, deadline February 12th 2020)". For the full proposal stage applicants must choose the programme category "I – International Projects". Both steps are mandatory. 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. Detailed information may be found under the Internet 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) http://www.fwo.be/
National contact person	Alain Deleener +32 2 550 15 45 Toon Monbaliu +32 2 550 15 70 eranet@fwo.be
Funding commitment	0.7M€
Overheads	Both the FWO Strategic Basic Research Projects (SBO), which are directed towards future applications and valorisation potential, next to the 'classic' FWO projects, with a more fundamental (FO) nature, are integrated in this call, each with specific regulations. Determining the overhead amount depends consequently on the FWO funding channel in which the Flemish subproject fits: **For FO projects:** A mandatory 6% overhead cost has to be included in the requested funding of max. 350.000 EUR per project/consortium. This structural overhead cost of 6%, calculated on the applied for budget or 'direct costs' (personnel, consumables, travel, equipment, other), needs to be inserted in the 'overhead' category. A practical example: if 330.000 EUR (excl. overhead) is requested by a researcher, and comprises for example personnel, consumables and travel costs, then a 6% structural overhead cost has to be calculated on this amount (19.800 EUR). The total requested budget in this example would thus be 349.800 EUR (incl. overhead). **For SBO projects:** The specific SBO overhead regulations apply, which can be consulted on the FWO website. Researchers are advised to contact the central coordination unit or relevant contact points at their host institution, as the overhead requirements for SBO projects might differ per institution. **The total applied amount can never, for both funding channels, exceed 350.000 EUR, overhead included.**

Anticipated number of fundable research partners	2-3
Eligibility of project duration	Projects have to respect a maximum 36 month duration and projects have to be budgeted accordingly. I.e. 'automatic cost extensions', like for the 'national' projects, cannot be taken into account.
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	Who can be eligible for FWO funding? The eligibility of institutions and its researchers can be verified in the relevant regulations: → For FO projects, see articles 10-12 of the appropriate regulations. → For SBO projects, see articles 4-8 of the appropriate regulations. **Valorisation – with an economic and/or societal finality - is an essential feature of the SBO programme.** Additional conditions for FWO funding: Researchers have to inform the central research coordination unit at their host institution about their participation. **One and the same researcher can only participate in 2 different research projects/consortia when applying for FWO funding, within the same call. Double funding is not allowed.**
Eligibility of costs, types and their caps	▪ Only temporary personnel can be remunerated. ▪ For FO cost categories see chapters 7 and 8 of the regulations. ▪ For SBO cost categories see the SBO cost model.
Submission of the proposal at the national level	No. When the strategic basic research channel (SBO) would be the appropriate choice of funding, **we ask researchers to provide us with a 'valorisation plan' before the pre-proposal submission deadline**. There is no fixed format and one A4 page should suffice. What the FWO wants to know is how the valorisation within Flanders - and potentially internationally – will take place and which Flemish actors are involved in this. This information can be submitted to the general eranet@fwo.be email address.

Submission of financial and scientific reports at the national level	Financial reporting: Yes Scientific reporting: depends on the funding channel ▪ FO projects: Reporting at ERA-NET level only; ▪ SBO projects: Besides the reporting at ERA-NET level, 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 (re-)verify the choice of funding channel. 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. **Interesting links:** FWO call page for European programmes (ERA-NET) https://www.fwo.be/nl/mandaten-financiering/europese-programmas/era-net/oproepen/ SBO programme regulations https://www.fwo.be/nl/mandaten-financiering/onderzoeksprojecten/sbo-projecten/ FO programme regulations https://www.fwo.be/nl/mandaten-financiering/onderzoeksprojecten/junior-en-senior-onderzoeksproject/

BELGIUM, FNRS

Country / Region	Belgium (French Speaking Community)
Funding organisation	Fund for Scientific Research - FNRS (F.R.S.-FNRS)
National contact person	Florence Quist Phone: +32 2 504 93 51 Email: florence.quist@frs-fnrs.be Joël Groeneveld Phone: +32 2 504 92 70 E-mail: joel.groeneveld@frs-fnrs.be
Funding commitment	240.000 €
Overheads	Overheads are not eligible costs for FNRS
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
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 (To be confirmed)

Country	Canada
Funding organisation	Canadian Institutes of Health Research, Institute of Genetics (CIHR-IG) in partnership with Ataxia Charlevoix-Saguenay Foundation and Muscular Dystrophy Canada
National contact person	Jennifer Vineham Phone: +1 613 941-0796 jennifer.vineham@cihr-irsc.gc.ca Etienne Richer Email: Etienne.Richer@cihr-irsc.gc.ca
Funding commitment	1.875
Overheads	Not an allowable cost.
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 http://www.cihr-irsc.gc.ca/e/22630.html#1-D1-1 **Investigator (early career)** A researcher who, at the time of application, has held a full time, independent research appointment, for a period of 0 to 5 years (60 months). All time spent in research appointments/positions will be taken into consideration when determining eligibility

	irrespective of time spent in a clinical component or other duties (i.e. administrative, academic, etc). Should an applicant hold or have held a part-time appointment/position, CIHR will count that time as 50% (e.g., a one-year part-time appointment/position will count for 6 months towards the maximum). Leaves of absence will be considered in the calculation of eligibility (i.e., will not count towards the maximum) and should be included in the Employment section under Leaves of Absence in your Common CV.
Eligibility of costs, types and their caps	http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/FundsUse-UtilisationSubventions_eng.asp
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	

CANADA, FRQS

Country	Canada - Québec
Funding organisation	Fonds de recherche du Québec – Santé (FRQS) http://www.frqs.gouv.qc.ca
National contact persons	Maxime Beaudoin 1+ (514) 873-2114, ext 1369 maxime.beaudoin@frq.gouv.qc.ca
Funding commitment	$500,000 CAD (~ € 360,000) ; Anticipated number of funded research groups: 1-2 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. Funds are subject to availability of funds voted annually to FRQS by the National Assembly of Québec and FRQS Board of Directors' approval.
Overheads	Overheads means "frais indirects de recherche" and will be managed separately by the FRQS. They should not be included in the requested budget.
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.	NO
Eligibility of principal investigator or other research team member	Quebec applicants must meet the eligibility criteria for FRQS research grants. Eligible institutions are Quebec Universities or Institutions within Quebec's health and social services network. Further information about eligibility of applicants and institutions is available in section 2 of the Common Rules and Regulations **RULE FOR SELECTED PROPOSALS:** Basic research ethics training is **mandatory** for all recipients of an FRQS grant when their part of research project involve human beings. **PI and Co-PI** on the project must therefore successfully complete levels 1 and 3 of MSSS Ethics online training by the Ministère de la Santé et des Services sociaux. Post-doctorate on the project are also encouraged to complete this training. Ethics approval of the project will have to be sent to FRQS before the first payment of the grant.

Eligibility of costs, types and their caps	Operational costs (research personnel, consumables, animals) Costs related to scientific and ethical evaluation (clinical research projects) Coordination-related cost (project administration and travel expenses for attending joint meetings) Costs related to knowledge translation and translation Conference attendance (up to **5%** per year of the grant amount starting the first year **with justifications**) Further information about eligible costs is available in section 8 of FRQS Common Rules and Regulations. **Note: There is NO support for salaries of investigators.**
Submission of the proposal at the national level	**NEW: Quebec Principal investigator (PI)** must submit a short application form through FRQS electronic portfolio. **Quebec Co-investigator** has to consent to be part of this application before the institutional approval. CCV of all the investigators must be updated with the most recent information for the eligibility check. **Institutional (university)** approval must be done lastly which automatically activates the final submission. **$CAD Budget form** will be requested only for invited PIs at the Full proposal stage through FRQ application form. Once the application is submitted, it will no longer be possible to modify it. Transmission via the FRQS electronic portfolio only. Documents sent via mail or e-mail will NOT be accepted. **FRQS short application form will follow the exact Call deadlines.** In addition: *FRQS requests that Quebec applicants applying for funding from FRQS/CIHR also complete an abbreviated CIHR application and submit it via ResearchNet*
Submission of financial and scientific reports at the national level	Scientific reports according to EJP RD template and requirements only. Annual financial reporting according to FRQS Common Rules and Regulations. *The FRQS reserves the right to request any additional or complementary information related to the project granted.*
Further guidance	***Early-Career Scientists (Junior Researchers) – FRQS definition*** *Early career researchers (Junior 1 and Junior 2) are encouraged to submit an application as a Principal Investigator (the Junior status begins no more than six (6) years after obtaining a Ph.D. and lasts no more than eight (8) years).* *Postdoctoral trainees cannot apply to this Competition as Investigators.*

CZECH REPUBLIC, MEYS

Country	Czech Republic
Funding organisation	Ministry of Education, Youth and Sports (MEYS) www.msmt.cz
National contact person	Judita Klosaková (MSMT) Phone: +420 234 811 504 E-mail: judita.klosakova@msmt.cz
Funding commitment	0.6 M€
Overheads	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.
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. 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 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. 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**. 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. 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: - 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. - 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. Template available on websites of the Ministry of Education, Youth and Sports: http://www.msmt.cz/vyzkum-a-vyvoj2/era-net-cofund. 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. Detail information may be found under the Internet address (http://www.msmt.cz/vyzkum-a-vyvoj-2/era-net-cofund). The **electronic version** of requested documentation shall be sent to the address of electronic correspondence Daniel.Hanspach@msmt.cz. 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

FINLAND, AKA

Country	Finland
Funding organisation	Academy of Finland (AKA) http://www.aka.fi
National contact person	Heikki Vilen +358 29 5335 135 heikki.vilen@aka.fi
Funding commitment	600 000 €
Overheads	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.
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 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

Country	France
Funding organisation	French National Research Agency (Agence Nationale de la Recherche –ANR-) http://www.agence-nationale-recherche.fr
National contact person	Health & Biology Department Agence Nationale de la Recherche –ANR 50 avenue Daumesnil - 75012 Paris, France Florence Guillot Email: **EJPRDcall@anr.fr** Phone: (33) (0) 1 78 09 80 01
Funding commitment	3 M€ Funding limits apply per partner for this call: Each partner may be granted up to **300 000 € as a coordinating partner** or **250 000 € as a non-coordinating partner**. The minimum funding amount per partner is 15 000 €.
Overheads	The ANR heading for "overheads" in the ANR funding breakdown is «frais d'environnement». 8% of the total eligible costs must be applied for if the partner belongs to a public research organisation (or other organisation funded at "marginal" costs), or up to 68% of the total personnel costs and 7% of other costs for partners funded at full economic cost (such as enterprises) (cf "Règlement financier ANR 2019 – section 3.1.1e")
Anticipated number of fundable research partners	TBC
Eligibility of project duration	2-3 years
Eligibility of a partner as a beneficiary institution	**Only ONE French[2] partner per consortium will be eligible for funding by ANR**, with an exception for the addition of an Early Career Researcher as full partner (see call text). **Partners awarded funding under EJP-RD JTC2019 are not eligible.** **Eligible institutions:** - Public research organisation or related-one[3] such as EPST, EPIC, universities, university hospitals, non-university research institutes (max. rate of support: 100% of marginal costs)

[2] Partners that have their primary establishment in France and/or Partners established in the EU and have a secondary establishment in France

[3] Include public law entities engaged in research activity and private law entities engaged in research and/or teaching activity

	- Enterprises: large & SMEs (max. rate of support: 45% of total costs for SMEs & 30% for larger companies) Additional eligibility criteria: - The coordinator (if from a French institution) must belong to a public research organisation. - ANR will not provide double funding to finance projects or part of projects that have been funded through other national and international calls. ANR will cross-check the proposals submitted to ensure they have not been submitted to the ANR through other calls.
Eligibility of costs, types and their caps	Eligible costs include (but are not limited to) the following: 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 max 50% of requested budget per partner). Eligible costs depend on the type of partner and consortium makeup. Please refer to the ANR Funding regulations for more details.
Submission of the proposal at the national level	No.
Submission of other information at the national level	No. However, please contact the national contact point for the ANR to confirm eligibility before submitting a proposal.
Submission of financial and scientific reports at the national level	Financial reporting: must be completed according to ANR regulations, and the funding contract that future beneficiaries must sign. Scientific reports: individual scientific reports are not required. However, ANR funded partners should contribute to the project report to be submitted by the coordinator of the project to EJP RD. These reports will be the basis for validation of yearly advancements of the project by ANR.
Further guidance	Règlement financier: http://www.agence-nationale-recherche.fr/RF Please read the modalities document for this call on the ANR website

FRANCE, FFRD

Country / Region	France
Funding organisation	French Foundation for Rare Diseases (Fondation maladies rares) https://fondation-maladiesrares.org/eng/
National contact person	Fondation Maladies Rares Plateforme Maladies rares 96 rue Didot - 75014 Paris, France **aap-bio@fondation-maladiesrares.com** Ingrid Zwaenepoel - Phone : (33) (0) 1 58 14 22 85 Diana Désir-Parseille - Phone : (33) (0) 1 58 14 22 81
Funding commitment	100 000€
Overheads	Overheads are not eligible costs.
Anticipated number of fundable research partners	TBD
Maximum funding per grant awarded to a partner	20 000€
Eligibility of project duration	2-3 years
Eligibility of a partner as a beneficiary institution	Eligible institutions: - 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. Overheads are not eligible costs.

Submission of the proposal at the national level	No
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. 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

Country	Germany
Funding organisation	German Federal Ministry for Education and Research (BMBF) www.gesundheitsforschung-bmbf.de
Management organisation	German Aerospace Center, DLR Project Management Agency (DLR-PT) www.pt-dlr.de
National contact person	***German Aerospace Center*** DLR Project Management Agency | Health | Division Clinical Research, University Medicine, Digital Health Heinrich-Konen-Straße 1 53227 Bonn Germany Dr. Katarzyna Saedler Phone: +49 (0)228 3821-1947 E-mail: Katarzyna.Saedler@dlr.de Dr. Michaela Fersch Phone: +49 (0)228 3821-1268 E-mail: Michaela.Fersch@dlr.de Dr. Ralph Schuster Phone: +49 (228) 3821-1233 E-mail: Ralph.Schuster@dlr.de
Funding commitment	3 Mio€
Overheads	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.

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
Eligibility of costs, types and their caps	Personnel, consumables, animals, subcontracts, equipment, travels, documentation according to national regulations. 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 https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=1752

GERMANY, DFG (Decision Pending)

Country	Germany
Funding organisation	German Research Foundation (DFG) www.dfg.de
National contact person	***DFG: Deutsche Forschungsgemeinschaft (DFG)*** Kennedyallee 40 53175 Bonn Germany Dr. Katja Grossmann Tel. +49 (228) 885-2565 Fax +49 (228) 885-2777 katja.grossmann@dfg.de
Funding commitment	3 Mio€
Overheads	The "Programmpauschale" generally will amount to 22% of the applied total project expenditure. See www.dfg.de for further details.
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. Overheads : 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 the national level	Yes, according to national regulations.
Further guidance	http://www.dfg.de/en/research_funding/programmes/individual/research_grants/index.html

GREECE, GSRT

Country / Region	Greece
Funding organisation	General Secretariat for Research and Technology (GSRT) Directorate for International Scientific &Technological Cooperation www.gsrt.gr
National contact person	DIMITROPOULOU Sofia s.dimitropoulou@gsrt.gr Tel. 00 30 2131300 187
Funding commitment	0.8M€ 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). Maximum funding per project 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.
Overheads	15% calculated on the basis of the personnel budget of the partner.
Anticipated number of fundable research partners	4 projects tentatively envisaged to be funded
Eligibility of project duration	24 months without prolongation
National Programme	**National Research and Innovation Strategy for Smart Specialization 2014-2020** 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*** 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). ***Eligible applicants*** 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 are not eligible under this scheme.** ***Eligible costs*** (a) personnel costs: researchers, technicians and other supporting staff to the extent employed on the project. (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. (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. (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. (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). **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. ***Aid of intensity***

	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)). **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. - 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: (a) by 10 percentage points for medium-sized enterprises and by 20 percentage points for small enterprises; (b) by 15 percentage points if one of the following conditions is fulfilled: **(i)** the project involves effective collaboration: — 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 — 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; **(ii)** the results of the project are widely disseminated through conferences, publication, open access repositories, or free or open source software. -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. ***Project Duration*** The duration of a funded project will be strictly 24 months. ***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. 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: http://www.gsrt.gr/central.aspx?sId=108I334I1106I646I444510&olID=777&neID=673&neTa=12_20503_1&ncID=0&neHC=0&tbid=0&lrID=2&oldUlID=aI777I0I119I428I1089I0I3&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)
Further guidance	All applicants are strongly encouraged to contact the NCP prior to submission.

HUNGARY, NKFIH

Country	Hungary
Funding organisation	National Research, Development and Innovation Office (NKFIH) http://nkfih.gov.hu/; http://nkfih.gov.hu/for-the-applicants
National contact person	National Research, Development and Innovation Office, Kéthly Anna tér 1, Budapest, H-1077, Hungary Dr. Előd Nemerkényi Assistant of International Affairs, Department of Research and Development, NKFIH Phone: +36 1 8963987 E-mail: elod.nemerkenyi@nkfih.gov.hu Dr. Gábor Tóth Head of unit, Unit for Medical and Biological Sciences, NKFIH Phone: +36 1 8961727 E-mail: gabor.toth@nkfih.gov.hu
Funding commitment	200.000€
Overheads	10% of the total costs of the project. Applicants should consult NKFIH '2019-2.1.7-ERA-NET' call regulations for details.
Anticipated number of fundable research partners	1-2
Maximum funding per grant awarded to a partner	Up to 150.000 €. If more than one partner applies from Hungary, their total requested funding should not exceed 150.000 euros.
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 10 % of total costs. The maximum funding of 150.000 € per project includes the overhead. 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 NKFIH '2019-2.1.7-ERA-NET' call (https://nkfih.gov.hu/palyazoknak/nkfi-alap/era-net-ejp-cofund-2019-217-era-net/palyazati-felhivas-2019-217-era-net) or the latest relevant national 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. Researchers cannot participate in more than one proposal submitted to the same joint transnational call.
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. Upon the EJP RD funding decision a proposal should be formally submitted to NKFIH in its electronic proposal system (EPTK). This is necessary for managing the project by NKFIH.
Submission of financial and scientific reports at the national level	Required annually

ISRAEL, CSO-MOH

Country	Israel
Funding organisation	Chief Scientist office, Ministry of Health (CSO/MOH) http://www.health.gov.il/
National contact person	Dr. Irit Allon Phone: +972-2-5082167 E-mail: Irit.allon@moh.health.gov.il
Funding commitment	Up to 300.000 euros
Overheads	10% of the entire project
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.
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

Country / Region	Ireland
Funding organisation	Health Research Board
National contact person	Louise Drudy ldrudy@hrb.ie
Funding commitment	Up to €370,000 in total
Overheads	Yes included in the overall funding commitment
Anticipated number of fundable research partners	Up to two depending on the requested funding
Maximum funding per grant awarded to a partner	€370,000
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-grantconditions/policies-and-position-statements/approval-of-host-institutions/
Eligibility of principal investigator or other research team member	The Lead Applicant must: • 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** • 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** • Be an individual who will be recognised by the Host Institution upon receipt of the EJP-RD JTC 2020award 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. The Lead Applicant must: i. Show appropriate evidence of expertise matched to the nature and context of the project; ii. Show evidence of achievement as an independent researcher in their chosen research field by:

	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 book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field. b) Demonstrating record of independence by showing that they have secured at least one 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 will not be considered in this regard. 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 • Salary related costs • small equipment costs • travel • direct running costs • dissemination and knowledge exchange costs overheads 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	• For full proposal stage: Irish partners are asked to provide a copy of the submitted full proposal to the HRB following submission to the European Portal. In addition, Irish partners will be requested to provide a list of **deliverables and supplementary budget information requested to the HRB**. This will expedite contract negotiations with HRB in the case of successful consortia with applicants from Ireland. Relevant templates will be provided by the HRB.
Submission of financial and scientific reports at the national level	Annually
Further guidance	

ITALY, MoH-IT

Country	Italy
Funding organisation	Ministry of Health (Ministero della Salute) www.salute.gov.it
National contact person	Dr. Gaetano Guglielmi Phone : + 39 06 5994 2197 mailto:g.guglielmi@sanita.it mailto:research.EU.dgric@sanita.it Dr. Monica Paganelli Office 5, (Health Research IRCCS) Directorate General for Research and Innovation in Healthcare Ministry of Health, Viale Giorgio ribotta, 5 -00144 Rome, Italy Phone : +39 06 5994 2408 mailto:m.paganelli@sanita.it
National programme	Framework National Programme "IRCCS Health Research" of the Ministry of Health.
Funding commitment	2.5 Mio Euro
Overheads	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.
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. 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.
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

Country	Italy
Funding organisation	Ministry for Education, Universities and Research (MIUR)
National contact person	Aldo Covello - aldo.covello@miur.it - +39 06.9772.6465 Maria Bianco - maria.bianco@miur.it - +39 06.9772.7146
National programme	FIRST – Fund for Investments on Scientifics and Technological Research
Funding commitment	600.000 €
Overheads	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.
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. 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".
Eligibility of principal investigator or other research team member	No prescriptions

Eligibility of costs, types and their caps

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).
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.
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:

Applicant Typology / Activity typology		Funding Rates			
		Enterprises and private research bodies (which meets the requirements of research organization under EU Reg. no. 651/2014 of the Commission - June 17, 2014)			Universities, public research institutions, research organizations (public and private) in accordance with Reg. EU n. 651/2014 of the Commission - June 17, 2014)
		Small Enterprises	Medium Enterprises	Large Enterprises	
Basic Research	grant	40%	30%	20%	70%
Industrial Research	grant	40%	30%	20%	50%
Experimental Research	grant	30%	20%	10%	25%

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 **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.** Additional documents will be required at the Full proposal phase. 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. 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. Applicable laws and rules: - Decreto legge n. 83/2012 - Decreto Ministeriale n. 593 del 26 luglio 2016 - Linee guida al D.M. del 26 luglio 2016 n. 593 - Procedure operative per il finanziamento dei progetti internazionali ex art. 18 D.M. del 26 luglio 2016 n. 593

ITALY, FRRB

Country / Region	Italy
Funding organisation	Fondazione Regionale per la Ricerca Biomedica - Regional Foundation for Biomedical Research (FRRB)
National contact person	Via Taramelli 12, 20124 – Milano Tel: +39 02 67650174 Miss Paola Bello Mrs. Carmen De Francesco Dr. Paola Larghi, PhD Mail to: bandi@frrb.it
Funding commitment	€ 1.000.000
Overheads	Up to 20% flat rate calculated on direct costs – Subcontracting costs excluded from this calculation.
Anticipated number of fundable research partners	2-3
Maximum funding per grant awarded to a partner	Maximum € 500,000 **per project** MAXIMUM TWO PARTNERS PER PROJECT
Eligibility of project duration	Maximum 3 years
Eligibility of a partner as a beneficiary institution	Public or Private IRCCS (Scientific Institutes for Research, Hospitalization and Health Care), Public Health Care Providers (ASST), Universities and Research Institutes located on the Lombardy territory. It is COMPULSORY that at least one IRCCS (public or private) or ASST is partner in the project proposal. Other types of organisation are eligible ONLY in partnership with them. 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 eligible institutions. If an applicant has a currently funded FRRB grant, he/she cannot submit an application (neither as PI nor as WP leader) Coexisting FRRB awards and applications for new awards are not permitted
Eligibility of costs, types and their caps	Direct costs: • Personnel (for public IRCCS and ASST, ONLY temporary contracts): max 50% of the total direct costs (*overheads and subcontracting costs excluded*) • Consumables, animals purchase, maintenance and breeding; • Equipment (on hire or eligible amortization rate); • Travel: max 10% of the total direct costs(*overheads and subcontracting costs excluded*) • Publications: max 5% of the total direct costs (*overheads and subcontracting costs excluded*) • Overheads: 20% flat rate calculated on direct costs (*Subcontracting costs excluded from this calculation*). • Subcontracting: max 20% of the total direct costs (*overheads costs excluded*) 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. Only costs generated over the lifetime of the project will be considered eligible.
Submission of other information at the regional 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. The eligibility check will be based on the verification of a dedicated form ("Eligibility check form"), also available on the FRRB institutional website, to be returned, by email, to FRRB (bandi@frrb.it) , duly completed and signed by the Principal Investigator at least 10 working days before the pre-proposal submission deadline. FRRB will provide feedback on the Eligibility check form ONLY in case of major issues or non-eligibility. PIs who submit a proposal without sending the "Eligibility check form" to FRRB beforehand will be automatically excluded. In addition, FRRB provides an excel sheet to help applicants abide by FRRB funding rules. This form is meant to support the PIs in the elaboration of the budget, but it does not need to be sent to FRRB.
Submission of financial and scientific reports at regional level	Lombardy beneficiaries will be requested to submit annual scientific and financial reports.

Further guidance	Administrative and financial guidelines will be provided by FRRB in due time to the contact persons of the funded organisations.

ITALY, RT/Tuscany

Country / Region	Italy
Funding organisation	Tuscany Region http://www.regione.toscana.it/
Regional contact person	Donatella Tanini Phone:+39 055 4383256 Teresa Vieri Phone:+39 055 4383289 Email: ejprare@regione.toscana.it Office for Legal advice and, administrative support to health research Directorate for citizenship right and social cohesion, Tuscany Region
Funding commitment	Up to 300.000 euros
Overheads	Up to 10% of the direct cost of the project, intended to cover the general cost of the institution that hosts the research team.
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. B. Universities and other research institutes located in the territory of Tuscany. **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 member	The Principal Investigator must be affiliated to one of the eligible bodies
Eligibility of costs, types and their caps	Only costs generated over the lifetime of the project will be considered eligible. - *Personnel* (ad hoc temporary contracts ONLY) - *Consumables (no limit)*; - *Equipment* (on hire/leasing or eligible amortisation rate ONLY); - *Travel* (up to 10% of the requested fund) Travel expenses and subsistence allowances associated with activities only linked to the project; - *Other direct costs*: ◦ dissemination of results (publications, organization of meetings/workshops etc.- up to 5% of the requested fund); ◦ data handling and analysis (no limit) • subcontracting (up to 20% of the direct cost of the project) - *Overheads* (Up to 10% of the direct cost of the project excepted subcontracting).
Submission of the proposal at the regional level	Yes **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

Country / Region	Lithuania
Funding organisation	Lietuvos mokslo taryba (LMT) / Research Council of Lithuania http://www.lmt.lt
National contact person	**Dr. Živilė Ruželė** **Phone:** (+370) 676 14383**, E-mail**: zivile.ruzele@lmt.lt
Funding commitment	0.1M€
Overheads	Up to 30 % from the direct costs - personnel, travel, consumables, subcontracting, contractual research, consultancy.
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)
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://www.lmt.lt/lt/mokslo-finansavimas/era-net-ir-kitos-koordinavimo-veiklos/europos-jungtine-programa-retos-ligos/3033

LUXEMBOURG, FNR

Country / Region	Luxembourg
Funding organisation	Luxembourg National Research Fund - FNR www.fnr.lu
National contact person	Dr. Sean Sapcariu 2, avenue de l'Université L-4365 Esch-sur-Alzette Telephone: +352 261925-33 Email: sean.sapcariu@fnr.lu
Funding commitment	0,30 M€
Overheads	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.
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: (http://storage.fnr.lu/index.php/s/g4OPmRwEYhYwRkZ/download) 1. He/she must have a proper employment contract with the eligible beneficiary institution at the starting date of the project. 2. The employment contract must last for the full duration of the research project. 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	
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 : - INTER Budget form 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/

POLAND, NCBR

Country	Poland
Funding organisation	National Centre for Research and Development (NCBR) (http://www.ncbr.gov.pl/)
National contact person	Marcin Chmielewski, Department for International Cooperation, Nowogrodzka Str. 47a, 00-695 Warsaw, Poland, phone: +48 22 39 07 109, e-mail: marcin.chmielewski@ncbr.gov.pl
Funding commitment	600 000 EUR
Overheads	Overheads cannot account for more than 25% of eligible project costs (excluding subcontracting).
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: • Micro, Small, Medium and Large Enterprise; • Research organization; • Group of entities (within the meaning of art. 37 section 1 point 1a of The Act of 30 April 2010 on the National Centre for Research and Development, published in Journal of Laws item 1770, 2019;).
Additional eligibility criteria	• Organization must be registered in Poland. • For enterprises it is strongly advised to state in the Pre-proposal application form in table for Project coordinator/Project partner, in the column "Type of entity": the KRS number of the enterprise and the size of the enterprise (micro/small, medium, large). • A condition for the participation of a group of entities as the Applicant in the competition is its formal existence on the date of submission of the pre-proposal, confirmed by its members concluding, at least conditionally, agreement on the creation of a group of entities. • Please note that group of entities counts as two project partners from Poland (it meets the limit on the number of participants from the same country, please see call text for details).

Eligibility of costs, types and their caps	The eligible costs shall be the following: 1. personnel costs (researchers, technicians and other supporting staff to the extent employed on the research project); 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; 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; 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; 5. other operating costs including costs of materials, supplies and similar products incurred directly as a result of the research activity; 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%.
Submission of the proposal at the national level	Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established

National funding rates

Funding quota of Polish participants can be up to 100% for universities or research organisations. In the case of enterprises, funding quota will be decided on a case-by-case basis depending on the size of the company, type of research/development,
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.

	Large Enterprises	Medium Enterprises	Small Enterprises	Universities and research organizations
Fundamental/ Basic Research	Not eligible	Not eligible	Not eligible	Not eligible
Industrial/Applied Research	Up to 50+15 (max 65 %)	Up to 50+10+15 (max 75 %)	Up to 50+20+15 (max 80 %)	Up to 100 %
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.

PORTUGAL, FCT

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. €
Overheads	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.
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**; **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 the national level	Yes. Submission of financial and annual scientific reports at national level is required according with the rules of FCT.
Further guidance	https://www.fct.pt/apoios/projectos/regulamentofundosnacionais.phtml.pt

SLOVAKIA, SAS

Country	Slovakia
Funding organisation	Slovak Academy of Sciences (SAS): https://www.sav.sk/?&lang_change=en
National contact person	Zuzana Cernakova, PhD. International Cooperation Dpt., SAS Phone: +421257510118 Email: cernakova@up.upsav.sk
Funding commitment	120.000 €
Overheads	Up to 20% of the direct costs (excluding subcontracting)
Anticipated number of fundable research partners	2 (TBC)
Eligibility of project duration	3 years
Eligibility of a partner as a beneficiary institution	- Only research institutes of the Slovak Academy of Sciences are eligible organisations for funding (up to 100%). A letter of commitment of the institute's in-kind personnel contribution equivalent to 15 000 EUR/year (spoluucast) is required by SAS at the time of application and a template can be requested from the national contact person. - Applicants from other Slovak R&D centres (universities and/or other organisations from Slovakia) can join project consortia only as collaborators that have to secure their own funding.
Eligibility of principal investigator or other research team member	- Each core member of a consortium's Slovak partner's research team must have an employment contract or a fellowship with the Slovak partner organisation lasting until the end of the project or beyond. - The principal Investigator of the Slovak partner's research team must be a senior researcher having an employment contract with the Slovak partner lasting until the end of the granted project or beyond.

Eligibility of costs, types and their caps	Funding of projects is regulated by the SAS Financial Rules for awarding grants for research projects (Financne pravidla na udelovanie grantov SAV na medzinarodne vyskumne projekty) approved by the SAS Presidium on 1 July 2018. 1. Eligible direct costs 1.1. Personnel costs - must accurately reflect the work on the project - may be used only to cover the costs (including health and social insurance) related to work agreements performed outside of employment - maximum of 15 % of all direct costs (ERA.Nets) or - maximum of 30% of all direct costs, if Slovak team is a coordinator of consortium (ERA.Nets) 1.2. Material costs and expenditures a. Consumables: minor equipment and instruments, small-scale office and laboratory material (no basic equipment of the workplace; essential computer equipment is exception) b. Costs and expenditures for services directly related to the project: subcontracts, consultations, publication of project results, conference fees c. Travel costs and living expenses: limits for travel costs and daily subsistence allowance vary depending on destination country (pursuant to Slovak Act. 283/2002 Col. Of Laws on travel reimbursement) d. Capital expenditures: to a maximum of 40% of all direct costs 2. Eligible indirect costs - administration, energy and infrastructure - maximum of 20% of all direct costs The SAS Financial Rules for awarding grants for research projects (Financne pravidla na udelovanie grantov SAV na medzinarodne vyskumne projekty) include detailed information on eligible costs and applicants should read them thoroughly to ensure compliance.
Submission of the proposal at the national level	Submission of the proposal at the national level will be required once the international evaluation has taken place and the ranking list has been endorsed by the Joint Call Steering Committee (CSC).The Slovak partner will be informed about recommendation for funding by the project consortium coordinator and invited by SAS to submit the national proposal form (MVTS form) and to present the project to the SAS Presidium. Final approval of funding of selected projects lies with the SAS Presidium(according to internal rules of SAS).
Submission of financial and scientific reports at the national level	Annual scientific and financial reports and a scientific report at the end of the project.

Further guidance	Further guidance: www.sav.sk; Act No. 133 Act of 19 February 2002 on the Slovak Academy of Sciences; SAS Financial Rules for awarding grants for research projects (Financne pravidla na udelovanie grantov SAV na medzinarodne vyskumne projekty) ; Principles of allocation of funds for the institutes of SAS to support projects in the field of international scientific cooperation (Zasady pridelovania financnych prostriedkov v SAV na podporu projektov medzinarodnej vedeckej spoluprace (MVTS) na rok 2020) For more information, please contact the national contact person.

SPAIN, ISCIII

Funding Organisation	National Institute of Health Carlos III (ISCIII) www.isciii.es
National Funding Programme	Acción Estratégica en Salud (AES 2020) http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/fd-financiacion/convocatorias-ayudas-accion-estrategica-salud.shtml
National Contact Point for the 10th call of E-RARE	Maria Druet Email: mdruet@isciii.es Tel: (+34) 9182 22530
Initial funding pre-commitment	500.000€ Only 3 years projects 3-5 projects tentatively envisaged to be funded.
Maximum funding per awarded Spanish project partner	Maximum funding per awarded Spanish project partner • Up to 175,000 € per partner (overheads included) • Up to 250,000 € per coordinator (overheads included)
Eligible institutions	• **Hospitals, primary health care or public health administration of the Spanish National Health System** (SNS) 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). • **Accredited Health Research Institutes** (Institutos de Investigación Sanitaria acreditados, IIS) Accredited according to the RD 339/2004, of February 27th or RD 279/2016 (These institutions may manage research 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.shtml • **CIBER or CIBERNED**. Team members applying to the call must be from at least two groups belonging to CIBER in two different home institutions and one of these two should be a Hospital, primary health care or public health administration of the Spanish National Health System (SNS) or Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS). • **Academia or Other Research Centers**. 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), or Accredited Health Research

Additional eligibility criteria	Institutes (Institutos de Investigación Sanitaria acreditados, IIS) in the same proposal. It is not allowed to apply independently, thus **there must be two beneficiary Spanish institutions requesting funding to ISCIII in the same proposal.** PLEASE NOTE: I. Applicants from ISCIII are eligible. Eligibility criteria from AESI 2020 apply. II. Durations of national grants are up to 3 years. III. Same institution cannot participate with more than one partner in the same project proposal. IV. Only one PI per beneficiary institution may be funded within the same proposal. V. There is no other incompatibility with AES 2020. -
Eligibility of PI and team members	•Principal Investigators (PI) can only participate in one project proposal per call. •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. Excluded personnel as Principal Investigator (PI): •Those undergoing a postgraduate training in Health Specialization (MIR, FIR, QIR, BIR, PIR). •Those undergoing research training (e.g. PhD students, or "Río Hortega" contracts). • Researchers contracted by a RETIC or a CONSOLIDER. - • Those undergoing postdoctoral training (e.g. "Sara Borrell" or "Juan de la Cierva" contracts). -
Eligible costs	• Personnel costs for temporary employment contracts (scholarships are not eligible). • Current costs, small scientific equipment, disposable materials, travelling expenses and other costs that can be justified as necessary to carry out the proposed activities. • Overheads, according to AES 2020.
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. • Double funding of the same concept is not allowed. Due to administrative and legal regulations, the National Institute of Health Carlos III declares the end of September 2020 as national deadline for the decision on fundable project consortia which include Spanish partners to be funded by ISCIII. Any

	concerned applicant in a proposal for which no final decision has been made by the deadline, could be declared not fundable by ISCIII.
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). • ISCIII may no fund project that requires the construction of new repositories without decommissioning plans or ensured sustainability after the project´s end.

SWITZERLAND, SNSF

Country	Switzerland
Funding organisation	Swiss National Science Foundation: www.snf.ch
National contact person	Christoph Meier Email: christoph.meier@snf.ch Tel: (+41) 31 308 23 62
Funding commitment	1 Mio Swiss Francs (equivalent to approx. 0.9 Mio €)
Overheads	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.
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: • SNSF Funding Regulations • General Implementation Regulations for the Funding Regulations • SNSF Regulations on Project Funding 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. 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. 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. Grants given to Swiss partners will be managed according to SNSF Funding Regulations.
	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

Country	Sweden
Funding organisation	Swedish Research Council: www.vr.se
National contact person	Sverker Lundin, sverker.lundin@vr.se, +46(0)8 546 12315
Funding commitment	approx. 1.4 M€
Overheads	The grant amount includes indirect costs.
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	2-3
Eligibility of project duration	3 years
Eligibility of a partner as a beneficiary institution	Not applicable
Eligibility of principal investigator or other research team member	Researchers applying for funds from the Swedish Research Council must hold a PhD. Only researchers at an administrating organisation approved by the SRC may apply. The applicant may not have an ongoing EJP RD grant or any other project grant concerning the same project concept, funded by the Swedish Research Council, at the start of the grant period. No restrictions apply for other research team members.
Eligibility of costs, types and their caps	The project grant may be used to fund all types of project-related costs, such as salaries (including your own salary, however no more than corresponding to the person's activity level in the project), running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment), premises and depreciation costs. Grants may not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary during teaching or other departmental duties.
Submission of the proposal at the national level	• All Swedish project leaders participating in the call for support from the Swedish Research Council shall also submit a parallel application using the Swedish Research Council's application system Prisma. The application form in Prisma can be reached from the call text at the SRC website: Swedish and English

	Parallel application is a mandatory eligibility criterion. Failure to submit the parallel application to the Swedish Research Council before the deadline of the Prisma call will result in the Swedish partner being declared ineligible. • All Swedish applicants must communicate with the EJP RD national contact person regarding their intention to participate in the call, before submission of the consortium application.
Submission of financial and scientific reports at the national level	Yes. According to the terms and conditions of the grant.
Further guidance	See national call texts for all national requirements: Swedish and English

THE NETHERLANDS, ZonMw

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 Dr. Harald Moonen Phone: +31-(0)70 349 53 49 E-mail: moonen@zonmw.nl Dr. Sonja van Weely E-mail: weely@zonmw.nl
Funding commitment	1.8 M€ maximum
Overheads	Overheads are not eligible costs for ZonMw
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 Dutch 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 (only possible if one partner classifies as Early Career Scientist), the total amount of the ZonMw funding for the project is still maximised to 250.000 euro

Eligibility of a partner as a beneficiary institution	A. Dutch universities, research institutes affiliated to universities and university medical centres having an establishment or branch in The Netherlands. B. Research hospitals, health promotion institutes and knowledge institutes, centres having an establishment or branch in The Netherlands. C. Private companies having an establishment or branch in The Netherlands: up to 20% (incl VAT) of the Dutch budget in the project concerned. • Please read the eligibility of costs for Category A, B and C very carefully below. • Max. 1 application as coordinator is allowed. • 1 Dutch partner per application is allowed; a second Dutch partner is only allowed in case it concerns an Early Career Scientist (see 4.5 in the Call text). • The track record of the PIs is part of the assessment. • Cofinancing by private 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 to ZonMw 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	• Aid for the concerning activities 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. Organisations in category A 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). • Aid to organisations in **categories B and C** is state aid and will be granted under the General Block Exemption Regulation: EC REGULATION No 651/2014, section 25 ('GBER'). All relevant conditions of the GBER apply, including but not limited to: o section 1.4 (no outstanding recovery order following a previous Commission decision, no aid to undertakings in difficulty) o section 1.5 (non violation of Union law by means of conditions or financing method), o section 8 (cumulation) o consideration 18 (the work on the aided project or activity starts only after the beneficiary has submitted a written application for the aid)

	○ The aid intensity depends on the Technology Readiness Level (TRL) of the activities of the Dutch partner, which should be clearly specified in a separate document to be sent to ZonMw at the deadline of application of the full proposal. Eligible costs of research projects executed by organisations in category A can be costs for personnel as 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). In most cases (e.g. in case of university/university medical centers) overhead is not allowed and the salary scales of VSNU (universities) or NFU (University Medical Centres) have to be used. Please use the ZonMw budget formats as basis for the budget calculations. Eligible costs of research and development projects executed by organisations in categories B and C shall be allocated to a specific category of research and development and may be the following: (a) personnel costs: researchers, technicians and other supporting staff to the extent employed on the project; (b) 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. (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; (d) other operating expenses, including costs of materials, supplies and similar products, incurred directly as a result of the project. **National Funding rates** Funding quota of Dutch participants can be up to 100% for organisations in Category A. The funding quota for organisations in category B and C will be decided on a case-by-case basis depending on the size of the company, type of research/development in accordance with GBER, section 25.5 and 25.6. Fundamental/ Industrial/Experimental development will be funded. Other type of activities (e.g. coordination, management) is not eligible for funding as separate research tasks in the project schedule.
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. • The Dutch consortium partners in honoured consortia have to comply with ZonMw procedures for granted projects (e.g. uploading via ProjectNet - including the ZonMw budget format, and reporting annually). Scientific personnel has to be appointed at a scientific institution in The Netherlands. Granted consortia with a Dutch partner have to draw up and sign a Consortium Agreement in which also the intellectual property rights are incorporated. • A final draft version of the Consortium agreement (approved by all parties but not yet signed) will be required in order to assess conformity with applicable European state aid law, IP conditions and the general grant provisions of ZonMw. If the Consortium agreement is rejected, the funding by ZonMw cannot be granted. For more details (in Dutch): ZonMw juridische aspecten bij samenwerking. • 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 granted Dutch researchers. (https://www.zonmw.nl/nl/over-zonmw/toegang-tot-data/). • If a co-financer is not included in the consortium agreement, a Letter of Commitment needs to be submitted to ZonMw with the application. For more details (in Dutch): ZonMw financiele aspecten bij samenwerking.
Further guidance	• Collaboration with patient organisations is recommended; see also 4.4 in the Call text. • The ZonMw grant terms and conditions from 1st July 2013) apply for Dutch consortium partners.

TURKEY, TUBITAK

Country	Turkey
Funding organisation	The Scientific and Technological Research Council of Turkey (TUBITAK) http://www.tubitak.gov.tr
National contact person(s)	Dr. Jale Şahin Phone : +90 312 298 1796 E-mail : jale.sahin@tubitak.gov.tr
Funding commitment	1.4 M Euro (inc. Project Incentive Payment (PIP) and overheads)
Overheads	Overheads are eligible costs and subjected to the terms and conditions stated in TUBITAK 1071 Programme.
Anticipated number of fundable research partners	6-8 projects
Maximum funding per grant awarded to a partner	Maximum funding per coordinator: 1400.000 TL (excl. PIP and overheads) Maximum funding per partner : 720.000 TL (excl. PIP and overheads)
Eligibility of project duration	Up to 36 months
Eligibility of a partner as a beneficiary institution	Legal body: university, university hospital, public research institutes, industry, SMEs
Eligibility of principal investigator or other research team member	The PI and research team members are subjected to the terms and conditions stated in the TUBITAK 1071 Programme
Eligibility of costs, types and their caps	Personnel, consumables, subcontract, equipment, travel, dissemination expenses.
Submission of the proposal at the national level	Required 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/. For further information please contact to national contact person.

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_2019.pdf), Legal Permission Licences (https://www.tubitak.gov.tr/sites/default/files/281/yasal_izin_bilgi_notu_08_01_2019.pdf) at the time of the full proposal submission
Submission of financial and scientific reports at the national level	1. Pre-financing 2. Report of scientific progress and justification of expenses 3. Interim payments based on the progress reports 4. Comprehensive final report submitted at the end of the project
Further guidance	jale.sahin@tubitak.gov.tr

EUROPEAN JOINT PROGRAMME RARE DISEASES

Call for Proposals 2020

"PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES"

Submission deadline for pre-proposals:
February 18th, 2020; 2 p.m. (CET)

Pre-proposal application form

Please note:

- **Proposals that do not meet national/regional eligibility criteria and requirements will be declined without further review.**
- **Format is Century Gothic font size 11, single-spaced, with 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 in the application form shall prevail.**
- **The information given in the pre-proposal is binding. Thus, any fundamental changes between the pre- and full proposals, e.g. composition of the consortia, objectives of the project, or the budget must be communicated to the JCS with detailed justification and will only be allowed under exceptional circumstances[1].**
- ***Text marked in Italics and highlighted in yellow can be deleted for proposal submission.***

[1] Such as when partners are added during the widening process (see guidelines).

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 (check out national limits that apply, in "Guidelines for Applicants").

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

☐ 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, Hungary, Lithuania, Poland, and Turkey) or early career researchers, the project involves a maximum of 8 eligible partners.

☐ There are a maximum of 8 research 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.

☐ 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 (bandi@frrb.it) 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) Slovak partners have submitted a Letter of Commitment of the partner institute's personnel contribution (spoluucast) to SAS.

☐ (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/.

General Data Protection Regulation

In the framework of this form we collect Personal Data freely provided by the user including (but not limited to): name, email address, and any other details specifically asked in the survey. EJP RD does not share personally identifiable information with unrelated Third Parties. However, we may disclose, transfer or share your Personal Data - anonymized or in its original format- with certain third parties without further notice to you, only for reasons related to the purposes of this survey.

☐ **I agree with the following conditions:**

Information and Data protection conditions

The information of this form will be used for this purpose only and may be shared within the EJP RD consortium, external experts and SEC members. The title and abstract of this proposal, and names of the consortium members may also be shared with researchers from underrepresented/undersubscribed countries as part of the widening step (see Guidelines for Applicants). The information you should provide includes personal data referred to contact details, such as your name, email address and phone number. Personal data will be collected to allow contacting for further details, if needed. No sensitive data will be collected.

All the collected data will be kept confidential and will not circulate beyond the EJP RD consortium, external experts and SEC members.

All the information will be made available in an aggregated manner (e.g. cumulative data and statistics).

The call secretariat will be responsible for the collection of personal data (see Privacy policy). The call secretariat will be responsible for processing the personal data.

Declaration

- **I have read the above information and:**

☐ **I authorise the processing of personal data, in compliance with the European General Data Protection Regulation, Reg (EU) 2016/679 for the specific purpose they are collected (any communication of personal data to private or public subject will be allowed only for the specific purpose they are collected).**

☐ **I authorise to be contacted for involvement in future collaborative initiatives, which might fall within the scope of my research activity.**

☐ **I authorise to be contacted for dissemination and communication activities (e.g. newsletters, invitations to meetings).**

1.a. Project title:

1.b. Project acronym:

The application is: ☐ a new proposal
☐ a resubmission from a previous E-Rare or EJP RD call
☐ JTC 2015 ☐ JTC 2016 ☐ JTC 2017 ☐ JTC 2018 ☐ JTC 2019
☐ a proposal that is an extension of a previously funded E-Rare or EJP-RD project
If so, please state the acronym of the project:

2. Consortium coordinator:

Last 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 Researcher (yes/no)	

3. Project Partners:

3a. 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 Researcher (yes/no)	Type of entity Academia, Clinical or Public Health, SME and Industry	Type of entity (public/private-for-profit/private-non-for-profit)

1							
2							
3							
4							
5							
6		(partner is an early career researcher, or from usually underrepresented countries)					
7		(partner is an early career researcher, or from usually underrepresented countries)					

3b. Patient advocacy organisation partners asking for funding: add lines as necessary

No.	Zip code, City, Country	Responsible person	Organisation, full affiliations (address, phone + fax)	Email address	Type of entity (public / private-non-for-profit)
1					
2					
xx					

3c. Collaborators (not funded): add lines as necessary

No.	Zip code, City, Country	Research Partner (principal investigator)	Institution, Department, full affiliations (address, phone + fax)	Email address	Early Career Researcher (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							
xx							

4. Duration of the project (max. 36 months) _____ **months**

5. Total funding in application _____ **€**

6. Keywords

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

1	
2	
3	
4	
5	
6	
7	

7. Lay summary (max. 1600 characters including spaces) *Please note that if your proposal is selected for full proposal submission, this abstract may be communicated to researchers from underrepresented or undersubscribed countries as part of the widening process (see Guidelines for Applicants for details).*

8. Description of the project (once converted into PDF: max. 5 pages DIN-A4, Century Gothic 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

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

3. *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;*
4. *Added value of the transnational collaboration;*
5. *Description of patient organizations within the proposal, including their role and contribution.*

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

Type of project	Clinical/epidemiological register or cohort study
Probands	Key inclusion and exclusion criteria

Main outcomes to be analysed	
Statistical analysis	Anonymisation/pseudonymisation of data, statistical details
Size and duration of register/cohort	Expected number of patients, duration in months

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.

9. Diagram of the work plan, timeline, workflow and interconnections of work packages (Gantt chart, Pert or similar, max. 1 page)

10. 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*

11. Budget table (see last page for template)

12. Brief CV for each principal investigator (once converted into Pdf document: max. 1 page per CV, DIN-A4, Century Gothic 11, single-spaced, margins of 1.27 cm).
Brief CV for each principal investigator or collaborator where relevant, 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 researchers (not included in page limit; see "Guidelines for Applicants" section 3).

13. Date and signature of the coordinator

14. Budget plan of the project (only requested budget, or amount of full budget and requested budget if nationally required)

No.	Project coordinator[4]	Partner 1	Partner 2	Partner 3	Partner 4	Partner 5	Partner 6 (partner is an early career researcher, or from usually underrepresented countries)	Partner 7 (partner is an early career researcher, or 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 €	0	0	0	0	0	0	0	0	0
Total budget if required (e.g. MIUR)									

[1]Travel expenses should include the participation to intermediate status symposium
[2] e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according to national/regional regulations)
[3] Overhead costs and eligible expenses: funding according to national/regional legal framework and funding body regulations
[4] The coordinator can apply for specific budget for the management of the project if these are eligible costs according to 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