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The aim of the Joint Transnational Calls 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.

The topic of the Joint Transnational Call 2021 (JTC2021) is "Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease"

This deliverable contains the public documents for the JTC2021:

- Call text
- Guidelines for applicants
- Preproposal template

Call for Proposals 2021

"Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease"

Call Text

Submission deadline for pre-proposals: February 16th, 2021 at 2 PM (CET)

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

Or contact:

Joint Call Secretariat (FFRD, France)

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1. Background – Aim of the call

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, better care and everyday life improvement for 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 standardized, (4) **The complex and multiple problematics of these diseases require interdisciplinary cooperation to improve everyday life and care.**

Health is more than bioscience and medicine. Health also strongly relies on adequate social, psychological, cultural and historical resources[1]. **Care is more than healthcare**: it is "the provision of what is necessary for the health, welfare, maintenance, and protection of someone or something"[2]. Social sciences and Humanities (SSH) help understanding all dimensions of health and care: human condition, suffering, personhood, our responsibility to each other, implementation within cultural and social contexts[3]. **Therefore, SSH research in the field of rare diseases is of crucial importance to help better understanding and better implementation of solutions for those living with a rare disease.**

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 **European Joint Programme on Rare Diseases (EJP RD)** has successfully implemented two Joint Transnational Calls since 2019 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). These actions are following the ten Joint Transnational Calls for rare diseases research projects launched previously by the ERA-Net E-Rare since 2006. 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.

[1] *Clarke B, Ghiara V, Russo F. Time to care: why the humanities and the social sciences belong in the science of health. BMJ Open 2019;9:e030286. doi: 10.1136/bmjopen-2019-030286*
[2] *Oxford languages dictionary*
[3] *https://guides.uflib.ufl.edu/hsclwellness*

2. Participating organizations

A number of national and regional funding organizations will participate in the **EJP RD Joint Transnational Call (JTC) 2021** and will fund research projects on rare diseases. The call opens simultaneously with the involvement of the following funding organizations 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
- Ministry of Social Affairs (MOSAE), Estonia
- French National Research Agency (ANR), France
- German Ministry of Education and Research (BMBF), Germany
- National Research, Development and Innovation Office (NKFIH), Hungary
- Chief Scientist Office of the Ministry of Health (CSO-MOH), Israel
- Italian Ministry of Health (MoH-IT), Italy
- Tuscany Region (RT/TuscReg), Tuscany (Italy)
- Research Council of Lithuania (LMT), Lithuania
- National Research Fund (FNR), Luxembourg
- National Centre for Research and Development (NCBR), Poland
- Slovak Academy of Sciences (SAS), Slovakia
- National Institute of Health Carlos III (ISCIII), Spain
- Swiss National Science Foundation (SNSF), Switzerland
- The Scientific and Technological Research Council of Turkey (TUBITAK), Turkey
- The French National Institute of Health and Medical Research (INSERM), France (will provide dedicated funding only to Patient Advocacy Organisations).

3. 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**) (FFRD, 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, the final selection and the award of research projects.

The Call Steering Committee (CSC) is composed of a single representative from each country/region funding organization that joins the JTC2021. The CSC will supervise the progress of the call and the evaluation of proposals. The CSC will make the final funding recommendation to the national/regional funding organizations on the proposals to be funded, based on the final ranking list provided by the SEC. All decisions concerning the call procedures will be taken by the CSC.

The Scientific Evaluation Committee (SEC) is a panel of internationally recognized, 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.

4. Scope 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.

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 or has the capacity to elucidate common disease problematics.

Topic: **Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease**

4.1 SSH disciplines covered

The following list of health-related Social sciences and Humanities (SSH) disciplines is used for definition (taken from the European Commission (EC) that was adapted from the UNESCO International Standard Classification of Education (ISCED 2011)):

Social sciences, business and law

- Social and behavioral sciences: economics, management, sociology, anthropology, demography, geography, psychology, neuropsychology, cognitive science, human rights, law, political sciences, communication, and social studies of science and technology;
- Education science: educational research;
- Governance: public and institutional administration, social and health economic and systems, policy, and social policy.

Humanities and the arts

- Humanities: cultural studies, linguistics, philosophy, ethics, and history.

4.2 Topics list

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

- **Health & social care services research to improve patient and familial/household health outcomes**
- **Economic Impact of Rare diseases**
- **Psychological and Social Impact of Rare diseases**
- **Studies addressing the impact/burden of the delay in diagnosis and of the lack of therapeutic intervention**
- **e-Health in rare diseases: Use of innovative technology systems for care practices in health and social services**

- **Development and enhancement of health outcomes research methods in rare diseases**

- **Effects of pandemic crisis and the global outbreak alert and response on the rare disease field, and the emergence of innovative care pathways in this regard**

See details on subtopics for each above mentioned area in Annex 1.
Other research topics are possible as long as they focus on SSH research and are not in the excluded topics list.

4.3 Excluded approaches and topics

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

- Interventional clinical trials to prove efficacy of drugs, treatments, surgical procedures, medical technology procedures. This also includes studies comparing efficacy, e.g. B. two surgical techniques or therapies. Clinical phase IV pharmacovigilance studies cannot be funded either.
- Studies on the exclusive testing of the safety of medical devices.
- Health technology assessment reports (HTA) for a specific product
- Projects focusing on meta-analyses and systematic reviews
- Creation of new registers or establishment of new long-term cohorts and / or promotion of existing registers or long-term cohorts beyond the specific research question of the submitted project.
- Development of new digital or technological tools.
- Projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases as covered in EJP RD JTC 2019.
- Development of new therapies as covered in EJP RD JTC 2020.
- Projects focusing only on rare neurodegenerative diseases which are within the main focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND). These are: Alzheimer's disease and other dementias; Parkinson's disease (PD) and PD-related disorders; Prion diseases; 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**.
- Rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases.

4.4 Type of studies

Qualitative Analysis
Description and analysis of patient's lifepath, as well as healthcare and social care processes and structures, using qualitative methods, form an important part of SSH research. Qualitative studies are often the starting point for identifying relevant questions for further quantitative studies. The projects can also include further development of scientific instruments and methods and their validation in practice. The sole translation, evaluation and/or testing of individual questionnaires is not funded.

Non-interventional quantitative studies
In order to be able to name the strengths and weaknesses of a system, in a scientifically sound manner, the collection and evaluation of relevant and valid data using recognized methods and procedures are necessary, as well as the further development and validation of scientific instruments and methods. Adequate comparison groups are essential. In this type of studies, the system is preferably analyzed prospectively. This includes observational studies like anthropological studies, case control studies, cross-sectional and longitudinal studies as well as cost-effectiveness studies.

Interventional studies on care implementation
These are comparative interventional studies to evaluate the effectiveness of practices under everyday conditions. The study design must be multi-armed. Structural equality of the groups can be achieved through suitable measures, e.g. by randomization. In contrast to clinical studies that show the efficacy of a therapeutic measure, e.g. test a drug, the interventional studies funded within the scope of this Call require proof of effectiveness and the effect of measures in everyday care e.g. in heterogeneous patient groups examined. This requires the use of patient-relevant endpoints, e.g. health-related quality of life, as the primary targets of the studies. Other methodological prerequisites for an interventional study on care implementation include broad inclusion and exclusion criteria, if possible, no requirements for the patients going beyond everyday care and the conduct of the study in the facilities in which the examined intervention is used as part of regular practices. Project proposals must clearly demonstrate the potential health impact as well as the added value of transnational collaboration.
This includes participatory action research.
For interventional studies on care implementation, feasibility must be clearly demonstrated regarding the 3-year duration of the project, including realistic timelines for regulatory aspects like ethical approval etc. in different countries.
For interventional studies on care implementation, ECRIN, the European Clinical Research Infrastructure Network, partner of the EJP RD can provide advice for the planning and design of cluster randomized controlled trials or randomized and practice-based studies. **It is highly encouraged from the preproposal stage to contact ECRIN's team** (marta.delalamo@ecrin.org).

4.5 Project description

Applicants will describe and justify the following elements (see section 3 – Project Description of the Guidelines for Applicants for complete information on the content of pre and full proposal templates):

- Background, rationale, present state of the art in the SSH research field, preliminary results
- Objectives and hypothesis
- Soundness and pertinence, originality, social care and public health interest
- Workplan & methodology *(highlighting feasibility)*
- Ethical and legal issues, data management
- Work packages, timeline and budget
- Responsibilities and workloads, complementarity of participants, management plan
- Impact of expected results, benefits and implementation in care

- Valorization, measures to exploit and disseminate the results, possible actions in social, health and/or socio-economic care, translatability and sustainability

5. Funding and eligibility criteria

5.1 Funding

The maximum duration of the project is three years.

Double funding of research projects is not permitted. The JCS and national/regional funding organizations 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 EJP RD or 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.

5.2 Categories of partners

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 organizations),
- enterprises (all sizes of private companies). Participation of small and medium-sized enterprises (SMEs) is encouraged when allowed by national/regional regulations,
- patient advocacy organizations

5.3 Countries 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 organization. **Applicants therefore must contact their respective funding organizations 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 organizations.

5.4 Consortium Makeup

❖ 5.4.1 Multidisciplinarity – Matchmaking

The aim of this call is to support multinational, innovative, and multidisciplinary **humanities and social sciences research** projects **to improve healthcare implementation and everyday life** of people living with a rare disease.
Consortia **have to include both SSH and clinical expertise's** in their consortium. Moreover, 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 (see section 5.5).
The **use of the matchmaking tool is strongly encouraged** to build multidisciplinary research projects:
https://live.eventtia.com/en/jtc2021matchmaking

❖ 5.4.2 Limit number of partners

Only transnational projects will be funded. Each consortium submitting a proposal must involve **three to six eligible principal investigator partners (referred to as partners below)** from **at least three 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/regional limits may apply, see "Guidelines for Applicants".** The limit of 8 partners applies to inclusion of Early Career Researchers and partners from underrepresented countries (see below). PAOs requesting funding do not count toward this total.

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

1. The inclusion of partners from participating countries usually underrepresented in projects (Slovakia, Hungary, Lithuania, Poland, and Turkey).
2. The inclusion of Early Career Researchers as full partners (see section 5.6).

❖ 5.4.3 What is a partner? a collaborator? a sub-contractor?

In order to be **considered as an eligible partner**, a group must contribute substantially to at least one of the projects work packages. If the only role of a group is to provide patient access, 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 consortium must be described (where relevant a CV can 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 (nor is there a limitation of collaborators per country, as long as their participation is justified).

If necessary, to implement the action, consortia may also include **sub-contractors, according to country/regional regulations**. Sub-contractors may cover only a limited

part of the action, and their contribution to the consortium must be described. They do not count toward the limit of 8 partners requesting research funding (nor is there a limitation of collaborators per country, as long as their participation is justified and if subcontracting is possible according to national/regional funding rules).

❖ 5.4.4 Consortium organization

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 2021 funding country/region. The project coordinator will **represent the consortium externally**, to the JCS and to 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 organization.

5.5 Patient Advocacy Organizations and Patient Involvement

Consortia are strongly advised to include patient representatives and patient advocacy organizations (PAOs).
From an early stage in proposal development, applicants should consult relevant disease-specific patient organizations and/or alliances of rare disease patient organizations. 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 organization directory
- Rare Diseases Europe (EURORDIS)
- European Reference Networks (ERNs)
- European Patient's Academy on Therapeutic Innovation (EUPATI).

The consortia will clearly present the role and responsibilities of the patient representatives and PAOs, how they will operate, at what levels and stages of the research, and provide justifications for allocated resources. Patient representatives and PAOs can be involved in all levels of the proposed work, including in project design, by advising on prioritization, sitting on advisory groups, being a member of the consortium steering group or the governance group. Patient representatives and 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 outcome measures,
- possible patient intervention in the project,
- review of the data collected,
- dissemination of research findings.

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

- EJP RD Short guide on patient partnerships in rare diseases research projects

- 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.

It is highly recommended that PAOs first explore funding opportunities from their respective funding organisations (see Guidelines for applicants).
If PAOs cannot be funded by their respective national/regional funding organisations, they can be eligible for direct funding through INSERM.
Exceptions:
Estonian PAOs cannot be funded directly by INSERM; please refer to the guidelines for applicants.
Spanish PAOs cannot be funded directly by INSERM; please refer to the guidelines for applicants to check the eligibility conditions for PAOs funding by ISCIII.
PAOs from Italy applying in collaboration with IRCCS funded by the MoH-IT, can participate in a Consortium as a "collaborator" with their own funding (see point 5.4.3 of this call) or can be financed as a "sub-contractor" through the IRCCS's budget. In any case, they cannot be funded by INSERM directly.

5.6 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. A definition of ECRs according to European Research Council criteria is provided in the "Guidelines for Applicants", section 4.1. **Please note that national/regional definitions and time limits might differ.** Therefore, please refer to national guidelines and contact your national/regional funder. Please refer to the "Guidelines for Applicants", section 4.2 for requirements for the identification of ECRs.

6. 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/ejprd21. 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). 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. Proposals must be prepared using the templates provided on the EJP RD web page (**www.ejprarediseases.org**). Proposals not conforming to template instructions (including length and format) will be rejected.

Call Timeline

16th February 2021	Pre-proposal submission deadline
End of April 2021	Invitation to full proposal
15th June 2021	Full proposal submission deadline
30th July 2021	Deadline for rebuttals
December 2021	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 feasibility 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 organization.

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

7. Evaluation process

At the pre-proposal stage, applicants should focus on presenting the scientific idea/hypothesis and supporting preliminary results, studies or data. The proposal should describe the project, starting from an unmet need, and follow through to the expected end-point of the study. Pre-proposals will be evaluated by SSH and rare diseases 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).

7.1 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.

❖ 7.1.1 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.

❖ 7.1.2 Criteria

1. **Excellence (0-5)**
   a. Clarity and pertinence of the objectives,
   b. Credibility of the proposed approach and methodology,
   c. Soundness of the concept,
   d. Feasibility of the project (adequate requested resources, time schedule, access to and engagement of patients, data and material),
   e. Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific expertise),
   f. PAOs and patient representatives have an active and meaningful participation 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 exploitation and for future social, public health and/or other socio-economic relevant applications
   b. *Added value of transnational collaboration: gathering a critical mass of patients/ material, sharing of expertise and resources, harmonization of data,
   c. **Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data. A data management strategy in the full proposal is mandatory,
   d. Innovative potential: relevant application for rare diseases care, possible actions in social, health and/or socio-economic care.
   e. Inclusion of Early Career Researchers as full partners,
   f. Benefit to patients, their families, and carers with an active and meaningful involvement of patient organizations and patient representatives,

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 timeframe,
   b. Complementarity of the participants within the consortium, including the integration of PAOs or patient representatives 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.

7.2 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 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 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. General recommendations from the SEC will be forwarded to applicants invited for the second step of the evaluation process. The summary review report will only be forwarded to applicants not invited for the second step.

At this stage research teams of underrepresented or undersubscribed countries may join successful pre-proposals (see 5.2 in Guidelines for Applicants for more details).

7.3 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 2021) for this **optional** response to the reviewers' comments.

SEC Meeting Evaluation
The JCS will send full proposals, reviews and rebuttals to the SEC members. The SEC will meet to discuss each proposal and, **after consideration of the evaluation criteria, external reviews, rebuttals, and their own discussions**, the SEC will assign final scores, make a classification of the proposals, and rank proposals recommended for funding. The final summary review report prepared by the SEC members will be sent to all applicants.
Three groups of reviewers will be present at the SEC meeting to evaluate projects:

1. **SSH and clinical experts**
2. **Patient representatives**
   Proposals will be evaluated by expert patient reviewers according to the relevant evaluation criteria listed above (subcriteria 1g, 2f, 3b; see section 7.1.2) with a 3-levels scoring system. These reviewers will be present at the SEC meeting to discuss proposals and provide their feedback.
3. **Statistical / methodological experts**
   Proposals will be evaluated by experts in methodology or statistics according to the relevant evaluation criteria listed above (subcriteria 1b, 1e, 1f; see section 7.1.2) with a 3-levels scoring system. These reviewers will be present at the SEC meeting to discuss proposals and provide their feedback.

Ethical evaluation
After the second SEC meeting, full proposals recommended for funding by the SEC 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**.

7.4 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 organizations. Final decisions will be made by the national/regional funding organizations 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.

8. Responsibilities, Reporting requirements and Dissemination

The Joint Call Secretariat (JCS) is the Foundation for Rare Diseases (FFRD, France) 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 organizations, 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 2023 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 organizations**, 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 organizations.

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.

9. Contacts 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	Organization	Contact Details
Joint Call Secretariat	FFRD (France)	**Diana Désir-Parseille** diana.desir-parseille@fondation-maladiesrares.com JTC2021@ejprarediseases.org +33 (0) 1 58 14 22 81 **Laura Benkemoun** JTC2021@ejprarediseases.org

10. National and 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 Organization	Contact Details
Austria	FWF	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
Belgium	The Fund for Scientific Research – FNRS (F.R.S.-FNRS)	Dr. Florence Quist Florence.quist@frs-fnrs.be +32 (0)2 504 9351 Joël Groeneveld Joel.groeneveld@frs-fnrs.be +32 (0)2 504 9270
Belgium	The Research Foundation – Flanders (FWO)	Toon Monbaliu eranet@fwo.be +32 (0)2 550 15 70
Canada	Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG) www.cihr-irsc.gc.ca	Jennifer Vineham jennifer.vineham@cihr-irsc.gc.ca +1 343 552-2760

Estonia	Ministry of Social Affairs of Estonia - MoSAE	Mari Teesalu Mari.teesalu@sm.ee +372 626 9715 Heli Paluste heli.paluste@sm.ee +372 626 9127
France	The French National Agency for Research - ANR	Dr. Florence Guillot florence.guillot@anr.fr EJPRDcall@anr.fr
Germany	Federal Ministry of Education and Research (BMBF) / Project Management Agency of the German Aerospace Centre (BMBF/ PT-DLR)	Dr. Katarzyna Saedler Dr. Michaela Fersch Dr. Ralph Schuster +49228-38212453 SelteneErkrankungen@dlr.de
Hungary	National Research, Development and Innovation Office (NKFIH)	Előd Nemerkényi Phone: +36 1 8963987 elod.nemerkenyi@nkfih.gov.hu Gábor Tóth Phone: +36 1 8961727 gabor.toth@nkfih.gov.hu
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Italy	MOH-IT	Dr. Monica Paganelli + 39 06 5994 2408 m.paganelli@sanita.it research.eu.dgric@sanita.it Dr. Raffaele Ruocco +39 06 5994 3233 r.ruocco@sanita.it
Italy	RT/Tuscany	Donatella Tanini Phone: +39 055 4383256 Teresa Vieri Phone: +39 055 4383289 Email: ejprare@regione.toscana.it
Lithuania	Research Council of Lithuania	Dr. Živilė Ruželė zivile.ruzele@lmt.lt (+370) 676 14383

Luxembourg	Luxembourg National Research Fund	Dr. Sean Sapcariu sean.sapcariu@fnr.lu +352 691 362 831@fnr.l
Poland	National Centre for Research and Development	Dr Marcin Chmielewski marcin.chmielewski@ncbr.gov.pl (+48) 0 22 39 07 109
Slovakia	Slovak Academy of Sciences	Dr. Zuzana Cernakova Cernakova@up.upsav.sk +421 (0) 2 5751 0 118
Spain	National Institute of Health Carlos III	Clara Martín c.martin@isciii.es +34 91822 2567
Switzerland	Swiss National Science Foundation	Dr. Florence Ettlin florence.ettlin@snf.ch +41 31 308 21 87
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK)	Dr. Jale Sahin EJPRD@tubitak.gov.tr +90(312)298 1796
Multinational, for funding of PAO	The French National institute of Health and Medical Research (INSERM)	Coordination EJP RD pao@ejprarediseases.org

Annex 1 – areas and topics examples

Transnational research proposals must cover at least one of the following areas, which are equal in relevance for this call. The description below is not exhaustive, other research topics in the described areas are possible as long as they focus on SSH research and are not in the excluded topics list.

Research on health & social care systems to improve rare disease patient and familial/household health outcomes

Research on challenges and solutions for improvement of the **care pathways**; integrated social and holistic care service models for people with rare disease, including transition from pediatric to adults' services and including psychosocial services for patients.

Patients, families and carers' involvement in research on health & social services; participative research, patient-research partnerships & patient and stakeholders engagement models; emphasis on outcomes related to patient experience (patients' descriptions and/or evaluations of the care they receive).

Research on **accessibility (equity of access)** and appropriateness of healthcare/ social services; their impact on Quality of Life (QoL). Research on transnational and/ or transcultural measurements, comparison and improvement of well-being/quality of life of patients with rare disease through **non-medical/non-pharmacological intervention.**

Sustainability and resilience of health and social care for patients with rare diseases; implementation of care management, coordination and clinical practice guidelines, including palliative care, financial assistance and ERNs support; **equity, access and sustainability** of social and health care systems. Impacts of legal and public administration system set-ups. Impact of international disease organizations, their role in improving equity and their interaction with national and local politics.

Economic impact of Rare diseases

Economic impact of living with rare diseases; modelling of care pathways including studies with cost measures (e.g. healthcare costs, out of pocket payments, productivity, transportation costs, education costs, loss of earnings, home adaptions, etc.).

Cost-effectiveness evaluation of healthcare treatments pathways for rare diseases, assistive technologies, costs of inappropriate/low-quality care, evaluation of (lack of) centralization, spillover effects, use of HTA (Health Technology Assessment), key challenges to develop cost-effectiveness models in RD research and orphan drugs indication.

Development of new **health outcomes measures** that can be translated into cost-effectiveness, QoL, burden of disease or the use of existing disease progression models

or models like Markov models for reimbursement submissions or outcome-based managed entry agreements, etc.

Development of new models and methods for assessing rare disease treatments that are useful to reimbursement or funding or financing of therapies, especially highly innovative therapies (including cellular and gene therapies) that defy conventional HTA parameters, such as Quality of Life scales, calculation of pharmacoeconomic value using conventional ICERs or ICURs, uncertainty in long-term outcomes and reliance on future-facing real-world evidence. Ethical issues surrounding the cost of experimental treatments.

Economic impact of the delay in diagnosis and in the lack of therapeutic intervention, on rare disease patients, their families or the society; economic impact of bottlenecks and limiting factors hindering access to available diagnostic tools or therapies for rare disease patients.

Identification of **cost-effective and useful social interventions and health care best practices.** Patient and/or family/carer preferences over management/therapeutic interventions.

Psychological and social impact of living with a Rare disease

Research on **everyday life** improvement and reduction of **psycho-social burden** for people with rare diseases, their families and caregivers; psycho-social impact and support, mental health, relationships, social integration, school integration, employment, impact on family, siblings, etc.

Identification of barriers and facilitators in social care or health care for patients coming to medical attention with a rare disease; comparison/mapping between countries regarding useful social and health care systems best practices; assessment of social equity, ethical considerations, and identification of bottlenecks for rare disease patients to access to services and to enter a globally coordinated diagnostic and research pipeline.

Research on **social inequalities, Human rights** and **Forms of Discriminations** and for rare diseases patients and their families in the society: exploring the links between discrimination and social, economic, territorial and cultural diversity. Perception of the term or category of "rare disease" by public and by rare disease patients/families themselves.

Studies addressing the impact/burden of the delay in diagnosis and of the lack of therapeutic intervention

Research on **adequate** (effective, reproducible, reliable or innovative) **tools to assess impacts** of the lack of diagnosis or therapy.

Impact of delayed diagnosis or lack of effective therapies for rare disease patients and their families including ethical perspectives: their impact on quality of life,

psychological burden, patients and family relations (care givers and non-care givers/ impact on siblings), including school integration, employment, etc.

Prenatal and neonatal screening impact and access to early therapeutic intervention. Research on **available, achievable, accessible, affordable and sustainable routes to avoid delays in diagnosis and treatment** (including roles of ERNs, registries, biobanks, infrastructures, centers of excellence, innovative and shared resources technologies, combination of diagnostic approaches-integrated genotype and phenotype analysis, equity and heterogeneity of patient access, development strategies for open science approaches, etc.).

e-Health in rare diseases: Use of innovative technology systems for care practices

Research on the application of digital health focused on rare diseases health and social care services: eHealth, telemedicine and related technologies (for e.g., diagnosis, genetic counselling and clinical management, equity of access, electronic records, self-management of the care pathway towards a chronic model of care, issues of implementation and reimbursement, etc.); its impact on QoL of the patient, PROMs, impact on diagnosis, care pathways and support. This may include research on the innovative use of existing technology, and models for registries with patient's involvement.

Research on e-learning for rare diseases: evaluation of effectiveness and impact of e-learning opportunities for healthcare and social services in rare diseases management, learning healthcare systems.

Digital literacy: Practices/Uses of e-health technologies applied to rare diseases, acceptance of these technologies, capacity to understand such technologies.

Development and enhancement of health outcomes research methods in rare diseases.

Methodologies to study the qualitative natural history data including research on factors influencing progression and prognosis of rare disease.

Methodologies to investigate, collect and use real world data, e.g.: Health technology assessments of new interventions, dynamic registries, use of digital technology to gather real world evidence using the patient-centered outcome measures (PCOMs), patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs), etc.

Impact of patient access to personalized digital tools on patient empowerment and health outcomes. Inequities reduction across jurisdictions. Ethical and equity considerations, and transparency enhancement in the use of digital tools.

Big data Analysis to improve health outcomes: exploration in a wide range of SSH fields including anthropology, economics, history, psychology, public health etc. including

computational approaches, the data acquisition workflow, data storage, metadata construction and translating text into knowledge.

Effects of pandemic crisis, of the global outbreak alert, response on the rare disease field and the emergence of innovative care pathways

Effects of COVID-19, of the global outbreak alert and response on specific rare diseases diagnosis, treatment and follow-up of patients with rare diseases, accessibility to health/social services and education, care, costs, research, etc. Effects of prevention measures on patients, carers and families.

Shared **success factors and barriers** (and opportunities for collaboration) between the global endemic of rare diseases and epidemics. Methods to assess impact of future epidemics.

Learnings from reliance on e-health, e-learning, e-collaboration, e-communication in the era of COVID-19 that could and should be applied on regular basis, perhaps in anticipation of or preparation for COVID-19 redux.

Call for Proposals 2021

"Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease"

Guidelines for Applicants

Submission deadline for pre-proposals: February 16th, 2021 at 2 PM (CET)

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

Or contact:

Joint Call Secretariat (FFRD, France)

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+33 (0) 1 58 14 22 81

Laura Benkemoun
JTC2021@ejprarediseases.org

1. Application Process

1.1 Registration

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/ejprd21. 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).

1.2 Pre- and Full Proposals

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: https://ptoutline.eu/app/ejprd21. Proposals must be prepared using the templates provided on the EJP RD web page (**www.ejprarediseases.org**). Proposals not conforming to template instructions (including length and format) will be rejected.

You will not need to submit a paper version of your 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 16th, 2021 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 15th, 2021 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 7.3 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, evaluation criteria and national eligibility criteria and requirements.

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

- Make sure that your proposal falls into the scope of the call (Section 4 of the call text)
- Make sure that your proposal fulfils the eligibility criteria of the call (Section 5 of the call text)
- Make sure that all consortium members have understood the national eligibility criteria and requirements (Annex 1) and that they fulfil these criteria
- Make sure that all consortium members contacted their national representative and confirmed eligibility with their respective funding organisations in advance of submitting an application (see Annex 1)
- 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 templates provided on the EJP RD website (www.ejprarediseases.org)
- Respect the length limitations of each section in the proposals

3. Project description

Applicants will describe and justify the following elements:
The elements marked with a "" will have to be developed only for full proposals*

Background, present state of the art in the SSH research field
- Need for research rationale: description of the unmet need that is addressed by the proposed work, rationale of the rare diseases chosen
- Present state of the art, recent insight from literature
- Preliminary results obtained by the consortium members

Objectives and hypothesis
- SSH research question
- Main and secondary hypothesis

Soundness and pertinence
- Innovative aspects, originality, novelty
- Social care and public health interest
- Applicants should include information about other ongoing development work and explain why their approach should be supported*.

Workplan & methodology *(highlighting feasibility)*
- Research strategy, study type (see section 4.4)
- SSH methodologies justification and presentation
- Enrollment: study location(s), inclusion/exclusion criteria, total number of corresponding patients followed by partners and collaborators of the project.
- Number of participants calculation (if applicable): description, justification, expected response rate.
- Statistical power (if applicable): appropriate statistical methods description, name and affiliation of the responsible biostatistics' expert.
- *Quality monitoring: risk management, contingency plans (identification of possible bottlenecks and go/no go steps).

Impact

- Results: description of expected results and their implementation
- Impact: description of the potential impact of the expected results on the addressed unmet need
- Benefits: description of individual and collectives benefits that could be expected

***Valorization**

- Effective measures to exploit and disseminate the project results, to communicate the project, and to manage research data
    - Present / future position with regard to intellectual property rights, both within and outside the consortium
    - Scientific communication (articles, presentations…): description of plan, tools and responsibilities for communication towards clinical and SSH community
    - PAO/Public communication: description of plan, tools and responsibilities for communication towards PAOs, patients, any concerned people
- Innovative potential: relevant application for rare diseases care: possible actions in social, health and/or socio-economic care
- Translatability: opportunities to exploit the methodology and/or expected results for other rare and non-rare diseases
- Sustainability: description of plan for sustainability of infrastructures or resources initiated by the project, follow-on funding and/or draft study plans past the grant end, articulation with other existing research infrastructures**.

***Ethical and legal issues, data management**

- Ethical and legal issues management plan description, including:
    - the recruitment of participants (e.g. direct/indirect incentives for participation, the risks and benefits for the participants etc.)
    - the material collection (e.g. sensitive or personal data etc.)
    - ensuring the wellbeing of the children involved
    - ensuring consent

  See H2020 Guidance "How to complete your ethics self-assessment" that can be found here: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
- GDPR management: plan description, name and affiliation of the Data Protection Officer (DPO).
- Data management strategy: plan description to make research data findable, accessible, interoperable and re-usable (FAIR).

Work packages, timeline and budget

- Description of the aims/work packages: synopsis and timeframe, including project coordination and management as well as *innovation management activities
- *Scientific justification of requested budget: rational distribution of resources in relation to project's activities, partners responsibilities and time frame; please also specify co-funding from other sources necessary for the project if applicable

- Diagram which compiles the work plan, timeline, sequencing of work packages, contribution of the partners to each work package and their interactions (Gantt chart, Pert or similar)

Responsibilities and workloads

- For each research partner: competence and experience in the field(s) of the proposal (previous work in the field, specific expertise); responsibilities in each work package; *ongoing or submitted research grants.
- For PAO/patient representative: role and contribution, access to and engagement of patients, responsibilities in each work package.
- Added values: complementarity of the participants within the consortium, benefit of transnational collaboration
- *Management plan: operating and coordination methods

**Those elements will have to be developed only for full proposals*

***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 mobilized, in particular for long-term data curation and preservation, when needed (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:

- *ECRIN European Clinical Research Infrastructure Network*
- *EATRIS European Infrastructure for Translational Medicine*
- *IRDiRC recognized resources*
- *Horizon 2020 FAIR Data Management Plan Annex 1*

4. Early Career Researchers (ECRs)

4.1 Definition

ECRs are 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.

4.2 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*

5. Financial and Legal Issues

5.1 Funding model and Call governance

The EJP RD JTC 2021 Funding Partners have agreed to launch a joint call using the **"virtual common pot" funding mode**. This means that national/regional funding will be made available through national/regional funding organisations according to national/regional funding regulations. In addition, the EC will provide funding for Patient Advocacy Organisations (PAOs) that cannot be funded by their respective national/regional funding organisations. This funding will be administrated by Inserm, France (see Annex 1).

FFRD (France) is acting as Joint Call Secretariat (JCS) to assist the Call Steering Committee (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 point of contact referring to the call procedures between the research consortia, the funding organisations (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 to other partners.
CSO-MOH (Israel) and FNRS (Belgium) will be responsible for the follow-up phase until the funded research projects have ended.

5.2 Widening for the inclusion of under-represented or under-subscribed countries

5.2.1 Definition of widening

For proposals invited to the full proposal stage, there will be a widening step to provide the **opportunity to add partners** to the consortium (up to a maximum total of 8, see section *5.4 Consortium Makeup* of the 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.**

5.2.2 Process

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 that are invited to write a full proposal.

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.
The coordinator/partners of projects invited to the 2nd stage of evaluation can also 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.

5.3 Funding contracts

Each project includes several partners (including a project coordinator) as beneficiaries. **Each partner will have a separate funding contract/letter of grant with their respective national/regional funding organisations, 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, an independent expert may be consulted to help with the final decision of the funding organisations. **Research partners must inform the JCS and the respective funding bodies of any event that might affect the implementation of the project**.

5.4 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 see 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

1). This consortium agreement must be made available on request to the relevant EJP RD JTC 2021 funding organisations.

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)
- evolution of the consortium (renewal or end of the consortium, amendments)

5.5 Ownership of intellectual property rights

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the EJP RD JTC 2021 will be owned by the beneficiaries' organisations 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.

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, in the respect of European law on State aid for research and development.

The funding organisations 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.

5.6 IRDiRC policies and guidelines

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

5.7 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 General Data Protection Regulation (GDPR): the European Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data: https://publications.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/language-en)*
- 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.
- General ethical and legal requirements: Ethics is an integral part of research. Ethics should be embedded in the research and considered from the outset, and although legal and regulatory considerations may vary across different countries, EJPRD will only fund proposals which comply with national and international ethical standards, rules and legislations.
- International Ethical Guidelines for Biomedical Research Involving Human Subjects CIOMS-WHO (2016)
- Oviedo Convention and its Additional Protocol on human rights and biomedicine, concerning biomedical research (2005)
- COUNCIL OF EUROPE COMMITTEE OF MINISTERS. Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological material of human origin (Adopted by the Committee of Ministers on 11 May 2016).

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

6. General Data Protection Regulation

The following Data Privacy Notice applies

By submitting an application to the co-funded call JTC2021, 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 call;
- 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 consortium 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 call award which may be awarded to them.

Data on Funding Parties including contact details of FC members and National Contact Points/Regional Contact Points are kept for the purpose of the call communication. The information will be published with prior consent of the respective management bodies.

7. PAOs funding conditions

Country	Funding organisation	Conditions for PAO funding
Austria	Fonds zur Förderung der Wissenschaftlichen Forschung (FWF) / Austrian Science Fund http://www.fwf.ac.at	No funding of PAOs.
Belgium (Flanders)	The Research Foundation - Flanders (FWO)	PAO funding possible as subcontractor.
Belgium	Fund for Scientific Research – FNRS (F.R.S.-FNRS)	Participating Belgian patients organisations could be financed via subcontracting, provided that the criterion for subcontracting detailed in the PINT-MULTI regulations are fulfilled (see art. III.3).
Canada	Canadian Institutes of Health Research, Institute of Genetics (CIHR-IG)	Canadian patient advocacy organisations (PAOs) are not eligible to participate in the role of Nominated Principal Applicant (NPA) nor Principal Applicant (PA). However, it is possible for a PAO to be represented by an individual in the role of co-applicant or collaborator. In this case, the NPA may request funds in their budget to support the activities of the PAO representative on the project.
Estonia	MoSAE	PAO funding possible as subcontractor.

France	Agence Nationale de la Recherche – ANR	French PAO can be funded as a partner if they perform SSH research activities. Otherwise, French PAO can be funded as sub-contractor of a French partner and if they fulfil the eligibility criteria of the EC.
Germany	German Federal Ministry for Education and Research (BMBF)	Participating German patient organisations can be funded either directly or through subcontracting by a research partner.
Hungary	Ministry of Innovation and Technology	No funding of PAOs.
Israel	Chief Scientist office, Ministry of Health (CSO/MOH)	No funding of PAOs.
Italy	Ministry of Health – (Ministero della Salute)	Italian PAOs can be funded for a PAO a sub-contractor through and IRCCS's budget if they fulfil the eligibility criteria of the EC. The maximum cost eligible for a sub-contract is 25.000 Euros Italian PAOs can still participate in Consortia as "Collaborators" with their own funds
Italy	Tuscany Region	Italian PAOs can still participate in Consortia as "Collaborators" with their own funds
Lithuania	Lietuvos mokslo taryba (LMT) / Research Council of Lithuania	PAO can be funded as subcontractor
Luxembourg	Luxembourg National Research Fund - FNR	FNR can fund PAOs which are eligible beneficiaries of FNR funding. For further information, please contact the FNR.
Poland	National Centre for Research and Development (NCBR)	Funding is only available for project partners

Slovakia	Slovak Academy of Sciences (SAS)	SAS does not fund PAOs/patient representatives. The Slovak partner can use part of their budget to pay for work, services or materials provided by PAOs/patient representatives in direct relation to the project.
Spain	National Institute of Health Carlos III (ISCIII)	Participating Spanish patients' organisations (PAOs) cannot be funded by ISCIII directly. PAOs could be financed via subcontracting, provided that they develop research activities and the criteria for subcontracting detailed in the Spanish Act 38/2003, of November 17th are fulfilled.
Switzerland	Swiss National Science Foundation (SNSF)	According to our eligibility criteria, PAO are not eligible as partners.
Turkey	The Scientific and Technological Research Council of Turkey	PAOs are not eligible for funding. However, the project coordinator can make a payment to a PAO only if the PAO is able to bill the provided service.

ANNEX 1: 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
Conditions for PAO funding	No funding of PAOs.
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 16. February 2021)". 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	Belgium (Flanders)
Funding Organisation	The Research Foundation - Flanders (FWO)
National Contact Person	Toon Monbaliu eranet@fwo.be +32 (0)2 550 15 70
Funding Commitment	0,35 m. EUR
Overhead	Overhead has to be included – see category 'Eligibility of costs, types and their caps'.
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	350.000 EUR (overhead included)
Eligibility of a partner as a beneficiary institution	Both the FWO Strategic Basic Research (SBO) and junior/senior research project (FO) funding channels are integrated in this call, each with specific regulations. It is, in the light of the projects eligibility, of utmost importance to respect their particular regulations. For example when it comes to the **mandatory valorisation aspect for the SBO projects** (see *'additional conditions for FWO funding'* below). Who can be eligible for FWO funding? The eligibility of institutions and its researchers can be verified in the relevant regulations: - For junior/senior research projects, see articles 10-12 - For Strategic Basic Research, see articles 4-8 Additional conditions for FWO funding: 1. When the strategic basic research channel (SBO) would be the appropriate source 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 i) how the valorisation within Flanders - and potentially internationally – will take place and ii) which Flemish actors are involved in this. This information can be submitted to the general eranet@fwo.be email address. 2. SBO projects aiming at the development of a spin-off company are not eligible here. 3. Non-eligible partners/parties/actors (e.g. PAO's) for FWO funding can potentially be involved within a consortium through subcontracting, when linked to an eligible institution/researcher. The FWO administration should be contacted in that regard.

	4. Researchers have to inform the central research coordination units, at their host institutions, about their participation. 5. 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. 6. Projects may last up to 36 months, which implies the funding has to be budgeted and spent accordingly. ERA-NET participation does not interfere with the 'regular' project submission framework, and is consequently not taken into account for calculating the max. available number of new applications and running projects combined.
Eligibility of costs, types and their caps	The regular FWO cost categories from the (junior/senior) 'research project' or SBO project funding channels are eligible: The maximum requested budget per partner amounts to 350.000 EUR (incl. overhead). **Beware, the funding rules differ per FWO funding channel (FO and SBO):** **- FO:** a 6% structural overhead should be calculated on the direct costs. E.g., a practical example: when the sum of all costs (personnel, consumables, travel, etc.) amounts to 300.000 EUR, then the overhead will be 18.000 EUR (6% of 300.000 EUR) and the total requested cost 318.000 EUR. This total requested cost may never exceed 350.000 EUR (for further detailed financial information, see chapters 6, 7 and 8 in the project regulations). **- SBO:** The SBO cost model applies. Generally a 17% overhead rate is applicable.
Conditions for PAO funding	PAO funding possible as subcontractor.
Submission of the proposal at the national level	No submission at the national/regional level is required. However, if SBO, a valorisation plan has to be submitted.
Further guidance	It is always strongly advised to contact the FWO before submission, in order to verify the eligibility of the researchers and avoid ineligible projects/research consortia. Information available at: - Call page for European programmes - Junior/senior research projects (FO) - SBO research projects (SBO)

BELGIUM, F.R.S.-FNRS

Country	Belgium
Funding organisation	Fund for Scientific Research – FNRS (F.R.S.-FNRS)
Management organisation	Fund for Scientific Research – FNRS (F.R.S.-FNRS)
National contact person	Dr. Florence Quist Phone: +32 (0)2 504 9351 E-mail: Florence.quist@frs-fnrs.be Joël Groeneveld Phone: +32 (0)2 504 9270 E-mail: joel.groeneveld@frs-fnrs.be
Funding commitment	0,2 Mio€
Overheads	"Overhead" is not an eligible cost. If the project is selected for funding, these costs will be subject to a separate agreement between the institution of the beneficiary and the F.R.S.-FNRS.
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	200.000 €
Eligibility of project duration	Maximum 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 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.
Conditions for PAO funding	Participating Belgian patients organisations could be financed via subcontracting, provided that the criterion for subcontracting detailed in the PINT-MULTI regulations are fulfilled (see art. III.3).

Submission of the proposal at the national level	**Applicants to F.R.S.-FNRS funding must provide basic administrative data by submitting an administrative application on e-space within 5 working days after the general deadline of EJP RD call to be eligible. Please select the "PINT-MULTI" funding instrument when creating the administrative application. Proposals invited to the second stage will be able to complete the pre-proposal form and provide information for the full proposal upon validation by the F.R.S.-FNRS.**
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 F.R.S.-FNRS
Further guidance	PINT-MULTI regulations, e-space

CANADA, CIHR-IG

Country	Canada
Funding organisation	Canadian Institutes of Health Research, Institute of Genetics (CIHR-IG)
National contact person	**Jennifer Vineham** **Phone: +1 343 552-2760** **Email: jennifer.vineham@cihr-irsc.gc.ca** **Etienne Richer** **Email: Etienne.Richer@cihr-irsc.gc.ca**
Funding commitment	CAD1,500,000 CAD100,000 per year per project maximum.
Overheads	Not an allowable cost.
Anticipated number of fundable research partners	5 projects
Eligibility of project duration	3 years
Eligibility of a partner as a beneficiary institution	
Eligibility of costs, types and their caps	**Eligibility of principal investigator or other research team member** Academia, Clinical, Public Health https://cihr-irsc.gc.ca/e/50805.html#g-3 **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. Please note that due to the impact of COVID-19 on early career researchers, CIHR is temporarily adjusting the period of eligibility for an ECR. All those who held ECR status as of March 1, 2020 – or who secured their first academic appointment after this date – will have their status extended by one year. CIHR will closely monitor the pandemic and its impact on ECRs overall and on specific groups with the intent that further interventions may be warranted. **Eligibility of costs, types and their caps** https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/TAFA-AFTO/guide-guide_eng.asp
Conditions for PAO funding	Canadian patient advocacy organisations (PAOs) are not eligible to participate in the role of Nominated Principal Applicant (NPA) nor Principal Applicant (PA). However, it is possible for a PAO to be represented by an individual in the role of co-applicant or collaborator. In this case, the NPA may request funds in their budget to support the activities of the PAO representative on the project.
Submission of the proposal at the national level	Short application as per CIHR Funding Opportunity (link to follow)
Submission of other information at the national level	NA
Submission of financial and scientific reports at the national level	The Nominated Principal Applicant will be required to submit an electronic Final Report to CIHR. This online report will be made available to the Nominated Principal Applicant on ResearchNet at the beginning of the grant funding period and can be filled in as the research progresses.
Further guidance	NA

Estonia, MoSAE

Country	Estonia
Funding organisation	Ministry of Social Affairs
National contact person	Heli Paluste Ministry of Social Affairs Head of Health Care Unit Phone : +372 626 9127 E-mail: Heli.Paluste@sm.ee Mari Teesalu Ministry of Social Affairs Scientific Adviser in Health Policy Phone: +372 E-mail: mari.teesalu@sm.ee
Funding commitment	75 000 euros
Overheads	Overheads are eligible and the maximum amount is 10% of the direct cost of the project
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	75 000 euros
Eligibility of a partner as a beneficiary institution	Research proposals may be submitted by representatives of Estonian legal persons in private law or in public law that are based and registered in Estonia and: (i) are research and development institutions according to the § 3 (1) of Organisation of Research and Development Act; OR (ii) are health services providers according to Health Services Organisation Act § 4;
Eligibility of costs, types and their caps	Only costs generated over the lifetime of the project are considered eligible. • **Personnel costs incl. taxes** can only be paid for the time used to carry out the grant project. Such participation should be clearly identifiable and the salary should take into account the past 12-month average salary of that person. If new staff member will be hired for the project, his salary has to comply with salaries commonly paid for staff carrying out similar work within the institution. • **Consumables.** Only consumables directly related to the project can be funded.

	• **Subcontracting** (≤50% of total costs) includes all external services and need a detailed justification in the application. • **Equipment** (only depreciation costs) • **Travels** need to be justified. Travel costs cover expenses for transport, accommodation and for international travels, also daily allowances if relevant; • **Fees for participating in scientific forums and conferences** **All other costs** (≤20% of total costs). Costs which are clearly required for the implementation of the project and respectively identifiable;
Conditions for PAO funding	PAO funding possible as subcontractor.
Submission of the proposal at the national level	• All the applicants need to contact Estonian Ministry of Social Affairs (contact e-mail addresses: mari.teesalu@sm.ee ; heli.paluste@sm.ee) at least two weeks before the call deadline, to confirm their eligibility, to provide a timeline and short description of activities and budget; • Applicants need to ensure that their activity in the project falls under the exception for R&D activities: https://www.hm.ee/sites/default/files/ta_erand_juhend.pdf;
Further guidance	N/A

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**
Funding commitment	2 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 ")
Anticipated number of fundable research partners	7-10
Eligibility of project duration	2-3 years
Eligibility of a partner as a beneficiary institution	**Eligible institutions:** - Public research organisation or related-one[1] such as EPST, EPIC, universities, university hospitals, non-university research institutes (max. rate of support: 100% of marginal costs) - 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.
Conditions for PAO funding	French PAO can be funded as a partner if they perform SSH research activities. Otherwise, French PAO can be funded as sub-contractor of a French partner and if they fulfil the eligibility criteria of the EC.
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 Please read the modalities document for this call on the ANR website

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 Dr. Michaela Fersch Dr. Ralph Schuster +49228-38212453 SelteneErkrankungen@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	Partners in about 10 projects
Maximum funding per grant awarded to a partner	Max. 300.000 EUR per consortium including overheads (i.e. if two German partners participate in a consortium, the sum of funding requested by both groups must not exceed 300.000 EUR)

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, patient organisation
Eligibility of costs, types and their caps	Personnel, consumables, animals, subcontracts, equipment, travels, documentation, overheads according to national regulations.
Conditions for PAO funding	Participating German patient organisations can be funded either directly or through subcontracting by a research partner.
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

HUNGARY, NKFIH

Country	Hungary
Funding organisation	Ministry of Innovation and Technology
Management 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, Department of Research and Development, 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	2
Maximum funding per grant awarded to a partner	Up to 100.000 €. If more than one partner applies from Hungary, their total requested funding should not exceed 100.000 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). An SME or a non-profit organisation is eligible if its main activity is research according to its deed of foundation [category: 'research and knowledge-dissemination organisation' – see *Commission Regulation (EU) No. 651/2014 Article 2 (83)*]. All eligibility rules and criteria can be found in the '2019-2.1.7-ERA-NET' call regulations. It is strongly advised to contact NKFIH prior to submission regarding the eligibility criteria.
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 100.000 € 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).
Eligibility of principal investigator	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.
Conditions for PAO funding	No funding of PAOs.
Submission of the proposal at the national level	Hungarian applicants are strongly requested to contact NKFIH to confirm eligibility before submitting a proposal. Basic information should be provided to NKFIH, including applicant name and institution, 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 funding and managing the project by NKFIH.
Submission of financial and scientific reports at the national level	Yes, according to national regulations.

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 Email: Irit.allon@moh.health.gov.il
Funding commitment	Up to 200.000 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 100,000 Euros
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 costs, types and their caps	Materials and consumables; Travel (up to 10%); No salaries for applicants; No heavy equipment, Institutional overhead - 10%
Conditions for PAO funding	No funding of PAOs
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.
Further guidance	**CSO-MOH will only fund the following research areas under the current call:** • **Economic impact of rare diseases** • **Studies addressing the impact/burden of the delay in diagnosis and of the lack of therapeutic intervention** • **Development and enhancement of health outcomes research methods in rare diseases** If the application involves human or animal experiments, bioethics approvals must be submitted with the application or up to 4 months later. Please see detailed instructions at www.health.gov.il/research-fund

ITALY, MoH-IT

Country **Funding organisation**	Italy Ministry of Health – (Ministero della Salute) www.salute.gov.it
National contact person	Dr. Monica Paganelli Phone : +39 06 5994 2408 m.paganelli@sanita.it; research.EU.dgric@sanita.it Dr.. Raffaele Ruocco Phone: +39 06 5994 3233 r.ruocco@sanita.it
National Programme	Framework Research National Programme "IRCCS Health Research" of the Ministry of Health
Funding commitment	0,5 M€
Overheads	Up to 10% of the direct costs of the project, intended to cover the general costs of the institution that hosts the research team and which cannot be used by the research team.
Anticipated number of fundable research partners	02/03/20
Maximum funding per grant awarded to a project partner	Maximum funding per project: 0.25 M€. In case that more than one eligible partner will be involved in the Consortium, the total amount will be shared between the beneficiary Institutions. Max. 2 beneficiary Institutions can be financed in the same project.
Eligibility of project duration	Max. 3 years
Eligibility of a partner as a beneficiary institution	Only IRCCS (Scientific Institute for care and Research) and ISS (National Institute of Health) can be funded.
Eligibility of principal investigator or other research team members	Researchers are not allowed to participate as PI/WP Leader in more than one 2021 call launched in the framework of different transnational calls (ERANET and/or other European Joint Actions) funded by the It MoH. The Italian Ministry of Health will check for the pre-eligibility of the applicants before the submission of the pre-proposals to speed up the eligibility check process. To this end, it is mandatory that the applicants fill out and return a pre-eligibility check form through IRCCS Scientific Directorate or ISS Directorate of Human and Economic Resources using WFR System (Code ER) before the submission of their pre-proposals to the Joint Call Secretariat. The form, completed and duly signed, has to be returned at least 10 working days before the pre-proposal submission deadline. Applicants will receive 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. Transfer of eligible funds abroad for leasing, sub-contracts, etc is not allowed Sub-contracts are not allowed except in case of absolute necessity and to fund the Italian PAOs (see below); the costs for sub-contracts need to be authorized by the It MoH in advance, following a detailed request. **In this case, the pre-eligibility must be requested 20 working days before the deadline of the call.** • Direct Costs: Personnel: only ad hoc temporary contracts/fellowship/consultants contracts -max 50% Consumables/animals – no limit Equipment: rent/leasing only – no limit Travel and accommodation costs: only linked to the project - max 10% Dissemination of results: publications, meetings, workshops etc.- max 1% Data handling and analysis - no limit • Indirect Costs: Overhead - max 10%.
Conditions for PAOs funding	Italian PAOs can be funded for a PAO a sub-contractor through and IRCCS's budget if they fulfil the eligibility criteria of the EC. The maximum cost eligible for a sub-contract is 25.000 Euros Italian PAOs can still participate in Consortia as "Collaborators" with their own funds
Submission of the proposal at the national level	No.
Submission of other information at the national level	After the joint EJP RD 2021 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 an 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 can be found at www.salute.gov.it or requested to the national contact points.

Tuscany Region, Italy

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, organisation 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).
Conditions for PAO funding	PAO cannot be directly funded by Tuscany Region in the framework of this call.
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.** **All actions must guarantee adequate conformity with regional programming acts and with regional sectoral steering documents.**
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, LMT

Country	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 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 or a state healthcare institution. Eligible institution manages the state budget funds allocated to the project, 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).
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.
Conditions for PAO funding	PAO can be funded as subcontractor
Submission of the proposal at the national level	No
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: +352 691 362 831 Email: sean.sapcariu@fnr.lu
Funding commitment	0,30 M€
Overheads	
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	Personnel costs; Consumables; Equipment (only depreciation costs); Travel (according to travel plan); Subcontracting (up to 25% of direct costs - needs detailed justification, includes all external services, project core activities cannot be subcontracted); Indirect costs

	Please see INTER application guidelines for more information (https://www.fnr.lu/funding-instruments/inter/)
Conditions for PAO funding	FNR can fund PAOs which are eligible beneficiaries of FNR funding. For further information, please contact the FNR.
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, 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)
National contact person	Marcin Chmielewski Department for International Cooperation, ul. Nowogrodzka 47a, 00-695 Warszawa, Poland Tel: (+48) 22 39 07 109 marcin.chmielewski@ncbr.gov.pl
Funding commitment	0.6 Mio. €
Overheads	Maximum 25% of eligible project costs (excluding subcontracting)
Anticipated number of fundable research partners	1 - 3
Maximum funding per grant awarded to a partner	Maximum 200 000 € per project, regardless of the number of Polish research groups in the project consortium.
Eligibility of a partner as a beneficiary institution	Following entities are eligible to apply: • Micro, Small, Medium and Large enterprise; • Research organisation; • 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;). • Organisation must be registered in Poland. • For enterprises it is strongly advised to state in the Pre-proposal application form 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 refer to 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. **operating costs** including costs of instruments, equipment, technical knowledge, patents, costs for buildings and land, costs of materials, supplies and similar products incurred directly as a result of the research activity;

<table>
<tr><td></td><td>3. 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;
4. 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 (3); It means 4=(1+2)*25%.

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.
<table>
<tr><th></th><th>Large Enterprises</th><th>Medium Enterprises</th><th>Small Enterprises</th><th>Universities and research organisations</th></tr>
<tr><td>Fundamental/Basic Research</td><td>Not eligible</td><td>Not eligible</td><td>Not eligible</td><td>Not eligible</td></tr>
<tr><td>Industrial/Applied Research</td><td>Up to 50+15 (max 65 %)</td><td>Up to 50+10+15 (max 75 %)</td><td>Up to 50+20+15 (max 80 %)</td><td>Up to 100 %</td></tr>
<tr><td>Experimental development</td><td>Up to 25+15 (max 40 %)</td><td>Up to 25+10+15 (max 50 %)</td><td>Up to 25+20+15 (max 60 %)</td><td>Up to 100 %</td></tr>
</table>
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.</td></tr>
<tr><td>Conditions for PAO funding</td><td>Funding is only available for project partners, meeting eligibility criteria given above.</td></tr>
<tr><td>Submission of the proposal at the national level</td><td>Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established.</td></tr>
<tr><td>Further guidance</td><td>Please refer to full call documentation.</td></tr>
</table>

Country	Slovakia
Funding organisation	Slovak Academy of Sciences (SAS)
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
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	120,000 €
Eligibility of a partner as a beneficiary institution	**Only research institutes and/or centres of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up to 100%).** The main applicant must have, at the time of submission, a contract(s) with one or several of the institutes/centres equivalent to at least 1 full-time employment valid for the whole duration of the project. Each member of the applicant's team must also have an employment contract or a fellowship with the same or another SAS institute/centre. 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 costs, types and their caps	Funding available for eligible Slovak researchers is up to 120,000 EUR per project (i.e. 40,000 EUR per year) in accordance with the SAS Presidium's resolution no. 1103, of which 45,000 EUR is an in-kind contribution (spoluúčasť) of the respective SAS institute or centre. This must be declared in a Letter of Commitment sent to the national contact point by the application deadline. A template will be published alongside the Call announcement at www.sav.sk in the International Cooperation section (Medzinárodná spolupráca). **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; – Up to 15 % of all direct costs excluding the institute's/centre's in-kind contribution or up to 30% of all direct costs excluding the institute's/centre's in-kind contribution, if the Slovak team is the consortium's coordinator.

	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 an exception); b. *Costs and expenditures* for services directly related to the project: contracts, 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; d. *Capital expenditures*: up to 40% of all direct costs excluding the institute's/centre's in-kind contribution. **2. Indirect Costs** – Administration, energy and infrastructure; – Up to 20% of all direct costs excluding the institute's/centre's in-kind contribution. Further information on eligible costs can be found in the Financial rules for awarding SAS grants for international research projects approved by the SAS Presidium on 1 July 2018. **Applicants are strongly encouraged to read this document carefully and to contact the national contact point before submission in order to ensure compliance.**
Conditions for PAO funding	**SAS does not fund PAOs/patient representatives.** The Slovak partner can use part of their budget to pay for work, services or materials provided by PAOs/patient representatives in direct relation to the project within the cost categories 1.1 and 1.2b above (proof of supply required).
Submission of the proposal at the national level	Submission of the proposal at the national level will be required in parallel to the international evaluation. The submission will be carried out once the international evaluation and the ranking list have been performed and endorsed by the Call Steering Committee and the Slovak partner has been informed about recommendation for funding by the project consortium's coordinator. S/he will be invited by SAS to submit the proposal to it. The final decision on funding of selected projects is made by the SAS Presidium.
Further guidance	• www.sav.sk • 133 Act of February 19, 2002 on the Slovak Academy of Sciences • Financial rules for awarding SAS grants for international research projects

Spain, ISCIII

Country	Spain
Funding Organisation	National Institute of Health Carlos III (ISCIII) www.isciii.es
National Funding Programme	Acción Estratégica en Salud (AES 2021) http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/fd-financiacion/convocatorias-ayudas-accion-estrategica-salud.html
National Contact Point for the 10th call of E-RARE	**Maria Druet** Email: mdruet@isciii.es Tel: (+34) 9182 22530 **Clara Martín** Email: c.martin@isciii.es Tel: (+34) 91 822 25 67
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) https://eng.isciii.es/eng.isciii.es/QuienesSomos/IIS/Paginas/Acreditacion.html • **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). Please contact Cristina Rodríguez (cristina.rodriguez@ciberisciii.es) for more information related to CIBER's eligibility.

Additional eligibility criteria	• **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 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 2021apply. 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. Researches with ongoing EJP RD projects in **2022** can not apply to the current call unless the alive project or the new application is as Coordinator VI. There is no other incompatibility with AES 2021.
Eligibility of PI and team members	•Principal Investigators (PI) can only participate in one project proposal in this 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. • 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) according to AES 2021. • 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 2021.
Conditions for PAO funding	Participating Spanish patients organisations (PAOs) cannot be funded by ISCIII directly. PAOs could be financed via subcontracting, provided that they develop research activities and the criteria for subcontracting detailed in the Spanish Act 38/2003, of November 17th are fulfilled.

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 2021 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.
Requirements for clinical studies	Spanish groups participating in a proposal performing a clinical study are encouraged to contact and include as members of the team personnel from the Clinical Research Unit (Unidades de Investigación Clínica y Ensayos Clínicos - UICEC) of their institutions. These Units belong to ISCIII's platform that supports Clinical Research and participate in ECRIN-ERIC. Find here the list of UICECs. For additional information please contact: sectec.scren.hcsc@salud.madrid.org or Tel.: (+34) 91 330 38 58
Acknowledgements	Any publication resulting from the granted projects must acknowledge "Award no. XX by ISCIII thorough AES 2021 and within the European Joint Programme Rare Diseases framework" even after the end of the project.

Switzerland, SNSF

Country	Switzerland
Funding organisation	Swiss National Science Foundation (SNSF)
National contact person	Swiss National Science Foundation (SNSF) Division Humanities and Social Sciences Wildhainweg 3, P.O. Box, CH-3001 Bern Phone: +41 31 308 21 87 florence.ettlin@snf.ch|www.snf.ch
Funding commitment	600'000 Swiss Francs (equivalent to approx. 559'000 €)
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	2-3, each Swiss applicant may be partner in only one EJP RD JTC 2021 proposal (Art.7.3, SNSF Regulations on Project Funding).
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 Humanities and Social Sciences must contact the national contact point to confirm their eligibility as an applicant prior to submitting a proposal to the EJP RD JTC 2021. Foreign members of the international consortia applying for funding through the EJP RD JTC 2021 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	According to the regulations on project funding (article 8), the following costs may be covered:

	- the salaries of scientific and technical staff in research projects within the scope of the salary ranges and rates prescribed by the SNSF; - material costs that are directly related to the research work, namely material of enduring value, expendable items, field expenses, travel expenses, third-party charges, cost of computing time and data as well as of providing open access to research data; - direct costs incurred through the use of research infrastructure linked to the research work; - costs for the organisation of conferences and workshops in connection with the funded research; - costs for national and international cooperation and networking activities carried out in connection with the funded research.
Conditions for PAO funding	According to our eligibility criteria, PAO are not eligible as partners.
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. Please select the "Programmes/ERA-NET: Pre-proposal" funding instrument when creating the application for the pre-proposal. 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.

Turkey, Tubitak

Country	Turkey
Funding organisation	The Scientific and Technological Research Council of Turkey, https://tubitak.gov.tr/
National contact person	Dr. Jale Şahin Phone : +90 312 298 1796 E-mail : jale.sahin@tubitak.gov.tr , EJPRD@tubitak.gov.tr
Funding commitment	0,3 M Euro
Overheads	Overheads are eligible costs only for academy and public institutions and subjected to the terms and conditions stated in TUBITAK 1071 Programme.
Anticipated number of fundable research partners	2-3 projects
Maximum funding per grant awarded to a partner	720,000 TL (excluded overhead and PIP)
Eligibility of project duration	Maximum 3 years
Eligibility of a partner as a beneficiary institution	Legal body: university, public research institutes, industry, SMEs.
Eligibility of costs, types and their caps	Personnel, consumables, equipment, travel, consultantship & service procurement.
Conditions for PAO funding	PAOs are not eligible for funding. However, the project coordinator can make a payment to a PAO only if the PAO is able to bill the provided service.
Submission of the proposal at the national level	YES Applicants from Turkey must make a national application through TUBITAK 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	YES, for proposals selected for funding. Turkish partners in the projects selected for funding are obliged to provide Ethics Approval Certificate (https://tubitak.gov.tr/sites/default/files/20689/ekbn_2020.pdf), and/or Legal Permission Licences (https://tubitak.gov.tr/sites/default/files/20689/yasal_ozel_izin_belgesi_bilgi_notu.pdf).
Submission of financial and scientific reports at the national level	Yes, according to national regulations.
Further guidance	For national submissions please follow the procedure decribed in the EJPRD-JTC2021-National Rules – Turkey document

INSERM, France is responsible for administering the funding of 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	389 775€
Overheads	Overheads cost category corresponding to « frais généraux » are limited to 15% of total grant amount (that is 15% * 25 000 € = 3750 €).
Anticipated number of fundable research partners	15
Maximum funding per grant awarded to a partner	25.000 € 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.
Conditions for PAO funding	**It is highly recommended that PAOs first explore funding opportunities from their respective funding organisations.** If PAOs cannot be funded by their respective national/regional funding organisations, they can be eligible for direct funding through INSERM. Exceptions: Estonian PAOs cannot be funded directly by INSERM; please refer to the guidelines for applicants. Spanish PAOs cannot be funded directly by INSERM; please refer to the guidelines for applicants to check the eligibility conditions for PAOs funding by ISCIII. PAOs from Italy applying in collaboration with IRCCS funded by the MoH-IT, can participate in a Consortium as a "collaborator" with their own funding (see point 5.4.3 of this call) or can be financed as a "sub-contractor" through the IRCCS's budget. In any case, they cannot be funded by INSERM directly
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. **Applying PAOs have to complete and sign Annex 1 of the Pre-proposal form "Declaration of Honour for Patient Advocacy Organisation"**
Further guidance	pao@ejprarediseases.org

EUROPEAN JOINT PROGRAMME RARE DISEASES

Call for Proposals 2021

"Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease"

Submission deadline for pre-proposals:
February 16th, 2021; 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.

- **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 3 eligible research partners from at least 3 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 additional 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 is 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 Tuscany Region involved in the proposal have submitted a pre-submission eligibility check form to their regional funding organization 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) 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 in-kind 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) 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 form. 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 call.

☐ **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, SEC members, and ethics experts. 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, SEC members and ethics experts.

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 proposal that is built on the results of a project or by a consortium 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	
PIC number of the institution (EC Participant Identification Code)	
Department	
Position	
Address	
Zip code, City Country	
Phone + Fax	
E-mail address	
Type of entity (Academia, Clinical or Public Health or SME)	
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)	PIC number of the institution (EC Participant Identification Code)	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								
7		(7th partner is an early career researcher, or from usually underrepresented countries)						
8		(8th partner is an early career researcher, or from usually underrepresented countries)						

3b. Patient advocacy organisation: 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 requested funding in application | | **€**

6. Keywords

Please identify between three and seven keywords that represent the scientific content (SSH field, medical domain, disease, etc.), approach(es), methodology

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 section 4.2 of Guidelines for Applicants for details).*

8. Description of the project

(once converted into PDF: max. 5 pages DIN-A4, single-spaced, and margins of 1.27 cm).
Please describe all the following elements:

- **Background, present state of the art in the SSH research field**
  - Need for research rationale: description of the unmet need that is addressed by the proposed work, rationale of the rare diseases chosen.
  - Present state of the art, recent insight from literature.
  - Preliminary results obtained by the consortium members
- **Objectives and hypothesis**
  - SSH research question
  - Main and secondary hypothesis
- **Soundness and pertinence**
  - Innovative aspects, originality, novelty
  - Social care and public health interest
- **Workplan** *(highlighting feasibility)*
  - Research strategy
  - SSH methodologies justification and presentation
  - Enrollment: study location(s), total number of corresponding patients followed by partners and collaborators of the project.
  - Statistical power (if applicable): appropriate statistical methods description, name and affiliation of the responsible biostatistics' expert.

- Please also complete the following table:

Study type (see section 4.4 of the call text)	
Inclusion/exclusion criteria	
Main outcomes to be analysed	
Anonymisation/pseudonymisation of data and statistical details	
Number of participants calculation (if applicable): description, justification, expected response rate, duration in months	

- **Impact**
  - Results: description of expected results and their implementation
  - Impact: description of the potential impact of the expected results on the addressed unmet need
  - Benefits: description of individual and collective benefits that could be expected
- **Added values of the consortium**
  - Competence, experience and complementarity of all the participants including PAOs and patient representatives within the consortium (active and meaningful participation), benefit of transnational collaboration

If the application builds on results obtained in a project or by a consortium funded in previous EJP RD or 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) or Harvard referencing style (see: https://www.mendeley.com/guides/harvard-citation-guide) and include PUBMED, WoS or SCOPUS IDs*. Apply the chosen style consistently throughout the whole proposal.

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 (electronic signature or a scanned copy of the signature page will be accepted)

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

[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 Project Coordinator budget.
[5] 7th and 8th partner are early career researchers, or from usually underrepresented countries
Applicants are encouraged to confirm their eligibility with their national contact points

	Project coordinator[4]	Partner 1	Partner 2	Partner 3	Partner 4	Partner 5	Partner 6	Partner 7[5]	Partner 8[5]	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	0
Total budget if required (e.g. MIUR)										

Annex 1

Declaration of Honour for Patient Advocacy Organisation

(Complete or delete the parts in grey italics in parentheses)

The undersigned: *(insert name of the signatory of this form)*

Representing the following Patient Advocacy Organisation: *(insert name of the PAO)*

Declares that the above mentioned Patient Advocacy Organisation (PAO) is fulfilling the following conditions:

☐ is a not-for-profit organisation, which is patient focused, and where patients and/or carers and/or family members of patients represent a majority of members in governing bodies;

☐ is formally established and registered for more than 1 year as a not-for-profit organisation in one of the Member States of the EU/EEA/participating in the EJP RD;

☐ includes in its governing structure a designated representative legally authorised to sign a contract with a public funder/Inserm;

☐ is financially independent, particularly from the pharmaceutical industry (max. 50% of funding of the PAO comes from one or several companies).

Date: *(insert date of signature)*

Full name: *(insert name of the signatory of this form)*

Signature: