EJP RD
European Joint Programme on Rare Diseases

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Fourth Public Call documents
JTC2019-2022:
call text, guidelines for applicants, proposal templates JTC 2019-2022

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Public

Call text

Guidelines for applicants

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 expected impact to use the results in the future for benefit of patients.

The Topic of the call is : **"Development of new analytic tools and pathways to accelerate diagnosis and facilitate diagnostic monitoring of rare diseases"**

This deliverables contains the public documents of the JTC 2022:

- Call text
- Guidelines for applicants
- Preproposal template

Call for Proposals 2022

"Development of new analytic tools and pathways to accelerate diagnosis and facilitate diagnostic monitoring of rare diseases"

Call Text

Submission deadline for pre-proposals: February 16th, 2022, at 2 PM (CET)

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

Or contact:

Joint Call Secretariat (ISCIII, Spain)

Ignacio Baanante
ibaanante@isciii.es

Maria Druet
mdruet@isciii.es

1. Background

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

Therefore, research on rare diseases is needed to provide knowledge for prevention, diagnosis, 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 clinical phenotypes of these diseases require interdisciplinary cooperation to improve research and treatment.

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

In this context, the **European Joint Programme on Rare Diseases (EJP RD)** has successfully implemented three 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.

2. Participating organizations

A number of national and regional funding organizations will participate in the **EJP RD Joint Transnational Call (JTC) 2022** 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:

- Medical Research Future Fund (MRFF), Australia
- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders

- Fund for Scientific Research - FNRS (F.R.S.-FNRS), Belgium, French-speaking community
- Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG), Canada
- Fonds de recherche du Québec-Santé (FRQS), Québec (Canada)
- Ministry of Education, Youth and Sports (MEYS), Czech Republic
- Academy of Finland (AKA), Finland
- French National Research Agency (ANR), France
- Foundation For Rare Diseases (FFRD), France
- German Ministry of Education and Research (BMBF), Germany
- National Research, Development and Innovation Office (NKFIH), Hungary
- Health Research Board (HRB), Ireland
- Chief Scientist Office of the Ministry of Health (CSO-MOH), Israel
- Italian Ministry of Health (MoH-IT), Italy
- Regional Foundation for Biomedical Research (FRRB), Lombardy (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
- Swedish Research Council (SRC), Sweden
- Vinnova, Sweden
- Swiss National Science Foundation (SNSF), Switzerland
- Netherlands Organization for Health Research and Development (ZonMw), The Netherlands
- The Scientific and Technological Research Council of Turkey (TUBITAK), Turkey

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**) (ISCIII, Spain). 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 JTC2022. 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. Aim of the call

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

Projects shall focus on **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, Australia and Canada. Applicants are encouraged to assemble groups of rare diseases based on relevant criteria and commonalities if this leverages added value in sharing resources or expertise.

Topic: "Development of new analytic tools and pathways to accelerate diagnosis and facilitate diagnostic monitoring of rare diseases"

❖ 4.1 Topics list

Research proposals should cover at least one of the following areas**:**

1. Phenotype-driven diagnosis: integration across different ontologies, integration of shared pathways, digital phenotyping, development of artificial intelligence approaches/applications to extract health related data in aid of diagnosis;
2. Prognostic markers/biomarkers investigations for early diagnosis and monitoring;
3. Methodologies for solving cases that are currently difficult to analyze due to different underlying mechanisms (e.g., mosaicism, genomic (non-coding) alterations, gene regulation, complex inheritance), including new genomics / functional genomics technologies, multi-omics, mathematics, biostatistics, bioinformatics and artificial intelligence approaches.
4. Functional strategies to globally stratify variants of unknown significance (VUS) for clinical use; setting up of (in vitro) systems to distinguish between VUS and pathogenic variants (e.g., confirming disruption of splicing for deep intronic variants, loss of protein function, and gain of toxic protein function);
5. Development of pathway models to enable diagnosis, especially for newly discovered diseases that may share underlying molecular mechanisms with already known diseases.

It is possible to use cellular and animal models for validation of the new diagnostic approaches in the subtopics listed above where relevant.

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

• The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and has to be part of the proposal;

• For natural history studies and patient registries: strategies and timelines for patient recruitment, retention, assessment, and analysis must be included. Data supporting the proposed recruitment numbers is mandatory. The study design and objectives should take into consideration what information regarding the rare disease population would be needed in order to pursue clinical trials or other health care related studies in that rare disease. There always need to be clear research questions that are addressed in the study/registry. Clear plans for sustainability of the resources must be described. Consideration of common data elements as outlined in the recent publication "Set of Common Data Elements for RD Registration";

• Integration of appropriate bioinformatics and statistical skills should constitute, whenever justified, an integral part of the proposal, and the relevant personnel should be clearly specified;

• Proposals are expected to consider how sex and/or gender might shape research activities. Applicants are encouraged to visit CIHR's Sex, Gender and Health Research resource page for more information on key considerations for the appropriate integration of sex and gender in their proposal.

• The new research data resulting from the project should be treated permissible according to the FAIR[1] principles, and deposited and shared, according to the national/regional rules of the countries involved. It is strongly advised to make data accessible through RD-Connect and through Elixir - compiling a list of resources for the deposition of experimental, biomolecular data). To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy for the proposed full project is mandatory in the full proposal stage. Some countries involved in EJP RD JTC 2022 will also ask for a data management plan (DMP) at national level at the stage of full proposal or after granting of the project.

❖ 4.2 Excluded approaches and topics

The following approaches and topics will be excluded from the scope of the JTC2022:

- Interventional clinical trials to prove efficacy of drugs, treatments, surgical procedures, medical technology procedures. This also includes studies comparing efficacy, e.g. 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.
- Development of new therapies as covered in EJP RD JTC 2020.

[1] FAIR: Findable, Accessible, Interoperable, Reusable (for more information: see "The FAIR Guiding Principles for scientific data management and stewardship"

- 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. **However, childhood dementias/neurodegenerative diseases are not excluded.**
- Rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases. **Rare diseases with a predisposition to cancer are not excluded.**

❖ 4.3 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, present state of the art in the research field
- Objectives and hypothesis
- Soundness and pertinence
- Workplan & methodology *(highlighting feasibility)*
- Impact
- Valorization, translation to practice
- PAOs engagement/involvement
- Ethical and legal issues, data management
- Work packages, timeline and budget
- Responsibilities and workloads

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. In addition, there can be no double funding for activities already funded by EC H2020 and Horizon Europe 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 (PAOs).

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

The **use of the matchmaking tool is strongly encouraged** to build multidisciplinary research projects: https://live.eventtia.com/en/jtc2022matchmaking

❖ 5.4.1 Limit number of partners

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

❖ 5.4.2 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 subcontractors per country, as long as their participation is justified and if subcontracting is possible according to national/regional funding rules).

❖ 5.4.3 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 2022 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,
- 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.

The funding conditions for the PAOs will be set out for each country in the guidelines for applicants.

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/ejprd22. 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 December 2021	Information webinar for potential applicants
16th February 2022	Pre-proposal submission deadline
End of April 2022	Invitation to full proposal
15th June 2022	Full proposal submission deadline
28th July 2022	Deadline for rebuttals
December 2022	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/).

An **information webinar** will be held on **December 16**, 14.00-15.30 (CET). You will need to register to participate in the webinar here:
https://forms.office.com/r/P7cYnbLLYG

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.

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. Innovative potential,
   e. Feasibility of the project (adequate requested resources, time schedule, access to and engagement of patients, data and material),
   f. Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific expertise),
   g. Active and meaningful participation of PAOs and patient representatives in the project (including where possible in the design and definition of research priorities, interpretation and implementation of results, their dissemination, and communication).

2. **Impact (0-5)**
   a. *Potential of the expected results for exploitation and for future clinical, public health and/or other socio-economic health relevant applications, including patient's needs,
   b. *Added value of transnational collaboration: gathering a critical mass of patients/ material, sharing of expertise and resources, harmonization of data, sharing of specific know-how and/or innovative solutions,

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. Inclusion of Early Career Researchers as full partners,
e. Benefit to patients, their families, and carers with an active and meaningful involvement of patient organizations and patient representatives,
f. Involvement of industry (when appropriate/applicable/available).

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.

Widening
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).

EJP RD Mentoring programme
Applicants that are invited to submit a second stage proposal are strongly encouraged to make use of the EJP Rare Diseases Mentoring Programme. This completely free service offered by EJP RD matches your project with mentors that have expertise in applied research and translational development (see 5.3 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 2022) 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 reviews and 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.
Two additional groups of reviewers will be present at the second SEC meeting to evaluate projects:

1. **Patient representatives**
   Proposals will be evaluated by expert patient reviewers according to the relevant evaluation criteria listed above (subcriteria 1g, 2e, 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.
2. **Statistical / methodological experts**

Proposals will be evaluated by experts in methodology or statistics according to the relevant evaluation criteria listed above (subcriteria 1b, 1f, 1g; 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.
- Proposals with meaningful engagement/involvement of PAOs.

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 Institute of Health Carlos III (ISCIII, Spain) 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 regarding 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 an **annual scientific project report** (usually first due on the 28th of February 2024 and then similarly in 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	ISCIII Spain	Ignacio Baanante ibaanante@isciii.es Maria Druet mdruet@isciii.es +34 91 822 2530

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
Australia	Medical Research Future Fund (MRFF)	Elspeth Langford Elspeth.LANGFORD@Health.gov.au
Austria	Austrian Science Fund (FWF)	Stephanie Resch Phone: +43 (1) 505 67 40-8201 stephanie.resch@fwf.ac.at Anita Stürtz Phone: +43 (1) 505 67 40-8206 anita.stuertz@fwf.ac.at
Belgium	Research Foundation – Flanders (FWO)	Toon Monbaliu eranet@fwo.be +32 (0)2 550 15 70 Kristien Peeters eranet@fwo.be +32 (0)2 550 15 95
Belgium	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
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
Québec (Canada)	Fonds de recherche du Québec - Santé, (FRQS),	Maxime Beaudoin maxime.beaudoin@frq.gouv.qc.ca +1 514 873-2114 ext. 4369

Czech Republic	Ministry of Education, Youth and Sports (MEYS)	Judita Klosaková judita.klosakova@msmt.cz + 420 234 811 504
Finland	Academy of Finland (AKA)	Heikki Vilen heikki.vilen@aka.fi +358 29 533 5135 Rita Rinnankoski-Tuikka rita.rinnankoski-tuikka@aka.fi +358 29 533 5096
France	The French National Agency for Research - ANR	Dr. Florence Guillot florence.guillot@anr.fr EJPRDcall@anr.fr
France	Foundation For Rare Diseases (FFRD)	Diana Desir-Parseille Diana.desir-parseille@fondation-maladiesrares.com aap-bio@fondation-maladiesrares.com
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)	Dr. Előd Nemerkényi Phone: +36 1 8963987 elod.nemerkenyi@nkfih.gov.hu Dr. Gábor Tóth Phone: +36 1 8961727 gabor.toth@nkfih.gov.hu
Ireland	Health Research Board (HRB)	Amanda Daly Amanda.Daly@hrb.ie

Israel	Chief Scientist Office Israeli Ministry of Health (CSO-MOH)	Dr. Irit Allon IRIT.ALLON@moh.gov.il +972-2-5082167
Italy	Italian Ministry of Health, MOH-IT	Dr. Chiara Ciccarelli +39 06 5994 3919 c.ciccarelli@sanita.it Dr. Anna Ceccarelli +39 06 5994 3835 a.ceccarelli-esterno@sanita.it
Lombardy (Italy)	Regional Foundation for Biomedical Research (FRRB)	Paola Bello Tel: + 39 02 67650174 paola.bello@frrb.it Giusi Caldieri, PhD Tel: + 39 02 67650173 giusi.caldieri@frrb.it *Carmen De Francesco* Tel: 02/67650170 carmen.defrancesco@frrb.it
Italy	RT/Tuscany	Donatella Tanini Phone: +39 055 4383256 Teresa Vieri Phone: +39 055 4383289 ejprare@regione.toscana.it
Lithuania	Research Council of Lithuania	Dr. Živilė Ruželė zivile.ruzele@lmt.lt (+370) 676 14383
Luxembourg	Luxembourg National Research Fund (FNR)	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, (+48) 571 226 666

Slovakia	Slovak Academy of Sciences (SAS)	Dr. Zuzana Cernakova Cernakova@up.upsav.sk +421 (0) 2 5751 0 118
Spain	National Institute of Health Carlos III	Ignacio Baanante Ibaanante@isciii.es +34 91822 2576 Maria Druet mdruet@isciii.es + 34 822 2530
Sweden	Swedish Research Council (SRC)	Louise Rügheimer Louise.rugheimer@vr.se
Sweden	Vinnova	Gunnar Sandberg Gunnar.sandberg@vinnova.se +46 8 4546445
Switzerland	Swiss National Science Foundation (SNSF)	Dr. Tobias Braun tobias.braun@snf.ch +41 31 308 21 67
The Netherlands	Netherlands Organization for Health Research and Development (ZonMw)	Sonja van Weely Kirsten Wilkens ERareJTC2018@zonmw.nl (e-mail preferred) +31 70 349 54 67/52 20 +31 70 515 0390
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK)	Dr. Jale Sahin Jale.sahin@tubitak.gov.tr +90(312)298 1796

Call for Proposals 2022

"Development of new analytic tools and pathways to accelerate diagnosis and facilitate diagnostic monitoring of rare diseases"

Guidelines for Applicants

Submission deadline for pre-proposals: February 16th, 2022 at 2 PM (CET)

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

Or contact:

Joint Call Secretariat (ISCIII, Spain)

Ignacio Baanante
ibaanante@isciii.es

Maria Druet
Mdruet@isciii.es

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/ejprd22 . 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/ejprd22 . 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, 2022 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, 2022 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 organizations 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 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

- 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
- 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, translation in practice**

- 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 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
- 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
- * 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

PAOs engagement/involvement

*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:

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

*** *The EJP RD's Resource Finder provides scientific partners with a vast number of existing research data and services grouped into categories and represented as 11 `nodes´ in the mindmap.*

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 2022 Funding Partners have agreed to launch a joint call using the **"virtual common pot" funding mode**. This means that national/regional funding will be made available through national/regional funding organizations according to national/regional funding regulations.

ISCIII (Spain) 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 organizations (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 EJP RD Mentoring programme

Applicants that are invited to submit a second stage proposal are strongly encouraged to make use of the EJP Rare Diseases Mentoring Programme. This completely free service offered by EJP RD matches your project with mentors that have expertise in applied research and translational development. During full proposal development the service will provide independent feedback and advice to applicants in critical methodological areas. This will help to ensure robust and reliable

study results so that the project – if successful – has the best chances of advancing towards implementing the results for patient care. These areas include:

- Appropriate use of analytical technologies and read-outs;
- Appropriate sampling methods and sample handling;
- Statistical methodology;
- Good practice in validation and follow-on study planning;
- Risk management strategies for the development process.

Applicants should indicate in the pre-proposal form if they wish to make use of the Mentoring service. If they are invited to full proposal submission, the Mentoring team will soon after contact the applicants to schedule a planning call, after which mentors will be assigned to the project based on the individual needs.
Please note that in order to provide a reliable and useful service, applicants must request the mentoring service no less than 4 weeks before the full proposal submission deadline.

5.4 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 organizations, 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 organizations. **Research partners must inform the JCS and the respective funding bodies of any event that might affect the implementation of the project**.

5.5 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 2022 funding organizations.

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)

5.6 Ownership of intellectual property rights

Results and Intellectual Property Rights (IPR) resulting from projects funded through the EJP RD JTC 2022 will be owned by the beneficiaries' organizations 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.

The funding organizations 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.

5.7 IRDiRC policies and guidelines

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

5.8 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);* The EC Directive 2010/63/EU on the protection of animals used for scientific purposes,
- European Research Council Guidelines on Implementation of Open Access to Scientific Publications and Research Data,
- To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy is mandatory in the full proposal. Example questions for a data management strategy.
- 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).

5.9 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 organizations. 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 (Name of funding agency) partner of the EJP RD. The EJP RD initiative has received

funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 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 call JTC2022, 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.

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

Country	
Funding organization	
National contact person	
Funding commitment	
Overheads	
Anticipated number of fundable research partners	
Maximum funding per grant awarded to a partner	
Eligibility of a partner as a beneficiary institution	
Eligibility of costs, types and their caps	
Conditions for PAO funding	

Submission of the proposal at the national level
Further guidance

MEDICAL RESEARCH FUTURE FUND (MRFF), AUSTRALIA

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

Country	Australia
Funding organization	Medical Research Future Fund (MRFF) https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund
National contact person	Michael Nutt (National Health and Medical Research Council (NHMRC) – Managing Organisation) Michael.Nutt@nhmrc.gov.au
Funding commitment	$1 Million AUD
Overheads	Overheads are not eligible costs for MRFF
Anticipated number of fundable research partners	3
Maximum funding per grant awarded to a partner	$300,000 AUD
Eligibility of a partner as a beneficiary institution	MRFF Eligible Organisations may apply for and receive funding
Eligibility of costs, types and their caps	All eligibility rules including budget requirements are outlined in the MRFF 2022 Joint Transnational Call Grant Opportunity Guidelines available on GrantConnect
Submission of the proposal at the national level	Yes
Submission of financial and scientific reports at the national level	Yes
Further guidance	Refer to the MRFF 2022 Joint Transnational Call Grant Opportunity Guidelines available on GrantConnect

AUSTRIAN SCIENCE FUND (FWF), AUSTRIA

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

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 the number of ongoing/approved/submitted projects in which one researcher can serve as principal investigator is 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	Not applicable
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 2022 / 02:00 p.m. CET)". For the full proposal stage applicants must choose the programme category "I – International Projects" (full proposal, deadline 15. June 2022 / 02:00 p.m. CET). 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/

RESEARCH FOUNDATION FLANDERS (FWO), BELGIUM, FLANDERS

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

Country	Belgium (Flanders)
Funding Organization	The Research Foundation - Flanders (FWO)
National Contact Person	Toon Monbaliu (FO) eranet@fwo.be +32 (0)2 550 15 70 Kristien Peeters (SBO) eranet@fwo.be +32 (0)2 550 15 95
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. Researchers have to inform the central research coordination units, at their host institutions, about their participation. 4. 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. 5. Projects may last up to 36 months, which implies the funding has to be budgeted and spent accordingly. 6. The PI, for each of the participating institutions from Flanders, must hold an appointment that fully covers the duration of the research project. 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 only 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 (see 'National Contact Persons' above). Information available at: - Call page for European programmes - Junior/senior research projects (FO) - SBO research projects (SBO)

FUND FOR SCIENTIFIC RESEARCH-FNRS (F.R.S.-FNRS), BELGIUM, FRENCH SPEAKING COMMUNITY

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

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 organizations 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

CANADIAN INSTITUTES OF HEALTH RESEARCH- INSTITUTE OF GENETICS (CIHR-IG), CANADA

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

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	CIHR: CAD $1,350,000, Ataxia Canada: CAD $450,000 Total funding available: CAD $1,800,000 CAD $150,000 per year per project maximum.
Overheads	Not an allowable cost.
Anticipated number of fundable research partners	4 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)** For this competition only: a researcher who, at the time of application, has held a full time, independent research appointment, for a period of 0 to 7 years (84 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., are credited as twice the amount of time taken) 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 temporarily adjusted 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 to 0-84 months from 0-60 months. 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 organizations (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). Summary of the applications potentially relevant for funding by Ataxia Canada will be made available to that organization to confirm relevancy of the proposals to their mandate.
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

FONDS DE RECERCHE DU QUÉBEC - SANTÉ (FRQS), QUÉBEC (CANADA)

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

Country	QUÉBEC (CANADA)
Funding organisation	FONDS DE RECERCHE DU QUÉBEC - SANTÉ (FRQS) – **https://frq.gouv.qc.ca/**
National contact person	**Maxime Beaudoin, Programs Manager** **Tel: (+1) 514-873-2114 ext.4369** **Maxime.beaudoin@frq.gouv.qc.ca**
Funding commitment	$450, 000 CAD (~0.32 Mio. €) available for Quebec researchers. The total maximum amount that can be requested in support of a Quebec/Canada component is $150,000 CAD per year for up to 3-years from all Canadian funding sources CIHR-IG, FRQS and their funding partners. Funds are subject to availability of funds voted annually to FRQS by the National Assembly of Québec and FRQS Board of Directors' approval.
Overheads	Overheads means "frais indirects de recherche" and will be managed separately by the FRQS. They should not be included in the requested budget.
Anticipated number of fundable research partners	Anticipated number of funded research groups: 1-2* FRQS is providing funding to support up to one project as outlined in the call text. *Canadian funders agencies (FRQS and CIHR-IG) will be working together to maximize participation from the Canadian research community.

Eligibility of project duration	Up to 3-years
Eligibility of a partner as a beneficiary institution	Quebec applicants must meet the eligibility criteria of FRQ research grants. Eligible institutions are Quebec Universities or Institutions within Quebec's health and social services network. Please consult the full list of Quebec Eligible managing institutions.
Eligibility of costs, types and their caps	• Operational costs (research personnel, consumables, animals) • Costs related to scientific and ethical evaluation (clinical research projects) • Coordination-related cost (project administration and travel expenses for attending joint meetings) • Costs related to knowledge translation and translation • Conference attendance (up to 5% per year of the grant amount starting the first year with proper justification) There is NO support for salaries of investigators or equipment. There is NO supplement for the Coordinator of an international consortium. Further information about eligible and ineligible expenses is available in section 8 of the FRQ Common General Rules. *Overheads means "frais indirects de recherche (FIR)" are not an eligible expense. It will be managed separately.*
Conditions for PAO funding	FRQS cannot fund Quebec/Canada PAOs directly nor be an eligible partner (Investigator(s)) on the application. *However, it is possible for a PAO to be represented by an individual in the role of Individual contributor or collaborator. In this case, the Quebec Principal Investigator (PI) may request funds in their budget to support the activities of the PAO representative on the project or they could be supported as subcontractors.*

Submission of the proposal at the national level	*Non-extensive requirements* Quebec Principal investigator (PI) must submit a short application form through FRQS **e-portfolio.** Quebec Co-investigator(s) has to consent to be part of this application before the institutional approval. CCV of all the investigators must be updated with the most recent information for the eligibility check. Managing institutions approval must be done lastly which automatically activates the final submission. $CAD Budget form will be requested. Please consult the ***FRQ webpage of JTC2022 EJP RD program*** for complementary information about the requirements. Documents sent via mail or e-mail will NOT be accepted. **FRQS short application form will follow the exact Call deadlines.**
Submission of other information at the national level	*Quebec Investigators applying for funding from FRQS and CIHR must also complete an abbreviated CIHR form at the Proposal stage only (second stage) in order to be eligible to receive funding from both agencies. **Please contact CIHR representative for more information.**
Submission of financial and scientific reports at the national level	Yes, according to regional/national regulations. Scientific reports according to EJP RD template and requirements. Minimum requirements such as electronic Annual financial reporting according to FRQ Common General Rules and Grant Regulations. A Final scientific report under FRQ template will be requested at the very end of the project. *The FRQS reserves the right to request any additional or complementary information related to the research project granted.* **Note:** Further requirements will be stated in the official FRQS Letter of Grant addressed to the selected Quebec Principal Investigator(s).

Further guidance	Basic research ethics training is mandatory for all recipients of an FRQS grant when their part of research project that involve human beings. PI and Co-PI(s) on the project must therefore successfully complete levels 1 and 3 of MSSS Ethics online training by the Ministère de la Santé et des Services sociaux. Post-doctorate on the project are also encouraged to complete this training. 5.5 Research Ethics and Conformity (FRQ Common General Rules) Funding holders and managing institutions must demonstrate the highest standards of research ethics and scientific integrity. All research projects involving human beings, including biological material (body parts, products, tissues, cells or genetic material from a human body, of a living or dead person) or administrative, scientific or descriptive data from human beings, usually require the approval of the research ethics board of the institution under whose authority or auspices the project is conducted (or a research ethics board recognized by that institution). In the case of grants, the managing institution is responsible for obtaining all necessary ethics approvals. For complementary information about FRQ standards adopted please consult FRQ Ethics and integrity section.

MINISTRY OF EDUCATION, YOUTH AND SPORTS (MEYS), CZECH REPUBLIC

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

Country	Czech Republic
Funding organization	Ministry of Education, Youth and Sports (MEYS) www.msmt.cz
National contact person	Judita Klosaková MSMT, Department of Research and Development Phone : +420 234 811 504 E-mail : judita.klosakova@msmt.cz
Funding commitment	0.6 M€
Overheads	Eligible costs for a Czech participant involved in a project consortium are defined by § 2 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds and on Amendment to Some Related Acts. The maximum indirect costs set for the present call are 25 % (flat rate) of direct costs without the sub-contracting.
Anticipated number of fundable research partners	(2-3)
Maximum funding per grant awarded to a partner	No restriction
Eligibility of a partner as a beneficiary institution	The participants from the Czech Republic in the projects´ consortia must meet the criteria of the **research and knowledge-dissemination organisation**(hereinafter referred to as "research organisation") in accordance with the Framework for State Aid for Research and Development and Innovation (2014/C 198/03). These might be public universities, public research institutes and/or another entities classified as research organisations. It is obligatory that the Czech participants involved in the projects´ consortia prove compliance with the eligibility criteria and fulfilment of the conditions set by **§ 18 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds** and on Amendment to Some Related Acts by means of a **Statutory Declaration**.
Eligibility of costs, types and their caps	Eligible costs for a Czech participant involved in a project consortium are defined by **§ 2 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds** and on Amendment to Some Related Acts. The maximum indirect costs set for the present call are **25 % (flat rate)** of direct costs without the sub-

	contracting. **The aid intensity** for activities carried out by a research organisation might be at the level of **100 %** provided that the research organisation complies entirely with requirements stipulated by the Article 2.1.1 "Public funding of non-economic activities" of the Framework for State Aid for Research and Development and Innovation (2014/C 198/03) and proves it by means of the above-mentioned **Statutory Declaration**. Should the above-stated criteria not be fulfilled by the Czech participant, funding rates will be adjusted appropriately by the Ministry of Education, Youth and Sports and will reach the level of **100 % for fundamental/basic research** activities, **50 % for applied research** activities and **25 % for experimental development** activities. For further information on the eligibility cost please see https://www.msmt.cz/vyzkum-a-vyvoj-2/ejp
Conditions for PAO funding	The MEYS does not fund PAOs/patient representatives.
Submission of the proposal at the national level	It is obligatory: -that the Czech participants involved in the projects´ consortia prove compliance with the eligibility criteria and fulfilment of the conditions set by §18 of the Act No. 130/2002 Coll. on Support of Research, Experimental Development and Innovation from Public Funds and on Amendment to Some Related Acts by means of a Statutory Declaration. -that each Czech participant in a project consortium is requested to specify the costs related to the envisaged R&D activities in detail by using the Eligible Costs Specification. The template and detail information will be available on websites of the Ministry of Education, Youth and Sports dedicated to the EJP RC JTC 2022. All of the requested documentation (i.e. Statutory Declaration and Eligible Costs Specification) shall be sent by each Czech participant in a project consortium to the Ministry of Education, Youth and Sports no later than the date of the official submission deadline for pre-proposals, both by **electronic correspondence and data box/post**. The electronic version of requested documentation shall be sent to the address of electronic correspondence: Judita.Klosakova@msmt.cz. One signed and stamped hard copy (by the statutory representative of research organisation) of requested documentation shall be submitted as well following the instructions stipulated on websites of the Ministry of Education, Youth and Sports.
Further guidance	• https://www.msmt.cz/vyzkum-a-vyvoj-2/ejp

ACADEMY OF FINLAND (AKA), FINLAND

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

Country	Finland
Funding organisation	Academy of Finland (AKA) http://aka.fi
National contact person	Heikki Vilen Heikki.vilen@aka.fi +358 29 533 5135 Rita Rinnankoski-Tuikka rita.rinnankoski-tuikka@aka.fi +358 29 533 5096
Funding commitment	0,6M€
Overheads	According to full cost model SOCIAL
Anticipated number of fundable research partners	2
Maximum funding per grant awarded to a partner	Maximum funding is 300 000 € / consortium (full cost model, Academy's 70 % share of expenses so maximum total budget is ~428 570 €) – if there are several Finnish partners in the same consortium, they must share this among themselves.
Eligibility of a partner as a beneficiary institution	Eligibility rules for the applicants are the same as with Academy project funding: https://www.aka.fi/en/research-funding/apply-for-funding/calls-for-applications/apply-now2/academy-project-funding-2021-all-research-fields/. AKA funds only Finnish research organizations (universities, public research institutes, university hospitals). Applicant needs to have an affiliation in such organization. Private not-for-profit research organizations such as VTT and CSC are also eligible – please check with the contact person.
Additional specific rules	NA
Conditions for PAO funding	AKA cannot fund PAOs directly – minor expenses (such as travel costs to a few meetings) can be included in the budget of a Finnish academic partner

Submission of the proposal at the national level	At the plan of intent stage of the call all Finnish applicants are advised to contact the national contact person. Submission of a national proposal will only be required in autumn 2022 from projects to be funded.
Submission of financial and scientific reports at the national level	Yes, according to national regulations.
Further guidance	NA

FRENCH NATIONAL RESEARCH AGENCY (ANR), FRANCE

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

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	3.11 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 maximum amount that can be requested by French partners per project is 500 000 € The minimum funding amount per partner is 15 000 €.
Overheads	The ANR heading for "overheads" in the ANR funding breakdown is «frais d'environnement». 13% 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	10-12
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, foundations (max. rate of support: 100% of marginal costs, for organisations funded at "marginal cost") - 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 organisation) 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 research activities. Before applying, contact ANR for the rate of support your organisation is eligible to. Be aware that PAOs are often private entities and thus can generally not request a 100% support rate. Otherwise, French PAO can be funded as sub-contractor of a French partner. The maximum amount to sub-contract to a PAO is 20 k€ per project.
Submission of the proposal at the national level	No. Please note that some funding agencies that request submission at national level may be made available upon request applications (pre-proposals and full proposals) after the publication of the funding decision (i.e. SRC).
Submission of other information at the national level	No. However, please contact the national contact point for the ANR to enquire about their eligibility before submitting a proposal. In the proposal, justification of all costs must be provided especially sub-contracting, other direct costs...
Submission of financial and scientific reports at the national level	Financial reporting: must be completed according to ANR regulations, and the funding contract that beneficiaries will have to 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. Consortium agreement signed by all consortium's members and a data management plan **must** be provided.
Further guidance	Règlement financier Please read the Modalities for French applicants for this call on the ANR website.

FRENCH FOUNDATION FOR RARE DISEASES (FFRD), FRANCE

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

Country	France
Funding organisation	Foundation for Rare Diseases (Fondation Maladies Rares) https://fondation-maladiesrares.org/eng/
National contact person	Fondation Maladies Rares Plateforme Maladies rares 96 rue Didot - 75014 Paris, France **aap-bio@fondation-maladiesrares.com** Diana Désir-Parseille - Phone : (33) (0) 1 58 14 22 81
Funding commitment	100 000€
Overheads	Overheads are not eligible costs.
Anticipated number of fundable research partners	TBD
Maximum funding per grant awarded to a partner	20 000€
Eligibility of project duration	3 years max
Eligibility of a partner as a beneficiary institution	Eligible institutions: - Public research institutes such as EPST, EPIC, universities, university hospitals, non-university research institutes (max. rate of support: 100% of marginal costs)
Eligibility of principal investigator or another research team member	The coordinator (if from a French institution) must belong to a public research organisation.

Eligibility of costs, types and their caps	Personnel costs for temporary contracts; small equipment; consumables and animal costs; travel; and sub-contracting, if necessary to carry out the proposed activities. Overheads are not eligible costs.
Conditions for PAO funding	No funding of PAOs
Submission of the proposal at the national level	No
Submission of other information at the national level	No
Submission of financial and scientific reports at the national level	Yes. Financial reporting is submitted to FFRD financial modalities and must be followed according to the contract that will be signed with the future beneficiaries. Scientific reports: individual scientific reports are not required. However, French partners should contribute to the central report to be submitted by the coordinator of the project.
Further guidance	

BMBF/PT-DLR, GERMANY

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

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 organization
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 organizations 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

NATIONAL RESEARCH, DEVELOPMENT AND INNOVATION OFFICE (NKFIH), HUNGARY

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

Country	Hungary
Funding organization	Ministry of Innovation and Technology
Management organization	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	300.000 €
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 150.000 €. If more than one partner applies from Hungary, their total requested funding should not exceed 150.000 euros.
Eligibility of project duration	Up to 3 years
Eligibility of a partner as a beneficiary institution	Universities, academic and public research institutions, public health institutions (university or non-university hospitals and clinics). An SME or a non-profit organization 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 150.000 € per project includes the overhead.

	Detailed list of eligible costs (basically personnel, consumables, animals, equipment, travel, subcontracts, overhead) and guidelines to prepare the budget plan can be found in the call text and guideline of NKFIH '2019-2.1.7-ERA-NET' call (https://nkfih.gov.hu/palyazoknak/nkfi-alap/era-net-ejp-cofund-2019-217-era-net/palyazati-felhivas-2019-217-era-net).
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.

HEALTH RESEARCH BOARD (HRB), IRELAND

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

Country	Ireland
Funding organization	Health Research Board, HRB, **www.hrb.ie**
National contact person	Dr. Amanda Daly Dr. Louise Drudy Email: eujointprogrammes@hrb.ie
Funding commitment	€370.000
Overheads	In accordance with the HRB Policy on Usage of research overheads, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for laboratory or clinically-based research and 25% of Total Direct Modified Costs if desk-based research.
Anticipated number of fundable research partners	1-2
Maximum funding per grant awarded to a partner	Up to €370,000 in total
Eligibility of a partner as a beneficiary institution	Lead applicants (Principal Investigators) from Ireland working in a recognized HRB Host Institution (Policy on Approval of HRB Host Institutions) are eligible for HRB funding in this call. Please see HRB Funding Schemes for HRB Guidance and FAQ for eligibility details.
Eligibility of costs, types and their caps	Funding available is inclusive of overheads and pension contributions • Salary related costs • Small equipment costs (€10,000) • Travel • Direct running costs (including costs for PAO participation)

	• FAIR data management costs • Dissemination and knowledge exchange costs • Overheads
Conditions for PAO funding	Patient advocacy organisations (PAOs)are not eligible to participate as a partner (Lead applicant). However, it is possible for the Lead applicant to request funds in their budget to support the activities of a PAO representative on the project. Eligible costs include consultation workshops, costs of participation in advisory groups, travel expenses, payments for time reviewing material (in line with the Host institutions policies) etc.
Submission of the proposal at the national level	For full proposal stage: Irish partners are asked to provide a copy of the submitted full proposal to the HRB National contact person following submission to the European Portal. Applicants from Ireland who are part of consortia invited to submit Full Applications will have to submit further budget and deliverables templates for the HRB. Templates will be provided by the HRB to invited applicants
Further guidance	Applicants from Ireland must consult the HRB Guidance and FAQs for this call, for important eligibility information: HRB Funding Schemes Irish Partner(s) are not eligible for HRB funding for: • Proposals involving basic biomedical research • Proposals seeking to evaluate a pilot or feasibility study Proposals from Irish partners that include Human Embryonic Stem Cell Research will be deemed ineligible.

CHIEF SCIENTIST OFFICE, MINISTRY OF HEALTH (CSO-MOH), ISRAEL

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

Country	Israel
Funding organization	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 300.000 Euros
Overheads	10% of the entire project
Anticipated number of fundable research partners	Up to 2
Maximum funding per grant awarded to a partner	Up to 140,000 Euros (Additional EUR 20,000 for coordination of a consortium)
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 of the pre-proposal to EJP RD, Israeli researchers need to submit to CSO-MOH an ILabstract approved by their research authority including budget distribution**. The IL abstract will contain the project title, acronym and partners and will **elaborate the part of the Israeli group in the project**. IL abstract is not the abstract of the entire project. No submission of IL abstract can result in declaration of the consortium as ineligible. Researchers cannot apply for more than one grant from any ERA-Net funded by CSO-MOH or submit more than one proposal to any programme.
Further guidance	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

ITALIAN MINISTRY OF HEALTH (MoH-IT), ITALY

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

Country	Italy
Funding organisation	Italian Ministry of Health www.salute.gov.it
Management organisation	Italian Ministry of Health General Directorate for Innovation & Research in Health
National contact person	Italian Ministry of Health Gaetano Guglielmi g.guglielmi@sanita.it Chiara Ciccarelli +39 06 5994 3919 c.ciccarelli@sanita.it Research.eu.dgric@sanita.it Anna Ceccarelli +39 06 5994 3835 a.ceccarelli-esterno@sanita.it
Funding commitment	1.5 M€
Overheads	Overhead (maximum 10% of the requested fund).
Additional documents required	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 (sent to all IRCCSs) through the IRCCS Scientific Directorate or ISS Directorate of Human and Economic Resources using the 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. The pre-eligibility form can be downloaded here:

	http://www.salute.gov.it/imgs/C_17_pagineAree_4441_listaFile_itemName_0_file.pdf
Maximum funding per grant awarded to a partner	Max. 250.000 EUR per consortium i(i.e., if two IRCCSs participate in a consortium, the sum of funding requested by both groups must not exceed 250.000 EUR)
Eligibility of project duration	Maximum 3 years
Eligibility of a partner as a beneficiary institution	Only Scientific Institutes for Research, Hospitalisation and Healthcare (IRCCS) are eligible. No academic and industrial partners are eligible.
Eligibility of costs, types and their caps	Only the costs generated throughout the duration of the project can be eligible. • Personnel (only ad hoc contracts/consultants/fellowships, max 50% of the requested fund). • Travel costs and subsistence allowances (max 10% of the requested fund) only if associated with training o activities linked to the project. • Equipment (rent/leasing only, no limits), consumables (no limits), dissemination of results (publications, o meetings/workshops etc.- max 1% of the requested fund). • Data handling and analysis (no limits). • 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.
Conditions for PAO 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 2022 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 information	The pre-eligibility form can be downloaded here: http://www.salute.gov.it/imgs/C_17_pagineAree_4441_listaFile_itemName_0_file.pdf

REGIONAL FOUNDATION FOR BIOMEDICAL RESEARCH (FRRB), ITALY, (LOMBARDY)

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

Country	Italy
Funding organization	Fondazione Regionale per la Ricerca Biomedica - Regional Foundation for Biomedical Research (FRRB)
National contact person	Paola Bello, Marcello De Amico Via Taramelli 12, 20124 – Milano Tel: +39 02 67650174 bandi@frrb.it
Funding commitment	€ 1.500.000,00
Overheads	Up to 20% flat rate calculated on direct costs – Subcontracting costs excluded.
Anticipated number of fundable research partners	3-4
Maximum funding per grant awarded to a partner	Maximum € 500,000 **per project. MAXIMUM TWO PARTNERS FROM LOMBARDY PER PROJECT.** (If there are two Lombardy partners in the same consortium, the amount of 500,000 will be shared)
Eligibility of a partner as a beneficiary institution	**Eligible applicants:** •Public or Private Italian IRCCS (Scientific Institutes for Health Research, Hospitalization and Health Care) •Public Health Care Providers (ASST) •Universities (only in in partnership with one IRCCS, public or private, or ASST located in Lombardy and requesting funding to FRRB) •Research Institutes (only in in partnership with one IRCCS, public or private, or ASST located in Lombardy and requesting funding to FRRB) All applicants must be located in Lombardy and their activities should take place in Lombardy. Enterprises and for-profit Organisation are **NOT** eligible. **A Principal Investigator (PI) cannot simultaneously hold more than one FRRB active grant.** PIs who are currently FRRB grant holders cannot apply to the EJP RD JTC 2022 unless their project is closed before the deadline for EJP RD JTC 2022 pre-proposals. A project is considered closed when the final financial and scientific reports have been sent to FRRB. This rule applies only to PIs (grant holders), not to their team members.

Eligibility of costs, types and their caps	Direct costs: •Personnel (for **public** IRCCS and ASST, **ONLY** staff recruited specifically on the project) •Consumables, animals purchase, maintenance and breeding. •Equipment (on hire or eligible amortization rate). •Travel: max 10% of the total direct costs (*overheads and subcontracting costs excluded*) •Publications (only open access): max 5% of the total direct costs (overheads and subcontracting costs excluded). •Overheads: 20% flat rate calculated on direct costs (Subcontracting costs excluded from this calculation). •Subcontracting: max 20% of the total direct costs (overheads costs excluded) •Other direct costs: please include here other costs, including those related to patient involvement (insurance, reimbursement, etc.). FRRB will require the submission of a financial audit certificate together with the final financial report. This cost, to be included under the "Subcontracting" category will be eligible up to a maximum of € 8.000. Only costs generated over the lifetime of the project will be considered eligible.
Conditions for PAO funding	PAO are not eligible for FRRB funding
Submission of the proposal at the regional level	It is not necessary to send the proposal to FRRB. However, FRRB requires a **Pre-eligibility form**. According to internal procedures, Regional Foundation for Biomedical Research (FRRB) will carry out an **eligibility check** to potential applicants prior to the submission of the pre-proposals. The eligibility check will be based on the verification of a dedicated form ("***Pre-eligibility form***"), also available on the FRRB institutional website, to be returned, by email, to FRRB (bandi@frrb.it), duly completed and signed by the Principal Investigator at least 10 working days before the pre-proposal submission deadline. FRRB will provide feedback on the "*Pre-eligibility form*", **ONLY** in case of major non-eligibility issues. Principal Investigators (PIs) who submit a proposal without sending the "*Pre-eligibility form*" to FRRB beforehand will be automatically excluded. In addition, FRRB provides an excel sheet to help applicants abide by FRRB funding rules. This form is meant to support the PIs in the elaboration of the proposal budget, but it does not need to be sent to FRRB. Information and instructions on how to fill the Pre-Eligibility check form will be published on the dedicated webpage (https://www.frrb.it/it/ejp-jtc-2022)

	Following the award, Lombardy beneficiaries will be requested to submit annual scientific and financial reports.
Further guidance	Administrative and financial guidelines will be provided by FRRB in due time to the contact persons of the funded organisations.

TUSCANY REGION (RT/TuscReg), TUSCANY (ITALY)

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

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 Health Research and investments, Directorate for Health, welfare 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 : o dissemination of results (publications, organization of meetings/workshops etc.- up to 5% of the requested fund); o data handling and analysis (no limit) o patients costs - subcontracting (up to 20%of the direct costs of the projects) - *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 and by the legal representative of the beneficiary**The form should be sent to Tuscany Region (ejprare@regione.toscana.it), at least, 10 working days before the pre-proposal submission deadline.**
Submission of other information at the regional level	No
Submission of financial and scientific reports at the regional level	Yes/Submission of intermediate/final scientific and financial reports at the regional level could be required according to regional agreement
Further guidance	Financial guidelines will be published in due time on Tuscany Region's website.

RESEARCH COUNCIL OF LITHUANIA (LMT), LITHUANIA

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

Country	Lithuania
Funding organization	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	0.15M€
Overheads	Up to 30 % from those direct costs - personnel, subcontracting, contractual research, consultancy.
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	100-150K€ (up to 100K€ for consortium partner or up to 150K€ for coordinator)
Eligibility of a partner as a beneficiary institution	Eligible for funding institutions are Lithuanian research and higher education institutions included in the Register of Education and Research institutions and public healthcare institutions. Beneficiary institution manage the state budget funds allocated to the project following the rules stated in the legal acts, as well as representing the project partners (if applicable 'project partner' means public or private legal entity that, together with the eligible institution, created the conditions for project implementation).
Eligibility of costs, types and their caps	Only costs generated during the lifetime of the project, related to project are eligible: staff, travel, consumables, subcontracts, contractual research, consultancy, equipment and instruments, dissemination of results, data handling and analysis, overheads (up to 30 % from the listed direct costs - staff, subcontracts, contractual research, consultancy).
Conditions for PAO funding	PAO can be a subcontractor or a 'project partner' of the eligible beneficiary institution (see section Eligibility of a partner as a beneficiary institution)
Submission of the proposal at the national level	No

Further guidance	Further information: https://www.lmt.lt/lt/mokslo-finansavimas/era-net-ir-kitos-koordinavimo-veiklos/europos-jungtine-programa-retos-ligos/3033 The proposals are submitted by the researcher(s) together with the eligible beneficiary institution. The beneficiary institution employs the principal investigator to work in the project and his workload must be at least 20 hours multiplied by the number of months to execute the project. Hourly rates approved by the Chairman of the Lithuanian Research Council must be applied for the personnel costs. All other general rules for competitive funding of Research Council of Lithuania apply: https://www.e-tar.lt/portal/lt/legalAct/0a8bead0577611e9975f9c35aedfe438/asr

NATIONAL RESEARCH FUND (FNR), LUXEMBURG

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

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/

NATIONAL CENTRE FOR RESEARCH AND DEVELOPMENT (NCBR), POLAND

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

Country	Poland
Funding organization	National Centre for Research and Development (NCBR)
National contact person	Dr Marcin Chmielewski Department for International Cooperation, ul. Nowogrodzka 47a, 00-695 Warszawa, Poland Tel: (+48) 22 39 07 109, (+48) 571 226 666 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 partners 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 organization. • Group of entities (within the meaning of art. 37 section 1, point 1a of The Act of 30 April 2010 on the National Centre for Research and Development, published in Journal of Laws item 1861, 2020;). • Organization 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).

<table>
<tr><td>Eligibility of costs, types and their caps</td><td>
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.
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 expert panel.
4. additional overheads incurred indirectly as a result of the research project; those 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 organizations. 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 19 August 2020 on criteria and rules on granting state aid by the National Centre for Research and Development, published in Journal of Laws item 1456, 2020.
<table>
<tr><th></th><th>Large Enterprises</th><th>Medium Enterprises</th><th>Small Enterprises</th><th>Universities and research organizations</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>
</table>

Submission of the proposal at the national level	Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established.
Further guidance	Please refer to full call documentation.

SLOVAK ACADEMY OF SCIENCES (SAS), SLOVAKIA

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

Country	Slovakia
Funding organization	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 the SAS (up to 100%).** The main applicant must have an employment contract with the SAS institute/centre on behalf of which the application is being submitted. If his/her contract is on a part-time basis, it must be for more than 50% of standard working time. All members of the applicant's team except doctoral students must, too, have employment contracts 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 who must 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. 136 (of 14 October 2021), of which 45,000 EUR is an in-kind contribution (spoluúčasť) of the respective SAS institute or centre in the form of permanent salaries. 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).

	Costs other than the in-kind contribution (Personnel costs, Consumables, Travel costs, Equipment, Other direct costs, Overheads) up to 75,000 EUR must comply with specific rules and limits outlined in the financial rules for awarding SAS grants for international research projects available at: https://www.sav.sk/?lang=sk&doc=services-news&source_no=25&news_no=7569 **Applicants are strongly encouraged to read the said document carefully and to contact the national contact point before submission in order to ensure compliance.**
Conditions for PAO funding	**The SAS does not fund PAOs/patient representatives.**
Submission of the proposal at the national level	Submission of an application at the national level will be required once the international evaluation and the ranking list have been performed and endorsed by the Call Steering Committee. Only the Slovak partners of the projects recommended for funding will be invited to submit the national-level application. The final decision on funding of the Slovak partners must be approved 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

INSTITUTE OF HEALTH CARLOS III (ISCIII), SPAIN

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

Funding Organisation	National Institute of Health Carlos III Instituto de Salud 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	**Ignacio Baanante** Email : ibaanante@isciii.es Tel : (+34) 9182 22576 **Maria Druet** Email: mduet@isciii.es Tel: (+34) 91822 2530
Initial funding pre-commitment	*2 M€* *8-12 groups tentatively envisaged to be funded.*
Maximum funding per awarded Spanish project partner	**Maximum funding from ISCIII per awarded Spanish project partner** r • 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)

Additional eligibility criteria	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**. 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. • **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.** • **Institutions belonging to the INB/ELIXIR-ES** (The Spanish Institute of Bioinformatics) as long as the participants are those from the Institute of Bioinformatics**.** **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. IPs 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.

	VII. A given PI can apply only once to this call.
Eligibility of PI and team members	• Principal Investigators (PI) can only participate in one project proposal per call. • Principal Investigators (PIs) belonging to any IIS could apply from the IIS or from any of the institutions belonging to the IIS •The Principal Investigator (PI) and all members of the research group must belong to the eligible institution or be affiliated to CIBER or an IIS. **Excluded** personnel as Principal Investigator (PI): •Those undergoing a postgraduate training in Health Specialization (MIR, EIR, FIR, QIR, BIR, PIR, RFIR) •Those undergoing research training (e.g. PhD students, or "Río Hortega" contracts). •Researchers contracted by a RETIC/RICOR. • 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), with a maximum of 36 PM in total for the personnel contracts altogether. • Current costs, small scientific equipment, disposable materials, travelling expenses and other costs as included in AES 2022 that can be justified as necessary to carry out the proposed activities. • Overheads, according to AES 2022. • 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.
Conditions for PAO funding	The ISCIII does not fund PAOs/patient representatives.
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 2022 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.

SWEDISH RESEARCH COUNCIL (SRC), SWEDEN

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

Country	Sweden
Funding organization	Swedish research council, SRC www.vr.se
National contact person	Louise Rügheimer E-mail: Louise.rugheimer@vr.se Phone: +46(0)8 122 13 618
Funding commitment	20 MSEK, approximately 1 820 000€
Overheads	The grant amount includes indirect costs.
Anticipated number of fundable research partners	**2-4**
Maximum funding per grant awarded to a partner	For Swedish participation in a consortium, the maximum amount that may be applied for is 4 500 000 SEK (approximately 450 000 EUR) for a consortium with 1 Swedish partner, or 6 000 000 SEK (approx. 600 000 EUR) if the consortia contain two Swedish partners. Use the exchange rate of 1 EURO=10,13 SEK to calculate actual grant amounts for the application
Eligibility of a partner as a beneficiary institution	Not applicable
Eligibility of costs, types and their caps	The project grant may be used to fund all types of project-related costs, such as salaries (including your own salary, however no more than corresponding to the person's activity level in the project), running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment), premises and depreciation costs. Grants may not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary during teaching or other departmental duties.
Conditions for PAO funding	

Submission of the proposal at the national level	All Swedish project leaders participating in the call for support from the Swedish Research Council shall also submit a parallel application using the Swedish Research Council's application system Prisma. The application form in Prisma can be reached from the call text at the SRC website: Swedish and English **Parallel application is a mandatory eligibility criterion. Failure to submit the parallel application to the Swedish Research Council before the deadline of the Prisma call will result in the Swedish partner being declared ineligible.** All Swedish applicants must communicate with the EJP RD national contact person regarding their intention to participate in the call, before submission of the consortium application.
Further guidance	See national call texts for all national requirements: Swedish and English

VINNOVA, SWEDEN

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

Country	**Sweden**
Funding organization	**Vinnova www.vinnova.se**
National contact person,	Gunnar Sandberg, gunnar.sandberg@vinnova.se +46 8 4546445
Funding commitment	9MSEK, 900 000 Euro.
Overheads	
Anticipated number of fundable research partners	**3-5**
Maximum funding per grant awarded to a partner	The maximum amount of funding for Swedish participation is 3 million SEK for 1 Swedish partner and 4.5 million SEK for 2 Swedish partners. **The consortia need to include at least one Swedish partner from industry when applying for funding from Vinnova.**
Eligibility of a partner as a beneficiary institution	**The Swedish participation applying for funding from Vinnova should have at least one partner from industry.** Universities, public research institutes, healthcare providers and industry. For more information see Vinnova.se
Eligibility of costs, types and their caps	Universities, public research institutes and public healthcare providers may receive funding of up to 100 % of their eligible costs, provided that the project is part of their non-economic activities. Large companies can apply for 20 % of their eligible costs. Small and medium sized companies can apply for 70 % of their eligible costs The eligible cost are defined in: Terms and conditions for Vinnova funding | Vinnova
Conditions for PAO funding	Approved administrating organisations see Vinnova.se

Submission of the proposal at the national level	General condition for grant application (Find the right funding | Vinnova Swedish applicants must also apply via the Vinnova web portal (Find the right funding | Vinnova), where the Swedish project partner/s should add the requested information and upload the EJP-RD JTC 2022 project plan. Please follow the instructions on the national call page. If you have any questions don't hesitate to email or call one of the Vinnova contact persons.
Further guidance	General condition for grant application (Find the right funding | Vinnova

SWISS NATIONAL SCIENCE FOUNDATION (SNSF), SWITZERLAND

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

Country	Switzerland
Funding organisation	Swiss National Science Foundation (SNSF)
National contact person	Dr Tobias Braun Division Biology and Medicine Wildhainweg 3, P.O. Box, CH-3001 Bern Phone: +41 31 308 21 67 tobias.braun@snf.ch
Funding commitment	1 Mio Swiss Francs (equivalent to approx. 0.9 Mio €)
Overheads	Overhead costs may not be included in the Swiss project budget. Overhead contributions, calculated on the basis of the total research funding given to a particular institution through all SNSF funding instruments, are paid directly to the applicant's institution on a yearly basis.
Anticipated number of fundable research partners	3-4, each Swiss applicant may be partner in only one EJP RD JTC 2022 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 Biology and Medicine must contact the national contact point to confirm their eligibility as an applicant prior to submitting a proposal to the EJP RD JTC 2022. Foreign members of the international consortia applying for funding through the EJP RD JTC 2022 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 SNSF 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. 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.

NETHERLANDS ORGANIZATION FOR HEALTH RESEARCH AND DEVELOPMENT (ZonMw), THE NETHERLANDS

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

Country	The Netherlands
Funding organization	ZonMw, The Netherlands organisation for health research and development, PO Box 93245, 2509 AE The Netherlands, https://www.zonmw.nl/nl/
National contact person	Sonja van Weely, PhD Kirsten Wilkens, MSc Email: ERareJTC2018@zonmw.nl (preferred) Tel. +31 70 349 5467/5220 Tel. +31 70 515 0390
Funding commitment	1.6 million euro
Overheads	Overheads are not eligible costs for ZonMw
Anticipated number of fundable research projects	6-7 projects
Maximum funding per grant awarded to research partner or research project	Up to 250,000.- euro for a Dutch research project partner or coordinator for a 3-year project proposal. In case a project consists of two Dutch research partners (only possible if one partner classifies as Early Career Researcher), the total amount of the ZonMw funding for the project is still maximized to 250,000.- euro.

Eligibility of a partner as a beneficiary research institution	**Category A**. Dutch research organisations as defined in EU state aid legislation.[2] **Category B**. Other Dutch rare diseases centers of expertise that are recognised by the Dutch Ministry of Health. • Please read the eligibility of costs for categories A and B very carefully below. • Max. 1 application as coordinator is allowed. • A specific Dutch researcher is allowed to take part in max. 2 applications. • 1 Dutch researcher per application is allowed; a second Dutch researcher in an application is only allowed in case it concerns an Early Career Researcher (see 4.1 in the Guidelines for Applicants). • The track record of the principle investigator (PI) is part of the assessment. • Cofinancing (in cash or in kind) is encouraged.
Eligibility of principal investigator or other research team member	The principle investigator (PI) should have (or get upon granting of the project) an employment contract at the eligible institution for at least the duration of the project; the PI does not need to have a permanent position at the institute. A signed letter from the department head or other responsible official of the institute has to be submitted to ZonMw at the deadline of application of the full proposal in which information on the employment contract of the PI is indicated. Furthermore, in this letter the department head or other responsible official should also guarantee that the applicant will have the time and facilities to perform the research properly and according to plan. The PI should show strong commitment to (the results of) the project.
Eligibility of costs, types and their caps	• Aid for the concerning activities to the organisations in **category A** does not result in state aid according to the Framework for State Aid for Research and Development and Innovation. Organisations in category A must meet the criteria of the research and knowledge-dissemination organisation (hereinafter referred to as "research organisation") in accordance with the Framework for State Aid for Research and Development and Innovation (2014/C 198/03). • Aid to organisations in **category B** is state aid and will be granted under the General Block Exemption Regulation: EC REGULATION No 651/2014, section 25 ('GBER'). All relevant conditions of the GBER apply, including but not limited to: • section 1.4 (no outstanding recovery order following a previous Commission decision, no aid to undertakings in difficulty)

[2] Framework for state aid for research and development and innovation (2014/C 198/01), Article 15(ee).

- section 1.5 (non violation of Union law by means of conditions or financing method),
- section 8 (cumulation)
- consideration 18 (the work on the aided project or activity starts only after the beneficiary has submitted a written application for the aid)
- The aid intensity depends on the Technology Readiness Level (TRL) of the activities of the Dutch partner, which should be clearly specified in a separate document to be sent to ZonMw 1 week before the deadline of application of the full proposal as well as the other mandatory declarations:
  - Declaration order for recovery of state aid (in Dutch).
  - Declaration company not in difficulty.
  - Declaration of accumulation of state aid.

Eligible costs of research projects executed by organisations in **category A** are (see the ZonMw grant terms and conditions from 1st July 2013):

- personnel. Scientific personnel has to be appointed at a scientific institution in The Netherlands.
- consumables, animals,
- equipment,
- travels,
- costs for dissemination of results (implementation)
- In most cases (e.g., in case of university/university medical centers) overhead is not allowed and the salary scales of VSNU (universities) or NFU (University Medical Centres) have to be used.

Please use the ZonMw budget formats as basis for the budget calculations.

Eligible costs of research and development projects executed by organisations in **category B** shall be allocated to a specific category of research and development and may be the following:
(a) personnel costs: researchers, technicians and other supporting staff to the extent employed on the project;
(b) costs of instruments and equipment to the extent and for the period used for the project. Where such instruments and equipment are not used for their full life for the project, only the depreciation costs

	corresponding to the life of the project, as calculated on the basis of generally accepted accounting principles are considered as eligible. (c) other operating expenses, including costs of materials, supplies and similar products, incurred directly as a result of the project. **National Funding rates** Funding quota of Dutch participants can be up to 100% for organisations in **category A**. The funding quota for organisations in **category B** will be decided on a case-by-case basis depending on the size of the company, type of research/development in accordance with GBER, section 25.5 and 25.6. Fundamental/ Industrial/Experimental development will be funded. Other type of activities (e.g. coordination, management) is not eligible for funding as separate research tasks in the project schedule.
Conditions for PAO funding	Patient advocacy organisations (PAO) that are located in the Netherlands can be eligible and may apply for maximum of 20,000.- euro subsidy for joining a project of three years under the de minimis aid (EC Regulation 1407/2013). All relevant conditions of this Regulation apply, including but not limited to: Art. 3.2: The total amount of de minimis aid granted in the Netherlands to a single PAO shall not exceed 200,000.- euro over any period of three fiscal years. The PAO part of the grant application will be rejected if: 1. one of the situations referred to in Article 1 of the de minimis regulation occurs which would preclude application of the de minimis regulation; or 2. the de minimis ceiling would be exceeded by allocation of the requested grant funding; or 3. your application does not meet the conditions of the de minimis regulation in some other way. • If several patient organisations located in the Netherlands are involved in the project, the maximum of 20,000,- euro has to be divided. The de minimis regulation has to be used for every PAO in a project. • A specific PAO is allowed to take part in max. 2 applications.

- A PAO cannot be coordinator of a project.

Eligibility PAOs
Eligible PAOs are defined as not-for-profit organisations located in the Netherlands, 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.

PAOs has to fulfil the following criteria and this will be checked at the eligibility phase of the preproposal. Please send the following information to ERareJTC2018@zonmw.nl before **February 16, 2022**:
(1) to prove that you follow these criteria,
(2) information on the proposed activities of the PAO mentioned in the preproposal,
(3) include a https://www.zonmw.nl/fileadmin/zonmw/documenten/Subsidieoproepen/Staatssteun/Verklaring_de-minimissteun.pdf (in Dutch) in which you list the de minimis aid that you have received in the two previous tax years and in the current tax year.

Legitimacy:

- 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 The Netherlands

	• **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 the Netherlands or throughout the EU/EEA.
	• **Structure:**
	  • The organisation should have governing bodies which includes a majority of rare disease patients or family members of rare disease patients.
	  • Includes in its governing structure a designated representative legally authorised to sign a contract with ZonMw
	• **Accountability:**
	  • 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.
	• **Transparency:**
	  • The organisation shall be financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies) and disclose to ZonMw 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 ZonMw on an annual basis.
	  • The organisation shall publish on its website the registered statutes, sources of funding, and information on their activities.
	• **Communication**
	To facilitate communication, one contact person shall be identified for each PAO.

	Eligible costs are (a) personnel for the specific research project; (b) travels; (c) dissemination of results (implementation). Non-eligible costs are office and IT equipment (workstation, mobile phone, tablets, etc.) and overhead.
Submission of the proposal at the national level	• Submission of the full proposal to ZonMw will be carried out once the international evaluation and the ranking list have been performed and endorsed by the Call Steering Committee and European Commission. ZonMw will send a letter to invite the selected researcher or PAO to submit the granted full proposal. • The Dutch consortium partners in honoured consortia have to comply with ZonMw procedures for granted projects (e.g. uploading via ProjectNet or AIMS - including the ZonMw budget format, and reporting annually). Scientific personnel has to be appointed at a scientific institution in The Netherlands. Granted consortia with a Dutch partner have to draw up and sign a Consortium Agreement in which also the intellectual property rights are incorporated. • A final draft version of the Consortium agreement (approved by all parties but not yet signed) will be required in order to assess conformity with applicable European state aid law, IP conditions and the General Terms and Conditions Governing Grants of ZonMw as of July 2013. If the Consortium agreement is rejected, the funding by ZonMw cannot be granted. For more details and conditions: https://www.zonmw.nl/en/research-and-results/co-financing/grants-and-collaborationscontributions-from-third-parties/ • Before the start of the granted project the Dutch researcher needs to compose a data management plan and complete key items to explain how to make the data collection from the Dutch part of the research project FAIR. If a co-financer is not included in the consortium agreement, a signed Letter of Commitment needs to be submitted to ZonMw with the application. For more details (in Dutch): ZonMw financiele aspecten bij samenwerking.

Further guidance	• Collaboration with patient organisations is recommended; see also 5.5 in the Call text. • The ZonMw grant terms and conditions from 1st July 2013) apply for Dutch consortium partners.

THE SCIENTIFIC AND TECHNOLOGICAL RESEACH COUNCIL OF TURKEY (TUBITAK), TURKEY

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

Country	Turkey
Funding organization	The Scientific and Technological Research Council of Turkey, https://tubitak.gov.tr/
National contact erson	Dr. Jale Şahin Phone : +90 312 298 1796 E-mail : jale.sahin@tubitak.gov.tr , uidb@tubitak.gov.tr
Funding commitment	0,5 M Euro
Overheads	Tbc*
Anticipated number of fundable research partners	tbc
Maximum funding per grant awarded to a partner	tbc
Eligibility of project duration	tbc
Eligibility of a partner as a beneficiary institution	tbc
Eligibility of costs, types and their caps	tbc

Conditions for PAO funding	tbc
Submission of the proposal at the national level	Yes
Submission of other information at the national level	Yes, for proposals selected for funding.
Submission of financial and scientific reports at the national level	Yes, according to national regulations.
Further guidance	tbc

*tbc – to be confirmed

EUROPEAN JOINT PROGRAMME RARE DISEASES

Call for Proposals 2022

"Development of new analytic tools and pathways to accelerate diagnosis and facilitate diagnostic monitoring of rare diseases"

Submission deadline for pre-proposals:
February 16th, 2022; 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 change 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[3].**
- ***Text marked in Italics and highlighted in yellow can be deleted for proposal submission.***

[3] 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 4 eligible research partners from at least 4 different countries participating in the call.
☐ The project proposal does not include more than two eligible research partners from the same partner country participating in the call (check out 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. Including the coordinator. 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 asking for funding.

- **Eligibility of consortium partners:**

☐ I have checked that each research 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.
I have used the matchmaking tool to create the consortium and/or to add a partner
☐ (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 authorize the use of my personal data to be contacted by the EJP RD Mentoring service program.

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

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

1.a. Project title:

1.b. Project acronym:

The application is:

☐ a new proposal
☐ a resubmission from a previous E-Rare / EJP RD call JTC 2018, JTC 2019, JTC 2020
☐ a proposal asking for an extension of a previously funded E-Rare. EJP RD project

If so, please state the acronym of the project:

2. Consortium coordinator:

Last Name, First Name	
ID (ORDIC or otherwise)	
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)	ID (ORDIC or otherwise)	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 asking funding from their national/regional funding agency

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): PAOS not asking for funding may be collaborators

No.	Zip code, City, Country	Research Partner (principal investigator)	Institution, Department, full affiliations	Email address	Early Career Researcher (yes/no)	Type of entity Academia, Clinical or Public	Type of entity (public / private-for-

			(address, phone + fax)			Health, SME or Industry	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 (medical domain, disease, etc.), approach (es), tools (animal models, OMICS, etc.) 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 5.2 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).

- Description of the working plan including: **Background, present state of the art in the 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**
  - Main and secondary hypothesis. Please highlight the main hypothesis (es) for the proposed research plan and sample size calculation (if applicable) in separate boxes :

Main hypothesis(es) for the proposed research plan
Sample size calculation (if applicable)

Name and affiliation of the responsible biostatistics expert (if applicable)

- **Soundness and pertinence**
  - Innovative aspects, originality, novelty
  - Public health interest
- **Workplan & methodology** *(highlighting feasibility)*
  - Research strategy
  - 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 if the proposal includes a natural history cohort/registry study

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, benefit of transnational collaboration
- **PAOs engagement/involvement**
  - role of PAOs and patient representatives within the consortium (active and meaningful participation)

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 4).

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										