

Call for Proposals 2021

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

Guidelines for Applicants

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

For further information, please visit us on the web:

http://www.eiprarediseases.org/

Or contact:

Joint Call Secretariat (FFRD, France)

JTC2021@ejprarediseases.org

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1. Application Process

1.1 Registration

Research consortia who intend to submit a transnational project proposal should **register as soon as possible** via the electronic proposal system: https://ptoutline.eu/app/ejprd21. Please fill in the data sheet in the system. The same data sheet can be used for the submission of pre-proposals and full proposals (if invited).

1.2 Pre- and Full Proposals

There will be a **two-stage submission procedure for joint applications**: a pre- and full proposal stage. In both cases, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal and must be submitted by the coordinator only to the JCS via the electronic submission system: https://ptoutline.eu/app/ejprd21. Proposals must be prepared using the templates provided on the EJP RD web page (www.ejprarediseases.org). Proposals not conforming to template instructions (including length and format) will be rejected.

You will not need to submit a paper version of your proposal; however, both the **electronic pre-proposals and full proposals need to be signed** (electronic signature or a scanned copy of the signature page will be accepted).

Joint pre-proposals (in English) must be received by the JCS in an electronic version no later than February 16th, 2021 at 2:00 p.m. Central European Time (CET).

Full proposals (in English) must be received by the JCS in an electronic version no later than June 15th, 2021 at 2:00 p.m. Central European Summer Time (CEST).

1.3 Rebuttal stage

Please note that project coordinators will be provided with the opportunity to study the assessments of external reviewers and comment on their evaluations of full proposals (for details see section 7.3 in the "Call text" document).

2. Advice for preparing your proposal

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

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

- Make sure that your proposal falls into the scope of the call (Section 4 of the call text)
- Make sure that your proposal fulfils the eligibility criteria of the call (Section 5 of the call text)
- Make sure that all consortium members have understood the national eligibility criteria and requirements (Annex 1) and that they fulfil these criteria



- Make sure that all consortium members contacted their national representative and confirmed eligibility with their respective funding 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 SSH research field

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

Objectives and hypothesis

- SSH research question
- Main and secondary hypothesis

Soundness and pertinence

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

Workplan & methodology (highlighting feasibility)

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

Impact

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



*Valorization

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

*Ethical and legal issues, data management

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

See H2020 Guidance "How to complete your ethics self-assessment" that can be found here:

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020 hi ethics-self-assess en.pdf

- GDPR management: plan description, name and affiliation of the Data Protection Officer (DPO).
- Data management strategy: plan description to make research data findable, accessible, interoperable and re-usable (FAIR).

Work packages, timeline and budget

- Description of the aims/work packages: synopsis and timeframe, including project coordination and management as well as *innovation management activities
- *Scientific justification of requested budget: rational distribution of resources in relation to project's activities, partners responsibilities and time frame; please also specify co-funding from other sources necessary for the project if applicable
- Diagram which compiles the work plan, timeline, sequencing of work packages, contribution of the partners to each work package and their interactions (Gantt chart, Pert or similar)



Responsibilities and workloads

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

**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:

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

4. Early Career Researchers (ECRs)

4.1 Definition

ECRs are defined as per the regulations of the European Research Council criteria for starting grants. In short, the researcher must have been awarded their first doctoral degree (PhD) two to seven years prior to the pre-proposal submission deadline. Extensions to this period are allowed (with documentation) in the case of reasonably justified career breaks: absence for maternal, paternal or long-term sick leave, and compulsory military service.

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

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



4.2 Eligibility of ECRs

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

Medical doctors with PhD

Medical Studies: indicate dates (start and end) of your studies (year and month)

End of studies: indicate date of your medical certificate

PhD Time: indicate dates (start and end) of your PhD time (year and month)

PhD: indicate date of your PhD certificate

Appointment: indicate dates (start and end) of the appointment that requires doctoral equivalency (e.g. post-doctoral fellowship or professorship appointment), only if applicable

Medical doctors without PhD

Medical Studies: indicate dates (start and end) of your studies (year and month)

End of studies: indicate date of your certificate

Appointment: indicate dates of the appointment that requires doctoral equivalency

(e.g. post-doctoral fellowship or professorship appointment)

Other Early Career Scientists with PhD

Studies: indicate dates (start and end) of your studies (year and month)

End of studies: indicate date of your certificate

PhD Time: indicate dates (start and end) of your PhD time (year and month)

PhD: indicate date of your PhD certificate

Other Early Career Scientists without PhD

Studies: indicate dates (start and end) of your studies (year and month)

End of studies: indicate date of your certificate

Appointment: indicate dates of the appointment that requires doctoral equivalency

(e.g. post-doctoral fellowship or professorship appointment)

Reasons for Extensions, if applicable

Clinical Training: indicate dates (start and end) of clinical training (year and month); Parental leave: Women: number of children (1.5 years are given per child; in case of longer maternal leave, please indicate the exact dates); Men: indicate exact dates of paternal leave (per child)

Career Break: indicate dates (year and month) of other career breaks: long-term sick leave, compulsory military service, carer's leave

5. Financial and Legal Issues

5.1 Funding model and Call governance

The EJP RD JTC 2021 Funding Partners have agreed to launch a joint call using the "virtual common pot" funding mode. This means that national/regional funding will be



made available through national/regional funding organizations according to national/regional funding regulations.

FFRD (France) is acting as Joint Call Secretariat (JCS) to assist the Call Steering Committee (CSC), and the national/regional funding bodies during the implementation of the call.

The JCS will be responsible for the administrative management of the call. It will be the primary point of contact referring to the call procedures between the research consortia, the funding 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 undersubscribed 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 2^{nd} stage). This inclusion will not be considered as a fundamental change between preand full proposal. Inclusion of new research teams is not mandatory. The new teams included should bring an added value and expertise to the projects.

5.2.2 Process

A list of countries eligible for this widening procedure will be published on the EJP RD website after completion of the 1st stage of evaluation and sent to the coordinators that are invited to write a full proposal.

The relevant national funding agencies may produce a list of research teams that could provide additional expertise to projects. For this, the title, pre-proposal abstract, and composition of the consortium will be shared with potentially interested research teams. The JCS will then provide this list to the coordinators of projects invited to the full proposal stage and give them the option of adding them to the existing consortium.

The coordinator/partners of projects invited to the 2nd stage of evaluation can also inquire themselves about suitable partners from among listed countries. The new prospective partner must then contact their national funding agency to confirm their eligibility.

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



5.3 Funding contracts

Each project includes several partners (including a project coordinator) as beneficiaries. Each partner will have a separate funding contract/letter of grant with their respective national/regional funding 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.

5.4 Project start and consortium agreement

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

The project consortium partners must sign a CA for cooperation. For reference see the <u>DESCA 2020 Model Consortium Agreement</u>. It is recommended that the CA be signed by all relevant parties before the official project start date. Please note that national/regional regulations may apply concerning the requirement for a CA (please contact your national/regional contact point or check Annex 1). This consortium agreement must be made available on request to the relevant EJP RD JTC 2021 funding 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 decisionmaking capability and is able to work together in a synergistic manner

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

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



- the liabilities of the research partners towards one another (including the handling of default of contract)
- Evolution of the consortium (renewal or end of the consortium, amendments).

5.5 Ownership of intellectual property rights

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the EJP RD JTC 2021 will be owned by the beneficiaries' 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, in the respect of European law on State aid for research and development

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.

5.6 IRDiRC policies and guidelines

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

5.7 European and International standards

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

- <u>H2020 ethics manual</u> for research projects,
- <u>The Declaration of Helsinki</u> Ethical Principles for Medical Research Involving Human Subjects,
- The new EC Regulation EC 2016/679 (GDPR) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. This Regulation applies in all Member States from May 25, 2018 and thus all EJPRD JTC 2020 projects,
- The EC Directive 2010/63/EU on the protection of animals used for scientific purposes,
- <u>European Research Council Guidelines on Implementation of Open Access to Scientific Publications and Research Data,</u>
- 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.

5.8 Publication of Results



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

Funding recipients must ensure that all outcomes (publications, etc.) of transnational EJP RD projects include a proper acknowledgement of EJP RD and the respective national/regional funding partner 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
- 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 JTC2021, applicants consent to the use, processing and retention of their data for the purposes of:

- processing and evaluating the application where processing shall be lawful
 only if and to the extent that processing is necessary for the performance of a
 task carried out in the public interest or in the exercise of official authority vested
 in the controller;
- administering any subsequent funding award;
- managing the Funding Party's relationship with them;
- analysing and evaluating the call;
- reporting to the European Commission/ Research Executive Agency (REA) on the Co-funded call;
- providing aggregate data to national and European surveys and analyses;
- complying with audits that may be initiated by the Funding Parties and the European Commission (or its agencies).

The members of the EJP RD consortium may share an applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies). In case of data transfers outside the European Union, the members of the EJP RD must respect the General Data Protection Reglementation (the GDPR) and must sign the Standard Contractual Clauses (SCC), elaborated by the European Commission. These SCC have to be signed by the importer(s) and the exporter(s) of data.



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.

Personal Data will be treated as confidential by the partners in accordance with all applicable laws governing the confidentiality and privacy of Personal Data and shall use these Personal Data only in accordance with applicable laws and the applicable consents provided by the data subjects. Each party should indicate a contact point of his Data Protection Officer, who will be in charge of the data subjects and Parties' questions about personal data processing.



ANNEX 1: Country and Region-Specific Guidelines

Country	pplicants contact their EJP RD National/Regional Contact Point in good time before the submission of a proposa
Funding organization	
National contact person	
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	
conditions for 1 Ac forfalling	
Submission of the proposal at	
the national level	
Frontle and an indicate a	
Further guidance	



BELGIUM, FWO

Country	Belgium (Flanders)
Funding Organization	The Research Foundation - Flanders (FWO)
National Contact Person	Toon Monbaliu
	<u>eranet@fwo.be</u>
	+32 (0)2 550 15 70
Funding Commitment	0,35 m. EUR
Overhead	Overhead has to be included – see category 'Eligibility of costs,
	types and their caps'.
Anticipated number of fundable research partners	1
Maximum funding per grant awarded to a partner	350.000 EUR (overhead included)



Eligibility of a partner as a beneficiary institution

Both the FWO Strategic Basic Research (SBO) and junior/senior research project (FO) funding channels are integrated in this call, each with specific regulations. It is, in the light of the projects eligibility, of utmost importance to respect their particular regulations. For example when it comes to the **mandatory valorisation aspect for the SBO projects** (see 'additional conditions for FWO funding' below).

Who can be eligible for FWO funding?

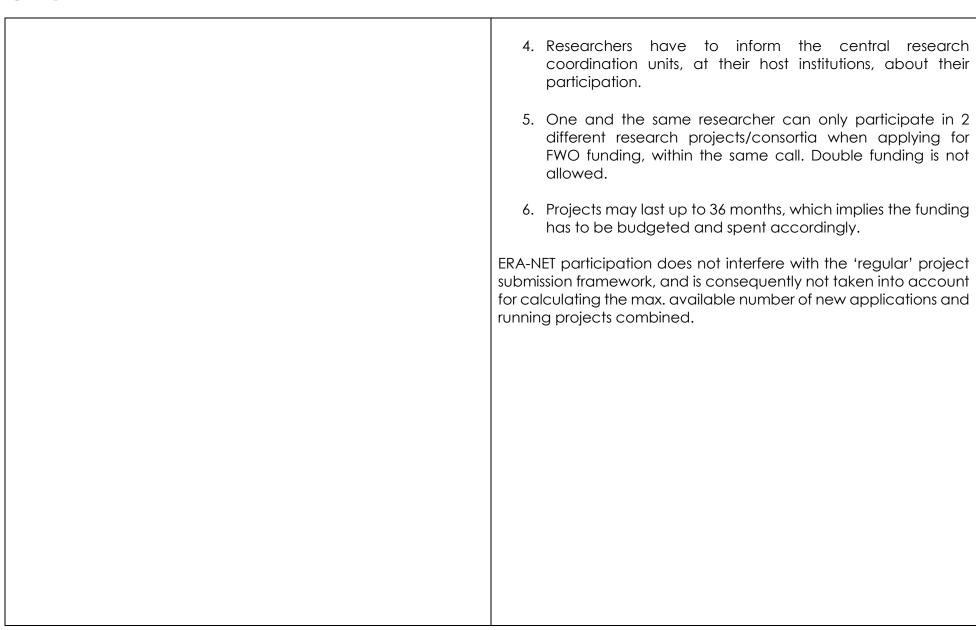
The eligibility of institutions and its researchers can be verified in the relevant regulations:

- For junior/senior research projects, see articles 10-12
- For Strategic Basic Research, see articles 4-8

Additional conditions for FWO funding:

- 1. When the strategic basic research channel (SBO) would be the appropriate source of funding, we ask researchers to provide us with a 'valorisation plan' before the pre-proposal submission deadline. There is no fixed format and one A4 page should suffice. What the FWO wants to know is i) how the valorisation within Flanders and potentially internationally will take place and ii) which Flemish actors are involved in this. This information can be submitted to the general eranet@fwo.be email address.
- 2. SBO projects aiming at the development of a spin-off company are not eligible here.
- 3. Non-eligible partners/parties/actors (e.g. PAO's) for FWO funding can potentially be involved within a consortium through subcontracting, when linked to an eligible institution/researcher. The FWO administration should be contacted in that regard.







Eligibility of costs, types and their caps	The regular FWO cost categories from the (junior/senior) <u>'research</u> <u>project'</u> or <u>SBO project</u> 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 <u>SBO cost model</u> applies. Generally a 17% overhead rate is applicable.
Conditions for PAO funding	PAO funding possible as subcontractor.
Submission of the proposal at the national level	No submission at the national/regional level is required. However, if SBO, a valorisation plan has to be submitted.
Further guidance	It is always strongly advised to contact the FWO before submission, in order to verify the eligibility of the researchers and avoid ineligible projects/research consortia.
	Information available at:
	- Call page for European programmes
	- Junior/senior research projects (FO)
	<u>- SBO research projects</u> (SBO)



CANADA, CIHR-IG

Country	Canada
Funding organisation	Canadian Institutes of Health Research, Institute of Genetics (CIHR-IG)
National contact person	Jennifer Vineham Phone: +1 613 941-0796 Email: jennifer.vineham@cihr-irsc.gc.ca Etienne Richer Email: Etienne.Richer@cihr-irsc.gc.ca
Funding commitment	CAD1,500,000 CAD100,000 per year per project maximum.
Overheads	Not an allowable cost.
Anticipated number of fundable research partners	5 projects
Eligibility of project duration	3 years
Eligibility of a partner as a beneficiary institution	
Eligibility of costs, types and their caps	Eligibility of principal investigator or other research team memberAcademia, Clinical, Public Healthhttps://cihrirsc.gc.ca/e/50805.html#g-3 Investigator (early career) A researcher who, at the time of application, has held a full time, independent research appointment, for a period of 0 to 5 years (60 months). All time spent in research appointments/positions will be taken into consideration when determining eligibility irrespective of time spent in a clinical component or other duties (i.e. administrative, academic, etc.). Should an applicant hold or have held a part-time appointment/position, CIHR will count that time as 50% (e.g., a one-year part-time appointment/position will count for 6 months towards the maximum). Leaves of absence will be considered in the calculation of eligibility (i.e., will not count towards the maximum) and should be



	included in the Employment section under Leaves of Absence in your Common CV. Please note that due to the impact of COVID-19 on early career researchers, all those who held ECR status as of March 1, 2020 – or who secured their first academic appointment after this date – will have their status extended by one year. Eligibility of costs, types and their capshttp://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/FundsUse-UtilisationSubventions_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)
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



FRANCE, ANR

Country	France
Funding organisation	French National Research Agency (Agence Nationale de la Recherche –ANR-) http://www.agence-nationale-recherche.fr
National contact person	Health & Biology Department Agence Nationale de la Recherche –ANR 50 avenue Daumesnil - 75012 Paris, France Florence Guillot Email: EJPRDcall@anr.fr
Funding commitment	2 M€ Funding limits apply per partner for this call: Each partner may be granted up to 300 000 € as a coordinating partner or 250 000 € as a non-coordinating partner. The minimum funding amount per partner is 15 000 €.
Overheads	The ANR heading for "overheads" in the ANR funding breakdown is «frais d'environnement». 8% of the total eligible costs must be applied for if the partner belongs to a public research organisation (or other organisation funded at "marginal" costs), or up to 68% of the total personnel costs and 7% of other costs for partners funded at full economic cost (such as enterprises) (cf "règlement financier")
Anticipated number of fundable research partners	5
Eligibility of project duration	2-3 years
Eligibility of a partner as a beneficiary institution	 Eligible institutions: Public research organisation or related-one! such as EPST, EPIC, universities, university hospitals, (max. rate of support: 100% of marginal costs) Enterprises: large & SMEs (max. rate of support: 45% of total costs for SMEs & 30% for larger companies) Associations/foundationsAdditional eligibility criteria: The coordinator (if from a French institution) must belong to a public research organisation.



	- ANR will not provide double funding to finance projects or part of projects that have been funded through other national and international calls. ANR will cross-check the proposals submitted to ensure they have not been submitted to the ANR through other calls.
Eligibility of costs, types and their caps	Eligible costs include (but are not limited to) the following: personnel costs; equipment, materials, consumables and animal costs; general expenses; 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, especially private beneficiaries.
Conditions for PAO funding	French PAO can be funded as a partner if they perform SSH research activities. Otherwise, French PAO can be funded as sub-contractor of a French partner and if they fulfil the eligibility criteria of the EC. Information for funding associations are provided in § 3.3.3 of the "règlement financier".
Submission of the proposal at the national level	No.
Submission of other information at the national level	No. However, please contact the national contact point for the ANR to confirm eligibility before submitting a proposal.
Submission of financial and scientific reports at the national level	Financial reporting: must be completed according to ANR regulations, and the funding contract that future beneficiaries must sign. Scientific reports: individual scientific reports are not required. However, ANR funded partners should contribute to the project report to be submitted by the coordinator of the project to EJP RD. These reports will be the basis for validation of yearly advancements of the project by ANR.
Further guidance	Règlement financier Please read the modalities document for this call on the ANR website



GERMANY, BMBF/PT-DLR

Country	Germany
Funding organisation	German Federal Ministry for Education and Research (BMBF) <u>www.gesundheitsforschung-bmbf.de</u>
Management organisation	German Aerospace Center, DLR Project Management Agency (DLR-PT) <u>www.pt-dlr.de</u>
National contact person	German Aerospace Center DLR Project Management Agency Health Division Clinical Research, University Medicine, Digital Health Heinrich-Konen-Straße 1 53227 Bonn Germany Dr. Katarzyna Saedler Phone: +49 (0)228 3821-1947 E-mail: Katarzyna.Saedler@dlr.de Dr. Michaela Fersch Phone: +49 (0)228 3821-1268 E-mail: Michaela.Fersch@dlr.de Dr. Ralph Schuster Phone: +49 (228) 3821-1233 E-mail: Ralph.Schuster@dlr.de
Funding commitment	3 Mio€
Overheads	Overheads refer to "Gemeinkosten" (applicable for Helmholtz-centres and Fraunhofer-Society) as well as "Projektpauschale" (applicable for universities and university hospitals). The "Projektpauschale" generally will amount to 20% of the applied total project expenditure. For further information on the "Projektpauschale" please refer to https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=179



	(Pos. 0865) or contact the German national contact point for this EJP RD call.
Anticipated number of	Partners in about 10 projects
fundable research	
partners	
Maximum funding per	Max. 300.000 EUR per consortium including overheads (i.e. if two German partners participate in a consortium, the sum of
grant awarded to a	funding requested by both groups must not exceed 300.000 EUR)
partner	
Eligibility of project	Maximum 3 years
duration	
Eligibility of a partner as	Legal body: university, university hospital, non-university public research institute, industry, patient organization
a beneficiary institution	
Eligibility of costs, types	Personnel, consumables, animals, subcontracts, equipment, travels, documentation, overheads according to national
and their caps	regulations.
Conditions for PAO	Participating German patient organizations can be funded either directly or through subcontracting by a research
funding	partner.
Submission of the	No
proposal at the national	
level	
Submission of other	Yes, for proposal selected for funding
information at the	
national level	
Submission of financial	Yes, according to national regulations.
and scientific reports at	
the national level	
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



ISRAEL, CSO-MOH

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 200.000 Euros
Overheads	10% of the entire project
	Up to 2
fundable research partners	LL
Maximum funding per grant	Up to 100,000 Euros
awarded to a partner	
Eligibility of a partner as a	Position in a university, research center or hospital. Research authority must approve position prior to submission.
beneficiary institution	
Eligibility of costs, types and	Materials and consumables; Travel (up to 10%); No salaries for applicants; No heavy equipment, Institutional overhead -10%
their caps	
Conditions for PAO funding	No funding of PAOs
Submission of the proposal at	Prior to submission, researchers will submit to CSO-MOH an ILabstract approved by their research authority including budget
the national level	distribution. The ILabstract will contain the project title, acronym and partners and will elaborate the part of the Israeli group
	in the project . ILabstract is <u>not</u> the abstract of the entire project. No submission of ILabstract can result in declaration of the
	consortium as ineligible.
Further guidance	CSO-MOH will only fund the following research areas under the current call:
	Economic impact of rare diseases
	Studies addressing the impact/burden of the delay in diagnosis and of the lack of therapeutic intervention



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

If the application involves human or animal experiments, bioethics approvals must be submitted with the application or up to 4 months later.

Please see detailed instructions at www.health.gov.il/research-fund



Lithuania, RCL

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	0.1M€
Overheads	Up to 30 % from the direct costs - personnel, travel, consumables, subcontracting, contractual research, consultancy.
Anticipated num	1
ber of fundable research	
partners	
Maximum funding per gran	100K€
awarded to a partner	
Eligibility of a partner as a	Eligible for funding institutions are Lithuanian research and higher education institution which is included in the Degister of
beneficiary institution	Eligible for funding institutions are Lithuanian research and higher education institution which is included in the Register of
	Education and Research institutions or a state healthcare institution. Eligible institution manages the state budget funds
	allocated to the project, as well as representing the project partners (if applicable 'project partner' means public or private
	legal entity that, together with the eligible institution, created the conditions for project implementers for the implementation
	of the project).
	Only costs generated during the lifetime of the project, related to project can be eligible: personnel, travel, consumables,
their caps	subcontracting, contractual research, consultancy, equipment and instruments, dissemination of results, data handling and
	analysis, overheads.
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
	All eligibility rules and criteria can be found in the https://www.lmt.lt/lt/mokslo-finansavimas/era-net-ir-kitos-koordinavimo-
	veiklos/europos-jungtine-programa-retos-ligos/3033



LUXEMBOURG, FNR

Country / Region	Luxembourg			
Funding organisation	Luxembourg National Research Fund - FNR <u>www.fnr.lu</u>			
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/



Slovakia, SAS

Country	Slovakia
Funding organization	Slovak Academy of Sciences (SAS)
National contact person	Zuzana Cernakova, PhD.
	International Cooperation Dpt., SAS
	Phone: +421257510118
	Email: <u>cernakova@up.upsav.sk</u>
Funding commitment	120,000 €
Overheads	Up to 20% of the direct costs
Anticipated num	1
ber of fundable research	
partners	
Maximum funding per grant	120,000 €
awarded to a partner	
Fligibility of a partner as a	Only were much institutes and for contract the Slevels Academy of Sciences are clinible examinations for fireding by SAS (up
	Only research institutes and/or centres of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up
	to 100%). The main applicant must have, at the time of submission, a contract(s) with one or several of the institutes/centres
	equivalent to <u>at least 1 full-time employment</u> valid for the whole duration of the project. Each member of the applicant's team must also have an employment contract or a fellowship with the same or another SAS institute/centre.
	learn most also have an employment contract of a fellowship with the same of another SAS institute/certife.
	Applicants from other Slavak B&D control (universities and/or other organisations from Slavakia) can join project consertia
	Applicants from other Slovak R&D centres (universities and/or other organisations from Slovakia) can join project consortia only as collaborators that have to secure their own funding.
	only as collaborators that have to secure their own fortaling.
Eligibility of costs types and	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. (TBA), of which 45,000 EUR is the in-kind contribution (spoluúčasť) of the respective
· · · · · · · · · · · · · · · · · · ·	SAS institute or centre. This must be declared in a Letter of Commitment sent to the national contact point by the application
	deadline. A template will be published alongside the Call announcement at www.sav.sk in the International Cooperation
	section (Medzinárodná spolupráca).
	1. Eligible direct costs
	1. Liigible direct cosis



	1.1. Personnel costs
	 Must accurately reflect the work on the project;
	 May be used only to cover the costs (including health and social insurance) related to work agreements performed outside of employment;
	 Up to 15 % of all direct costs excluding the institute's/centre's in-kind contribution or up to 30% of all direct costs excluding the institute's/centre's in-kind contribution, if the Slovak team is the consortium's coordinator.
	1.2. Material costs and expenditures
	 a. Consumables: minor equipment and instruments, small-scale office and laboratory material (no basic equipment of the workplace; essential computer equipment is an exception);
	 b. Costs and expenditures for services directly related to the project: contracts, consultations, publication of project results, conference fees;
	 c. Travel costs and living expenses: limits for travel costs and daily subsistence allowance vary depending on destination country;
	d. Capital expenditures: up to 40% of all direct costs excluding the institute's/centre's in-kind contribution.
	2. Indirect Costs
	– Administration, energy and infrastructure;
	- Up to 20% of all direct costs excluding the institute's/centre's in-kind contribution.
	Further information on eligible costs can be found in the <u>Financial rules for awarding SAS grants for international research</u>
	projects approved by the SAS Presidium on 1 July 2018. Applicants are strongly encouraged to read this document carefully and to contact the national contact point before submission in order to ensure compliance.
Conditions for PAO funding	SAS does not fund PAOs/patient representatives. The Slovak partner can use part of their budget to pay for work, services or materials provided by PAOs/patient representatives in direct relation to the project within the cost categories 1.1 and 1.2b above (proof of supply required).
the national level	Submission of the proposal at the national level will be required in parallel to the international evaluation. The submission will be carried out once the international evaluation and the ranking list have been performed and endorsed by the Call Steering Committee and the Slovak partner has been informed about recommendation for funding by the project consortium's coordinator. S/he will be invited by SAS to submit the proposal to it. The final decision on funding of selected projects is made by the SAS Presidium.



Further guidance	• www.sav.sk
	133 Act of February 19, 2002 on the Slovak Academy of Sciences
	Financial rules for awarding SAS grants for international research projects



Spain , ISCIII

Funding Organisation	National Institute of Health Carlos III (ISCIII)					
	<u>www.isciii.es</u>					
National Funding	Acción Estratégica en Salud (AES 2021)					
Programme	http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/fd-financiacion/convocatorias-ayudas-accion-estrategica-					
	<u>salud.html</u>					
National Contact Point	Maria Druet					
for the 10th call of E-RARE	Email: <u>mdruet@isciii.es</u>					
	Tel: (+34) 9182 22530					
	Clara Martín					
	Email: <u>c.martin@isciii.es</u>					
	Tel: (+34) 91 822 25 67					
Initial funding	500.000€					
pre-commitment	Only 3 years projects					
	3-5 projects tentatively envisaged to be funded					
Maximum funding per	Maximum funding per awarded Spanish project partner					
awarded Spanish project	• Up to 175,000 € per partner (overheads included)					
partner	• Up to 250,000 € per coordinator ((overheads included)					
	Hospitals, primary health care or public health administration of the Spanish National Health System (SNS)					
Eligible institutions	These institutions may manage research via a foundation regulated in accordance to the Spanish Act 50/2002,					
	of December 26th (a copy of the foundation's statutes may be submitted).					
	Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS)					
	Accredited according to the RD 339/2004, of February 27th or RD 279/2016 (These institutions may manage					
	research via a foundation regulated according to the Spanish Act 50/ 2002, of December 26th)					
	https://eng.isciii.es/eng.isciii.es/QuienesSomos/IIS/Paginas/Acreditacion.html					
	CIRED or CIREDNED. To see grouple on small in a to the small result by from all booth we arrow to be also single to CIRED in					
	CIBER or CIBERNED. Team members applying to the call must be from at least two groups belonging to CIBER in the different bases institutions and are of these two should be at least two groups belonging to CIBER in the different bases institutions and are of these two should be at least two groups belonging to CIBER in the different bases institutions and are at least two groups belonging to CIBER in the different bases are at least two groups belonging to CIBER in the different bases.					
	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.					
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	 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 (Institutes 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.
Additional eligibility criteria	PLEASE NOTE: I. Applicants from ISCIII are eligible. Eligibility criteria from AESI 2021 apply. II. Durations of national grants are up to 3 years. III. Same institution cannot participate with more than one partner in the same project proposal. IV. Only one PI per beneficiary institution may be funded within the same proposal. V. Researches with ongoing EJP RD projects in 2022 can not apply to the current call unless the alive project or the new application is as Coordinator VI. There is no other incompatibility with AES 2021.
Eligibility of PI and team members	 Principal Investigators (PI) can only participate in one project proposal in this call. The Principal Investigator (PI) and all members of the research group must belong to the eligible institution or be affiliated to CIBER, CIBERNED or an IIS. Excluded personnel as Principal Investigator (PI): Those undergoing a postgraduate training in Health Specialization (MIR, FIR, QIR, BIR, PIR). Those undergoing research training (e.g. PhD students, or "Río Hortega" contracts). Researchers contracted by a RETIC. Those undergoing postdoctoral training (e.g. "Sara Borrell" or "Juan de la Cierva" contracts).
Eligible costs	 Personnel costs for temporary employment contracts (scholarships are not eligible) according to AES 2021. Current costs, small scientific equipment, disposable materials, travelling expenses and other costs that can be justified as necessary to carry out the proposed activities. Overheads, according to AES 2021.
National phase	 National applications will be required by ISCIII. Spanish Applicants should periodically check in the web page of ISCIII if they are qualified. ISCIII may not send invitations to the mandatory national phase. Double funding of the same concept is not allowed.



	Due to administrative and legal regulations, the National Institute of Health Carlos III declares the end of September 2021 as national deadline for the decision on fundable project consortia which include Spanish partners to be funded by ISCIII. Any concerned applicant in a proposal for which no final decision has been made by the deadline, could be declared not fundable by ISCIII.
Requirements on data and repositories	 Researchers funded by ISCIII must make public the human genomic data, as well as relevant data (phenotype and exposition data) generated inside the funded project and will use open access repositories. Researchers must also make public all the necessary information for the interpretation of these genomic data, including lab protocols, data instruments survey tools. Regarding genomic data it is understood: association of complete genomes (GWAS), matrixes of de polymorphism of a single nucleotide (SNP) and sequence of genome, and transcriptomic, metagenomic, epigenomic and gene expression data. The researchers whose projects are funded by ISCIII are recommended to store their scientific data at the "ELIXIR Core Data Resources" or if non-European repositories or data bases they must be certified by ELIXIR or the US National Center for Biotechnology Information (NCBI). ISCIII may no fund project that requires the construction of new repositories without decommissioning plans or ensured sustainability after the project's end.
Requirements for clinical studies	Spanish groups participating in a proposal performing a clinical study are encouraged to contact and include as members of the team personnel from the Clinical Research Unit (Unidades de Investigación Clínica y Ensayos Clínicos - UICEC) of their institutions. These Units belong to ISCIII's platform that supports Clinical Research and participate in ECRIN-ERIC. Find here the list of UICECs. For additional information please contact: sectec.scren.hcsc@salud.madrid.org or Tel.: (+34) 91 330 38 58
Acknowledgements	Any publication resulting from the granted projects must acknowledge "Award no. XX by ISCIII thorough AES 2021 and within the European Joint Programme Rare Diseases framework" even after the end of the project.



Switzerland, SNSF

Country	Switzerland					
Funding organisation	Swiss National Science Foundation (SNSF)					
National contact person	Swiss National Science Found Division Humanities and Socic	, ,				
	Wildhainweg	3,	P.O.	Box,	CH-3001	Bern
	Phone: +41 31 308 21 87					
	florence.ettlin@snf.ch www.s					
Funding commitment	600'000 Swiss Francs (equivale					
Overheads	Overhead costs may not be					
	total research funding giver	•	institution throug	gh all SNSF tunding	instruments, are paid di	rectly to the
	applicant's institution on a ye	,	5 ID DD 170	0001	2 0 10 5 7 1 11 7 5 1	1.5 (1.)
· · · · · · · · · · · · · · · · · · ·	2-3, each Swiss applicant may	be partner in only	one EJP RD JTC :	2021 proposal (Art./.	3, SNSF Regulations on Proj	ect Funding).
fundable research partners						
Eligibility of a partner as a	n.a.					
beneficiary institution			· · · ·			
	Where not otherwise specified	d, the SNSF Funding	g Regulations, in	particular, the SNSF	Regulations on Project Fur	nding apply:
investigator or other research team member	0 0	ions for the Eurodin	a Dogulations			
ream member	neral Implementation Regulat F Regulations on Project Fund		g Regulations			
	r kegulations on Floject Fund 	irig				
	All Swiss partners in EJP RD pro	niacts must maat th	ne eliqible criteri	ia for applicants in SI	USE Project Funding Swiss	nartners who
	have not previously obtained	•	-			•
	contact point to confirm their					ine nanonai
	Foreign members of the inter		•			declared as
	"project partners" in the sens			•		
	Swiss partner.	0 01 7 11 11 11 2 01 11 1	o o	Trogoramono ama	,	,
	Article 17 of the SNSF Funding	Regulations applie	es, i.e. EJP RD pro	oposals with overlaps	oing funding periods with a	ongoing SNSF
	grants are only allowed if the		•		0.	
	Grants given to Swiss partners				<u>o</u>	
	Please note: The SNSF exclusi					viss Research
	and Innovation Promotion Ac	•		•	·	



	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	According to the regulations on project funding (article 8), the following costs may be covered:
their caps	
	- 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	Swiss partners are required to submit the pre-proposal and the full proposal to www.mySNF.ch together with the submission
the national level	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	Yearly financial reports for the use of SNSF funds and a scientific report at the end of the project.
scientific reports at the	
national level	
_	Consortia including Swiss partners must submit a data management plan (DMP) which complies with the SNSF policy on open research data.