EUROPEAN JOINT PROGRAMME RARE DISEASES

Call for Proposals 2020

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

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

Pre-proposal application form

Please note:

- **Proposals that do not meet national/regional eligibility criteria and requirements will be declined without further review.**
- **Format is Century Gothic font size 11, single-spaced, with margins of 1.27 cm. Incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review.**
- **Once completed, the pre-proposal must be converted in a single PDF document before being uploaded to the submission website.**
- **In case of inconsistency between the information registered in the submission tool and the information included in the PDF of this application form, the information in the application form shall prevail.**
- **The information given in the pre-proposal is binding. Thus, any fundamental changes between the pre- and full proposals, e.g. composition of the consortia, objectives of the project, or the budget must be communicated to the JCS with detailed justification and will only be allowed under exceptional circumstances[1].**
- ***Text marked in Italics and highlighted in yellow can be deleted for proposal submission.***

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

CHECKLIST FOR THE COORDINATOR:

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

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

- **General conditions:**

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

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

- **Ethical standards:**

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

- **The composition of the consortium:**

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

☐ The project proposal does not include more than two eligible research partners from the same partner country participating in the call (check out national limits that apply, in "Guidelines for Applicants").

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

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

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

- **Eligibility of consortium partners:**

☐ I have checked that each partner involved in the project proposal is eligible to receive funding by its funding agency.

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

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

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

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

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

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

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

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

☐ (if applicable) Slovak partners have submitted a Letter of Commitment of the partner institute's personnel contribution (spoluucast) to SAS.

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

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

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

General Data Protection Regulation

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

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

Information and Data protection conditions

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

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

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

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

Declaration

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

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

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

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

1.a. Project title:

1.b. Project acronym:

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

2. Consortium coordinator:

Last Name, First Name	
Institution/Department	
Department	
Position	
Address	
Zip code, City Country	
Phone + Fax	
E-mail address	
Type of entity	Academia, Clinical or Public Health, SME or Industry
Type of entity (public/private-for-profit/private-non-for-profit)	
Early Career Researcher (yes/no)	

3. Project Partners:

3a. Research partners asking for funding:

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

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

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

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

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

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

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

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

6. Keywords

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

1	
2	
3	
4	
5	
6	
7	

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

8. Description of the project (once converted into PDF: max. 5 pages DIN-A4, Century Gothic 11, single-spaced, and margins of 1.27 cm). Description of the working programme including:

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

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

3. *Description of the unmet medical and patient need that is addressed by the proposed work and the potential health impact that the results of your proposed work will have;*
4. *Added value of the transnational collaboration;*
5. *Description of patient organizations within the proposal, including their role and contribution.*

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

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

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

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

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

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

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

11. Budget table (see last page for template)

12. Brief CV for each principal investigator (once converted into Pdf document: max. 1 page per CV, DIN-A4, Century Gothic 11, single-spaced, margins of 1.27 cm).
Brief CV for each principal investigator or collaborator where relevant, including a description of the main domain of research and a list of the 5 most relevant publications within last five years regarding the proposal. Please include dates/requirements for the identification of early career researchers (not included in page limit; see "Guidelines for Applicants" section 3).

13. Date and signature of the coordinator

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

No.	Project coordinator[4]	Partner 1	Partner 2	Partner 3	Partner 4	Partner 5	Partner 6 (partner is an early career researcher, or from usually underrepresented countries)	Partner 7 (partner is an early career researcher, or from usually underrepresented countries)	Patient advocacy organization(s)
Name (principal investigator)									
Country									
Funding organization									
Personnel €									
Consumables €									
Equipment €									
Travel €[1]									
Other direct costs €[2]									
Overheads €[3]									
Total requested budget €	0	0	0	0	0	0	0	0	0
Total budget if required (e.g. MIUR)									

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