

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 circumstances¹.
- Text marked in Italics and highlighted in yellow can be deleted for proposal submission.

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



CHECKLIST FOR THE COORDINATOR:

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

• General conditions:

The project proposal addresses the AIM/s of the call

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

• Ethical standards:

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

• The composition of the consortium:

The project proposal involves at least 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 <u>www.mySNF.ch</u> 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: <u>http://uidb-pbs.tubitak.gov.tr/</u>.

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, Count ry	Research Partner (principal investigator)	ID (ORDIC or otherwis e)	Institution, Departme nt, full affiliations (address, phone + fax)	PIC number of the institution (EC Participant Identificati on Code)	Email addre ss	Early Care er Rese arch er (yes/ no)	Type of entity Academi a, Clinical or Public Health, SME and Industry	Type of entity (public/priva te-for- profit/private -non-for- profit)
1									
2									
3									
4									
5									
6									
7		(7 th partner is an early career researcher, or from usually underrepresent ed countries)							
8		(8 th partner is an early career researcher, or from usually underrepresent ed 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 (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	x	xx

4. Duration of the project (max. 36 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	
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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: <u>https://www.mendeley.com/guides/harvard-citation-guide</u>) and include <u>PUBMED</u>, WoS or SCOPUS IDs. <u>Apply the chosen style consistently throughout the whole proposal</u>.

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)

¹Travel expenses should include the participation to intermediate status symposium

²e.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										