Une image contenant bouteille, assis, signe, assiette

Description générée automatiquement

**Call for Proposals 2023**

**"Natural History Studies addressing unmet needs in Rare Diseases”**

**Submission deadline for pre-proposals:**

**February 15th, 2023; 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[[1]](#footnote-1).**
* ***Text marked in Italics and highlighted in yellow can be deleted for proposal submission.***

**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 (Hungary, Lithuania, Poland, Slovakia, Sweden and Türkiye) 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) 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](http://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 EJP RD call JTC 2019, JTC 2020, JTC 2021, JTC2022

a proposal asking for 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 |  |
| ID (ORDIC or otherwise) |  |
| Institution/Department |  |
| PIC number of the institution (EC Participant Identification Code) |  |
| 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) |
| Coo |  |  |  |  |  |  |  |  |  |
| P2 |  |  |  |  |  |  |  |  |  |
| P3 |  |  |  |  |  |  |  |  |  |
| P4 |  |  |  |  |  |  |  |  |  |
| P5 |  |  |  |  |  |  |  |  |  |
| P6 |  |  |  |  |  |  |  |  |  |
| P7 |  | (7th partner is an early career researcher, or from usually underrepresented countries) |  |  |  |  |  |  |  |
| P8 |  | (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 |  |  |  |  |  |

Each Patient Advocacy Organisation from a participating country, requesting funding at its national/regional funding agency (if eligible) should complete and sign the letter in Annex 1 and send it by email to the contact person of this funding agency before June 14th, 2023; 2 p.m. (CEST)

3c. Collaborators (not funded): (PAOS not asking for funding may be collaborators)

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

|  |  |  |
| --- | --- | --- |
| **4. Duration of the project (max. 36 months)** |  | **Months** |

|  |  |  |
| --- | --- | --- |
| **5. Total requested funding in application** |  | **€** |

**6. Keywords**

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

|  |  |
| --- | --- |
| 1 |  |
| 2 |  |
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| 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).*

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**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:**
* 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: appropriate statistical methods description, name and affiliation of the responsible biostatistics’ expert.
* Please also complete the following table

|  |  |
| --- | --- |
| 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.*

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**9. Diagram** **of the work plan**

Timeline, workflow and interconnections of work packages (Gantt chart, Pert or similar, max. 1 page)

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

* a page of results-related 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*](https://www.mendeley.com/guides/harvard-citation-guide)*) and include PUBMED, WoS or SCOPUS IDs*. Apply the chosen style consistently throughout the whole proposal.

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**11.** **Budget table** (see last page for template)

**12. Brief CV for each principal investigator**

**Coordinator or  Partner or  Collaborator**

|  |  |
| --- | --- |
| Name, First Name |  |
| Country |  |
| Phone, email | **, @** |
| URL for Website |  |
|  |  |

**PROFESSIONAL EXPERIENCE & EDUCATION**

|  |  |  |
| --- | --- | --- |
| **Dates** | **Institution** | **Function** |
|  |  |  |
|  |  |  |
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|  |  |  |
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**RESEARCH FOCUS** (4 lines max)

**SCIENTIFIC PRODUCTIONS** (grants, awards….)

**VALORISATION** (patents, spin-offs, tools/databases development….)

**FIVE SELECTED PUBLICATIONS** (five most relevant within last five years)

Number of publications and citations :

|  |  |
| --- | --- |
| **1** |  |
|  |  |
| **2** |  |
|  |  |
| **3** |  |
|  |  |
| **4** |  |
|  |  |
| **5** |  |
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**FOR EARLY CAREER RESEARCHERS** Indicate career breaks

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**13. Date and signature of the coordinator** (electronic signature or a scanned copy of the signature page will be accepted)

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**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

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 coordinator4 | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 | Partner 75 | Partner 85 |
| Name (principal investigator) |  |  |  |  |  |  |  |  |
| Country |  |  |  |  |  |  |  |  |
| Funding organization |  |  |  |  |  |  |  |  |
| Personnel € |  |  |  |  |  |  |  |  |
| Consumables € |  |  |  |  |  |  |  |  |
| Equipment € |  |  |  |  |  |  |  |  |
| Travel €1 |  |  |  |  |  |  |  |  |
| Other direct costs €2 |  |  |  |  |  |  |  |  |
| Overheads €3 |  |  |  |  |  |  |  |  |
| Total requested budget € |  |  |  |  |  |  |  |  |
| Total budget if required |  |  |  |  |  |  |  |  |

Justification of the other direct costs per partner:

**Annex 1**

**Declaration of Honour for Patient Advocacy Organisation**

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

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

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

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

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

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

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

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

Date: *(insert date of signature)*

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

Signature:

1. Such as when partners are added during the widening process (see guidelines). [↑](#footnote-ref-1)