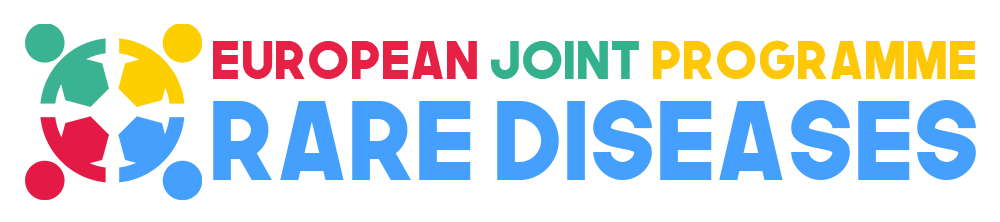
****

**Call for Proposals 2020**

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

**Submission deadline for full proposals:**

**June 16th, 2020; 2 p.m. (CEST)**

# Full proposal application form

**Please note:**

* **Please note that incomplete full-proposals, proposals using a different format or exceeding length limitations of any section will be rejected without further review.**
* **Format is Arial 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.**
* **All the information requested in this document must be compiled into one single Pdf-document and uploaded to the electronic submission system. The pre-proposal document will be replaced by this full proposal.**
* **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 by the Call Steering Committee (CSC) under exceptional circumstances[[1]](#footnote-1). One justification can be that because of additional advice gathered on the translatability of the project, additional expertise or resources are needed. However, the national/regional regulations on budget caps will still apply and the budget change needs to be pre-approved by the national/regional funding organisation.**
* **All headings and all sub-points in section “Project description” need to be addressed and clearly indicated**
* ***The text with instructions for the applicants that is marked in Italics and highlighted in yellow in this proposal form can be deleted for proposal submission.***

**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).**

**Basic project data**

|  |  |
| --- | --- |
| **Project Title** |  |

|  |  |
| --- | --- |
| **Acronym (max. 20 characters)** |  |

|  |  |  |
| --- | --- | --- |
| **Project duration** |  | **Months (max. 36 months)** |

|  |  |  |
| --- | --- | --- |
| **Total requested funding** |  |  |

**Keywords and medical domain:** *please identify between three and seven keywords that represent the scientific content (medical domain, disease, etc.), approach(es), and tools*

*(animal models, OMICS, etc.)*

|  |  |
| --- | --- |
| 1 |  |
| 2 |  |
| 3 |  |
| 4 |  |
| 5 |  |
| 6 |  |
| 7 |  |

**Project abstract**: *please give a comprehensive and readable summary of the primary aims and methods of the project. Please note that if your proposal is selected for funding this abstract could be used for communication purposes by the EJP RD or national funding agencies* (max. ½ page)

|  |
| --- |
|  |

**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 not-for-profit) |  |
| Early Career Researcher (yes/no) |  |

**Project Partners:**

1. Research partners asking for funding:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | 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/undersubscribed countries) |  |  |  |  |  |
| 7 |  | (partner is an early career researcher, or from usually underrepresented/undersubscribed countries) |  |  |  |  |  |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Zip code, City, Country | Responsible person | Organisation, full affiliations (address, phone + fax) | Website | Email address | Type of entity (public / private-non-for-profit) |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| xx |  |  |  |  |  |  |

Each Patient Advocacy Organisation requesting funding through the JTC 2020 should complete and sign the letter in Annex 1 and send it by email to [pao@ejprarediseases.org](mailto:pao@ejprarediseases.org) before June 16th, 2020; 2 p.m. (CEST)

1. Collaborators (not funded): add lines as necessary

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | 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 |  |  |  |  |  |  |  |

**Project description**

**1a. Background and present state of the art in the research field** (max. 2 pages)

|  |
| --- |
|  |

**1b. Preliminary/previous results obtained by the consortium members** *(if the application concerns a request for extension of a project funded in a previous E-Rare Joint Transnational Call, please describe the scientific results achieved in that project so far, including: publications, collaboration, impact on clinical and public health applications and relevance to patients’ needs.)* (max. 2 pages)

|  |
| --- |
|  |

**2. Description of the aims,** including project coordination and management as well as innovation management activities

|  |  |  |
| --- | --- | --- |
| Aim No. | Description | Partner(s) responsible for the aim / workload |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| N |  |  |

**3. Workplan** (max. 15 pages). **Must contain items a-d:**

1. ***Description of the work program*** *including the objectives, the rationale and the methodology, highlighting the novelty, translatability, and feasibility of the project;*

*Taking into account that results of the projects submitted in this call should be translatable, the following elements (if relevant) should be taken into account in the description of the work:*

*Consortia performing preclinical development of therapeutics are strongly advised to engage or consult experts in the various stages of product development, with the aim to establish one or more of the following:*

1. ***Target validity:*** *Strong link between target and disease, differentiated efficacy, available and predictive biomarkers.*
2. ***Right Tissue:*** *Adequate bioavailability and tissue exposure, definition of pharmacodynamics biomarkers, clear understanding of preclinical pharmacokinetics.*
3. ***Right safety profile:*** *Differentiated and clear safety margins (in models), understanding of secondary pharmacology risk which consist in evaluating the potential off-target or unintentional effects of a drug, including understanding of reactive metabolites, genotoxicity, drug–drug interactions, and off-target liability. These studies are important in predicting potential toxicities and demonstrating safety of a therapy.*
4. ***Right patient:*** *Identification of the most responsive patient population, with a risk–benefit analysis.*

***For the development of novel therapies or proof-of-principle studies,*** *the following issues should be addressed in the proposal:*

* *Orphan drug designation (ODD) planning: has an ODD been granted? If not, the path to ODD development should be described (including target product profile for therapy development).*
* *Exploration of scale-up feasibility for clinical trials and manufacturing.*
* *For projects developing a new target (not extensively validated in the literature), target revalidation in preclinical models should be a first step in project.*

***For validation or development of predictive and pharmacodynamics biomarkers*** *(predictive biomarkers are important to help guide patient selection, pharmacodynamics biomarkers can provide information on the pharmacologic effects of a drug on its target), the following issues should be addressed in the proposal:*

* *Ensure in the first stage that the biomarker (signature) undergoes analytical validation using high quality samples from an independent collection (different from the collection in which the signal was discovered), which have been collected and stored under quality controlled conditions and following international standards.*

*Samples used in validation should be sourced from certified biobanks (e.g.* [*http://www.eurobiobank.org/*](http://www.eurobiobank.org/)*). Upon sample provision biobanks should provide a report including information on:*

* *Identification and specific properties of the materials*
* *Relevant quality information of the materials and clinical data*
* *Method used for identification and characterisation of materials*
* *Method used for testing of the materials*
* *Method used for sample collection, preparation, preservation, storage*
* *Accreditation of the lab performing the analytical validation of the biomarker for the method used (e.g. ISO 17025 or 15189).*
* *Validation should follow a risk-based approach wherein depending on potential confounding variables such as genetic diversity, multiple biobanks from multiple regions may be utilised. Sample size and number should reflect such risk.*

*Applicants should* ***describe and justify the use of any disease models*** *(animal or otherwise) described in the proposal:*

* *Describe how the model replicates the pathology or human condition (aetiology, pathophysiology, symptomatology and response to therapeutic intervention),*
* *Whether the model duplicates aspects of the therapy target including expression, distribution and primary structure, pharmacodynamics, metabolism and other pharmacokinetic aspects,*
* *If the project involves the use of animals, provide sound scientific justification for their use, explain why there are no realistic alternatives, and demonstrate that the numbers proposed will allow meaningful results to be obtained from the research. Please also specify the sex of the animals, and rationale for the numbers of each sex,*
* *Describe how the proposed pre-clinical work correlates and aligns with any planned future stages of the research in humans.*

***If the proposal includes animal studies, these need to be described in accordance with the suggestions of the ARRIVE-Guidelines[[2]](#footnote-2), especially if these are not small exploratory but larger confirmatory studies****:*

*1. Background and objectives*

*Explain the experimental approach and rationale; and how the animal model being used can address the scientific objectives, explain the study’s relevance to human biology.*

*2. Study design (number of experimental and control groups, steps to minimise the effects of subjective bias, experimental unit)*

*3. Experimental procedures (drug formulation and dose, anaesthetic and surgical procedures, equipment – How, When, Where, Why)*

*4. Experimental animals (species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc.)*

*5. Housing and husbandry (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions, type of food, access to food and water, environmental enrichment etc.)*

*6. Sample size: •specify the total number of animals used in each experiment, and the number of animals in each experimental group; •explain how the number of animals was arrived at; •provide details of any sample size calculation used. Indicate the number of independent replications of each experiment, if relevant*

*7. Allocating animals to experimental groups (details of how animals were allocated to experimental groups, including randomisation or matching if done; order of treatment and assessment)*

*8. Experimental outcomes (define the primary and secondary experimental outcomes assessed e.g. cell death, molecular markers, behavioural changes)*

*9. Statistical methods: •provide details of the statistical methods used for each analysis; •specify the unit of analysis for each dataset (e.g. single animal, group of animals); •describe any methods used to assess whether the data met the assumptions of the statistical approach*

*Furthermore, the following* ***additional elements need to be considered in all proposals:***

* *The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.*
* *Appropriate bioinformatics and statistical methods should constitute, whenever justified, an integral part of the proposal, and the relevant personnel should be clearly specified.*
* *Preliminary data should be described in a manner that would allow a skilled peer to replicate the data, including positive and negative controls, and suitable n values for statistical analysis. All data points should be included in the analysis and presented with error bars where relevant.*
* *Risk management should be considered including the identification of possible bottlenecks and go/no go contingencies.*
* *Feasibility of the project given requested resources (budget) and schedule must be demonstrated: timelines should be realistic, and lead times should be accounted for (e.g. regulatory or scientific advice).*
* *If relevant, the consortium will identify technology transfer officer responsible for intellectual property management. Project plan should include innovation management activities (e.g. ongoing monitoring, expert panels to identify high potential results), and may describe follow-on funding and/or draft study plans past the grant end (e.g. natural history studies with relevant stakeholders including patient groups, or approaching companies for potential in-licensing or co-development).*
* *Applicants should include information about other ongoing development work on the target/indication, and explain why their approach should be supported.*
* *Study design and preclinical models (vectors, reagents etc.) may be selected to facilitate approval in human trials and future clinical grade manufacturing.*

Nominated statistician and Quality assurance/data management partner

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Statistician | | | | |
| # | Name | Affiliation | | Signature |
|  |  |  | |  |
| Quality Assurance / Data Management | | | | |
| # | Name | Affiliation | Responsibility / Role | Signature |
|  |  |  |  |  |

1. **Clearly defined responsibilities and workloads** (expressed in person months) of each participating research partner;

*Please use the following table for detailing the responsible partner for each WP and the distribution of work in person months (PM) in different work packages (WP) (adapt as necessary):*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | WP1 (PM) | WP2 (PM) | WP3 (PM) | WP4 (PM) | WP5 (PM) | WP6 (PM) | WPxx (PM) |  |
| Responsible partner | |  |  |  |  |  |  |  |  |
| No. | Consortium member | WP1 (PM) | WP2 (PM) | WP3 (PM) | WP4 (PM) | WP5 (PM) | WP6 (PM) | WPxx (PM) | SUM |
| Co |  |  |  |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |
| 6 | partner is an early career researcher, or from usually underrepresented/undersubscribed countries |  |  |  |  |  |  |  |  |
| 7 | partner is an early career researcher, or from usually underrepresented/undersubscribed countries |  |  |  |  |  |  |  |  |
| PAO |  |  |  |  |  |  |  |  |  |
|  | SUM |  |  |  |  |  |  |  |  |

1. **Diagrams and figures, including a diagram which compiles the work plan, timeline, sequencing of work packages, the contribution of the partners to each work package and their interactions** (Gantt chart, Pert or similar, max. 1 page)

|  |
| --- |
|  |

1. **References** (not included in the page limit of the workplan of 15 pages)

*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*

|  |
| --- |
|  |

**4. Added value of the proposed transnational collaboration** (max. 1 page)

|  |
| --- |
|  |

**5. Description of the unmet medical and patients’ need and that are addressed by the proposed work, the potential health impact that the results of your proposed work will have and exploitation / dissemination of project results** (max. ½ page)

|  |
| --- |
|  |

**6. Translatability of the project results:**

**Description of the potential of the expected results for future clinical, public health and/or other socio-economic health relevant applications (if applicable also for commercial exploitation)** (max. ½ page)

|  |
| --- |
|  |

**7. Description of patents and present / future position with regard to intellectual property rights, both within and outside the consortium** *(e.g. any barriers to sharing materials or translating the results into clinical application)*(max. ½ page)

|  |
| --- |
|  |

**8. Description of ongoing or submitted research grants of each participating partner related to the present topic** *(indicating funding sources [include at least: ID number, amount and duration of funded project; funding agency] and possible overlaps with the project proposed)* (max. ½ page per research partner)

|  |
| --- |
|  |

**9. Ethical and legal issues**

(*Please provide a short description of ethics and legal aspects in your proposal. For this, the following questions stemming from the H2020 Ethics self-assessment should be answered. If your answer is “Yes” please provide* ***additional information*** *listed in the H2020 Guidance “How to complete your ethics self-assessment” (see column “Information to be provided” of ethics issues checklist of each section; the guidance can be found at http://ec.europa.eu/research/participants/data/ref/h2020/grants\_manual/hi/ethics/h2020\_hi\_ethics-self-assess\_en.pdf). Additionally, please provide an overview on* ***related tasks, responsible partners and documents to be provided for each question by each partner****.*

*Please provide, if applicable, especially:*

* *A detailed information on the animal welfare measures and adherence to the Three Rs principle.*
* *Details on incidental findings and re-contact policy.*
* *A confirmation that all the human samples used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval needs.*
* *The procedures that will be used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc.). Additionally, the nature of the material that will be collected (e.g. human biological samples, sensitive or personal data etc.) as well as specific procedures to ensure the wellbeing of the children involved and the procedures for ensuring assent have to be defined.*

*Please attach any supporting documents that are already available and for those that are not state when they are expected to be available. All relevant documents listed have to be kept on file and ready to be submitted upon request. Please also name a person that will be* ***the ethics contact point*** *for the consortium. He/she will be responsible to monitor the ethical issues in this project and to maintain the relevant ethics file, for perusal, upon request, and interact with the correspondent Ethics Advisor of the EJP RD. Please note that an ethics report must be drafted annually by the contact point and submitted together with the periodic scientific reports.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: HUMAN EMBRYOS/FOETUSES** | | YES/NO | If yes,  indicate page of description in proposal |
| **Does this research involve Human Embryonic Stem Cells (hESCs)?** | |  |  |
| **If** **YES**: | - Will they be directly derived from embryos within this project? |  |  |
| - Are they previously established cells lines? |  |  |
| **Does this research involve the use of human embryos?** | |  |  |
| **If** **YES**: | - Will the research lead to their destruction? |  |  |
| **Does this research involve the use of human foetal tissues / cells?** | |  |  |
| **Section 2: HUMANS** | | YES/NO | Page |
| **Does this research involve human participants?** | |  |  |
| **If YES**: | - Are they volunteers for social or human sciences research? |  |  |
| - Are they persons unable to give informed consent? |  |  |
| - Are they vulnerable individuals or groups? |  |  |
| - Are they children/minors? |  |  |
| - Are they patients? |  |  |
| - Are they healthy volunteers for medical studies? |  |  |
| **Does this research involve physical interventions on the study participants?** | |  |  |
| **If YES**: | - Does it involve invasive techniques? |  |  |
| - Does it involve collection of biological samples? |  |  |
| **Section 3: HUMAN CELLS / TISSUES** | | YES/NO | Page |
| **Does this research involve human cells or tissues?** (o*ther than from Human Embryos/Foetuses, see section 1)* | |  |  |
| **If YES:** | - Are they available commercially? |  |  |
| - Are they obtained within this project? |  |  |
| - Are they obtained from another project, laboratory or institution? |  |  |
| - Are they obtained from a biobank? |  |  |
| **Section 4: PERSONAL DATA** | | YES/NO | Page |
| **Does this research involve personal data collection and/or processing?** | |  |  |
| **If YES:** | - Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*? |  |  |
| - Does it involve processing of genetic information? |  |  |
| - Does it involve tracking or observation of participants? |  |  |
| **Does this research involve further processing of previously collected personal data (secondary use)?** | |  |  |
| **Section 5: ANIMALS** | | YES/NO | Page |
| **Does this research involve animals?** | |  |  |
| **If YES:** | - Are they vertebrates? |  |  |
| - Are they non-human primates (NHPs)? |  |  |
| - Are they genetically modified? |  |  |
| - Are they cloned farm animals? |  |  |
| - Are they endangered species? |  |  |
| *Please indicate the species involved* ***C. elegans, O. cuniculus (rabbit)*** | |  |  |
| **Section 6: THIRD COUNTRIES** | | YES/NO | Page |
| **In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?**  *Specify the countries involved:* | |  |  |
| **Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?** | |  |  |
| **Is it planned to import any material – including personal data – from non-EU countries into the EU?** | |  |  |
| **If Yes**: | *Specify material and countries involved*  Personal data, primary cell cultures; UK, USA, Australia, New  Zealand |  |  |
| **Is it planned to export any material – including personal data –from the EU to non-EU countries?** | |  |  |
| **In case this research involves** [**low and/or lower-middle income countries,**](http://data.worldbank.org/about/country-classifications/country-and-lending-groups) **are any benefit-sharing actions planned?** | |  |  |
| **Could the situation in the country put the individuals taking part in the research at risk?** | |  |  |
| **Section 7: ENVIRONMENT & HEALTH AND SAFETY** | | YES/NO | Page |
| **Does this research involve the use of elements that may cause harm to the environment, to animals or plants?** | |  |  |
| **Does this research deal with endangered fauna and/or flora/protected areas?** | |  |  |
| **Does this research involve the use of elements that may cause harm to humans, including research staff?** | |  |  |
| **Section 8: DUAL USE** | | YES/NO | Page |
| **Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?** | |  |  |
| **Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS** | | YES/NO | Page |
| **Could this research raise concerns regarding the exclusive focus on civil applications?** | |  |  |
| **Section 10: MISUSE** | | YES/NO | Page |
| **Does this research have the potential for misuse of research results?** | |  |  |
| **Section 11: OTHER ETHICS ISSUES** | | YES/NO | Page |
| **Are there any other ethics issues that should be taken into consideration?** | |  |  |
| **Section 12: ETHICS COMPLIANCE** | | YES |  |
| **The consortium confirms the full compliance with national and EU law on the protection of individuals with regard to the processing of personal data and that the ethical standards and guidelines of Horizon 2020 will be applied.** | |  |  |

**10. Concept for sustainability of infrastructures initiated by the project** *(e.g. registries, cohorts, biobanks, databases etc.) and their possible interaction with European Infrastructure Initiatives (where applicable, e.g. BBMRI, ECRIN, ELIXIR, EU-Openscreen, INFRAFRONTIER, INSTRUCT, RD-Connect, etc.)* (max. 1 page)

|  |
| --- |
|  |

**11. Data management strategy[[3]](#footnote-3) (mandatory):** *description how the new research data in this project will be findable, accessible, interoperable and re-usable (FAIR): the handling of research data during & after the end of the project; what data will be collected, processed and/or generated and/or reused; which methodology & standards will be applied; whether data will be shared/made open access; how data will be curated & preserved (including after the end of the project).* *Please name a Data Protection Officer* (max. 2 pages)

|  |
| --- |
|  |

**12. Description of participation/engagement of Industry within the proposal, including their role and contribution (**max. ½ page, only if applicable).

|  |
| --- |
|  |

**13. Description of patient organizations within the proposal, including their role and contribution** max. 2 pages) *Please consider the questions of the checklist below for your description of role and contribution of the PAO: The checklist is purely indicative and not prescriptive. It is intended to show the type of information evaluators will look for in a proposal specifically regarding patient partnerships.*

* *Have discussions between researchers and patient representatives taken place before identifying the research questions and writing the proposal?*
* *Have you described how the patient partner(s) was/were identified and selected?*
* *Has the input of patients been integrated in the development of the proposed research project? Have you described what changed/improved as a result of this input?*
* *Have clear roles and responsibilities been assigned to the patient partners in the project?*
* *Have the patient partnership activities been clearly explained (who, what and when)?*
* *Have the available resources of respective partners been maximised to the benefit of the research project (e.g. registries, know-how, networks, communication channels)?*
* *Have the approaches through which the patients will be engaged/involved/participate in the project been described (e.g. focus groups, interviews, surveys etc.)?*
* *Has a process been included to ensure 2-way communication between the partners throughout the life of the project?*
* *Are patient representatives included in the governance of the research project e.g. as steering committee member, leader or co-leader of a work package?*
* *Are there specific deliverables relating to the patient partnership activities described (e.g. follow up report, publication of guidelines, analysis of a focus group and/or a survey, development of a video etc...)?*
* *Has the   overall added value of the patient partnership for the project been clearly highlighted?*

|  |
| --- |
|  |

**14. 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* (max. ½ page per partner)

|  |
| --- |
|  |

**15. Financial plan: sum of year 1-3. Please describe the requested budget only** (or amount of full budget and requested budget if nationally required)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Acronym:** |  |  | | | | | | Partner is an early career researcher, or from usually underrepresented/undersubscribed countries | | Patient advocacy organization(s) |
| No. |  | Project coordinator5 | Partner 1 | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 | Partner 7 | PAO |
| Name (principal investigator) |  |  |  |  |  |  |  |  |  |  |
| Funding organization |  |  |  |  |  |  |  |  |  |  |
| Person Months, (1)1 | € |  |  |  |  |  |  |  |  |  |
| Person Months, (2)1 | € |  |  |  |  |  |  |  |  |  |
| Person Months, (3)1 | € |  |  |  |  |  |  |  |  |  |
| Personnel total € |  |  |  |  |  |  |  |  |  |  |
| Consumables € |  |  |  |  |  |  |  |  |  |  |
| Equipment € |  |  |  |  |  |  |  |  |  |  |
| Travel €2 |  |  |  |  |  |  |  |  |  |  |
| Other direct costs €3 | |  |  |  |  |  |  |  |  |  |
| Overheads €4 | |  |  |  |  |  |  |  |  |  |
| **Total requested budget €** | |  |  |  |  |  |  |  |  |  |
| **Total budget if**  **nationally required** | |  |  |  |  |  |  |  |  |  |
| 1 Please detail number of person months (PM), qualification (**Si**: scientist, e.g. postdoc; **PhD**: PhD-student; **N**: non-scientist, e.g. technician; **Ot**: other) and € requested. Please use one cell per person to provide this information. Please note that students are funded according to national regulations. | | | | | | | | | | |
| 2 Travel expenses should include the participation of the coordinators and/or national partner leaders at an intermediate status symposium to present the results of their projects (organized by the Joint Call Secretariat). | | | | | | | | | | |
| 3 e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according legal framework and funding body regulations; see Annexes in **Guidelines for Applicants** for more information). | | | | | | | | | | |
| 4 Overhead costs: funding according to national/regional legal framework and funding body regulations. Please see Annexes in the **Guidelines for applicants** for more information. | | | | | | | | | | |
| 5 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. | | | | | | | | | | |
| \* no funding is requested, position is listed as a part of total budget according to MIUR regulation | | | | | | | | | | |

**16. Brief CVs for each participating partner leader** with a list of up to five relevant publications within the last five years demonstrating the competence to carry out the research project (max. 1 page per partner, and 1 page per collaborator if necessary). *Please include dates/requirements for the identification of early career researchers (not included in page limit; see “Guidelines for Applicants” section 3). Please use Vancouver Style for the references (see: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15) and include PUBMED IDs.*

|  |
| --- |
|  |

**17. Signature of project partners (including PAOs)**

|  |
| --- |
| Project partner Name:  Project partner Institution:  I confirm that I have been involved in the preparation of the project and am informed of the content of the project proposal  Date:  Signature: |

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/Inserm;

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 §4.2). [↑](#footnote-ref-1)
2. The ARRIVE Guidelines: Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010 (http://www.nc3rs.org.uk/arrive-guidelines [↑](#footnote-ref-2)
3. For more information on preparing a data management strategy/plan, please consult Annex 1 of <http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf> and <http://www.snf.ch/en/theSNSF/research-policies/open_research_data/Pages/data-management-plan-dmp-guidelines-for-researchers.aspx> [↑](#footnote-ref-3)