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**ERA-CVD Joint Transnational Call 2020**

**“Prevention of Vascular Cognitive Impairment through Early Detection of Cardiovascular Diseases”**

**Proposal Application Form**

**All fields must be completed using "Arial font, size 11" characters, margins of 1.27 cm.**

**Please note that 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.**

***Please don’t forget to register at*:**

**https://ptoutline.eu/app/era-cvd\_jtc2020**

**Basic project data**

**1.a Project Title**

**1.b Project acronym** *(max. 20 characters. Please fill as well the project* ***ACRONYM*** *in the Header)*

**2. Duration of the project** (months)

**3. Total funding applied for** (€) *(please take the final requested budget from the electronic submission tool)*

**4. Keywords** *Identify between three and seven keywords that represent the scientific content as precise as possible*

**5. 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 ERA-CVD or national funding agencies (max. 1600 characters including spaces)*

**6. Consortium coordinator** (Partner 1)

|  |  |
| --- | --- |
| **Family Name, first Name** |  |
| **Name of Institution** |  |
| **Department** |  |
| **Position** |  |
| **Address** |  |
| **City, Country** |  |
| **Type of entity** | Academia, Clinical or Public Health, SME or Industry |

**7. Research Partners(XX):**

7a. Research partners asking for funding:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Research Partner (Principal investigator)** | **Institution, Department, full affiliations** | **Type of entity: Academia, Clinical or Public Health, SME and Industry** |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  | Only possible if partner is from Estonia, Latvia, Poland, Slovakia or Turkey |  |  |

\* 7. Associated research partner not asking for funding (one maximum):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Research Partner (Principal investigator)** | **Institution, Department, full affiliations** | **Type of entity: Academia, Clinical or Public Health, SME and Industry** |
|  |  |  |  |  |

**Project description**

**1. Background and present state of the art in the research field and preliminary results obtained by the consortium members** *(max. 2 pages)*

**2. Description of the aims** *(max. 1 page in total)*

|  |  |  |
| --- | --- | --- |
| Aim No. | Description | Partner(s) responsible for the aim / workload |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |

**3. Work plan** *(max. 18 pages)* – Note: ***For animal/clinical exploratory studies, please fill exclusively the attached Experimental design template instead of going along the point below.***

1. **Objectives, hypotheses and evidence** *- primary and secondary objectives of the study and specific hypotheses being tested, background of the study, relate to relevant previous studies*
2. **Relevance** *- why is this study needed and what impact will it have:*

* *Rationale behind the study and, in case of (pre)clinical studies, the use of this/these animal, patient, human cohort sample(s)/group(s) for this specific study*
* *In case of human cohort/sample studies, please elaborate on the prevalence, incidence, mortality and burden of the disease, the expected improvement of the therapy/measure or impact of the study and patient participation*

1. **Methodological approach**
2. – ***For animal/clinical exploratory studies, fill exclusively the attached Experimental design template***

* *Primary and secondary (experimental) outcomes*
* *Describe the experimental and control groups and the experimental procedures: type, duration, frequency and time points of the measurements and the equipment that will be used*
* *Proposed sample size(s) / power calculations: Specify the N of each experiment and each condition and how this N was arrived at with power calculations including justification of the effect size. Where power calculations are not appropriate (for example in exploratory research), explicitly explain why. Statements as ‘this N has been used in previous publications’ are not acceptable*
* *Strategies to minimise the effects of bias (e.g. randomization, blinding, order of assessment), or an explanation why these are not relevant*
* *In case of human cohort/sample studies, list recruiting centres, describe inclusion/exclusion criteria and elaborate on the feasibility of recruitment / evidence that intended recruitment rate is achievable.*
* *Please specify “stopping rules” / “discontinuation criteria” for   
  a) the individual subject / patient / sample,   
  b) participating / recruiting centres, which fail to include the estimated number of subjects / patients,  
  c) for the whole study.*

1. **Statistical analysis**

* *Describe the details of the statistical methods used for each (subgroup) analysis and the methods used to assess whether the data met the assumptions of the statistical approach*
* *Describe the dataset that will be used for the analyses and the number of replications (if applicable)*
* *Details of any statistical advice sought (seeking advice is strongly recommended)*
* *Data Management Plan (DMP): If a DMP is considered please refer to the ERA-CVD webpage for a template. And if so, please include the costs related to your data sharing in the resources section of the proposal form. This may include people, equipment, infrastructure and tools to manage, store, analyse and provide access to data. Where the costs of managing legacy data and sharing are substantial, the proposal should differentiate the resources and funding for the following activities:*
* *Collecting and 'cleaning' new data*
* *Own research on newly-acquired and legacy data*
* *Ongoing data curation and preservation*
* *Providing access and data sharing*

1. **Ethical considerations**

* *Describe how data protection is handled*

*In case of human cohort/sample studies: Please describe the ethical considerations concerning the protection of participants, confidentiality, use of human samples etc.*

*In case of preclinical (animal) studies: Describe the ethical considerations concerning the use of animals (3R principles, see ANNEX3 in the Guidelines for Applicants)*

1. **Work package structure**

* *Describe the work packages, the project coordination and management, the involvement of the partners in each work package*

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** | **Research Partner** (principal investigator) | **WP1 (PM)** | **WP2 (PM)** | **WP3 (PM)** | **WP4 (PM)** | **WP5 (PM)** | **WP6 (PM)** | **WPxx (PM)** | **SUM** |
| 1 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| … |  |  |  |  |  |  |  |  |  |
|  | SUM |  |  |  |  |  |  |  |  |

**4.** **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)*

**5. Added value of the proposed transnational collaboration and the multidisciplinary expertise within this collaboration** *(max. 1 page)*

**6. 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. Please carefully consider gender differences.** *(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 - according to national regulations if applicable** (e.g., research on humans, animals or biomaterials including stem cells, data protection, use of animals in accordance with the suggestions of the ARRIVE-Guidelines[[1]](#footnote-1)) *(max. ½ page)*

**10. Possible interaction with European Infrastructure Initiatives should be named** (where applicable, e.g. BBMRI, ELIXIR, EATRIS, EU-Openscreen, etc.)*(max. ¼ page)*

**11. Description of participation/engagement of Industry and/or patient organizations within the proposal, including their role and contribution** *(max. 1 page, only if applicable)*

**12. 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 research partner)*

**13. Brief CV for each principal investigator** (once converted into Pdf document: *max. 1 page DIN-A4, Arial 11, single-spaced, margins of 1.27 cm per PI*) Please follow this format:

**NAME**

**DATE OF BIRTH**

**POSITION TITLE**

**EDUCATION/TRAINING (Master, PhD, Clinical Specialization … only mention Institution, Degree, Year, Field)**

**A. Positions and Honours**

1. Positions and Employment
2. Other Experience and Professional Memberships
3. Honours and awards

**B. Publications**

1. Number of publications: 1) total, 2) as first author and 3) as second last and last author
2. Best 5 selected peer-reviewed scientific publications, relevant for this proposal
3. Best 5 selected non-scientific publications, e.g. policy documents, guidelines or newspaper articles etc.

**C. Research Support (over the last 10 years, if applicable)**

1. Ongoing Research Support
2. Completed Research Support

**D. Activities on knowledge management (translation of results for the public, participation of patients in the research, etc.)**

*Check for the coordinator:*

*- Does the consortium meet with the eligible consortium composition?*

*- Does each partner comply with his/her national regulations (see Guidelines for Applicants,* *ANNEX2 )?*

*- Did you think of including a partner from an Underrepresented country? (This is stimulated only)*

*- If applicable: Did you fill out the Experimental design template below?*

***I declare that I addressed all the detailed information asked for in the full proposal form (i.e. items 1, 3A to 3E, and 4 to 14)*** *(mandatory tick box in the online application form)*

**14. Date and signature of the coordinator**

**Experimental design template**

|  |  |
| --- | --- |
| **APPLICANT/COORDINATINGINVESTIGATOR** | Name, address, telephone, fax, e-mail  *In case of multiple applicants the principal investigator / coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.* |
| **TITLE OF PROJECT** | *Descriptive title identifying the study design, population, and interventions.*  ***Please fill ACRONYM in the Header*** |
| **CONDITION** | *The medical condition being studied (e.g. M. Parkinson)* |
| **OBJECTIVE(S)** | *Which principal research questions are to be addressed? Specify clearly the primary hypotheses that determine sample size calculation.* |
| **INTERVENTION(S)** | *Brief description of the experimental and the control treatments or interventions, if applicable: dose and mode of application.*  Experimental intervention:  Control intervention:  Duration of intervention per patient:  Follow-up per patient: |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Key inclusion criteria:,  Key exclusion criteria: |
| **OUTCOME(S)** | Primary efficacy endpoint:  Key secondary endpoint(s):  Assessment of safety: |
| **STUDY TYPE** | *e.g. randomized / non-randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over* |
| **STATISTICAL ANALYSIS** | Efficacy:  Description of the primary efficacy analysis and population:  Safety: *Please describe the strategy for assessment of safety issues in the study. Which are relevant safety variables?*  Secondary endpoints: |
| **SAMPLE SIZE** | To be assessed for eligibility (n = …)  To be allocated to trial (n = …)  To be analysed (n = …) |
| **TRIAL DURATION** | Time for preparation of the trial (months):  Recruitment period (months):  First patient in to last patient out (months):  Time for data clearance and analysis (months):  Duration of the entire trial (months): |
| **PARTICIPATING CENTERS** | To be involved (n): *if applicable; how many centres will be involved? Please also list the cities.* |

1. The [ARRIVE Guidelines](https://www.nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20ARRIVE%20Guidelines%202013.pdf): Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010 [↑](#footnote-ref-1)