**ERA4Health Joint Transnational Call for Proposals 2023**

**“Research targeting development of innovative therapeutic strategies in cardiovascular disease” (CARDINNOV)**

**Pre-Proposal application form**

**Submission Deadline: February 7th, 2023 (16h CET)**

*All fields must be completed using "Arial font, size 11" characters. Paper format: A4 with all margins minimum 1.27 cm. Please remove instructions in the final application.*

*One joint full proposal document (in English) shall be prepared by the partners of a joint transnational project. All the information requested in this document must be compiled into one single pdf-document and uploaded into the electronic submission system by the coordinator.*

*Please note that incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review. (see Annex I of the call text)*

*Proposals that do not meet the national eligibility criteria may be declined without further review.*

*In case of inconsistency between the information registered in the electronic submission tool and the information included in the PDF of this application form, the information registered in the electronic submission tool shall prevail.*

**Checklist for the Coordinator**

In order to make sure that your proposal will be eligible for this call, please collect the information required to tick all the sections below. Please consult the call text for further details.

* *Topic of the proposal:*

The project proposal addresses the aims of the call.

The project proposal meets the topics in this call.

* *The composition of the consortium:*

The project proposal involves at least 3 eligible project partners requesting funding from at least 3 different countries participating in the call.

The project proposal does not include more than 2 eligible project partners from the same country participating in the call.

The project proposal does not exceed the maximum of 5 project partners (6 or 7 if the consortium includes 1 or 2 partners, respectively, from the following countries Latvia, Lithuania, Romania, Slovakia, Turkey).

Each eligible partner is represented by a single principle investigator.

The coordinator is eligible for funding.

The project proposal does not exceed the maximum of 2 collaborators (self-funded partners) and the letter of intent is included in the joint pre-proposal PDF for each collaborator.

The coordinator and the majority of partners in the consortium are eligible partners (not collaborators).

* **Eligibility of project partners:**

Each project partner involved in the proposal has checked its eligibility to receive funding by its funding organisation (see Annex I of the call text).

All partners should sign the pre-proposal application form and declare they did not receive other public funding to perform the described tasks.

If my consortium includes a partner funded by F.R.S.-FNRS, only pre-clinical studies can be funded for this partner.

If my consortium includes a partner funded by FWO, only pre-clinical studies can be funded for this partner.

If my consortium includes a partner funded by AEI, clinical trials are eligible but only up to phase 1 for this partner.

If my consortium includes a partner funded by FWF, F.R.S.-FNRS, FWO, CSO-MoH, It-MoH, MUR, FCT, CSCJA, or TUBITAK, I made sure that this partner performed the national requirements / sent required information (submission of national documents to its funding organization).

* **National general conditions:**

Please check the national and regional rules applicable to each project partner in the Annex I of the call text.

**A. General Information**

**Project title**

|  |
| --- |
|  |

**Acronym (max. 15 characters)**

|  |
| --- |
|  |

**Project duration (months)**

|  |
| --- |
|  |

**Total project costs (€)\***

|  |
| --- |
|  |

**Total requested budget (€)\***

|  |
| --- |
|  |

\* *this budget should be identical to the one filled in the electronic submission too)*

1. **. Technology Readiness Levels (TRL**)

**TRL at the start of the project**

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| --- |
|  |

**TRL at the end of project**

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|  |

*TRL 1: Review of scientific knowledge base*

*TRL 2: Development of hypotheses and experimental designs*

*TRL 3: Target/candidate identification and characterization of preliminary candidate(s)*

*TRL 4: Candidate optimization and non-GLP (Good Laboratory Practice) in vivo demonstration of activity and efficacy*

*TRL 5: Advanced characterization of candidate and initiation of GMP (Good Manufacturing Practice) process development*

*TRL 6: GMP pilot lot production, IND (Investigational New Drug) submission, and Phase 1 clinical trial(s)*

*TRL 7: Scale-up, initiation of GMP process validation, and phase 2 clinical trial(s)*

*TRL 8: Completion of GMP validation and consistency lot manufacturing, pivotal animal efficacy studies or clinical trials 3, and FDA (Food and Drug Administration) approval or licensure*

*TRL 9: Post-licensure and post-approval activities*

1. **Sub-topic selection** *(please tick the box(es) accordingly)*

Topic 1: Repair and/or regeneration of the heart and/or the blood vessels Yes  No

Topic 2: Chronic heart failure and atrial fibrillation Yes  No

1. **Keywords**

Identify between five and seven keywords that represent the scientific content.

1. **Abstract** (max. 350 words)

**B The consortium**

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

|  |  |
| --- | --- |
| **Family Name, first Name** |  |
| **Name of Institution** |  |
| **Department** |  |
| **Position** |  |
| **Address** |  |
| **City** |  |
| **Country** |  |
| **Type of entity** | University, Hospital, Research Institute, SME, Large Industry, Associations, other |

1. **Research Partners:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Name and Surname of the Principal investigator** | **Institution, Department, full affiliations** | **Type of entity:**  **University, Hospital, Research Institute, SME, Large Industry, Associations, other** |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  | Only possible if there is a partner from Latvia, Lithuania, Romania, Slovakia or Turkey in the consortium |  |  |
| 7 |  | Only possible if there are two partners from Latvia, Lithuania, Romania, Slovakia or, and Turkey in the consortium |  |  |

1. **Collaborators not asking for funding (two maximum):**

*Please remember that each collaborator has to precisely describe the resources that it will dedicate to the project (personnel, material, in kind/in cash…) and the origin of these resources in a letter of intent. The letter of intent has to be signed by the director of the institution (NOT by the researcher himself). The letter has to be included in the compiled PDF of the proposal.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Research Partner (Principal investigator)** | **Institution, Department, full affiliations** | **Type of entity: Academia, Clinical or Public Health, Enterprise, Operational stakeholder** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |

**C. Project description**

1. **Project background** *(max 1 page)*

* Background, current state of the art;
* Description of the knowledge gap, unmet medical/societal need and/or technical or implementation challenge that is addressed by the proposed work;
* Highlight any prior work related to proposal and preliminary results obtained by the consortium.

1. **Description of the aims** *(max 1 page)*.List the main objectives in order of priority

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

Please adapt as necessary.

1. **Relevance of the aims of the call** *(max 1 page)***:**

Describe how the research question(s) of your proposal address the topic(s) of the call

1. **Work plan** *(max 3 pages)*

* Description of the work plan including the objectives, rationale and methodology (power calculation, randomisation, blinding and bias, target groups, approach to responsible research and innovation), highlighting the novelty, originality, and feasibility of the project, expected deliverables, translatability of the proposed research to human health. Use of existing biobanks and existing cohorts should be described when appropriate.
* Clearly defined role and responsibilities and workloads [expressed in person months] of each participating research partner. Comment on how participation and integration of partners in the project is allowed and facilitated. Comment on how the management of the proposal will be achieved.

Please use the following table for detailing the distribution of work in person months (PM) in different work packages (WP) including collaborators (partners not asking for funding). This table should include all the persons working in the project (PI, researchers, technicians, PhD, post-docs). Please adapt as necessary.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** |  |  | **Research Partner** | **WP1 (PM)** | **WP2 (PM)** | **WP3 (PM)** | **WP4 (PM)** | **WP5 (PM)** | **WP6 (PM)** | **WPxx (PM)** | **SUM** |
| 1 |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |  |
| N |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | SUM |  |  |  |  |  |  |  |  |

1. **Work plan and timeline as diagram** *(max 1 page)*

The diagram must demonstrate the work plan, timeline, sequencing of work packages, the contribution of the partners to each work package and their interactions (i.e. Gantt chart, Pert or similar).

1. Expected added value of transnational collaboration and potential for a long-term international network *(max. 1 page)*
2. **Responsible Research and Innovation (RRI) and other cross cutting issues:**
   1. **General RRI aspects** *(max 0,5 page)*

**Responsible research and innovation (RRI)** is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation to ensure a true societal impact.

RRI implies that societal actors (researchers, health care systems, citizens, policy makers, industry, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.

As the involvement of societal groups is essential in RRI it is often connected to co-creation, co-design and co-production – methodologies in which R&I projects are structured to include stakeholders from the outset (e.g. users or interest groups) – and is related to the general Open Science agenda. RRI can also involve interdisciplinarity, with the inclusion of expertise from the social sciences and humanities (SSH). Being inclusive also implies taking diversity seriously.

**Implementation of RRI in ERA4Health:**

Taking an RRI approach implies to take actions that may include to

**a)** Anticipate the future known and unknown risks associated with a science or technology;

**b)** Include a broad range of stakeholders in the development of science and technologies;

**c)** Reflect on the underlying assumptions and values driving a scientific research project; and

**d)** Respond to these processes by incorporating their outcomes into the design of research projects and funding programmes.

RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/user engagement, open science or ethical assessments

Guidelines for RRI:

<https://rri-tools.eu/> - provides numerous resources for practical RRI.

https://thinkingtool.eu/ - The Societal Readiness Thinking Tool guides you through the steps of including RRI in a project.

Explain how the project will demonstrate a commitment to investigating and addressing the social, ethical, political, environmental or cultural dimensions of the proposed research.

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* 1. **Stakeholder Involvement** *(max 0.5 page)*
     + Describe the role and contribution of operational stakeholders (e.g. patient advocacy groups, citizens and/or citizen representatives, local communities, schools, municipalities, local/national NGOS, consumer organisations.)
     + Describe the level of involvement for each stage of the research
     + Explain reasoning behind involving/not involving certain stakeholders
  2. **For projects with high potential of applicability at short/medium term** *(max 0,5 page)*

Expected time for market and transfer to patient towards clinical and public health applications, pharmaceutical/health device applications, other industrial applications including market and end user’s scenario, quality of dissemination, exploitation and business plan.

* 1. **Ethical considerations**

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](https://allea.org/code-of-conduct/) — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).

If research activities are undertaken in a non-European country, the applicants should verify that the research activities will follow the Ethical recommendations of the country where the research will be conducted as well as the EU Ethical recommendations. Full proposals will be checked by an independent ethical board. You can already check [here](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf) the Ethical Issues potentially raised by your proposal.

Yes  No

1. **References** *(max 1 page)*
2. **Scientific justification of requested budget**

* Describe the requested budget. Comment on the 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).

D. Budget

**Financial plan: sum of year 1-3.**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Acronym:** |  | | | | | | | | |
| No. |  | Partner 1 (Project coordinator) | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 | Partner 7 | |
| PI |  |  |  |  |  |  |  |  | |
| Country |  |  |  |  |  |  |  |  | |
| Funding organisation |  |  |  |  |  |  |  |  | |
| Person Months requested |  |  |  |  |  |  |  |  | |
| Person Months In Kind |  |  |  |  |  |  |  |  | |
| Personnel € | Sum requested |  |  |  |  |  |  |  | |
| Total =  Requested + In kind |  |  |  |  |  |  |  | |
| Consumables € | Requested |  |  |  |  |  |  |  | |
| Total =  Requested + In kind |  |  |  |  |  |  |  | |
| Equipment € | Requested |  |  |  |  |  |  |  | |
| Total =  Requested + In kind |  |  |  |  |  |  |  | |
| Subcontracting \*\* | Requested |  |  |  |  |  |  |  | |
| Total =  Requested + In kind |  |  |  |  |  |  |  | |
| Other direct costs €\*\*  (including travels\*\*\*) | Requested |  |  |  |  |  |  |  | |
| Total =  Requested + In kind |  |  |  |  |  |  |  | |
| Overheads €\*\*\*\* |  |  |  |  |  |  |  |  | |
| **Total requested budget €** |  |  |  |  |  |  |  |  | |
| **Total cost of the project** | =  Requested + In kind |  |  |  |  |  |  |  | |
|  | \*\*e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according legal framework and funding body regulations). Check at the respective national funding organisations. | | | | | | | |
|  | \*\*\*Travel expenses should include the participation of the coordinators and/or national partner leaders at an intermediate and/or a final status symposium to present the results of their projects | | | | | | | |
|  | \*\*\*\*Overhead costs: funding according to national legal framework and funding body regulations. Check at the respective national funding organisations in Annex 1 of the call text. | | | | | | | |
|  |  | | | | | | | |

**PLEASE CHECK THAT THE INFORMATION ENTERED IN THE PLATFORM AND IN THE TEMPLATE ARE CONSISTENT**

**E. Annexes**

1. **Brief CV of each Principal Investigator** (max. 1-page DIN-A4, Arial 11, single-spaced, margins of 1.27 cm per Principal Investigator)

Each partner should be represented by a **single** Principal Investigator (co-PI are not accepted). Proposals with extra-CVs will be rejected.

|  |  |
| --- | --- |
| **Personal information** | *First name, last name, academic title*  *Institution and department (complete name)* |
| **Expertise** | Max: 200 words |
| **Role within the consortium** | Please indicate the WP you will be working in. |
| **Publications** | *Please list your five most relevant publications of the last ten years* |
| **Additional information** | *Honors, awards, memberships or references; up to 5 relevant third-party funded projects conducted in the area in the past 5 years* |

***Please add more as required***

1. **Project Collaborators -not applying for funding.** (*max 2 Collaborators in total).*

*Please remember that each collaborator has to precisely describe the resources that he will dedicate to the project (personnel, material, in kind/in cash , …) and the origin of these resources* ***in a letter of intent****. The letter of intent has to be signed by the director of the institution (NOT by the researcher himself). The letter has to be included in the compiled PDF of the proposal.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Name and Surname of the Principal Investigator** | **Institution, Department, full affiliations and email** | **Type of entity: e.g.** **University, Hospital, Research Institute, SME, Large Industry, associations, other** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |

1. **Date and signature of all partners and collaborators**

***General Data Protection Regulation***

*By submitting and signing this application, the applicants consent to the use, processing and retention of their personal data[[1]](#footnote-1), in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) and for the purposes of:*

* *processing and evaluating the application where processing shall be lawful only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;*
* *administering any subsequent funding award;*
* *managing the Funding Organisations relationship with them;*
* *analysing and evaluating the call;*
* *providing aggregate data to national and European surveys and analyses on the funded projects;*
* *and complying with audits that may be initiated by the Funding Organisations and the European Commission (or its agencies).*

*The members of the Call Steering Committee (CSC), i.e. representatives of the funding organisations that fund this JTC, may share applicant’s data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).*

*The members of the CSC may link the data that funding recipients provide in the application with national, bibliographic or external research funding data which are available through public subscription-based databases (e.g. Scopus, Web of Science, etc.) or other national / open datasets.*

*In addition, the applicants declare their willingness to cooperate with the research consortium and they did not receive other public funds to accomplish any tasks described in the project proposal.*

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Full name of partner 1, place, date, signature

I declare my willingness to cooperate with the research consortium

I declare not receive other public funds to perform the described tasks in this application

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Full name of partner 2, place, date, signature

I declare my willingness to cooperate with the research consortium

I declare not receive other public funds to perform the described tasks in this application

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Full name of partner 3, place, date, signature

I declare my willingness to cooperate with the research consortium

I declare not receive other public funds to perform the described tasks in this application

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Full name of partner 4, place, date, signature

I declare my willingness to cooperate with the research consortium

I declare not receive other public funds to perform the described tasks in this application

Full name of collaborator 1, place, date, signature

I declare my willingness to cooperate with the research consortium

***Please adapt according to the composition of your consortium. Each partner (eligible partner and collaborator) has to sign. Electronic or scanned signature possible***.

1. Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of projects, pre-proposals, project proposals (scientific document, administrative and financial appendix). [↑](#footnote-ref-1)