Joint Transnational Call for Investigator-Initiated Clinical Studies

(JTC IICS) – 2025

“Fostering Pragmatic Comparative-Effectiveness Trials

in Non-communicable Diseases” (EffecTrial)

**Pre-proposal application form**

**Submission Deadline: 28th January, 2025 (16:00 h 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.*

*The clinical study plan must not exceed* ***10 pages****; this* *includes from section 1 to 8: synopsis, abstract, footnotes, illustrations, formulas, tables (and, if applicable, the table of contents), but not the bibliography and the budget table.*

*-* *No additional annexes are permissible,* *apart from the ones that are specifically mentioned in this pre-proposal application form (Annex 1 and Annex 2 +).*

*- Please remove instructions in the final application.*

*- Make sure that pages are numbered.*

*One joint pre-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.***

***Proposals with missing signatures from partners or collaborators will be rejected.***

*Proposals that do not meet the national eligibility criteria may be declined without further review (see Annex I of the call text).*

*In case of inconsistency between the information registered in the electronic submission tool (PT-Outline) 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**

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.

* **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. In addition, collaborators should sign the pre-proposal application form, providing a statement that they can secure their own funding.

[ ] Proposals that include a partner applying for funding from BMBF/DLR (Germany) are only eligible if the comparison includes the use of at least one nutrition and/or lifestyle intervention (see Annex I of the call text).

* **National general conditions:**

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

1. **GENERAL INFORMATION**

**Project title**

|  |
| --- |
| *Insert a descriptive title identifying the study design, population and interventions (Maximum 180 characters, incl. spaces).* |

**Acronym (max. 15 characters)**

|  |
| --- |
|  |

**Project duration (months)**

|  |
| --- |
|  |

**Requested budget (to national/regional funding organisations) (€)\***

|  |
| --- |
|  |

*\* Requested budget does not include the additional budget for management costs. This must refer to the sum of each partner´s requested budget.*

**Management budget (If applicable)** **(€)\***

|  |
| --- |
|  |

*\*Additional budget for management costs for the whole consortium (cross-cutting activities) as specified in Section 10.2 Up to 15% of the requested budget (budget of the collaborators is excluded)*

**In-Kind costs (€)\***

|  |
| --- |
|  |

*\*Costs provided by the partners and collaborator’s own funds (e.g. Personnel cost for a researcher with a permanent position, etc)*

**Total Budget (Requested + Additional management budget + In-Kind) (€)\***

|  |
| --- |
|  |

*All these budgets should be identical to the ones entered in the PT-Outline electronic submission tool.*

**Keywords**

*Identify five keywords that represent the scientific content of your proposal.*

**Scientific Abstract**

*(max. 2 000 characters)*

1. **CONSORTIUM**

##  Consortium Coordinating investigator (Partner 1):

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

## Sponsor/Sponsor representative:

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

##  Research Partners (Please add the partners in the same order as in the submission tool PT-Outline):

*List of the research partners that request budget to their respective national/regional funding organisations. This list of research Partners needs to be added in the submission tool* ***PT-Outline.*** *If there are partners eligible by a funding organisation, which will fund several partners for this country/region in the consortium, the consortium can be composed with a maximum of 3 (three) partners eligible by this funding organisation. These partners shall be specified in this table of research partners**, expand the table if needed. Respect the maximum countries per consortium as specified in the call text document.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **City, Country** | **Name and Surname of the Principal investigator** | **Institution, Department, full affiliations** | **Type of entity:****University, Hospital, Research Institute, SME, Associations, other** |
| 1 |  |  |  |  |
| 2 |   |   |   |  |
| 3 |   |   |   |  |
| 4 |   |   |   |  |
| 5 |  |  |  |  |
| X |  |  |  |  |

## Additional recruiting sites per partner (Please add the additional recruiting sites in the same order as in the submission tool PT-Outline):

*Inclusion of additional national/regional recruiting sites associated to each partner of the consortia.* *This list of additional recruiting sites per partner needs to be added in the submission tool* ***Pt-Outline****. If a partner is eligible by a funding organisation which will only grant a single partner, only one partner should be part of the consortium and this single partner shall be reflected in the above table of Research partners (Point 1). This partner will have the opportunity to establish a collaboration agreement with other national recruiting sites (eligible by the same funding organisation) and allocate a budget to the recruitment sites. These recruitment sites will be associated partners (as defined in call text). Please list them in the table below. The number of additional national/regional recruiting sites can be expanded if needed.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Partner****(Principal Recruiting Site)** ***(Name of organisation, city)*** | **Country** | **Additional national/regional Recruiting Site 1*****(Name of organisation, city)*** | **Additional national/regional Recruiting Site 2****(Name of organisation, city** | **Additional national/regional Recruiting Site 3****(Name of organisation, city** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |   |   |  |  |  |
| 4 |   |   |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |
| 7 |  |  |  |  |  |

## Collaborators not asking for funding (three maximum):

The collaborators have to be listed in PT-Outline. *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). 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, Patient organisation**  | **Type of contribution to the consortia** |
| 1 |   |   |   |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |

1. **PROJECT DESCRIPTION**
2. **Project background** *(max 1 page)*
* Background, evidence supporting the objective of the trial (current state of the art, systematic literature search carried out, databases searched, studies that have been conducted, relevance of their results);
* Description of the unmet medical, societal and public health need, knowledge gap, 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. **Hypothesis and objectives***(max ½ page)*.
* Describe the hypotheses and specific objectives. Please differentiate between primary and secondary objective(s).
1. **Relevance of the aims of the call** *(max 1 page)***:**
* Describe the relevance of your proposal for clinical practice and the healthcare system,
* 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 methodology, highlighting the novelty, originality, and feasibility of the project. Use of existing biobanks, existing cohorts and metadata repositories should be described when appropriate. Participation/engagement with end-users such as patients, industry, clinicians must be described and justified if there is no participation. Describe how this participation will shape decision making within the project. Comment on how participation and integration of partners in the project is facilitated.
* Study design and feasibility of the project. Please describe and justify the appropriateness of the selected design and suitability of methodological approach. Add information on inclusion / exclusion criteria, outcome measures and proposed strategy of statistical analysis. Provide a schematic diagram that describes the trial design, interventions/ observations and procedures. Please see below, as reference, the CONSORT example for interventional trials.



* 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 facilitated. Comment on how the management of the trial will be achieved.
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 (including collaborators) 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 trial network** *(max. 1 page)*
* Definition of the expected added value of transnational collaboration that can be provided by the consortia and description of further possibility for establishing an international trial network that can operate in a long-term framework.
1. **Quality of the research team (expertise in relation to the project, expertise in multicentric clinical studies, experience with multinational collaboration)***(max. 1 page)*
* Justification of the suitability of the clinicians, involved partners and clinical trial sites, considering the nature of the intervention and/or the use of the investigational medicinal product, the suitability of the facilities, equipment, human resources and a description of specialized knowledge, description of how their previous clinical trials were registered and how the results were published, how the transparency requirement were fulfilled in previous clinical research conducted.
1. **Responsible Research and Innovation (RRI) and other cross cutting issues** *(max. 1,5 page)*
* ERA4Health has developed RRI Guidelines to support you in your RRI work, you will find them in the Guidelines for applicants in the “ERA4Health Responsible Research and Innovation (RRI) Guidelines” section.
	1. **Overview of RRI**
* In straightforward terms, please provide a brief overview of the relevant social, political, environmental, equity or cultural dimensions of the proposed clinical study. What might the potential positive or negative impacts on public health and health systems be? You may use tools such as the AIRR framework (Anticipation, Inclusion, Reflection, Responsiveness) to assist you.
* Detail how you have designed the project to enable consideration of, and responsiveness to, these issues throughout its implementation.
* Outline what resources and person-time will be allocated to RRI activities.
	1. **Stakeholder Involvement**
* Describe the role and contribution of operational stakeholders to ensure socio-economic and health impact for patients and for clinical practice (e.g. patient advocacy groups, caregivers, health care providers.)
* Describe the level of involvement for each stage of the research and the reasoning behind involving/not involving certain stakeholders
* Explain how stakeholders will shape decision making in your project. If they will not, explain why that is the case.
	1. **Patient Involvement**
* Describe the level of involvement and participation of patients in the planning, execution of the study as well as the dissemination of the results of the IICS.
	1. **Ethical considerations**

Does your proposal comply 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).

Yes ☐ No ☐

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 recommended for funding 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.

1. **References** *(max 1 page)*

This list should only contain the works you cited. Please include DOI/URL if available.

1. **Requested budget**

### 10.1. Requested budget to national/regional funding organisations

Add one table for each partner of your consortium

|  |  |
| --- | --- |
| N° of the Partner |   |
| PI  |   |
| Country  |   |
| Funding organisation |  |
|   |  PM/Costs  | Tasks attributed to the budget  |
| Person Months requested    |    |     |
| Person Months In Kind\*   |    |    |
| Personnel €   | 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 €\*\*\*\*   | Requested   |    |
| **Total requested budget €**   | Requested   |    |
| **Total costs: Requested + In-kind budget €**   | Total =  Requested + In kind  |    |

\*In kind: budget not requested to a participating funding organisation but on your own funds (e.g. Personnel cost for a researcher with a permanent position; depending on the funding organisation rules (see Annex I of the call text))

\*\*e.g. services providers supported at the national/regional level, the main budget for the service provider should be requested below. Here the costs could include monitoring, insurance at the national/regional level.

\*\*\* Publications, travel expenses should include the participation of the coordinators and/or the PIs of the other partners in the consortia 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. Allocation of In-kind overheads is not allowed.

### 10.2 Additional Budget for management costs for the whole consortium (cross-cutting activities)

Only if ECRIN (or an entity subcontracted directly by ECRIN in the case that ECRIN is not able to provide the service) is selected as service provider for the cross-cutting activities of the research consortium, there is the possibility to include this additional budget to the requested budget to the national/regional funding organisations. In that case, the maximum that could be requested is up to 15% of the **total requested budget for all partners (budget of the collaborators is excluded).** Those costs should not overlap with the cost already requested to national/regional funding organisations. Examples of cross-cutting activities: overall project management, regulatory submission, data management and statistics, safety or monitoring.

|  |  |
| --- | --- |
| Total requested budget for all partners to the national/regional funding organisations (in €) |   |
| Budget available for Management costs (i.e. 15% of the sum mentioned above, in €) |   |
| Type of cross-cutting activities to be covered with this budget |  |

### 11. Budget provided by the collaborators

Add one table for each collaborator of your consortium

|  |  |  |
| --- | --- | --- |
| **No. of the collaborator** | **PM/Costs** | **Tasks attributed to the budget** |
| PI  |   |    |
| Country  |   |   |
| Person Months In Kind\*  |   |   |
| Resources dedicated to the project In Kind\* |  |  |
| **Total cost of the project**  |  |   |

\*In kind: costs provided by the collaborator’s own funds

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

**Annexes**

**Annex 1. General information of each Principal Investigator**

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

Each partner/collaborator 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 on clinical trials of the last ten years (please include information on trial ID in register)* |
| **Additional information** | *Honors, awards, memberships or references; up to 5 relevant previous participation in other clinical studies in the past 5 years, which roles they assumed, GCP training.* |

***Please add more as required***

**Annex 2. General information of Recruiting Sites and Collaborators and signatures**

1. **Description of recruiting sites**

*This is addressed to the justification of the suitability of the clinical trial site, considering the nature and use of the investigational medicinal product (if applicable), the suitability of the facilities, equipment, human resources, description of specialized knowledge include number of studies that will be run at the same time.*

|  |  |
| --- | --- |
| **Partner**  |  |
| **Recruiting site Name (include site name as in section B-4)** |  |
| **Department** |   |
| **Address** |   |
| **City** |   |
| **Country** |  |
| **Type of entity** |  |
| **Contact person** |  |
| **Justification of the suitability of the clinical trial site** *(facilities, equipment, human resources, specialized knowledge, etc)* |  |
| **Number of studies running at the same time** |  |

***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/she 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*

1. *Letter of intent of the collaborator 1: NAME OF ITS ORGANISATION:*
2. *Letter of intent of the collaborator 2: NAME OF ITS ORGANISATION:*

**Proposals containing letters of support (from patient associations, stakeholders or other type of entities) will be rejected. Only a letter of intent from the organisation of each collaborator are requested (if applicable)**

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*

---------------------------------------------------------------------

Full name of partner 1, place, date, signature of PI

[ ]  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 partner 2, place, date, signature of PI

[ ]  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 partner 3, place, date, signature of PI

[ ]  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 partner 4, place, date, signature of PI

[ ]  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 of PI

[ ]  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)