Co-funded by the European Union

THCS Guidance for applicants

"HEALTHCARE OF THE FUTURE"

Purpose of this document

This document is there to inform applicants on the aspects of the submission process. In this guidance you find a couple of documents:

- The *How to apply to THCS call 2023* provides a brief overview of all the important steps in the process of applying for funding. Read this to inform yourself about the important steps in the application process.
- The *Intent to apply template* provides insight in which information requested in the intent to apply. It has to be filled in by the project coordinator via the online submission tool.
- The *proposal template* provides in insight on all the elements that need to be answered in the application. It has to be filled in by the project coordinator via the online submission tool.
- The C*hecklist for interventional studies* is only relevant in case you are planning to perform an interventional study. In the checklist you find an overview of important elements that you need to consider when writing a proposal for such a study.

Table of Content

How to apply to THCS Call 2023?

1. Read the call text.

In the call text all the ins and outs of this call for proposals are described. Amongst others you find the information on the following aspects:

- Aim of the call
- The expected outcomes
- Scope of the call
- General conditions for participation
- What other countries and funding organisations take part in the call
- How to apply
- How the proposals will be evaluated.
- A timeline

2. Find your project partners

In order to find project partners you can make use of the Partner search tool. Go to the tool: Click here

3. Read the national or regional eligibility criteria

Make sure that project partners meet their national or regional eligibility criteria. These criteria can be found in the call text (Annex I).

In case you have any questions about the national/regional eligibility criteria, please contact your national contact person. Contact details can found in Annex I of the call text.

4. Submit the Intent to Apply

Each consortium has to express their interest in this call. Submitting the Intent to Apply form is mandatory. The project coordinator must submit the Intent to Apply in the online submission tool on the THCS website. Without the Intent to Apply, submitting a proposal is not possible. To see what the Intent to Apply form contains, please check section 2 in this guidance for applicants.

The deadline for submitting the Intent to Apply form is **May 23rd 2023, 14.00 CET**.

5. Write your proposal and submit it in time.

In the online submission platform on the THCS website you can fill the different elements of the proposal template, it can be saved in between. We advise you to start early. All submissions need to be written in English. To see what the proposal form contains, please check section 3 in this guidance for applicants.

The deadline for submitting your proposal is Tuesday **June 13 2023, 14.00 CET.**

6. Evaluation procedure

Over the summer period different reviewers will evaluate the proposals based on the evaluation criteria. Each proposal will be reviewed by three reviewers, they will score and write comments utilising the evaluation criteria as shared in the call text.

7. Rebuttal stage

Between **29 August – 6 September, 2023** the project leader must be available to respond to possible questions and comments of the reviewers. Project coordinators will receive an email from the THCS Call secretariat if their proposal scores above the threshold. Project coordinators get one week to send in a response.

8. Nomination for funding

Based on the assessments a ranking list will be established at the panel meeting. The result of the meeting is expected in October 2023 and will be communicated with the project coordinators by email.

9. Start of project

Funded projects are expected to start late 2023 or early 2024.

Co-funded by the European Union

Transforming Health and Care Systems Partnership

Joint Transnational Call 2023

"HEALTHCARE OF THE FUTURE"

Intent to Apply form

Submission deadline for obligatory "Intent to Apply": 23 May 2023, 14:00 CET

Submission deadline for proposals: 13 June 2023, 14:00 CET

Electronic proposal submission

For further information, visit our website:

http://www.thcspartnership.eu

or contact the

THCS Joint Call Secretariat:

THCS@zonmw.nl

Important notice

- The Intent to Apply is restricted for the needs of the Joint Call Secretariat and involved funding agencies only.
- The Intent to Apply aims to provide the Joint Call Secretariat with information on potential proposals that will be submitted. These details will allow the Joint Call Secretariat to adjust the composition of the peer-review panel responsible for the evaluation, ensuring proposals receive a proper and adequate expertise.
- The Joint Call Secretariat may provide guidance to the coordinator on the composition of the consortium. However, the Joint Call Secretariat will not provide feedbacks on the content of the Intent to Apply.
- The Intent to Apply is mandatory but will not be evaluated and will not be taken into consideration for establishing the final ranking list and the selection decision.
- **The Intent to Apply must be completed in the online submission system. All fields must be completed.**
- **The Intent to Apply must submitted via the online submission system.**

Checklist for the Coordinator

I declare to have the explicit consent of all applicants on their participation and on the content of this Intent to Apply.

A. General Information

Acronym (max. 15 characters, including spaces)

Project title (maximum 255 characters, including spaces)

Project duration (months, max. 36)

Keywords

Please indicate five to seven keywords that represent the scientific content and the methodological approach

Aim of the call addressed by the proposal

Please tick the appropriate box to specify which of the two aims of the call for proposals your application is addressing

☐ Aim 1: to provide the necessary knowledge to build the health and care of the future.
☐ Aim 2: to support the implementation of innovative solutions on a larger scale.

Research areas addressed by the proposal

Please tick the appropriate box(es) to specify which of the research areas relevant to the call your application is addressing. More than one option can be selected.

☐ Health Policy and Systems Research (HPSR)
☐ Health Technology Research (HTR)
☐ Social and economic research

Contribution of the proposal to the expected outcomes of the call

Please tick the appropriate box(es) to specify which of the expected outcomes of the call your application is contributing. More than one option can be selected.

- ☐ Citizens and patients are better informed and engaged and have access to more distributed, community-based health and care facilities that better support their needs. This will include new/adapted sustainable concepts of care, prevention models, personalised approaches in prevention and care on different intervention areas to be translated in different contexts.
- ☐ Primary care and community-based health and care services are better equipped with integrated and cost-effective intervention tools to help prevent, monitor and manage age-related diseases, conditions and disabilities, while promoting healthy lifestyles.
- ☐ Health and care providers and professionals are engaged and have access to validated customized and largely adopted solutions for health and care delivery supporting continuity of care and integration of the different settings.
- ☐ Health and care authorities and policy makers and other stakeholders involved in the decision-making processes have access to evidence-based strategies and learn from good practices supporting the transformation towards people-centred services and the optimisation the delivery of health and care services across different settings.

Proposal classification

Please tick the appropriate boxes to specify the category of your application. E.g. if your category is applied research tick Research + Applied. Multiple choices are possible

- ☐ Research
  - ☐ *Basic*
  - ☐ *Translational*
  - ☐ *Applied*
  - ☐ *Implementation*
- ☐ Demonstrator projects
  - ☐ *Proof of concept*
  - ☐ *Validation of concept*

Project abstract (maximum 4,000 characters including spaces, equivalent to about one A4 page)

Please give a comprehensive and readable summary of the primary aims and methods of the project (why the research is being suggested, what you aim to achieve, how this may impact on the rest of the research community and society).

B. Project consortium

1. Project coordinator (= Partner 1)

Please note that organisations which label themselves as end-user organisations must fit into the definition as provided by the THCS program (see the Call Text). This will have to be reflected in the description of the partner, in the work plan and in the dissemination activities.

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutions or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: ……
Address	
Postal Code	
City	
Country	
Website	
Envisaged Funding agency/organisation	*Please select from the drop-down list*

Principal investigator (main contact)

Last Name	
First Name	
Gender	❑ F (Female) ❑ M (Male) ❑ X (Non-binary)
Title	
E-mail	

2. Project partners applying for funding (min. 3 - max. 9 in total, including coordinator)

Please note that organisations which label themselves as end-user organisations must fit into the definition as provided by the THCS program (see the Call Text). This will have to be reflected in the description of the partner, in the work plan and in the dissemination activities.

Partners 2 to 9 (to be duplicated for each separate project partner)

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutions or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: ……
Address	
Postal Code	
City	
Country	
Website	
Envisaged Funding agency/organisation	*Please select from the drop-down list*

3. Project Collaborators - not applying for funding (max 2 collaborators in total)

Please remember that each collaborator will have to precisely describe in the proposal the resources that he/she will dedicate to the project (personnel, material, in kind/in cash , …) and the origin of these resources.

Project collaborator 1 (to be duplicated if needed)

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutions or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: ……
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Transforming Health and Care Systems Partnership

Joint Transnational Call 2023

"HEALTHCARE OF THE FUTURE"

Proposal application form

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Electronic proposal submission

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THCS Joint Call Secretariat:

THCS@zonmw.nl

Important notice

- The Proposal is composed by six sections (from A to F).
- Sections A to E must be completed in the online submission system
- The Annexes indicated in Section F of the Proposal Application Form must be uploaded a separate pdf files in the online submission system.
- All fields must be completed.
- The Proposal must submitted via the online submission system.

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 sections below. Please consult the call text for further details. All boxes must be ticked to allow the submission of the proposal.

General conditions:

☐ All applicants provded their consent on their participation in the priject proposal and on its contents.

☐ The project proposal do not
- aim at human cloning for reproductive purposes;
- intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
- lead to the destruction of human embryos (for example, for obtaining stem cells)

These activities are excluded from funding.

Composition of the consortium:

☐ At least 3 eligible partners from at least 3 different countries from which funding agencies are participating in the call.

☐ Maximum number of 9 eligible partners.

☐ Maximum amount of 3 eligible partners from the same country. Please note that for some countries, only 1 eligible partner from this country is allowed (see annex I of the call text).

☐ Maximum amount of 2 collaborators

☐ The coordinator and all 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 from its funding organisation (see annex I of the call text).

☐ Each project partner involved has read carefully and followed the instructions and rules given by the national/regional funding organisation in annex I of the call text, e.g. to submit additional documents to the respective funding organisation if required

☐ All partners declare they did not receive other public funding to perform the described tasks.

A. General Information

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Proposal classification
Please tick the appropriate boxes to specify the category of your application. E.g. if your category is applied research tick Research + Applied. Multiple choices are possible

- ☐ Research
  - ☐ *Basic*
  - ☐ *Translational*
  - ☐ *Applied*
  - ☐ *Implementation*
- ☐ Demonstrator projects
  - ☐ *Proof of concept*
  - ☐ *Validation of concept*

Project abstract (maximum 4,000 characters including spaces, equivalent to about one A4 page)
Please give a comprehensive and readable summary of the primary aims and methods of the project (why the research is being suggested, what you aim to achieve, how this may impact on the rest of the research community and society).
Please note that if your proposal is selected for funding this abstract could be used for communication purposes by THCS or national funding agencies. Please use short, clear sentences broken up into paragraphs for readability, and avoid complex grammatical structures.

B. Project consortium

Please use this numbering in all parts of your proposal

1. Project coordinator (= partner 1)

Please note that organisations which label themselves as end-user organisations must fit into the definition as provided by the THCS program (see the Call Text). This will have to be reflected in the description of the partner, in the work plan and in the dissemination activities.

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutes or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: .....
Website	
Address	
Postal Code	
City	
Country	
VAT number	
Envisaged Funding agency/organisation	*Please select from the drop-down list*
PIC number	If you want to participate in a project proposal, your organisation need to be registered and have a 9-digit Participat Identification Code (PIC). Please fdin details below: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
NACE code	Please find details here https://nacev2.com/en

Principal investigator (main contact)

Last Name	
First Name	
Gender	❑ F (Female) ❑ M (Male) ❑ X (Non-binary)
Title	
E-mail	

Department

Full name	[max 200 characters] If not applicable, write “Not applicable”
Address	
Postal Code	
City	
Country	

2. Project partners applying for funding (min. 3 - max. 9 in total, including coordinator)

Please note that organisations which label themselves as end-user organisations must fit into the definition as provided by the THCS program (see the Call Text). This will have to be reflected in the description of the partner, in the work plan and in the dissemination activities.

Partner 2

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutions or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: .....
Website	
Address	
Postal Code	

City	
Country	
VAT number	
Envisaged Funding agency/organisation	*Please select from the drop-down list*
PIC number	If you want to participate in a project proposal, your organisation need to be registered and have a 9-digit Participant Identification Code (PIC). Please find details below: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
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Principal investigator (main contact)

Last Name	
First Name	
Gender	❑ F (Female) ❑ M (Male) ❑ X (Non-binary)
Title	
E-mail	

Department

Full name	[max 200 characters] If not applicable, write "Not applicable"
Address	
Postal Code	
City	
Country	

3. Project Collaborators - not applying for funding (max 2 collaborators in total)

Please note that organisations which label themselves as end-user organisations must fit into the definition as provided by the THCS program (see the Call Text). This will have to be reflected in the description of the partner, in the work plan and in the dissemination activities.
Please remember that each collaborator will have to precisely describe in the proposal the resources that he/she will dedicate to the project (personnel, material, in kind/in cash , …) and the origin of these resources.

Project collaborator 1 (replicate if needed)

Organisation

Legal name	
Short Name	
Type of partner	❑ Academia (research teams working in universities, other higher education institutions or research institutes) ❑ Healthcare and/or social welfare service provider ❑ Small or medium enterprises ❑ Large companies ❑ Patient organisations ❑ Non-profit private partner (for instance NGO's) ❑ Other, please specify: .....
Website	
Address	
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Country	
VAT number	
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NACE code	Please find details here https://nacev2.com/en

Principal investigator (main contact)

Last Name	
First Name	
Gender	❑ F (Female) ❑ M (Male) ❑ X (Non-binary)
Title	
E-mail	

Department

Full name	[max 200 characters] If not applicable, write “Not applicable”
Address	
Postal Code	
City	
Country	

4. Researchers involved in the proposal

The following fields of the table, must be chosen from the following options:

TITLE (Dr. / Prof. /Ms. /Mrs./ Mr.)

GENDER (Woman=F / Man=M / Non-binary=X)

CAREER STAGE (as defined in Frascati 2015 Manual):

- Category A Top grade officer/researcher: the single highest grade/post at which management/research is normally conducted. Example: Director/Head of Unit/Full professor or Director of research.
- Category B Senior officer/researcher: Managers/Researchers working in positions not as senior as top position but more senior than newly qualified doctoral graduates (IsCED level 8). Examples: Programme Managers, associate professor or senior researcher or principal investigator.
- Category C Recognised officer/researcher: the first grade/post into which a newly qualified doctoral graduate would normally be recruited. Examples: Project Manager, assistant professor, investigator or post-doctoral fellow.
- Category D First stage officer/researcher: Either training contracts or doctoral students at the IsCED level 8 who are engaged as junior project managers, researchers, or researchers working in posts that do not normally require a doctorate degree. Examples: junior training contracts, PhD students or junior researchers (without a PhD).

TYPE OF IDENTIFIER:

- Google Scholar
- Orcid ID
- Researcher ID
- Scopus researcher ID
- Other ID: please specify

Organisation short name	Title	First name	Last name	Gender	Nationality	Email	Career stage	Contribution in the project	Role in the ptoject	Contract duration	Reference identifier	Type of identifier
				M F X			A B C D	High Medium Low	Leading PhD candidate Team Member	Short Long		Google Scholar; ORCID; Researcher Id; SCOPUS Id: Other (specifiy)

C. Project description

Please note

- This template must be used to write the proposal for submission to call 1-2023 *Healthcare of the future* of the European Partnership on Transforming Health and Care Systems.
- The proposed research and/or innovation should be presented clearly, using language understandable to individuals with a general scientific understanding of the field. Please note that the referees in the panel where your application is reviewed do not necessarily work in precisely the same area as you.
- The template is designed to address all the elements of the assessment criteria. **The applicant is strongly advised to read the assessment criteria and the call text carefully.**

1. Excellence

1.1 Relevance and scope (maximum 2,000 characters including spaces, equivalent to about half an A4 page)

Describe how and why the proposed project is relevant to the aims and scope of the call

1.2 Background, current state-of-the-art in the research field, knowledge needs and preliminary results obtained by the consortium members (maximum 8,000 characters including spaces, equivalent to about two A4 pages)

- *Describe the need for your project. Which challenge(s) are you going to tackle with your project?*
- *Summarise the state of the art of the research and innovation area/field the project aims to contribute to and describe the knowledge needs and challenges that justify the initiation of this project.*
- *Describe the Health and Care systems necessity(ies) covered by the project.*
- *Describe the preliminary results obtained by the consortium members.*

1.3 Project objectives (maximum 3000 characters including spaces, equivalent to about ¾ of an A4 page)

State the overall project objectives and aims in the context of the state of the art and knowledge needs.

1.4 Research and innovation questions (maximum 3,000 characters including spaces, equivalent to about ¾ of an A4 page)

Describe in more detail the research and/or innovation questions and/or hypotheses.

1.5 Methodology and approach (maximum 8,000 characters including spaces, equivalent to about two A4 pages)

Make sure that the theoretical approach and/or choice of methods is well accounted for and described in detail, and that it is clear how the methods are adequate for addressing the research and/or innovation questions, hypotheses, and project objectives.

- *Describe thoroughly the approach chosen to address the project objectives, research questions/innovation idea(s). In particular, describe how relevant stakeholders/users are integrated in to the project and, if relevant, specify why an interdisciplinary approach has been chosen.*
- *Describe thoroughly the methodology chosen to address the project objectives, research questions/innovation idea(s). In particular indicate the methods of data collection (Indicate the data that will be collected, the tools used), the statistic plan (calculation of statistical data), the statistical analysis and the timing of data analysis.*
- *Describe how gender perspectives will be taken into account in the research and/or innovation content.*
- *Describe the role of social sciences and humanities in the project or provide a justification if you consider that these disciplines are not relevant to your proposed project.*

2. Impact

2.1 Significance and innovation (maximum 8,000 characters including spaces, equivalent to about two A4 pages)

Make sure you clearly highlight the added value of transnational collaboration and the project's relevance in relation to the impact on the transformation of health and care systems.

- *Describe how the proposed project contributes to the objectives of THCS partnership.*
- *Describe the translational relevance of the proposal, and in particular what is already known about this topic and what the proposed research would add.*
- *Describe the novelty of the proposal in translating innovation into health and care systems.*

2.2 Expected impacts of the proposed research and/or innovation (maximum 8,000 characters including spaces, equivalent to about two A4 pages)

The description of the potential impact should be project specific and related to the planned research and/ or innovation. General elaborations on the benefits of research and/or innovation in a wider context should be avoided.

- *Building on the description of knowledge needs and challenges in section 1, describe why and how the project outcomes, if successful, have the potential to meet the challenge(s) described in the call text.*
- *Building on the description of project objectives and novelty in chapter 1, describe clearly why and how the project outcomes may address important present and/or future (scientific) challenges and have an impact on the research and/or innovation area/field, if successful.*
- *Describe the expected impacts of your project (For example: societal, economic, scientific, policy, etc).*
- *Describe why and how the project output will create value for the public sector and/or civil society and/or the industry. Describe how your project will affect people's health and/or care in practice.*
- *Describe how new knowledge and project outputs have the potential to address one or more of the UN sustainable development goals. (https://www.un.org/sustainabledevelopment/)*
- *When do you expect the results of this projects to be ready for use in daily practice? Please explain.*

2.3 Measures for impact maximisation

a. Stakeholder Involvement (maximum 4,000 characters including spaces, equivalent to about one A4 page)

- *Describe the role and contribution of operational stakeholders (e.g. citizens and/or citizen representatives, local communities, hospitals, municipalities, local/national NGOs, consumer organisations)*
- *Describe the level of involvement of stakeholders for each stage of the project*
- *Explain reasoning behind involving/not involving certain stakeholders*
- *Describe the impact of your project on the different involved stakeholders*

b. Open Science, data management and data sharing (maximum 3,000 characters including spaces, equivalent to about ¾ of an A4 page)

Develop a data management strategy. Take into account the FAIR data management principles. Include a description of how the data gathered through the project will be available to the wider research community and the sustainability of the research results within the wider research community.

c. Exploitation and dissemination of expected results (maximum 4,000 characters including spaces, equivalent to about one A4 page)

- *Describe the target audience and stakeholders/users of the project outputs;*
- *Describe the measures of the consortium to exploit, disseminate and communicate the expected project results;*
- *Outline the scope and plan for dissemination, communication and engagement activities;*
- *Describe how the stakeholders/users are involved in the dissemination and utilisation of the project results;*
- *Describe pathways of transfer into practice, e.g. translation of the results into policy recommendations or actions;*
- *Describe arrangements between participating partners regarding IPR, if applicable.*

3. Implementation

3.1 Work Plan

Overall structure

Provide a brief description of the overall structure of the work plan (list of work packages).
A maximum of ten work packages is allowed.

WP no.	WP title	Lead part. nº	Lead part. short name	Person months	Start Month	End month
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
TOTAL						

Timeline and milestones (maximum 2,000 characters including spaces, equivalent to about half an A4 page).
This section should include a graphic representation of the project time plan and the milestones (Gantt chart).

Diagram which compiles the work plan, the contribution of the partners to each work package and their interactions (Pert diagram).
Please note that Pert diagram and Gantt chart (see previous section) must be assembled and uploaded in a single PDF document.

3.2 Work Packages and activities
For each Work Package describe its objectives, the allocation of tasks to the project team members, linking the tasks to specific work packages **(maximum 2,000 characters including spaces per each Work Package, equivalent to about half an A4 page).**

WP1

WP2

WP3 (to be duplicated as required)

3.3 Describe the organisation and management structure, i.e. the project governance (maximum 2,000 characters including spaces, equivalent to about half an A4 page).

3.4 Added value of the collaboration in the proposed transnational project (maximum 4,000 characters including spaces, equivalent to about one A4 page).
This section should describe the quality of the transnational research consortium, illustrating:

a. *the level of expertise of the project coordinator and the individual partner research teams in the field(s) of the proposal (team scientific track record, publications, patents, etc.) to complement the information in the CVs.*
b. *the quality of the collaboration among the research teams and added value of the research consortium with respect to the individual teams. In particular, describe the consortium, the partners (including collaborating organisations), their role and complementarity in the context of the proposed project. If partners cover their own costs- please indicate that.*
c. *the expected added value of collaboration on scientific and transnational level – sharing of resources, data, know-how etc.*

3.5 Outside resources, if applicable (maximum 2,000 characters including spaces, equivalent to about half an A4 page).

If you do not have all skills/resources in-house, describe the reasons and how you intend to get them (contributions of members, partner organisations, subcontracting, etc.). If there is subcontracting, please also complete the information in section 4 (Budget).
Please note that core tasks of the Project cannot be subcontracted.

3.6 Critical risks for implementation (maximum 4,000 characters including spaces, equivalent to about one A4 page).

- *Describe possible risks that might endanger achieving the objectives by indicating for each of them the level of likelihood and severity.*
- *Describe how these risks will be managed and in particular the proposed risk mitigation measures.*

D. Financial Plan

Please note that:

- *All categories of the costs may not be eligible for all countries (it will be handled according to national regulations (see call text Annex 1 and/or contact the relevant regional/national funding organisation). Please ensure you adhere to any specific national rules.*
- *In addition, specification of co-funding from other sources necessary for the project as well as secured funding of additional collaborators of the consortium should be explained here, if applicable.*
- Thousand separators and whole numbers should be used only (e.g. 200.000).

IMPORTANT NOTICE

- Travel and subsistence costs: 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
- Other direct costs: please note that 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.
- Indirect costs (Overhead): funded according to national legal framework and funding body regulations. Check at the respective national funding organisations in Annex 1 of the call text.

Overview of the project financial plan (in €)

Cost categories	TOTAL	Partner 1 (Project coordinator)	Partner 2	Partner 3	Partner 4	Partner 5	Partner …	Partner 9	Collaborator 1	Collaborator 2
Personnel €	Requested									
	Total = Requested + In kind									
Consumables €	Requested									
	Total = Requested + In kind									
Equipment €	Requested									
	Total = Requested + In kind									
Travel and subsistence €	Requested									
	Total = Requested + In kind									
Other direct costs	Requested									
	Total = Requested + In kind									
Indirect costs (Overhead) €										
Total requested budget €										
Total cost of the project	= Requested + In kind									

Detailed financial plan per partner (in €)

Each partner who requests funding as well as each collaborator has to fill in the following budgetary table. Please justify each of the budget items with a short description in the right column. You can use the examples and instructions that are given in purple.

IMPORTANT NOTICE

- Travel and subsistence costs: 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
- Other direct costs: please note that 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.
- Indirect costs (Overhead): funded according to national legal framework and funding body regulations. Check at the respective national funding organisations in Annex 1 of the call text.

Duplicate for all consortium partners

	Partner 1 (Coordinator)/SHORT NAME		
Cost category	**Requested Amount (€)**	**Own contribution in-kind (if applicable)**	**Mandatory: Details and justification**
Personnel			*Person Months, position of employment, and role/tasks*
Consumables			*e.g., questionnaires, material*
Equipment			*e.g., laboratory devices, IT infrastructure*
Travel and subsistance			*Please provide information on expected travel expenses, e.g. travel budget for participation to THCS intiatives*
Other direct costs			*e.g., subcontracting, licensing fees*
Total direct costs			
Indirect costs (Overhead)			*Brief information on the calculation of overheads*
Total requested budget (€)			
Total costs (€)			

Duplicate for all collaborator

	Collaborator 1/SHORT NAME	
Cost category	**Own contribution in-kind**	**Mandatory: Details and justification**
Personnel		*Person Months, position of employment, and role/tasks*
Consumables		*e.g., questionnaires, material*
Equipment		*e.g., laboratory devices, IT infrastructure*
Travel and subsistance		*Please provide information on expected travel expenses, e.g. travel budget for participation to THCS initiatives*
Other direct costs		*e.g., subcontracting, licensing fees*
Total direct costs		
Indirect costs (Overhead)		*Brief information on the calculation of overheads*
Total requested budget (€)		
Total costs (€)		

E. Ethics

1. HUMAN EMBRYOS/FOETUSES	
Does your research involve Human Embryonic Stem Cells (hESCs)?	Yes No
Does your research involve the use of human embryos?	Yes No
Does your research involve the use of human foetal tissues / cells?	Yes No
2. HUMANS	
Does your research involve human participants?	Yes No
Does your research involve physical interventions on the study participants?	Yes No
3. HUMAN CELLS / TISSUES	
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses?	Yes No
4. PERSONAL DATA	
Does your research involve personal data collection and/or processing?	Yes No
Does your research involve further processing of previously collected personaldata (secondary use)?	Yes No
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	Yes No
Please describe (up to 500 characters including spaces)	
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	Yes No
Please describe (up to 500 characters including spaces)	
5. ANIMALS	
Does your research involve animals?	Yes No

6. NON EU-COUNTRIES	
Will some of the activities be carried out in non-EU countries?	Yes No
Please describe (up to 500 characters including spaces)	
7. ARTIFICIAL INTELLIGENCE	
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	Yes No
8. OTHER ETHICS ISSUES	
Are there any other ethics issues that should be taken into consideration? Please specify	Yes No

☐ I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents

F. Annexes

The following Annexes must be uploaded in the submission system a separate pdf files.

- Pert diagram and Gantt Chart
- CVs
- Research projects
- Bibliography
- Signatures

1. **Brief CV of each principal investigator (maximum 4,000 characters including spaces, equivalent to about 1 A4 page, for each CV).**
   Each partner should be represented by a single Principal Investigator (co-PI are not accepted). Proposals with extra-CVs will be rejected
   The project coordinator and each principal investigator shall include a description of their main domain of research and a list of the five most relevant publications within the last five years, demonstrating the competence to carry out the project.

2. Past and ongoing most relevant research projects of each participating group related to the present topic.
Please note that maximum 5 projects per Partner can be indicated.

Participant Short name	**Project Reference No and Title, Funding programme**	**Period** (start and end date)	**Role** (COO, BEN, OTHER)	**Amount** (EUR)	**Website (if any)**
[name]					
[name]					

3. Bibliography (maximum 6,000 characters including spaces, equivalent to about one and half A4 page).

4. Signatures

Digital signatures or scanned signatures are accepted. These signatures should be from the principal investigators listed in part 2. An official signature of the respective institutions is not necessary. A stamp of the Coordinator's institution (e.g. the relevant university institution or company) should be added. Signatures has to be included as a separate PDF attachment of the proposal.

Coordinator	**Stamp and Signature**
Last Name:	
First Name:	
	Date:
Institution:	

The project partners below have checked their regional/national regulations. They are informed about the content of this joined application.

Signature Partner 1: _____

Signature Partner 2: _____

Signature Partner 3: _____

Signature Partner 4: _____

Signature Partner 5: _____

Signature Partner 6: _____

Signature Partner 7: _____

Signature Partner 8: _____

Signature Partner 9: _____

Please add further signature positions, if needed.

Checklist for intervention studies

Make use of this checklist in case you plan an intervention study

Please note: this list is only meant to double-check if you have included all relevant information on your interventional study in the proposal.

General:

- The need for the study
- What is the problem to be addressed?
- What is/are the principal research question(s) to be addressed?
- Is there a robust evidence-based rationale/coherent hypothesis for the study
- What outcome are you aiming for and how might this bring about change?
- Describe any risks to the safety of participants involved in the intervention

The Proposed Study

- Describe the planned intervention. Fully describe the intervention in PICO terms (Population/Patient group, Intervention, Comparison group/Control, Outcomes)
- Has any pilot or feasibility work been conducted to be confident that the intervention can be implemented as intended?
- What are the proposed practical arrangements for allocating participants to study groups?
- What are the proposed methods for protecting against sources of bias? e.g. Blinding or masking.
- What are the planned inclusion/exclusion criteria?
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate.
- What is the planned recruitment rate (overall and per site if relevant)? What evidence is there that the planned recruitment rate is achievable over a given timeframe
- What are the planned Stopping criteria?
- Are you planning to include health economics and/or quality of life measures? If yes, provide full details regarding the type of analysis to be undertaken, the rationale of the design proposed, the personnel who will conduct analysis, power calculations and inclusion/exclusion criteria.
- Have you considered compliance issues, acceptability testing, user involvement, any local or other contextual issues?

Data Collection and Management

- Describe arrangements for day-to-day management and monitoring of the trial e.g. randomisation, data handling, and coordination.
- Will the design chosen really enable you to draw conclusions about effectiveness?