Co-funded by the European Union

Joint Transnational Call for Proposals (2027) for

Transforming the Health and Care Workforce for Sustainable and Resilient Systems

***(THCS Grant* 101095654)**

Full-proposal application template

Please note:

- This template is an indicative model of full-proposal application form. All information has to be filled in directly online via the electronic proposal submission system (EPSS) with the exception of the annexes (Section 10) https://proposals.etag.ee/thcs/2027.
- All Participants i.e. Consortium Partners and Collaborators must log in onto the EPSS to confirm their participation in a full-proposal and complete their information as required.
- Proposals that do not meet the regional/national eligibility criteria and requirements will be deemed ineligible without further review.
- The content of the full-proposal must be written in English and follow the set guidelines. The different sections of the full-proposal should not exceed the prescribed maximum space. Incomplete full-proposals that do not adhere to the general eligibility criteria and to the national/regional eligibility requirements will be rejected and will not be evaluated.
- Any documents other than those requested as part of the proposal will not be forwarded to the Peer-Review Panel members.
- The full-proposal can be submitted by the Consortium Coordinator multiple times before the full-proposal submitting deadline on 24 June 2027, 14H00 CEST. Only the very last submitted copy will be used by the Joint Call Secretariat (JCS). It is not possible to edit / submit the full-proposal after this deadline.

Checklist for the Coordinator

In order to make sure that your proposal will be eligible for this call, please collect the information required (help provided through the "Call Text", "Guidelines for Applicants" and your regional/national contact points).

General conditions:

☐ The project proposal addresses the **AIM/s** of the call.

☐ I am aware of the **regional/national requirements** of the corresponding funding organisations**.**

Composition of the consortium:

☐ The consortium must include at least three (3) eligible Partners from three different countries whose funding organisations participate in the call. At least two (2) Partners should be legal entities from two different EU Member States or Horizon Europe associated countries. Each of these Partners must be eligible and request funding from the respective funding organisation. All Partners must be independent legal entities of each other.

☐ The project Coordinator is eligible to be funded by one of the participating funding organisations.

☐ Maximum two (2) eligible project Partners from the same country. For some funding organisations, the maximum number of eligible Partners, who can be funded in a project, is limited to one (1) (see also Annex I of the Call Text for individual funding rules).

☐ No more than two (2) Collaborators (Partners with own funding) are part in the consortia with at least three (3) Partners eligible for funding or a maximum of three Collaborators if one or more of the Collaborators is an operational stakeholder.

☐ The maximum number of Partners is nine (9), including the Coordinator and excluding the Collaborators.

☐ Widening measure [1](optional): the consortium invited to the 2nd stage of the call is smaller than the maximum of nine (9) Partners, and adds one (1) new project Partner, eligible for funding by an underrepresented funding organisation (tick this section, if applicable).

Eligibility of consortium Partners:

☐ I have checked that no Partner of this consortium is a member of the THCS Partnership consortium, Peer Review Panel (PRP), Call Steering Committee (CSC).

☐ I have checked that Partners involved in the project proposal and requesting budget are eligible to receive funding from their funding organisation.

☐ If the consortium includes a Collaborator: For the Collaborator, a signed (written) statement (letter of commitment) should be uploaded as annex in the electronic submission tool, declaring that this Partner will be able to run the project with its own resources.

☐ I have checked that all Partners, including Collaborators, have signed the signature page.

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[1] Widening concept: consortia are allowed to include in the full-proposal phase a new project Partner that is eligible to receive funding from a funding organisation that is underrepresented in the first stage of the call and that agrees to participate in the widening option.
Applicants and organisations interested in the widening measure (both those searching for consortia and consortia searching for new Partners) are encouraged to use the Partner Search Tool https://partfinder.ncbr.gov.pl/.

1. General information

This part will have to be filled in directly in the EPSS. This section will be pre-filled with information submitted in the pre- proposal.

Project title

Acronym (max. 15 characters)

Duration (in months)

Keywords (from 5 up to 7)

Please list 5 to 7 keywords describing your proposal, separate keywords with a comma or with a new line

Scientific abstract (500 - 2000 characters, including spaces)

Popular Science Summary (500 - 2000 characters, including spaces)

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 remember that the text should be written in an easily readable style. You should use short, clear sentences broken up into paragraphs for readability, and avoid complex grammatical structures where possible. You should use every day English words instead of complex words.

Scientific disciplines involved

Dropdown list

Medical Domains

Dropdown list:

- Cardiology/cardiovascular diseases
- Dentistry and related pathologies
- Dermatology and related diseases
- Endocrinology and related diseases
- Gastroenterology and related diseases
- Haematology/immunology and related diseases
- Infectious diseases
- Mental Health and Social Issues
- Metabolic diseases
- Musculoskeletal diseases
- Nephrology/urology and related diseases
- Neurodegenerative diseases
- Neurology and related diseases
- Oncology/Cancer
- Otolaryngology and related diseases
- Paediatrics, Pregnancy, Gynaecology
- Pulmonary/Respiratory Diseases
- Rheumatology
- Other

Continuation of a previously funded EU project

Is the submitted project a continuation of, or linked to, a previous project funded under another European Commission program, such as JA HEROES, BEWell, Erasmus+ projects, or other EU-funded actions?

☐ YES ☐ NO

If YES, please specify:

Submission of the research proposal to the previous THCS call

This application is:

☐ a new proposal

☐ a derivate from the previous THCS call 2026

☐ a derivate from the previous THCS call 2025

☐ a derivate from the previous THCS call 2024

☐ a derivate from the previous THCS call 2023

Submission of the same research proposal to other calls

Is this submitted proposal subject to another evaluation process?

☐ YES ☐ NO

If YES, please specify:

2. Project consortium

This part will have to be filled in directly in the EPSS. This section will be pre-filled with information submitted in the pre- proposal.

***For the Consortium Coordinator (indicated as "Partner 1" in this form) and each scientific Partner** (others than the Coordinator, including **Collaborators**), please fill in the following table.*

Reminder on eligibility criteria and consortium composition: maximum number of Partners is 9, including the Coordinator (no more than 2 Partners from the same country).

2.1 Partner details

Details of the Principal Investigator

First name	
Last name	
Title	• CEO • CTO • COO • Dr • MD • Mr • Mrs • Ms • MSc • PhD • Prof.
Nationality	
Gender	
PI identifier	• Google Scholar • ORCID • Researcher ID • Scopus ID
PI identifier link	
Phone number	
Email	
URL / Website of the PI	
Professional status	• Assistant professor • Associate professor • PhD-student • Post-Doc • Professor • Senior scientist

	• Other:
Career stage	• 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).

Details of the Institution

Legal full name of the institution	
Department	
Short name (acronym), if any	
Participant Identification Code (PIC)	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 at the following link: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
Type of entity	• Academia • Healthcare and/or social welfare service provider • Large enterprises • Small and Medium Enterprises (SMEs) • Patient organisations • Non-profit private Partner (for instance NGO's) • Other:
Status	• Private • Public
Statistical Classification of Economic Activities (NACE)	For more information: https://nacev2.com/en
Participant Organisation Type	• Public Bodies (PUB) • Research Organisations (REC)

	• Private for-profit entities (PRC) • Higher or Secondary Education Establishments (HES) • Other (OTH)
SME status if private	YES/NO
Enterprise other than SME	
Organisation website	
Address Street Name	
Address Number	
PO Box	
Postal Code	
Cedex	
City	
Town	
Country	
Department has same address	Tick box: YES/NO. If NO, need to fill Department address fields
Department Address Street Name	
Department Address Number	
Department PO Box	
Department Postal Code	
Department Cedex	
Department Town	

Details of the Teams Members

First name	
Last name	
Title	• CEO • CTO • COO • Dr • MD • Mr • Mrs

	• Ms • MSc • PhD • Prof.
Nationality	
Gender	
PI identifier	• Google Scholar • ORCID • Researcher ID • Scopus ID
Email	
Career stage	• 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).

2.2 Collaborators

Maximum of two (2) Collaborators per consortium are permitted or a maximum of three (3) Collaborators if one or more of the Collaborators is an operational stakeholder. Collaborators are self-funded Partners that do not request funds from one of the participating funding organisations(i.e. Partners from non-funding countries or Partners who are not eligible according to national/regional regulations of the participating funding organisations)., i.e. Partners that do not request funds in this JTC provided from one of the participating funding organisations (i.e. Partners from non-funding countries or Partners who are not eligible according to national/regional regulations of the participating funding organisations).

Details of the Principal Investigator

First name	
Last name	
Title	• CEO • CTO

	• COO • Dr • MD • Mr • Mrs • Ms • MSc • PhD • Prof.
Nationality	
Gender	
PI identifier	• Google Scholar • ORCID • Researcher ID • Scopus ID
PI identifier link	
Phone number	
Email	
URL / Website of the PI	
Professional status	• Assistant professor • Associate professor • PhD-student • Post-Doc • Professor • Senior scientist • Other:
Career stage	• 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).

Details of the Institution

Legal full name of the institution	
Department	
Short name (acronym), if any	
Participant Identification Code (PIC)	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 at the following link: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
Type of entity	• Academia • Healthcare and/or social welfare service provider • Large enterprises • Small and Medium Enterprises (SMEs) • Patient organisations • Non-profit private Partner (for instance NGO's) • Other:
Status	• Private • Public
Statistical Classification of Economic Activities (NACE)	For more information: https://nacev2.com/en
Participant Organisation Type	• Public Bodies (PUB) • Research Organisations (REC) • Private for-profit entities (PRC) • Higher or Secondary Education Establishments (HES) • Other (OTH)
SME status if private	YES/NO
Enterprise other than SME	
Organisation website	
Address Street Name	
Address Number	
PO Box	
Postal Code	
Cedex	
City	
Town	

Country	
Department has same address	Tick box: YES/NO. If NO, need to fill Department address fields
Department Address Street Name	
Department Address Number	
Department PO Box	
Department Postal Code	
Department Cedex	
Department Town	

Details of the Teams Members

First name	
Last name	
Title	• CEO • CTO • COO • Dr • MD • Mr • Mrs • Ms • MSc • PhD • Prof.
Nationality	
Gender	
PI identifier	• Google Scholar • ORCID • Researcher ID • Scopus ID
Email	
Career stage	• 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).

3. Changes between the pre- and full-proposal stage (3 000 characters, spaces including)

This part will have to be filled in directly in the EPSS.

Outline any modification applied that deviate from the pre-proposal (including modifications in the consortium or eventual implementation of the widening measure). Please include information for the reviewers or comments on the reviewers' feedback from the pre-proposal evaluation.

4. Work packages, deliverables and milestones

This part will have to be filled in directly in the EPSS.

4.1 Work packages

This part is only dedicated to title, detailed description should be included in the project description section.

No. of WP	Title	Partner(s) responsible for the WP
1		
2		
3		
4		
N		

4.2 Contribution in person.months

Please use the following table for detailing the distribution of work in person.months (PM) in different work packages (WP) (adapt, if necessary). This table should include all the persons working in the project (PI, researchers, Technicians, PhD, post-docs).
Person.months contribution should not be limited to the person.months for which funding is requested. For example, person.months provided in kind by your research institution should be indicated in this table as well.

No. of WP	Partner 1	Partner 2	Partner 3	Partner N	Collaborator	Total PM
1						
2						
3						
N	*Add more rows as required*					
	Total					

4.3 Deliverables

Deliverables	Title of the deliverables	Delivery Month[2]	Related to No. of WPs
1			
2			
3			
N	*Add more rows as required*		

4.4 Milestones

Milestones	Title of the milestones	Delivery Month[3]	Related to No. of WPs
1			
2			
3			
N	*Add more rows as required*		

5. Project description

This part will have to be filled in directly in the EPSS.

5.1 Proposed work (15 000 characters, spaces including)

1. *Transformative Dimension and Ecosystem Alignment: Highlight the transformative dimension of the proposed work for health and care systems. Explain how the project adopts an ecosystem-wide approach to ensure relevance to key actors (policy, regulatory, and end-users) and how it anticipates future needs within national, regional, or local change processes;*
2. *Background, State of the Art, and Novel Models & Solutions: Describe the scientific objectives and the novelty of the proposed concepts. Address the development of new organisational and business models as a core component of the ecosystem approach, including necessary changes in the mindset and behavior of users to support uptake;*

[2] Delivery month - indicate month number from the start of the project, e.g. 12, 24…
[3] Delivery month - indicate month number from the start of the project, e.g. 12, 24…

3. *Objectives per Work Package: Quantify objectives for each WP. Ensure the workplan encompasses activities for meaningful collaboration with ecosystem actors, such as iterative co-design loops and strategic advisory boards involving decision-makers;*
4. *Approach and Methodology: Detail the chosen methodology, highlighting its multidisciplinary and intersectoral nature. Describe how the approach integrates the "quadruple helix" (academia, government, industry, and end-users) to ensure the proposed solutions are user-centered and sustainable. Give a detailed description of the approach and methodology chosen to achieve the objectives. Highlight the particular advantages of the methodology chosen; quantify the expected project result(s). Break down the research program into individual tasks, showing the interrelationship between the tasks;*
5. *Added Value and Transnational Synergy: in instances where the proposed work builds on previous activities, describe how this collaborative proposal will complement or build on previous activities. Demonstrate how the project will increase synergy between teams across Partner countries and how transnational collaboration adds a particular value. Explain why there is synergy between different tasks of the project and how this is going to be exploited).*

5.2 Impact (15 000 characters, spaces including)

1. *Strategic Impact: Describe your plan of impact and to what extent it is ambitious to improve the sustainability, resilience and efficiency of the health and care workforce in Europe and beyond. Indicate how the proposal could address persistent challenges in the recruitment and retention of health and care workers under Subtopic 1, or in the training, education and professional development of the health and care workforce under Subtopic 2;*
2. *Societal, Policy, and Regulatory Relevance: Describe the importance of your project for solving pressing societal and policies issues. Specify how results will contribute to evidence-based policy development and create synergies within existing regulatory frameworks. Explain to what extent your project could lead to novel/original contribution for tackling societal and/or policy and/or industrial challenges;*
3. *Exploitation and Sustainability Strategy: Detail the plan for exploitation of results by end-users, as well as plans for knowledge and/or technology transfer to practitioners, policy makers, and/or other relevant end-users. Explain how project objectives are embedded within the organisational strategies to ensure long-term commitment and sustainability beyond the project duration;*
4. *Stakeholders and End-users engagement: describe how you plan to engage stakeholders directly in your project and at which stage of the project; identify the stakeholders to be engaged in your project, describing their specific interest and/or contributions to the project and the status of their engagement at the proposal development stage. Explain to what extent your project implies that societal actors (researchers, healthcare systems, citizens, policy makers, industry, third sector organisations, etc.) work together during the whole process (co-creation, co-design and co-production) in order to better align both the process and its outcomes with the values, needs and expectations of society. Highlight potential arrangements for wider uptake. Identify additional actors outside the consortium (e.g., policymakers, regulators, NGOs, or service providers) and describe the strategies for long-term collaboration with them to maximize the project's reach and impact;*
5. *Measures to Maximise Impact: Specify the quality of measures for dissemination, communication, and knowledge transfer (education, literacy, training etc.) to scientists, non-scientific stakeholders, general public etc. Describe what, why, when and how they will receive it. Specify planned project publications and outputs (scientific and other), and their expected*

exploitation and impact. Explain how the project will communicate findings to healthcare authorities to contribute to evidence-based policy development and the creation of synergies within existing regulatory frameworks.

5.3 Description of project coordination and management (12 000 characters, spaces including)

1. *Describe how the overall coordination, monitoring and control of the project will be implemented. Outline the management processes foreseen in the project (decision boards, coordination meetings, etc.) and clearly indicate the distribution of tasks among the consortium members.*
2. *It is recommended that milestones be presented in a detailed diagram (e.g. PERT or Gantt charts) providing the time schedule of the tasks and marking their interrelationships; add when decisions on further approaches will have to be made; indicate a critical path marking those events which directly influence the overall time schedule in case of delays. [Please note that the Pert or Gantt chart should be included as annex (see section "Annexes" below);*
3. *Explain how information flow and communication will be managed and enhanced within the project (e.g. collaboration and task meetings, exchange of scientists, dissemination of results and engagement with stakeholders).*
4. *Risk management Describe potential barriers to the expected outcomes and impacts (e.g. regulatory environment, targeted markets, user behaviour) and mitigation measures proposed, if any.*

6. Open Science, data management and data sharing (4 000 characters, spaces including)

This part will have to be filled in directly in the EPSS.

Develop a data management strategy. Description of how the research data in this project will be findable, accessible, interoperable and re-usable: the handling of research data during and after the end of the project; proposed frequency and scope of data collection; what data will be collected, processed or generated or reused; which methodology and standards will be applied; whether data will be shared/made open access; how data will be curated and preserved. Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate.
In this section, the Data Management Plan (DMP) must be outlined in brief. Consortia of projects selected for funding must submit a detailed DMP (a template will be provided to the respective consortia). Include Open Science practices and intellectual property management.

7. Inclusion of gender and/or sex analysis and underrepresented populations (2 000 characters, spaces including)

This part will have to be filled in directly in the EPSS.

Please provide information about the consideration of sex and/or gender aspects in research teams and the inclusion of sex and/or gender analysis, as well as underrepresented populations and/or social components in the research, if applicable.

8. Financial plan of project budget (in €)

This part will have to be filled in directly in the EPSS.

Please ensure that all fields in the table are completed. Submissions with incomplete tables may be rejected. If the partner does not request funding under one of the categories, they should enter "0".

*Please note that **not** all types of expenditure are fundable by all funding organisations (see the Call Text for details on the eligibility criteria and contact the relevant THCS regional/national funding organisation). Thousand separators and whole numbers should be used only (e.g. 200.000).*

All project Collaborators (self-funded Partners) are required to submit a financial plan as part of the application process, even if no funding is requested from the program.

Please adapt the table and add columns in this section, if Collaborators or patient organisations are included as Partners.

	Coordinator (Partner 1)		**Partner 2**		**Partner 3**		**Partner 4**		**Partner 5**	
PI (group lead)										
Institution										
Country										
Funding organisation										
PROJECT COSTS (€)	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested
Person Months										
Personnel €										
Consumables €										
Equipment €										
Travel €[1]										
Other direct costs €[2]										
Overheads €[3]										
Subcontracting €[2]										
TOTAL										

	Partner 6		Partner 7		Partner 8		Partner 9	
PI (group lead)								
Institution								
Country								
Funding organisation								
PROJECT COSTS (€)	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested
Person Months								
Personnel €								
Consumables €								
Equipment €								
Travel €[1]								
Other direct costs €[2]								
Overheads €[3]								
Subcontracting €[2]								
TOTAL								

	Collaborator 1		Collaborator 2	
PI (group lead)				
Institution				
Country				
Funding organisation				
PROJECT COSTS (€)	Total = *requested + in-kind*	Requested	Total = *requested + in-kind*	Requested
Person Months				
Personnel €				
Consumables €				
Equipment €				
Travel €[1]				
Other direct costs €[2]				
Overheads €[3]				
Subcontracting €[2]				
TOTAL				

[1] Travel expenses should include the participation of the Coordinator and regional/national Partner leads for at least two status seminars to present the project results.

[2] e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according legal framework and funding body regulations).

[4] Overhead costs: funding according to regional/national legal framework and funding body regulations. Check the respective funding organisation Annex II "Guidelines for Applicants" or contact your relevant funding agency for further information.

9. Brief CVs of each Principal Investigator (PI)

This part will have to be filled in directly in the EPSS, using the CV template below.

Please provide a brief CV for the Project Coordinator (Partner 1) and each Project Partner's Principal Investigator (PI) including Collaborators.

Please be reminded that Collaborators and patient organisations/representatives added as consortium Partners should be also presented.

When relevant, please specify in the CVs, the Partners' capacity to involve stakeholders.

Partner	Please indicate what applies: Coordinator (Partner 1), Partner 2, Partner 3, etc.
Name	
Nationality	
Institution, City, Country	
URL / Website	(including complete list of publications if any)
Professional Status	- Professor - Assistant professor - Associate professor - Senior scientist - Post-Doc - PhD-student - Other
Education	Year; type of education; organisation; country
Positions	Year; Position; organisation; country
Awards received / other responsibilities	(max 1,000 characters including spaces)
General expertise and its relevance for the project	(max 1,000 characters including spaces)
Publications	Up to 5 most important achievements, publications, IP (e.g. patents) relevant to the proposal over 20**23**-20**27**, if any
Additional information	Honours, awards, memberships or references; up to 5 relevant third-party funded projects conducted in the area in the past 5 years

10. Annexes (page limits per optional section as indicated below)

The annexes have to be uploaded as single PDF on the EPSS. Please note that letters of support are NOT requested and will NOT be considered for the evaluation. The letters of commitment from Collaborators are mandatory at the full-proposal stage.

- *Annex I: List of references (max. 1 page A4)*
- *Annex II: Diagram which compiles the work plan, timeline and milestones (max. 1 page A4). The diagram must demonstrate the work plan, timeline, sequencing of work packages, milestones as well as the contribution of the Partners to each work package and their interactions (i.e. time plan, Gantt and/or PERT or similar).*
- *Annex III: Figures. Page with diagrams, figures, etc. to support the project description (max. 1 page A4)*
- *Annex IV: Letters of Commitment. 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 commitment. The letter of commitment has to be signed by the director of the institution (NOT by the researcher himself).*
- *Annex V: Description of interventional studies - to fill in case interventional studies are included in the proposal (please see section Annex Description of interventional studies below).*

11. Signatures

The signature document has to be uploaded as single PDF on the EPSS. It must be signed by all Partners, including Collaborators.

- *The signature template is available for download from the EPSS system.*

12. Annex: Ethical self-assessment

This part will have to be filled in directly in the EPSS.

Please note that all participants in a proposal must follow regional/national ethical regulations for their part of the proposed work. All proposals appoint an ethics contact point for the consortium in the self-assessment. Ideally, this person also oversees that the proposal holds cross-border high ethical standards.

Ethic contact point for the consortium:

In order to complete this section, please ensure you provide all information requested. Please remove all red guiding text.

Contact information for ethics contact point for the consortium	Please indicate here the person in charge of monitoring the ethical issues raised in your project. This person will also be in charge of maintaining the project's ethics file. The contact point can be the Coordinator of the consortium or one of the project Partners.
Name and surname	
Email address	
Phone	

Short description of ethics and legal aspects in your proposal:

In order to complete the ethics self-assessment, please go through the table below and, for each section for which your answer is "YES" ***, please add a description of information at the end of each relevant section.*** *Please also provide an overview on related* ***tasks, responsible Partners and documents to be provided for each question.***

For more information, please see: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf.

Please attach any supporting documents that are already available and, for the documents that are not yet available, indicate when you expect that they will be available. All relevant documents listed in the table, and that are not yet available, have to be ready to be submitted upon request.

Section 1: Human embryonic stem cells and human embryos		**YES/NO**	**If yes, Add description in the appropriate section at the end of the table**
Does this research involve Human Embryonic Stem Cells (hESCs)?			
If YES:	Will they be directly derived from embryos within this project?		
	Are they previously established cells lines?		

	Are the cell lines registered in the European registry for human embryonic stem cell lines?		
Does this research involve the use of human embryos?			
If YES:	Will the research lead to their destruction?		
Does this research involve the use of other human embryonic or foetal tissues / cells?			
Description (mandatory if this section is relevant to your project):			

Section 2: Humans		**YES/NO**	**If yes, Add description in the appropriate section at the end of the table**
Does this research involve human participants?			
If YES:	Are they volunteers?		
	Are they healthy volunteers for medical studies?		
	Are they patients for medical studies?		
	Are they potentially vulnerable individuals or groups?		
	Are they children/minors?		
	Are they persons unable to give informed consent?		
Does this research involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?			
If YES:	Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)?		
	Does it involve collection of biological samples?		
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products).			
Description (mandatory if this section is relevant to your project):			

Section 3: Humans cells / tissues		**YES/NO**	**If yes, Add description in the appropriate section at the end of the table**
Does this research involve human cells or tissues? (other than from Human Embryos/Foetuses, see section 1)			
If YES:	Are they human embryonic or foetal cells or tissues?		

	Are they available commercially?		
	Are they obtained within this project?		
	Are they obtained from another project, laboratory or institution?		
	Are they obtained from a biobank?		
Description (mandatory if this section is relevant to your project):			

Section 4: Personal data		**YES/NO**	**If yes, Add description in the appropriate section at the end of the table**
Does this research involve processing of personal data?			
If YES:	Does it involve the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?		
	Does it involve processing of genetic, biometric or health data?		
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?		
Does this research involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)?			
Is it planned to export personal data (data transfer) from the EU to non-EU countries?			
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non- EU country to another non-EU country?			
Does this research involve the processing of personal data related to criminal convictions or offences?			
Description (mandatory if this section is relevant to your project):			

Section 5: Animals	**YES/NO**	**If yes, Add description in the appropriate section at the end of the table**
Does this research involve animals?		

If YES:	Are they vertebrates?		
	Are they non-human primates (NHPs)?		
	Are they genetically modified?		
	Are they cloned farm animals?		
	Are they endangered species?		
Please indicate the species involved:			
Description (mandatory if this section is relevant to your project):			

Section 6: Non-EU countries		YES/NO	If yes, Add description in the appropriate section at the end of the table
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? Specify the countries involved:			
Is it planned to use local resources (e.g. animal or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?			
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non- EU country to another non-EU country?			
If YES:	Specify material and countries involved:		
Is it planned to export any material (other than data) from the EU to non-EU countries?			
Does your activity involve low or lower-middle income countries?			
Could the situation in the country put the individuals taking part in the research at risk?			
Description (mandatory if this section is relevant to your project):			

Section 7: Environment, Health and Safety	YES/NO	If yes, Add description in the appropriate section at the end of the table
Does this activity involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?		

Does this research deal with endangered fauna and/or flora/protected areas?		
Does this activity involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, or the deployment of the technology as a possible impact)?		
Description (mandatory if this section is relevant to your project):		

Section 8: Artificial Intelligence	YES/NO	If yes, Add description in the appropriate section at the end of the table
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?		
Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)?		
Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?		
Does the AI system/technique have the potential to lead to negative social (e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance) and/or environmental impacts either through intended applications or plausible alternative uses?		
Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above (e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.)?		
Description (mandatory if this section is relevant to your project):		

Section 9: Other ethics issues	YES/NO	If yes, Add description in the appropriate section at the end of the table
Are there any other ethics issues that should be taken into consideration?		

Description (mandatory if this section is relevant to your project):

Section 10: Crosscutting issues – Potential misuse of results	YES/NO	If yes, Add description in the appropriate section at the end of the table
Does this research have the potential for misuse of research results?		
Description (mandatory if this section is relevant to your project):		

13. Annex: Description of interventional studies

(to fill in case interventional studies are included in the proposal)

Please prepare your description in English not exceeding 7 pages for the headings 1. to 8.

1. Study Synopsis

Title of Study	
Objective(s)	
Intervention(s)	Experimental intervention: Control intervention: Duration of intervention per participant: Follow-up per participant:
Key Inclusion and Exclusion Criteria	Key inclusion criteria: Key exclusion criteria:
Outcomes	Primary endpoint: Key secondary endpoint(s):
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	Description of the primary analysis Analysis of secondary endpoints:
Sample Size	To be assessed for eligibility (n = …) To be allocated to study (n = …) To be analysed (n = …)
Study Duration	Time for preparation of the study (months): Recruitment period (months): First participant in to last participant out (months): Time for data clearance and analysis (months): Duration of the entire study (months):

2 Intervention Scheme

Describe the intervention scheme in depth and give a schematic diagram (flow chart) of design, procedures and stages.

3 Strategies for data handling

3.1 Frequency and Scope of Data Collection

What is the proposed frequency and scope of data collection and, if applicable, the duration of post-trial follow-up?

3.2 Strategies for Data Management

Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate

4 Justification of Design Aspects

Please provide justifications. It is not sufficient to list respective parameters only.

4.1 Control(s)/Comparator(s)

Justify the choice of control(s) / comparison group(s).

4.2 Type, Mode and Scheme of Intervention

Describe the intervention scheme in depth and give a schematic diagram (flow chart) of design, procedures and stages Justify the type, the mode and the scheme of the intervention. How does the intervention compare to other interventions for the same condition?

4.3 Additional Treatments

Please describe additional treatment(s) permitted and not permitted before and / or during the trial, if applicable.

4.4 Inclusion/Exclusion Criteria

Justify the population to be studied, include reflections on generalisability and representativeness, specifically with regard to gender and age.

4.5 Outcome Measures

Justify the endpoints chosen. Discuss the relevance of the outcome measures for the target population/patient. Have the measures been validated? Justify appropriateness and limitations of composite endpoints, if applicable.

4.5.1 Determination of primary and secondary measures

How will primary and secondary endpoints be derived from actual measurements, e.g. how is the figure used in the statistical test calculated from the variables initially measured in the subjects?

4.6 Methods against Bias/ Assessment of Confounding Factors

Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to trial groups? Will trial site effects be considered in randomisation?

Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome). What are possible confounding factors and how will they be considered?

4.7 Proposed Sample Size / Power Calculation

What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of difference that the trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial is powered to exclude. Give evidence / references for the estimated effect size. Sample size calculations need to take into account anticipated rates of non-compliance and losses to follow up.

4.7.1 Compliance / Rate of Loss to Follow Up

Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?

What is the assumed rate of loss to follow up? On what evidence is the loss to follow up rate based? How will losses to follow up or non-compliance be handled in the statistical analysis?

4.8 Feasibility of Recruitment

What is the evidence that the intended recruitment rate is achievable?

a) Pilot study

Has any pilot study been carried out using this design?

b) Achievability of recruitment rate

Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot studies and preceding trials in a similar population / same institutions).

4.9 Stopping Rules

Please specify the "stopping rules" or "discontinuation criteria"

a) for the individual participant,

b) for the whole study

5. Statistical Analyses

What is the proposed strategy of statistical analysis? If multiple hypotheses are foreseen for confirmatory testing what is the procedure to ensure Type I error control and what will be the primary data analysis set (e.g. ITT-population in case of superiority RCT). What is the strategy for analysing the primary outcome? If applicable, how will multiple primary end points be analysed statistically? If interim analyses are planned, please specify. Are there any subgroup analyses? How will missing data and subjects withdrawn from the trial be handled statistically?

6. Ethical Considerations

Give a description of ethical considerations relating to the study (assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, informed consent process).

7. Quality Assurance and Safety

7.1 Quality Assurance/Monitoring

What are the proposed measures for quality assurance? Which institution will perform the monitoring? Which SOPs will be utilized? Describe and justify the monitoring strategy (percentage of source data verification, number of monitor visits per study site).

7.2 Safety

Describe and justify briefly the proposed strategy for the assessment of participants' safety in the study (Monitoring of adverse events, documentation, reporting procedures, etc.).

7.3 Management Structure and Procedures

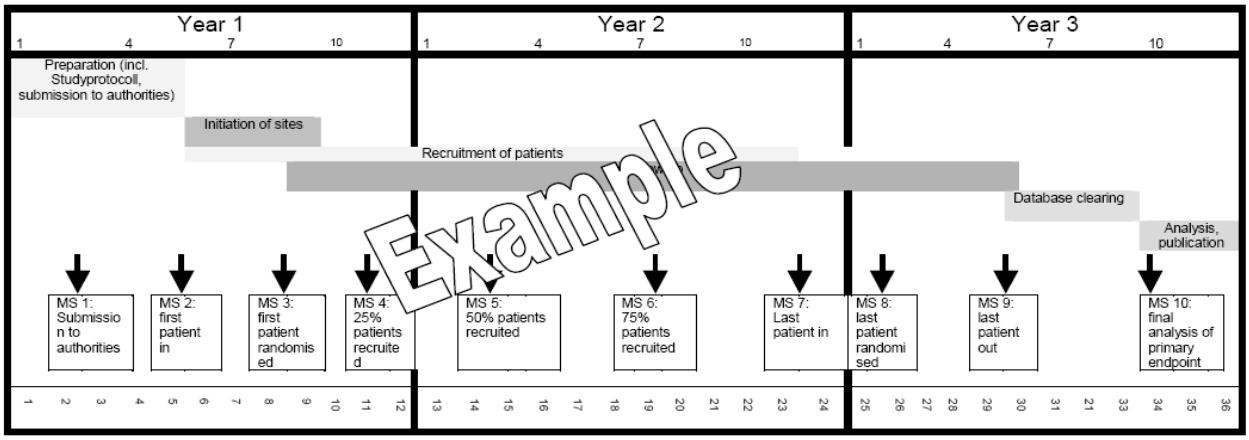
Arrangements for the management of the trials will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is entirely independent of the principal/coordinating investigator and the medical institutions involved. This can take the form of an external scientific supervisor with human clinical trial expertise.

8. References

For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

9. Trial Timeline Flow

Please provide a diagram reflecting preparation, recruitment, follow-up and data cleaning/analysis. An example of such a diagram is given below.



10. List of Investigators involved in the Study

Sponsor / Institution				
Management				
#	Name	Affiliation	Responsibility / Role	Signature
Statistician				
#	Name	Affiliation		Signature
1				
Supporting Facilities *(reference laboratories, food supplier etc.)*				
#	Name	Affiliation	Responsibility / Role	

A final version of the trial protocol has to be submitted to the funding agency together with the statement by the ethics committee after the review process. While funding for a preparatory phase might be provided upon the general funding decision, funding of the actual trial can only be provided if all necessary formal and legal requirements are met.