

# **Innovate to Prevent: Personalised Prevention in Health and Care Services**

Transforming Health and Care Systems Partnership - Call 2024

National Rules for Participation – For Public Entities and Public Research and Knowledge-Dissemination Organisations that do not carry out an economic activity within the meaning of <u>Article 107 TFEU</u>.

Version: 1

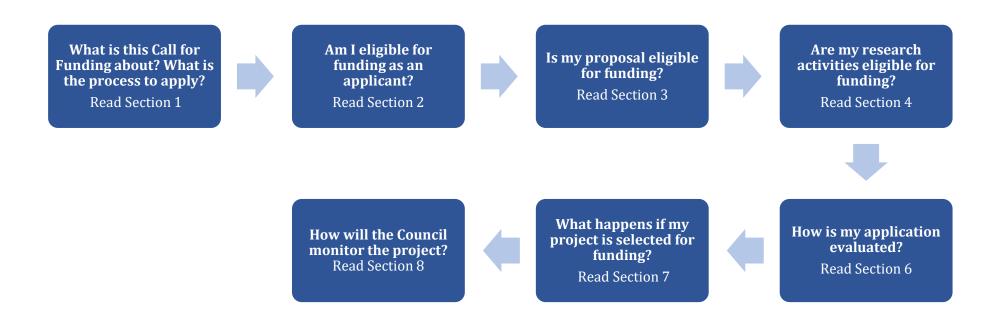
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# **Guide to this document**



## 1. Introduction

The Malta Council for Science and Technology (referred to as the 'Council' hereafter) is administering the **2024 Joint Transnational Co-Funded Call of the Transforming Health and Care Systems Partnership** *Innovate to Prevent: Personalised Prevention in Health and Care Services* for and on behalf of the Foundation for Science and Technology and is located at Villa Bighi, Kalkara, KKR 1320, Malta.

The Transforming Health and Care Systems Partnership (THCS) is a Horizon Europe Partnership that started in 2023. The aim of the THCS Partnership is to coordinate and optimize research and innovation efforts in Europe and its partner countries supporting health and care systems transformation.

This Call is the second of a series of annual co-funded Joint Calls that will be launched by this Partnership to tackle priority areas drawn from the <u>Strategic Research and Innovation Agenda (SRIA)</u> of the THCS. This Joint Call shall pool national and regional financial resources through participation of ministries and funding organisations from various countries responsible for funding research and innovation actions in the health sector, with the financial support from the European Commission.

The second co-funded THCS Joint Call aims to support the implementation of innovative person-centred health and care models addressing prevention strategies, with the key help of existing IT and digital technologies and services, as well as existing and emerging data. The ultimate goal is to improve health and care system dimensions such as quality, efficiency, equity, and sustainability. Improving the quality of preventive services will lead to improving the quality of life of citizens and patients, as well as reducing the burden and costs for the entirety of health and care services.

For further details on eligible topics for funding and list of funding organisations, please visit the <u>Partnership website.</u>

#### 1.1 Definitions

Applicant	The term refers to any representative of a local entity that is eligible for		
	participation in a Project in terms of these National Rules for Participation		
	and who applies for funding under this joint initiative.		
Arm's length	The term means that the conditions of the transaction between the		
	contracting parties do not differ from those which would be stipulated		
	between independent undertakings and contain no element of collusion. Any		
	transaction that results from an open, transparent and non-discriminatory		
	procedure is considered as meeting the arm's length principle.		
Beneficiary	The term beneficiary refers to the applicant whose project has been awarded		
	and hence will be receiving funding.		
Council	The term refers to the Malta Council for Science and Technology on behalf of		
	the Foundation for Science and Technology.		
Due Diligense	The term refers to an investigation of a business or person prior to signing		
Due Diligence	the Grant Agreement.		
Eligible direct	The term refers to those costs incurred directly by the national beneficiaries		
costs	during the duration of the project and used primarily for the purpose of		

	. 1		
	achieving the objectives of the project. All eligible expenses must be incurred		
	between the Start Date and the End Date of the Project and capped at the		
F. J.D	approved requested funding value.		
End Date	This term refers to the date when the Project Period, having commenced on		
T	the Start Date, expires.		
Innovation	The term is defined as the internationally novel scientific/technological		
	development of a technological process, product, or service. Also, the		
definition of innovation within the same context can also be apponent in ovel, yet step-change/ground-breaking enhancement of			
	technological processes, products, or services, or even the application of		
existing knowledge to new novel applications of these solutions to o			
step-change competitiveness through such an application.			
Legal Entity The term refers to any entity created within the European Union, have			
operating base in Malta and which has legal personality, which may, a			
Dantnon	under its own name, exercise rights and be subject to obligations.		
<b>Partner</b> The term is defined as an entity within a consortium of a fu			
transnational project.  Project The term refers to the individual, appointed to act on behalf of the Ap			
Contact Point	and who is responsible for communicating with the Council about the		
Contact I oint	Project.		
	The Project Contact Point(s) shall have the following responsibilities:		
	To ensure compliance with the obligations in terms of the Grant		
	Agreement.		
	To compile Periodic Reports and Final Reports including their timely		
	submissions and effective execution of the project.		
	To ensure the submission of all required financial reporting as per		
	the contractual obligations for the partner.		
	To execute the project activities according to set timeframes and		
	deliverables.		
Person months	The term refers to a calculation of 'human effort' to evaluate the relationship		
/Person hours	between the estimated work to be performed and the activities and		
	deliverables to be achieved during the implementation period in months or		
	hours. This is calculated as follows: if 1720 hours are worked in 1 year,		
	equivalent to 215 days of 8 hours each, then 1 person month is equivalent to		
143.3 person hours, and to circa 17.91 days.			
<b>Personnel</b> The term means the costs of researchers, technicians, and other s			
costs	staff to the extent employed on the relevant project or activity.		
Project	The term refers to one of the beneficiaries of a transnational project		
Coordinator	consortium that is appointed as the single point of contact between the THCS		
	Partnership Secretariat and/or the funding bodies and the consortium		
	partners from proposal submission to project end. The Project Coordinator		
	will have the responsibility of ensuring that all the transnational partners involved in the consortium are eligible and supervises the project workflow		
	with the help of WP leaders. Additionally, the Project Coordinator will be		
	with the help of wir leaders. Additionally, the Froject Coordinator will be		

	required to submit the project application on behalf of the consortium and			
	must also compile and submit reports / deliverables to the THCS Partnership			
	Secretariat.			
Principal	The term refers to the lead researcher on behalf of the local			
Investigator	applicant/beneficiary of a transnational project consortium. May be the			
	same as the Project Coordinator and/or the Project Contact Point.			
Project Grant	The term is defined as the granted funding provided by the Council.			
Project Period	The Project Period is the time required to execute the Project as indicated in			
	the Grant Agreement.			
Project Value	The term refers to the project budget needed by the Applicant to carry out			
1 roject value	the project, including any co-financing.			
Dublic Entity				
Public Entity	The term refers to any Ministry, Department, Entity, Authority, Public			
	Commission, Public Sector Foundation or a similar organisation that does			
	not carry out an economic activity within the meaning of Article 107 TFEU			
	and that exercises public power, or else acts in its own capacity as public			
	authority, where the activity in question forms part of the essential function			
	of the State or is connected with those functions by its nature, its aim and the			
	rules to which it is subject. However, the classification of a particular entity			
	as an undertaking depends entirely on the nature of its activities, and the			
	overriding criterion of consideration is whether it carries out an economic			
	activity or not, e.g., an entity that is formally part of the public administration			
	may nevertheless have to be regarded as an undertaking within the meaning			
	of Article 107(1) of the Treaty. Thus, an entity that carries out both economic			
	and non-economic activities is to be regarded as an undertaking only with			
	regards to the former. In this case, if the economic activity can be separated			
	from the exercise of public powers, then that entity acts as an undertaking in			
	relation to that activity and the financing, the costs and the revenues of that			
	economic activity shall be accounted for separately from the other non-			
	commercial activities.			
	If an economic activity cannot be separated from the exercise of public			
	power, the activities exercised by that entity as a whole, remain connected			
	with the exercise of those public powers and therefore fall outside the notion			
	of an undertaking.			
Research and	This term is defined as the systematic investigation, work or research carried			
Development				
Zevelopiiioiio	work or analysis undertaken to acquire new knowledge, primarily directed			
	towards a specific practical aim or objective, and includes:			
	i. <b>Fundamental Research</b> means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying			
	foundations of phenomena and observable facts, without any direct commercial application or use in view.			
	ii. <b>Industrial Research</b> means the planned research or critical			
	investigation aimed at the acquisition of new knowledge and skills for			
	developing new products, processes, or services or aimed at bringing			
	about a significant improvement in existing products, processes or			
	services, including digital products, processes or services, in any area,			

technology, industry or sector (including, but not limited to, digital industries and technologies, such as super-computing, quantum technologies, block chain technologies, artificial intelligence, cyber security, big data and cloud technologies). It comprises the creation of components parts of complex systems and may include the construction of prototypes in a laboratory environment or in an environment with simulated interfaces to existing systems as well as of pilot lines, when necessary for the industrial research and notably for generic technology validation.

iii. Experimental Development means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services, including digital products, processes or services, in any area, technology, industry or sector (including, but not limited to, digital industries and technologies, such as for example super-computing, quantum technologies, block chain technologies, artificial intelligence, cyber security, big data and cloud or edge technologies).. This may also include, for example, activities aiming at the conceptual definition, planning and documentation of new products, processes or services.

Experimental development may comprise prototyping, demonstrating, piloting, testing and validation of new or improved products, processes or services in environments representative of real-life operating conditions where the primary objective is to make further technical improvements on products, processes or services that are not substantially set. This may include the development of a commercially usable prototype or pilot which is necessarily the final commercial product, and which is too expensive to produce for it to be used only for demonstration and validation purposes.

Experimental development does not include routine or periodic changes made to existing products, production lines, manufacturing processes, services, and other operations in progress, even if those changes may represent improvements.

Research and Knowledge-Dissemination Organisation (RKDO) The term refers to an entity (such as universities or research institutes, technology transfer agencies, innovation intermediaries, research-oriented physical or virtual collaborative entities), irrespective of its legal status (organised under public or private law) or way of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development or to widely disseminate the results of such activities by way of teaching, publication or knowledge transfer. Where such entity also pursues economic activities the financing, the costs and the revenues of those economic activities must be accounted for separately. Undertakings that can exert a decisive influence upon such an entity, in the quality of, for example, shareholders or members, may not enjoy preferential access to the results generated by it.

Start Date	The date which is stated in the Grant Agreement for the official start of the			
	project.			
Start of Works	This refers to the earlier of either the start of works relating to the			
	investment, or the first legally binding commitment to order equipment or			
	any other commitment that makes the investment irreversible. Buying land			
	and preparatory works such as obtaining permits and conducting feasibility			
	studies are not considered 'start of works'. For take-overs, 'start of works'			
	means the moment of acquiring the assets directly linked to the acquired			
	establishment.			
Subcontracted	The term refers to any activity related to the project, (including but not			
Activity	limited to consultancy), which is not carried out directly by a Partner or its			
	employees but is carried out by any third party (local or foreign) individual,			
	company, partnership, or entity under whatsoever terms and conditions.			

# 1.2 Call Process and Snapshot

#### **Timeline**

The Call process consists of one (1) stage as per flow chart below:



#### **Intent to Apply**

The Project Coordinator must submit a brief Intent to Apply (ItA) to the THCS Partnership Joint Call Secretariat on the Online Submission Platform by the deadline 16<sup>th</sup> of April 2024 (14:00 CET) as per <u>Call Text 2024</u>. The ItA should include a brief description of the project and of the Consortium. Proposal without a proceeding ItA will not be eligible and will not be evaluated.

#### **Full proposal**

The Project Coordinator must submit the full project proposal on behalf of the Consortium to the THCS Partnership Joint Call Secretariat on the Online Submission Platform as per <u>Call Text 2024</u>.

Malta-based applicants are required to follow the latest version of the National Rules and check their eligibility as applicants (Section 2), check the eligibility of their project proposal (Section 3) and costings of the project (Section 4) and to submit a National Application Form accompanied by the relevant documentation (Section 1.3).

#### N.B: Applications must be submitted before the Start of Works [see definition in Section 1.1].

Project proposals will be evaluated, and applicants will be duly informed whether their proposal was successful or not.

The selection and funding of proposals under this Programme shall be on a competitive basis.

#### Call Snapshot

THCS Call Text	https://www.thcspartnership.eu/

MCST reference documents	https://mcst.gov.mt/funding-opportunities/		
TRL levels supported	TRL 3 - 7		
Project Duration	12-36 months		
Max. funds that can jointly be			
requested by Malta-based	6500,000		
eligible partner/s per project	€500,000		
(EUR)			
Submission deadline of the	16th April 2024 14:00 CET		
Intent to Apply	16 <sup>th</sup> April 2024, 14:00 CET		
<b>Updated</b> Submission deadline of	21st May 2024 14.00 CET		
the Full Proposal	21 <sup>st</sup> May 2024, 14:00 CET		
THCS Online Submission			
Platform	https://www.thcspartnership.eu/		
<b>Updated</b> Submission deadline of			
National Application Form and	21st May 2024, 23:59 CET		
Relevant documentation			
Submission MCST email	eusubmissions.mcst@gov.mt		

# 1.3 Application Submission Details

The applicant should ensure **complete** compliance to these 'Rules for Participation' prior to applying to this Call. No amendments or negotiations are allowed after submission, unless requested by the Council. Any unapproved deviations will result in the failure of the application during the administrative check.

The Intent to Apply and the Full Proposal need to be submitted electronically by the Project Coordinator via the THCS Online Submission Platform, on behalf of the transnational consortium, by the submission deadlines indicated below.

Project Coordinator

Intent to Apply
Submission
Platform

Deadline for Intent to Apply submission: 16/04/2024, 14:00 CET

Project Coordinator

Full Proposal
Submission
Platform

Deadline for Full Proposal Submission: **21/05/2024, 14:00 CET** 

Additionally, a National Application Form needs to be submitted electronically by each Malta-based applicant to <a href="mailto:eusubmissions.mcst@gov.mt">eusubmissions.mcst@gov.mt</a>, by the submission deadline indicated below<sup>1</sup>.



# Deadline for submission of National Application Form: **21/05/2024, 23:59 CET**

#### **Submission Documents**

- Only **complete** National Application Forms submitted by the deadline shall be considered.
- All documentation submitted must be in English.
- Each proposal will be checked for administrative eligibility before it is considered for scientific evaluation. This means that failure of one of the consortium partners to meet the eligibility criteria may cause the entire project to be rejected.
- In case of multiple submissions of the same application in the same selection round the last version submitted before the deadline will be that considered for evaluation.

#### **Documents Required for Submission**

Applicants need to submit a **National Application Form** accompanied by **declarations** in the form of annexes to the Application Form. These documents will be reviewed during the Eligibility check, and consist of the following:

- National Application Form in MS Word (.docx) and a signed scanned copy in PDF format.
- Declarations that the eligible applicant is a public entity and/or public RKDO that does not carry out an economic activity within the meaning of Article 107 TFEU. Where applicable, declarations of any indirect state aid, when an eligible undertaking (as defined in Section 1.1 of the National Rules for Participation State Aid) is a partner in the same project consortium as a public entity and/or public research and knowledge dissemination organisation that does not carry out an economic activity within the meaning of Article 107 TFEU.
- *Curricula Vitae* of Principal Investigator and other key researchers highlighting R&I related experience. These should clearly establish that the Consortium has the potential to carry out the assigned project tasks/activities.
- Detailed Budget Breakdown Form.

Other forms of documentation can be requested during the Call Process or during the Grant Agreement Preparation phase.

<sup>&</sup>lt;sup>1</sup>It should be noted that emails larger than 20MB shall be automatically rejected by the system. The applicant may make use of cloud storage and should ensure receipt of all documents by MCST, by the submission deadline.

Changes to the submitted proposal are not allowed, unless requested and/or approved by the Council.

#### **National Contact Point**

Annalisa Cartabia, **Lead Executive** Email: <a href="mailto:annalisa.cartabia@gov.mt">annalisa.cartabia@gov.mt</a>

Tel: 2360 2152

Christy Baldacchino, **Alternate Executive** Email: <a href="mailto:christy.baldacchino@gov.mt">christy.baldacchino@gov.mt</a>

Tel: 2360 2158

Correspondence should be directed to:

The Malta Council for Science & Technology Villa Bighi, Kalkara, KKR 1320, Malta Email: <a href="mailto:eusubmissions.mcst@gov.mt">eusubmissions.mcst@gov.mt</a>

For escalated matters kindly contact Dr. Maria Azzopardi, Internationalisation Deputy Director, on maria.azzopardi.2@gov.mt.

# 2. Applicant Eligibility

# 2.1 Eligibility of Entity

Any Public Entity or Public Research and Knowledge-dissemination Organisation, registered in Malta, that does not carry out an economic activity within the meaning of Article 107 TFEU may apply and will be eligible for funding subject to the terms and conditions laid out in this document and in particular the conditions for eligibility.

Any applicants that are non-compliant with respect to Grant Agreement obligations, or outside approved project timelines, on other active projects funded by the Council, may be immediately deemed ineligible at application stage. Similarly, should applicants become non-compliant during the call process, they will not be awarded funding under this programme.

Any application submitted by or including the participation of any legal person or legal entity having, in totality or in majority ownership, the same shareholders, partners or persons holding and / or exercising a controlling power in any other legal entity (Malta-based or otherwise) which will have been at any time declared as non-compliant or defaulting on any other contract or agreement entered with the Council and remained in default, shall be automatically declared as inadmissible.

# 2.2 Funding Consideration

The financial contribution to a Partner where State Aid is not applicable shall be 100% of the eligible costs incurred by that Partner.

All applications should be accompanied by the relevant declaration forms. Applicants should quantify **any possible indirect State aid** to undertakings through public research and knowledge dissemination organisations and public entities in cases of collaboration with undertakings or contract research or research services on behalf of undertakings.

# 3. Proposal Eligibility

The following criteria are mandatory and must be fulfilled when applying for this Call, in addition to eligibility conditions described in the <u>Call Text 2024</u>.

# 3.1 Types of Projects

The research type(s) of projects eligible within this Call encompass Fundamental Research, Industrial Research and Experimental Development, as defined in Section 1.1.

This is a Call for collaborative, transnational research, and innovation actions. Applied research, and implementation research, piloting, and testing are within the scope of the call. All projects must demonstrate proof of concept(s), validate of concepts, models, or solutions, and showcase demonstrations of solutions in relevant health and care ecosystems. Translation to other settings of already adopted solutions is also within scope of this call.

Malta-based applicants can propose projects of <u>Technology Readiness Levels (TRLs)</u> between TRL 3 and 7. Nevertheless, applicants should ensure that they are addressing the specific Research and Innovation activities described in the THCS Partnership Call Text 2024.

#### Proposals will be rejected if they:

- Predominantly concern development of new technological solutions, without a focus on integration of the solutions, organisational models or implementation in the health and care systems.
- Have a predominantly clinical, pre-clinical/bio-medical component or
- Are purely epidemiological studies mapping the extent of and causal factors behind illnesses, without a focus on solutions, models or implementation in the health and care systems.
- Solely concern social/welfare services and do not address issues in the health and care services.
- Do not take into consideration an ecosystem-wide approach and/or fail to consider endusers' perspectives.
- Predominantly concern actions on primary prevention.

# 3.2 Alignment to Scope

The proposal should be consistent with the scope and objectives of this Call [Refer to Section 1].

Malta-based Applicants can propose projects in all the topics proposed in the THCS Partnership Call Text 2024.

#### **Essential elements:**

- The research and innovation activities of the submitted projects should provide a broad range of knowledge and implementation-ready solutions for the use of data in prevention. Proposals may address a few or multiple dimensions of health and care systems.
- Proposals must address the economic and social impact of the proposed models, solutions, or approach.

- Proposals are required to address legal, financial, technological, educational and adaptative barriers to the implementation of the project outcome(s). Proposals should outline a clear strategy and roadmap from project output to implementation.
- Proposals are required to address necessary skills required of all relevant stakeholders, including health and care professionals and end-users.
- Proposals should address how end-users will be involved in the project. End-users may be the general public, patients, clinical professionals, policy makers, etc.
- Proposals must show how the project will be linked to the policy context and wider ecosystems. This includes cooperation and coordination between stakeholders, across the boundaries of traditional health and care domains, locally or regionally, involving endusers, health and care professionals, and/or other stakeholders e.g., health and care system owners, when relevant.
- Especially with respect to implementation approaches, companies and end-user organisations should be partners in the consortium. The embedding of the endeavour into organisational strategies will raise the transformational power of the consortium. If the consortium has a commercial component, the workplan needs to include the development of business plans and reflect the reaching out to relevant wider ecosystems.

# 3.3 Eligibility of Consortium Composition

Transnational project consortia must consist of **at least three independent legal entities** from at least three different countries participating in the THCS Partnership Joint Call 2024 (list available in the Call Text). Maximum two eligible partners per consortium can request funding from the same funding organisation. The total number of partners in a consortium is limited to nine excluding collaborators, i.e., partners participating with their own expenses and therefore fully self-financed.

Fully self-financed partners are not counted for the minimum requirement of eligible partners and countries and cannot act as the consortium coordinator.

Each principal investigator can submit up to two proposals as mere partner including one as coordinator.

Malta-based applicants should check their national application submission requirements in Section 1.3 and their eligibility in Section 2.

## 3.4 Budget and Grant Value

The National Budget for this Call is of €500,000.

The maximum amount that national partner/s can jointly request per project is €500,000.

Successful project submissions will receive periodic financing that will be regulated through a Grant Agreement establishing the terms and conditions governing the financing of the project. Refer to Section 6.

## 3.5 Project Duration

The minimum project duration is 12 months, and the maximum project duration is 36 months.

# 3.6 Project Contact Point(s)

Each applicant shall appoint at least one Project Contact Point. The Project Contact Point(s)'s responsibilities are as defined in Section 1.1.

#### 3.7 Deliverables

Deliverables are tangible outcomes of the project and must be submissible. They must be proposed between the start and end date of the project. Deliverables that are not submitted within the stipulated deadlines will not be considered. If the project is awarded, evidence should be submitted for each deliverable mentioned in the application form to ensure that it has been attained successfully. A milestone refers to a key deliverable or achievement within the project.

The project work plan must give sufficient details of foreseen activities and are to be included as deliverables in the project proposal. The sub-sections below list the Mandatory deliverables that are required by the Council and a non-exhaustive list of Recommended deliverables that may be considered.

It is recommended that file storing and synchronization service e.g., Google Drive or Dropbox, is set up and shared with the Council to support the project monitoring process. The shared folder should reflect the structure of deliverables provided in the Full proposal i.e., every deliverable should have its own sub-folder with evidence saved within.

The Beneficiaries shall always cooperate with the Council in the promotion of the Programme by delivering presentations about the Awarded Project or through other reasonable means at the request of the Council.

## **Mandatory deliverables**

- Publish at least two (2) articles per year in local newspapers, online platforms, or magazines including an acknowledgement to the Council and any other acknowledgements as stipulated in Section 7.2. These should not contain intellectual property but should raise awareness about the project and its benefits. A copy of this/these should be presented to the Council within two weeks of publication. Other forms of publications may be considered.
- Actively participate in MCST's Research Conferences / Events to disseminate the project results and the experience of obtaining funding from MCST. A budget of €5,000, will be deducted from the project grant for the beneficiary's participation in such conferences.
- Report on project progress through reports and meetings as per Section 7.3 and in line with the templates provided by the Council.

#### **Recommended deliverables**

- During the duration of the project, publish at least one (1) peer-reviewed research paper based on the work carried out throughout the Project in an open-access journal. The paper is to include an acknowledgement to the Council and any other acknowledgements as stipulated in Section 7.2.
- Oral presentation/s at international conference/s on the work carried out through the Project.
- The attainment of undergraduate degrees and/or postgraduate degrees and/or postdoctoral research. (In cases where the Project duration is insufficient for the purpose of submitting a degree, there has to be a commitment to complete the degree outside the duration of the project utilising other sources of funding).

- Additional project dissemination activities including but not limited to project exhibitions, workshops, and events (preferably open access). Examples include Science in the City, R&I cafes, Enterprise European Network events, project exhibitions etc.
- Registration of patents or other Intellectual Property Rights stemming from the Project, in Malta as well as in any other country, on the work carried out throughout the project (or any tangible outcomes during the patenting process).
- The formation of any spin-off entities that are envisioned. Kindly highlight if these spin-offs will also be licencing any IP generated.
- Commercial commitments such as technology innovations to be included in a partner's existing product or service.
- Commercial commitments such as technology transfer licences.

In the case of publications, these should take place during the duration of the project, and where available and possible, deposited in the entity's repository, including an acknowledgement to the Council. In cases were open access-fees were budgeted for, it is the responsibility of the beneficiary to account for the time it would take for the invoicing and payment of that fee.

Provided further that if the Beneficiary claims that such an attempt to publish this research paper will have been unsuccessful, the Beneficiary must prove to the satisfaction of the Managing Authority and through the submission of sufficient and adequate documentary evidence that such an attempt to publish a research paper in terms of the requirements of this Clause was in fact made. Sufficient and adequate documentary evidence includes evidence that the paper was actually submitted for publication and documentary evidence that the paper was rejected for publication. If the Managing Authority is satisfied with the evidence provided, then the Beneficiary will not be held in breach of this particular obligation.

A copy of all publications must be presented to the Council before any retention is disbursed.

MCST appreciates that the attainment of these deliverables may depend on externalities. The Consortium is expected to take these into consideration when submitting their application forms. Although these deliverables are non-compulsory, if quoted as committed deliverables in the Application stage, they must be adhered to.

# 4. List of Eligible Costs and Ineligible Costs

A grant must not exceed the overall amount which is established at the time of the project selection based on the estimated eligible costs indicated in the budget breakdown form. Eligible costs are costs actually incurred and claimed by the beneficiary of a grant which meet all the following criteria:

- They are incurred between the Start Date and the End Date of the project.
- They are necessary for the implementation of the project as outlined in the project proposal which is the subject of the grant.
- They are identifiable, verifiable and being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of Malta and according to the usual cost accounting practices of the beneficiary.

- They comply with the requirements of applicable tax and social legislation. They are reasonable, justified and comply with the principle of sound financial management, regarding economy and efficiency.
- Any calls for the recruitment of personnel on a project is to be conducted in a strictly transparent manner and is to include a public call in the form of an online advert and interview process.
- Commercial transactions between any applicants or consortium partners, or between any applicants or a consortium partner and a company with similar shareholding to a consortium partner, is not allowed. All transactions need to be carried out in line with the arm's length principle outlined within the Definitions (Section 1.1).
- Any expenses incurred during the Project must be consistent with the principles of economy, efficiency and effectiveness. Any purchases must be carried out at "arm's length" conditions. Commercial transactions between Beneficiaries within the same Project are not allowed.

# 4.1 Eligible Costs

#### Personnel

Personnel costs include wages of employees (researchers, technical staff, other research supporting staff) directly engaged by the Applicant to the extent and for the duration of the proposed research project.

- All employees in respect of whom costs are claimed must be registered with the competent local authorities and covered by a valid contract of employment in terms of the national legislation to employment.
- The total claimed hours worked by a full-time employee shall not exceed 1720 hours *per annum*. Person hours dedicated to the project can be claimed while respecting this maximum capping. Attention should be paid not to exceed this capping, particularly if researchers work on other funded projects. **Timesheets are to be completed and retained for all personnel, including students, as proof of number of hours spent on the project**.
- Annual stipends of € 6,000 for students reading for a master's degree or € 8,000 for students reading for a doctoral degree. In the case of a part-time post-graduate degree, the respective stipend will be calculated pro-rata and at the discretion of the Council. For every engaged student, a full-time researcher must be employed by the applicant.
- Personnel costs related to Project Management are capped at 10% of the total project value and such effort should be allocated to (and described within) research tasks to be eligible.
- *Table 1* shows the eligible hourly rates (inclusive of National Insurance, Inland Revenue, and other allowances) and personnel limits per applicant. The personnel hourly rate is calculated using the following formula:

€z = (basic salary + allowances) / yearly workable hours of the employee.

in 2025 in 2026 in 2027 project
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Management or equivalent	Up to	Up to	Up to	Max 2 per
	€57.89/hour	€60.78/hour	€63.82/hour	project
Senior Researcher <sup>2</sup>	Up to	Up to	Up to	Max 2 per
or equivalent	€40.80/hour	€42.84/hour	€44.98/hour	project
Researcher³ or equivalent	Up to €29.23/hour	Up to €30.69/hour	Up to €32.22/hour	No limits
Operational, technician, research support assistant or equivalent	Up to €16.03/hour	Up to €16.83/hour	Up to €17.67/hour	No limits

Table 1 Eligible Hourly Rates

The rates stated in the table above are for the years 2025-2027. For subsequent years a 5% increase per year is allowed.

- Personnel in salary brackets that are higher than those noted above will still only be reimbursed at the rates of the eligible brackets above depending on their role in the project.
- For personnel who are yet to be recruited for the project, applicants should submit a job description highlighting requirements of the role at the application stage.
- Research Organisations (recognised and as defined in L.N 212 of 2018) shall adhere to
  the conditions set for engaging and employing researchers from third countries within
  LN 212 of 2018: Conditions of Entry and Residence of Third-Country Nationals for the
  Purposes of Research, Studies, Training and Voluntary Service in the Mobility Project for
  Young People: Voluntary Projects Regulations, 2018.
- The maximum hourly rate (i.e., the highest hourly rate an individual is paid throughout the project duration) and the person hours that will be worked on the project per engaged individual, will have to be noted in the Detailed Budget Breakdown Form as requested at full proposal submission. In the case of existing personnel, CVs are to be provided. The actual hourly rate of each engaged individual will be reported in the financial reports during the monitoring process as per Section 7.

### **Instruments, Specialised Equipment and Research Consumables**

These costs include the purchase/leasing of specialised equipment including software. An explanation of the relevance of the equipment in relation to the project, including specification where applicable, is required. If a specialised laptop/PC is to be purchased, please specify its usage and specifications.

These costs also include the purchase of research consumables. The overall value of consumables typically cannot exceed 30% of project value. Proposals with consumables exceeding 30% of the project value need to be discussed at application stage.

<sup>&</sup>lt;sup>2</sup> The term 'senior researcher' is to be used for a postdoctoral researcher with a specialist and high level of local and international experience in the field. Individuals possessing a high level of experience in industry can still be considered.

<sup>&</sup>lt;sup>3</sup> The term 'researcher' is to be used for a Bachelor's, Master's or a Ph.D. degree holder and hence the hourly rate should be equivalent to the degree held by the relevant individual

#### **Travel and Subsistence**

Eligible costs under this section include the cost of economy flights, public transport and other expenses that have been incurred for the purpose of the project after selection of the most economic solutions. Per diems are payable for travel up to a maximum of 14 days in a row.

Type of Meeting	Number of persons funded	Comments
Consortium meeting	Max. of 2 persons per meeting	Within the project period.
International Conference	Max. of 2 persons per event	Max. of one conference every 6 months
'Other' project-related meetings	Max. of 2 persons per occasion	Need to be discussed and approved by the Council.

#### **Costs of IP and Knowledge Transfer Activities**

These costs include the costs of knowledge transfer activities and patents bought or licensed from outside sources shall be obtained at arm's length conditions. **Such activities should be discussed with the Council before submission of the application to ensure eligibility**.

#### **Subcontracted Activities**

Subcontracted activities shall be allowed up to a limit of 25% of the project value. Such activities should be discussed with the Council before submission of the application to ensure eligibility.

Where a component of the project work is a Subcontracted Activity, the following considerations shall apply:

- The PI remains responsible for the timely delivery of the subcontracted tasks;
- The PI shall ensure that such a third party is selected in a manner which is transparent, fair and impartial. Partners shall ensure that there is no discrimination between bidders and that all bidders are treated equally and transparently in all calls for quotations.
- The PI should ensure that the attainment of any services or goods respect the procurement criteria listed in Section 4.

#### **Overheads and Other Operating Expenses**

Overheads (also known as eligible indirect costs) and other operating expenses are eligible if they are incurred directly as a result of the project. These will be covered at **20%** of direct eligible costs claimed.

#### **Aid Intensity**

The financial contribution to an applicant under these Rules for Participation shall be 100% of the eligible costs incurred by that project Partner.

Should at any point in time the Council or any other relevant entity deems that the project constitutes State Aid, the beneficiary will be required to follow State Aid Regulations and this in turn may or may not result in the recovery of funds.

## 4.2 Ineligible Costs

The following shall be considered as a non-exhaustive list of ineligible costs:

- Expenses which are recoverable through other funding mechanisms, including recoverable value added tax.
- Re-purchase of equipment originally procured through other funding mechanisms.
- Personnel hours for travelling and/or overtime.
- Opportunity costs related to foregone production and production downtime arising from the allocation of resources to the Project.
- Standard office equipment and stationery.
- Purchase of equipment and services from partners or their subsidiaries.
- Any activity related to the reproduction of a commercial product or process by a physical examination of an existing system or from plans, blueprints, detailed specifications or publicly available information.
- Expenses related to loans, interest, etc.
- Any cost incurred to submit the Intent to Apply and the full proposal.
- Any cost incurred before the start date and after the end date of the project.
- Any other costs not listed down in Section 4.1.

Any line items not seen to be compliant with the nature of the programme will be subtracted from the grant.

### 5. Evaluation

Applications will be checked for administrative eligibility by the THCS Partnership Joint Call Secretariat. Applications involving at least one Malta-based applicant will also be checked for administrative eligibility by the Council. Once the project application is deemed eligible, this will be scientifically by three independent external reviewers in accordance with the THCS stipulated evaluation criteria as set in the Call Text.

THCS will only fund research of the highest ethical standards complying with European Directive and the relevant national/regional laws, rules, and regulations. Each applicant to a THCS call must comply with both THCS ethical considerations and the national/regional/local regulations in question. All proposed activities undertaken in countries outside the EU must also comply with EU regulations.

The Council may undertake a Due Diligence exercise through its contractors for the purpose of administrative compliance. Further assurances and documentations may be required at the discretion of the Council.

Changes to the submitted proposal are not allowed prior to the Grant Agreement, unless requested and/or approved by the Council.

#### 6. Post Selection Process

# 6.1 The Grant Agreement

A Grant Agreement will be signed between the successful applicant and the Council. This Agreement will serve as the basis for project funding and will regulate the transfer of funds to national beneficiaries. Hard copies of the Grant Agreement must be signed and endorsed by the respective legal representative(s) of the potential beneficiary within 15 days from the date on

which the potential beneficiary receives them. Failure to endorse the Grant Agreement within the stipulated timeframe may result in the withdrawal of the offer for funding.

The Council reserves the right not to proceed with signing any Grant Agreement if the Council deems that doing so would be too high an exposure risk.

The Project Contact Point must provide two (2) images related to the project and an abstract upon signing the Grant Agreement. These will be used by the Council to publicise the award.

### 6.2 Start Date and End Date

The Project Coordinator with the project partners, shall decide on a common Start Date for the project. This information needs to be communicated to all the funding bodies involved in the project, to ensure that the national contracts are synchronised to cover all periods of the project.

The pre-determined date as agreed will be stated in the Grant Agreement, in line with Section 6.1. The earliest possible Start Date for projects will be fixed at the beginning of the contract negotiations with the national funding organisations.

In view of the nature of the Grant Agreement, the said agreement will not be signed simultaneously by all parties but will be signed by all the parties separately. Each party will signify the date of signing and the Grant Agreement will come into force on the date on which the final signature is made thereon (hereinafter referred to as the "Agreement Date").

Between the Agreement Date and the Start Date, the Project Contact Point should ensure that all activities required for a smooth project start are completed.

To be eligible for funding, all expenses must be incurred between the Start Date and the End Date of the Project.

#### 6.3 Grant Amount

The acceptance of an application does not automatically lead to an award of value that is equal to the amount requested by the applicant. The funding requested may be reduced based on the specific funding regulation applied. It should be noted that the grant amount foreseen by the agreement is a maximum which cannot be increased during Grant Agreement preparation with the Council.

# 6.4 Double Funding

Funding under this Call is made available on the basis that the applicant has not benefited from any other grant or financial incentive of whatever nature, applied for and/or utilised for the same scope by the Council and/or other funding agencies as that for which funding is requested under this scheme. In the case where the application covers work that is part of a larger project, the applicant must submit a table as an appendix to the Application Form that shows a comprehensive list of the items of work and the source of funding for each item.

By signing the Grant Agreement, the applicant will be authorising the Council to exchange essential information related to the project with other funding agencies, both local and overseas, for any necessary checks. Any occurrence of double funding should be communicated in writing to the Council, prior to the signing of the Grant Agreement and as may arise during the implementation of the project.

# 7. Funding, Management and Progress Monitoring

# 7.1 Allocation and Disbursement of Funding

The funding of the project shall be disbursed in the following manner, including both direct and indirect costs:

Pre-Financing	50%
Interim Financing	30%
Retention	20%

Total financial contribution over the lifetime of the project shall not exceed the funding limit as established in the Grant Agreement, irrespective of actual expenditure.

The periodic funding will be allocated according to the following schedule:

- 1. The Council will make an initial advance payment (pre-financing) of 50% of the due financial contribution and will include both direct and indirect costs (i.e., total eligible costs).
- 2. The Project Contact Point will be required to submit a Technical and a Financial Interim Report to the Council with details of actual expenditure in the first half of the project, together with an updated forecast of projected expenditure for the remainder of the project. Both reports must be approved by the Council before proceeding with the project.
- 3. After the Interim reporting is reviewed, the Council will calculate the next due financial contribution based on the Financial Report submitted. This contribution will be calculated as forecast eligible expenditure.
- 4. The Council shall retain 20% of the total project grant to be transferred only upon successful completion of the project. This is referred to as the Retention Money.
- 5. Following the termination of the project or expiry of the Grant Agreement, the Project Contact Point will be required to submit a Final Technical Report together with a Final Financial Report for the whole project. The Final Financial Report needs to be audited by a certified auditor appointed by the applicant and approved by the Council once submitted. The audit should determine the total eligible costs and compare these to the funds forwarded.
- 6. As soon as the verifications and audits are finalised and cleared, the Council will release the Retention Money due. In the case of overpayment, the applicant will be required to refund the under-spent amount to the Council within a specific timeframe, or as agreed to with the Council.
- 7. Any changes to the project objectives, work-packages or any other parameter committed to in the application, are to be communicated in writing with clear justification to the Council prior to the deadline. The written request will be referred to the Unit Director for approval. The Council will acknowledge receipt and endeavour to reply in a timely manner so that the momentum of the project remains unaffected. Acceptance or otherwise of any changes shall be at the sole discretion of the Council and its decision shall be binding, final and irrevocable. Any other communication shall not be considered valid or binding.

The Council reserves the right to alter the funding parameters as deemed appropriate.

### 7.2 Dissemination and Externalisation

All dissemination and publication of information in relation to the proposal selected for award is to commence following the signing of the Grant Agreement.

Any articles and text material related to the project should include the words:

"Project [Project Name] is financed by the Malta Council for Science and Technology through the Transforming Health and Care Systems Partnership that is supported by the European Union through Horizon Europe."

Any websites or printed material related to the project should also include the Council logo, the **THCS Partnership** logo, the 'co-funded by the European Union' logo with the EU flag together with the words European Partnership as per the Operational Guidelines for European Partnerships.

During the term of Agreement and for five (5) years thereafter, the applicant shall include and prominently feature the Council and the **Transforming Health and Care Systems Partnership** in any publicity related to the project.

All publicity material shall be vetted and approved by the Council **before** publication. In the case where printed material is published without a mention of the initiative and the Council, the Applicant shall be obliged to publish a correction at their own expense in the subsequent issue of the publication.

# 7.3 Reporting

An Interim **Technical Report** and **Financial Report** are to be presented to the Council at the mid-point of the project.

On the last day of the project, the Project Contact Point is required to submit an **End of Project Technical Report**. The **End of Project Audited Financial Report** covering the work and expenditure undertaken during the entire project shall need to be submitted up to eight (8) weeks from the stipulated end of project date.

The Project Contact Point shall also set a schedule for periodical progress meetings with the Council to take place. During such meetings, beneficiaries should verbally update MCST on progress via a presentation.

The following example is based on a project timeline of 36 months:

Meetings	Project Timeline*	Reports
Progress Meeting	Month 6	
Progress Meeting	Month 12	
Progress Meeting	Month 18	Interim Technical and Financial Report
Progress Meeting	Month 24	
Progress Meeting	Month 30	
Progress Meeting	36	End of Project Technical Report
	38	End of Project Financial Report

\*The project timeline may vary according to the project duration.

The Interim Technical and Financial Reports shall contain the following details:

- i. An overview of project activity and achievements compared with the originally submitted application.
- ii. An account of actual expenditure over the first half of the project compared with the originally submitted overall budgeted expenditure. All financial reports must be signed by the person responsible for the financial management and assembled as per the instructions in the Grant Agreement.
- iii. An updated forecast of project activity and projected achievements for the remaining half of the project.
- iv. An updated forecast of projected expenditure for the remaining half of the project.

The End of Project Technical and Financial Reports shall contain details listed above as well as the financial audited reports as per below.

The audit will consist of, at least, the following checks:

- i. Accounts
- ii. Physical inventory
- iii. Timesheets and payslips / employee contracts
- iv. Receipts for all equipment and consumables
- v. Bank statements for the Project Account

The beneficiary shall appoint an auditor to conduct a detailed financial audit, following the completion of the project. The Council reserves the right to appoint an auditor to audit the Project Financial Audit as submitted.

The Council may at any time request supplementary information and documentation on the projects and may request additional progress meetings. The Council may make such additional enquiries into a project as deemed necessary. Any required documentation not submitted within Stage reports or Final Reports, or documentation not submitted within the specified timeframes, may render the whole project ineligible, and may result in the Council recovering all funds disbursed across the project.

If the project is found to be in breach of the Grant Agreement or to materially depart from the submitted application, the Council reserves the right to discontinue the award and the beneficiary may be required to refund the Grant in part or in full. In any such event, the Council may also exclude a beneficiary from participating in future calls.

Project Consortium must comply with the THCS mandatory reporting requirements and activities as outlined in the Call text.

# 7.4 Accountability

Beneficiaries must keep a separate bank account or records, which must be clearly distinguishable from its other accounting records. All relevant expenses must be recorded in this account.

Eligible expenses must have been determined in accordance with the usual accounting and management principles and practices of the beneficiary. Direct eligible costs must be backed up with the relevant documentation as specified in the Grant Agreement.

# 7.5 Project Extensions

Time extension requests are unlikely to be accepted unless these are due to extenuating circumstances that are deemed plausible and conditionally valid by the Council. Such circumstances need to be unavoidable, and partners need to provide evidence to the Council that all efforts and best practice project management have been undertaken to remedy the extraneous circumstances.

If the Council deems a request for extension as conditionally valid, the Malta-based Principal Investigator would need to communicate it to the Project Coordinator, who in turn will inform all the other funding agencies in the project. The Council will validate the extension upon confirmation of approval and consensus from all partners within the project of the new End Date.

# 7.6 Budget Transfers

Applicants should note that:

- Transfers of project funds between line items over the course of the project that are cumulatively less than 20% of the grant value are automatically eligible provided that:
  - o the limits mentioned in Section 4 are adhered to;
  - expenses are exclusively used throughout the project lifetime to the sole benefit of the project;
  - o requested costs should be eligible as per Rules of Participation.
- Should transfers of project funds between line items are cumulatively greater than 20% of the grant value, these will be considered as significant alterations to the proposal and will not be eligible.
- Transfers of project funds should be discussed in the project progress meetings and reflected in the Project Financial Reports, mentioned in Section 7.3.

In case of local Maltese consortia, the 20% transfer limit is set for the grant value of the respective partner.

#### The structure of the line items will be as follows:

- Transfers between budget categories will always contribute to the 20% limit.
- Each manager will be considered as its own line item (transfers between managers will contribute to the 20% limit)
- Research personnel will be considered a single line item (transfers between research personnel will **not** contribute to the 20% limit)
- Equipment under €5,000 will be considered a single line item (transfers between equipment under €5,000, will **not** contribute to the 20% limit). However, each piece of equipment over €5,000 will be considered their own line item (transfers between equipment over €5,000, **will** contribute to the 20% limit).
- Subcontracted activities of under €5,000 will be considered a single line item (transfers between subcontracting under €5,000, will **not** contribute to the 20% limit). However, subcontracting over €5,000 will be considered their own line item (transfers between subcontracting over €5,000, **will** contribute to the 20% limit).
- Consumables of under €5,000 will be considered a single line item (transfers between consumables under €5,000, will **not** contribute to the 20% limit). However, consumables over €5,000 will be considered their own line items (transfers between consumables over €5,000, **will** contribute to the 20% limit).

• Travel will be considered a single line item (transfers between travel will **not** contribute to the 20% limit).

The term 'own line item' refers to a whole budget category whereas 'single line item' refers to one individual line item within a budget category.

Should equipment/subcontracting originally proposed to be over  $\[ \in \]$ 5,000 get reduced to less than  $\[ \in \]$ 5,000 over the course of the project, this will be still considered as an individual line item. Should an item of equipment/subcontracting originally proposed to be less than  $\[ \in \]$ 5,000, be increased to over  $\[ \in \]$ 5,000 over the course of the project, this will be considered as an individual line item.

For reference purposes, please find the above transfers in a tabular format:

Will contribute to the 20% limit	Will <u>not</u> contribute to the 20% limit
Transfers between different budget	
categories	
Transfers between managers	Transfers between research personnel
Transfers between items of equipment (over	Transfers between items of equipment
€5,000)	(under €5,000)
Transfers between subcontracted activities	Transfers between subcontracted activities
(over €5,000)	(under €5,000)
Transfers between consumables (over	Transfers between consumables (under
€5,000)	€5,000)
	Transfers between travel activities

# 7.7 Supervening Circumstances

The Project Contact Point is obliged to immediately advise the Council of any internal or extraneous significant event which might affect the validity or implementation of the project. This obligation applies to the entire period between the submission of the Project Application and the completion of the project.

The Council, at its own discretion, shall either give such directives as it deems necessary for the furtherance of the project or re-assess the project in its entirety accordingly.

Failure on the part of the Project Contact Point to respect this obligation may lead the Council to suspend or terminate funding for the project and request a refund.

If during the project a partner withdraws from the Project Consortium, the beneficiary should immediately advise the Council. In this event, the relevant articles of the Project Consortium Agreement and the National Grant Agreement shall apply.

#### 7.8 Default

If the implementation of a project becomes impossible or if the beneficiary fails to implement it, the Council shall be entitled to take any action it deems necessary, including, but not limited to, the withdrawal of funding for the project and the collection of refunds of the money already paid out. A similar course of action may be followed if a project is in default as a result of not meeting one or more of its obligations. Prior to taking any drastic action, the Council will provide a maximum of two notices indicating a rectification period of one month each.

# 7.9 Interpretation of Rules

This document endeavours to establish comprehensive and unambiguous rules governing participation in this initiative. However, should circumstances arise where the rules are inadequate, unclear, ambiguous, or conflicting, the Council shall exercise its discretion in the interpretation of the rules through the setting up of an *ad hoc* committee.

These current Rules repeal any Rules previously issued and constitute exclusively the entire Rules issued by the Council.

# 8. Confidentiality of Submissions

Unless otherwise indicated, all project application submissions except for the name of the entity, project contacts, title of proposal and the abstract shall be treated in strict confidence.

The data collected by the Council via the application for the aid and its subsequent processing by the Council to evaluate the data subject's request for aid under the Scheme is in line with:

- The National Rules for Participation;
- ii. Data Protection Act (CAP 586 of the Laws of Malta) and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).
- iii. The legitimate basis to process personal data submitted by the data subject by virtue of his/her written application for aid is Regulation 6 (1)(b) of the General Data Protection Regulation ("GDPR"), as 'processing is necessary in order to take steps at the request of the data subject prior to entering into a contract'.