

Innovate to Prevent: Personalised Prevention in Health and Care Services

Transforming Health and Care Systems Partnership - Call 2024

National Rules for Participation – State Aid

These Rules for Participation are applicable to undertakings that carry out an economic activity within the meaning of <u>Article 107 TFEU.</u>

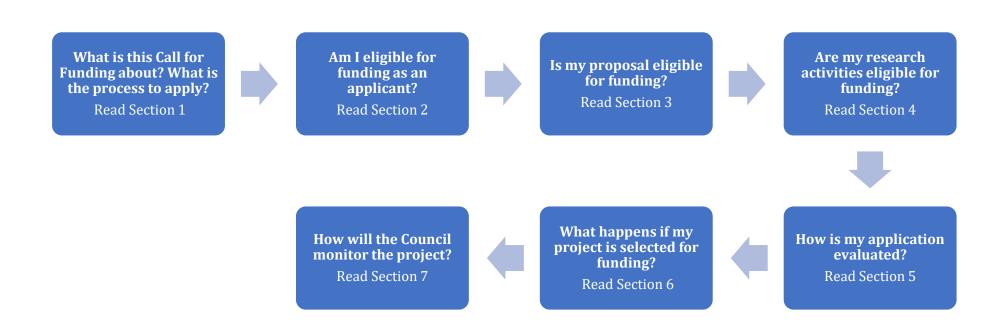
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Guide to this document



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** entitled *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</u> (<u>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 personcentred 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>.

	The term refers to any representative of a local entity that is eligible for
Applicant	participation in a Project in terms of these National Rules for Participation
	and who applies for funding under this joint initiative.
	The term means that the conditions of the transaction between the
	contracting parties do not differ from those which would be stipulated
Arm's length	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.
Donoficiam	The term refers to the Applicant whose project has been awarded and hence
Beneficiary	will receive funding.
Council	The term refers to the Malta Council for Science and Technology on behalf of
Councii	the Foundation for Science and Technology.
Due Diligence	The term refers to an investigation of a business or person prior to signing
Due Diligence	the Grant Agreement.

1.1 Definitions

Effective Collaboration	The term means collaboration between at least two independent parties to exchange knowledge or technology, or to achieve a common objective based on the division of labour where the parties jointly define the scope of the collaborative project, contribute to its implementation, and share its risks, as well as its results. One or several parties may bear the full costs of the project and thus relieve other parties of its financial risks. Contract research and provision of research services are not considered forms of collaboration. Through effective collaboration the aid intensity may increase if the conditions set in Article 25(6)(d) of Commission Regulation 651/2014, as amended, are satisfied.	
Eligible direct costs	achieving the objectives of the project. All eligible expenses must be incurred	
Eligible undertakings	 The term refers to undertakings planning to carry out Fundamental Research, Industrial Research and/or Experimental Development projects and must either be: a partnership constituted under the Companies Act, being a partnership <i>en nom collectif, en commandite</i> or a limited liability company; or be duly registered as a co-operative society under the Co-Operative Societies Act; professional body; NGOs; Non-profit making entities (including Foundations). 'Professional Body' may be an organisation, an association, a chamber, society, institute, or a group of professional persons not being enrolled or registered in terms of The Voluntary Organisations Act (Cap. 492 of the Laws of Malta) or not being otherwise recognised in terms of Law, and which is generally recognised and acknowledged by the professional persons it seeks to represent as their representative body. For the purposes of this Definition, a professional person is one who has undergone a period of study at a university or a recognised institution of higher learning and has obtained the formal qualification entitling the person to practise the respective profession; and who provides a specialised service to the public, based primarily on a fiduciary relationship between herself/himself and the party to whom s/he provides such service on his own personal credibility and responsibility. 	

	'Non-profit making' is an entity where (a) the statute of the entity contains an express exclusion of the purpose to make profits; and (b) there is express provision in the statute defining the purposes of the entity which do not include the promotion of private interests, other than a private interest which is a social purpose; and (c) no part of the income, capital or property is available directly or indirectly to any promoter, founder, member, administrator, donor or any other private interest. Provided that if a promoter, founder, member, administrator or donor is another enrolled non-profit making organisation, the limitation in paragraph (c) shall not apply provided the availability of such income, capital or property is subject to conditions which are consistent with the general purposes of the grantor entity: Provided further that an organisation shall continue to be deemed as non-profit making notwithstanding that:(i) it obtains a pecuniary gain from its activities when such gain is not received or credited to its members but is exclusively utilised for its established purposes; (ii) it buys or sells or otherwise deals in goods or services where such activities are exclusively related to its principal purposes; (iii) it is established for the general entertainment, pastime, education or other similar benefit only of its members; or (iv) it is established for the promotion of the social role, ethics, education and values of a trade or profession provided it does not promote the private interests of its members.
End Date	This term refers to the date when the Project Period, having commenced on the Start Date, expires.
In-kind	The term refers to any non-monetary contribution, such as a service or a good.
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 applied to non-novel, yet step-change/ground-breaking enhancement of existing technological processes, products, or services, or even the application of existing knowledge to new novel applications of these solutions to deliver step-change competitiveness through such an application.
Large Undertaking	The term is defined as an undertaking not fulfilling the criteria laid down in Annex I of Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Article 107 and 108 of the Treaty, as amended.
Legal Entity	The term refers to any entity created within the European Union, having an operating base in Malta and which has legal personality, which may, acting under its own name, exercise rights and be subject to obligations.
Operating base in Malta	 Having an operating base in Malta means if the legal entity: i. owns, leases, or has been given the right of use by a third party, an adequate premise from where to conduct an eligible economic activity in the region of Malta; and ii. employs at least one person that is based in Malta and is liable to pay income tax in Malta.

Partner	The term is defined as an entity within a consortium of a funded		
	transnational project.		
	The term refers to the individual, appointed to act on behalf of the Beneficiary and who is responsible for communicating with the Council about the Project.		
Project Contact Point	 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 / Person hours	The term refers to a calculation of 'human effort' to evaluate the relationship 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.		
Personnel	The term means the costs of researchers, technicians and other supporting		
costs	staff to the extent employed on the relevant project or activity.		
Project Coordinator	The term refers to one of the beneficiaries of a transnational project 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 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 Investigator	The term refers to the lead researcher on behalf of the local 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 the project, including any co-financing.		
Research and Development	This term is defined as the systematic investigation, work or research carried out in any field of science or technology through experiment, theoretical work or analysis undertaken to acquire new knowledge, primarily directed towards a specific practical aim or objective, and includes:		

	i. Fundamental Research 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. Industrial Research 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 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
Decourse and	changes may represent improvements.
Research and	The term refers to an entity (such as universities or research institutes,
Knowledge-	technology transfer agencies, innovation intermediaries, research-oriented
Dissemination	physical or virtual collaborative entities), irrespective of its legal status
Organisation	(organised under public or private law) or way of financing, whose primary
(RKDO)	goal is to independently conduct fundamental research, industrial research

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Single Undertaking	 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. The term includes all enterprises having at least one of the following relationships with each other: i. One enterprise has a majority of the shareholders' or members' voting rights in another enterprise. ii. One enterprise has the right to appoint or remove a majority of the members of the administrative, management or supervisory body of another enterprise. iii. One enterprise has the right to exercise a dominant influence on another enterprise pursuant to a contract entered into with that enterprise or to a provision in its Memorandum and Articles of association. iv. One enterprise, which is a shareholder in or member of another enterprise, controls alone, pursuant to an agreement with other shareholders in or members' voting rights in that enterprise. 		
	above through one or more other enterprises shall be considered to be a single undertaking		
Small and	single undertaking,<i>d</i> The term refers to an undertaking which fulfils the criteria laid down in		
Medium sized	5		
Enterprise	declaring certain categories of aid compatible with the internal market in		
(SME)	application of Articles 107 and 108 of the Treaty, as amended.		
	The term shall be defined as an undertaking that has been established for		
Start-up	less than five (5) years following its registration. For eligible undertakings that are not subject to registration, the five-year eligibility period shall start from either the moment when the undertaking starts its economic activity or the moment it becomes liable to tax with regard to its economic activity, whichever is earlier.		
Start Date	The term refers to the date is stated in the Grant Agreement for the official start of the project.		
Start of Works	The term 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. The term refers to an undertaking in respect of which at least one of the		
	following circumstances occurs:		
	i. In the case of a limited liability company (other than an SME that has been in existence for less than three years), where more than half of		
	its subscribed share capital has disappeared as a result of		
	accumulated losses. This is the case when deduction of accumulated		
	losses from reserves (and all other elements generally considered		
	as part of the own funds of the company) leads to a negative		
	cumulative amount that exceeds half of the subscribed share capital.		
	For the purposes of this provision, 'limited liability company' refers		
	in particular to the types of company mentioned in Annex I of		
	Directive 2013/34/EU and 'share capital' includes, where relevant,		
	any share premium.		
	ii. In the case of a company where at least some of its members have		
	unlimited liability for the debt of the company (other than an SME		
	that has been in existence for less than three years), where more		
Undertaking	than half of its capital as shown in the company accounts has		
in Difficulty	disappeared as a result of accumulated losses. For the purposes of this provision, 'a company where at least some of its members have		
	unlimited liability for the debt of the company' refers in particular		
	to the types of company mentioned in Annex II of Directive		
	2013/34/EU.		
	iii. Where the undertaking is subject to collective insolvency		
	proceedings or fulfils the criteria under its domestic law for being		
	placed in collective insolvency proceedings at the request of its		
	creditors.		
	iv. Where the undertaking has received rescue aid and has not yet		
	reimbursed the loan or terminated the guarantee or has received		
	restructuring aid and is still subject to a restructuring plan.v. In the case of an undertaking that is not an SME, where, for the past		
	two years:		
	a. the undertaking's book debt to equity ratio has been greater		
	than 7.5 and		
	b. the undertaking's EBITDA interest coverage ratio has been		
	below 1.0.		
	The term refers to the criterion stipulated by Commission Regulation (EU)		
	No 651/ 2014, as amended. For the purposes of this scheme, the results of		
Wide	the project are deemed to be widely disseminated if this is done in at least		
Dissemination three Member States or contracting parties to the EEA Agreement			
	conferences, publication, open access repositories, or free or open-source		
	software.		

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**th **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 proposal 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	€500,000	
eligible partner/s per project		
(EUR)		
Submission deadline of the	16 th April 2024, 14:00 CET	
Intent to Apply	10 April 2024, 14.00 CE1	
Updated Submission deadline	21 st May 2024, 14:00 CET	
of the Full Proposal	21° May 2024, 14:00 CE1	
THCS Online Submission		
Platform	https://www.thcspartnership.eu/	

Updated Submission deadline	
of National Application Form	21 st May 2024, 23:59 CET
and 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 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 deadline indicated below:



Additionally, a **National Application Form needs to be submitted electronically by each Malta-based applicant** to <u>eusubmissions.mcst@gov.mt</u>, by the submission deadline indicated below¹.

¹It 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.

Malta-based Applicant

National Application Form Submission Malta Council for Science and Technology

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 applicable to Indirect State Aid, when an eligible undertaking is a partner in the same project consortium as a public entity and/or public research and knowledgedissemination 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
- Additional documents will need to be submitted to MCST, based on the preferred State Aid regulation chosen (see Section 2.2):
 - *De Minimis* (Regulation A):
 - De Minimis Declaration form
 - General Block Exemption Regulation (Regulation B):
 - Enterprise Size Declaration Form & Undertaking in Difficulty
 - Declaration for Augmented Aid Intensity (GBER)

In addition, Eligible Undertakings are required to provide the **Memorandum & Articles of** Association [or other constitutive document/s] in addition to the National Application Form.

Other forms of documentation can be requested depending on the nature of the Eligible Undertaking.

Eligible Undertakings that are Professional Bodies or NGOs are still required to provide constitutive documents, and may be requested to provide other documents, including but not limited to, a Statute/Deed (Authenticated) and Voluntary Organisation (VO) certificates.

Eligible Undertakings, **including professional Bodies or NGOs**, are also required to provide **audited financial statements** for the last three (3) fiscal years. Where unavailable, applicants are to provide **management accounts** including (i) a detailed profit and loss, and (ii) a balance sheet for the current year.

Eligible undertakings that are **Start-Ups**, who may not have the above-mentioned financial documents, are required to provide **financial projections** for three (3) years signed by an independent certified public accountant, including (i) an income statement, (ii) a cash flow statement, and (iii) a statement of financial position.

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

Undertakings will be subjected to a Due Diligence evaluation which will make use of the documents submitted as well as documents within public record. Additional documentation may be requested by the Council, based on the outcomes of the Due Diligence evaluation.

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

National Contact Points

Annalisa Cartabia, Lead Executive	Christy Baldacchino, Alternate Executive		
Email: <u>annalisa.cartabia@gov.mt</u>	Email: <u>christy.baldacchino@gov.mt</u>		
Tel: 2360 2152	Tel: 2360 2158		
Correspondence should be directed to: The Malta Council for Science & Technology Villa Bighi, Kalkara, KKR 1320, Malta Email: <u>eusubmissions.mcst@gov.mt</u>			

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

These Rules for Participation are applicable to undertakings that carry out an economic activity within the meaning of <u>Article 107 TFEU</u>.

Malta-based applicants that are Eligible Undertakings, with an Operating Base in Malta, as defined in Section 1.1, are eligible for funding, subject to the terms and conditions laid out in the latest version of the National Rules.

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

Applicants may opt to be funded under one (1) of the following two regulations.

Regulation A <i>de minimis</i>	Regulation B GBER
(Annex 1)	(Annex 2)

Applicants are required to **select their preference** within the National Application Form.

Malta-based applicants must **ensure that they are eligible** to be funded under the selected Regulation before applying. Applicants should read through and understand the regulations governing the State Aid regimes before applying (Refer to Annexes 1 and 2).

All applications should be accompanied by the relevant State Aid declaration forms. Applicants should quantify **any possible indirect State aid** that may result from collaboration with partners applying under the non-state aid route, i.e., Public Entities and Public Research and Knowledge-Dissemination Organisations that do not carry out an economic activity within the meaning of Article 107 TFEU in the relevant Annex.

Successful applicants will be requested to update their declaration forms at the time of the signing of the Grant Agreement, to ensure that the applicant remains eligible for funding under the State Aid regimes.

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 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 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 research conferences / events possibly organised by MCST, 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 must 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 spinoffs 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 course of the Project must be consistent with the principles of economy, efficiency and effectiveness. Any purchases must be carried out at arm's length. Commercial transactions between Beneficiaries within the same Project are not allowed.

As a reminder, applicants may opt for one of the two regulations indicated in Section 2: *de minimis* or GBER. Applicants are required to select their preference within the National Application Form. The sub-sections below list eligible costs under *de minimis* (Section 4.1 and 4.2) and GBER (Section 4.1 and 4.3).

4.1 Common Eligible Costs for both Regulations

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 direct 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:

Role in Project	Hourly rates	Hourly rates	Hourly rates	Limits per
	in 2025	in 2026	in 2027	project
Management or	Up to	Up to	Up to	Max 2 per
equivalent	€57.89/hour	€60.78/hour	€63.82/hour	project
Senior Researcher ²	Up to	Up to	Up to	Max 2 per
or equivalent	€40.80/hour	€42.84/hour	€44.98/hour	project
Researcher ³ or	Up to	Up to	Up to	No limits
equivalent	€29.23/hour	€30.69/hour	€32.22/hour	
Operational, technician, research support assistant or equivalent	Up to €16.03/hour	Up to €16.83/hour	Up to €17.67/hour	No limits

$\mathbf{\epsilon}$ z = (basic salary + allowances) / yearly workable hours of the employee.	
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² 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.

³ 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.

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.

Costs of IP and Knowledge Transfer Activities

These costs include the costs of knowledge transfer activities and patents bought or licensed from outside sources 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 shall remain 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 shall 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.

4.2 *De Minimis*-Specific Considerations

Aid Intensity

The financial contribution to a project partner applying under *de minimis* shall be **up to 75%** of the eligible costs incurred on the project by that project partner. The partner must finance the remaining percentage of the eligible costs. **It is not possible for a Partner to cover this percentage contribution 'in-kind'**.

Travel and Subsistence

Travel and subsistence costs are only accepted under the *De minimis* regulation.

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.

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.

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.

4.3 GBER-specific Considerations

Aid Intensity

The aided part of the research and development project shall completely fall within one or more of the following categories (as defined in Section 1.1):

Fundamental ResearchIndustrial ResearchImportantDevelopmentDevelopment
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The financial contribution to a Beneficiary applying under GBER shall be **25%** of the eligible costs incurred to perform the research tasks described in the proposal by the Beneficiary. The aid intensity can be topped up as follows:

Aid Intensity for	Top-up according to	Additional top-up if the project
Large	Undertaking Size	is selected following an open
Undertakings		call and involves Effective
		Collaboration, and Wide

			Dissemination or making licences available, as described below
25%	Small Undertaking	+20%	+25%
	Medium Undertaking	+10%	

The Beneficiary must finance the remaining percentage of the eligible costs. **It is not possible for a Beneficiary to cover this percentage contribution 'in-kind'.**

The aid intensity may be increased by 25% if the following conditions are satisfied:

- a. Project has been selected by a Member State following an open call to form part of a project jointly designed by **at least three Member States or contracting parties to the EEA Agreement;** and
- b. Project involves effective collaboration between undertakings in at least two Member States or contracting parties to the EEA Agreement when the beneficiary is a SME, or in at least three Member States or contracting parties to the EEA Agreement when the beneficiary is a large enterprise; <u>and</u>
- c. The Project satisfies at least one of the following requirements:
 - i. The results of the project are widely disseminated in at least three Member States or contracting parties to the EEA Agreement through conferences, publications, open-access repositories, or free or open-source software. For the results of the project to be considered as being widely disseminated, this must be done through conferences, publications, open access repositories, or free or open-source software at the beneficiary's **own** expense. **The activities to be undertaken to satisfy these criteria must be clearly made visible in the National Application Form.**

ii. The beneficiary commits to, on a timely basis, make available licenses for research results of aided R&D projects, which are protected by intellectual property rights, at a market price and on non-exclusive and non-discriminatory basis for use by interested parties in the EEA.

Travel-related and Dissemination-related costs are deemed ineligible direct costs under this state aid route.

The amount of assistance granted to participants will not exceed the thresholds laid down in Article 4(1) (i) of Commission Regulation (EU) No. 651/2014, as amended.

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.

Research consumables must be incurred directly as a result of the project.

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.

Under Regulation B (GBER) of these National Rules for Participation, the costs of instruments and equipment are eligible to the extent and for the period used for the project.

Where such instruments and equipment are not used for their full life for the project, **only the depreciation costs** corresponding to the life of the project, as calculated on the basis of the generally accepted accounting principles considered as eligible. **The depreciation costs must be verified by a Certified Public Accountant**.

4.4 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.
- Travel and Subsistence and Dissemination-related expenses are ineligible direct costs in relation to applications submitted under Regulation B (GBER).
- 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 Sections 4.1, 4.2 and 4.3

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 evaluated 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 following words.

"Project *[Project Name]* is part-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 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 the details listed above as well as the financial audited report details as requested 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 Interim 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:
 - \circ the limits mentioned in Section 4 are adhered to;
 - expenses are exclusively used throughout the project lifetime to the sole benefit of the project;
 - 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 \notin 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 \notin 5,000, be increased to over \notin 5,000 over the course of the project, this will be considered as an individual line item.

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 €5,000)	Transfers between items of equipment (under €5,000)
Transfers between subcontracted activities (over €5,000)	Transfers between subcontracted activities (under €5,000)
Transfers between consumables (over €5,000)	Transfers between consumables (under €5,000)
	Transfers between travel activities

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

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:

- i. The National Rules for Participation;
- ii. Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, as amended by Commission Regulation (EU) No 2017/1084 of 14 June 2017 amending Regulation (EU) No 651/2014 as regards aid for port and airport infrastructure, notification thresholds for aid for culture and heritage conservation and for aid for sport and multifunctional recreational infrastructures, and regional operating aid schemes for outermost regions and amending Regulation (EU) No 702/2014 as regards the calculation of eligible costs, as amended by Commission Regulation (EU) 2020/972 of 2 July 2020 amending Regulation (EU) No 1407/2013 as regards its prolongation and amending Regulation (EU) No 651/2014 as regards its prolongation and relevant adjustments, by Commission Regulation (EU) 2021/1237 of 23 July 2021 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, and by Commission Regulation (EU) 2023/1315 of 23 June 2023 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty and Regulation (EU) 2022/2473 declaring certain categories of aid to undertakings active in the production, processing and marketing of fishery and aquaculture products compatible with the internal market in application of Articles 107 and 108 of the Treaty (for projects implemented in line with Regulation B of these National Rules for Participation).
- iii. Commission Regulation (EU) 2023/2831 of 13 December 2023 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid (the de minimis Regulation), for projects implemented in line with Regulation A of these National Rules for Participation).
- iv. 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).
- v. 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'.

9. Annex 1 - Regulation A: de minimis aid

Assistance provided under Regulation A of these National Rules for Participation is in line with the terms and conditions of Commission Regulation EU 2023/2831 of 13 December 2023 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to *de minimis* aid (*OJ L, 2023/2831, 15.12.2023*) (herein referred to as *de minimis* regulation (link below)).

The *de minimis* Regulation stipulates that **a single undertaking cannot receive more than €300,000 in** *de minimis aid* **over 3 years**, including *de minimis* aid from schemes offered by entities other than the Council. This period covers the year concerned as well as the previous two years.

Any *de minimis* aid received more than the established threshold will have to be recovered, with interest from the undertaking receiving the aid.

Assistance approved under this aid scheme is **<u>NOT</u>**:

- i. Aid granted to undertakings active in the primary production of fishery and aquaculture products.
- ii. Aid granted to undertakings active in the processing and marketing of fishery and aquaculture products, where the amount of the aid is fixed on the basis of price or quantity of products purchased or put on the market.
- iii. Aid granted to undertakings active in the primary production of agricultural products.
- iv. Aid granted to undertakings active in the processing and marketing of agricultural products, in one of the following cases:
 - a. Where the amount of the aid is fixed on the basis of the price or quantity of such products purchased from primary producers or put on the market by the undertakings concerned;
 - b. Where the aid is conditional on being partly or entirely passed on to primary producers.
- v. Aid granted to export-related activities towards third countries or Member States, namely aid directly linked to the quantities exported, the establishment and operation of a distribution network or other current expenditure linked to the export activity.
- vi. Aid contingent upon the use of domestic good and services over imported goods and services.

Where an undertaking is active in the sectors referred to in points (i), (ii), (iii) or (iv) above, and is also active in one or more of the other sectors falling within the scope of the *de minimis* Regulation or has other activities falling within the scope of the *de minimis* Regulation, the *de minimis* Regulation shall apply to aid granted in respect of the latter sectors or activities, provided that the Council ensures, by relying on appropriate means such as separation of activities or separation of accounts, that the activities in the sectors excluded from the scope of this Regulation do not benefit from the *de minimis* aid granted in accordance with this Regulation.

The rules on cumulation of aid as outlined in Article 5 of the *de minimis* Regulation (link below) will be respected.

In line with Article 6(1) of the *de minimis* Regulation, as of 1 January 2026, information on *de minimis* aid granted under this scheme shall be made publicly available in the central register at national or Union Level.

MCST shall retain the following records:

- the identification of the beneficiary,
- the aid amount,
- the granting date,
- the aid instrument, and
- the sector involved on the basis of the statistical classification of economic activities in the Union ('NACE classification').

More information on the *de minimis* Regulation can be found on the following link: <u>https://eur-lex.europa.eu/eli/reg/2023/2831</u>

10. Annex 2 - Regulation B: General Block Exemption Regulation

Assistance provided under Regulation B of these National Rules for Participation is in line with the terms and conditions of Commission Regulation (EU) No 651/2014 of 17th June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, as amended by Commission Regulation (EU) No 2017/1084 of 14 June 2017 amending Regulation (EU) No 651/2014 as regards aid for port and airport infrastructure, notification thresholds for aid for culture and heritage conservation and for aid for sport and multifunctional recreational infrastructures, and regional operating aid schemes for outermost regions and amending Regulation (EU) No 702/2014 as regards the calculation of eligible costs, by Commission Regulation (EU) 2020/972 of 2 July 2020 amending Regulation (EU) No 1407/2013 as regards its prolongation and amending Regulation (EU) No 651/2014 as regards its prolongation and relevant adjustments, by Commission Regulation (EU) 2021/1237 of 23 July 2021 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, and by Commission Regulation (EU) 2023/1315 of 23 June 2023 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty and Regulation (EU) 2022/2473 declaring certain categories of aid to undertakings active in the production, processing and marketing of fishery and aquaculture products compatible with the internal market in application of Articles 107 and 108 of the Treaty, referred to as the General Block Exemption Regulation, GBER *[link* below].

Assistance will not be granted if the aid is:

- i. related to export activities towards third countries or Member States, namely aid directly linked to quantities exported, to the establishment and operation of a distribution network or to the other current expenditure linked to export activity.
- ii. contingent upon the use of domestic over imported goods.
- iii. granted in the sector of processing and marketing of agricultural products, in the following cases:
 - a. where the amount of the aid is fixed on the basis of the price or quantity of such products purchased from primary producers or put on the market by the undertakings concerned.b. where the aid is conditional on being partly or entirely passed on to primary producers.
- iv. granted in favour of a beneficiary which is subject to an outstanding recovery order following a previous Commission decision declaring an aid granted by Malta illegal and incompatible with the internal market.
- v. granted in favour of an undertaking in difficulty defined in terms of the Commission Regulation (EU) No 651/2014 of 17 June 2014, as amended, unless the undertaking was not in difficulty on 31 December 2019 but then became an 'undertaking in difficulty' in the period from 1 January 2020 to 31 December 2021.

Rules on cumulation of aid shall be in line with Article 8 of the GBER (link below).

In determining whether the notification thresholds and the maximum aid intensities are respected, the total amount of State aid for the aided activity or project or undertaking shall be considered.

Where EU funding centrally managed by the institutions, agencies, joint undertakings or other bodies of the EU that is not directly or indirectly under the control of the Member State is combined with State aid, only the latter shall be considered for determining whether notification thresholds and maximum aid intensities or maximum aid amounts are respected, provided that the total amount of public funding granted in relation to the same eligible costs does not exceed the most favourable funding rate laid down in the applicable rules of Union law.

Aid granted under this incentive may only be cumulated with:

a) any other State aid, if those measure concern different identifiable eligible costs,

b) any other State aid, in relation to the same eligible costs, partly or fully overlapping, only if such cumulation does not exceed the highest aid intensity or aid amount applicable to the aid under GBER.

Aid awarded under Regulation B (GBER) of these National Rules for Participation shall not be cumulated with any *de minimis* aid in respect of the same eligible costs if such cumulation would result in an aid intensity exceeding those laid down in these National Rules for Participation.

For any individual aid awarded in excess of $\leq 100,000$ (or for beneficiaries active in primary agricultural production or in the fishery and aquaculture sector, each individual aid award exceeding $\leq 10,000$), the details of the beneficiary, the aid awarded, and the project details shall be published as provided for in Article 9 of the General Block Exemption Regulation.

More information on the GBER can be found on the following links: <u>Commission Regulation (EU) No</u> 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty as amended by Commission Regulation (EU) No 2017/1084 of 14 June 2017 amending Regulation (EU) No 651/2014 as regards aid for port and airport infrastructure, notification thresholds for aid for culture and heritage conservation and for aid for sport and multifunctional recreational infrastructures, and regional operating aid schemes for outermost regions and amending Regulation (EU) No 702/2014 as regards the calculation of eligible costs, by Commission Regulation (EU) 2020/972 of 2 July 2020 amending Regulation (EU) No 1407/2013 as regards its prolongation and amending Regulation (EU) No 651/2014 as regards its prolongation and relevant adjustments, by Commission Regulation (EU) 2021/1237 of 23 July 2021 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, by Commission Regulation (EU) 2023/1315 of 23 June 2023 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty and Regulation (EU) 2022/2473 declaring certain categories of aid to undertakings active in the production, processing and marketing of fishery and aquaculture products compatible with the internal market in application of Articles 107 and 108 of the Treaty.