

D2.3 Tender documents

Version 1.0

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THERESA - Treat HEalthcaRE System wAstewater

Abstract

Hospital Wastewater (HWW) poses a significant environmental and health risk due to the presence of pharmaceuticals, pathogens, and other hazardous substances that are administered in healthcare institutions. Unfortunately, current urban Wastewater Treatment (WWT) plants are not capable of effectively removing many of the pollutants generated by hospitals. As a result, these contaminants reach and accumulate in natural water bodies, threatening ecosystems and biodiversity, and public health through the contamination of drinking water or food. To reduce the risk associated to these contaminants, it is key to remove them as close to their source as possible, and before they are discharged to the municipal water network. Despite the existence of different technologies that efficiently remove contaminants from HWW, currently, there is no single process that can be used for the comprehensive treatment of HWW regarding the elimination of a mix of pollutants to a high degree. In this context, the main objective of THERESA PCP is to launch a Pre-Commercial Procurement (PCP) process based on the development of environmentally sustainable on-site systems to 1) decontaminate HWW, being capable of effectively removing, among other contaminants, cytostatic drugs, X-ray contrast agents, antibiotics, ARB and ARG, from HWW and/or 2) to prevent that these contaminants enter the HWW.



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Glossary of terms

Term	Description
Background	Any material, document, technology, solution, data, know-how or information (Background information) — whatever its form or nature (tangible or intangible), regardless of whether or not it can be protected, including any attached rights such as IPR ('Background IPR') — that (1) is held prior to the signing of the Framework Agreement or a Specific Contract, (2) identified by the parties involved in the PCP as Background and (3) needed to implement the PCP or exploit the results of the PCP.
Background rights	Any rights, including industrial and intellectual property rights on Background information. They may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the creator, the contracting authority, the PBG or to any other third parties, including subcontractors.
days	If nothing is specified, days means natural days.
FRAND	Terms and conditions for licensing Project results that ensure fair, reasonable and non-discriminatory access to the outcomes of the Theresa PCP project.
Open Market Consultation (OMC)	A preliminary procurement phase where buyers engage with the market to gather information, validate technical requirements, assess innovation readiness, and refine procurement specifications before launching a formal tender process.
Parties	FMS, the PBG and the contractor(s) shall be referred to together as “parties”, unless otherwise specified.
Phase Contract	Contract/s defining the specific terms and conditions for a phase of the Theresa PCP in order to implement the PCP procurement of R&D services (TD3-TD4-TD5).
Phases	The phases of the Project as described in the tender documentation.
Pre-Commercial Procurement (PCP)	A European procurement approach where public sector buyers procure research and development services across multiple competitive phases to drive innovation and develop solutions that do not yet exist on the market.
Pre-existing	Any material, document, technology, solution, data, know-how or information (Background information) — whatever its form or nature (tangible or intangible), regardless of whether or not it can be protected, including any attached rights such as IPR ('Background IPR') — that (1) is held prior to the signing of the Framework Agreement or a Specific Contract, (2) identified by the parties involved in the PCP as Background and (3) needed to implement the PCP or exploit the results of the PCP.
Pre-existing rights	Any rights, including industrial and intellectual property rights on Pre-existing information. They may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the creator, the

	contracting authority, the PBG or to any other third parties, including subcontractors.
Project	The Theresa PCP project. It includes all activities, phases, tasks and deliverables carried out under Theresa PCP.
Public Buyers Group (PBG)	The consortium of healthcare organizations and public health authorities jointly procuring R&D services through the THERESA PCP. In this Project, seven hospitals and two supporting entities from six European countries.
Results	Any tangible or intangible output that is generated in the PCP, whatever its form or nature, whether or not it can be protected. This includes any material, document, technology, solution, data, knowledge or information as well as any rights attached to it, including IPR (rights on Results or IPR attached to the Results).
Sideground	Any material, document, technology, solution, data, know-how or information (Sideground information) — whatever its form or nature (tangible or intangible), regardless of whether or not it can be protected, including any attached rights such as IPR ('Sideground IPR') — that is generated during the timespan of the PCP but not related under the PCP.
Sideground Rights	Any rights, including industrial and intellectual property rights on sideground material. They may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the creator, the contracting authority, the PBG or to any other third parties, including subcontractors.
Specific Contract/s	Contract/s defining the specific terms and conditions for a phase of the Theresa PCP in order to implement the PCP procurement of R&D services (TD3-TD4-TD5).
working days	Days of the week, excluding Saturdays and Sundays and festivities according to the working calendar of FMS.



Glossary of acronyms

Acronyms	Description
AI	Artificial Intelligence
AMR	Antimicrobial Resistance
APC	Administrative Procurement Committee
AZM	<u>Academisch Ziekenhuis Maastricht</u>
CHV	<u>Consorti Hospitalari de Vic</u>
COTS	Commercial Off-The-Shelf
CP	Contract Performance
<u>CPS</u>	<u>Corvers Procurement Services BV</u>
CSA	Coordination Support Action
EAFIP	European Assistance For Innovation Procurement
ECA	European Court of Auditors
EPPO	European Public Prosecutor's Office
ESPD	European Single Procurement Document
ETV	Environmental Technology Verification
EU	European Union
FMS	Fundacion Publica Miguel Servet
FPS	<u>Fundacion Publica Andaluza Progreso y Salud M.P.</u>
FRAND	Fair, Reasonable and Non-Discriminatory
GDPR	General Data Protection Regulation
GPA	Government Procurement Agreement from the World Trade Organisation (WTO)
H2020	Horizon 2020
<u>HCWH</u>	<u>Health Care Without Harm</u>
HE	Horizon Europe
HWW	Hospital Waste Water



<u>IETU</u>	<u>Instytut Ekologii Terenow Uprzemyslowionych</u>
IPR	Intellectual Property Rights
IoT	Internet of Things
KPI	Key Performance Indicator
MEAT	Most Economically Advantageous Offer
MUMC+	Maastricht University Medical Centre+
NDA	Non-Disclosure Agreement
OLAF	European Anti-fraud Office
OMC	Open Market Consultation
<u>P4H</u>	<u>Procure 4 Health</u>
PBG	Public Buyers Group
PC	Project Coordinator
PCP	Pre-Commercial Procurement
PEC	Procurement Evaluation Commttee
<u>PERH</u>	<u>Sihtasutus Põhja-Eesti Regionaalhaigla</u>
PIN	Prior Information Notice
PPI	Public Procurement of Innovative solutions
RFT	Request For Tenders
R&D	Research and Development
SAS	Servicio Andaluz Salud
SILO	Science & Innovation Link Office SL
SOTA	State Of The Art
SUNINN	Science Union For Innovation
SVP	Specific Verification Protocol
TBM	Ticbiomed Tecnologias De La Informacion Para La Salud En La Region De Murcia Asociacion
TCO	Total Cost of Ownership
TD	Tender Document



TEC	Technical Evaluation Committee
TED	Tenders Electronic Daily
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the EU
TRL	Technology Readiness Level
UM	Universiteit Maastricht
UN	United Nations
VB	Verification Body
WSS	Wojewodzki Szpital Specjalistyczny W Olsztynie
WTO	World Trade Organization
WWT	Wastewater Treatment
ZAS	Ziekenhuis Aan De Stroom



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Document abstract

The Tender Documents draft is based on the Horizon Europe Guidelines and templates to implement Pre-Commercial Procurement (PCP). The Deliverable includes in one compilation the draft of the different Tender Documents (TD), including the Request for Tenders (TD1) and the following TDs:

Tender Document 2 (TD 2): Framework Agreement

Tender Document 3 (TD 3): PCP Specific Contract for Phase 1

Tender Document 4 (TD 4): PCP Specific Contract for Phase 2

Tender Document 5 (TD 5): PCP Specific Contract for Phase 3

Tender Document 6 (TD 6): PCP End of Phase (1, 2, 3) report

Tender Document 7 (TD 7): Contractor details and Project abstracts

Tender Document 8 (TD 8): Technical form

Tender Document 9 (TD 9): Financial form

Tender Document 10 (TD 10): ESPD (European Single Procurement Document)

Tender Document 11 (TD 11): Consortia Statement

Tender Document 12 (TD 12): Generic test plan template

Tender Document 13 (TD 13): Generic test report template

Keywords

Pre-Commercial Procurement (PCP), Request For Tenders (RFT), Framework Agreement (FA), Specific Phase Contract, Exclusion, Selection, Award and Compliance Criteria, Evaluation, Intellectual Property Rights (IPR).





**Pre-Commercial Procurement of
innovative and sustainable
solutions to Treat
HEalthcaRE System wAstewater**

THERESA PCP

**PCP TENDER DOCUMENT 1
REQUEST FOR TENDERS (TD1)**



PCP TENDER DOCUMENT 1 (TD1): REQUEST FOR TENDERS

This Request for Tenders (RFT), designated as Tender Document 1 (TD1), should be read in conjunction with other Tender Documents related to this PCP, listed hereunder:

Tender Document 2 (TD 2): Framework Agreement

Tender Document 3 (TD 3): PCP Specific Contract for Phase 1

Tender Document 4 (TD 4): PCP Specific Contract for Phase 2

Tender Document 5 (TD 5): PCP Specific Contract for Phase 3

Tender Document 6 (TD 6): PCP End of Phase (1, 2, 3) report

Tender Document 7 (TD 7): Contractor details and Project abstracts

Tender Document 8 (TD 8): Technical form

Tender Document 9 (TD 9): Financial form

Tender Document 10 (TD 10): European Single Procurement Document (ESPD)

Tender Document 11 (TD 11): Consortia Statement

Tender Document 12 (TD 12): Generic test plan template

Tender Document 13 (TD 13): Generic test report template

Annex 1. Test sites

Annex 2. Preexisting rights of the Public PBG

Annex 3. List of environmental, social and labour law obligations established by EU law, national legislation, collective agreements or the international environmental, social and labour conventions which Bids must comply with.

Annex 4. OMC report

Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1

Annex 6. Phase 1 testing strategy & requirements

Annex 7. Phase 3 verification strategy & requirements

Annex 8. Guide for ETV applicants

Annex 9. Contract template .

Annex 10. ETV Application .

Annex 11. Quick Scan Document .



PREFACE

This THERESA PCP Request for Tenders (RFT) invites all interested parties to present their offers to help to reduce the environmental impact of the healthcare sector and to protect public health from emerging contaminants.

THERESA PCP is a Research & Development (R&D) services procurement which is conducted through a Pre-Commercial-Procurement (PCP).

The RFT in Tender Document 1 (TD1) contains the following sections:

1. Section 1. General Context and Background
Provides the underlying rationale of THERESA PCP and explains the PCP approach and how it differs from traditional procurement.
2. Section 2. Tender Profile
Introduces the tender profile, including the description of the services to be procured. It explains the different phases of the PCP and the expected outcome of each phase. In addition, a general introduction to the procurers involved (also referred to as ‘Public Buyers Group’ - PBG) is provided. This Section also provides an overview of the timeline, budget, and procurement approach. Finally, Intellectual Property Right (IPR) considerations are addressed.
3. Section 3. Evaluation of Tenders
Explains the preconditions for submitting a tender, and an overview of the criteria to be used in the evaluation of the tenders. The process for the evaluation is also clarified in this section.
4. Section 4. Content and Format of Tenders
Describes how the bids should be presented in the administrative, technical and financial sections. It also explains the conditions of the contracts between the winning tenderers and the PBG, including the monitoring process, results evaluation, payment conditions and communication with the PBG.
5. Section 5. Miscellaneous: addresses issues such as language, bidding offer, communication, confidentiality, cancellation of the tender and the procedures for appeal.

This THERESA PCP procurement is part of a project that is funded by Horizon Europe Research and Innovation Programme, under Grant Agreement (GA) No 101226565. The contracts are therefore subject to additional rules based on the EU GA No 101226565.

***Attention:** *The EU (and/or any of its services) is not participating as a Contracting Authority in this procurement.*



1. GENERAL CONTEXT AND BACKGROUND

This PCP is a cross-border joint procurement of R&D services to reinforce public demand driven innovation in end-user services in the area of Hospital Waste Water (HWW). Solutions are expected to achieve Technology Readiness Level (TRL) 7-8¹. The PCP should deliver successful innovative and fully tested product(s) and/or service(s) that meet the common needs of the PBG to procure research, develop innovative marketable solutions, speed up the time-to-market and provide best value for money.

More concretely, THERESA PCP aims to develop environmentally sustainable on-site systems to sanitize and decontaminate HWW, being capable of effectively removing contaminants from HWW and/ or preventing that these contaminants enter HWW.

The joint PCP will include activities for awareness raising, networking, training, evaluation, validation and dissemination of results, to which providers are expected to cooperate.

The PCP builds on the outcomes coming from the Procure4Health (P4H) project (101057209) funded under HORIZON-HLTH-2021-CARE-05.

The jointly identified challenge fits into the mid-to-long-term innovation plans of the PBG. The Open Market Consultation (OMC) carried out in the context of P4H confirmed that solutions currently available on the market or under development are not meeting their needs of the end-to-end solutions as expressed in the challenges above, to tackle concrete targets for the desired functionality/performance improvement in the quality and efficiency of their public services.

In this context, **the main common challenge will be tackled through this PCP to improve the sustainability of European healthcare systems by treating the toxic substances which are disposed of through HWW.**

¹ Please note that TRLs are to be understood under the Horizon Europe Work Programme 2026-2027 15. General Annexes: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2026-2027/wp-15-general-annexes_horizon-2026-2027_en.pdf



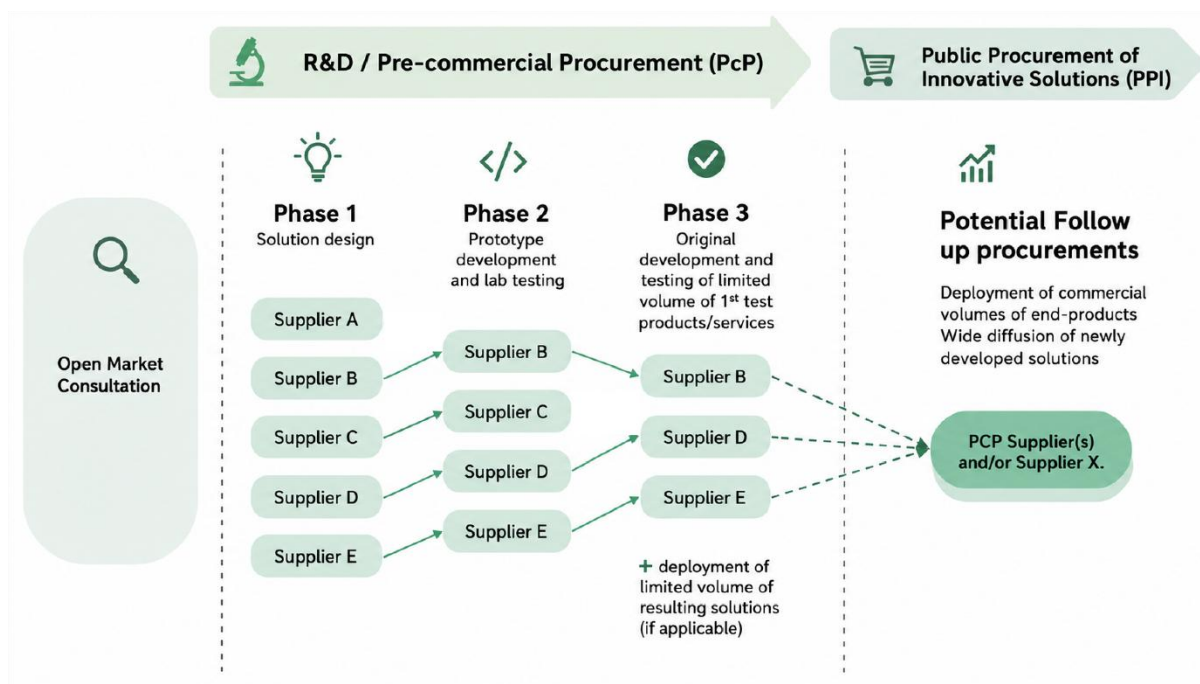


Figure 1. PCP phased process and a follow up PPI

PCP is characterized by the following five **features**:

1. Competitive development in phases to identify the solutions offering the best value for money

PCP targets situations that require radical innovation or R&D and for which there are typically no solutions on or close to the market yet. Different competing providers may have different ideas for solutions to the problem. As R&D is yet to take place, there is not yet any proof as to which of these potential alternative solutions would best meet customers' needs.

PCP therefore awards R&D contracts to a number of competing contractors at the same time, in order to compare different approaches to solving the problem. It thus offers innovators an opportunity to show how well their solution compares with others. It also allows a first customer test reference to be obtained from countries of the procurers that will test the solutions.

The R&D for this PCP is split into 3 phases (Phase 1: solution design, Phase 2: prototype development Phase 3: validation in real operational environment).

Evaluations after each phase will progressively identify the solutions that offer the best value for money and meet the customers' needs. This phased approach allows successful contractors to improve their offers for the next phase, based on lessons learnt and feedback from procurers in the previous phase. Using the phased approach with gradually growing contract sizes per phase will also make it easier for smaller companies to participate in the PCP and enable SME to grow their business step-by-step with each phase.

Depending on the outcome of the PCP (whether it will result in innovative solutions that meet the tender requirements and offer best value for money), procurers may

or may not decide to follow-up the PCP with a Public Procurement of Innovative solutions (PPI).

2. Public procurement of R&D services

PCP addresses mid- to long-term public procurement needs for which either no commercially stable solutions yet exist on the market, or existing solutions exhibit structural shortcomings which require further R&D to resolve. PCP is a way for procurers to trigger the market to develop new solutions that address these shortcomings. PCP focuses on specific identified needs and provides customer feedback to businesses from the early stages of R&D. This improves the likelihood of commercial exploitation of the newly developed solutions.

PCP is explained in the [PCP communication COM/2007/799](#) and the associated [staff working document SEC/2007/1668](#). The R&D services can cover R&D activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. Original development of a first product/service may include limited production/supply in order to incorporate the results of field-testing and demonstrate that the product/service is suitable for production/supply in quantity to acceptable quality standards. However, R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs.¹ It also excludes commercial development activities such as incremental adaptations or routine/periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements.

3. Open, transparent, non-discriminatory approach — No large-scale deployments

Unless there are specific participation and/or control restrictions (*see section 3.1*), PCP procurements are normally open at least to all operators in EU Member States or HE associated countries, on equal terms, regardless of the size, geographical location or governance structure².

In all cases, there is, however, a place of performance requirement that a predefined minimum percentage of the contracted R&D services must be performed in EU Member States or HE associated countries (or a more restricted list of countries; *see section 3.1*).

All communication (before, during and after the procurement) will normally be carried out in English (and other languages, if mentioned in section 5).

Any subsequent PPI for the supply of commercial volumes of the solutions developed in the PCP, will be carried out under a separate procurement procedure. Participation in the PCP is thus not a prerequisite for the provisioning of a solution on a commercial scale.

4. Sharing of IPR-related risks and benefits under market conditions

¹ See also Article XV(1)(e) [WTO GPA 1994](#) and the Article XIII(1)(f) of the [revised WTO GPA 2014](#).

² [Horizon Europe associated countries](#)

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their R&D.

Giving each contractor the ownership of the IPR attached to the results (foreground) they generate during the PCP means that they can widely commercially exploit the newly developed solutions. In return, the tendered price must contain a financial compensation for keeping the IPR ownership—compared to the case where the IPR would be transferred to the procurers (the tendered price must be the ‘non-exclusive development price’). Moreover, the procurers must receive license-free rights to use the R&D results for internal use, and licensing rights subject to certain conditions.

The contractors also retain ownership of their Background rights (albeit subject to certain rights of use by the procurers, see section 2.7)¹.

5. Exemption from EU Public Procurement Directives, World Trade Organization (WTO) Government Procurement Agreement (GPA) and EU state aid rules

PCP procurements are exempted from the EU Public Procurement Directives because the procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).²

They are also exempted from the WTO GPA because this Agreement does not cover R&D services³ (the PCP being limited to such services and any subsequent PPI relating to commercial-scale supply of such solutions not being part of the PCP).

PCP does not constitute state aid under the EU state aid rules⁴ if they are implemented as defined in the PCP communication⁵, namely by following an open, transparent, competitive procedure with risk- and benefit-sharing at market price. The division of all rights and obligations (including IPR) and the selection and award criteria for all phases must be published at the outset; the PCP must be limited to R&D services and clearly separated from any potential follow-up PPI; PCP contractors may not be given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.

Other things to know

The start of this PCP procurement was proceeded by an Open Market Consultation (OMC). Please note that participation in this OMC is not a prerequisite to submit a bid to THERESA PCP. The information on the OMC is available on THERESA PCP website at the following link: [OMC – Theresa PCP](#). This procurement is part of a

¹ For more information, see PCP on the [Europa website](#)

² See Article 16(f) of Directive [2004/18/EC](#) (Article 14 of Directive [2014/24/EU](#)), Article 24(e) of [Directive 2004/17/EC](#) (Article 32 of Directive [2014/25/EU](#)) and Article 13(f)(j) of Directive [2009/81/EC](#).

³ See the EU’s Annex IV of Appendix I to the [WTO GPA](#).

⁴ See Point 33 of the [Commission Communication on a framework for state aid for research and development and innovation](#) (C(2014) 3282).

⁵ [Commission Communication: Pre-Commercial Procurement: driving innovation to ensure sustainable, high quality public services](#) (COM(2007) 799) and [PCP staff working document](#) (SEC(2007)1668).

project that is funded by the European Union's Horizon Europe Research and Innovation Programme, under GA No 101226565 — THERESA PCP.



2. TENDER PROFILE

2.1 Description of services to be procured

THERESA PCP seeks to develop innovative and sustainable technologies for on-site treatment of hospital wastewater that demonstrate high-performance while resulting in environmental added value.

This PCP – i.e. a joint cross-border procurement of R&D services – is intended to reinforce public demand-driven innovation. PCP has the potential to be an effective demand-side innovation action and a useful tool to close the gap between supply and demand for innovative solutions. Solutions are expected to achieve TRL 7-9 at the end of Phase 3¹. The PCP should deliver successful innovative and fully tested product(s) and/or service(s) that meet the common challenge of the PBG to procure R&D and innovative marketable solutions, speed up the time-to-market and provide best value for money.

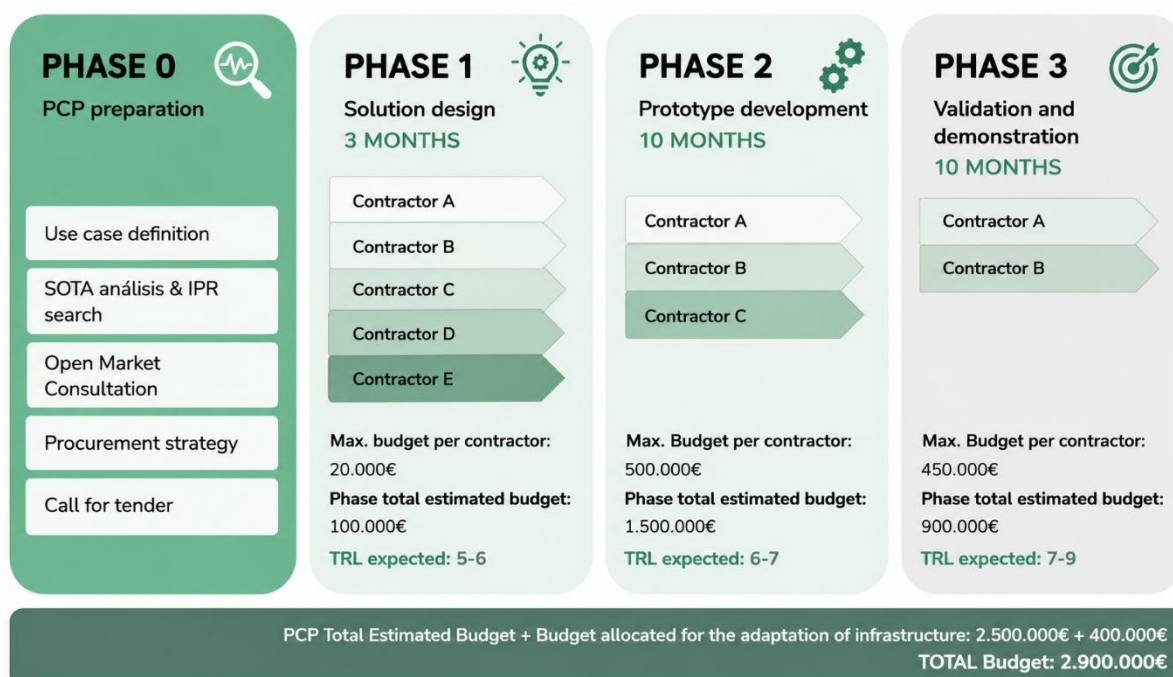


Figure 2. THERESA PCP Timeline

The PCP phases

The R&D for THERESA PCP will be split into 3 phases (Phase 1: solution design, Phase 2: prototyping and lab testing, Phase 3: original development, installation, wider field testing and validation of a limited set of ‘first’ products or services).

¹ The complete solution will be at lower TRL than 9, but some integrated parts maybe TRL9.

PCP PHASE 1 – SOLUTION DESIGN: During this phase, the contractors will be asked to present the concept and describe the solution providing the complete architecture and design thereof and present relevant supporting documentation enabling verification of the technical, economic and organisational feasibility of their solution to address the PCP challenge.

PCP PHASE 2 – PROTOTYPE DEVELOPMENT: This phase concerns the development of prototypes of the solutions and testing their performance under controlled conditions. Based on the conceptual designs and documentation presented in phase 1, the contractors shall develop a prototype of the solution and perform its testing under laboratory conditions to demonstrate its performance in terms of measurable technical parameters related to the performance of the technology in fulfilling its purpose related to THERESA PCP challenge and environmental parameters related to the environmental aspects or impacts during its operation. During and at the end of phase 2, the PBG will request from the contractors a series of deliverables in order to evaluate their progress, the performed activities and the obtained results, as well as an end of phase report.

PCP PHASE 3 – VALIDATION IN REAL OPERATIONAL ENVIRONMENT: This phase will validate the final solutions through independent verification and third-party test data generation to demonstrate their technical/functional and environmental performance achieved under real hospital conditions, using detailed scenarios and processes developed in the verification and validation strategy.

Evaluations by the relevant committee after each phase will progressively identify the solutions that offer the best value for money and meet the customers' needs.

This phased approach allows successful contractors to improve their offers for the next phase, based on lessons learnt and feedback from procurers in the previous phase.

Expected outcomes (per phase)

The following tables describe the objectives, the associated output, results and the tasks to be carried out (milestones and deliverables) for each of the PCP phases):

Table 1

Expected outcomes (table for 3 phases)	
Phase 1: Solution design	
Objective:	<p>Perform research to:</p> <ol style="list-style-type: none"> 1. Elaborate the solution design and determine the approach to be taken to develop the new solutions and 2. Demonstrate the technical, financial and commercial feasibility of the proposed concepts and approach to meet the procurement need 3. Demonstrate the potential of the technology to deliver environmental added value when meeting the procurement need i.e. identify major environmental impacts

	<p>(e.g. use of raw materials, water, energy and other consumables, together with all types of emissions, by-products and waste) likely to be generated by the technology related of the solution related to its operation and performance.</p> <p>During this phase, the contractors shall provide a conceptual design of the complete system including its architecture and components together with detailed information sufficient to i) understand the operation and performance of the proposed solution and the environmental impacts resulting from its performance and operation; ii) verify the technical, economic and organisational feasibility of the solution to address the PCP challenge.</p> <p>The information provided by the contractors shall include but is not limited to: blueprints, description and technical specifications of the components, processes, algorithms and calculations, technical or scientific principles on which the solution is based, any existing performance test data, information on major environmental impacts, health and safety aspects related to the use and operation of the solution with quantitative data whenever available.</p>			
Output and results:	Solution design (Proof of Concept)			
Milestones and deliverables		By when?	How?	Output and results
Milestones:	M1.1) Kick off meeting	Week 1 of month 1 of phase 1	Online meeting with procurer	Initial work plan and project abstracts (in the format required by the EU for publication)
	M1.2) Follow up meeting	Week 3 of month 2 of phase 1	Online meeting with procurer	Follow up on work performed
	M1.3) End of phase report	Week 4 of month 3 of phase 1 - End of phase 1	Online meeting with procurer and report sent via email.	Solution design
Deliverables:	D1.1) Plan for phase 1	Week 1 of month 1 of phase 1	Send planning via email to contact person of procurer	Phase 1 plan and project abstracts (in the format required by the EU for publication)

	D1.2) End of phase report and abstract	Month 3 of phase 1 - End of phase 1	Send end of phase report to procurer	End of phase report with the Solution Design and a section that explains the IPR measures taken by the contractors to protect the results and lists the names and location of personnel that carried out the R&D activities. Please follow TD6. END OF PHASE REPORT template
	D1.3) End of phase report and abstract	Month 3 of phase 1 - End of phase 1	Send summary in the EU format for publication	A summary of the main results achieved by each contractor and conclusions from phase 1 (in the format required by the EU for publication). Please follow TD7. CONTRACTOR DETAILS AND PROJECT ABSTRACTS
Phase 2: Prototype Development				
Objective:	<p>Develop, demonstrate and validated prototypes in lab conditions.</p> <p>In Phase 2, the contractor shall validate the performance of the prototype through testing conducted under controlled laboratory conditions. The objective of Phase 2 testing is to generate reliable and traceable performance data under conditions representative for the intended application of the solution. All testing activities shall be performed under the supervision of the procurers' representatives, SAS and CHV,</p>			

who shall oversee the implementation of the testing activities and compliance with the approved test plan.

Testing may be carried out either:

- At the laboratory facilities of **SAS**. In this case all analyses including sampling performed for solution testing shall be performed by SAS, CHV and where relevant by laboratories subcontracted by SAS or CHV. The costs of these analyses will be covered by SAS or CHV. Testing costs other than analyses including sampling, logistics, transportation shall be covered by the contractor.
- At laboratory facilities provided by the **contractor**. All the test costs including analyses are covered by the contractor.

Where testing is conducted at facilities provided by the contractor, the contractor shall ensure that the laboratory infrastructure, analytical capabilities, operating conditions, and testing procedures are **equivalent to the testing conditions defined by SAS**, as defined under *Annex 6. Phase 2 testing strategy & requirements*. SAS and CHV shall have the right to review and confirm the suitability of the proposed testing facilities prior to the start of testing.

Regardless if testing is performed at SAS facilities or contractor's facilities, the contractor shall be fully responsible for:

- preparation, installation, operation, and optimisation of the prototype during the testing period;
- provision of all equipment, utilities, consumables, and operational resources required for the tests;
- safe operation of the installation and management of any wastes or discharges generated during testing.

All testing shall be conducted in accordance with a **test plan prepared by the** contractor following *TD12. Generic test plan template*. The test plan shall:

- comply with the **Phase 2 testing requirements specified in Annex 6. Phase 2 testing strategy & requirements**;
- follow the **test plan template provided in TD12. Generic test plan template**.

The contractor shall submit the test plan to **SAS for review and formal approval prior to the start of any testing activities**. Testing may only begin once the test plan has been approved.

The contractor shall perform all tests in accordance with the approved test plan following *TD12. Generic test plan template* and the Phase 2 testing requirements specified in *Annex 6. Phase 2 testing strategy & requirements*. The contractor shall ensure that all test data are **complete, traceable, and properly documented**.

	<p>Upon completion of the testing activities, the contractor shall submit a test report prepared in accordance with the template provided in <i>TD13. Generic test report template</i>. The test report shall include:</p> <ul style="list-style-type: none"> • a description of the testing conditions; • the results of all tests performed; • the complete datasets generated during testing; • documentation of any deviations from the approved Test Plan and their impact on the results. <p>SAS and CHV reserve the right to review the test implementation and verify the completeness and consistency of the reported test data. Any comments arising from this review shall be communicated to the contractor with a request to complement missing information, if relevant.</p>			
Output and results:	<p>Tested solutions and corresponding performance test data sets. Initial performance claims related to the technical, functional, and environmental performance of the solution relevant to the THERESA PCP challenges shall be established based on the testing results.</p> <p>Each contractor or consortium shall allocate sufficient resources and include the costs of the Phase 2 testing activities in their budget proposal.</p>			
Milestones and deliverables		By when?	How?	Output and results
Milestones:	M2.1) Kick off meeting	Week 1 of month 1 of phase 2	Online meeting with procurer	Agreement on Phase 2 implementation plan, confirmation of prototype development schedule, submission of project abstracts (in the format required by the EU for publication)
	M2.2) Submission of Initial Test Plan for approval by SAS	End of Month 3 of Phase 2	Test Plan submitted to SAS for review	Initial test plan prepared according to <i>TD12. Generic test plan template</i> and <i>Annex 6</i> .

				<i>Phase 2 testing strategy & requirements approved by SAS</i>
	M2.3) Prototype Installation and Commissioning	Month 7 of Phase 2	Installation and commissioning of prototype	Installed and operational prototype ready for testing.
	M2.4) Refinement of Test Plan	Beginning of Month 8 of Phase 2	Update of testing plan after prototype commissioning	Final Test Plan adjusted to actual installation conditions and approved by SAS.
	M2.5) Start of Laboratory Testing	Week 1 of month 8 of Phase 2	Testing under supervision of SAS and CHV	Controlled testing initiated according to the approved Final Test Plan.
	M2.6) Prototype Demonstration	End of Month 10 of Phase 2	Prototype demonstration	Demonstration of functional prototype with initial performance claim.
Deliverables:	D2.1) Initial Test Plan	Month 3 of Phase 2	Submission to SAS for review	Initial Test Plan prepared according to <i>TD12. Generic test plan template</i> and <i>Annex 6. Phase 2 testing strategy & requirements.</i>
	D2.2) Final Test Plan	Month 7 of Phase 2	Submission to SAS for approval	Final test plan reflecting actual prototype installation and operational conditions according to <i>TD12. Generic test plan template</i>

				and Annex 6. Phase 2 testing strategy & requirements approved by SAS.
	D2.3) Interim Testing Report	Month 9 of Phase 2	Report submitted to procurers	Progress report presenting initial test results and operational observations.
	D2.4) End of Phase 2 Report	Month 10 of Phase 2	Report submitted to procurers	Description of the developed prototype, testing results, environmental added value verification, and IPR measures taken by the contractor. Please follow TD6. END OF PHASE REPORT template
	D2.5) Phase 2 Summary for EU Publication	Month 10 of Phase 2	Submission in EU publication format	A summary of the main results achieved by each contractor and conclusions from phase 2 (in the format required by the EU for publication). Please follow TD7. CONTRACTOR DETAILS AND PROJECT ABSTRACTS
	D2.6) Prototype Demonstration Validation	Month 10 of Phase 2	Demonstration documentation	Validation of functional prototype and initial performance claim.

Phase 3: Validation in real operational environment

Objective:

The purpose of Phase 3 is to validate the solutions in achieving PCP THERESA objectives through third-party verification of their **technical, functional, and environmental performance** under real operational conditions and to confirm their readiness for deployment, upscaling, and potential market uptake.

In Phase 3, the prototype solutions developed and validated under controlled laboratory conditions in Phase 2 shall be **upscaled to fully integrated pilot systems** and deployed in real hospital environments. The pilot installations shall be implemented at hospital test sites located in four EU Member States:

- Hospital Universitario de Navarra (Spain)
- Maastricht University Medical Center (Netherlands)
- Põhja-Eesti Regionaalhaigla (Estonia)
- Wojewódzki Szpital Specjalistyczny in Olsztyn (Poland)

as described in *Annex 1. Test sites*.

The performance verification shall be carried out through the Environmental Technology Verification (ETV) scheme according to **ISO 14034**, implemented by the designated verifier **ETV Body IETU**. The verification shall follow the standard **five-step ETV process**, consisting of:

- Application
- Pre-verification
- Verification
- Reporting
- Post-verification

A contract will be signed with ETV Body IETU following the template under *Annex 9. Contract template*

Based on Phase 2 results, the contractor shall submit a short **Quick Scan** document following the template under *Annex 11* and a **ETV Application File** following the template under *Annex 10* to ETV Body IETU and propose a performance claim related to THERESA PCP objectives and substantiated with test data acquired from Phase 2. During the pre-verification stage, ETV Body IETU shall develop a **Specific Verification Protocol (SVP)** defining the parameters to be verified and the testing requirements relevant to the performance claim. For the verification step, the contractor shall provide performance test data generated according to the requirements specified in the SVP.



The test data shall be generated by an independent test body selected by the contractor subject to confirmation of its competences and quality requirements by ETV Body IETU. To generate the performance test data, the contractor in cooperation with a test body shall develop and provide a **Test Plan** according to *TD12. Generic test plan template* and *Annex 7. Phase 3 verification strategy & requirements* to ETV Body IETU for approval.

The performance test data shall be generated by the test body compliant with **ISO/IEC 17025** during **a minimum three-month continuous pilot operation period**. Upon testing completion, the contractor shall submit a **Test Report** according to *TD13. Generic test report template* developed by the test body containing complete datasets. Based on the assessed data, ETV Body IETU shall prepare a **Verification Report and Verification Statement** confirming the verified performance.

The contractor shall fully cooperate with the designated accredited ETV Verification Body - ETV Body IETU according to the roles and responsibilities for ETV applicants as stated in *Annex 8. Guide for ETV applicants*. This includes in particular entering into a contractual arrangement with ETV Body IETU - following the template under *Annex 9. Contract template* - to conduct the verification in accordance with ETV procedures as specified in *Annex 8. Guide for ETV applicants*, the provision of all necessary technical documentation, generation of performance test data, cooperation with test bodies in the scope relevant to test data generation, access to pilot solutions tested, operational support and any additional information required as deemed necessary.

Each pilot solution shall be tested in two hospitals as indicated in *Annex 1. Test sites*. The allocation of pilot sites shall ensure coverage of representative northern and southern European climatic conditions relevant to the declared operating envelope of the solution. Unless otherwise agreed by the procurers, no hospital shall host more than one pilot installation simultaneously. Each contractor/consortium shall set aside the resources necessary to fulfil the responsibilities of the ETV applicant, including the organisation of third-party testing and the operation of the pilot installations in parallel at the selected sites, for the purpose of conducting the limited test series in two testing locations.

The costs of performing verification procedures other than third party testing shall be covered by ETV Body IETU. This includes formal and technical reviews of the ETV Application file, development of the Specific Verification Protocol, review of the test body competences and test system audit to confirm test data generation compliant to ETV requirements, review and approval of the test plan and test report, development of the

	verification Report and Statement of Verification, test site visits relevant to perform ETV.			
Output and results:	<p>Technical and environmental performance of solutions verified and validated in operational environments (see annex 1 for more information on the test sites)</p> <p><i>Please consider field testing in the four test site locations (suppliers need to consider in their budget for the phase at least 1 travel to each test site location). In the case a hospital doesn't have any information about their effluent, suppliers have to take charge of this analysis, so they would need to pay for it.</i></p> <p><i>Suppliers will be asked to provide 1) a budget considering the possibility of hospitals keeping the prototype at the end of phase 3 and 2) a budget considering the possibility of hospitals returning the prototype at the end of phase 3</i></p>			
Milestones and deliverables		By when?	How?	Output and results
Milestones:	M3.1) Phase 3 Kick-off Meeting	Week 1 of Phase 3	Online meeting with procurers and ETV Body	Confirmation of Phase 3 implementation plan including pilot deployment schedule and ETV verification process planning. Quick Scan submission.
	M3.2) Submission of ETV Application File	Month 2 of Phase 3	Application submitted to ETV Body IETU	ETV Application File including technology description, intended application, relevant alternatives and proposed performance claim based in results from phase 2
	M3.3) Pilot Installation and Commissioning	Month 3 of Phase 3	Installation at selected hospital sites	Installed and operational pilot systems.

	M3.4) Stable Pilot Operation Confirmed	Month 4 of Phase 3	Operational review	Confirmation that the pilot operates reliably and is suitable for performance verification data generation.
	M3.5) Start of pilot performance testing	Month 6 of Phase 3	Independent third-party performance testing	Start of test data generation on pilot performance under real operational conditions.
	M3.6) Completion of pilot performance testing	Month 9 of Phase 3	Submission of Test Report	Complete performance datasets generated during the minimum 6-month testing period.
Deliverables:	D3.1 ETV Application File	End of Month 2 of Phase 3	Submitted by contractor and approved by ETV Body IETU	Application file including technology description, intended application and proposed performance claim.
	D3.2) SVP	End of Month 4 of Phase 3	Developed by ETV Body in cooperation with contractor	Approved SVP defining verification parameters and test design and test data from pre-testing phase demonstrating system readiness for performance testing
	D3.3) Phase 3 test plan	Month 5 of Phase 3	Developed by contractor in cooperation	Test Plan detailing testing procedures and

			with Test Body and approved by ETV Body	monitoring requirements according to <i>TD12. Generic test plan template</i> and <i>Annex 7. Phase 3 verification strategy & requirements.</i>
	D3.4 Phase 3 test report	Month 9 of Phase 3	Report developed by Test Body and submitted by Contractor to ETV Body	Complete test data sets generated during pilot testing according to <i>TD13. Generic test report template.</i>
	D3.5 Verification Report	End Month 10 of Phase 3	Prepared by ETV Body IETU	Report presenting verification results, verified performance and test conditions.
	D3.6 Verification Statement	End Month 10 of Phase 3	Issued by ETV Body IETU	Public summary confirming the verified performance of the technology.
	D3.7) End of phase report	Week 1 of month 10 of phase 3	End of phase report sent to contact person	End of phase report with recommendation and a section that explains the IPR measures taken by the contractors to protect the results and lists the names and location of personnel that carried out the R&D activities. Final report summarising pilot operation,

				<p>verification results, lessons learned and readiness for deployment.</p> <p>Please follow TD6. END OF PHASE REPORT template</p>
	D3.8) Deadline for lessons learned	Month 10 of phase 3 - End of phase 3	Online meeting and deadline agreement	A deadline by which the contractors must agree on the text for the summary of overall lessons learnt and results achieved from the PCP, for publication
	D3.9) Summary of results	Month 10 of phase 3 - End of phase 3	End of phase report sent to contact person	<p>A summary of the main results achieved by each contractor and conclusions from the PCP in the format required by the EU for publication.</p> <p>Please follow TD7. CONTRACTOR DETAILS AND PROJECT ABSTRACTS</p>
	D3.10) Demonstration of services	Month 10 of phase 3 - End of phase 3	Demonstration (also to the EU where relevant)	A final demonstration (also to the EU where relevant) of the final products or services developed during the 3 phases.

**The timeline may be adjusted as needed for duly justified reasons in agreement with the parties.*

**Additional informal online meetings - where the contractor will have to submit the minutes -may be requested by the PBG to ensure the adequate completion of the project. These meetings will be requested with sufficient time and will take place in the least disruptive (to the work) manner possible.*

2.2 Tender closing time

Tender closing time will be: 31 August 2026, 23:59 CEST (local time in Spain)

2.3 Public buyers and other parties involved in the PCP

This procurement relates to a joint PCP that will be carried out by the following lead procurer:

1. FUNDACION PUBLICA MIGUEL SERVET (FMS), PIC 966802493, Spain.
Its aim is to promote and manage the R&D in the public healthcare sector of Navarra (Navarra is a region with more than 680.000 inhabitants). FMS also manages the Navarrabiomed biomedical research centre. In THERESA PCP, FMS coordinates the participation of the HUN the main hospital in the region. Its Clinical Microbiology group is the leading group in AMR guidance and research in Navarra, participating in several European projects in AMR.

And the following public buyers:

2. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH), PIC 973828494, Estonia.
It is one of the top healthcare providers in the country. As a regional hospital, it has the highest-level competence to provide specialised medical care. The hospital consists of seven clinics and 32 specialist centres. In a year, the Medical Centre gives specialised medical care to 144.000 patients.
3. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS), PIC 889548201, Poland.
Highly specialized facility with fast diagnostics and access to consultations with high-class specialists. Each year there are over 25,000 patients treated in 30 departments, and approximately 140,000 consultations are provided in 47 specialist outpatient clinics.
4. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM), PIC 999576562, Netherlands.
Maastricht University Medical Centre+ (MUMC+) is a partnership between Maastricht University Hospital and Maastricht University's Faculty of Health, Medicine & Life Sciences. The hospital and university collaborate intensively and have ample experience with EU projects. MUMC+ is committed to sustainability, having signed the National Green Deal (3.0) to implement actions that reduce the emission of medicines into surface waters. With 6700 employees and 564 beds, the MUMC+ provides health care for various patient groups. On a yearly basis there are 24.000 hospital admissions, 25000 daycare treatments, 390.000 polyclinic consultations, and 145.000 distant consultations.
5. ZIEKENHUIS AAN DE STROOM (ZAS), PIC 991685709, Belgium.
ZAS is the largest healthcare organization in Belgium. Their 10,000 employees, including 1,000 doctors, provide 1,400,000 consultations, 140,000 day admissions and 8,500 deliveries annually. They operate on 13 campuses spread across Antwerp from north to south, providing better basic and highly specialized care.
6. CONSORCI HOSPITALARI DE VIC (CHV), PIC 951359802, Spain.
The Consorci Hospitalari de Vic is an institution that offers healthcare services at a health, socio-health and mental health level. Its purpose is to make available to the inhabitants of the Osona region (around 160,000 people) a quality healthcare service, both at public and private level, applying criteria of social responsibility.



7. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS), PIC 998619463, Spain.

Non-for-profit organization which belongs to the Regional Ministry of Health on Andalusia. As part of FPS, the Public Procurement of Innovation Technical Office (OT-CPI) supports the development of PPI in the Andalusian Public Health System.

The following entities are participating in THERESA PCP as technical partners, but without being part of the PBG or giving in-kind contributions for carrying out the PCP, nor having rights to the results of the PCP or to the IPR:

8. SERVICIO ANDALUZ DE SALUD (SAS)¹,
9. SCIENCE & INNOVATION LINK OFFICE SL (SILO), PIC 892413775, Spain,
10. HEALTH CARE WITHOUT HARM EUROPE (HCWH Europe), PIC 898754859, Belgium,
11. CORVERS PROCUREMENT SERVICES BV (CPS), PIC 951486193, Netherlands,
12. TICBIOMED TECNOLOGIAS DE LA INFORMACION PARA LA SALUD EN LA REGION DE MURCIA ASOCIACION (TBM), PIC 969492400, Spain,
13. SCIENCE UNION FOR INNOVATION (SUNINN), PIC 875684864, Spain,
14. INSTYTUT EKOLOGII TERENOW UPRZEMYSLOWIONYCH (IETU), PIC 998693862, Poland – acting as an Environmental Technology Verification Body accredited for compliance to ISO/IEC 17020 by the Polish Centre for Accreditation to perform ETV according to ISO 14034.

2.4 Contracting approach

The PCP will be implemented by means of a **Framework Agreement (TD2)** with call-offs for **Specific Contracts** (TD3, 4 and 5) for each of the PCP R&D phases (altogether 'contracts').

Following the tendering stage, a Framework Agreement and a Specific Contract for phase 1 will be awarded to at least 5 (five) contractors. If less contractors than 5 (five) will present a bid, the PBG shall motivate a decision to stop or continue the PCP².

A call-off will be organized for phase 2, with the aim of awarding 3 phase 2 contracts. Only offers from contractors that successfully completed phase 1 will be eligible for phase 2. The procurers will validate the phase 2 prototypes.

A second call-off will be organized for phase 3, with the aim of awarding a minimum of 2 phase 3 contracts. Only offers from contractors that successfully completed phase 2 will be eligible for phase 3.

Testing of the first products/services is expected to take place in the test sites indicated in *Annex 1. Testing sites* during phase 3.

More information on the evaluation and the testing can be found under *Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1; Annex 6. Phase 2 testing*

¹ PIC 998853621. Acting as Affiliated Entity of FPS in THERESA PCP, its main purpose is to provide high-quality and patient-centred public health care to the citizens, being responsible for the provision of healthcare to the population of Andalusia (8.4 million inhabitants).

² If there are not sufficient R&D providers, THERESA PCP consortium has the right (but not the obligation) to select only 2 providers for phase 1. If only 1 provider can be selected, THERESA PCP consortium reserves the right either to cancel the PCP or to start a negotiated procedure without prior publication with the tenderer as defined under article 32.2.a of Directive 2014/24/EU.



strategy & requirements and Annex 7. Phase 3 verification strategy & requirements.

The framework agreement will set all the framework conditions for the duration of the PCP (covering all three phases). There will be no renegotiation. The framework agreement will remain binding for the duration of all phases for which contractors remain in the PCP. Tenderers that are awarded a framework agreement will also be awarded a specific contract for phase 1 (evaluation of tenders for the framework agreement and phase 1 are combined). Tenderers are therefore asked not only to submit their detailed offer for phase 1, but also to state their goals, and to outline their plans (including price conditions) for phases 2 and 3 — thus giving specific details of the steps that would lead to commercial exploitation of the R&D.

The offers for the next phase will be requested only *after* the end-of-phase deliverables (TD6) of the previous phase have been submitted and evaluated and only after the contractors have been informed of successful completion of the previous phase. I.e, only the contractors that successfully completed the previous phase will be invited to make offers for the next phase.

2.5 Total budget and budget distribution (per phase)

The total budget for the PCP (excluding VAT), the maximum budget per phase and the maximum budget per tender per phase, as well as the desired number of contractors and the duration of each is expressed in the table below.

Table 2

PCP Phase	Contractors	Duration	Budget per contractor	Total Budget
Phase 1	5	3 months	19.477 €	97.385 €
Phase 2	3	10 months	486.921 €	1.460.763 €
Phase 3	2	10 months	438.229 €	876.458 € + 389.537,04 € for the adaptation of infrastructure
			Total	2.434.606 € + 389.537,04 € ¹ for the adaptation of infrastructure in Phase 3

Table 7: PCP phases, number of suppliers, budget and phase duration

Flexibility will be provided to transfer leftover budget from one phase to the next phase in case offers with lower price than expected are received. For all phases, contracts will be financed until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. As leftover

¹ This amount will be divided among and paid to the contractors of phase 3.

budget from the previous phase will be transferred to the next phase, the total budget available for phase 2 (and 3) may eventually be higher than stated here (but the maximum budget per contractor for phase 2 (and 3) will remain the same). The lower the price of tenders, the more contracts can be awarded.

The number of expected contractors may increase to allow more contracts than initially expected to be awarded if there are more high-quality tenders at lower prices than expected.

However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria. In any case, the contract implementation can start with a minimum of 3 contractors¹. In that case, the leftover budget from Phase 1 will be transferred to the next phases.

The reasoning for the PCP budget allocation with emphasis in Phase 2 is based on the complexity of the technology and the development required given use cases that will be clustered and tackled in Phase 2.

In the event that infrastructure adaptations are required in any or all of the four hospitals designated for Phase 3 validation, up to a total amount of €389,537.04 may be allocated and distributed according to the specific requirements of each validation scenario, subject to the decision of the contracting authority.

Since all Contractors will be paid by FMS by way of centralised payments, and as FMS is based in Spain, EU rules and the valid 21% VAT legislation will be applied.

FMS may either cover any additional costs related to applicable VAT from its own funds or be entitled to deduct input VAT.

In case of suppliers from EU Member States, the reverse charge process, i.e. invoicing without VAT will be applied.

For suppliers from Spain (in the case of joint consortia, the consortium coordinator's headquarters are of relevance) national VAT procedures apply.

In case of suppliers from third countries, the VAT is calculated and reported by the Lead Procurer. If the supplier upon import is obliged to report VAT according to the rules of the home country and the invoice contains VAT, that VAT is non-deductible in Spain. Instead, VAT amount is to be considered as a cost of the service

2.6 Time schedule

The time schedule, which may be adjusted as needed for duly justified reasons in agreement with the parties, is the following.

Table 3

Planned time schedule (table for 3 phases)

¹ If there are not sufficient R&D providers, THERESA PCP consortium has the right (but not the obligation) to select only 2 providers for phase 1. If only 1 provider can be selected, THERESA PCP consortium reserves the right either to cancel the PCP or to start a negotiated procedure without prior publication with the tenderer as defined under article 32.2.a of Directive 2014/24/EU.



Date (M)	Date	Activity
		<u>First tender procedure (framework agreement and phase 1 contracts)</u>
May-26	27/05/2026	Publication of contract notice in <u>TED</u>
May-26	27/05/2026	Tender documents available for download (in Amica platform and THERESA PCP website)
Jun-26	17/06/2025	Info webinar
Jul-26	27/07/2026	Deadline for submitting questions about the tender documents
Jul-26	31/07/2026	Deadline for FMS to publish replies to questions (Q&A document)
Aug-26	31/08/2026	Deadline for submission of tenders for the framework agreement and phase 1
Sep-26	01/09/2026	Opening of tenders
Oct-26	28/10/2026	Tenderers are notified about the decision on awarding contracts
Nov -26	12/11/2026	End of standstill period
Dec-26	14/12/2026	Signature of framework agreements and phase 1 specific contracts
Dec-26	16/12/2026	Publication of the contract award notice in TED
		<u>Implementation of phase 1</u>
Jan-27	04/01/2027	Start of phase 1
Feb-27	03/02/2027	Names of winning phase 1 contractors and their project abstracts to be sent to EU (<u>template*</u>) and published on THERESA PCP website
Mar-27	31/03/2027	Deadline for phase 1 final milestone(s)/final report/deliverable(s)
Apr-27	15/04/2027	Assessment of phase 1 final milestone(s)/final report/deliverable(s)
Apr-27	16/04/2027	Phase 1 contractors notified as to whether they have completed this phase satisfactorily and successfully
Apr-27	30/04/2027	End of phase 1



Apr-27	30/04/2027	Summary of the results and conclusions achieved by each contractor during the phase sent to EU (template*)
Apr-27	30/04/2027	Payment of balance for phase 1 to contractors that completed this phase satisfactorily
		<u>Second tender procedure (call-off for phase 2)</u>
May-27	03/05/2027	Launch call-off for phase 2 (only offers from contractors that successfully completed phase 1 are eligible)
May-27	13/05/2027	Deadline for submitting questions on phase 2 call-off documents
May-27	17/05/2027	Deadline for FMS to circulate replies to questions to phase 2 tenderers
May-27	24/05/2027	Deadline for submitting phase 2 offers
May-27	25/05/2027	Opening of phase 2 offers
Jun-27	21/06/2027	Contractors are notified about the decision on awarding phase 2 contracts
Jun-27	28/06/2027	End of standstill period
Jun-27	30/06/2027	Signature of phase 2 specific contracts
		<u>Implementation phase 2</u>
Jul-27	01/07/2027	Start of phase 2
Jul-27	30/07/2027	Names of winning phase 2 contractors and their project abstracts to be sent to EU (template*) and published on THERESA PCP website
Sep-27	30/09/2027	Deadline for submission of phase 2 intermediate milestone(s)/intermediate report /deliverable(s)
Oct-27	30/10/2027	Intermediate payment for phase 2 to contractors that completed the first milestone
Apr-28	28/04/2028	Deadline for submission of phase 2 final milestone(s)/final report /deliverable(s)
May-28	05/05/2028	Demonstration of prototype for the EU technical review of phase 2; where applicable
May-28	16/05/2028	Assessment of phase 2 final milestone(s)/final report/deliverable(s)



May-28	16/05/2028	Phase 2 contractors notified as to whether they have completed this phase satisfactorily and successfully
		End of phase 2
May-28	31/05/2028	Summary of the results and conclusions achieved by each contractor during the phase sent to EU (template*)
May-28	31/05/2028	Payment of balance for phase 2 to contractors that completed this phase satisfactorily
		<u>Third tender procedure (call-off for phase 3)</u>
Jun-28	01/06/2028	Launch call-off for phase 3 (only offers from contractors that successfully completed phase 2 are eligible)
Jun-28	06/06/2028	Deadline for submitting questions about phase 3 call-off documents
Jun-28	13/06/2028	Deadline for FMS to circulate replies to questions to phase 3 tenderers
Jun-28	20/06/2028	Deadline for submitting phase 3 offers
Jun-28	21/06/2028	Opening of phase 3 offers
Jul-28	21/07/2028	Contractors are notified about decision to award phase 3 contracts
Jul-28	28/07/2028	End of standstill period
Jul-28	31/07/2028	Signature of phase 3 specific contracts
		<u>Implementation phase 3</u>
Aug-28	01/08/2028	Start of phase 3.
Sep-28	01/09/2028	Names of winning phase 3 contractors and their project abstracts to be sent to EU (template*) and published on THERESA PCP project website
Dec-28	22/12/2028	Deadline for submission of phase 3 intermediate milestone(s)/intermediate report /deliverable(s)
Jan-29	26/01/2029	Intermediate payment for phase 3 to contractors that completed the first milestones/ deliverables
Jun-29	31/05/2029	Deadline for submission of phase 3 final milestone(s)/final report/ deliverable(s)



Jun-29	09/06/2029	Final demonstration of products/services developed during phase 3 (including to EU representatives)
Jun-29	28/06/2029	Assessment of phase 3 final milestone(s)/final report/deliverable(s)
Jun-29	29/06/2029	Phase 3 contractors notified as to whether they have completed this phase satisfactorily and successfully
Jun-29	29/06/2029	End of phase 3
Jul-29	28/08/2029	Summary of the results and conclusions achieved by each contractor during the PCP sent to EU for publication purposes (template*).
Jun-29	27/07/2029	Payment of balance for phase 3 to contractors that completed this phase satisfactorily

2.7 Intellectual Property Rights (IPR)

Ownership of results (foreground)

Each contractor will keep the ownership of the IPR attached to the results they generate during the PCP implementation. As the IPRs will not be transferred to the PBG, the price offered by the participants should take this into account, meaning the price should explicitly include a discount. Additionally, the ownership of the IPRs will be subject to the following conditions:

- The PBG has the right to:
 - receive an irrevocable, royalty free, non-exclusive license for all healthcare centres, services and establishments belonging to the PBGs to use the developed technology up until TRL7 or 8 (or up to the point it was developed by contractors of Phase 1 and 2) for indefinite time. This entails the access to the PCP Results, on a royalty-free basis, for their own use, non-commercially and at no additional cost. This includes all IPRs of what has been developed in the PCP and the pre-existing rights that are needed to perform the Project for the purpose of executing the Project as well as for non-commercial research purposes.
 - grant (or require the contractors to grant) non-exclusive licences to third parties to exploit the results under Fair, Reasonable and Non-Discriminatory (FRAND) conditions (without the right to sub-license).
- The PBG has the right to require the contractors to transfer ownership of the IPR if the contractors fail to comply with their obligations, notably concerning the protection or exploitation of the results or to protect public interests (including security interests) – this applies for Results under the three phases - or to commercialize the solution - this applies for Results under phase 3.

In particular, the PBG will also have the unconditional right to require the contractor(s) to transfer ownership of the IPRs if the contractor(s) fail to comply with their obligation to commercially exploit the results of the R&D undertaken

in the PCP (within a period of 4 years after the end of the Framework Agreement) or in case they use the results to the detriment of the public interest (including security interests).

The contractor(s) must ensure that the results are not subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries set out in section 3.1 of this RFT — unless otherwise agreed with the granting authority.

Each contractor shall inform the PBG of the results of each phase that can be exploited, whether they can be protected or not. However, if the contractor does not seek protection for the Results that can be protected, the procurer will have the right to do so.

Commercial exploitation of results

The contractors are expected to commercialize their results before 4 (four) years have elapsed after the end of the framework agreement.

Contractors are required to undertake specific activities beyond product development to commercially exploit the results, e.g. certification of solutions or contribution to standardization.

The PBG will undertake the actions help remove barriers to the introduction onto the market of the solutions to be developed during the PCP (e.g. promotion of R&D results among other public procurers, contribution made by the demand side to regulation, standardization and certification).

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria.

The contractor(s) may transfer the ownership of the results to a third party only after successful conclusion of phase 3, giving at least a 90 (ninety) days advance notice to the PBG. The new owner will be bound by the Framework Agreement. The PBG can object if its access rights will be affected. In this case, the transfer won't take place until an agreement is reached. The contractor(s) may not transfer ownership or the results or give exclusive licenses, if this would conflict with the right of first refusal for the PBG to buy the results.

The contractors may not transfer ownership of their results or grant licenses to third parties which are not established in EU Member States nor HE associated countries (or, if applicable, are controlled by such countries or entities from such countries) — unless they have requested and received prior approval by PBG who will request prior approval from the granting authority that is co-financing the PCP.

The contractor(s) must promote the dissemination of their results, in particular through publications and contribution to standardization. The contractor(s) must — up to 4 (four) years after the end of the PCP — inform the contracting authority, who will inform in its turn the granting authority that is co-financing the PCP, if the results could reasonably be expected to contribute to European or international standards.

In case of a public emergency, the contractors must (if requested by the granting authority) grant for a limited period of time specified in the request, non-exclusive licences — under FRAND conditions — their results to legal entities that need them to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at FRAND conditions.



For more information, see articles 8 and 12 of the Framework Agreement (TD2) that describe in more detail the IPR and the rights and obligations regarding exploitation of results.

Declaration of pre-existing rights (Background and Sideground)

The ownership of pre-existing rights will remain unchanged.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom):

- Tenderers are requested to elaborate the proposed list of pre-existing rights that they wish to use for their proposed solution in their offers, as indicated under TD8. Technical form, section 9. Declaration of pre-existing information (including IPR)
- The PBG and contractor(s) will establish an agreed list of pre-existing rights to be used (under *Annex 2. Pre-existing rights of the PBG*), before the start of the Framework Agreement and this list will be updated at the start of each specific contract.

The contractors must ensure that Background that is subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries set out in section 3.1 and that impact the exploitation of the results (i.e. would make the exploitation of the results subject to control or restrictions) must not be used and must be explicitly excluded from the list of pre-existing rights agreed between the contractors and the contracting authority that will be used for the PCP — unless otherwise agreed with the contracting authority.

The contractors must ensure that if exploitation requires the agreement of a third entity owning the Background IPR, this must be agreed with the PBG and it is the sole responsibility of the contractor that lists that Background IPR.

The members of the PBG will receive rights to use the Background IPR related to the developed solution for free for the performance of the tasks assigned to them in the PCP. They are not buying developed prototypes or first products/services as part of this PCP. However, they will receive rights to use the Background rights and information related to the developed solution after the PCP at FRAND conditions, the price for which will be established if and when the procurers conduct after the PCP a follow-up procurement to buy developed solutions or first prototypes.

Rights to use the Background related to the developed solution must be granted under the same conditions as above also to entities that are under the direct or indirect control of procurers of the PBG, or under the same direct or indirect control as procurers of the PBG, or directly or indirectly controlling procurers of the PBG, subject to applicable control restrictions.

The Framework Agreement (TD2) regulates in more detail the rights and obligations of the different parties regarding the pre-existing rights and results in article 8.

3. EVALUATION OF TENDERS

3.1 Eligible tenderers, joint tenders and subcontracting

Eligibility of tenderers

Participation in this call for tenders and the subsequent tendering procedure is open on equal terms to all types of operators that are established in and/or controlled from EU Member States or HE associated countries.¹

'Control' is defined as the possibility to exercise decisive influence on the operator, directly or indirectly, through one or more intermediate entities, 'de jure' or 'de facto'.

Each tenderer **must complete TD10 ESPD** to indicate its country of establishment and its country/ies of control and must present the supporting evidence normally acceptable under the law of that/those country/ies (enrolment in a trade register kept in the EU Member State or HE associated country of its establishment).

In addition, such a declaration (and supporting evidence) must be submitted for each subcontractor, expert and other entities on whose capacity the tender relies. Additional evidence may be requested by the contracting authority after the submission deadline.

I.e., a subsidiary from a third country **established in a Member State or HE Associated country** can be partner in a consortium to submit an offer. **A company established in a third country and not established in and/or controlled by an EU Member State or HE associated country can act as a subcontractor, but not as main contractors.**

Participation in the PCP contract is **not open to entities that are subject to EU restrictive measures** under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)² — in any capacity (not as main contractor, member of a grouping/consortium, subcontractors, experts or any other type of entity on whose capacity the tender relies or other third parties that are cooperated with).

In addition, the contractors must ensure that none of the contracted services are performed in countries - neither by entities - that are subject to EU restrictive measures (sanctions). They must ensure that none of the services/goods procured or used for the procurement were developed, produced or supplied in countries or by entities that are subject to such EU restrictive measures. In order to ensure that the EU restrictive measures are respected throughout the supply chain that will be involved in delivering the contract results, the contractors must ensure that these obligations also apply to their subcontractors, affiliated entities and other third parties (including suppliers of components used for the innovative solution) they

¹ [List of Horizon Europe participating countries.](#)

² Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the [EU Sanctions Map](#).



cooperate with in the research, development, testing and subsequent commercialization of the results, as well as to any entities succeeding them in their ownership or development of the results.

- Please note that the contractors will have to ensure that the participation and/or control requirements are extended to their subcontractors (only what refers to entities that are subject to EU restrictive measures), affiliated entities and other third parties (including suppliers of components used for the innovative solution) and that any cooperation with nationals of third countries that are not eligible countries or that are controlled by such a country and/or by a national of such a country does not affect the strategic assets, interests, autonomy or security of the EU and its Member States and avoids potential negative effects over security of supply of inputs that are critical to the procurement.

Tenders submitted in collaboration with others

Tenders may be submitted by a single entity or in collaboration with others. The latter can involve either submitting a joint tender or subcontracting, or a combination of the two approaches.

For joint tenders:

This refers to the situation in which one tenderer, consisting of a combination of companies (consortium) participates in this RFT. Such a combination can in addition make use of third parties (sub-contractors). Combinations of companies may participate in this PCP tender procedure, provided that their participation is in accordance with the principles of the EU and applicable national competition law. The following requirements apply for joint tenders:

- The members of a consortium must jointly appoint a lead contractor as a party authorized to act in the name and on their behalf, who will deal with all the matters regarding the PCP (including the signing of each phase contracts) and to whom all communications will be directed. The lead contractor will bear the overall responsibility for the contracts, irrespective of whether tasks are to be performed by a Subcontractor or by another consortium member or not.
- All members of the consortium shall complete, sign and submit TD10. ESPD.
- The members of the consortium must jointly meet the Selection Criteria.
- All members of the consortium are jointly and separately bound to fulfil the terms of the Framework Agreement and Phase Contracts. Each member of the consortium must accept joint and several liability by completing and adding the TD11 Consortia Statement.
- Each member of the consortium must be listed in the professional register or trade register or a foreign equivalent in accordance with the legislation in force in the country where it is established.
- The PBC reserves the right (but does not have the obligation) to check the information and ask for clarifications (as long as this does not imply a substantial modification of the tender).

For subcontracting:

Subcontracting is any kind of contract between the tenderer and third parties, in which the latter agrees to provide part of the services that the tenderer has offered

in his bid. Subcontracting is allowed in this PCP, as far as the sub-contractors selected are not under exclusion grounds.

- Please note that in terms of eligibility, a company established in a third country and not established in and/or controlled by an EU Member State or HE associated country can act as a subcontractor, but not as a main contractor.

The sub-contractors must comply with all the contractual conditions, rights and obligations that are in the Framework Agreement (TD2) and specific contracts (TD3, TD4 and TD5) (including, without limitation, complying with the definition of R&D services, confidentiality, results and IPRs, visibility of EU funding, conflicts of interest, language, obligation to provide information and keep records, audits and checks by the EU, processing of personal data, liability for damages as well as environmental, ethics and security requirements). Therefore, the tenderer must make sure that subcontractors are aware of the provisions set out in the tender documents.

- Please note that, in any case, the contractor(s) remain fully liable to the PBG for the performance of the contract.

No essential parts of the contracts may be subcontracted, nor the management of the PCP activities (these tasks will have to be performed by the contractor or at least by full-subsidiary companies owned by the contractor). Essential parts are linked to the mandatory requirements of Theresa PCP. See section 3.5. Award criteria – PASS/FAIL AWARD CRITERIA

Nevertheless, the sub-contractor on whose experience the contractor has relied on to satisfy the technical competence (reference criterion) is obliged to perform the relevant work. I.e., the execution of tasks assigned to a subcontractor as per the submitted tender may not be the subject of further subcontracting. To ensure this, the tender must clearly mention which parts of the contract will be subcontracted.

The tenderer must specify in TD10. ESPD which part of the R&D services they intend to subcontract. The tenderer will also identify who the sub-contractor(s) is/are and which services they will deliver.

In TD8 Technical form and TD9 Financial form the tenderer shall describe their approach (processes and procedures) in managing and monitoring their sub-contractors. In any case, the contractor will be the ultimate responsible for the services provided.

A contractor that wishes to rely on the resources of a third party for the fulfilment of the requirements for participation in the PCP (and, where applicable, an awarded contract), should demonstrate that these resources will be available to them. In order to demonstrate this, a written commitment signed by such third party, showing that the resources required will be at the contractor's disposal for the entire duration of the contract should be submitted together with Tender Form (TD8) (i.e., any third party needs to complete, sign and submit TD10 ESPD).

Participation in only one tender

- Each tenderer may submit/participate in one tender only (alone, as part of a consortium, main contractor or as subcontractor). This means that the tenderer may only submit a bid on his own or in one (temporary) consortium. It also means that an economic operator or affiliated entity can participate as a

subcontractor in one tender. Failure to do so leads to the exclusion of all bids in which they take part¹.

- In the case of joint tenders, all the participating entities shall ensure that none of them are part of more than one consortium in any role (e.g. as partner, subcontractor, third party), as this will lead to exclusion. The signed ESPD will be verified to confirm that the same entity has not provided a declaration for more than one tender for the THERESA PCP.
- The condition of exclusive participation in one tender also applies to Universities and Research Institutions if different research teams wish to participate as part of different consortia, to prevent any conflicts of interest.
- To avoid an exclusion based on the fact that a same entity participates in more than one tender, the interested parties must take measures to safeguard the exclusive participation of an entity through, for example, an exclusivity agreement. This is in any case an internal decision/action of the consortium that submits a bid.
- Tenderers are responsible for verifying compliance with these conditions before submitting a tender.
- The PBG reserves the right (but does not have the obligation) to check the information and ask for clarifications (as long as this does not imply a substantial modification of the tender).

Modifications in consortia and/or subcontractors

Modifications in the consortia and/or sub-contractors will only be allowed where (alternatively):

- exceptional reasons that could not be foreseen apply; and/or
- a new contractor replaces the one to which the contracting authority had initially awarded the contract as a consequence of an universal or partial succession into the position of the initial contractor, following corporate restructuring, including takeover, merger, acquisition or insolvency, of another economic operator that fulfils the criteria for qualitative selection initially established.

Other

Prior participation in the open market consultation is not a pre-condition for submitting a tender.

However, for phase 2 and 3, participation is limited to contractors that successfully completed the preceding phase.

3.2 Exclusion criteria

The exclusion criteria are as follows:

Table 4

Exclusion criteria	Evidence
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¹ Affiliated Entity means any legal entity directly or indirectly controlling, controlled by, or under common control with that economic operator or its subsidiary, for so long as such control lasts.

Exclusion grounds as defined in article 57 of Directive 2014/24/EU: <ul style="list-style-type: none"> • Grounds relating to criminal convictions • Grounds relating to the payment of taxes or social security contributions • Grounds of insolvency or professional misconduct • Conflict of interest¹ • Distortion of competition 	TD8 Technical form and TD10 ESPD
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*Tenderers that do not comply with these criteria will be excluded, with the exception of self-cleaning measures. The exclusion criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for phases 2 and 3.

3.3 Selection criteria

The PBG reserves the right (but does not have the obligation) to check the documents and references. Should there be any doubt as to any of the below-specified criteria, tenderers may be requested to provide additional information. Tenderers have 5 (five) working days to reply to this request.

The tenderer may rely on the capabilities of a third party (e.g., sub-contractor or consortium partners) for compliance with the selection (always in accordance with the eligibility aspects described under 3.1). In case of reliance on the capabilities of a subcontractor, the respective subcontractor shall be involved in delivering the activities in this PCP that require these capabilities.

The selection criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for Phases 2 and 3.

Failure to comply with any of the selection criteria will lead to the automatic exclusion of the tenderer from the PCP.

- Selection criteria 2, 3, 4, 5, 6, 7 and 8 are also linked to the execution of the contract and will be part of the Framework Agreement (TD2) as performance conditions for the implementation of the contract. **I.e., the personnel mentioned in criteria 2, 3, 4, 5, 6 and 7; and the testing location(s) proposed under criterion 8 will be required to execute the contract.** The tenderer will reflect this in his proposal (Financial Form (TD9)).

¹ A conflict of interest covers both personal and professional conflicts. Personal conflicts are any situation where the impartial and objective evaluation of tenders and/or implementation of the contract is compromised for reasons relating to economic interests, personal life (e.g. family or emotional ties) or any other shared interest. Professional conflicts are any situation in which the contractor's (previous or ongoing) professional activities affect the impartial and objective evaluation of tenders and/or implementation of the contract. Tenderers that are subject to a conflict of interest will be excluded when it cannot be effectively remedied by other less intrusive measures. If there is a potential conflict of interest, tenderers must immediately notify the PBG in writing. **If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the contract), the contractor(s) must notify the PBG and take steps to rectify the situation. The PBG may verify the measures taken and require additional information to be provided and/or further measures to be taken.**

- Changes in the personnel executing the contract (who will need the same qualifications, knowledge and experience) will be duly notified to and authorized by FMS.
- Please note that suppliers acting in consortia need to comply with the selection criteria together, i.e., not each member of the consortium needs to comply with all the criteria.

Table 5

	Selection criteria	Evidence
1	Suitability to pursue the professional activity	Proof regarding enrolment in one of the professional or trade registers kept in their Member State or HE associated country of establishment.
2	Project Management Role (Non-technical Oversight)	<p>One CV of a professional who will be part of the project management team and will be responsible for overarching coordination tasks.</p> <p>The CV must clearly demonstrate at least 5 (five) years of experience in managing multi-disciplinary innovation projects and/or multi-disciplinary integration projects with challenges on a European scale. The individual must have verifiable experience in monitoring tasks, managing planning and budgets, coordinating stakeholders, and ensuring project governance.</p> <p>Together with the CV it is necessary to submit at least one reference letter signed by a public or private client referred to at least 1 (one) such project, in which the expert has taken part.</p> <p>The role is not technical in nature: the primary focus is on a multi-disciplinary project delivery and strategic alignment across domains, rather than on content-level or technical development.</p> <p>They must be employed by the contractor(s) at the time of executing the contract.</p>
3	Experience in Specific Contaminants – cytostatics, contrast agents and antibiotics	<p>At least 1 (one) CV of an expert with experience and knowledge on cytostatics, and/or contrast agents and/or antibiotics (in water) over the past 5 (five) years.</p> <p>The CV will specifically indicate at least 1 (one) project/research linked to the removal of cytostatics, and/or contrast agents and/or antibiotics in water in the last 5 (five) years.</p>

		They must be employed by the Contractor(s) at the time of executing the contract.
4	Expertise and Experience in Wastewater Treatment	<p>At least 1 (one) CV of an expert with minimum 5 (five) years of experience in any of the following areas (highlight them in the CV):</p> <p>Hospital or industrial wastewater treatment and contaminants ´removal</p> <p>Hydrology modelling (urban/rural)</p> <p>Treatment system design or integration</p> <p>Maintenance and operations planning</p> <p>The CV must demonstrate experience with any of the following aspects (highlight them in the CV):</p> <p>Flow capacity adaptation</p> <p>Peak flow behaviour</p> <p>Solids handling</p> <p>The CV (which can be from a different person than the previous one, i.e., it is possible to submit 2 different CVs to comply with this selection criterion) should include at least 1 (one) project in the last 5 (five) years in which these elements were included. Please specifically highlight in the project description in the CV the:</p> <p>Description of the wastewater matrix</p> <p>Target contaminants</p> <p>Applied removal technologies</p> <p>Achieved removal performance (if available)</p> <p>Client/entity and year</p> <p>The project should also refer to:</p> <p>Energy efficient system design</p> <p>Evaluation of GHG emissions or energy intensity (kWh/m³)</p> <p>Management of chemical consumption and chemical safety (REACH, CLP)</p> <p>Waste/by product handling</p> <p>Occupational health & safety in technical environments</p> <p>The CV can refer to various projects that together cover all these aspects.</p> <p>They must be employed by the Contractor(s) at the time of executing the contract.</p>

5	Environmental sustainability experience	<p>At least 1 (one) CV of an expert with minimum 5 (five) years of experience in sustainability experience projects/designs.</p> <p>The CV will specifically indicate at least 1 (one) project linked to sustainability design, assessment, or implementation in the last 5 (five) years.</p> <p>They must be employed by the Contractor(s) at the time of executing the contract.</p>
6	Ability and experience of the personnel regarding legal knowledge in the field of IPR management	<p>One CV of personnel with legal knowledge in the fields of IPR management.</p> <p>The CV will specifically indicate at least 1 (one) project involving IPR management in the last 5 (five) years.</p> <p>They must be employed by the Contractor(s) at the time of executing the contract.</p>
7	Ability and experience of the personnel regarding data processing and integration	<p>One CV of personnel with knowledge in the fields of data processing and integration.</p> <p>The CV will specifically indicate at least 1 (one) project involving data processing and integration in the last 5 (five) years.</p> <p>They must be employed by the Contractor(s) at the time of executing the contract.</p>
8	Ability to perform up to original development of the first products or services in an EU Member State and/or a HE Associated country	<p>Proof of availability of testing facilities and necessary materials and/or equipment (e.g., the development and testing environment should be located in an EU Member State and/or HE Associated country).</p> <p>Description of the testing facilities, laboratories, etc., as well as property documents and/or renting invoices.</p>

3.4 Compliance criteria

Compliance criteria are intended to check whether the tender complies with the R&D services definition and the PCP principles.

Table 6

	Compliance criteria	Explanation	Evidence
1	Definition of R&D services as described in the most	R&D covers fundamental research, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework. It may include exploration and design of	Technical form (TD8)

	<p>recent version of the Frascati Manual.¹</p> <p>solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities. The purchase of commercial volumes of products or services is not permitted.</p> <p>The definition of R&D services means that the value of the total amount of products covered by the contract must be less than 50 % (fifty) of the total value of the PCP framework agreement:</p> <ul style="list-style-type: none"> • The offers for all 3 Phases may include only products needed to address the challenge in question and to deliver the R&D services described in this RFT. • The total value of products offered in Phase 1 and in Phase 2 must be less than 50% (fifty) of the value of the Phase 1 and Phase 2 contracts' value. <p>Tenders that go beyond the provision of R&D services will be excluded.</p>	
2	<p>Place of performance requirement</p> <p>At least 70% (seventy) of the total value of activities covered by the framework agreement (i.e. the total value of the activities covered by all phases) must be performed in the EU Member States or HE associated countries. This means that at least 70% (seventy) of the total value of activities covered by each specific contract for PCP phase 1 and 2 must be performed in the EU Member States or in HE associated countries. Both percentages for phase 1 and phase 2 must be set at the minimum percentage (i.e. 70% (seventy)) to ensure that tenders that do not go through to phase 2 (or phase 3) still satisfy the place of performance requirement.</p> <p>The principal R&D staff working on the PCP (on each specific contract) must be located in the EU Member States or Horizon Europe associated countries².</p> <p>All activities covered by the contract are included in the calculation (i.e. all R&D and operational activities that are needed to perform the R&D services, e.g. research, development, testing and certifying solutions). This includes all activities performed</p>	Technical form (TD8)

¹ OECD (2015), Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris, <https://doi.org/10.1787/9789264239012-en>.

² The principal R&D staff are the main researchers, developers and testers responsible for leading the R&D activities covered by the contract.

		<p>under the contract by contractors and, if applicable, their subcontractors¹.</p> <p>The contractors must in addition ensure that the implementation of the contract takes place in EU Member States or HE associated countries.</p>	
3	Laws and regulations regarding artificial intelligence, privacy, ethics, health and safety and water	<p>Tenders will be excluded if they do not comply with:</p> <ul style="list-style-type: none"> • Ethical principles (including the highest standards of research integrity, notably as set out for example in the <u>European Code of Conduct for Research Integrity</u> ², and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct). • Applicable international, EU and national law including GDPR provisions³ and the EU AI Act. • Regulations listed under <i>Annex 3. List of environmental, social and labour law obligations established by EU Law, national legislation, collective agreements which bids must comply with</i> and regulations under <i>Annex 1. Test sites</i>. • Applicable EU Wastewater Regulations - the provisions related to the medicines that are listed under the Urban Wastewater Treatment Directive (UWWTD) – 91/271/EEC and the Water Framework Directive (WFD) – 2000/60/EC and existing discharge limits. • Cybersecurity compliance for operational systems (ISO/IEC 27000 or equivalent security standards) • Include plans to carry out activities in a country outside the EU, which do not comply with the requirements indicated in this RFT. 	Technical form (TD8)
4	Proposed solution already available on the market	<p>Tenders whose proposed solution is already readily available on the market will be excluded from the PCP</p>	Technical form (TD8)
5	Compatibility with other public financing	<p>Tenders that receive public funding from other sources will be excluded, if this leads to double public financing or an accumulation of different</p>	Technical form (TD8)

¹ If applicable, 100% of the contracted R&D services on security components of the solution must be performed in EU Member States or HE associated countries.

² <https://allea.org/code-of-conduct/>

³ The Tenderers shall comply with the legislation and regulations applicable to the processing of personal data in Europe. In particular and if applicable, the Tenderer, members of a Consortium, subcontractors and Third Parties will have to ensure compliance with Article 28(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council and Article 29(7) of Regulation (EU) 2018/1725 of the European Parliament and of the Council (on standard contractual clauses between controllers and processors).



		types of public financing that is not permitted by EU legislation, including EU state aid rules.	
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- Failure to comply with any of the compliance criteria will automatically lead to the exclusion of the tenderer and submitted bid from the PCP.
- The compliance criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for phases 2 and 3.

3.5 Award criteria

PASS/FAIL AWARD CRITERIA

The tenders will be evaluated on the pass/fail award criteria only if the tenderer is not subject to any of the exclusion criteria, compliance criteria and fulfils the selection criteria.

The tender must comply with all the requirements and their evaluation methods/KPIs listed below and under *Annex 5. Performance Criteria/KPI and evaluation/measurement methods* for pass/fail award criteria and weighted award criteria of Phase 1.

Failure to comply with any of the pass/fail award criteria will lead to the automatic exclusion of the tender from the PCP. Compliance with these requirements is mandatory and cannot be subject to any assumptions, limitations, conditions, or reservations on the part of a tenderer. Please use *section 4. Pass/fail award criteria of TD8. Tender Form* to demonstrate compliance.



Table 7

Category	Requirement ID	Requirement Title	Short Description
CONTAMINANT REMOVAL REQUIREMENTS	CRR 1.1	Cytostatics Removal	The solution shall demonstrate removal/degradation performance of cytostatic drugs. Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.
	CRR 1.2	Watersoluble, nephrotropic, low osmolar iodinated x-ray contrast media removal	Solution shall demonstrate removal/degradation performance of watersoluble, nephrotropic, high osmolar Iodinated CT contrast media (ATC code: V08AB). Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.

	CRR 1.3	Gadolinium-Based Magnetic resonance imaging contrast media removal	Solution shall demonstrate removal/degradation performance of Paramagnetic Gadolinium based contrast media (ATC code: V08CA). Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.
	CRR 1.4	Antibiotics Removal	Solution shall demonstrate the removal/degradation performance of antibiotics. Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.
OPERATIONAL & TECHNICAL REQUIREMENTS	OPR1.1	Wastewater flow capacity and system stability	The solution shall be technically adaptable to varying hospital wastewater volumes while maintaining stable operation and consistent treatment performance. The solution shall demonstrate the ability to: operate effectively across a range of wastewater flow rates representative of different hospital sizes; the proposed operating range shall be consistent with the proposed solution layout (SSI 1.5)); and maintain stable treatment performance within this operational range. Adaptability may be achieved through modular design, scalable reactor configuration, adjustable hydraulic retention time, variable-speed pumping, parallel treatment lines, or other technical means

	OPR1.2	Wastewater flow peaks	Suppliers shall clearly describe: 1. the defined design peak flow capacity (m ³ /month); 2. stable system operation under short-term peak inflow conditions and daily high/low flow variability; 3. the defined and controlled system behaviour during exceedance conditions, safeguards to prevent uncontrolled discharge or system failure, operational procedures for temporary bypass under exceptional inflow conditions.
	OPR1.3	Wastewater temperature tolerance	The solution shall be capable of continuous operation within a discharge temperature of the water treated within a range 10°C to 40 °C, without loss of operational integrity or treatment performance. The solution shall demonstrate the ability to operate continuously within an influent temperature range of 10 °C to 40 °C; maintain stable mechanical, hydraulic, and process performance within this range; avoid material degradation, safety risks, or system instability due to temperature variation.
	OPR1.4	pH tolerance and variability	The solution shall be capable of operating within a discharge wastewater average pH variability and fluctuations (6.0-9.0) expected during routine hospital operation, without loss of treatment performance or system integrity. The solution shall demonstrate: a supported operational average pH range 6.0-9.0; stable mechanical, hydraulic, and process operation within this range; no significant deterioration of key treatment performance parameters due to pH fluctuations within this interval; no material degradation, corrosion risk, or structural instability within this range. The Contractors shall specify: the full supported average pH operating range; the acceptable short-term pH variability tolerance; whether pH adjustment is required for stable operation; the impact (if any) of pH variation on removal performance.
	OPR1.5	Baseline organic load compatibility	The solution shall be technically compatible with hospital wastewater organic load characteristics. Its operational envelope with respect to COD (Chemical Oxygen Demand) and/or BOD ₅ (Biochemical Oxygen Demand) shall be clearly defined and justified. Where relevant, the solution shall demonstrate: a clearly defined applicable operating range for COD and/or BOD ₅ ; technical coherence between the selected treatment processes and the expected organic load characteristics; explicit identification of operational constraints or performance dependencies related to organic load variability.

	OPR1.6	Operational autonomy, staffing, and maintenance	"The solution shall be designed for operational autonomy and low maintenance burden, minimising manual intervention by hospital staff during normal operation. Suppliers shall provide a clear description of operational and maintenance requirements, such as: Standard Operating Procedures (SOPs), fail safe behaviours and recovery mechanisms, expected frequency and type of routine and corrective interventions; easy access for inspection, replacement of parts and repair; required number of personnel for operation and maintenance; whether continuous on-site supervision is required or remote monitoring and automated operation; required training effort, expressed as training hours per operator; required skill level of operators (e.g. technician, engineer, basic operator).
	OPR1.7	Performance	The solution shall work 24/7 without unplanned downtime and without interruption of treatment performance. The solution shall demonstrate the capability to operate continuously (24 hours per day, 7 days per week) under normal operating conditions, ensuring: no unplanned treatment interruption; no uncontrolled discharge of untreated wastewater; no system shutdown required for routine operation. Temporary interruptions are only permitted if: they are planned, they do not interrupt treatment (e.g., redundancy, parallel lines); they do not result in untreated discharge.
	OPR1.8	Cybersecurity	The solution architecture shall be capable of incorporating structured cybersecurity controls aligned with recognised standards (e.g., ISO/IEC 27001/27002 principles or equivalent frameworks (e.g E-ITS) for systems deployed in hospital environments), including secure operation/communication when integrated/interoperable with other legacy systems.

	OPR1.9	Suspended Solids and solid fractions handling capability	<p>The solution shall be capable of handling suspended solids (Total Suspended Solids, TSS) and typical solid fractions (eg Uricacid crystals) present in hospital wastewater without loss of treatment performance, hydraulic blockage, fouling, or mechanical damage.</p> <p>Suppliers shall specify:</p> <ul style="list-style-type: none"> - Maximum allowable influent suspended solids concentration (expressed in mg/L TSS); - Maximum allowable particle size (if applicable to the technology); - Required pre-treatment measures, where applicable (e.g., screening, coarse filtration, grit removal, equalisation); - Design and operational measures implemented to prevent clogging, fouling, scaling, or hydraulic disruption, including: hydraulic design features; anti-fouling mechanisms; backwashing or cleaning procedures; protective barriers or filters; operational safeguards under variable solids load. The supplier shall clearly define the applicable operating envelope for suspended solids and indicate any operational constraints or performance dependencies related to solids loading.
	OPR1.10	Monitoring System/Dashboard	<p>The solution shall provide a monitoring system depicting the process parameters (technology specific) responsible for the proper operation of the system (connected with alarms indicating that the system is not working properly, maintenance logs and O&M instructions)</p>
	OPR1.11	Fault Handling mechanisms	<p>The solution shall be robust and include appropriate automatic mechanisms to detect, isolate, and manage operational faults (e.g., blockages, pump failure, sensor malfunction) with minimal manual intervention. The system shall incorporate fail-safe behaviour and, where applicable, automatic protective responses to prevent performance degradation or equipment damage.</p>

	OPR1.12	Interoperability and Communication Compliance with existing systems	The solution shall be interoperable and capable of secure communication and integration with existing hospital Building Management Systems (BMS) (e.g., Siemens Desigo CC or equivalent systems), through standardised network protocols (e.g., BACnet/IP, Modbus RTU, or equivalent), regardless of vendor or architecture. Third-party remote access to the BMS shall not be permitted.
SPACE & SITE INTEGRATION REQUIREMENTS	SSI1.1	Site Compatibility and Installation	<p>The solution shall be compatible with hospital site constraints as defined in Annex 1. Test sites, and shall be installable either indoors or outdoors, or as a combination of both, as appropriate for the proposed deployment scenario. The supplier shall clearly specify installation requirements, including: Required infrastructure (e.g., electrical supply, drainage, ventilation, access needs); Environmental installation conditions (e.g., temperature range, weather exposure, ventilation requirements); Water loss prevention measures (e.g., sealed piping, containment, leak detection); Any required site adaptations or structural provisions.</p> <p>The solution shall demonstrate practical feasibility for installation within hospital environments without imposing extensive infrastructure modifications. The supplier may perform site visits at the start of Phase 1 or propose the collection techniques for the detailed information on the site layout.</p>

	SSI1.2	Space Efficiency & Scalability	<p>The solution shall be suitable for deployment in hospitals with limited available space and complex built environments (e.g., multiple buildings, urban hospitals), as described in Annex 1. Test sites.</p> <p>The contractor shall demonstrate that the solution: Is space-efficient, with clearly defined physical footprint and height requirements relative to treatment capacity; is modular in design, enabling installation as independent or interconnected units; can be adapted to different installation scenarios, including: indoor technical rooms, toilets , outdoor areas, distributed configurations across multiple buildings, while maintaining the required treatment performance parameters.</p> <p>The solution shall include a clear upscaling and downscaling strategy, describing: the achievable treatment capacity range without fundamental redesign; the method of capacity expansion (e.g., parallel modules, staged expansion, containerised units); the impact of scaling on space requirements; preservation of treatment performance when scaling, and demonstrate that the solution maintains technical coherence between space efficiency and performance (i.e., performance shall not depend on disproportionate spatial expansion).</p>
	SSI1.3	Climate Adaptability	<p>The solution shall be capable of continuous and stable operation under representative European climatic conditions, including temperature, humidity, and precipitation extremes relevant for both northern and southern European regions. For outdoor installations, the solution shall be designed to withstand environmental exposure without loss of performance, structural integrity, or operational stability. The contractors shall define the environmental operating envelope (including minimum and maximum ambient temperature, relative humidity, and weather exposure conditions) and demonstrate that treatment performance and system integrity are preserved within this range.</p>

	SSI1.4	Solution Layout	<p>The solution shall be adaptable to different hospital wastewater discharge configurations, including hospitals with single or multiple discharge networks, decentralised plumbing layouts, or distributed wastewater streams.</p> <p>The Supplier shall propose and justify the most suitable collection and treatment configuration (e.g., centralised (all hospital waste water), decentralised (eg.hospital department), or hybrid), taking into account: existing discharge infrastructure; potential multiple collection points; hydraulic constraints; space limitations.</p> <p>The proposed configuration shall demonstrate technical feasibility and operational coherence within the hospital environment as described in Annex 1. Test sites.</p>
Water reuse & Water efficiency	WR1.1	Water Reusability	<p>The quality of the treated water is sufficient to allow reuse for at least one practical reuse application like eg. irrigation, cleaning, toilet flushing, cooling water for energy, etc. The suppliers are expected to: 1. Identify the applicable regulatory or technical quality requirements; 2. Provide measured (or projected) effluent quality values; 3. Demonstrate compliance with the minimum thresholds for that reuse application.</p>
Sustainability aspects	SCA1.1	Energy efficiency	<p>The proposed solution shall demonstrate and report energy efficiency per unit of treated wastewater. Energy consumption data will be assessed in relation to the achieved treatment performance (volume, efficiency) .</p> <p>Suppliers shall report: Energy intensity (kWh/m³ treated);</p> <p>The solution shall also be compatible with integration into hospital electrical infrastructure (renewable energy supply, where feasible).</p>

	SCA1.2	Cost Efficiency	The proposed solution shall include cost efficiency as a design consideration and provide transparent cost information across all procurement phases to enable assessment of economic sustainability. Suppliers shall provide a structured cost breakdown including CAPEX and OPEX.
	SCA1.3	Health & safety	The solution shall be designed to minimise exposure risks for hospital staff during installation, operation, maintenance, and handling of consumables, residues, or treatment by-products (if present). Suppliers shall disclose any potential occupational health and safety risks associated with the solution; the technical and organisational measures implemented to minimise exposure to wastewater, chemicals, and treatment processes; safe procedures for operation, maintenance, and handling of consumables and waste.
	SCA1.4	Supply-chain sustainability and responsible sourcing	Suppliers shall confirm compliance with Regulation (EU) 2017/821 on supply chain due diligence for conflict minerals, and where applicable, provide any available supporting documentation demonstrating or committing to supply chain due diligence and responsible sourcing principles.
	SCA1.5	Environmental added value	Suppliers shall identify an appropriate relevant alternative technology and clearly describe the major differences in environmental impacts, whether positive or negative, associated with the proposed technology in comparison with that alternative. The comparison shall focus primarily on the operation phase, considering where relevant: energy consumption and energy source; emissions to water (including residual pollutants and by-products); emissions to air (including greenhouse gases where applicable); consumption of chemicals or consumables; water consumption; generation of hazardous and non-hazardous waste; other operational environmental trade-offs, such as noise or odour emissions. The information provided shall allow verification that the proposed solution does not introduce disproportionate environmental impacts compared to the identified relevant

			<p>alternative(s).</p> <p>Where an aspect is not relevant, a brief justification shall be provided.</p>
General Requirements	GER1.1	Phase 2 Prototype Testing	<p>In Phase 2, the solution shall undergo a minimum of three (3) months of controlled testing following prototype development in order to ensure the technical performance, relevance, applicability, and suitability of the solution to users' needs. Testing shall be conducted under controlled laboratory or simulated conditions reflecting, to the extent feasible at prototype stage, the operational characteristics of the solution relevant for its intended application (matrix and purpose) and its compatibility with the operational environment including constraints and limitations as described in Annex 1. Test sites The supplier shall provide also information to the staff supervising the testing on the standard operating procedures of the prototype, its maintenance and servicing requirements , the development plan during the testing activities ,safety and hazard aspects related to the testing and operation of the installation, and ensure adequate training of the staff responsible for the tests supervision.</p> <p>Testing may take place either at the premises of SAS or at the supplier's premises, provided that it is conducted under defined and supervised conditions. The supplier shall remain fully responsible for prototype installation, operation, optimisation, utilities, consumables, waste handling, and safe discharge management throughout the testing period. Testing shall be performed in accordance with the Phase 2 testing requirements as specified in Annex 6. Phase 1 testing strategy & requirements. Contractor shall be responsible for the development of a Test Plan according to the template provided in Tender Document 12 (TD 12): Generic test plan template. At the end of Phase 2, the contractor shall submit a comprehensive Test Report developed according to the template provided in Tender Document 13 (TD 13): Generic test report template. The Test Report shall include full performance data, results against the defined KPIs, and documentation of testing conditions and methodologies. The report shall also include information about any deviations from the test plan and description of their impact on the test results, The Test Report shall form part of the End of Phase 2 Report.</p>

	GER1.2	Phase 3 Pilot deployment	<p>In Phase 3, the solution shall be deployed, installed, and operationally demonstrated in hospital environments located in Estonia, Poland, Spain, and the Netherlands (see Annex X – Baseline). Piloting shall be performed in accordance with the Phase 3 pilot requirements as specified in Annex 7. Phase 3 verification strategy & requirements. The supplier shall implement the solution at a minimum of two hospital sites (to be defined during Phase 2), in close coordination with the procurers and relevant end users. Prior to installation, the supplier shall conduct site visits to verify technical feasibility, infrastructure compatibility, spatial constraints, safety conditions, and integration requirements. The procurers shall provide reasonable access to relevant technical documentation and applicable hospital procedures. The supplier shall document the site assessment and confirm installation feasibility before deployment. The supplier shall be fully responsible for delivery, installation, commissioning, integration with utilities and hospital infrastructure, and safe operation of the solution at each site. Installation shall comply with applicable regulatory and safety requirements and shall not disrupt critical hospital functions.</p> <p>Before formal pilot performance verification begins, the supplier shall complete commissioning and pre-testing activities to ensure stable and safe operation under real-site conditions. All necessary documentation for installation, operation, maintenance, safety, and troubleshooting shall be provided. Structured on site training shall be delivered to designated hospital staff and adapted to the user profile. The supplier shall ensure that the pilot installation complies with site-specific safety requirements proportionate to the scale and nature of the system, including risk assessment, operational safeguards, emergency procedures, and required protective measures. During Phase 3, the supplier shall ensure stable and predictable operation of the pilot under real operational conditions. Performance shall be monitored against Phase 3 KPIs, operational data shall be documented, deviations recorded, and structured user feedback collected. Any optimisation affecting performance shall be completed and documented prior to formal performance data generation for verification purposes. Suppliers shall also describe their multi-site deployment strategy, including logistics, site adaptation, technical support, and operational continuity across pilot locations. The installed solutions shall remain at the participating hospital premises after completion of the PCP process provided that Phase 3 results demonstrate compliance with defined performance thresholds and KPI requirements, stable operation under real hospital conditions, fulfilment of procurer and user needs (including regulatory requirements), and absence of unresolved safety or integration concerns.</p>
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			Final determination shall be based on documented performance results verified through an independent third-party verification process conducted in accordance with ISO 14034 (Environmental Technology Verification) and GER 1.3, and formal acceptance by the procurers in accordance with the contractual framework.
	GER1.3	Phase 3 Verification (ETV)	Suppliers shall commit to undergoing an independent Environmental Technology Verification (ETV) process in accordance with ISO 14034 requirements, as specified in Annex X – Guide for ETV Applicants. The ETV shall be applied to the solution deployed in Phase 3 and shall aim to demonstrate compliance with user needs through third-party validation of pharmaceutical removal efficiency and the sustainability performance of the technology under real hospital operating conditions.
	GER1.4	Testing compliance	The suppliers should demonstrate in Phase 2 & 3 compliance with the testing requirements listed in the current Tender Requirements, the evaluation methodology defined in Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1 and the ISO 14034 ETV scheme Annex 8. Guide for ETV applicants

	GER1.5	Pilot (Phase 3) user feedback collection	During Phase 3 pilot testing, the supplier shall ensure the systematic collection of feedback from end users through structured evaluation questionnaires. Questionnaires shall be designed to capture user experience, usability, operational performance, and perceived effectiveness of the solution. The supplier shall ensure that feedback is collected from relevant user groups, including non-technical end users where applicable, and that responses are sufficiently addressed in the technical developments of Phase 3 and documented to support evaluation of the pilot results.
	GER1.6	Bug reporting, helpdesk, and feedback management	The supplier shall establish and operate a helpdesk and maintenance support function for the duration of the pilot phase(Phase 3) The supplier shall provide a simple, intuitive, and easily accessible mechanism for error reporting, bug reporting, and general user feedback submission by end users. The feedback and bug reporting mechanism shall allow users to report issues related to functionality, performance, usability, and operational reliability. The supplier shall document all reported issues and feedback and demonstrate how these inputs have been addressed, mitigated, or incorporated into the solution in the Phase 3 final deliverable.
	GER1.7	Pilot operation and maintenance support	The supplier shall ensure continuous operation and maintenance of all deployed systems at each pilot site for the full duration of Phase 3. Systems shall be maintained at full operational quality and performance in accordance with the agreed specifications. The supplier shall provide qualified personnel and resources capable of responding to incidents, malfunctions, or performance degradation, either remotely or on-site, within reasonable response times. All corrective actions taken during the pilot shall be recorded and reported as part of the Phase 3 results.

WEIGHTED AWARD CRITERIA

These criteria and related sub award criteria will be used to evaluate the award of the Framework Agreement (TD2) and the Phase 1 Contract (TD3), according to a quality assessment.

At least 5 (five) tenderers (and a minimum of 3 (three)¹) will be awarded a Framework Agreement and a Phase 1 Contract on the basis of the Most Economically Advantageous Offer (MEAT) according to the award criteria described below. The tenders will be evaluated on the weighted award criteria (according to a quality assessment and a price assessment) only if the tenderer(s) is not subject to any of the exclusion criteria, compliance criteria and fulfils the selection criteria and the tender complies with the pass/fail award criteria.

The award criteria and related sub award criteria will also be used to evaluate the award of the Phase 2 Contract (TD4) and the Phase 3 Contract (TD5), according to a quality assessment. **Please note that the sub award criteria, its relative weighting (and consequently the maximum points), the minimum (and maximum) thresholds, as well as the performance criteria/KPI and evaluation/measurement methods (based on this sub award criteria may be finetuned and/or updated depending on the outcomes of Phase 1 (and 2)).**

The technical quality and price award criteria, weightings and thresholds are set so as to favour the MEAT. The weighted award criteria shall ensure that the PBG gets the best value for money. Therefore, the lowest price as the sole criterion is not used, without taking quality into account, neither the highest quality is used as the sole criterion, without taking price into account.

Table 8

No.	Weighted award criteria	Max points	Threshold
A.	Impact on the challenge	70	0
B.	Validity of the technical approach	10	0
C.	Quality of the tender	10	0
	Total	90	

¹ If there are not sufficient R&D providers, THERESA PCP consortium has the right (but not the obligation) to select only 2 providers for phase 1. If only 1 provider can be selected, THERESA PCP consortium reserves the right either to cancel the PCP or to start a negotiated procedure without prior publication with the tenderer as defined under article 32.2.a of Directive 2014/24/EU.

Table 9

#	Description	Max. Points
A.	IMPACT ON THE CHALLENGE	70
A1.	Removal Rates	20
A1.1	<p>The solution shall demonstrate a removal efficiency at least 80%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1), or, where applicable, verified transformation into non-toxic metabolites for the selected cytostatic drugs (A 2.1. , A2.6 & CRR 1.1.). This requirement shall apply to all mandatory cytostatics and to any optional / nice-to-have cytostatics included in the offer.</p> <p>0 points -80% or less 3 point - 81 to 90% 4 points- 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions) . This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach . If not, zero points will be awarded.</p>	4



A1.2	<p>The solution shall demonstrate a removal efficiency of at least 40%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of the selected contrast media (A2.2, A2.3, A2.5 & CRR1.2., CRR1.3)</p> <p>0 points - > 40% or less 2 point - 41 to 60% 3 points - 61 to 80% 4 points - 81 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions). This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach. If not, zero points will be awarded.</p>	4
A1.3	<p>The solution shall demonstrate a removal efficiency of at least 90%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of antibiotics (A2.4 & CRR1.4):</p> <p>0 points - 90% or less 4 point - 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions). This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach. If not, zero points will be awarded.</p>	4



A1.4	<p>The solution shall demonstrate a removal efficiency (log reduction) of at least 90%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of ARB (CRR1.5).</p> <p>0 points - 90% or less 4 point - 91 to 100%</p> <p>Provide a concise description of how your solution achieves the required removal rate, including the key treatment mechanisms, process steps, and any supporting evidence from laboratory, pilot, or full-scale applications.</p>	4
A1.5	<p>The solution shall demonstrate a removal efficiency of at least 90%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) ARG patterns (A2.7)</p> <p>0 points - 90% or less 4 point - 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions). This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach. If not, zero points will be awarded.</p>	4
A2.	Contaminants	15
A.2.1	<p>The solution shall demonstrate removal/degradation performance of (mandatory) cytostatic drugs, specifically: IFOSFAMIDE; TEMOZOLOMIDE; CYCLOPHOSPHAMIDE; ENZALUTAMIDE; FLUOROURACIL; METHOTREXATE; ABIRATERON; MYCOPHENOLATE; CISPLATIN; CARBOPLATIN; OXALIPLATIN</p> <p>In case adequately justified, suppliers may propose additional cytostatic compounds (CYTARABINE,</p>	3

	<p>GEMCITABINE, HYDROXYCARBAMIDE, CAPECITABINE, SORAFENIB, ALPELISIB, ALECTINIB) beyond the above listed substances (as long as at least one (1) of the mandatory cytostatic drugs listed above is addressed).</p> <p>Scoring: The Supplier must address at least one (1) cytostatic drug from the mandatory list in order to be eligible for scoring.</p> <p>Points will be awarded as follows:</p> <ul style="list-style-type: none"> • 0.5 points for each cytostatic drug addressed from the mandatory list; • 0.2 points for each additional cytostatic drug provided that its selection is adequately justified. <p>The total score under this criterion will not exceed 3 points.</p> <p>Examples:</p> <p>Example 1 Supplier A addresses the following mandatory cytostatic drugs: IFOSFAMIDE; TEMOZOLOMIDE; CYCLOPHOSPHAMIDE; ENZALUTAMIDE; FLUOROURACIL; METHOTREXATE;</p> <ul style="list-style-type: none"> • 6 mandatory cytostatic drugs × 0.5 points = 3.0 points <p>Total score awarded: 3.0 points</p> <p>Example 2 Supplier B addresses the following mandatory cytostatic drugs: METHOTREXATE; ABIRATERON; MYCOPHENOLATE; CISPLATIN; CARBOPLATIN; as well as the following additional cytostatic drugs: CYTARABINE, GEMCITABINE, HYDROXYCARBAMIDE.</p> <ul style="list-style-type: none"> • 5 mandatory cytostatic drugs × 0.5 points = 2.5 points • 3 additional justified cytostatic drug × 0.2 points = 0.6 points • Calculated total: 3.1 points <p>Total score awarded: 3.0 points</p>	
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	<p>Example 3</p> <p>Supplier C addresses the following cytostatic drugs: CYTARABINE, GEMCITABINE, HYDROXYCARBAMIDE, CAPECITABINE, SORAFENIB, ALPELISIB, ALECTINIB</p> <p>As none of the mandatory cytostatic drugs are addressed, the proposal is considered will receive 0 points.</p>							
A.2.2	<p>Solution shall demonstrate removal of watersoluble, nephrotropic, high osmolar Iodinated CT contrast media (ATC code: V08AB). Substances include: Iohexol ; Iopamidol ; Iopromide ; Iodixanol. Solution shall demonstrate removal of Paramagnetic Gadolinium based contrast media (ATC code: V08CA). Substances include: Gadopentetic acid; Gadoteric acid ; Gadodiamide; Gadoteridol; Gadobutrol; Gadoxetic acid ; Gadopiclenol.</p> <p>In case adequately justified, the solution supports additional contrast media removal in any of the below categories (as long as one (1) of the contrast media listed above is addressed) : Watersoluble, nephrotropic, high osmolar x-ray contrast media (ATC code V08AA), Watersoluble, hepatotropic x-ray contrast media (ATCcode: V08AC), Non-watersoluble x-ray contrast media (ATC code: V08AD), X-ray contrast media, non-iodinated(ATC code:V08B).</p> <p>Scoring : The Supplier must address at least one (1) contrast media belonging to the predefined ATC families (V08AB, V08CA) in order to be eligible for scoring.</p> <p>Points will be awarded as follows:</p> <ul style="list-style-type: none"> • 0.5 points for each contrast media addressed from the predefined ATC families listed above; • 0.2 points for each additional contrast media addressed from other families, provided that the selection is adequately justified. <p>The total score under this criterion will not exceed 3 points.</p>	3						
A.2.3	<p>Solution shall demonstrate the removal of antibiotics classified according to the families listed below:</p> <table> <tr> <th>ATC-Code</th> <th>Sub-group</th> </tr> <tr> <td>J01CA</td> <td>Penicillins with extended spectrum</td> </tr> <tr> <td>J01CE</td> <td>Beta-lactamase sensitive penicillins</td> </tr> </table>	ATC-Code	Sub-group	J01CA	Penicillins with extended spectrum	J01CE	Beta-lactamase sensitive penicillins	3
ATC-Code	Sub-group							
J01CA	Penicillins with extended spectrum							
J01CE	Beta-lactamase sensitive penicillins							

	<p>J01CF Beta-lactamase resistant penicillins J01CR Combinations of penicillins, incl. beta-lactamase inhibitors J01DD Third-generation cephalosporins J01DH Carbapenems J01FA Macrolides J01MA Fluoroquinolones J01XA Glycopeptide antibacterials</p> <p>Each additional antibiotic (regardless) of the family for which validated removal/degradation performance is demonstrated is welcome (as long as at least one (1) antibiotic from the list above is addressed).</p> <p>Scoring: The proposal must address at least one (1) antibiotic belonging to the predefined ATC families above in order to be eligible for scoring.</p> <p>Points will be awarded as follows:</p> <ul style="list-style-type: none"> • 0.5 points for each antibiotic from the predefined ATC families listed above; • 0.2 points for each additional antibiotic, provided that sufficient justification is provided regarding its clinical and/or ecotoxicological relevance. <p>The total score under this criterion will not exceed 3 points.</p>	
A.2.4	<p>The solution shall demonstrate removal/degradation performance of ARB (log reduction) , as follows: <i>Enterobacterales carbapenem resistant; Enterobacterales 3rd generation cephalosporin resistant; Acinetobacter baumannii carbapenem resistant</i></p> <p>Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.</p> <p>3 points: All 3 priority ARB groups addressed with experimental evidence 2 points: 2 priority ARB groups addressed with experimental evidence 1 point: 1 priority ARB group addressed; or all 3 addressed with only indirect/mechanistic evidence (no</p>	3

	<p>direct experimental data)</p> <p>0 points: No ARB group addressed, or no evidence provided</p>	
A.2.5	<p>The solution supports the ARG agents removal, in any of the below list: blaKPCgr, blaVIMgr, blaNDMgr, blaIMPgr, blaOXA-48gr, blaCTX-M-1gr, blaCTX-M-9gr, blaCTX-M-2gr, blaCTX-M-25gr, blaSHVESBL (-2, 5, ...), blaDHAPAmC, blaCMYPAmC</p> <p>Scoring: Points will be awarded based on the number of genes addressed from the predefined list above.</p> <ul style="list-style-type: none"> • 0.5 points for each gene addressed from the predefined list. <p>The total score under this criterion will not exceed 3 points.</p>	3
A3.	Operational and Technical Criteria	12
A3.1	<p>Automated or advanced monitoring dashboards shall be considered (i. automatically acquires data from sensors, processes and visualises data in real time, generates automated alerts, calculates performance indicators, supports operational decision-making). Monitoring parameters controlling the quality of the effluent (treatment efficiency) shall be depicted.</p> <p>3 points: Advanced concept: real-time automated data acquisition, centralised dashboard, alarm management, data storage/export, auto-calculation, AND at least one of: predictive analytics, remote/cloud access, digital twin, BIM integration, or regulatory compliance auto-tracking</p> <p>2 points: Standard automated dashboard: real-time data acquisition, centralised dashboard, alarm management, digital data storage and export capability; clear cybersecurity and data integrity approach described</p> <p>1 point: Basic monitoring concept: automated data collection from main sensors described; local display or simple dashboard; limited alarm or logging functionality</p> <p>0 points: Manual monitoring only, or no monitoring system described</p>	3
A3.2	<p>The proposed solution will be evaluated on its durability and dependency on consumables over its expected service life. Higher scores will be awarded to solutions demonstrating a longer lifecycle and lower dependency on consumables.</p>	3

	<p>Consumables, Replacement & Maintenance (max 1.5 points) 1.5 points: Consumables identified with type, indicative service life, projected replacement frequency, AND indicative maintenance frequency, cleaning procedures and estimated downtime 1 point: Consumables identified with some service life or replacement frequency but missing maintenance frequency, downtime, or cleaning details; OR minimal consumables with partial justification 0.5 point: Consumables listed but no service life, replacement frequency, or maintenance detail provided 0 points: Consumables clearly implied by technology but not addressed</p> <p>Durability & Service Life of System Components (max 1.5 points) 1.5 points: Lifetime of major components AND overall system lifetime stated, with at least one form of supporting justification (reference installation, manufacturer data, comparable technology, or quantified operational evidence) 1 point: System or component lifetime stated but with no supporting justification beyond a claim 0 points: No lifetime information provided</p>	
A3.3	<p>The proposed solution will be evaluated on its space efficiency in relation to treatment capacity and deployment feasibility in hospital environments. Higher scores will be awarded to solutions demonstrating compact physical footprint relative to treatment capacity without compromising treatment performance.</p> <p>6 points: Highly compact design with clear layout documentation and justified spatial calculations 4 points: Compact design 2 points: Moderate footprint, or space estimate provided without justification 0 points: Large footprint</p>	6
A4.	Sustainability aspects	23
A4.1	<p>Solutions demonstrating lifecycle cost efficiency, credible cost models, and favourable cost-performance balance will receive higher scores.</p> <p>CAPEX (max 2 points) 2 points: Acceptable cost < €800,000 1 point : Moderate cost € 800,00 - €1,400,000 0.5 points : High cost €1,400,000 - €2,000,000 0 points : > €2,000,000 OPEX (max 3 points)</p>	5



	3 points : Acceptable cost < €50,000/yr 2 points : Moderate cost €50,000/yr - €150,000/yr 1 point : High cost €150,000/yr - €350,000/yr 0 points : > €350,000/yr	
A4.2	<p>The proposed solution will be evaluated on the magnitude of operational environmental impacts per unit of treated wastewater, complementing the environmental added value assessment performed under the corresponding mandatory requirement.</p> <p>Measured Energy Consumption (max 3 points) 3 points: $\leq 1.0 \text{ kWh/m}^3$ 2 points: $1.0\text{--}2.5 \text{ kWh/m}^3$. 1 point: $2.5\text{--}5.5 \text{ kWh/m}^3$ 0 points: $> 5.5 \text{ kWh/m}^3$</p> <p>Chemical Consumption (max 2 points) 2 points: No chemicals or reagents used 1.5 points: Low/moderate chemical use clearly described with types stated; AND CLP classification provided or commitment to provide at Phase 2 1 point: Chemicals used; types stated; mitigation included for high-hazard chemicals 0 point: High chemical use with no mitigation; or no information</p> <p>Waste streams (max 2 points) 2 points: No or negligible secondary waste streams; OR all streams identified with generation intensity AND clear recovery/reuse/disposal pathway 1 point: Waste streams identified by type but generation intensity not quantified; OR disposal pathway described but intensity missing; OR only some streams identified 0 points: Waste streams present but not disclosed; OR membrane/AOP technology with no mention of concentrate or by-product management; OR no information</p>	7
A4.3	<p>The proposed solution will be evaluated on environmental aspects related to environmental safety, circularity of consumables and operational compatibility with hospital environments, which cannot be expressed per unit of treated wastewater.</p>	4

<p>By-products (max 1.5 points)</p> <p>1.5 points: No relevant by-products generated OR by-products acknowledged, specifically identified, AND concrete mitigation/polishing/monitoring approach described with supporting evidence</p> <p>1 point: By-products acknowledged but not specifically identified; OR mitigation described in general terms only without specific measures; OR process likely generates by-products but only partial acknowledgement</p> <p>0 points: By-products not addressed despite process likely generating them (AOP, chlorination, ozonation)</p> <p>Circularity (max 1 point)</p> <p>1 point: At least one circularity measure clearly described with supporting detail - regeneration cycles, reuse of components, recovery pathway, or documented end-of-life management; OR consumable lifespan exceeds testing period with technical documentation of expected regeneration/reuse provided</p> <p>0.5 points: Component or system lifetime stated with some justification; OR consumables identified but end-of-life/recovery route not properly described; OR general circularity intent stated without supporting evidence</p> <p>0 points: No circularity information provided</p> <p>Noise (max 1 point)</p> <p>1 point: Measured noise level ≤ 40 dB(A) reported; OR no dB(A) measurement but effective mitigation measures clearly described with technical specification (e.g. acoustic enclosure, containerisation, vibration damping) and plausible effectiveness</p> <p>0.5 points: Noise described qualitatively as low or minor without supporting technical detail; OR mitigation mentioned but not specified</p> <p>0 points: No noise information provided; OR noise > 40 dB(A) with no mitigation</p> <p>Odour (max 0.5 points)</p> <p>0.5 points: Low expected odour emissions with process justification; OR odour mitigation measures clearly described with specific technical measures</p> <p>0 points: No odour information; OR significant odour expected with no mitigation described</p>	
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A4.4	<p>The proposed solution shall enable the safe reuse of treated effluent and demonstrate a system configuration that technically supports such reuse in hospital environments. The proposed solution shall be designed so that treated effluent can be reused to a maximum possible level for at least one practical urban or industrial application (e.g. cleaning, toilet flushing, cooling water or other relevant uses). The treated effluent intended for reuse shall comply with the minimum quality requirements applicable to urban or industrial reuse classes defined in Spanish Royal Decree 1085/2024 of 22 October 2024 regulating water reuse.</p> <p>The solution architecture shall demonstrate that reuse can be technically implemented through an appropriate configuration enabling the treated effluent to be directed to reuse points within hospital infrastructure or to additional polishing or reuse modules where required. At the concept stage (Phase 1), the evaluation will focus on the technical feasibility of enabling at least 20% reuse of treated effluent, based on the proposed treatment configuration, expected effluent quality and system architecture.</p> <p>In Phase 2 and Phase 3, the evaluation will consider the actual reuse capability demonstrated by the prototype and pilot systems, including: the proportion of treated effluent that can be reused, and the reuse quality class achieved according to Spanish Royal Decree 1085/2024. Higher scores will be awarded to solutions demonstrating: a greater proportion of treated effluent suitable for reuse, compliance with higher reuse quality classes, and the ability to achieve such reuse without disproportionate increases in operational impacts such as energy consumption, chemical use or secondary waste generation. This criterion therefore promotes solutions that combine high reuse potential, compliance with reuse quality requirements, and technically feasible integration with hospital reuse infrastructure.</p> <p>Reuse capability (max 5 points)</p> <p>Planned proportion of treated effluent meeting Class B reuse quality</p> <p>0 points : < 20%</p>	7
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	3 points : $\geq 20\%$ – $< 50\%$ 5 points : $\geq 50\%$ Bonus – reuse integration readiness (2 point) Condition : System configuration clearly enables routing treated effluent to hospital reuse infrastructure or reuse module without major redesign	
B. VALIDITY OF THE TECHNICAL APPROACH		10
B.1. Quality of the methodology – Design, development and installation of the solution		3
B1.1.	<p>Explain briefly in TD8 – Point 5 how the proposed solution will be designed, developed and installed during the PCP phases. The description should outline the engineering methodology and implementation process that will be used to realise the proposed solution. A thorough explanation will receive the maximum points. This shall be further developed in detail in the Solution Design of PCP Phase 1. Depending on the shortcomings of the explanation, the score will be reduced.</p>	
B.2. Technical validity and robustness of the solution proposed		7
B2.1	<p>Explain briefly in TD8 point 5 how your proposal addresses this point. The extent to which the proposed solution design demonstrates coherence, feasibility, robustness, novelty and effective alignment of its components to deliver the intended objectives. A thorough explanation will receive the maximum points. This shall be further developed in detail in the Solution Design of PCP Phase 1. Depending on the shortcomings of the explanation, the score will be reduced.</p>	
C. QUALITY OF THE TENDER		10
C.1. Commercial potential		5

C.1.1.	<p>The extent to which the proposal contributes to a sustainable market introduction and scaling of the solution, assessed on:</p> <ul style="list-style-type: none"> - Market Entry and scaling strategy - Target market segments and end-user groups - Planned marketing channels and dissemination approach - IPR plan: arrangements on ownership, usage rights, and transparency. Transparency of exploitation arrangements and possible royalty models - Tenderers shall demonstrate how they will establish connections with funding mechanisms (national, private or EU or own funding) before the end of PCP Phase 3 in order to support the commercialisation of the solution. This includes activities aimed at preparing the commercialisation of the solutions beyond the project on the one hand and ensuring their uptake and future procurements by additional buyers on the other hand. <p>Explain briefly in TD8 point 5 how your proposal addresses this point. This shall be further developed in detail in the Solution Design of PCP Phase 1. A thorough explanation – addressing all the above-mentioned aspects – will receive the maximum points. Depending on the shortcomings of the explanation, the score will be reduced.</p>	5
C.2. Implementation methodology		5
C2.1.	<p>First draft plan of Project management methodology for the contract implementation for the three phases of the PCP. This should be supported by both gantt charts (timeline and sequencing) and PERT charts (critical path and dependency mapping).</p> <p>Suppliers should also include potential risks and mitigation measures. I.e., application Risk Management methodology aimed at ensuring schedule adherence, financial management, delivery of final outcomes, and maintaining effective relationships among clients, users, and contractors. This implies a formal risk register, including identification of key risks across, for example, but not exclusively): technical, clinical, commercial and management. The risk register should consider for each risk, its likelihood, its impact and its mitigation strategy.</p> <p>The project plan should clearly define work packages, such as:</p> <ul style="list-style-type: none"> - Project Management 	5

	<ul style="list-style-type: none">- Technical Development- Commercialisation/ Deployment <p>Each work packages should be linked to:</p> <ul style="list-style-type: none">- Defined tasks (as indicated under section 2.1)- Deliverables (as indicated under section 2.1)- Milestones (as indicated under section 2.1) <p>The project plan should explicitly define dependencies and interdependencies between tasks and work packages.</p> <p>Explain in TD8 point 5 how your proposal addresses this point. A thorough explanation – addressing all the above mentioned aspects - will receive the maximum points. Depending on the shortcomings of the explanation, the score will be reduced.</p>	
Total		90

The PBG reserves the right (but does not have the obligation) to ask for proof of compliance with the exclusion/selection/award criteria at any moment throughout the procedure. The tenderer shall provide all the necessary evidence within 5 (five) working days.

Call-offs for phases 2 and 3 may request that this information be updated in the offers submitted for these phases.

3.6 Evaluation procedure

Opening of tenders

See 2.6 Time schedule for the date on which the tenders for PCP phase 1 will be opened.

The Administrative Procurement Committee (APC) composed by at least three members of FMS will open the tenders. The APC will check the tenders vis-à-vis the exclusion, selection and compliance criteria.

Tenders not complying with the formal requirements will be excluded from the tender evaluation.

Evaluation

For the purpose of the evaluation of the bids, the following different Committees are appointed. In addition, the four bodies will guarantee the soundness of the procedure during the implementation of the PCP tender:

The Administrative Procurement Committee (APC) - The APC will be composed by at least three (3) members of the Lead Procurer and will have a dedicated role with the view to support and spend up the tender procedures during the procurement execution. In this regard, the APC members will support the Lead Procurer in the tender's evaluation (evaluating the tenders versus the exclusion and selection criteria, contact excluded bidders). **The Technical Evaluation Committee (TEC)** - The TEC will be comprised of one (1) representative from each member of the PB which are technical and/or domain-specific experts, and chaired by the Lead Procurer's representative. It will receive support (without voting rights) from expert advisors and end users as needed (among others the Consortium partners CPS, SILO, TBM, HCWH, SUNINN and IETU). The primary responsibility of the TEC is to ensure the project progresses in a timely manner and the delivery of high-quality results. Regular meetings of the TEC will be scheduled at least monthly, with an additional meeting held at the conclusion of the project for comprehensive review. The Committee will work closely with the PEC, assisting in various tasks including defining tender specifications, establishing evaluation criteria and designing testing procedures. Throughout all phases of the PCP process, the TEC shall review the end of phase reports and the proposals submitted by contractors, ensuring compliance with technical requirements. The TEC shall propose acceptance or rejection of deliverables and the proposals to the PEC. The TEC shall address complaints submitted by economic operators during the tendering process, providing recommendations to the PEC for final decision. Decisions within the TEC will be reached through consensus, reflecting a collaborative approach to project oversight and decision-making. The TEC will



permanently stay in contact, mainly using e-mail and regular teleconferences. Regular meetings of the TEC will be scheduled at least monthly, with an additional meeting held at the conclusion of the project for comprehensive review.

The Procurement Evaluation Committee (PEC) - The PEC chaired by the Lead Procurer representative and integrated of one (1) representative from each member of the PBC, will serve as the decision-making body overseeing the tendering process and subsequent contract execution.

It holds the responsibility of defining terms and conditions throughout the tendering phases as well as overseeing the tender awarding and contracting processes, and monitoring contract execution. The PEC analyses, makes proposals and sets guidelines for the whole PCP tendering process. The PEC will evaluate the tenders received and guarantee that the evaluation runs according to the scope of the project. The PEC will decide on possible complaints submitted during the tendering process based on the opinion of the TEC.

On the basis of the evaluation of the TEC, the PEC will make the formal acceptance of the milestones, as well as give authorization to the Lead Procurer for associated payments and the continuation to the next phase. To ensure agility in decision-making, the PEC will be flexible in arranging meetings at any necessary point during the tendering procedure, as well as for critical milestones like the tender release, contract award, and the evaluation of PCP results. A decision procedure based on the consensus principle will be established. If an agreement still cannot be reached and further delays are expected, the Lead Procurer will decide the deadlock.

Whenever feasible, electronic means will be prioritized over physical meetings. In cases of physical meetings, efforts will be made to integrate them alongside consortium meetings for efficiency. The PEC will receive support from expert advisors and other end users as needed (such as the Consortium partners CPS, SILO, TBM, HCWH, SUNINN and IETU), actively participating in meetings and offering guidance when required, although they will not possess voting rights in the decision-making process.

Bids will be evaluated in a non-discriminatory and transparent manner.

At the end of the evaluation procedure, a ranking will be drawn up, in which the tenderers/consortia will be listed based on the overall score achieved, in descending order.

The provisional award will be made to 5 (five) tenderers/consortia (depending on budget restrictions) (and a minimum of 3 (three) ²⁴) who submitted the MEAT, i.e., they will have obtained the highest overall scores following the sum of the overall scores awarded, resulting from the technical offer and the financial offer.

²⁴ If there are not sufficient R&D providers, THERESA PCP consortium has the right (but not the obligation) to select only 2 providers for phase 1. If only 1 provider can be selected, THERESA PCP consortium reserves the right either to cancel the PCP or to start a negotiated procedure without prior publication with the tenderer as defined under article 32.2.a of Directive 2014/24/EU.



In the event that the bids of two or more tenderers obtain the same overall score, but obtain partial scores for the price and for all the other different evaluation elements, the tenderer who obtained the best score on the technical offer will be placed first in the ranking of the two or more tenderers.

In the event that the bids of two or more tenderers obtain the same overall score and the same partial scores for the technical offer and the financial offer, and the number of winning tenderers still exceeds the maximum number of contracts that can be awarded (due to budget constraints), the bids that received a higher score in award criteria A) will be preferred. In case this score is the same, there will be a draw. To ensure transparency the tenderers in this situation will be invited to witness the draw.

At the end of the evaluation procedure, a ranking will be drawn up, in which the bids will be inserted based on the overall score achieved, in descending order; this ranking list will not include those that have not achieved the minimum technical score. The provisional award of the contract will take place in the order of the ranking, starting from the first competitor to the last one. The ranking will be scrolled until the possible maximum number of successful bidders is reached. Final award will take place after 15 calendar days of the publication of the provisional award.

The tenderers that are not selected after the whole evaluation procedure will receive information on why their tender was not selected.

The evaluation process and initial contract award will follow these steps:

- Step 1: Checking the eligibility and the exclusion criteria per tenderer/consortium. Performed by the APC.
- Step 2: For tenderers/consortia passing step 1, checking the selection criteria per tenderer/consortium. Performed by the APC.

Formal approval by the PEC of the outcome of the two prior steps:

- Step 3: For tenderers/consortia passing step 2, checking the compliance criteria per tender. Opening and evaluation of the technical offers (TD8. Technical form). Performed by the TEC.
- Step 4: For tenderers/consortia passing step 3, evaluating the bids based on the pass/fail award criteria. Performed by the TEC.
- Step 5: For tenderers/consortia passing step 4, evaluating the bids based on the weighted award criteria. Performed by the TEC.

Formal approval by the PEC of the outcome of the three prior steps:

- Step 6: For tenderers/consortia passing step 5, opening and evaluation of the financial offers (TD9. Financial form). Performed by the TEC. Formal Approval by the PEC of the outcome of the step.
- Step 7 Final ranking conducted by the PEC.
- Step 8: Provisional award decision by the PEC & communication thereof.
- Step 9: Final award decision after the standstill period (15 calendar days) & signing of framework agreement and phase 1 contract. Done by FMS acting on behalf of the PBG.

If a bid scores the maximum number of points for every criterion, it will receive the total maximum technical score of 90 (ninety) points. The maximum scoring



obtained after the proposal evaluation shall be 100 (one hundred) points, where:

- 90 (ninety) points correspond to the **technical offer, and**
- 10 (ten) points correspond to the **financial offer**

Following the Scoring Model:

*Explanation: The bids are evaluated with two separate price evaluations:

1. **Price for Phase 1 only** – maximum **10 points**
2. **Price for Phases 1, 2 and 3 combined** – maximum **30 points**

Points on the price for Phase 1

The maximum budget per contractor for PCP-phase 1 is € 19.477 (as described in section 2.5). Amounts over € 19.477 will lead to the exclusion of the bid. The score for the price criterion is assessed on the basis of the offered total price for phase 1 with shared IPR (Financial Form (TD9)) and the maximum score is 10 points.

The minimum for PCP-phase 1 with shared IPR is € 10.000. Between these limits, the points are calculated with the formula as described below:

$$PP \frac{P_r - P_b}{P_r - P_t} = 10 \frac{19.477 - P_b}{19.477 - 10.000}$$

PP=10

Maximum number of points available to bidders for price offers = 10

**Explanation : Maximum score for the Financial Offer=3*

Pr= Reserve Price, the price above which bidders are excluded = € 19.477

Pt= the price threshold is a lower bound: the bidder cannot improve his score with further price reductions = € 10.000

Pb= Price bid by the supplier

The score will be rounded to 2 decimals.

- Please note that prices below € 10.000 will NOT receive additional points.
- Please note that “negative” or 0 price offers will be excluded.

Points on the price for Phases 1, 2 and-3 combined

A price for PCP phase 1, PCP phase 2 and PCP phase 3 is also required as part of the bid evaluation.

The maximum budget per contractor for PCP phases 1, 2 and 3 is € 19.477, € 486.921 and € 438.229 respectively (see section 2.5). Amounts over the maximum budget per PCP phase will lead to the exclusion of the tender. The score for the price criterion is assessed on the basis on the offered total price with shared IPR (See Financial Form (TD9)) and the maximum score is 30 points.



The minimum amount for PCP-phase 1 with shared IPR is € 10.000. The minimum amount for PCP-phase 2 with shared IPR is € 300.000. The minimum amount for PCP-phase 3 with shared IPR is € 250.000.

Between these limits, the points are calculated with the formula as described below:

$$PP \frac{P_{r\ 1,2,3} - P_{b\ 1,2,3}}{P_{r\ 1,2,3} - P_{t\ 1,2,3}}$$

$$= 10 \left(\frac{19.477 - P_{b\ 1}}{19.477 - 10.000} + \frac{486.921 - P_{b\ 2}}{486.921 - 300.000} + \frac{438.229 - P_{b\ 3}}{438.229 - 250.000} \right)$$

PP = 10

Maximum number of points available to bidders for price offers=30

**Explanation : Maximum score for the Financial Offer=7*

Pr = Reserve Price, the price above which bidders are excluded

Pr 1 = € 19.477

Pr 2 = € 486.921

Pr 3 = € 438.229

Pt = the price threshold is a lower bound: the bidder cannot improve his score with further price reductions

Pt 1 = € 10.000

Pt 2 = € 300.000

Pt 3 = € 250.000

Pb = Prices per PCP-phase bid by the supplier

The points will be rounded to 2 decimals.

- Please note that prices below € 10.000, € 300.000 and € 250.000 will NOT receive additional points.
- Please note that “negative” or 0 price offers will be excluded.
- For phases 2 and 3, differences in the composition of the evaluation committees or in the procedure may be finetuned and communicated in due time.
- The evaluation of offers for phase 2 and 3 has only 1 step: evaluating the offers based on the pass/fail and the weighted award criteria.
- Please note that the maximum estimated budget indicated in the THERESA PCP Phase 1 offer for Phases 2 and 3 will act as a cap during the Call-Offs for Phase 2 and 3 respectively.

***Explanation: Total Score of the Financial Offer**

The 10 points available in the Phase 1 price calculation are not used directly. Instead, they are proportionally converted to a maximum of 3, as described below:



$$\text{Financial Score (Phase 1)} = (\text{Phase 1 Points}/10) \times 3$$

Similarly, the 30 points available for the combined phase pricing (Phase 1-3) must be converted into their assigned weight of 7, as described below:

$$\text{Financial Score (Phase 1-3 combined)} = ((\text{Phase 1-3 combined Points}) / 30) \times 7$$

Thus, the **maximum possible Financial Offer Score is 10.**

$$\text{Total Financial Offer Score} = \text{Financial Score (Phase 1)} + \text{Financial Score (Phases 1-3 combined)}.$$



4. CONTENT AND FORMAT OF TENDERS

4.1 Format

The tenders must meet the formal requirements (including the address for submission of the tender and requirements relating to the presentation of the offer and its packaging).

The tenders must:

- Contain administrative, technical and financial sections.
- Be signed by an authorized representative.
- Please ensure to include the different documents in the correct ENVELOPE. Incorrectly placed documents (e.g. TD9 Financial in envelope B) could lead to exclusion.

Table 10

ENVELOPE25	Evaluation	Documentation
ENVELOPE A Administrative section	First to be assessed by the APC. It should include all the documents required to demonstrate selection and non-exclusion grounds	Documentation regarding enrollment in a trade register, CVs, Documentation regarding proof of availability of testing facilities and necessary materials and/or equipment, TD10. ESPD, TD11. CONSORTIA STATEMENT.
ENVELOPE B Technical section	Second to be assessed by TEC. It includes aspects related to compliance criteria and award criteria, except for the price	TD8. Technical form
ENVELOPE C Financial section	Third to be assessed by TEC.	TD9. Financial form

Tenders that do not comply with the formal requirements will be automatically rejected. The PBG reserves the right (but does not have the obligation) to check the documents and references. Tenderers have 5 (five) working days to reply to this request and correct any clerical errors in ENVELOPE A – Administrative section.

Please note that for ENVELOPE B – Technical section - and ENVELOPE C – Financial section, the PBG reserves the right (but does not have the obligation) to check the

25 Please note that it will be an electronic submission.



information and ask for clarifications (as long as this does not imply a substantial modification of the tender).

More detailed information about the final layout requirements for the phase 2 and 3 offers will be provided in the call-off.

Submission and communication via the Studio Amica e-Procurement platform

This is a fully digital tendering procedure that runs through the **Studio Amica e-Procurement platform**. This means that all communications including the Tenders are only possible via the **Studio Amica platform** and must be directed to the contact person of FMS as lead procurer. It is not permitted to have any other contact about this PCP tender with other employees of the contracting authority, unless explicit written permission from a contact person has been received. Failure to comply with this provision may lead to exclusion.

The use of this platform is done on a voluntary base, as this procurement is a PCP that falls outside the scope of the EU Public Procurement Directives and the Ley 9/2017, de 8 de noviembre, de Contratos del Sector Público, por la que se transponen al ordenamiento jurídico español las Directivas del Parlamento Europeo y del Consejo 2014/23/UE y 2014/24/UE, de 26 de febrero de 2014.

A tenderer must register on the **Studio Amica platform**, free of charge. If Tenderer already has a company registration on the **Studio Amica platform**, no new registration is needed. Registration is possible via <https://theresapcp.tuttogare.it/register.php> by filling in a web form.

A tenderer is expected to have all the required knowledge to be able to correctly complete a tender procedure in the **Studio Amica platform**. The functioning of the **Studio Amica platform** is explained in the Quick User Guide that can be downloaded from the attachments section (<https://theresapcp.tuttogare.it/>).

On the basis of this Request for Tender, the tenderer must fill-out the requested data on the **Studio Amica platform** and add the accompanying statements and information.

For technical questions about the **Studio Amica platform**, the tenderer should contact the helpdesk, which can be reached on workdays via the e-mail address assistenza@tuttogare.it.

Tenderers must ensure that FMS has the correct e-mail address and telephone number of the Tenderer's contact person.

The tenderer is responsible for ensuring that these e-mail notifications are permitted by e-mail protection (firewall, spam filters). Neither FMS, nor **Studio Amica** is responsible in the event that these e-mail notifications are blocked by the e-mail security of the tenderer. Advice: add the e-mail address to trusted addresses or contact your own system manager for this. If a tenderer (for whatever reason) has not received an email notification, the consequences thereof will be for the account and risk of the tenderer.

The date and time indications in this Request for Tender are leading. Only updated date and time indications written in notices of information of FMS will prevail over the indications in this Request for Tender.



FMS reserves the right to switch to another electronic platform during the term of the Framework Agreement. FMS will inform the tenderer of this change in a timely manner, at least one month in advance.

FMS cannot guarantee (and also provides no guarantee) that **Studio Amica platform** can be accessed or used at any time without any problems. If there are problems with gaining access to **Studio Amica platform** and / or the use thereof, the tenderer must immediately report this to the **Studio Amica platform** support team, whereby the tenderer also sends an e-mail to the e-mail communicated by FMS. If there is a disruption at **Studio Amica platform** just before the expiry of the term for submission of the tender, FMS reserves the right to extend this term provided that it has not yet opened the already submitted tenders.

If the tenderer wishes to withdraw from participating in the tender at any time, he must announce this on the **Studio Amica platform** in accordance with the Quick User Guide.

Format requirements

The following requirements will apply regarding the format of tenders. tenderers or contractors that do not comply with the formal requirements will be excluded from further participation in the PCP:

- Where a signature is requested, the relevant document must be validly signed by a duly authorized person(s). The signature must be from a staff member or staff members who according to the extract from the professional register or trade register is authorized to represent the tenderer. If a document is signed by a person not listed in the professional register or trade register, an adequate proxy must be attached. Such a proxy must be signed by a person or persons who according to the extract from the trade register or the professional register or according to the articles of association are authorized to represent and bind the company. The proxy must clearly state that the proxy holder is authorized to represent the company in connection with this tender.
- The tender must be submitted in English.
- All tenders must be made using the Tender Forms (TD8, TD9, TD10 and T11).
- Tenders must not be qualified or accompanied by statements or a covering letter that might be construed as rendering the tender equivocal.
- The tender has the character of an irrevocable offer with a validity period of 60 calendar days, counting from the closing date for submission of tenders. If the award decision is objected to in preliminary relief proceedings, the validity period will be extended. The validity period will then be extended by 30 calendar days, counting from the first day on which it ceased to be possible to appeal from the court judgment regarding the objection to the provisional award.
- Amounts must be stated in euros, excluding VAT, unless otherwise stated.
- All tenders must contain an administrative, technical, and financial section.
- More detailed information about the final layout requirements for the phase 2 and 3 offers will be provided in the call-off for that specific phase.

Tenders that do not comply with the formal requirements may be rejected.

4.2 Technical section



The tender must include a detailed technical offer. The technical section of the tender should be drafted according to the template provided (TD8). The information provided in the technical section of the tender will be used to evaluate the tenders, on the basis of the award criteria. Please use the tender form to specify:

- A technical plan that outlines:
 - 1) the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and performance; and
 - 2) technical details of how this would be implemented, including also the proposed approach for complying with the do no significant harm principle.
- A project plan and methodology, and a description of the resources that the tenderer will use during the PCP process, to increase the chance of reaching milestones and deadlines for deliverables during and after the PCP process.
- A draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market.
- A list of the pre-existing rights (background) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed.
- A risk assessment and risk mitigation strategy.

More detailed information for the PCP phase 2 and 3 offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

4.3 Financial section

The tender must include a detailed financial offer, as part of the Tender form (TD9). Please use the tender form to specify:

- Binding unit prices for all items needed for carrying out phase 1 and for items that are expected to be needed for phase 2 and phase 3 (given in euros, excluding VAT but including any other taxes and duties).
- A fixed total price for phase 1 and an estimated total price for phase 2 and 3, broken down to show unit prices and the number of each unit needed to carry out phase 1 (given in euros, excluding VAT but including any other taxes and duties).

In addition, the financial section must include:

- A price breakdown that shows the price for R&D services and the price for supplies of products (to demonstrate compliance with the definition of R&D as described in 3.4 Compliance criteria).
- A price breakdown that shows the location or country in which the different categories of activities are to be carried out (*e.g. x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour*), which personnel profile corresponds to principle R&D personnel.



To demonstrate compliance with the requirement relating to place of performance as described in 3.4 Compliance criteria.

- The financial compensation valuing the benefits and risks of the allocation of ownership of the IPRs to the contractors (i.e. IPRs generated by the contractors during the PCP), by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted were IPR ownership to be transferred to the procurers) in order to ensure compliance with the EU R&D&I state aid framework.

The information provided in the financial section of the tender will be used to evaluate the tenders on the basis of the compliance criteria and the price award criteria. For on/off criterion B, the financial section can contain a self-declaration asking the tenderer to declare compliance of his offer with other public financing sources.

- The unit prices quoted for each category of items (*e.g. hourly rates for junior and senior researchers, developers and testers*) remain binding for all phases (i.e. for the duration of the framework agreement).
- The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement. Where new units/unit prices (*e.g. for new tasks or equipment*) are subsequently added to the phase 2 or 3 offers, they will become binding for the remaining phases.
- The price paid to the contractor will cover all costs incurred by the contractor. The PBG is not going to pay any additional costs.

Similar price breakdowns will be requested for the call-offs for phase 2 and 3. More detailed information for the phase 2 and 3 offers will be provided in the call-off.

Since all Contractors will be paid by FMS by way of centralised payments, and as FMS is based in Spain, EU rules and the valid 21% VAT legislation will be applied.

FMS may either cover any additional costs related to applicable VAT from its own funds or be entitled to deduct input VAT.

In case of suppliers from EU Member States, the reverse charge process, i.e. invoicing without VAT will be applied.

For suppliers from Spain (in the case of joint consortia, the consortium coordinator' headquarters are of relevance) national VAT procedures apply.

In case of suppliers from third countries, the VAT is calculated and reported by the Lead Procurer. If the supplier upon import is obliged to report VAT according to the rules of the home country and the invoice contains VAT, that VAT is non-deductible in Spain. Instead, VAT amount is to be considered as a cost of the service

4.4 Checklist of documents and proof

Hereby an overview of the documents and actions to be taken by a tenderer as part of the tender for PCP-phase 1.



Table 11

Name	Action to be taken by tenderer	Envelop (if applicable)
TD1. RFT (this document)	It provides the rules of the Tender, including the evaluation scheme. By the submission of a tender, all requirements mentioned in the tender documentation will be accepted by the tenderer. No action.	NO
TD2: Framework Agreement	Contains the provisions that will regulate Phase 1, Phase 2 and Phase 3 of the PCP. TD2 should be signed by contractors who have been awarded the Framework Agreement and Phase 1 Contract. To be signed by selected contractors.	NO
TD3: PCP Specific Contract for Phase 1	The Contract awarded for Phase 1 after the evaluation of Bids and final award. To be signed – together with the Framework Agreement - by selected contractors.	NO
TD4: PCP Specific Contract for Phase 2	The Contract awarded to contractors for phase 2 after the Call-Off for Phase 2 of the PCP. To be signed by selected contractors.	NO
TD5: PCP Specific Contract for Phase 3	The Contract awarded to contractors for Phase 3 after the Call-Off for Phase 3 of the PCP. To be signed by selected contractors.	NO
TD6: PCP End of Phase (1, 2, 3) report	Template to be used by selected contractors to report the outcomes of Phase 1, Phase 2 and Phase 3.	NO
TD7: Contractor details and Project abstracts	Template to be filled in by selected contractors in Phase 1, Phase 2 and Phase 3 of the PCP.	NO
TD8: Technical form	Template to be completed by Tenderers with their technical proposal. ENVELOPE B.	B
TD9: Financial form	Template to be completed by Tenderers with their Financial Offer and Cost Breakdown. ENVELOPE C.	C
TD10: ESPD	It is a self-declaration which includes a declaration of honour, and, if applicable, a consortium Statement and a Subcontracting Statement To be filled in, signed and submitted by Tenderer, by the Consortium of Tenderers (if applicable) and/or subcontractors (if applicable) as part of the tender for phase 1. ENVELOPE A.	A
TD11: Consortia Statement	Template to be filled in by Tenderers only in case of a consortium presenting a bid. ENVELOPE A.	A (if applicable)

Name	Action to be taken by tenderer	Envelop (if applicable)
Tender Document 12 (TD 12): Generic test plan template	Template to be used by selected contractors in Phase 2 and Phase 3.	NO
Tender Document 13 (TD 13): Generic test report template	Template to be used by selected contractors in Phase 2 and Phase 3.	NO
Annex 1. Test sites	No action. For information.	NO
Annex 2. Preexisting rights of the PBG	No action. For information.	NO
Annex 3. List of environmental, social and labour law obligations established by EU law, national legislation, collective agreements or the international environmental, social and labour conventions which Bids must comply with.	No action. For information.	NO
Annex 4. OMC report	No action. For information.	NO
Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1	No action. For information.	NO
Annex 6. Phase 1 testing strategy & requirements	No action. For information	NO
Annex 7. Phase 3 verification strategy & requirements	No action. For information	NO
Annex 8. Guide for ETV applicants	No action. For information	NO
Annex 9. Contract template	No action. For information. For phase 3 Contractors with minor modifications if needed.	NO
Annex 10. ETV Application	No action. For information.	NO
Annex 11. Quick Scan Document	No action. For information.	NO



5. MISCELLANEOUS

5.1 Language

All communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English.

Tenders as well as offers for phase 2 and 3 call-offs must be submitted in English. Contractors are aware that the Framework Agreement (and subsequent contracts, if applicable) will be signed in its English version. With the submission of their tenders, contractors accept this fact.

Deliverables must be submitted in English.

Hence, the representative of the successful tenderer in the performance of the contract, as well as the representative of any subcontractor involved in the negotiation of the contract, shall be proficient, both orally and in writing, in English.

5.2 Tender constitutes binding offer

A signed tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer/consortium that submitted the tender. By submitting a tender, the tenderer accepts all requirements mentioned in the tender documentation.

The signature of an authorised representative of the tenderer will be considered as the signature of the tender (and will be binding for the tenderer or, for joint tenders, the consortium).

5.3 Unauthorised communication — Questions

The OMC report in English can be found under Annex 4.

Questions can be submitted via the tender platform **Studio Amica platform** (<https://theresapcp.tuttogare.it/>). The summary of all questions and answers will be presented in an anonymised Q&A document. For phase 2 and 3, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

- All other contacts (or attempted contacts) will be considered unauthorized and may lead to the exclusion of your tender.

5.4 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure.

5.5 Contract implementation



Successful tenderers will be requested to sign both a framework agreement for the entire duration of the PCP and specific contracts for each phase (if successful) (see TD2 and TD3, 4 and 5).

Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables and output or results) for the phase.

Each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

The TEC might decide to hold regular monitoring meetings with the contractor(s). The meetings may take place at the contractors' venue. This will be detailed in the call-offs. The contractors could be asked to discuss the results achieved in the preceding period and present their updated work plan; the contractors could visit the testing sites (in particular at the start of a phase to get to know better the operational environment that solutions need to be designed for). The contractor must cover its own costs and thus foresee personnel and travel budgets in its offer.

The monitoring team will provide regular feedback to contractors after meetings or visits.

Payments based on satisfactory completion of milestones and deliverables of the phase

Payments corresponding to each PCP phase will be subject to the satisfactory completion of the deliverables and milestones for that phase.

Satisfactory completion will be assessed by the TEC and the PEC, according to the following requirements:

- If the work corresponding to that milestone/deliverable has been carried out.
- If a reasonable minimum quality has been delivered.
- If the reports have been submitted on time.
- If the monies have been allocated to the planned objectives.
- If the monies have been allocated and the work has been carried out according to the on/off award criteria (place of performance, public funding and R&D definition criteria).
- If the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractors have duly protected and managed IPRs generated in the respective phase).
- This will be evaluated against the weighted award criteria and subaward criteria (as finetuned for each phase).
- It also includes compliance with Annex 1. Test sites, Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1, Annex 6. Phase 1 testing



strategy & requirements, Annex 7. Phase 3 verification strategy & requirements and Annex 8. Guide for ETV applicants.

'Reasonable minimum quality' of a report means that:

- The report can be read by somebody who is familiar with the topic, but not an expert.
- The report gives insight in the tasks performed in and the results.
- The report is made using the end of phase report form and the requirements of this form have been met.

'Reasonable minimum quality' of a demonstration for phase 2 and/or 3 means:

- The demonstration can be understood by somebody who is familiar with the topic, but not an expert (for instance, somebody with operational but not technical knowledge).
- The demonstration shows how the innovation works, how it can be used and (if applicable) how it is operated and maintained.
- The demonstration is accessible to parties appointed by the PBG, unless these are direct competitors of the contractors.

Satisfactory completion in each of the phases does not mean successful completion. The assessment will consider the efforts made by contractors to take into account the feedback from the main contact person (their supervisor) or the monitoring team.

Where the PEC judges the completion of deliverables to be unsatisfactory, the pre-payments (if applicable) made to the benefit of the contractors at the beginning of a phase shall be reimbursed in full and the framework agreement (TD2) and respective phase contract shall be terminated.

Payments will be done in case of satisfactory or successful evaluation. The invoice must provide:

- a price breakdown showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D).
- a price breakdown showing the location or country in which the different categories of activities were performed (e.g. x hours of senior researchers in country L at y euro/hour, a hours of junior developers in country M at b euro/hour) (to demonstrate compliance with the requirement demanding that at least 70% (seventy) of the R&D services will be developed in the EU Member States or in HE associated countries).

Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to successful completion of the preceding phase. Successful completion of a phase will be assessed by the FEC, the TEC and the PEC against the following requirements:

- If all milestones have been successfully completed.



- If the R&D results meet the minimum functionality/performance requirements of the challenge description (*i.e. the minimum quality/efficiency improvements which the procurers set forward for the innovative solutions to achieve*).
- If the results of the R&D are considered to be promising.

‘Promising’ means:

- For phase 1, that the feasibility is convincing.
 - For phase 2, that the feasibility, the applicability in an operational setting and the potential impact of the product is convincing.
- **Please note that there is a difference between satisfactory completion and successful completion: a satisfactory completion is a requirement to receive the payment for that phase. Satisfactory completion includes completion of all the deliverables & milestones in the specific phase, and meeting minimum requirements set for that phase.**
 - **A successful completion is a prerequisite for passing from one phase to the next and includes the same aspects as satisfactory completion but will also depend on the assessment of how promising the R&D is. Please note, that a successful completion and an invitation for the subsequent phase doesn’t automatically mean that the contractor will participate in this phase.**

5.6 Cancellation of the tender procedure

FMS (on behalf of the PBG) may, at any moment, cease to proceed with the tender procedure and cancel it. In particular, FMS (on behalf of the PBG) reserves the right to suspend or terminate the procedure in whole or in part, to change the time schedule (with the exception of shortening the legally established minimum periods) and to revoke and/or revise the award decision stating the reasons without being obliged to pay any compensation until the moment of signing the Framework Agreement.

The PBG reserves the right not to award any contracts at the end of the tender procedure.

The PBG is not liable for any expense or loss the tenderers may have incurred in preparing their offer.

5.7 Procedures for appeal

Considering that PCP is exempted from the EU Public Procurement Directives and subsequently from the national transposition laws, the Spanish (and Navarra’s) public procurement law will be applied on a subsidiary basis, if the tender documents do not cover a potential legal loophole.

Any legal claim, petition or application for judicial review, with regard to the present procurement procedure, shall be lodged:



- For preparatory and award decisions, as well as contract modifications: before the Head of the Department of Health of Navarre (Spain), within a period of one month from the publication or notification of the contested decision. This prior appeal is mandatory before escalating to the administrative courts of Pamplona (Navarra, Spain) for a period of two months after the decision of the Head of the Department of Health of Navarre.
- For the execution and termination of the contract(s): before the civil courts of Pamplona (Navarra, Spain).

5.8 Inaccuracies, inconsistencies, defects and errors

This RFT (TD1) including annexes has been compiled with great care. Should the tenderer nevertheless come across imperfections, defects, inconsistencies, inaccuracies and uncertainties in the tender documents and/or otherwise object to the tendering procedure and/or the set of requirements and conditions, the tenderer must inform the PBG thereof as soon as possible. Failure to submit a detailed complaint immediately after discovery, leads to losing the right to file a claim as the PBG will legitimately assume that the tenderer agrees with the tendering procedure and/or the set requirements and criteria.

If the tenderer submits an objection and the PBG rejects it, the tenderer must act proactively. If the tenderer still disagrees with the position of the PBG, the tenderer must initiate preliminary injunction proceedings as soon as possible and, if necessary, before submitting its tender.

If the tenderer fails to do so, it forfeits the right to raise those objections at any later stage (including after submitting the tender). In such a case, the PBG is entitled to assume that the tenderer accepts its position.





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THERESA PCP

**PCP TENDER DOCUMENT 2
FRAMEWORK AGREEMENT (TD2)**



TD2. PCP FRAMEWORK AGREEMENT

This is a framework agreement (“Agreement” or “Framework Agreement”) between the following parties:

on the one part, the “lead procurer” (contracting authority), **FUNDACIÓN PÚBLICA MIGUEL SERVET (FMS)**, based in Spain, acting in the name and on behalf of the [other] members of the Public PBG (PBG) (together with FMS: “procurers”):

1. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH) (EST)
2. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS) (PL)
3. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM) (NL)
4. ZIEKENHUIS AAN DE STROOM (ZAS) (BE)
5. CONSORCI HOSPITALARI DE VIC (CHV) (ES)
6. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS) (ES)

and on the other hand, [insert details of the contractor], hereinafter the “contractor”,

[for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]
- 2.

The members of the group of tenderers are hereafter collectively referred to as “the contractor” and will be jointly and severally liable vis-à-vis FMS for the performance of this Framework Agreement and the Specific Contracts.]

FMS, the PBG and the contractor(s) shall be referred to together as “parties”, unless otherwise specified.

By signing this Agreement, the parties agree to implement the Pre-Commercial Procurement (PCP) in accordance with the Agreement and all the obligations it sets out, as well as TD1. Request for Tender (and related documentation) and their submitted TD8. Technical form and TD9. Financial form.

Now therefore, between the parties, as above represented,

IT IS AGREED AS FOLLOWS:



TERMS AND CONDITIONS

Article 1 — Subject of the agreement

- 1.1. This Framework Agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D services and for the specific contracts that will be awarded for each of the PCP phases.
- 1.2. The contractor irrevocably undertakes towards FMS to carry out the activities referred to in the Request for Tenders (TD1), in the Technical Form (TD8) and the Financial Form (TD9) submitted by the contractor and to comply with all obligations incumbent thereupon under this Framework Agreement (TD2) and any awarded Phase Contracts (TD3, TD4, TD5) in a professional and skilful manner, meeting best industry practice.
- 1.3. The contractor confirms to be aware of and to agree with the fact that FMS may enter into similar agreements, relating to the same project, with other contractors of phase 1, phase 2 and/or 3.

Article 2 — Conditions for the execution of activities

- 2.1. The contractor undertakes to fulfil the obligations under this Framework Agreement with its own means, by organizing and managing at its own risk.
- 2.2. The contractor shall inform FMS in compliance with and, in any case, promptly upon FMS's first request, of the progress of the Project. Without prejudice to other provisions hereunder, especially in Article 5 Duties of the Parties, the contractor shall notify FMS of any proposed deviation from the agreed scope of work or if significant developments occur as R&D work progresses as soon as possible after the contractor becomes aware of the necessity or usefulness of such deviation.
- 2.3. The contractor shall ensure the communication between the parties of this Framework Agreement and any other third party as may be required and duly notified to the contractor by FMS. Moreover, if needed, the contractor shall provide advice to FMS as required on the Project.
- 2.4. The contractor shall implement the contract in compliance with all of the following obligations in line with the requirements of TD1. Request for Tender (TD1):
 - a) The 'Compliance with the definition of R&D Services'.
 - b) The 'Place of performance obligation'.
 - c) The 'Place of establishment and control'.

In case of breach of any of the above contractual obligations, FMS is entitled to require that the contractor transfers the ownership of the Results to FMS.

- 2.5. During the execution of the Framework Agreement and without any interference in the contractor internal processes, FMS and the PBG reserve the right to monitor periodically the progress of the contractual performance.



- 2.6. The contractor undertakes not to subcontract essential parts of the contracts, nor the management of the PCP activities (these tasks will have to be performed by the contractor or at least by full-subsidiary companies owned by the contractor), unless deemed necessary by both parties and agreed upon in writing between the Parties. FMS shall terminate this agreement forthwith in case of failure by the contractor to comply with the provisions under this article.
- 2.7. In providing the Services as required under this Framework Agreement and Phase Contract(s), the contractor shall ensure full compliance with the requirements on R&D Services as defined in the most recent version of the Frascati Manual and, where applicable, its latest annexes.²⁶
- 2.8. Subject to the confidentiality obligations set forth in Article 9, the contractor grants to FMS (acting, as the case may be, through agents authorized for that purpose) and to any statutory or regulatory auditors of FMS, a right to access (and, if necessary, to copy) the relevant financial records during normal business hours.
- 2.9. Upon signing of this Agreement, the contractor shall appoint a representative for this Framework Agreement, which will be the contact person with FMS. The contractor's representative will then have the ability, unless otherwise decided, to represent for all purposes the same contractor.
- 2.10. At the execution date of this agreement, the contractor will have to communicate the name, phone number and e-mail address of the representative.

Article 3 — Duration

- 3.1. The Project is divided into the following Phases:
- a) Phase 1: Solution design.
 - b) Phase 2: Prototype development.
 - c) Phase 3: Validation in real operational environment.
- 3.2. Each Phase will have a duration in accordance with the planning provided in the Request for Tenders (TD1) and as agreed in each Phase Contract.
- 3.3. The Framework Agreement becomes effective upon signing by both Parties and shall remain in effect (unless terminated in accordance with Article 22) until the completion date (as defined in the Request for Tender) of Phase 1 or of a later Phase that has been awarded to the contractor. However, confidentiality related obligations shall remain applicable for a period of 4 (four) years after the end of the Framework Agreement in accordance with Article 9.
- 3.4. The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks, in compliance with the provisions of Article 24.

²⁶ OECD (2002). Frascati Manual 2002: [Version: 2002]. OECD Publishing [online].



Article 4 — R&D services to be provided

The contractor shall provide the R&D services (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the tender and the specific contracts, in compliance with the rules of the state aid framework for R&D&I in its latest version.²⁷

Article 5 — Duties of the Parties

- 5.1. The contractor is entering into this Framework Agreement based on the information about the Project made available by FMS during the tender procedure, which is assumed to be materially accurate and complete to the best of FMS's knowledge at that time
- 5.2. The contractor undertakes to perform all the activities subject of this Framework Agreement in accordance with its provisions, the applicable regulations and the terms and conditions contained in the Tender Documents and related annexes, as well as their submitted Technical Form (TD8) and the Financial Form (TD9). The contractor undertakes to allocate sufficient resources to each Phase of the PCP that the contractor is awarded, in order to comply with its obligations in each Phase. The contractor also undertakes to ensure that each member of the contractor's staff engaged on the Project observes the terms and conditions of this Framework Agreement and any amendment entered into between the parties hereto. The contractor's staff will be informed of any changes in the scope of the Framework Agreement or the PCP Project.
- 5.3. The contractor undertakes to:
- a) Co-operate with FMS in all matters relating to the project.
 - b) Obtain and at all times maintain during the collaboration all necessary licenses and consents required for the performance of this Framework Agreement.
 - c) Subject to the prior written approval of FMS, appoint or, at the written request of FMS, holding reasonable grounds for the request, replace without delay:
 - i. The contractor's representative; and/or
 - ii. The key staff, who shall be suitably skilled, experienced and qualified to carry out the Project.
 - d) Ensure the availability of the contractor's representative and (key) staff for the purposes of the Project. The contractor undertakes to ensure that all required key staff will be available to deliver the required services at agreed levels of quality and in a timely manner. Notwithstanding the provisions of Article 22, FMS may terminate this Framework Agreement with a contractor if any of the contractor's key staff are not available for the entire period needed to fulfil their duties in the project, subject to prior discussion having first been held with the contractor to attempt to identify and agree a

²⁷ Framework for state aid for research and development and innovation https://ec.europa.eu/competition/state_aid/modernisation/rdi_framework_en.pdf



mutually acceptable replacement and where the lack of availability of one or more of the key staff causes a material risk to the fulfilment of the delivery objective of the project.

- e) Promptly inform FMS of the absence of the contractor's representative and/or key staff. If required by FMS, the contractor shall provide a suitably qualified replacement.
- f) Not make any changes to the contractor's representative, sub-contractors or the key staff without the prior written approval of FMS. Such approval is not to be unreasonably withheld or delayed.
- g) Ensure that the contractor's team uses reasonable skill and care during the project.
- h) Be responsible for the accuracy and completeness of all drawings, documentation and information supplied to FMS in connection with delivery of this Framework Agreement. The contractor shall:
 - i. Observe, comply and ensure that the contractor's team observes and complies with all rules, regulations and technical requirements and all any other reasonable requirements and safety regulations as well as those that may subsequently be enacted or issued by FMS. For the avoidance of any doubt, the contractor undertakes that any increased costs, resulting from the need to observe the rules and regulations referred to in the previous paragraph, even if entered into force after the signing of the Framework Agreement, will remain the exclusive responsibility of the contractor, unless it would be unreasonable for contractor to, in which case the Parties will consult with each other in all fairness how to deal with any of these increased costs. Therefore, the same contractor cannot claim any payments against FMS, the members of the PBG and/or any other third parties, to the extent of its jurisdiction, and will assume all the risks related to any subsequent amendments to the law in force, which may impose additional charges subsequent to those provided at the time of the submission of bids. The contractor expressly agrees to indemnify and hold harmless FMS, the members of the PBG and/or any third party, for all the consequences arising from any breach by the contractor of the rules and technical requirements, safety, and other related regulations.
 - ii. Acknowledge and adjust to any modification with respect to the specifications made by FMS.
 - iii. Notify FMS as soon as it becomes aware of any issues which arise in relation to the Project.

5.4. FMS shall:

- a) Co-operate with the contractor in all matters relating to the project. The main contact point will be unidad.innovacion.salud@navarra.es, to which all relevant legal, administrative, and technical representatives will have access to.
- b) Provide access to FMS's (and, if needed, the members of the PBG) premises and sensitive data if it is in accordance with data protection officials, office accommodation and other facilities as may reasonably be requested by the



- contractor and in line with the rules and regulations agreed in writing in advance with the contractor for the purposes of the project.
- c) Provide such information as the contractor may reasonably request and the contractor considers reasonably necessary, in order to carry out the project, in a timely manner, and ensure that it is accurate in all material respects.
- 5.5. The contractor acknowledges and unconditionally accepts that FMS and the PBG are and remain unconditionally entitled to analyse the Results of the PCP Phases and to re-use, integrate and to publish the advice (or parts thereof), in whatever form or manner FMS deems necessary.
- 5.6. The contractor will allow the European Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their auditing rights. This obligation applies to all its subcontractors.
- 5.7. Due to the short duration of the PCP, no changes in the members of a consortium and/or subcontractors will be allowed unless in case of exceptional reasons that could not be foreseen or a new contractor replaces the one to which the contracting authority had initially awarded the contract as a consequence of an universal or partial succession into the position of the initial contractor, following corporate restructuring, including takeover, merger, acquisition or insolvency, of another economic operator that fulfils the criteria for qualitative selection initially established.

If that is the case, the new member of the consortium and/or subcontractor has to meet all exclusion, compliance and selection criteria, to comply with the pass/fail award criteria. The new member of the consortium and/or subcontractor will have to sign the declarations of honour and any other required statements. The replacement cannot entail a substantial modification of the contract conditions.

Article 6 — Warranties and representations

- 6.1. The contractor warrants and represents to have full capacity and authority to send all necessary usage licenses, permits and consents with the related rights related to the PCP Project and continues to have this full capacity, authority, usage Licenses, permits and consents during the duration of the Framework Agreement.
- 6.2. The contractor warrants that the information it will provide under the Framework Agreement will be correct, accurate and up to date.

Article 7 — Pricing, payment and accounting

- 7.1. FMS will be responsible for the payments on behalf of the PBG.
- 7.2. The total amount to be paid by FMS to the contractor shall not exceed the relevant amounts detailed in the Request for Tender (TD1).
- 7.3. The price for the R&D services to be implemented for each PCP phase will be set out in the specific Phase Contracts.



- 7.4. Prices indicated and submitted by the contractor in the Financial Form (TD9) during the tender shall be considered a binding maximum for the duration of the Framework Agreement and include all the costs and expenses. If FMS decides to shift remaining budget to Phase 2 and/or Phase 3, the binding maximum may be adjusted for the call offs of Phase 2 and/or Phase 3, allowing the formulation of bids accordingly.
- 7.5. Payments for the contractor's Services for each Phase will be made according to the following provisions:

PHASE 1

Table 12

	Date of Deliverable	Deliverable	%	Total
Phase 1	Week 4 of month 3 of phase 1	D1.1), D1.2) and D1.3)	100%	100%

PHASE 2

Table 13

	Date of Deliverable	Deliverable	%	Total
Phase 2	Month 3 of phase 2	D2.1)	50%	
Phase 2	Month 10 of phase 2	D2.2), D2.3), D2.4), D2.5) and D2.6)	50%	

PHASE 3:

Table 14

	Date of Deliverable	Deliverable	%	Total
Phase 3	Month 5 of phase 3	D3.1) D3.2) and D3.3)	55%	
Phase 3	Month 10 of phase 3	D3.4), D3.5) D3.6), D3.7) , D3.8), D3.9) and D3.10)	45%	



- 7.6. Payments will be made by FMS following the award of the Phase Contract and according to the payment schedule as defined in the PCP Request for Tender (TD1).
- 7.7. Payments for the contractor's services for each phase will be made according to the following provisions: Payments corresponding to each PCP phase will be subject to the satisfactory completion of the deliverables for that phase.
- 7.8. Payments will be made by FMS following the submission of the relevant invoices. The contractor will send the invoice once the deliverable has been accepted. Invoices are to be submitted in euros. The contractor shall state the price with and without VAT. Any other taxes, levies, tariffs and duties (including sales, service, use, lease, personal property, consumption, excise, withholding, or property) associated with the contractor's performance of the Framework Agreement or which may be levied on the price shall be the contractor's responsibility.
- 7.9. FMS will liquidate the mentioned invoices in the dedicated current account detailed by the contractor. FMS may suspend the payment at any time if, in the view of FMS or the PEC, acting reasonably, satisfactory progress on the Project has not been maintained, or reports have not been submitted as required.
- 7.10. All activities necessary to a full and regular compliance with the contractual terms and conditions shall be the sole responsibility of the contractor and are included in the consideration specified in the Financial Form (TD9), even if not specified in this Framework Agreement.
- 7.11. Prices shall be based on the maximum binding unit prices for all foreseeable items which have been stated in the economic offer and are binding (as a maximum) for the duration of the whole Framework Agreement. If unit prices are added to Phase 2 or 3 offers, they shall become binding for the remaining Phases.
- 7.12. The contractor accepts, upon request from FMS, to provide FMS with complete, relevant and clear information as well as documentary evidence about the allocation of amounts paid by FMS. The contractor shall maintain proper financial records relating to the Project at all times during the Project period and for a period of 4 (four) years after the end of the Project period.
- 7.13. Payments to third parties employed or hired by the contractor, if any, shall remain the sole responsibility of the contractor, who shall ensure that such payments are made promptly and hold FMS (and the PBG) harmless against any claim by such third parties.
- 7.14. Where the contractor enters into a subcontract with a supplier or contractor for the purpose of performing the Agreement, it shall include a clause requiring the payment of undisputed sums by the contractor to the subcontractor within a specified period not exceeding thirty (30) calendar days from the receipt of a valid invoice.
- 7.15. Wherever, under the Agreement, any sum of money is recoverable from or payable by the contractor (including any sum that the contractor is liable to pay to FMS in respect of any breach of the Contract), FMS may unilaterally deduct that sum from any sum then due, or which at any later time may



become due to the contractor under the Agreement or under any other agreement with FMS.

7.16. If at any time an overpayment has been made to the contractor for any reason whatsoever, the amount of such overpayment shall be considered when assessing any further payments or shall be recovered from the contractor at FMS's discretion.

7.17. The contractor shall make any payments due to FMS without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise, unless the contractor has a final and enforceable court order requiring an amount equal to such deduction to be paid by FMS to the contractor.

Article 8 — Rights and obligations regarding Foreground, Background and Sideground information and the related rights (including intellectual and industrial property rights)

IPR DEFINITIONS

8.1. The follow definitions apply to this Framework Agreement:

- a) 'Results' means any tangible or intangible output that is generated in the PCP, whatever its form or nature, whether or not it can be protected. This includes any material, document, technology, solution, data, knowledge or information as well as any rights attached to it, including IPR (rights on Results or IPR attached to the Results).
- b) 'Background' or "Pre-existing" means any material, document, technology, solution, data, know-how or information (Background information) — whatever its form or nature (tangible or intangible), regardless of whether or not it can be protected, including any attached rights such as IPR ('Background IPR') — that (1) is held prior to the signing of the Framework Agreement or a Specific Contract, (2) identified by the parties involved in the PCP as Background and (3) needed to implement the PCP or exploit the results of the PCP.
- c) 'Background or Pre-existing rights': any rights, including industrial and intellectual property rights on Background/Pre-existing information. They may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the creator, the contracting authority, the PBG or to any other third parties, including subcontractors.
- d) 'Sideground' means any material, document, technology, solution, data, know-how or information (Sideground information) — whatever its form or nature (tangible or intangible), regardless of whether or not it can be protected, including any attached rights such as IPR ('Sideground IPR') — that is generated during the timespan of the PCP but not related under the PCP.
- e) 'Sideground rights': any rights, including industrial and intellectual property rights on sideground material. They may consist in a right of ownership, a



licence right and/or right of use belonging to the contractor, the creator, the contracting authority, the PBG or to any other third parties, including subcontractors.

- f) 'Fair, Reasonable, and Non-Discriminatory (FRAND) conditions' means appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (*for example, the actual or potential value of the Results, Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged*).
- g) 'Generated in the PCP' means in the implementation of activities described in the PCP Framework Agreement or Specific Contracts.
- h) 'Not generated in the PCP' means not generated in the implementation of activities described in the PCP Framework Agreement or Specific Contracts.

PRE-EXISTING INFORMATION AND PRE-EXISTING RIGHTS (BACKGROUND AND SIDEGROUND)

8.2. All pre-existing rights remain the property of the Party introducing them (FMS, members of the PBG, contractor or any Third Party supplier that owns it) and nothing contained in this Framework Agreement or any License contract pertaining or pursuant to the Project shall affect the ownership rights of either Party in its pre-existing IPR.

8.3. The Parties must grant each other an indefinite royalty-free, non-exclusive, irrevocable and non-sublicensable License to use its Background information for the performance of the tasks assigned to them in the PCP.

The contractor grants to the members of the PBG, to entities that are under the direct or indirect control of members of the PBG, or under the same direct or indirect control as members of the PBG, or directly or indirectly controlling members of the PBG and also to (sub)contractors that practice the results for the PBG's own non-commercial use — a free license to use its Background to the extent needed to use the results for the PBG's own non-commercial purposes, beyond the execution of the Framework Agreement and Specific Contracts.

These Licenses are in addition to rights provided for by law, such as the unwaivable rights of, and exceptions for the benefit of lawful users of software or of databases, as foreseen by applicable law.

The contractor must ensure that Background information/rights that is subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries set out in section 3.1 of TD1 Request for Tenders and that impact the exploitation of the results (i.e. would make the exploitation of the Results subject to control or restrictions) must not be used and must be explicitly excluded from the list of Pre-existing rights agreed between the contractor and the contracting authority that will be used for the PCP — unless otherwise agreed with FMS.



- 8.4. In order to be able to distinguish clearly between pre-existing information and foreground information and to establish which pre-existing information is held by whom, the parties must establish an agreed list of all their pre-existing information that may be used for the performance of this Framework Agreement and Specific Contracts, including identification of the rights' owners.

The list of pre-existing information shall identify the tasks, deliverables or other aspects related to the performance of the Framework Agreement and Specific Contracts that may be affected by pre-existing information. Such list will include, but is not limited to, a list of the software necessary for the performance of the Framework Agreement and Specific Contracts (including but not limited to software necessary for the operation of the prototypes and products or services that will be developed during the Framework Agreement or Specific Contract), specifying which software is closed source software.

In particular, the contractor must provide in its bid for this Framework Agreement (TD8. Technical Form) a list of the relevant (for the Project) pre-existing information and preexisting IPRs it holds and/or has access to (e.g. via its subcontractors). The contractor must also provide an updated version of it to the PBG (via FMS) within the bid for each Phase Contract in order to have the updated list approved by the PBG at the latest thirty (30) days after the start of each Phase Contract. If there are no preexisting materials nor pre-existing IPR, the contractor must provide a declaration to that effect.

- 8.5. The contractor shall inform the PBG in writing about any evolutions in any of its preexisting information and pre-existing IPRs that affect the performance of this Framework Agreement. This includes any changes to the Background IPRs and the generation of new Sideground IPRs within thirty (30) days from the change or generation and at the latest by the end of the corresponding Phase and with each Bid for the next Phase.

- 8.6. The contractor acknowledges and agrees that:

- a) Data and/or data sets (or any parts thereof) provided for by the PBG are being qualified as pre-existing rights of the PBG; and
- b) The data and/or data sets (or any parts thereof) provided by the PBG shall be used for the sole purpose of executing the Project, including trials and/or pilots set up to test the validity of the Results. Any other use is forbidden.

- 8.7. Upon request by the PBG, the contractor must provide evidence in writing that it has the ownership or the right to use all the listed pre-existing information and IPR. The PBG (via FMS) may request this evidence even after the end of this Framework Agreement. This evidence must include, as appropriate:

- a) The name and version number of a software product.
- b) The full identification of the original work and authors with their affiliation and all following modifications addressing developer, creator, translator, data entry person.
- c) A copy of the license to use the Background IPR or of the agreement granting the relevant rights to the contractor or a reference to this license.



- d) A copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the Results were created by its personnel.
- e) The text of the disclaimer notice, if any.

Provision of evidence does not release the contractor from its responsibilities if it is found that it does not hold the necessary rights, regardless of when and by whom this fact is revealed.

FOREGROUND IPRs

8.8. Subject to the conditions set out in this Framework Agreement, the contractor retains the ownership of all the rights on the results that it generates. This includes (the rights on) newly created material generated by the contractor and Background/Sideground information provided/generated by the contractor that may be included in the results or that is essential for the functioning of the use of the results.

PROTECTION OF THE RESULTS

8.9. The contractor is responsible for the management of its IPR, including protection, and bears the costs associated with them, including for the protection, examination, grant, maintenance, defence and litigation of the rights on the results. FMS has the right to monitor the management of the IPRs.

This implies that the contractor shall take all appropriate and necessary measures to ensure the proper management of the IPR generated by the THERESA PCP project. This includes:

- a) Measures to ensure full compliance with the open co-creation goal and, open-source software Licenses, where applicable. This includes early identification of components subject to open-source obligations and compliance of the contractor's practices with the relevant license terms.
- b) The obligation of the contractor to clearly describe, detail, distinguish, manage and update the parts of the Results that are being qualified as Foreground and Sideground IPR.

If the contractor decides to protect its results, it shall ensure that an application for protection is filed to the relevant authority (national, European Patent Office (for patents) or European Union Intellectual Property Office (for trademarks and designs) within 1 (one) year after notifying FMS in writing, and in any case prior to any publication on them. Where possible, the applications for protection shall include the following statement: *'These results were achieved with EU support. The European Union has certain rights in these results'*.

The parties shall reasonably cooperate in the management of IPRs and in preparing responses to any communication or action issued by any competent office or authority; however, such actions shall in all cases remain the responsibility of the contractors.

8.10. The contractor is required to deposit copies of the Results (e.g. source codes of software and all related documentation, design specifications of prototypes, documentation about the foreground IP etc) to guarantee the PBG continued access to the Results:



- a) Under an ESCROW agreement with a reputable escrow agent. If requested by the contracting authority, a tri-party agreement shall be signed between the escrow agent, the contractor and the contracting authority (on behalf of the members of the PBG), duly protecting the interests of the contracting authority and the PBG in case of bankruptcy or liquidation of the contractor and ensuring that in such cases the members of the PBG shall obtain a copy of the results.
- b) By providing to the PBG a copy of designs, drawings, reports and specifications.

8.11. The rights and obligations in relation to protection of results are explained below:

- a) The contractor shall ensure that its Results are identified, recorded and carefully distinguished from outputs of other activities which are not covered by the THERESA PCP project.

The contractor shall ensure that prior to any dissemination of the Results, the protection of any protectable Results is duly considered and in case filed at the relevant Member State or European Patent Office. In such a case, the contractor shall ensure that all applications for the protection of Results are diligently executed and prosecuted having regard to all relevant circumstances.

- b) The contractor must inform the PBG (via FMS) in writing of results that can be exploited, regardless of whether they can be protected or not, within 30 days from when they are generated. The information submitted to FMS must include information about the contents of the results, the confirmation by the contractor to protect them and the planned timing for protection. The notification shall include information about the contents of the results, the confirmation by the contractor of its decision to protect said results, the type of protection that will be pursued and, for registered IPR such as patents and design rights, the planned timing and geographical scope of such protection/ jurisdictions for which the contractor will seek to obtain protection.
- c) The contractor shall respond in writing at any time to requests for information from the contracting authority and the PBG about the handling of the rights on the results.
- d) In case of any decision not to continue an application for protection, not to pay maintenance fees, or not to defend in a re-examination or opposition proceeding, the contractor shall notify FMS in writing not less than 60 (sixty) before the deadline for responding to the procedure for protection, maintenance or litigation.
- e) If the contractor becomes aware of any product or activity of any third party that involves or may involve infringement or other violation of the rights on the Results, the contractor shall immediately notify FMS in writing about the infringement or violation.
- f) The contractor must ensure that the results are not subject to control or other restrictions by a country (or entity from a country) which is not from



EU Member States or HE associated countries— unless otherwise agreed with the contracting authority.

- 8.12. FMS and members the PBG shall be entitled to monitor the management of all Results and rights on the Results held by the contractor. The contractor shall submit periodical reports in writing, when requested by PBG, no more frequently than annually on the exploitation of the Results, including the rights on the Results, by the contractor, its licensees or assignees.
- 8.13. The members of the PBG may exceptionally require transfer of the ownership of Results generated under the PCP procurement to them, if the contractor:
- a) Does not (or no longer) comply with one of the following obligations (as defined in section 3.4 of TD1 Request for Tenders):
 - i. 'Compliance with definition of R&D services'
 - ii. 'Place of performance obligation'
 - iii. 'Place of establishment and control'
 - b) Decides not to protect the Results that it generated or does not seek timely or sufficient protection to enable the PBG to use the Results as provided for in the Framework Agreement or a Specific Contract. In this case, FMS retains the unconditional and irrevocable right (but is not mandated to) to seek itself protection of these Results and to obtain ownership of the rights on these Results. In the event that FMS decides to exercise this right, it will inform the contractor in writing of its decision to exercise this right.
 - c) Fails to commercially exploit the results within the four (4) years' time period and the circumstances of the case show that it has not used its best efforts to do so. This applies to Results of contractors participating in Phase 3.
 - d) Uses the Results to the detriment of the public interest.
 - e) Is subject to a merger or acquisition and the impact analysis concludes that the merger or acquisition negatively impacts the access to or the commercial exploitation of the results, in particular the EU security interests and EU strategic autonomy objectives.
- 8.14. The members of the PBG will notify the contractor in writing of their intention to require the transfer of ownership of results through the contracting authority.
- 8.15. Before exercising their rights, the contracting authority will first contact the contractor to verify any measures that the contractor has taken to achieve successful commercial exploitation of the results, to safeguard EU strategic autonomy and security interests and rules, to prevent use of the results to the detriment of the public interest and to comply with its contractual obligations.
- 8.16. Following the transfer of the ownership of the results to the members of the PBG, the members of the PBG may grant licenses to third parties to ensure further protection, usage and exploitation of the results.



- 8.17. The contractor shall ensure that the commercial exploitation of the results by the members of the PBG will not infringe any of its other obligations under this Framework Agreement or a Specific Contract, such as its obligations regarding security, confidentiality and the protection of intellectual property or its obligations under data protection legislation.
- 8.18. Article 8.1 and all provisions on the protection of the results set out in Articles 8.9 to 8.17. will apply for Results of Phase 1, Phase 2 and Phase 3. An non exhaustive list of examples would be: prototypes and first products resulting from the R&D, design, prototype and first product/service specifications, simulations, Data models, drawings and source code.

ACCESS RIGHTS TO THE RESULTS FOR THE CONTRACTING AUTHORITY AND THE PBG

- 8.19. The contractor must ensure that it complies with its obligations under the Framework Agreement and Specific Contracts if it uses subcontractors; that it must obtain all necessary rights (transfer, licences or other) from the subcontractors, as if they were generated by itself; that it should refrain from using subcontractors if obtaining those rights is impossible).
- 8.20. The contractor grants the members of the PBG, including their affiliated entities (entities that are under the direct or indirect control of members of the PBG, or under the same direct or indirect control as members of the PBG, or directly or indirectly controlling members of the PBG) and to contractors and subcontractors of the PBG a royalty-free, non-exclusive, worldwide, irrevocable, non-sub-licensable (except as explicitly authorised under this Framework Agreement) license to use non-commercially the Results (and the THERESA PCP documentation) up until TRL7 or 8 (or up to the point it was developed by contractors of Phase 1 and 2) for their own purposes, during and after the Framework Agreement and Specific Contracts.

This means that during the execution of the three Phases of the PCP, the PBG will have the right to use the Project's Results the relevant Background Information and the Results related to the design specifications developed by the contractor non-commercially for free for the performance of the tasks assigned to them in the PCP. Non-commercial means that the members of the PBG cannot commercialize the PCP results, without impeding the use for other purpose (such as trials).

- 8.21. The contractor retains the right to commercial exploitation of the results for any purposes of using the Results beyond the scope of the current PCP.
- 8.22. In case of commercial exploitation of products, services or processes arising or developed from the Results by the contractor (or by entities affiliated to it or succeeding it in the ownership or development of the results), the contractor shall ensure that the members of the PBG (or any contracting authority appointed by the PBG to implement a procurement in their name and/or on their behalf) are offered the commercial products or services at the best price offered by the contractor (or the entities affiliated or succeeding it) in similar situations to any other third party (in particular without charging for



licenses or other rights which the PBG already have under other provisions of this Framework Agreement or a Specific Contract).

ACCESS RIGHTS TO THE RESULTS FOR THE EU

8.23. The EU has the right to use non-sensitive information relating to the PCP and materials and documents received from the contracting authority and the PBG for policy, information, communication, dissemination and publicity purposes — during the EU grant or afterwards. This concerns notably summaries for publication, as well as any other material, such as pictures or audio-visual material, and other deliverables submitted by the contracting authority and the PBG to the EU, in paper or electronic form.

8.24. The right for the EU to use these materials, documents and information is granted in the form of a royalty-free, non-exclusive and irrevocable licence, which includes the following rights:

- a) Use for its own purposes (in particular, making them available to persons working for the EU granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services).
- b) Distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes).
- c) Editing or redrafting (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation).
- d) Translation.
- e) Storage in paper, electronic or other form.
- f) Archiving, in line with applicable document-management rules.
- g) The right to authorise third parties to act on its behalf or sub-license to third parties the modes of use set out in points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority.
- h) Processing, analysing, aggregating the materials, documents and information received and producing derivative works.

The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned.

8.25. If materials or documents are subject to moral rights or third party rights (including IPR or rights of natural persons on their image and voice), the contractor must ensure that they comply with their obligations under this Framework Agreement and Specific Contracts in particular, by obtaining the necessary licences and authorisations from the rights holders concerned.



8.26. Where applicable, the EU granting authority will insert the following information: “© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the EU under conditions.”

ACCESS RIGHTS TO THE RESULTS FOR THIRD PARTIES

8.27. If requested by FMS or the members of the PBG, the contractor shall, within 30 (thirty) working days, grant to the third parties specified in the request a non-exclusive and non-sub-licensable license to use and to commercially or non-commercially exploit the Results and any Background which may be necessary for the use or exploitation of the results, under FRAND conditions.

8.28. If the contractor fails or refuses to grant the requested licenses, FMS and the members of the PBG retain the right to grant themselves a non-exclusive and non-sub-licensable license to the third parties to use and to commercially or non-commercially exploit the Results (or to appoint an independent third party to do so).

NON-EXCLUSIVE LICENSING OF RESULTS

8.29. The contractor may on its own initiative without prior authorisation from FMS, give non-exclusive licenses to third parties to exploit the Results that it owns to the extent that:

- a) such licenses do not affect the rights — including the access rights — of FMS, the PBG or the EU related to the Results, and
- b) such licenses do not affect the obligations — including the security and ethical obligations — of FMS and the PBG related to the Results, and
- c) such licenses are not granted to entities which are subject to EU restrictive measures under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)²⁸ (sanctions).

Otherwise, the contractor needs to ask for FMS permissions who (on behalf of the PBG) will authorise such license

8.30. The contractor must ensure in the licensing agreement that all its obligations under the Framework Agreement and Specific Contracts are passed on to the third party and that the third party has the obligation to pass on these obligations in any potential subsequent licensing.

EXCLUSIVE LICENSING AND TRANSFER OF OWNERSHIP OF RESULTS

8.31. Due to EU strategic autonomy and security reasons, exclusive licensing and transfers of ownership of the Results are restricted as follows:

- a) The contractor may not transfer ownership of its Results or give exclusive licenses if the Results would become subject to controls or other restrictions by a country (or entity from a country) which is not an EU Member State or country associated to Horizon Europe.
- b) The contractor may not transfer or give exclusive licenses to entities that are subject to EU restrictive measures under Article 29 of the Treaty on

²⁸ Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.



the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU) (sanctions)

- c) The contractor may not transfer or give exclusive licenses if this would affect the rights — including the access rights — of FMS, the PBG or the EU related to the Results.
- d) The contractor may not transfer or give exclusive licenses if this would affect the obligations — including the security and ethical obligations — of FMS and the PBG related to the Results.
- e) The contractor may not transfer ownership of the Results or give exclusive licenses, if this would conflict with the right of first refusal for the PBG to buy the Results²⁹.
- f) The contractor must ensure that its obligations under the Framework Agreement are passed on to the new owner and licensee and that this new owner/licensee has the obligation to pass them on in any subsequent transfer/licensing.
- g) Contractors that intend exclusive licensing or transfers of ownership of the Results to an entity from a country (or controlled by a country) that is not an EU Member State or country associated by Horizon Europe, must request prior authorisation from FMS.

8.32. The intention of such exclusively licensing or transfer must first be notified to FMS in writing at least 3 (three) months in advance and:

- a) Identify the specific Results concerned.
- b) Describe in detail the intended new owner and the planned or potential exploitation of the Results.
- c) Include a reasoned assessment of the likely impact of the intended transfer or exclusive License on the access rights to the Results and on the Background that is essential for accessing the Results as foreseen by the Framework Agreement for the members of the PBG and for Third Parties, as well as on the commercialization exploitation of the Results, including the EU security interests and EU strategic autonomy objectives.

8.33. FMS may request the contractor for additional information to verify the potential impact, upon which the contractor must promptly provide the requested information. Before granting the authorisation, FMS will verify the potential impact of the intended transfer or exclusive licensing. FMS may condition its authorisation to measures ensuring that the transfer or exclusive licensing will not have unintended or undesirable consequences. Before FMS gives its written authorization, the transfer may not take place and any transfer or exclusive licensing agreement concluded before or without a written authorization will be null and void.

8.34. Before granting the authorisation, the EU granting authority will verify the potential impact of the intended transfer or exclusive licensing. The EU granting authority may object to the transfer or exclusive licensing or may

²⁹ The process begins when the contractor receives a third-party offer, which they must then present to FMS. FMS can then decide to match the terms or allow the contractor to proceed with the sale to the third party.



condition its authorisation to measures ensuring that the transfer or exclusive licensing will not have unintended or undesirable consequences. Before the EU granting authority gives its written authorisation, the transfer may not take place and any transfer or exclusive licensing agreement concluded before or without a written authorisation will be null and void.

ADDITIONAL OBLIGATIONS/LIMITATIONS FOR THE EXPLOITATION OF RESULTS DUE TO PUBLIC INTERESTS

Security or strategic autonomy

- 8.35. The contractor shall ensure to safeguard EU strategic autonomy in the commercial exploitation of the results. For this purpose, the contractor shall ensure that a significant amount of the commercial exploitation of the results takes place in the EU Member States and/or countries associated to Horizon Europe. In particular, the contractor must produce minimum 70% of the products, services or processes that incorporate results or that are produced through the use of results in EU Member States or HE associated countries .
- 8.36. The contractor must ensure that, in the commercial exploitation of Results, any cooperation with entities established in other countries, or controlled by such countries or entities from such countries, does not affect the EU security or strategic autonomy interests and avoids potential negative effects over security of supply of inputs critical to the functioning of the PBG's infrastructure.
- 8.37. The contractors must promote the dissemination of their results, in particular through publications and contribution to standardisation. The contractors and FMS will establish and agree at the start of the Framework Agreement a list of planned publications about the results and appropriate standards to contribute to, and will keep this list updated throughout the Framework Agreement and for each Specific Contract. The contractors must — up to 4 (four) years after the end of the Framework Contract and Specific Contracts — inform FMS in writing, who will inform in its turn the granting authority that is co-financing the PCP, if the results could reasonably be expected to contribute to European or international standards.

Any publication related to the Results shall require the prior approval of the parties. In all cases, written authorisation must be requested and shall be responded to within a maximum period of thirty (30) calendar days. In the absence of a response to such request within that period, the authorisation shall be deemed granted.

Neither party shall have the right to publish or allow the publication of any data that include Background information or confidential information accessed during the performance of the activities under this contract, unless prior written authorisation has been obtained from the relevant party.

Prior to the publication of any Results, those that may be eligible for intellectual and/or industrial property protection shall be identified in accordance with article 8.11.b), and appropriate steps shall be taken to secure their registration and protection where feasible.



- 8.38. In case of a public emergency the contractor must, if requested by FMS on behalf of the PBG or the EU, commit to rapidly and broadly exploit the products and/or services resulting from the PCP at FRAND conditions to address the public emergency. This provision applies up to 4 (four) years after the end of the PCP.
- 8.39. These obligations also apply to the contractor's subcontractors, affiliated entities and other third parties it cooperates with in the commercialization of the results, as well as to any entities succeeding them in their ownership or development of the results.

OBLIGATIONS OF CONTRACTOR

- 8.40. The contractor is responsible for ensuring that all third parties that it collaborates with during and after the Framework Agreement and the Specific Contracts respect all intellectual and industrial property-related obligations towards the contracting authority and the PBG and must pass on its obligations to those entities.
- 8.41. The contractor must ensure that the rights of the contracting authority and the PBG under the Framework Agreement and the Specific Contracts are upheld under all circumstances, including in case of merger, split, takeover or other corporate restructuring.
- 8.42. THERESA PCP contractors will follow the principle of "as open as possible, as closed as necessary" and incorporate Open Science as a core component of their methodological approach. In particular, the following aspects will be considered and encouraged, without constituting an obligation, and without prejudice to the protection of intellectual property rights, commercially sensitive information, or security-related constraints:
- (a) Open Access and Data: Any scientific publications arising from the PCP contractors may be made available on open access platforms to the fullest extent. Research data may also be accessible, ensuring compliance with privacy standards and fundamental rights. Data will be shared as openly as possible (to support reproducibility and reuse) and restricted only as necessary (to protect sensitive information), in platforms such as ZENODO.
 - (b) Open Source: The project results developed may be shared on open repositories (e.g., GitHub) under open licenses (e.g., Apache), allowing for broad use and further development where possible.
 - (c) Open Hardware: Where applicable, hardware components developed within the project may be documented and shared following open hardware principles.

Article 9 — Confidentiality

- 9.1. The parties shall keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed. This applies during the implementation of the Framework Agreement and Specific Contracts and up to 4 (four) years after their end.



- 9.2. If information has been identified as confidential only orally, it shall be considered to be confidential only if this is confirmed in writing within 15 (fifteen) days of the oral disclosure.
- 9.3. Unless otherwise agreed between the parties, they may use confidential information only to implement the Framework Agreement and Specific Contracts.
- 9.4. The parties may disclose confidential information to their staff or to third parties involved in the PCP implementation only if:
- (a) They need to be aware of this information in order to implement the PCP activities under the Framework Agreement and Specific Contracts, and
 - (b) They are bound by an obligation of confidentiality.
- 9.5 FMS and members of the PBG may disclose confidential information to the EU granting authority if required under their Horizon Europe grant agreement.
- 9.6. The confidentiality obligations cease to apply if:
- (a) The disclosing party agrees to release the other party from the obligation,
 - (b) The information becomes generally and publicly available, without breaching any confidentiality obligation, or
 - (c) The disclosure of the information is required by EU or national law.

Article 10 — Staff appointment provisions

- 10.1. All staff providing services in connection with this Framework Agreement shall be bound by the same terms and conditions of service which are normally applicable to the contractor's staff.
- 10.2. FMS has a commitment to equal opportunities which the contractor must adhere to. The contractor must not discriminate on the grounds of gender, race, disability, sexuality, age, religion or otherwise allow any applicable employment law to be breached.

Article 11 — Promotion, publicity and communication

DISSEMINATION OBLIGATIONS

- 11.1. The contractor shall undertake communication activities to create publicity about its participation to the procurement and to promote the objectives and the results of the R&D carried out under the PCP (in particular, to other potential customers with the objective to achieve commercial exploitation of the results; see Article 12 on commercial exploitation of results).
- 11.2. When undertaking these activities, the contractor shall ensure that they do not infringe any of its other obligations under this Framework Agreement or Specific Contract(s), such as its obligations regarding protection of



intellectual property, confidentiality, security restrictions or its obligations under data protection legislation.

- 11.3. All communication activities shall comply with the applicable confidentiality and security restrictions.
- 11.4. During the implementation of the Framework Agreement and for a period of 3 (three) years after the end thereof, the contractor shall inform FMS 60 (sixty) days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the services or Results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow FMS to inform the EU.

The contractor must, in particular, submit a draft copy of any publications:

- a) For written publications — at the same time as the submission to the editor for publication or at least 1 (one) month before the date intended for publication, whichever is earlier.
- b) For oral communications or other types of disclosure — 20 (twenty) calendar days before the forecasted date of submission to the organiser of a scientific meeting or of said other type of disclosure.

If requested by FMS, the contractor shall remove any confidential or security sensitive information before the disclosure.

- 11.6. Both parties agree that they will balance any of their requests to remove confidentiality, security or intellectual property-sensitive aspects from a publication proposed by the other party against the other party's objective to maintain sufficient information related to the performance of the Framework Agreement and Specific Contracts or the results that is necessary for the appropriate presentation or understanding of the publication.

RECOGNITION OF EU FUNDING

- 11.7. All communication activities about the PCP and/or its results (including in electronic form and via social media), as well as infrastructure, equipment and major results financed by the PCP shall display the EU emblem and include the following text:
- a) For communication activities: 'This [publication][communication] is part of the THERESA PCP project that has received funding from the European Union's Horizon Europe Research and Innovation Programme'.
 - b) For infrastructure, equipment and major results: 'This [infrastructure][equipment][insert type of result] is part of the THERESA PCP project that has received funding from the European Union's Horizon Europe Research and Innovation Programme'.
- 11.8. If Results are incorporated in a standard, the contractor must — unless FMS or agrees otherwise in writing or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard: 'Funded by the European Union'.



- 11.9. When displayed together with another logo, the EU emblem shall have appropriate prominence. The contractor may use the EU emblem without first obtaining approval from the EU. This does not, however, give the contractor the right to exclusive use. Moreover, the contractor may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.
- 11.10. All communication activities shall indicate that the opinions expressed reflect only the author's views and do not represent FMS's, the PBG's or the EU's official position. FMS, in agreement with the EU granting authority, may waive this obligation in writing or provide the text of the disclaimer.

COMMUNICATION/PUBLICATION RIGHTS FOR THE CONTRACTING AUTHORITY AND THE PBG

- 11.11. FMS and members of the PBG may use, for the purposes of communication and publicity, all information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audio-visual material) from the contractor (including in electronic form).
- 11.12. FMS and members of the PBG may, in particular, publish the name of the contractor and its project abstracts, the summaries of the main results from the R&D and the lessons learnt during the PCP (*e.g. relating to the feasibility of the different approaches to meeting the procurers' requirements that were explored, and the lessons learnt for potential future use of the solutions proposed*). This does not change the confidentiality obligations under Article 9.

Moreover, before publishing this information, FMS shall consult the contractor, in order to avoid harm to legitimate business interests (*e.g. regarding aspects of the solutions that could be IPR-protected*) or distortion of competition.

COMMUNICATION/PUBLICATION RIGHTS FOR THE EU

- 11.13. The EU may use, for the purposes of communication and publicity, information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audiovisual material) from the contractor (including in electronic form).
- 11.14. If the EU's use of these materials, documents or information would risk compromising legitimate interests, the contractor may, however, ask FMS to request the EU granting authority not to use it.
- 11.15. The right to use the contractor's materials, documents and information includes:
- a) Use for its own purposes (in particular, making them available to persons working for the EU granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services).
 - b) Distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel,



- public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes).
- c) Editing or redrafting (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation).
 - d) Translation.
 - e) Storage in paper, electronic or other form.
 - f) Archiving, in line with applicable document-management rules.
 - g) The right to authorise third parties to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority.
 - h) Processing, analysing, aggregating the materials, documents and information received and producing derivative works.
- 11.16. If the right of use is subject to rights of a third party (including the contractor's staff), the contractor shall ensure that it obtains the necessary approval from the third parties concerned.

Article 12 — Commercial exploitation of the results

- 12.1. The contractor shall take prompt action to ensure that its Results are exploited commercially (directly or indirectly through another entity, through transfer or licensing) to clients other than the PBG, in order to ensure swift availability of the developed solutions on the wider market and to generate revenue by marketing commercial applications of the results.

In particular, the contractor must use its best (objective and reasonable) efforts to exploit its results up to 4 (four) years after the end of the Framework Agreement and Specific Contracts, including where they are capable of commercial exploitation, to exploit them commercially (i.e. marketing a commercial application of the results, directly or indirectly, through a subcontractor or licensee), in accordance with the exploitation plan for the developed products submitted in their tender, which was subject to evaluation under the award criteria set out in this procurement document.

The contractors shall be deemed not to have made objective and reasonable efforts to exploit the developed products if they exceed by four (4) years the timelines set out in their commercial exploitation plan for the R&D service results included in their tender, for reasons other than force majeure. In such case, the contractors shall be subject to the corresponding penalty as described in article 21 of this TD2. Framework Agreement

The PBG undertakes to support and collaborate with the contractors in the exploitation of the results with reasonable efforts.

- 12.2. The contractor is and remains entitled for 4 (four) years after the end of the Framework Agreement to request on a case-by-case basis a non-exclusive and not-transferrable licence for definite time to use PBG Pre-existing and



Foreground information, insofar duly justified by the contractor for the commercial exploitation of the Results of the PCP, under FRAND terms and conditions to be agreed upon. The contractor acknowledges and accepts that the PBG remains unconditionally entitled to conclude similar agreements with other third parties.

- 12.3. The contractor shall ensure that the commercial exploitation of the Results will not infringe any of its other obligations under this Framework Agreement, such as its obligations regarding security, confidentiality and the protection of IPR or its obligations under the data protection legislation.
- 12.4. FMS has the right to monitor the exploitation of the Results by the contractor during and after the Framework Agreement. The contractor shall submit reports, when requested by FMS, no more frequently than annually, on the exploitation of the Results, including the rights on the Results, by the contractor, its licensees or assignees. The contractor shall respond at any time to requests for information from FMS about the exploitation of the Results.
- 12.5. If the contractor fails to commercially exploit the Results within this period and the circumstances of the case show that it has not used its best efforts to do so (or uses the Results to the detriment of the public interest, including EU strategic autonomy or security interests), FMS has the right, subject to prior written notice and after having given the contractor a reasonable opportunity to present its observations and proposed remedial measures, to require that ownership of the Results be transferred to FMS and the members of the PBG at no cost so that the PBG can ensure that the results are commercially exploited. Failure to commercially exploit the Results means not marketing a commercial application of the Results (directly or indirectly, through a subcontractor or licensee).
- 12.6. Before exercising the right to require the transfer of the ownership of the Results, FMS will first contact the contractor to verify any measures that the contractor has taken to achieve successful commercial exploitation of the Results, to safeguard EU strategic autonomy and security interests and rules, to prevent use of the Results to the detriment of the public interest and to comply with its contractual obligations.
- 12.7. In this case, the contractor shall be requested to give prototypes and first products resulting from the R&D, design, prototype and first product/service specifications, simulations, data models, drawings and source code, among other documentation/items to the PBG at no cost. Equally, the PBG will own, including - but not limited to - any patents, trademarks, trade names, domain names, design rights, rights in databases, know-how, in each case whether registered or unregistered and including applications for the grant of any such rights, and all rights having equivalent or similar effect anywhere in the world. The PBG may transfer these rights to third parties to assure further product development and market deployment.
- 12.9. In order to safeguard the cross-border delivery of services against potential physical and cyber threats and to protect the exchange of security sensitive information, the contractor shall ensure the safeguard of EU security interests in the commercial exploitation of the Results. For this reason, if the contractor wishes to commercialize its solution outside the EU, it will have to comply



with the Regulation (EU) 2021/821 of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (if applicable).

- 12.10. The contractor must ensure that, in the commercial exploitation of the Results, any cooperation with entities established in other countries, or controlled by such countries or entities from such countries, does not affect the EU security or strategic autonomy interests. The contractor must ensure that these obligations also apply to its subcontractors, affiliated entities and other third parties it cooperates with in the commercialisation of the Results, as well as to any entities succeeding them in their ownership or development of the Results.

Article 13 — Conflicts of interest

- 13.1. The contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the Framework Agreement or a Specific Contract is compromised for reasons involving economic interests, political or national affinity, family, personal life or any other shared interest.

The contractor shall also take all measures necessary to prevent a situation in which its (previous or ongoing) professional activities affect the impartial and objective implementation of the Framework Agreement or a Specific Contract.

- 13.2. The contractor shall notify FMS without delay and no later than 5 (five) working days of any situation constituting or likely to lead to a conflict of interest (including changes of ownership) and shall immediately take all steps necessary to rectify this situation.

FMS may instruct the contractor to take specific measures to remedy the situation.

Article 14 — Cession of contractual position

- 14.1. In principle and due to the short duration of the PCP no changes on consortia or in subcontractors will be allowed unless exceptional reasons that couldn't be foreseen apply or a new contractor replaces the one to which the contracting authority had initially awarded the contract as a consequence of an universal or partial succession into the position of the initial contractor, following corporate restructuring, including takeover, merger, acquisition or insolvency, of another economic operator that fulfils the criteria for qualitative selection initially established, as indicated in TD1 Request for Tender and article 5.7 of this Framework Agreement, and subject in each case to the prior written approval of FMS.

If that is the case, the new member of the consortium and/or subcontractor has to meet all exclusion, compliance and selection criteria, to comply with the pass/fail award criteria. The new member of the consortium and/or



subcontractor will have to sign the declarations of honour and any other required statements. The replacement cannot entail a substantial modification of the contract conditions.

- 14.2. Contractors that are in a procedure to consider a possible merger with or a takeover by an entity from a country (or controlled by a country) that is not an EU Member State or country associated by Horizon Europe, must notify FMS at least 3 (three) months in advance of the decision to implement the possible merger or takeover and:
- a) Describe in detail the identity, ownership and control structure of the potential new merged entity or the potential new owner(s).
 - b) Include a reasoned assessment of the likely impact of the possible merger/takeover on the access to the Results and to the Background information that is essential for accessing the Results for the members of the PBG and for third parties and the commercialisation and exploitation of the Results, including the EU security interests and EU strategic autonomy.
- 14.3. FMS may request the contractor for additional information to verify the potential impact, upon which the contractor must promptly provide the requested information. In case the impact analysis concludes that the merger or takeover negatively impacts the access to or the commercial exploitation of the Results, including the EU security interests and EU strategic autonomy objectives, FMS is entitled to require that the contractor (both the contractor before or after the merger or takeover) transfers the ownership of the Results to the members of the PBG.

Article 15 — Ethics and research integrity

- 15.1. The contractor shall carry out the tasks assigned to it in the Framework Agreement and Specific Contracts in compliance with:
- a) Ethical principles (including the highest standards of research integrity).
 - b) Applicable international, EU and national law.
- 15.2. The contractor must commit to and ensure the respect of basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities). The contractor must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.
- 15.3. In case the development, deployment and/or use of the PCP solution involves Artificial Intelligence (AI), the contractor must ensure that the AI is trustworthy, i.e. lawful, ethical and technically robust. The AI system must preserve and protect the following six general ethical principles based on fundamental rights as enshrined in the Charter of Fundamental Rights of the



European Union (EU Charter), and in relevant international human rights law³⁰:

- a) Respect for human agency: human beings must be respected to make their own decisions and carry out their own actions. Respect for human agency encapsulates three more specific principles, which define fundamental human rights: autonomy, dignity and freedom.
- b) Privacy and data governance: people have the right to privacy and data protection and these should be respected at all times.
- c) Fairness: people should be given equal rights and opportunities and should not be advantaged or disadvantaged undeservedly.
- d) Individual, social and environmental well-being: artificial intelligence systems should contribute to, and not harm, individual, social and environmental wellbeing.
- e) Transparency: the purpose, inputs and operations of artificial intelligence programs should be knowable and understandable to its stakeholders.
- f) Accountability and oversight: humans should be able to understand, supervise and control the design and operation of artificial intelligence-based systems, and the actors involved in their development or operation should take responsibility for the way that these applications function and for the resulting consequences.

15.4. The contractor may not:

- a) Carry out activities in a Member State for an activity which is forbidden in that Member State.
- b) Carry out activities in a country inside or outside the EU, if they are prohibited in all EU Member States.

15.5. The contractor may not carry out activities that do not focus exclusively on civil applications in the context of THERESA PCP.

15.6. The contractor shall respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity³¹. This implies compliance with the following essential principles:

- a) Reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources.
- b) Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way.
- c) Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
- d) Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

³⁰ For more information, see [*Horizon Europe guidance on ethics by design and ethics of use approaches for AI*](#).

³¹ European Code of Conduct for Research Integrity of ALLEA (All European Academies).



- e) And means that the contractor must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.
- 15.8. Before starting any activity that raises an ethical issue, the contractor shall submit to FMS 1 (one) week in advance a copy of:
- a) Any ethics committee opinion required under national law.
 - b) Any notification or authorisation for activities raising ethical issues required under national law.

Article 16 — Processing of personal data

- 16.1. The contractor shall process personal data in compliance with the applicable EU and national law on data protection, in particular Regulation [2016/679](#)³² (including as relates to authorisations and notification requirements).
- 16.2. Contractors must ensure that personal data is:
- a) Processed lawfully, fairly and in a transparent manner in relation to the data subjects.
 - b) Collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.
 - c) Adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.
 - d) Accurate and, where necessary, kept up to date.
 - e) Kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed.
 - f) Processed in a manner that ensures appropriate security of the data.
- 16.3. The localisation of and access to the personal data processed by the contractor shall comply with the following:
- a) The personal data shall only be processed within the territory of the European Union and the HE associated countries³³ and will not leave that territory.
 - b) The data shall only be held in data centres located within the territory of European Union and the HE associated countries.
 - c) The contractor may not change the location of data processing without the prior written authorisation of FMS.
 - d) Any transfer of personal data under the Framework Agreement or a Specific Contract to third countries or international organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU) 2016/679.

³² 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 ('GDPR') (OJ L 119, 4.5.2016, p. 1).

³³ [List of Horizon Europe participating countries](#).



16.4. The contractor may grant its staff access to data only in so far as is strictly necessary for implementing, managing and monitoring the Framework Agreement and Specific Contracts.

16.5. The contractor must inform the staff whose personal data are collected and processed by the procurers and/or the EU. For this purpose, the contractor must provide them with the privacy statements of the procurers and the EU, before transmitting their data. If explicit prior consent from the data subjects is needed, the contractor must obtain such consent.

Article 17 — Obligation to provide information and keep records

17.1. The contractor must, at any time during the implementation of the Framework Agreement and Specific Contracts or afterwards, provide any information requested by the procurers in relation to the agreement or contracts.

17.2. The contractor must keep, for a period of up to 5 (five) years after the end of the Framework Agreement and Specific Contracts, records and other supporting documentation relating to their implementation.

This obligation includes records and other supporting documentation on scientific and technical implementation (in line with the accepted standards in the field) and on the price charged and the costs incurred by the contractor.

17.3. The contractor must keep the original documents. Digital and digitalised documents are considered originals if they are authorized under national law.

17.4. Should there be ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims (including claims by a third party against the procurers), the contractor must keep all records and other supporting documentation until the end of these procedures.

Article 18 — EU checks, reviews, audits and investigations

18.1. Should the EU (including the ECA), the European Public Prosecutor's Office (EPPO) or OLAF decide to carry out a check, review, audit or investigation, the contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.

18.2. Should there be an on-the-spot visit, the contractor must allow access to its premises and must ensure that the information requested is readily available.

Article 19 — EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the PBG), the contractor must make available all information, records and other supporting



documents relating to the implementation of the Framework Agreement and Specific Contracts.

Article 20 — Monitoring and reporting

- 20.1. During each PCP Phase, the implementation by the contractor of the R&D services will be monitored periodically and reviewed against the expected outcomes (deliverables and output or Results) for that phase. To this end, the contractor will be assigned a main contact person (their supervisor) from the Technical Evaluation Committee (TEC) appointed by FMS. There will be regular monitoring meetings between the contractor and the TEC.
- 20.2. For the purpose of such monitoring activities, FMS is entitled to carry out physical visits to the contractor's premises at any time during the implementation of the PCP. The meetings will take place after formal communication. The contractor could be asked to discuss the Results achieved in the preceding period and present their updated work plan.
- 20.3. FMS may request to witness (or request that a designated party witnesses) any tests or measurements to be performed by the contractor or his subcontractor(s). The contractor shall give FMS a prior notice - with sufficient time and, in any case, no less than 10 (ten) days - in writing of the date(s) and place(s) of such tests and measurements. Failure to notify with sufficient time will allow FMS to demand that such tests and measurements be repeated at the expense of the contractor, who shall be liable for any delay resulting thereof.
- 20.4. The Procurement Evaluation Committee (PEC) will provide regular feedback in writing to contractors after meetings or visits.

END OF PHASE REPORTING

- 20.5. The contractor shall submit to FMS a TD6 End of Phase (1, 2, 3) report at the end of each relevant Phase, on the completion date.
- 20.6. The contractor shall draft the End of Phase (1, 2, 3) report using TD6 and shall take into account any and all recommendations provided by FMS. The End of Phase (1, 2, 3) report shall include the data, methods, Results and final conclusions together with the information management and any other information relating to the project phase it concerns up to the completion date thereof. The ownership of necessary reports of all Phases will be transferred to FMS.
- 20.7. The evaluation of each End of Phase (1, 2, 3) Report shall be carried out at FMS premises or at any other place indicated thereby by the PEC.
- 20.8. The evaluation of the End of Phase (1, 2, 3) report (TD6) will be made within the timeline as provided in TD1 Request for Tender. The evaluation will assess whether the contractor has achieved the objectives mentioned in the TD9 Financial Form and the TD8 Technical Form, in accordance with TD1 Request for Tender and each phase objectives.
- 20.9. The evaluation will be documented in a specific report, indicating the date and the Results of the same and will be signed by all the members of the PEC.



SUCCESSION OF PHASE 1, PHASE 2 AND PHASE 3 OF THE PROJECT

20.10. By signing the Framework Agreement, FMS and the contractor accept the general conditions set by this Framework Agreement and the Phase Contract for Phase 1.

20.11. In case the contractor gets awarded contracts for Phase 2 and Phase 3, these have to be signed by FMS and the contractor. The contractor has the obligation of performing the services within the scope of the respective phases of the project.

ASSESSMENT OF PHASE 1 AND AWARD OF PHASE 2

20.12. On the completion date of phase 1, the contractor shall submit to FMS TD6 End of Phase 1 report together with the deliverables belonging to phase 1, which shall be reviewed and assessed by the TEC.

20.13. The outcome of the evaluation shall result in the decision of the PEC regarding the unsatisfactory, satisfactory or successful completion of phase 1 (as defined in TD1 Request for Tenders). This decision will be issued according to the timeline of TD1 Request for Tenders. In case a longer evaluation process is needed, the contractor will be duly informed of the new timeline for the evaluation outcome.

20.14. The following rules shall apply:

- a) In case the contractor has not satisfactorily completed phase 1:
 - i. The contractor shall reimburse the received pre-payment to FMS.
 - ii. The contractor will not receive further payment for the work carried out in phase 1.
 - iii. The contractor will not be invited to submit a bid for phase 2.
 - iv. This Framework Agreement and Phase 1 Contract shall terminate.
- b) In case the contractor has satisfactorily, but not successfully completed phase 1:
 - i. The contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 1.
 - iii. The contractor will not be invited to submit a bid for phase 2.
 - iv. This Framework Agreement and Phase 1 Contract shall terminate.
- c) In case the contractor has successfully completed phase 1:
 - i. The contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 1.
 - iii. The contractor will be invited to submit a bid for phase 2

20.15. The contractor that has successfully completed phase 1 will be invited to submit a bid for phase 2. FMS will communicate the award decision after the deadline for submitting the bids. This will take place according to the planning provided in TD1 Request for Tender. Any changes in the timeline above will be duly communicated to the contractors.

20.16. if the contractor is selected for phase 2, this Framework Agreement shall continue in force for the duration of the following phases. the contractor shall thereupon sign a contract for that phase. alternatively, if the contractor is not



selected for phase 2, this Framework Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by FMS for final award of phase 2.

ASSESSMENT OF PHASE 2 AND AWARD OF PHASE 3

20.17. On the completion date of phase 2, the contractor shall submit to FMS TD6 End of Phase 2 report together with the deliverables belonging to phase 2, which shall be reviewed and assessed by the TEC. This assessment shall be performed according to the planning provided in the TD1 Request for Tenders.

20.18. The outcome of the evaluation shall result in the decision of the PEC regarding the unsatisfactory, satisfactory or successful completion of phase 2 (as defined in TD1 Request for Tenders). This decision will be issued according to the planning provided in TD1 Request for Tenders. In case a longer evaluation process, the contractor will be duly informed of the new timeline for the evaluation outcome.

20.19. the following rules shall apply:

- a) in case the contractor has not satisfactorily completed phase 2:
 - i. The contractor shall reimburse the received pre-payment to FMS.
 - ii. The contractor will not receive further payment for the work carried out in phase 2.
 - iii. The contractor will not be invited to submit a bid for phase 3.
 - iv. This Framework Agreement and Phase 2 Contract shall terminate.
- b) In case the contractor has satisfactorily, but not successfully completed phase 2:
 - i. The contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 2.
 - iii. The contractor will not be invited to submit a bid for Phase 3.
 - iv. This Framework Agreement and Phase 2 Contract shall terminate.
- c) In case the contractor has successfully completed phase 2:
 - i. The contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 2.
 - iii. The contractor will be invited to submit a bid for phase 3.

20.20. The contractor that has successfully completed phase 2 will be invited to submit a bid for phase 3. FMS will communicate the award decision after the deadline for submitting the bids. This will take place according to the planning provided in TD1 Request for Tender. Any changes in the timeline above will be duly communicated to the contractors.

20.21. If the contractor is selected for phase 3, this Framework Agreement shall continue in force for the duration of the following Phases. The contractor shall thereupon sign a contract for that phase. alternatively, if the contractor is not selected for phase 3, this Framework Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by FMS for final award of phase 3.

ASSESSMENT OF PHASE 3



- 20.22. On the completion date of phase 3, the contractor shall submit to FMS TD6 End of Phase 3 report together with the deliverables belonging to phase 3, which shall be reviewed and assessed by the TEC. This assessment shall be performed according to the planning provided in TD1 Request for Tenders.
- 20.23. The outcome of the evaluation shall result in the decision of the PEC regarding the unsatisfactory, satisfactory or successful completion of phase 3 (as defined in TD1 Request for Tenders). This decision will be issued according to the planning provided in TD1 Request for Tender. In case a longer evaluation process, the contractor will be duly informed of the new timeline for the evaluation outcome.
- 20.24. the following rules shall apply:
- a) in case the contractor has not satisfactorily completed phase 3:
 - i. The contractor shall reimburse the received pre-payment to FMS,
 - ii. The contractor will not receive further payment for the work carried out in phase 3.
 - iii. This Framework Agreement and Phase 3 Contract shall terminate.
 - b) In case the contractor has satisfactorily, but not successfully completed phase 3:
 - i. The contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 3.
 - c) In case the contractor has successfully completed phase 3:
 - i. the contractor shall not reimburse the received pre-payment to FMS.
 - ii. The contractor will be entitled to the payment for the work carried out in phase 3.
- 20.25. Successful completion of phase 1 is a prerequisite to receiving an invitation for phase 2. Successful completion of phase 2 is a prerequisite to receiving an invitation for phase 3.
- 20.26. Any award for Phases 2 and 3 will be communicated in writing by FMS to the contractor.
- 20.27. Any reference in this Framework Agreement to the project refers also to any of the phases awarded to the contractor.
- 20.28. The members of the PBG cannot make use of any of the deliverables of the contractor of the particular phase in the event the contractor needs to reimburse the payment for the work carried out under a PCP Phase.
- 20.29. FMS reserves the right not to award contracts for phases for which it has not received any suitable or acceptable offer in relation to the project, as well as to stop, cancel, revoke, re-issue the PCP or not to award any phase contract for objective reasons. FMS assumes no obligation whatsoever to compensate or indemnify the contractors for any expense or loss that may occur in the preparation of their bids.

Article 21 — Breach of contract



- 21.1. The following provisions constitute a non-exhaustive list of clauses that lead to breach of contract.
- 21.2. The contractor shall ensure timely submission of deliverables. If the contractor fails to deliver the Results or other deliverables as described in TD1 Request for Tenders - including, but not limited to, TD6 End of Phase (1, 2, 3) Reports - and to comply with this TD2 Framework Agreement and the Phase Contracts (TD3, 4 and 5), FMS shall give the contractor the opportunity to remedy it within an appropriate period (no longer than 10 (ten) days), unless the delay is not attributable to the contractor. If FMS is still not satisfied after that period, it may - acting reasonably and taking into account the seriousness and consequences of the breach - at its discretion:
- a) Withhold payments until satisfactory delivery.
 - b) Cancel payments.
 - c) Have all sums previously paid by FMS to the contractor for and under the phase which is then running (not being previous phases), refunded by the contractor.
 - d) Hold the contractor accountable for additional costs, which the members of the PBG reasonably incurred.
 - e) Refuse to accept any subsequent performance of the project which the contractor attempts to make.
 - f) Exclude the contractor from any subsequent phases on the basis that the contractor has not successfully completed the present phase.
 - g) Terminate the Framework Agreement, in whole or in part, and/or any Phase Contract without liability to the contractor.
- 21.3. Acceptance by FMS of any deliverable or Result shall not limit the contractor's liability, if those deliverables or Results are later discovered to be non-compliant with the requirements of the Framework Agreement, nor for any loss or damage which may arise as a Result and shall not constitute a waiver of any rights or remedies of FMS or the PBG.

LIABILITY

- 21.4. The contractor undertakes to fulfil all the obligations arising out of this Framework Agreement, with the best possible diligence required by the nature of the services.
- 21.5. The contractor assumes liability for any and all damages caused to anyone, including third-party claims (except to the extent such claims result from an act or omission that is attributable to the PBG), in relation to the performance of the contractual services, relieving FMs and the PBG of any liability.
- 21.6. The liability referred to in article 21.5 for personal injury and damage to property and consequential loss or damage is limited to an amount of EUR 1,250,000 (one million two hundred and fifty thousand) per event. The number of events is limited to 4 (four). For this purpose, interrelated events will be treated as a single event.



- 21.7. The liability referred to in article 21.5 for loss or damages other than those referred to in article 21.6 will be limited to an amount not exceeding four (4) times the amount of the agreed price of the corresponding to the PCP phase where the breach occurred. For this purpose, interrelated events will be treated as a single event.
- 21.8. The limitations of liability set out in Articles 21.6 and 21.7 do not apply in case of:
- a) third-party claims for compensation as a result of death or injury, and/or
 - b) intent or gross negligence, willful misconduct, or a breach of confidentiality on the part of the contractor and its staff (in this case, liability extends to indirect or consequential losses or similar damage (such as loss of profit, loss of revenue or loss of contracts)), and/or
 - c) breaches of IPR as referred to in article 8; and/or
 - d) in the event of claims for compensation due to an infringement of legislation on the protection of personal data or actions contrary to the lawful instructions of the controller. Loss or damage includes fines imposed by the supervisory authority.
- 21.9. The contractor shall be liable for all obligations relating to its personnel, including those arising under tax, health insurance, and social security legislation.
- The contractor shall indemnify and hold harmless FMS against any liability arising therefrom.
- 21.10. The contractor hereby agrees to provide, within 10 (ten) days as of the signing of this Framework Agreement, evidence of the conclusion of a professional insurance/liability policy concluded with a primary insurance company and undertakes to keep such policy insurance in force for the entire duration of this TD2 Framework Agreement and TD3, 4 and 5 Phase Contracts to cover all direct or indirect material damage to persons or property. For the avoidance of any doubt, the limit for each event, corresponding at least to what the law provides for at least in the field of liability and insurance, cannot be considered, under any circumstances, as a limit to compensation for damage.
- 21.11. The contractor shall promptly notify FMS in writing of any liabilities, claims, actions, suits or proceedings, and in particular of any action brought against the contractor for infringement or alleged infringement of IPRs which might affect the project, within 30 (thirty) days after receipt of notice of any complaint, claim or injury opening an indemnification right.
- Upon the members of the PBG first request, the contractor shall take all reasonable measures to prevent or mitigate further damage, and shall fully cooperate with any investigations, audits, or legal or administrative proceedings relating to the services or activities performed under this Agreement.
- 21.12 In no event shall FMS (and the members of the PBG) be liable to the contractor for punitive damages, indirect or consequential loss or damage suffered by contractor.



21.15. The EU cannot be held liable for any damage caused to the contractor or caused by the contractor in connection with the implementation of the Framework Agreement or a Specific Contract.

Article 22 — Causes and consequences of termination

22.1. FMS may terminate this Framework Agreement without liability for any damage, loss or expenses arising as a Result of or in connection with such termination (except otherwise provided in specific clauses hereunder) in the following cases:

- a) Any approvals or licenses required under this Framework Agreement or to enable the services to be carried out lawfully are not given unconditionally within 1 (one) month of the commencement of the project; or lapse, terminate or otherwise cease to have effect during the term of this agreement and the contractor does not seek to have the necessary permits within 2 (two) weeks.
- b) An appeal under the bankruptcy law or any other law applicable to insolvency proceedings has been filed against the contractor, proposing the dissolution, liquidation, amicable composition, the debt restructuring or a settlement with creditors, or if a liquidator, a trustee, a guardian or a person having similar functions, which come into possession of the goods or is responsible for managing the business the contractor is appointed.
- c) Any of the members of the governing body or the managing director or the general manager or the technical manager of the contractor are subject to a judgment which has the force of res judicata for crimes against the public administration, public policy, public faith or public property.
- d) The contractor has informed FMS that they are not willing or not able for whatever reason to continue the project.
- e) the contractor is in breach of an obligation under this Framework Agreement, if:
 - i. the breach can be remedied and the contractor has failed to remedy the breach within 30 (thirty) days of written notice being sent to the contractor specifying the breach and requiring its remedy; or
 - ii. the breach cannot be remedied (but does not constitute a serious or repeated breach or grave professional misconduct by the contractor).
- f) The contractor, or any sub-contractor on whose resources he has relied in the PCP, becomes subject to any exclusion criteria listed in TD1 Request for Tenders.
- g) Failure by the contractor to comply with the contractual obligations (including those related to TD3, 4 and 5 Phase Contracts) in accordance with the law in force and the conditions, procedures, terms and requirements contained in this Framework Agreement, its Annexes and in the Phase Contracts, including, but not limited to:
 - i. Breach of any of its confidentiality obligations.



- ii. A situation of Conflict of Interest according to Article 13 arises during the implementation of the contract, including subcontractors.
 - iii. Breach of any of its data protection obligations.
 - iv. Failure to submit a deliverable or to meet any expected outcome/result within 10 (ten) days of the date by which it was meant to be achieved, or repeatedly fails over a period of 3 (three) consecutive months to submit a deliverable or to meet any expected outcome/Result by the date(s) on which they were meant to be achieved.
- h) The services are not in compliance with the requirements on R&D Services as defined in the most recent version of the Frascati Manual and, where applicable, its latest annexes³⁴ or in case of non-compliance with any other requirement mentioned in the TD1 Request for Tender and declared in the signed declaration that is part of the tender.
 - i) The necessary must and safety requirements are not complied with. Lack of the necessary must and safety requirements may also lead to partial termination of the Framework Agreement and the Phase Contract.
 - j) Any provision of this Framework Agreement which expressly entitles FMS to terminate this Framework Agreement.
- 22.2. In the event of serious or repeated breach of the agreement or grave professional misconduct by the contractor, leading FMS to conclude that the contractor is unsuitable to comply with its obligations hereunder, FMS reserves the right to terminate this Framework Agreement at the contractor's expense, subject only to a notice of termination by certified e-mail or registered letter with acknowledgement of receipt, without prejudice to the right to claim further damages.
- 22.3. In the event of termination of the Framework Agreement for serious or repeated breach or grave professional misconduct by the contractor, FMS shall be entitled to apply a penalty in the amount of maximum 10% (ten percent) of the price for the PCP set out in the Phase Contract concerning the ongoing phase, and/or claim for compensation of damages.
- 22.4. Termination of this Framework Agreement by FMS shall (at the option of FMS) take place with immediate effect as from the date of service of the notice of that termination or from the expiry of a period specified in that notice. If this occurs, FMS shall not be obliged to make any further financial payment to the contractor.
- 22.5. FMS is and remains unconditionally entitled to terminate this Framework Agreement and any Phase Contract hereunder without cause, by giving a 3 (three) month notice in writing. FMS shall in that case only be obliged to pay to the contractor for the reasonable costs for the remaining obligations of the contractor for that phase that can objectively not be undone.
- 22.6. FMS may, by giving due notice in writing, terminate this Framework Agreement without liability for any damage, loss or expenses arising as a

³⁴ OECD (2002). Frascati Manual 2002: [Version: 2002]. OECD Publishing [online].



result of or in connection with such termination if there is a change of control in the contractor which FMS can reasonably demonstrate is prejudicial. FMS shall only be permitted to exercise its rights pursuant to this clause for 6 (six) months after any such change of control and shall not be permitted to exercise such rights where FMS has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The contractor shall notify FMS within 2 (two) weeks of any change of control taking place, unless the new controlling entity originates from a country (or is controlled by a country) that is not EEA and HE associated, in which case the provisions of Article 14 will apply. FMS shall not unreasonably withhold its approval and provide contractor with a decision within 2 (two) weeks after receiving such a notification.

- 22.7. The assignments and/or licenses granted under the Framework Agreement by the contractor to FMS, any member of the PBG or any other third party shall continue notwithstanding any expiry or termination of this agreement.
- 22.8. Termination or expiry of this agreement shall be without prejudice to any rights, remedies or obligations of either party accrued under this Framework Agreement before termination or expiry.
- 22.9. Within 30 (thirty) days of the date of termination or expiry of this Framework Agreement, the contractor shall return or destroy at the request of FMS any personal data received from or on behalf of FMS and/or the members of the PBG, or Confidential Information belonging to FMS and/or the members of the PBG, either in its current format or in a format nominated by FMS.
- 22.10. Unless expressly stated to the contrary, the service of a notice to terminate this Framework Agreement shall operate as a notice to terminate any Phase Contract in force.

Article 23 — Force Majeure

- 23.1. In accordance with this Framework Agreement, neither party may be held responsible by the other party for circumstances beyond the party's control and which the party, on signing the Framework Agreement or the Phase Contract, could not have taken into consideration or avoided or overcome. Circumstances that a diligent contractor could have prevented by taking the customary and reasonable precautions are not considered force majeure, including those relating to internal strikes and illness, and/or any default of a service, defect in equipment or material or delays, unless they stem directly from a relevant case of force majeure.
- 23.2. Force majeure may only be asserted for the number of working days that the force majeure situation persists.
- 23.3. Insofar as a deadline for the contractor is deferred because of force majeure, the payments relating to this deadline will be deferred correspondingly.
- 23.4. Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects. Force majeure may only be cited if the affected party has given



written notification thereof to the other party no later than 10 (ten) working days after the commencement of the force majeure.

- 23.5. The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible. The party prevented by force majeure from fulfilling its obligations under the Framework Agreement cannot be considered in breach of them.
- 23.6. The party not affected by force majeure is entitled to cancel orders if the agreed delivery time is exceeded by 30 (thirty) working days as a consequence of force majeure.
- 23.7. The parties may terminate this Framework Agreement in writing without notice if the impediment or delay as a consequence of the force majeure situation will last or lasts longer than 6 (six) months.

Article 24 — Amendments

- 24.1. If at any time any provision of this Framework Agreement needs to be amended, the contractor shall immediately inform FMS in writing requesting an amendment, giving full details of the justification for the request and giving proposals for the amendment to this Framework Agreement at no additional cost to FMS. Upon receipt of such a request, FMS may:
- a) Agree to modify the Framework Agreement provided such variation is non-discriminatory and does not lead to a substantial change of the Framework Agreement, the scope of services or the scope of the Results as allowed following the case law of the European Court of Justice;
 - b) Amend the project in a manner which the contractor agrees can be carried out within the duration of the project and the price allocated to the relevant phases; or
 - c) Refuse the request and require the continuation of the project in accordance with the Framework Agreement; or
 - d) Give notice of termination in accordance with Article 23.
- 24.2. Any amendment to this Framework Agreement shall be made after agreement between the parties.
- 24.3. Any amendment to this Framework Agreement shall be set out in writing, in an addendum to it and signed by both parties.
- 24.4. No amendment shall have the purpose or the effect of making material changes to TD2 Framework Agreement and TD3. 4 and 5 Phase Contracts, which might call into question the decision awarding the contract or result in unequal treatment of technology providers. If it is not possible to continue with the project in accordance with the Framework Agreement, the agreement and Phase Contracts shall be terminated.
- 24.5. FMS may request an amendment to the agreement at any time, provided such amendment does not amount to a material change to this Framework Agreement, and provided that parties agree that the change is not unreasonable.



Article 25 — Interpretation

- 25.1. The Framework Agreement constitutes the entire Agreement between the Parties relating to its subject matter. Each Party acknowledges that it has not entered into this Framework Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Framework Agreement. Each party waives any claim for breach of this Framework Agreement, or any right to rescind this Framework Agreement in respect of, any representation, which is not an express provision of this Framework Agreement. However, this Article does not exclude any liability which either party may have to the other (or any right which either party may have to rescind this Framework Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this Framework Agreement.
- 25.2. In case of discrepancy between the Framework Agreement and the PCP Request for Tenders document, the documents shall prevail in the following descending order:
- a) Phase Contract
 - b) Framework Agreement
 - c) Request for Tenders
 - d) Other Tender Documents
- 25.3. The terms and conditions set out in the Request for Tenders (TD1) have precedence over the contractor's Bid.
- 25.4. A reference to any act, law, statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the act, law, statute, enactment, order, regulation or instrument as subsequently amended or re-enacted (regardless of whether or not expressly so stipulated).
- 25.5. The headings in this Framework Agreement are for ease of reference only and shall not affect its interpretation or construction.

Article 26 — Applicable law and dispute settlement

- 26.1. Considering that PCP is exempted from the EU Public Procurement Directives and subsequently from the national transposition laws, the Spanish (and Navarra´s) public procurement law will be applied on a subsidiary basis, if the tender documents do not cover a potential legal loophole.
- 26.2. Any disputes between the parties, arising with reference to the interpretation, performance, validity, effectiveness and termination of this Agreement and the Phase Contracts, shall be first topic of amicable settlement by Parties and if that is not possible:
- a) Contract modifications claims shall be lodged before the Head of the Department of Health of Navarre (Spain), within a period of one month from the publication or notification of the contested decision. This prior



appeal is mandatory before escalating to the administrative courts of Pamplona (Navarra, Spain) for a period of two month after the decision of the Head of the Department of Health of Navarre.

- b) Other execution topics and termination of the contract(s) shall be lodged before the civil courts of Pamplona (Navarra, Spain).

Article 27 — Entry into force

This Framework Agreement shall enter into force on the date it is signed by the parties hereto.

SIGNATURES

FMS signs for the PBG and — in case of joint tenders — the lead contractor for the group of contractors.





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THERESA PCP

**PCP TENDER DOCUMENT 3
PCP SPECIFIC CONTRACT FOR
PHASE 1 (TD3)**



PCP SPECIFIC CONTRACT FOR PHASE 1 (TD3) PREAMBLE

This procurement relates to a joint PCP that will be carried out by the following lead procurer: **FUNDACIÓN PÚBLICA MIGUEL SERVET (FMS)**, based in Spain, acting in the name and on behalf of the [other] members of the Public PBG (PBG) (together with FMS: “procurers”):

1. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH) (EST)
2. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS) (PL)
3. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM) (NL)
4. ZIEKENHUIS AAN DE STROOM (ZAS) (BE)
5. CONSORCI HOSPITALARI DE VIC (CHV) (ES)
6. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS) (ES)

and on the other hand, [insert details of the contractor], hereinafter the “contractor”, [

[for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]
- 2.

The members of the group of tenderers are hereafter collectively referred to as “the contractor” and will be jointly and severally liable vis-à-vis FMS for the performance of this Framework Agreement and the Specific Contracts.]

FMS, the PBG and the contractor(s) shall be referred to together as “parties”, unless otherwise specified.



WHEREAS:

- Based on the communication by the PBG of *[insert date]*, the above mentioned Contractor has been declared as one of the successful tenderers in the PCP Project;
- On *[insert date]*, the PBG and the contractor signed the Framework Agreement, which provides that the contractor shall proceed with the performance of the activities in accordance with the Phase Contracts, which constitutes integral and substantial part of the Agreement.

The conditions for the execution of the assignment subject of this Phase Contract, in accordance with article 4 and 5 of the Framework Agreement, are expressed as follows:



TERMS AND CONDITIONS

Article 1 — Subject of the contract

This Specific Contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 1 of the Framework Agreement (TD2) — for the PCP phase 1.

Article 2 — Duration

The duration of the specific contract is [] and starting date is [] and end date for the implementation of the tasks is []. The PBG reserves its right to execute the assessment/evaluation of the performed activities.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article 3 — R&D services to be provided

3.1 The contractor shall provide the R&D services (tasks, deliverables and milestones) set out in the offer for this phase in accordance with section 2.4 of the Request for Tenders (TD1) .

3.2. The following members of the contractor's staff shall be in charge of carrying out the R&D activities for the specific contract: [insert name].

3.3. The activities provided for under this article 3 shall be carried out in the premises of the contractor.

Article 4 — Price and payment arrangements

4.1. The price to be paid by the Procurer for the R&D services set out in Article 3 above shall be: **Phase 1**: Solution design: [...] €.

4.2. Payment schedule:

Table 15

	Date of Deliverable	Deliverable	%	Total
Phase 1	Week 4 of month 3 of phase 1	D1.1), D1.2) and D1.3)	100%	100%



- 4.3. The invoice must provide a price breakdown showing the price (excl. VAT) for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D).
- 4.4. The invoice should contain at least the following administrative details:
- A unique invoice number;
 - The name and address of the contractor;
 - The contractor's VAT number;
 - The contractor's bank account number;
 - The invoice date;
 - The payment due date;
 - The Purchase Order number: [XXXX] (to be provided separately);
 - The billing address of FMS: Fundación Miguel Servet Calle Irunlarrea, 3. 31008 Pamplona, Navarra, España. +34 848 42 86 29
- 4.5. The invoice must be sent by e-mail to: contabilidad.fms@navarra.es
- 4.6. Payments are based on satisfactory/successful completion the deliverables of the phase. The PEC shall issue its decision regarding the satisfactory or successful completion of the deliverables and/or phase 1, w2 (two) weeks after the completion date of the deliverables and/or phase.
- 4.7. Payments will be made 15 (fifteen) days from the decision of the Procurement Evaluation Committee (PEC), by bank transfer.

Article 5 – Termination

The cases and terms of termination are provided by article 22 of the Framework Agreement (TD2).

Article 6 - Individuals in charge

In relation to the activities provided by this Phase Contract, the individuals in charge of the activities are:

- Mr./Mrs. [insert name], on behalf of the contractor.
- Mr./Mrs. [insert name], on behalf of the PBG.

The individual responsible on behalf of the PBG will conduct weekly or biweekly review meetings with the contractor against the supplier's project plan. The focus of these meetings is to monitor:

1. Progress against milestones
2. Budget adherence
3. Emerging risks

Reports and notes that will be shared will be prepared ad hoc (if necessary).



Article 7 – Penalties and liabilities

Provisions contained in the Framework Agreement (TD2) will ensure the correct and prompt execution of obligation provided in this Phase Contract.

Article 8 — Applicable law and dispute settlement

Considering that PCP is exempted from the EU Public Procurement Directives and subsequently from the national transposition laws, the Spanish (and Navarra´s) public procurement law will be applied on a subsidiary basis, if the tender documents do not cover a potential legal loophole.

Any legal claim, petition or application for judicial review, with regard to the execution of this Phase 1 Contract, shall be lodged:

- For contract modifications: before the Head of the Department of Health of Navarre (Spain), within a period of one month from the publication or notification of the contested decision. This prior appeal is mandatory before escalating to the administrative courts of Pamplona (Navarra, Spain) for a period of two month after the decision of the Head of the Department of Health of Navarre
- For the execution and termination of the contract(s): before the civil courts of Pamplona (Navarra, Spain).

Article 9 — Entry into force

This Phase Contract shall enter into force on the date it is signed by the Parties hereto.

SIGNATURES

Same as for framework agreement: FMS signs for the PBG and — in case of joint tenders — the lead contractor for the group of contractors.





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THERESA PCP

**PCP TENDER DOCUMENT 4
PCP SPECIFIC CONTRACT FOR
PHASE 2 (TD4)**



PCP SPECIFIC CONTRACT FOR PHASE 2 (TD4) PREAMBLE

This procurement relates to a joint PCP that will be carried out by the following lead procurer: **FUNDACIÓN PÚBLICA MIGUEL SERVET (FMS)**, based in Spain, acting in the name and on behalf of the [other] members of the Public PBG (PBG) (together with FMS: “procurers”):

1. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH) (EST)
2. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS) (PL)
3. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM) (NL)
4. ZIEKENHUIS AAN DE STROOM (ZAS) (BE)
5. CONSORCI HOSPITALARI DE VIC (CHV) (ES)
6. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS) (ES)

and on the other hand, [insert details of the contractor], hereinafter the “contractor”, [

[for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]
- 2.

The members of the group of tenderers are hereafter collectively referred to as “the contractor” and will be jointly and severally liable vis-à-vis FMS for the performance of this Framework Agreement and the Specific Contracts.]

FMS, the PBG and the contractor(s) shall be referred to together as “parties”, unless otherwise specified.



WHEREAS:

- Based on the communication by the PBG of *[insert date]*, the above mentioned Contractor has been declared as one of the successful tenderers in the PCP Project;
- On *[insert date]*, the PBG and the contractor signed the Framework Agreement, which provides that the contractor shall proceed with the performance of the activities in accordance with the Phase Contracts, which constitutes integral and substantial part of the Agreement.

The conditions for the execution of the assignment subject of this Phase Contract, in accordance with article 4 and 5 of the Framework Agreement, are expressed as follows:



TERMS AND CONDITIONS

Article 1 — Subject of the contract

This Specific Contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 1 of the Framework Agreement (TD2) — for the PCP phase 2.

Article 2 — Duration

The duration of the specific contract is [] and starting date is [] and end date for the implementation of the tasks is []. The PBG reserves its right to execute the assessment/evaluation of the performed activities.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article 3 — R&D services to be provided

3.1 The contractor shall provide the R&D services (tasks, deliverables and milestones) set out in the offer for this phase in accordance with section 2.4 of the Request for Tenders (TD1) .

3.2. The following members of the contractor's staff shall be in charge of carrying out the R&D activities for the specific contract: [insert name].

3.3. The activities provided for under this article 3 shall be carried out according to the requirements of *section 2.1 Descriptions of the services to be provided of TD1. Request for Tender, Annex 6. Phase 2 testing strategy & requirements* and the offer for Phase 2 made by the contractor.

Article 4 — Price and payment arrangements

4.1. The price to be paid by the Procurer for the R&D services set out in Article 3 above shall be: **Phase 2**: prototype development [...] €.

4.2. Payment schedule:

Table 16

	Date of Deliverable	Deliverable	%	Total
Phase 2	Month 3 of phase 2	D2.1)	50%	100%
Phase 2	Month 10 of phase 2	D2.2), D2.3), D2.4), D2.5) and D2.6)	50%	



- 4.3. The invoice must provide a price breakdown showing the price (excl. VAT) for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D).
- 4.4. The invoice should contain at least the following administrative details:
- A unique invoice number;
 - The name and address of the contractor;
 - The contractor's VAT number;
 - The contractor's bank account number;
 - The invoice date;
 - The payment due date;
 - The Purchase Order number: [XXXX] (to be provided separately);
 - The billing address of FMS: Fundación Miguel Servet; Calle Irunlarrea, 3. 31008 Pamplona, Navarra, España. +34 848 42 86 29
- 4.5. The invoice must be sent by e-mail to: contabilidad.fms@navarra.es
- 4.6. Payments are based on satisfactory/successful completion the deliverables of the phase. The TEC shall issue its decision regarding the satisfactory or successful completion of deliverables and/or phase 2, within 2 (two) weeks after the completion date of the deliverables and/or phase.
- 4.7. Payments will be made 15 (fifteen) days from the decision of the Procurement Evaluation Committee (PEC), by bank transfer.

Article 5 – Termination

The cases and terms of termination are provided by article 22 of the Framework Agreement (TD2).

Article 6 - Individuals in charge

In relation to the activities provided by this Phase Contract, the individuals in charge of the activities are:

- Mr. /Mrs. [insert name], on behalf of the contractor.
- Mr. /Mrs. [insert name], on behalf of the PBG.

The individual responsible on behalf of the PBG will conduct weekly or biweekly review meetings with the contractor against the supplier's project plan. The focus of these meetings is to monitor:

1. Progress against milestones
2. Budget adherence
3. Emerging risks

Reports and notes that will be shared will be prepared ad hoc (if necessary).

The individual responsible on behalf of the PBG will be supported by expert of



SAS (if necessary).

Article 7 – Penalties and liabilities

Provisions contained in the Framework Agreement (TD2) will ensure the correct and prompt execution of obligation provided in this Phase Contract.

Article 8 — Applicable law and dispute settlement

Considering that PCP is exempted from the EU Public Procurement Directives and subsequently from the national transposition laws, the Spanish (and Navarra´s) public procurement law will be applied on a subsidiary basis, if the tender documents do not cover a potential legal loophole.

Any legal claim, petition or application for judicial review, with regard to the execution of this Phase 1 Contract, shall be lodged:

- For contract modifications: before the Head of the Department of Health of Navarre (Spain), within a period of one month from the publication or notification of the contested decision. This prior appeal is mandatory before escalating to the administrative courts of Pamplona (Navarra, Spain) for a period of two month after the decision of the Head of the Department of Health of Navarre..
- For the execution and termination of the contract(s): before the civil courts of Pamplona (Navarra, Spain).

Article 9 — Entry into force

This Phase Contract shall enter into force on the date it is signed by the Parties hereto.

SIGNATURES

Same as for framework agreement: FMS signs for the PBG and — in case of joint tenders — the lead contractor for the group of contractors.





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**PCP TENDER DOCUMENT 5
PCP SPECIFIC CONTRACT FOR
PHASE 3 (TD5)**



PCP SPECIFIC CONTRACT FOR PHASE 3 (TD5) PREAMBLE

This procurement relates to a joint PCP that will be carried out by the following lead procurer: **FUNDACIÓN PÚBLICA MIGUEL SERVET (FMS)**, based in Spain, acting in the name and on behalf of the [other] members of the Public PBG (PBG) (together with FMS: “procurers”):

1. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH) (EST)
2. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS) (PL)
3. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM) (NL)
4. ZIEKENHUIS AAN DE STROOM (ZAS) (BE)
5. CONSORCI HOSPITALARI DE VIC (CHV) (ES)
6. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS) (ES)

and on the other hand, [insert details of the contractor], hereinafter the “contractor”, [

[for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]
- 2.

The members of the group of tenderers are hereafter collectively referred to as “the contractor” and will be jointly and severally liable vis-à-vis FMS for the performance of this Framework Agreement and the Specific Contracts.]

FMS, the PBG and the contractor(s) shall be referred to together as “parties”, unless otherwise specified.



WHEREAS:

- Based on the communication by the PBG of *[insert date]*, the above mentioned Contractor has been declared as one of the successful tenderers in the PCP Project;
- On *[insert date]*, the PBG and the contractor signed the Framework Agreement, which provides that the contractor shall proceed with the performance of the activities in accordance with the Phase Contracts, which constitutes integral and substantial part of the Agreement.

The conditions for the execution of the assignment subject of this Phase Contract, in accordance with article 4 and 5 of the Framework Agreement, are expressed as follows:



TERMS AND CONDITIONS

Article 1 — Subject of the contract

This Specific Contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 1 of the Framework Agreement (TD2) — for the PCP phase 3.

Article 2 — Duration

The duration of the specific contract is [] and starting date is [] and end date for the implementation of the tasks is []. The PBG reserves its right to execute the assessment/evaluation of the performed activities.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article 3 — R&D services to be provided

3.1 The contractor shall provide the R&D services (tasks, deliverables and milestones) set out in the offer for this phase in accordance with section 2.4 of the Request for Tenders (TD1) .

3.2. The following members of the contractor's staff shall be in charge of carrying out the R&D activities for the specific contract: [insert name].

3.3. The activities provided for under this article 3 shall be carried out in the premises FMS, PERH, WSS, AZM, according to *section 2.1 Descriptions of the services to be provided of TD1. Request for Tender, Annex 1. Test sites, Annex 7. Phase 3 verification strategy & requirements* and the offer for Phase 3 made by the contractor.

Article 4 — Price and payment arrangements

4.1. The price to be paid by the Procurer for the R&D services set out in Article 3 above shall be: **Phase 3**: validation in real operational environment: [...] €.

4.2. Payment schedule:

Table 17

	Date of Deliverable	Deliverable	%	Total
Phase 3	Month 5 of phase 3	D3.1) D3.2) and D3.3)	55%	100%



Phase 3	Month 10 of phase 3	D3.4), D3.5) D3.6), D3.7) , D3.8), D3.9) and D3.10)	45%
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- 4.3. The invoice must provide a price breakdown showing the price (excl. VAT) for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D).
- 4.4. The invoice should contain at least the following administrative details:
- A unique invoice number;
 - The name and address of the contractor;
 - The contractor's VAT number;
 - The contractor's bank account number;
 - The invoice date;
 - The payment due date;
 - The Purchase Order number: [XXXX] (to be provided separately);
 - The billing address of FMS: Fundación Miguel Servet; Calle Irunlarrea, 3. 31008 Pamplona, Navarra, España. +34 848 42 86 29
- 4.5. The invoice must be sent by e-mail to: contabilidad.fms@navarra.es
- 4.6. Payments are based on satisfactory/successful completion the deliverables of the phase. The TEC shall issue its decision regarding the satisfactory or successful completion of deliverables and/or phase 3, within 4 (four) weeks after the completion date of the deliverables and/or phase. .
- 4.7. Payments will be made 30 (thirty) days from the decision of the ProcurementEvaluation Committee (PEC), by bank transfer.

Article 5 – Termination

The cases and terms of termination are provided by article 22 of the Framework Agreement (TD2).

Article 6 - Individuals in charge

In relation to the activities provided by this Phase Contract, the individuals in charge of the activities are:

- Mr./Mrs. [insert name], on behalf of the contractor.
- Mr./Mrs. [insert name], on behalf of the PBG.

The individual responsible on behalf of the PBG will conduct weekly or biweekly review meetings with the contractor against the supplier's project plan. The focus of these meetings is to monitor:

1. Progress against milestones



2. Budget adherence
3. Emerging risks

Reports and notes that will be shared will be prepared ad hoc (if necessary). Each hospital in which a pilot is conducted will name a responsible person for the testing who will support the individual responsible on behalf of the PBG and assist the contractors during phase 3.

Article 7 – Penalties and liabilities

Provisions contained in the Framework Agreement (TD2) will ensure the correct and prompt execution of obligation provided in this Phase Contract.

Article 8 — Applicable law and dispute settlement

Considering that PCP is exempted from the EU Public Procurement Directives and subsequently from the national transposition laws, the Spanish (and Navarra's) public procurement law will be applied on a subsidiary basis, if the tender documents do not cover a potential legal loophole.

Any legal claim, petition or application for judicial review, with regard to the execution of this Phase 1 Contract, shall be lodged:

- For contract modifications: before the Head of the Department of Health of Navarre (Spain), within a period of one month from the publication or notification of the contested decision. This prior appeal is mandatory before escalating to the administrative courts of Pamplona (Navarra, Spain) for a period of two month after the decision of the Head of the Department of Health of Navarre.
- For the execution and termination of the contract(s): before the civil courts of Pamplona (Navarra, Spain).

Article 9 — Entry into force

This Phase Contract shall enter into force on the date it is signed by the Parties hereto.

SIGNATURES

Same as for framework agreement: FMS signs for the PBG and — in case of joint tenders — the lead contractor for the group of contractors.





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**PCP TENDER DOCUMENT 6
PCP END OF PHASE REPORT (TD6)**



TD6. PCP END OF PHASE REPORT

- This report is NOT part of the tender for PCP phase 1.
- This report only to be filled in and signed by selected contractors at the end of PCP phase 1 (2 and 3). Please do not modify the template.
- This report will be treated as confidential. Except ABSTRACT PCP END OF PHASE REPORT, at the end of this TD6 which is not included in the maximum number of pages.
- The maximum number of pages of the end of phase report is 15 (fifteen) sides of A4. This includes images and annexes. The answers must be in Calibri (body), 11pt, after 3 pt, single line spacing.
- Pages that exceed the prescribed number of pages will not be taken into consideration.



1. General information

Table 18

Details	
Type of Organisation	Please Select One: Private sector, Public sector, Academic, Not for profit (third sector)
Registered Name of Organisation	
Registered Address	
Town/ City	
Postcode	
County	
Report Author	
Delivery date	
Telephone Number	
E-mail Address	
Project Reference	
Total Contract Cost (in euro)	
Start Date	
End Date	
Sub-contractors	

List of names and location of personnel that carried out the R&D activities.

Table 19

Name	Role	Location	Subcontractor (YES/NO)



--	--	--

Please note that any changes to this team had to be duly notified in writing to the THERESA PCP PBG for their approval.



2. Technical report

Write a report that *successively* addresses the following numbered topics:

- A. Provide a short description of the innovative solution (in its current form).

Provide a short description of the solution including intended application specified in terms of: matrix (the type of material for which it is intended), purpose (the measurable property of the matrix affected by the solution and how it is affected) and technical conditions of operation or testing for the given matrices and purposes described.

Does the solution meet user needs in terms of functionality, claimed performance and environmental added value thanks to innovation?
- B. At beginning of this Phase what were your aims and objectives?
- C. Please provide a short factual summary of the most significant outcomes summary of the most significant outcomes of your work and relate these to the original objectives. How do the outputs address the requirements of this PCP (see section 3.5 of TDI Request for Tenders)
- D. Describe any changes to the original plan in the tender. What was the reason for these changes? Please include any circumstances that aided or impeded the progress of the project and the actions taken to overcome them.
- E. Describe the innovative aspects of the work, including any new findings or techniques. In which ways and to which extent does the solution go beyond what existing solutions can achieve? Indicate if your innovative solution is (a) a totally new product / service / process / method; (b) an improvement to an existing product / service / process / method; (c) a new combination of existing products / services / processes / methods and (d) a new use for existing products / services / processes / methods).
- F. Describe where the R&D and other operational activities have been performed.
- G. Please describe what your organization has gained from this project. What new business opportunities have been created? Did the procurement enable you to work with procurers/end-users that you were not working with beforehand? What is the current commercialization success of the solution? Do you expect that participating in the PCP will shorten the time-to-market for your innovation? Do you expect your organization to grow as a result of this project (i.e., personnel growth; turnover growth; growth in market share)?
- H. How mature is the innovative solution in terms of its readiness to commercialise widely? How large is the potential market for your solution? is it a growing / steady / declining market? By when can commercialisation start (now / in 1 / in 3 / in 5 / in more than 5 years)? Is competition patchy (no major players) / established (but no comparable offering) / fierce? Describe the potential for exploiting the work. Please identify any new intellectual property which has been filed or for which filing is anticipated.



- I. Which future steps do you plan to take to further grow your business? (e.g. attracting additional investors to grow your business, mergers / acquisitions / joint ventures / spin-offs / IPO, setting up sales / distribution channels / marketing activities, expanding to other countries etc.)?
- J. Please insert additional information that may be pertinent. This may be in the form of text, pictures, diagrams, data, graphs that support the work.
- K. Describe the challenges that you have encountered. What are the remaining bottlenecks to commercialize your solution (e.g. certification, legislation etc.)? What type(s) of assistance do you need to address those bottlenecks and grow your business / commercialize your solution more widely? (e.g. EU regulation on x, finding investors, IPR help etc.)? How important was the procurement for your business (Would/could you have done it on your own?)?
- L. How does your methodology aligns with open science principles: (a) Open Access and Data: Any scientific publications arising from the PCP contractors may be made available on open access platforms to the fullest extent. Research data may also be accessible, ensuring compliance with privacy standards and fundamental rights. Data will be shared as openly as possible (to support reproducibility and reuse) and restricted only as necessary (to protect sensitive information), in platforms such as ZENODO; (b) Open Source: The project results developed may be shared on open repositories (e.g., GitHub) under open licenses (e.g., Apache), allowing for broad use and further development where possible, and; (c) Open Hardware: Where applicable, hardware components developed within the project may be documented and shared following open hardware principles.



3. Phase 1/2/3

* Please note that the questions to be answered will be finetuned in phase 2 and 3 respectively³⁵.

A. Description of the Proposed Solution Concept

Overview of the technology and treatment approach.

Description of the main treatment processes and expected removal mechanisms for target contaminants.

Process flow diagrams and conceptual system architecture.

Expected operating conditions and design assumptions.

B. Preliminary Performance Expectations

Expected contaminant removal performance based on available scientific evidence, previous tests, or technical documentation.

Description of how the proposed concept is expected to achieve the required treatment objectives.

C. Operational Concept and System Design

Description of the proposed system configuration.

Expected operating ranges (e.g. flow, pH, temperature).

Monitoring and control concept.

Description of system modularity, scalability, and installation concept.

D. Environmental Added Value (Phase 1 KPI)

The contractor shall demonstrate, based on available information and design assumptions, that the proposed solution does not introduce overall greater negative environmental impacts than environmental benefits compared to the identified relevant alternative(s), primarily during the operation phase.

The contractor shall therefore:

- a) Identify the relevant alternative(s) used for comparison.
- b) Provide qualitative or preliminary quantitative information regarding the expected environmental performance of the proposed solution during operation, including where applicable:
 - c) expected energy consumption;
 - d) operational chemical or consumable use;
 - e) expected emissions to water (including residual pollutants or by-products);
 - f) expected waste generation (hazardous and non-hazardous);
 - g) expected water consumption.

³⁵ The results of the detailed comparative analysis for each pilot tested in Phase 3 shall be included in the End of Phase 3 report.



- h) Explain the environmental benefits compared to the relevant alternative(s).
- i) Identify any potential environmental trade-offs or uncertainties associated with the proposed concept.

Where quantitative data are not available, the contractor shall clearly state the assumptions used and indicate whether the information is estimated, calculated, or based on reference data.

E. Risks and Assumptions

Identification of technical and operational risks.

Description of key assumptions used in the concept design.

F. Intellectual Property Rights (IPR)

Description of measures taken to protect intellectual property related to the solution concept.



4. Financial Report

Please provide complete and clear information about the allocation of the budget paid with consideration to the R&D service contract minimum requirement. Use the table below. Add explanation if required.

Table 20

CATEGORY	UNIT PRICE	QUANTITY	TOTAL PRICE (€)
Personnel incl. hourly rates	Price per hour	Number of hours per phase	
Personnel incl. hourly rates (junior)	Price per hour	Number of hours per phase	
Personnel incl. hourly rates (medior)	Price per hour	Number of hours per phase	
Personnel incl. hourly rates (senior)	Price per hour	Number of hours per phase	
Materials	Price per unit of material ³⁶	Number of unit of material per phase	
Facilities	Price of using the tenderers facilities for the purposes of THERESA PCP per hour ³⁷	Number of hours per phase allocated to THERESA PCP	
Overhead costs³⁸	Price per unit of item	Number of unit of item per phase	
Subcontract	Price per hour	Number of hours per phase	
Travel and accommodation	Price per planned trip	Number of trips planned	

³⁶ It will depend on the particular material that the tenderer is offering. Tenderers can add a table in this specific field.

³⁷ Simple example would be the tenders facilities' renting invoice divided by the number of monthly working hours and then the number of units would be the number of hours allocated to THERESA PCP.

³⁸ Tenderers can provide a brief description of what is included as overhead cost, considering that they refer to indirect, fixed expenses a business incurs to operate, such as rent, utilities, salaries, and insurance



Other (specify)	Price per unit of item	Number of unit of item per phase	
Total price with exclusive development (IPR owned by PBG) (Excl. VAT)			
Total price with shared IPR (owned by tenderers) (Excl. VAT)			
Total price with shared IPR (owned by tenderers) (Incl. VAT) (give VAT rate)			



ABSTRACT PCP END OF PHASE REPORT

For publication purposes

Table 21

Details	
Type of Organisation	Please Select One: Private sector, Public sector, Academic, Not for profit (third sector)
Registered Name of Organisation	
Country	
Project Reference	
Start Date	
End Date	
Sub-contractors	YES/NO
Consortia	YES/NO

Results & conclusions

Table 22

Contractors
<p>1. The innovative solution . Provide a short description of:</p> <p>The innovative solution (in its current form)</p> <p>Where exactly lies the innovation in the solution: In which ways and to which extent does the solution go beyond what existing solutions can achieve?</p> <p>The degree of innovation: indicate if your innovative solution is (a) a totally new product / service / process / method; (b) an improvement to an existing product / service / process / method; (c) a new combination of existing products / services / processes / methods and (d) a new use for existing products / services / processes / methods).</p> <p>Does the solution meet user needs in terms of functionality, claimed performance and environmental added value thanks to innovation?</p>



2. Commercialisation success. Provide a short description of:

How mature is the innovative solution in terms of its readiness to commercialize widely: Which steps towards wide scale commercialization have been completed so far? (IPR protection, certification, CE marking, attracting additional investors to grow the business, setting up sales / distribution channels / marketing activities to expand sales to other countries etc.)

What is the current commercialization success of the solution: e.g. awards / other forms of recognitions obtained, sales / increase in market share already achieved, licensing agreements already concluded, collaboration agreements with other partners (e.g. retailers) to commercialize the solutions already signed, additional investments attracted to further commercialize the solution.

3. Other benefits obtained. Provide a short description of any other benefits that you obtained from participating in the procurement, e.g.:

Getting easier access to (a new segment of) the public procurement market (e.g. did the procurement enable you to work with procurers/end-users that you were not working with beforehand?); growing your business across borders and/or to other markets (e.g. private markets) due to the first customer references provided by the procurement; shortening the time-to-market for your innovation due to early customer/end-user feedback

Other benefits / lessons learnt

4. Business growth. Provide a short description of:

How much has your business already grown during the procurement? (personnel growth; turnover growth; growth in market share, etc).

What are the prospects to grow your business via wider commercialisation of the solution: How large is the potential market for your solution? is it a growing / steady / declining market? By when can commercialisation start (now / in 1 / in 3 / in 5 / in more than 5 years)? Is competition patchy (no major players) / established (but no comparable offering) / fierce?

Which future steps do you plan to take to further grow your business? (e.g. attracting additional investors to grow your business, mergers / acquisitions / joint ventures / spin-offs / IPO, setting up sales / distribution channels / marketing activities, expanding to other countries etc.)

5. Challenges. Provide a short description of:

What are the remaining bottlenecks to commercialise your solution? (e.g. certification, legislation etc.)

What type(s) of assistance do you need to address those bottlenecks and grow your business / commercialise your solution more widely? (e.g. EU regulation on x, finding investors, IPR help etc.)

How important was the procurement for your business? (Would/could you have done it on your own?)





SIGNATURES

1. FUNDACION PUBLICA MIGUEL SERVET (FMS)

Signature(s)

Name(s):

Title(s):

Date



2. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS)

Signature(s)

Name(s):

Title(s):

Date



3. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH)

Signature(s)

Name(s):

Title(s):

Date



4. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS)

Signature(s)

Name(s): Patrik Krauspe

Title(s): State Secretary

Date



5. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM)

Signature(s)

Name(s):

Title(s): -

Date



6. ZIEKENHUIS AAN DE STROOM (ZAS)

Signature(s)

Name(s):

Title(s):

Date



7. CONSORCI HOSPITALARI DE VIC (CHV)

Signature(s)

Name(s):

Title(s):

Date



theresa

