THERESA OMC Document

Challenge and requirements of THERESA for the future Pre-Comercial Procurement

December 2025

www.theresa-pcp.eu | Funded by the European Union

Glossary of terms

Term	Description
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
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, while allowing suppliers to retain intellectual property rights
Public Buyers Group (PBG)	The consortium of healthcare organizations and public health authorities jointly procuring R&D services through the THERESA PCP. In this case, seven hospitals and two supporting entities from six European countries
Use Case Scenarios	Detailed descriptions of representative hospital contexts from participating organizations, including infrastructure constraints, wastewater characteristics, regulatory requirements, and operational parameters that solutions must address
Anonymization	The process of removing all personally identifiable information and company-specific details from questions, survey responses, and published materials to protect the identity and competitive position of market operators
Audit Trail	A complete, chronological record of all OMC activities (question submissions, responses, webinar attendance, survey submissions, bilateral meetings) maintained for transparency, compliance verification, and European Commission reporting
Intellectual Property Rights (IPR)	Legal rights protecting innovations, inventions, and creative works. In PCP, suppliers typically retain full ownership of IPR generated during R&D phases, with buyers receiving usage rights
Market operator /Technology Supplier	Any organization or entity (company, research institution, SME, start-up, consortium) interested in or participating in the OMC by submitting questions, attending webinars, responding to surveys, or engaging in bilateral dialogues

Glossary of acronyms

Acronyms	Description
AMR	Antimicrobial Resistance
ARG	Antibiotic Resistance Genes
ARB	Antibiotic-Resistant Bacteria
ATC	Anatomical Therapeutic Chemical Classification System
AZM	Academisch Ziekenhuis Maastricht (Maastricht University Medical Center+)
BE	Belgium
BMS	Building Management System
CHV	Consorci Hospitalari de Vic
COD	Chemical Oxygen Demand
CU	Clínica Ubarmin
CET	Central European Time
CR	Carbapenem-Resistant
CSTD	Closed System Drug Transfer Device
DO	Dissolved Oxygen
EC	European Commission
EE	Estonia
ETV	Environmental Technology Verification (ISO 14034)
ES	Spain
EU	European Union
FMS	Fundación Miguel Servet - Hospital Universitario de Navarra
GDPR	General Data Protection Regulation
GPA	Government Procurement Agreement
HUN	Hospital Universitario de Navarra
HUVM	Hospital Universitario Virgen Macarena
HVC	Hospital Virgen del Camino
HWW	Hospital Wastewater
IA	Artificial Intelligence
ICO	Institut Català d'Oncologia
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
KPI	Key Performance Indicator
MRI	Magnetic Resonance Imaging
NL	The Netherlands
OMC	Open Market Consultation

PBG	Public Buyers Group
PCP	Pre-Commercial Procurement
PERH	Põhja-Eesti Regionaalhaigla
PIN	Prior Information Notice
PPI	Public Procurement of Innovative Solutions
R&D	Research & Development
SAS	Servicio Andaluz de Salud
SME	Small and Medium-sized Enterprise
SOTA	State-Of-The-Art
TED	Tenders Electronic Daily
TRL	Technology Readiness Level
WTO	World Trade Organisation

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1 Executive Summary

The THERESA challenge at a glance

The **THERESA Pre-Commercial Procurement (PCP)** tackles an urgent and complex environmental and public health challenge: the presence of harmful contaminants in **hospital wastewater**. The project aims to support the development of **modular, scalable pre-treatment systems** capable of effectively removing a wide spectrum of priority substances, such as **pharmaceuticals, cytostatics, antibiotic residues, X-ray contrast agents**, and **antimicrobial-resistant bacteria and genes (ARB/ARG),** before wastewater is released into municipal networks.

THERESA builds on previous insights from the Procure4Health OMC and introduces a more targeted, performance-based approach, focusing on real hospital needs and regulatory constraints, with the ultimate goal of reducing ecological and health-related risks through innovative, cost-effective technologies.

Key figures

- **Total budget:** €2.9 million.
- **PCP timeline: December 2025 – May 2029.**
- **Participating hospitals:** 9 reference sites across 5 countries *(Spain, Netherlands, Belgium, Estonia, Poland).*
- **Top priority contaminants:** Antibiotic residues, Cytostatics, ARB/ARG, X-ray contrast agents, Hormones.

PCP structure and phases

The PCP will follow a phased competitive approach to identify, test and validate the most promising solutions:

- **Phase 1: Solution Design**. Up to **5 contractors, 3 months.**
- **Phase 2: Prototype Development & Lab Testing**. Up to **3 contractors, 10 months.**
- **Phase 3: Field Validation in Hospitals**. **2 contractors, 10 months.**

All phases will include structured evaluations, based on harmonised Key Performance Indicators (KPIs), with increasing levels of technical and operational maturity.

Expectations

THERESA is seeking **pre-treatment solutions** that are **modular, interoperable, and adaptable** to a variety of hospital settings. Solutions should be capable of targeting at least one of the priority contaminant groups and must demonstrate **technical feasibility, cost-effectiveness and readiness for integration** into real-world infrastructures.

Rather than prescribing specific technologies, the tender will define a set of **functional requirements** to be met across different stages of the treatment cycle, from pollutant load management and risk reduction to automation, monitoring and compliance support. Suppliers may address one or multiple functions, and collaborative proposals involving complementary partners are strongly encouraged.

The focus is on enabling **smart, decentralised and future-proof systems** that can be implemented near the source (e.g. hospital departments), scaled over time, and easily maintained. THERESA is particularly interested in **solutions combining technological innovation with operational robustness**, with the potential to be adopted in hospitals of varying size, geography and resource availability.

It is desirable the potential non-potable water reuse in any way such as greenery watering, toilet flushing, car washing, etc.

Participation timeline

- **OMC period:** December 2025 – February 2026
- **Deadline to participate in the OMC: 24 February 2026**
- **Tender publication:** Q2 2026
- **Phase 1 start:** December 2026

Why participate?

By joining the THERESA OMC, suppliers will have the opportunity to **influence the final tender**, present their capabilities to a transnational buyers' group, and explore cross-sector partnerships. The PCP offers **fully funded R&D contracts**, real validation settings, and a path toward **early adoption by hospitals** in Europe.

THERESA is more than a procurement, it is a call to co-create the next generation of wastewater pre-treatment technologies for a cleaner, safer and more resilient health system.

2 Introduction

This document serves as a cornerstone in the THERESA Pre-Commercial Procurement (PCP) process. It defines the technological and functional challenges to be addressed by future suppliers, offering a framework for the design, development and validation of innovative on-site hospital wastewater treatment solutions.

It is intended as a reference guide for multiple stakeholders:

- Technology providers preparing for the Open Market Consultation (OMC) and upcoming tender phases
- Consortium members, including procurers and support entities, responsible for refining requirements and evaluating proposals
- External experts, auditors and policy advisors who may assess the alignment of the project with Horizon Europe objectives

The content has been structured to ensure technical clarity, traceability and consistency across all subsequent stages of the PCP, from the market consultation to tender preparation and solution evaluation.

In particular, this document:

- Defines the technical challenge to be solved through the THERESA PCP.
- Lists the priority contaminants and functional capabilities required.
- Establishes the non-functional, regulatory and operational scope.
- Provides a foundation for the THERESA OMC Questionnaire and bilateral dialogue during the OMC.
- Anticipates the evaluation criteria to be applied in Phases 1 to 3 of the PCP.

All definitions, codes and requirement identifiers will be used throughout the PCP lifecycle to ensure consistency and transparency.

3 The THERESA project

THERESA is a European PCP initiative designed to stimulate the development of **innovative, environmentally sustainable and high-performing technologies** for the on-site treatment of hospital wastewater (HWW). The project responds to a pressing environmental and public health challenge: hospitals generate complex wastewater streams containing pharmaceuticals, Antibiotic-resistant Bacteria (ARB), Antibiotic-resistant Genes (ARG), cytostatic drugs and contrast agents, many of which cannot be fully removed by conventional municipal wastewater treatment plants.

THERESA brings together a consortium of public procurers, affiliated entities and expert organisations to jointly steer the development and validation of breakthrough solutions. The treatment cycle is conceived as a **modular and integrated hospital wastewater pre-treatment system**, enabling deployment across diverse hospital settings. It focuses on targeted pre-treatment functions rather than full effluent treatment, with optional modules allowing decentralised implementation and scalable expansion. This flexible approach supports different functional needs while adapting to varied hospital contexts and evolving regulatory and environmental requirements, contribute to the fight against AntiMicrobial Resistance (AMR) and support the EU's Green Deal and zero-pollution objectives.

3.1 Context and rationale

Hospital wastewater contains a concentrated mixture of hazardous substances and biological agents originating from healthcare activities. Hospitals, however, are not wastewater treatment plants, and the objective is not to develop systems equivalent to standalone or decentralised wastewater treatment facilities. Instead, **the focus is on on-site, central or decentralised, pre-treatment solutions** designed to reduce the load of specific hazardous and emerging contaminants at source, prior to discharge into the urban sewer system. Conventional municipal wastewater treatment systems may have limitations in effectively addressing certain emerging contaminants, which can persist through treatment processes and ultimately reach surface and groundwater bodies. This challenge has gained increased regulatory relevance following the adoption of **Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment**, which introduces stricter requirements for the removal of a broader range of pollutants, including pharmaceuticals and other micropollutants. Hospitals act as hotspots for **ARB and ARG**, contributing to the spread of AMR.

Existing on-site pilots across Europe tend to remove only one group of pollutants at a time, rather than providing a holistic, integrated treatment. There is currently **no single process or technology** capable of removing the full spectrum of key contaminants in HWW with high efficiency. This technological gap (combined with the urgent policy drive to reduce pharmaceutical pollution) creates a strong rationale for launching a PCP to stimulate a new generation of integrated, sustainable and cost-effective technologies.

3.2 Objectives of THERESA PCP

The **main objective** of THERESA PCP is to develop a cost-efficient and environmentally sustainable solution capable of effectively removing key contaminants from hospital wastewater at source, including hazardous antibiotics, chemotherapeutic agents and contrast agents, before discharge into the municipal wastewater system.

The **specific objectives** are to:

- Promote the **competitive development** of market-ready solutions removing antibiotics, cytostatic drugs, contrast agents, ARB and ARG.
- Facilitate the entry of **European technology providers** into this emerging market through a joint cross-country procurement.
- Support the future **commercialisation and adoption** of integrated HWW treatment solutions.
- Strengthen environmental sustainability in healthcare.
- Solutions must significantly reduce the environmental footprint of hospitals, align with the EU Taxonomy "Do No Significant Harm" principle and support greener, circular and climate-neutral healthcare systems.

These support long-term European goals for environmental protection and health resilience.

3.3 The Public Buyers Group (PBG)

The THERESA Public Buyers Group (PBG) brings together seven public procurers representing diverse hospital environments, regulatory contexts and wastewater treatment challenges across Europe.

The PBG consists of:

- Fundación Miguel Servet (FMS), in name of Navarra University Hospital. Lead Procurer. Spain.
- Servicio Andaluz de Salud (SAS). Spain.
- Consorci Hospitalari de Vic (CHV). Spain.
- Academisch Ziekenhuis Maastricht (AZM). The Netherlands.
- Ziekenhuis Aan De Stroom (ZAS). Belgium.
- Põhja-Eesti Regionaalhaigla (PERH). Estonia.
- Wojewódzki Szpital Specjalistyczny W Olsztynie (WSS). Poland.

The PBG is supported by affiliated entities and competence partners that provide technical, legal, environmental and administrative expertise throughout the PCP preparation and execution.

4 What is a Pre-Commercial procurement (PCP)?

A Pre-Commercial Procurement (PCP) is an EU-recognised procurement approach that enables the PBG to purchase research and development (R&D) services to stimulate the creation of innovative solutions that are not yet available on the market. PCP focuses on early-stage innovation and supports suppliers in designing, prototyping and validating breakthrough technologies.

PCP is characterised 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 the 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: prototyping and lab testing, Phase 3: original development, installation, wider field testing and validation of a limited set of 'first' products or services).

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, 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 structure[2].

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.

All communication (before, during and after the procurement) will normally be carried out in English.

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

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. Suppliers bear the development risk but retain ownership of the resulting IPR, while procurers benefit from competitive pricing during the PCP and may, where applicable, negotiate favourable conditions such as royalties or access rights to the final solutions developed.

The contractors also retain ownership of their background rights (albeit subject to certain rights of use by the procurers, see chapter 8)[3].

[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.

[3] For more information, see PCP on the Europa website

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

PCPs 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)[4].

They are also exempted from the WTO GPA because this Agreement does not cover R&D services[5] (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).

PCPs do not constitute state aid under the EU state aid rules[6] if they are implemented as defined in the PCP communication[7], 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.

Why PCP?

THERESA requires integrated, high-performance solutions capable of removing a complex mix of contaminants from hospital wastewater. These solutions do not exist on the market today. PCP enables suppliers to propose innovative combinations of technologies and validate them progressively under real conditions.

The PCP model is the most suitable approach for the THERESA challenge because:

- The required solution **does not yet exist on the market**, nor is it close to market-ready.
- Significant **R&D effort** is needed to combine and enhance multiple treatment technologies.
- Procurers must work closely with suppliers to validate feasibility and performance.
- The development pathway involves technical risk, which PCP mitigates through phased competitive development.

THERESA PCP will follow a **phased competitive structure** with decreasing numbers of suppliers: up to 5 in Phase 1, 3 in Phase 2, and 2 in Phase 3.

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[4] 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.

[5] See the EU's Annex IV of Appendix I to the WTO GPA.

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

[7] 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).

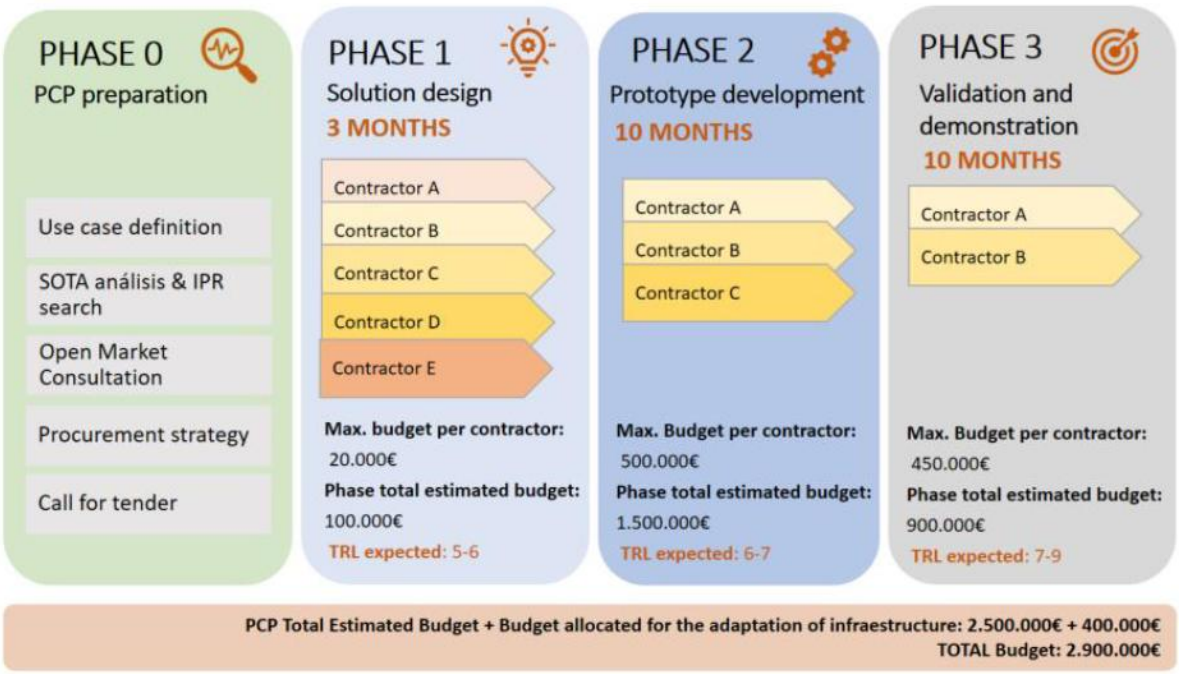

Figure 1. Theresa PCP´s phases

PCP is a **risk–benefit sharing model**, allowing suppliers to retain IPR in exchange for reduced R&D prices.

The integration of **ISO 14034 Environmental Technology Verification (ETV)** enables the independent validation of technical and environmental performance. Suppliers established in countries not eligible for Horizon Europe Innovation Actions may join consortia as subcontractors but cannot participate independently in the PCP.

Ultimately, PCP ensures a fair, transparent and innovation-friendly process while reducing technological and financial risks for both procurers and suppliers.

Legal and procedural aspects

Pre-Commercial Procurement (PCP) is exempted from the EU public procurement directives **under the conditions defined in the European Commission PCP framework**, as it concerns the procurement of research and development (R&D) services carried out under market conditions and allows participating suppliers to retain ownership of intellectual property rights. Nevertheless, PCP must be implemented through open, transparent and non-discriminatory procedures and must remain clearly separated from any subsequent commercial procurement phase.

In accordance with **Directive 2014/24/EU, Article 40**, and **Directive 2014/25/EU, Article 58**, contracting authorities and contracting entities may, prior to launching a procurement procedure, conduct preliminary market consultations, commonly referred to as Open Market Consultations (OMC), in order to prepare the procurement and inform economic operators of their plans and requirements. For this purpose, they may seek or accept advice from independent experts, authorities or market participants, provided that such consultations do not distort

competition or lead to a breach of the principles of transparency, equal treatment and non-discrimination.

PCP is further governed by the European Commission Communication *"Pre-commercial Procurement: Driving innovation to ensure sustainable, high-quality public services in Europe"* (COM (2007) 799), which establishes the strategic and legal framework for PCP as an instrument to stimulate innovation while ensuring fair competition and compliance with State aid rules.

In addition, PCP actions supported under Horizon Europe are expected to comply with the relevant requirements and guidance applicable to PCP and PPI instruments, including those set out in **Annex H of the Horizon Europe Work Programme 2023–2027** and in the guidance document *"How to set up and manage Horizon Europe PCP and PPI grants"*. These documents outline the conditions for eligibility, implementation and governance of PCP actions, as well as the required separation between PCP and any subsequent Public Procurement of Innovative Solutions (PPI).

This section is provided for information purposes only and does not replace or anticipate the provisions of the future PCP tender documentation.

Expected outcomes

By the end of the THERESA Pre-Commercial Procurement, the PBG expects to achieve the following outcomes:

- **Validated integrated solutions** for on-site hospital wastewater pre-treatment, capable of addressing priority contaminants under real hospital conditions.
- **Robust performance evidence**, generated through laboratory testing and field validation, supporting future procurement decisions and regulatory dialogue.
- **Improved market readiness** of innovative technologies, enabling suppliers to progress towards commercialization and wider deployment across Europe.
- **Replicable technical and operational models**, demonstrating how modular and decentralized treatment approaches can be integrated into diverse hospital environments.
- **Reduced technological and investment risk** for future adopters, through early-stage validation, benchmarking and comparative assessment of competing solutions.

These outcomes will provide a solid foundation for potential follow-up procurement actions and contribute to advancing environmentally sustainable and resilient wastewater management practices in the healthcare sector.

5 The Open Market Consultation (OMC)

The OMC is **a structured dialogue between the THERESA PBG and the market**, conducted in accordance with the **Directive 2014/24/EU, Article 40.**

Its purpose is to validate technical requirements, assess innovation readiness, and gather feedback from technology providers, research organisations, utilities, and other relevant stakeholders before the launch of the THERESA PCP. The OMC **ensures that procurement specifications reflect real market capabilities** and that potential suppliers clearly understand the challenge THERESA aims to address.

5.1 Objective and scope of the OMC

The THERESA OMC supports the preparation of a PCP that **seeks breakthrough solutions for on-site treatment of HWW**, targeting contaminants of emerging concern such as cytostatic drugs, antibiotics, contrast agents, antimicrobial-resistant bacteria (ARB), antimicrobial resistance genes (ARG), and other hazardous substances.

The consultation runs from 22 December 2025 to 28 February 2026, following publication of the Prior Information Notice (PIN). During this period, market operators can participate in multiple activities designed to:

- Validate findings from the State-of-the-Art (SOTA) analysis.
- Confirm the feasibility of preliminary technical and functional requirements.
- Identify potential risks, barriers, and innovation opportunities.
- Refine procurement conditions before tender publication.
- Facilitate early networking and consortium building among suppliers.

The OMC is not part of any pre-qualification or selection process, and participation does not confer any advantage in the future PCP. All contributions are voluntary, non-binding, and treated in accordance with the principles of equal treatment, transparency and confidentiality.

5.2 The role of the OMC in THERESA PCP

The Open Market Consultation is a central element of the preparatory phase, helping to:

- Verify that the proposed challenge is realistic and achievable.
- Validate and refine the functional and technical requirements.
- Identify state-of-the-art solutions, gaps and innovation potential.
- Build awareness and interest among European suppliers.
- Feed into the preparation of the tender specifications.

The OMC also facilitates early networking, consortium-building and dialogue with suppliers, ensuring that the future PCP tender is well aligned with market capabilities and that the technologies developed in THERESA truly address the needs of the PBG.

5.3 Who can participate in the OMC?

Participation is open to all organisations with an interest in the wastewater treatment, environmental technology, digital monitoring, automation, sensing, or hospital infrastructure sectors. This includes, but is not limited to:

- Technology providers (SMEs, large industry, start-ups).
- Research institutions and universities.
- Environmental and water-sector organisations.
- Hospitals, utilities, and wastewater authorities.
- Intermediaries supporting innovation procurement.

Additionally, companies from any sector of activity are welcome to participate, provided they offer technologies or solutions that could contribute to addressing the challenge identified by the procurers.

Participation in the OMC is cost-free and entirely voluntary.

How to prepare for the OMC

Before taking part in any OMC activity, suppliers are encouraged to:

- **Review the THERESA challenge and requirements**.
- **Gain familiarity with PCP procedures**, including phased competition, risk-benefit sharing, and IPR principles.
- **Identify internally which contaminants and functionalities** their technologies may address.
- **Assess readiness levels (TRLs)** of their solutions or R&D pipelines. As described in the **Commission Decision C(2014)4995**, where a topic description refers to a TRL, the following definitions apply, unless otherwise specified:
    - TRL 1 – basic principles observed.
    - TRL 2 – technology concept formulated.
    - TRL 3 – experimental proof of concept.
    - TRL 4 – technology validated in lab.
    - TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies).
    - TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).
    - TRL 7 – system prototype demonstration in operational environment.
    - TRL 8 – system complete and qualified.
    - TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).

- **Determine whether they wish to form or join a consortium** for the future PCP phases.
- **Register via the THERESA website**, which provides access to webinars, documentation, THERESA OMC Questionnaire, matchmaking tool and Q&A.

Suppliers may share information through the various OMC channels:

- THERESA OMC Questionnaire.
- Pitching in OMC events.
- Bilateral meetings.

5.4 OMC rules and process

- The OMC process is governed by the following principles:
- **Transparency**: All non-confidential questions and answers are published through the Q&A repository.
- **Equal Treatment**: No supplier receives privileged information; responses in bilateral meetings are also anonymised and published.
- **Voluntary Participation**: Engagement in any OMC activity is optional and confers no preference in the later PCP.
- **Applicable Law**: The OMC is conducted under Navarra Foral Law, as the Lead Procurer is Fundación Miguel Servet – Hospital Universitario de Navarra (FMS). The PCP tender will follow Horizon Europe rules, and the OMC must not restrict competition.
- **Confidentiality**: Confidential information may be shared –under conditions- during bilateral meetings but will be acronymised and compiled in the public OMC report.

THERESA OMC Questionnaire responses must not contain confidential information unless it is clearly labelled as such. Any information marked as confidential will be handled accordingly and will not be disclosed.

5.5 After the OMC

Once the OMC **closes on 28 February 2026**, suppliers can follow the progress of THERESA PCP through:

- The **THERESA OMC Summary Report** once published with the findings of the OMC.
- Monitor announcements regarding the **PCP Contract Notice** (expected May 2026).
- Begin preparing for **Phase 1 proposal submission**, including consortium setup and work planning.
- And our social media which will inform of any relevant news related to THERESA PCP.

6 OMC activities and agenda.

The OMC comprises a coordinated sequence of activities between December 2025 and February 2026, including online events, bilateral interviews, a THERESA OMC Questionnaire, and continuous Q&A support.

All suppliers may freely access the information published during the OMC. **Participation in interactive OMC activities such as the pitches, matchmaking tool and bilateral meetings require the completion of the questionaire.**

Participation is **free of charge**, voluntary and does not influence eligibility or evaluation in the upcoming tender.

Key dates include:

- **31 Oct 2025 –** Publication of PIN and dissemination campaign start.
- **22 Dec 2025 –** Publication of final OMC documentation and official start of the OMC.
- **8–26 Jan 2026 –** National webinars (Spain, Estonia, Poland, Belgium, the Netherlands).
- **24 Feb 2026 –** THERESA OMC Questionnaire submission deadline (17:00 CET).
- **6–24 Feb 2026 –** Bilateral interviews.
- **26 Feb 2026 –** Final OMC findings webinar.
- **28 Feb 2026 –** OMC closes; final Q&A updates published.
- **15 March 2026 –** Publication of the THERESA OMC Summary Report.

6.1 OMC events

Six online events hosted by Spain, Estonia, Poland, Belgium, the Netherlands. Each session combines THERESA project presentations, PCP explanations, national context and company pitches. Online events cover technical, regulatory, procurement and exploitation perspectives.

The Parties interested in participating in the OMC activities can register through:

THERESA website: https://theresa-pcp.eu.

Suppliers wishing **to pitch** during any online event **must indicate this in the THERESA OMC questionnaire**. Slots may be allocated on a first-come, first-served basis while ensuring diversity of technological approaches based on the information provided in the survey.

Date	Focus	Topics
Jan 8	Spain + Global Overview	PCP introduction, THERESA challenge, Spanish hospital context

Jan 13	Estonia + PCP Basics	THERESA challenge. How PCP works, IP rights, Dutch hospital context
Jan 19	Poland + Technical Requirements	THERESA challenge. SOTA analysis, performance targets, Estonian hospital context
Jan 23	Belgium + Legal Framework	THERESA challenge. Regulations, data protection, Belgian hospital context
Jan 26	The Netherlands + Validation	THERESA challenge. Testing methods, commercialization, Polish hospital context
Feb 26	Final Wrap-Up	Summary of findings, next steps

Table 1. Online events

The online events held within the framework of the OMC **will be recorded and published on the project's website.** Activating a camera or microphone during the webinars will be understood as providing consent to be recorded. Participants who do not wish their voice or image to be recorded may submit questions through the chat function. The THERESA Consortium will use these recordings solely for the purposes of the project. The list of participants will not be distributed.

In addition, photographs may be taken during the meetings. These images will be used by the THERESA Consortium exclusively for project-related purposes.

6.2 Engaging mechanisms

The OMC also offers multiple touchpoints for suppliers to understand the THERESA challenge and engage with procurers. The activities are detailed below:

Company pitch sessions

Company pitch sessions are short, **five-minute presentations** delivered by suppliers during the national webinars to showcase technologies, concepts or ongoing research.

These pitches provide visibility, support early networking and consortium-building, and help procurers understand the diversity of potential approaches. Slots are allocated on a first-come, first-served basis while ensuring a balanced representation of solutions.

Suppliers wishing **to pitch** during any online event must indicate this in the THERESA OMC questionnaire.

THRERESA OMC questionnaire

The **THERESA OMC questionnaire**, published on 22 December 2025 and closing on 24 February 2026, is a central tool for collecting structured market intelligence. It enables suppliers to:

- Provide technical details on their existing solutions and R&D pipelines.
- Identify which priority contaminants and functionalities they can address.
- Comment on feasibility, innovation challenges and expected development timelines.
- Highlight regulatory barriers or interoperability issues.
- Suggest improvements to the draft PCP specifications.

All inputs will be anonymised and aggregated for internal analysis and for the public OMC report. The THERESA OMC questionnaire responses must not contain confidential information unless it is clearly labelled as such. Any information marked as confidential will be handled accordingly and will not be disclosed.

Full link: https://ec.europa.eu/eusurvey/runner/THERESAOMCSurvey.

Q&A Repository

This platform enables interested parties to submit questions related to the THERESA PCP OMC and to receive clarifications from the consortium. New Q&A updates are published approximately every 14 days, and users are encouraged to check the platform regularly: https://theresa-pcp.eu/frequently-asked-questions/.

Matchmaking platform

The THERESA challenge is **complex and multidisciplinary**. No single company may have all capabilities. The **matchmaking platform** is an online tool to find consortium partners for the future THERESA PCP tender.

Suppliers might need partners for:

- Complementary treatment technologies (e.g., one supplier does filtration, other partner does oxidation).
- Monitoring and sensor systems.
- Civil engineering and installation.
- Software and data analytics.
- Regulatory compliance expertise.
- Different geographic coverage.

Within this platform, suppliers may create a short organisational profile and describe their expertise, enabling other participants to identify relevant complementarities. Suppliers may also assign predefined tags to their profiles to indicate their technological focus, capabilities or areas of interest, thereby improving visibility and supporting the formation of balanced and competitive consortia.

The set of functional labels to be used in the THERESA OMC for supplier self-identification:

1. Challenge-oriented functional labels		
Label	**Title**	**Formal definition**

C-LOAD-MANAGEMENT	Pollutant/hydraulic load management	Contribution to managing the incoming pollutant/hydraulic load to ensure treatment stability
C-TARGETED-CHALLENGE	Addresses specific contaminant groups	Ability to address the contaminant groups prioritised in THERESA, regardless of method
C-QUALITY-IMPROVEMENT	Water quality improvement	Contribution to improving water quality at any point in the treatment chain.
C-RISK-REDUCTION	Environmental or health-related risks reduction	Contribution to reducing operational, environmental or health-related risks in wastewater handling and treatment.
C-SYSTEM-RESILIENCE	Robustness under variable operating conditions	Contribution to increasing robustness under variable or challenging operating conditions.
C-COMPLIANCE-SUPPORT	Supports regulatory compliance	Contribution to enabling or facilitating compliance with relevant environmental, regulatory or operational requirements.
2. System-enabling functional labels		
Label	**Title**	**Formal definition**
E-MONITORING-CAPABILITY	Monitoring or data provision function	Contribution to generating operational, environmental or performance-related data to support system monitoring and decision-making.
E-CONTROL-AUTOMATION	Control, automation or coordination function	Contribution to supporting safe, stable or optimised system operation through control logic, automation or coordination.
E-SYSTEM-INTEGRATION	Supports interoperability between components	Contribution to facilitating interoperability, interfacing or harmonisation between components or subsystems in a multi-provider solution.
3. Role labels		
Label	**Name**	**Formal definition**
R-COORDINATOR	Coordinator	The supplier is willing and capable to act as consortium coordinator, leading technical and organisational aspects. This is non-binding.
R-PARTNER	Partner	The supplier prefers to participate as a consortium partner, contributing specific functional capabilities without coordinating.
R-BOTH	Coordinator or Partner	The supplier is open to either role depending on consortium composition and complementarity.

Table 2. Matchmaking platform functional labels

The matchmaking platform will be available through the THERESA website: https://theresa-pcp.eu/

Bilateral meetings

Suppliers may request bilateral meetings through the THERESA OMC questionnaire, which will be organised between 6–24 February 2026, ensuring transparency, equal treatment and fair competition. Procedure for the bilateral meetings is described in Annex VI.

All relevant details and clarifications shared by the buyers' groups during the bilateral meetings will be **summarised in an anonymised and non-confidential manner** and published in the **Q&A section of the project website**, in order to ensure transparency and equal access to information for all interested economic operators.

How market feedback will be used

Information gathered through online events, the THERESA OMC questionnaire pitch sessions, Q&A interactions and bilateral interviews will inform:

- Refinement of technical and functional requirements in the PCP tender.
- Refinement of feasibility assessments for removing priority contaminants.
- Refinement of testing conditions for the pilot sites.
- Refinement of time and budget distribution per phase, ensuring alignment with market capabilities and innovation maturity.
- Improvement of procurement documents, including risk-sharing, IPR and contractual provisions.

Market feedback plays a decisive role in ensuring that the PCP tender is well aligned with innovation potential and real-world constraints. OMC findings will be published in the THERESA OMC Summary Report after the OMC ends.

6.3 Next steps in the PCP procedure

Following the conclusion of the OMC on 28 February 2026, the THERESA Consortium will:

1. **Analyse THERESA OMC questionnaire data, webinar insights** and **bilateral meetings** to update requirements and KPIs.
2. **Publish the THERESA OMC Summary Report**, highlighting key messages and market readiness.
3. **Finalise the tender documentation**, incorporating validated requirements and market feedback.
4. **Prepare PCP contract templates**, criteria and instructions for suppliers.
5. **Launch the PCP Contract Notice** (expected May 2026), opening competition for Phase 1.
6. **Begin Phase 1 (Solution Design)** in early 2027, following evaluation and contracting.

These steps ensure continuity from market consultation to procurement execution, maintaining transparency and compliance with Horizon Europe PCP rules.

7 Definition of the challenge and required functionalities

THERESA PCP addresses the critical need to remove a wide spectrum of contaminants present in hospital wastewater. These contaminants include pharmaceuticals, cytostatics, antibiotic residues, contrast agents, antimicrobial-resistant bacteria (ARB) and antimicrobial-resistant genes (ARG). The **PBG** has carried out a thorough refinement of the functional and technical requirements, resulting in an initial shortlist of **priority contaminants** that future PCP solutions must be capable of addressing. This section summarises the AS IS / TO BE situation, the specific priority contaminant groups, and the required functional capabilities to be validated through the PCP phases.

7.1 The current situation (AS IS)

HWW contains a complex mixture of hazardous chemicals, pharmaceuticals, pathogens and antimicrobial-resistant microorganisms. Current treatment systems are unable to:

- Remove many cytostatic drugs and their metabolites.
- Remove persistent X-ray contrast agents (iodinated or gadolinium-based).
- Address the diversity of antibiotic families used in acute care settings.
- Control ARB/ARG spread at the source.
- Ensure stable operation under high loads of disinfectants and chemical reagents.

This leads to uncontrolled emissions of micro-pollutants into surface waters and urban wastewater treatment plants, posing environmental, ecological and human health risks.

7.2 Desired situation (TO BE)

A new generation of integrated on-site treatment solutions is needed. These solutions should:

- Efficiently remove priority contaminants at the hospital before discharge.
- Reduce the environmental risks associated with ARB/ARG spread.
- Enable compliance with current and emerging regulatory expectations for micro-pollutant removal.
- Reduce operational burdens for hospitals and allow stable, automated performance.
- Offer future potential for safe non-potable water reuse.

7.3 Detailed functional requirements and priority contaminants

The PBG has shortlisted priority contaminants and functional capabilities that PCP solutions must be able to significantly remove, inactivate or provide. To facilitate cross-references throughout this document (and later in the tender and the THERESA OMC questionnaire, each requirement is given a unique identifier.

Priority cytostatics

ID	ATC Code	Active substance	Pharmacological group/mode of action	Route	Priority
C-CYT-01	L01AA01	Ifosfamide	Alkylating agent	IV	High
C-CYT-02	L01AX03	Temozolomide	Alkylating agent	Oral	High
C-CYT-03	L01AA01	Cyclophosphamide	Alkylating agent	Oral / IV	High
C-CYT-04	L02BB04	Enzalutamide	Androgen receptor antagonist	Oral	High
C-CYT-05	L01BC02	Fluorouracil	Antimetabolite	IV	High
C-CYT-06	L01BA01	Methotrexate	Antimetabolite	Oral / IV	High
C-CYT-07	L02BX03	Abiraterone	Steroid hormone synthesis inhibitor	Oral	High
C-CYT-08	L04AA06	Mycophenolate	Immunosuppressant, anti-proliferative	Oral	High
C-CYT-09	L01XA01	Cisplatin	Platinum-containing agent	IV	High
C-CYT-10	L01XA02	Carboplatin	Platinum-containing agent	IV	High
C-CYT-11	L01XA03	Oxaliplatin	Platinum-containing agent	IV	High
C-CYT-12	L01BC01	Cytarabine	Antimetabolite	IV	High
C-CYT-13	L01BC05	Gemcitabine	Antimetabolite	IV	High
C-CYT-14	L01XX05	Hydroxycarbamide	Antimetabolite	Oral	High
C-CYT-15	L01BC06	Capecitabine	Antimetabolite (prodrug of fluorouracil)	Oral	High
C-CYT-16	L01EX02	Sorafenib	Kinase inhibitor (BRAF–VEGFR)	Oral	High
C-CYT-17	L01EM03	Alpelisib	PI3-kinase inhibitor	Oral	High

C-CYT-18	L01ED03	Alectinib	Tyrosine kinase inhibitor (ALK)	Oral	High

Table 3. Cytostatic contaminants (high-priority shortlist)

Note: Additional medium-priority cytostatics may be added at a later stage (IDs C-CYT-19+), following ongoing discussions by the buyers' group.

X-ray contrast agents

Rather than fixing a single molecule, the THERESA PCP will require coverage of **at least one CT and one MRI contrast agent**. For reference, the following agents have been most frequently prioritised by the PGB.

ID	Modality	Active substance	Description / note	Priority
C-CTA-01	CT	Iopromide	Iodinated X-ray contrast agent	High
C-CTA-02	CT	Iohexol	Iodinated X-ray contrast agent	High
C-CTA-03	MRI	Gadobutrol	Gadolinium-based MRI contrast agent	High

Table 4. Representative X-ray contrast agents

Antibiotic families

Solutions should target a broad range of antibiotic families due to their prevalence and their contribution to AMR. The PCP will focus on the ATC groups listed below.

ID	ATC Code	Sub-group description	Priority / WHO category
C-AB-01	J01CA	Penicillins with extended spectrum	High – WHO high/medium group
C-AB-02	J01CE	Beta-lactamase-sensitive penicillins	High – WHO high/medium group
C-AB-03	J01CF	Beta-lactamase-resistant penicillins	High – WHO high/medium group
C-AB-04	J01CR	Combinations incl. beta-lactamase inhibitors	High – WHO high/medium group
C-AB-05	J01DD	3rd-generation cephalosporins	High – WHO critical group
C-AB-06	J01DH	Carbapenems	High – WHO critical group
C-AB-07	J01FA	Macrolides	High – WHO high/medium group
C-AB-08	J01MA	Fluoroquinolones	High – WHO high/medium group

C-AB-09	J01XA	Glycopeptide antibacterials	High – WHO high/medium group

Table 5. Priority antibiotic groups

Antimicrobial-resistant bacteria (ARB) and genes (ARG)

ID	Target organism / phenotype	Description
C-ARB-01	Carbapenem-resistant Enterobacterales	CR-Enterobacterales
C-ARB-02	3rd-generation cephalosporin-resistant Enterobacterales	3GC-resistant Enterobacterales
C-ARB-03	Carbapenem-resistant *Acinetobacter baumannii*	CR-*A. baumannii*

Table 6. Priority ARB

ID	Gene group	Description / Examples
C-ARG-01	blaKPCgr	KPC carbapenemase genes
C-ARG-02	blaVIMgr	VIM carbapenemase genes
C-ARG-03	blaNDMgr	NDM carbapenemase genes
C-ARG-04	blaIMPgr	IMP carbapenemase genes
C-ARG-05	blaOXA-48gr	OXA-48-like carbapenemase genes
C-ARG-06	blaCTX-M-1gr	CTX-M-1 extended-spectrum beta-lactamase genes
C-ARG-07	blaCTX-M-9gr	CTX-M-9 extended-spectrum beta-lactamase genes
C-ARG-08	blaCTX-M-2gr	CTX-M-2 extended-spectrum beta-lactamase genes
C-ARG-09	blaCTX-M-25gr	CTX-M-25 extended-spectrum beta-lactamase genes
C-ARG-10	blaSHV-ESBL	SHV ESBL variants (e.g. SHV-2, SHV-5)
C-ARG-11	blaDHA-AmpC	DHA AmpC beta-lactamase genes
C-ARG-12	blaCMY-AmpC	CMY AmpC beta-lactamase genes

Table 7. Priority ARG

Functional capabilities of the THERESA solutions

In addition to targeting the specific contaminant groups above, PCP solutions must provide a set of **functional capabilities**. These will be used later to define evaluation criteria and to align with the THERESA OMC questions.

ID	Functional requirement
F-FUN-01	Centralise and safely channel hospital wastewater into a controlled treatment line.
F-FUN-02	Separate and/or treat highly soluble reagents (e.g. sodium azide) and other hazardous chemicals.
F-FUN-03	Remove large solid debris and coarse materials from the wastewater.

F-FUN-04	Operate stably under high concentrations of disinfectants and cleaning agents.
F-FUN-05	Treat persistent organic pollutants, including pharmaceuticals and cytostatics.
F-FUN-06	Achieve required wastewater discharge standards through effective disinfection.
F-FUN-07	Reduce nutrient concentrations (e.g. nitrogen and phosphorus).
F-FUN-08	Provide advanced treatment for hospital wastewater streams.
F-FUN-09	Manage and handle any sludge generated in a safe and sustainable way.
F-FUN-10	Integrate monitoring devices and sensors (pH, temperature, DO, pollutants, etc.).
F-FUN-11	Include odour control measures.
F-FUN-12	Where permitted, enable non-potable reuse of treated HWW within the hospital (e.g. irrigation, toilet flushing, cooling towers).

Table 8. Functional capability requirements

7.4 Non-functional requirements

These requirements are tentative.

Social requirements

1. Ensure worker safety and exposure control, minimising risks related to chemicals.
2. Take into consideration operational workload and training opportunities, and if additional skilled staff are required.
3. Ensure social acceptability in hospital settings, including:
    a. Low noise levels during normal operation and maintenance,
    b. Minimal or no odour emissions,
    c. A compact and space-saving physical footprint
4. Comply with responsible business conduct and human rights standards, including applicable EU labour and procurement regulations and internationally recognised frameworks (e.g. ILO Core Labour Standards, UN Guiding Principles on Business and Human Rights).
    a. This includes due consideration of human rights and labour risks linked to activities, sourcing, or manufacturing in high-risk or conflict-affected contexts.
5. Support gender inclusive design, operation and training.

Environmental & sustainability requirements (life cycle assessment perspective)

Solutions should be designed to minimise environmental impacts and avoid burden shifting, and should:

1. Demonstrate low environmental intensity, including reduced energy use, limited chemical/reagent consumption, and minimal waste generation;
2. Minimise greenhouse gas emissions, either through low GHG intensity or through transparent reporting of energy use and electricity assumptions;
3. Minimise material and resource use across the life cycle, and, where feasible, enable reuse or recycling of key components;
4. Avoid secondary pollution, including the formation of hazardous treatment by-products;
5. Optimise electricity consumption and water losses during normal operation;
6. Facilitate any potential for water recovery or reuse, where technically and legally feasible.

Reliability and operational stability requirements

1. Operate reliably under **variable influent loads**, contaminant concentrations, pH, temperature, and organic matter fluctuations,
2. Maintain stable performance without frequent recalibration or manual intervention,
3. Include fail-safe behaviours, alarms, and recovery mechanisms.

Safety & risk management requirements

1. Comply with health and **safety standards** for hospital staff, operators, and maintenance personnel,
2. Minimise risks associated with toxic by-products, chemicals, pathogens or aerosols,
3. Implement containment, shielding, or inactivation mechanisms as required.

Scalability & adaptability requirements

1. Be adaptable to different hospital sizes, specialisations, and wastewater profiles,
2. Offer modularity for scaling up or down,
3. Allow integration with existing sewer systems and future upgrades.
4. Allow integration with existing Hospital IT systems and future upgrades.

Maintainability & serviceability requirements

1. Require limited and predictable maintenance,
2. Allow easy access for inspection, replacement of parts, and repair,
3. Provide digital maintenance logs and clear O&M instructions.

Footprint & spatial requirements

1. Minimise required space and allow flexible placement (e.g., basement, container unit),
2. Not interfere with clinical pathways or utility flows.

7.5 Constraints and boundary conditions

The following entities are the hospitals participating in the project:

Representative entity (if any)	Acronym	Hospital	Acronym	Country	Acronym
Fundación Miguel Servet	FMS	Hospital Universitario de Navarra	HUN	Spain	ES
Fundación Miguel Servet	FMS	Clínica Ubarmin	CU	Spain	ES
Fundación Miguel Servet	FMS	Hospital Vigen del Camino	HVC	Spain	ES
Servicio Andaluz de Salud	SAS	Hospital Universitario Virgen Macarena	HUVM	Spain	ES
		Consorci Hospitalari de Vic	CHV	Spain	ES
		Maastricht University Medical Center+	AZM	The Netherlands	NL
		Ziekenhuis Aan De Stroom	ZAS	Belgium	BE
		Põhja-Eesti Regionaalhaigla	PERH	Estonia	EE
		Wojewódzki Szpital Specjalistyczny W Olsztynie	WSS	Poland	PL

Table 9. Participating Hospitals

Physical Infrastructure Constraints	
Space Availability • Most hospitals prefer **outdoor installation**, except where not allowed. • Indoor space is generally **very limited** (especially PERH and AZM).	**Access Constraints** Critical across hospitals: • Delivery and installation must avoid blocking: • Emergency routes (AZM). • Patient transfer zones. • Residential areas (HUN).
Modularity Needs • Most agree modularity is beneficial. • CHV does **not require** modularity. • PERH emphasises modularity as a **strong advantage**.	**Utilities** • All hospitals have: • Sewer connection. • Water supply. • Electrical systems (though may be limited or require cabling over. long distances, e.g., HUN).
Common Limitations • Almost no direct wastewater monitoring. • Very limited wastewater segregation. • Space constraints, especially indoors. • Strict noise and safety requirements. • Need for real-time alarms but restricted remote access (cybersecurity). • Handling solids remains a major operational challenge.	

Table 10. Hospital Infrastructure and Deployment Constraints

7.6 Verification and validation

Verification and validation approach (OMC version)

The THERESA Pre-Commercial Procurement will apply a structured verification and validation approach across the different PCP phases in order to assess the performance, robustness and suitability of proposed solutions. This section provides potential bidders with an overview of the envisaged evaluation logic. Detailed requirements, KPIs, methods and procedures will be defined and published upfront in the PCP tender documentation.

Verification refers to the generation of objective and reliable evidence on the performance achieved by a solution under stated conditions of application. In the THERESA PCP context, verification focuses on the characterisation of technical, functional and environmental performance parameters, enabling comparison and benchmarking of competing solutions. Verification does not constitute a conformity assessment or pass/fail judgement, but supports informed decision-making by the PBG.

Validation refers to the assessment of whether a solution is fit for its intended use in practice. It considers performance in context, including operational feasibility, integration into hospital environments and the ability to deliver the expected technical, environmental and operational outcomes under real or representative conditions.

PCP Phase 2 – Prototype verification

During Phase 2, participating suppliers are expected to develop and test prototype solutions under controlled conditions. Verification activities will focus on assessing compliance with the defined technical, functional and non-functional requirements, based on a common set of Key Performance Indicators (KPIs) and harmonised test procedures.

For planning purposes, prototype testing and verification activities are currently envisaged to take place at facilities associated with members of the PBG, including hospital sites in Spain (SAS/FPS and CHV). These sites are **indicative and subject to confirmation**, and are intended to provide controlled testing environments representative of hospital wastewater conditions.

Phase 2 verification aims to generate comparable and objective performance evidence across competing solutions, covering aspects such as treatment efficiency, operational stability, safety and environmental performance, and to reduce technological risks prior to any field validation activities.

PCP Phase 3 – Field validation

In Phase 3, a limited number of solutions are expected to undergo field validation in real hospital operational environments across different European contexts. Field validation will assess technical performance, operational robustness, usability and environmental effectiveness under realistic conditions, taking into account user needs and site-specific constraints.

For planning purposes, field validation activities are currently envisaged to take place at hospital sites associated with members of the PBG, including facilities in Spain (FMS), the Netherlands (AZM), Estonia (PERH) and Poland (WSS). These sites are **indicative and subject to confirmation**, and may be adjusted depending on operational feasibility and the final configuration of the PCP.

Further details regarding testing arrangements, validation protocols, performance criteria and verification methods will be defined and communicated in the PCP tender documentation.

8 Intellectual property rights (IPR)

This section outlines the tentative IPR model expected to guide the THERESA PCP. The purpose of presenting a clear IPR framework at the OMC stage is twofold: (1) to provide early visibility and predictability for suppliers regarding ownership and exploitation principles, and (2) to collect industry input on the feasibility, market attractiveness, and possible refinements to maximise participation and innovation impact.

8.1 General principles

The THERESA PCP will apply an IPR model that balances innovation incentives for suppliers with fair access to results for public procurers. The model operates under the following principles:

- Suppliers retain **ownership of the IPR generated** during the PCP phases (Foreground IP), **as well as full ownership of any pre-existing intellectual property, technologies or know-how (Background IP)** contributed to the project
- **Public procurers receive usage rights** allowing them to evaluate, test and operate the solutions developed under the PCP.
- **Ownership does not transfer**, but procurers benefit from preferential conditions when acquiring further deployments.
- **Risk–benefit sharing applies**: suppliers bear the development risk but retain ownership of the resulting IPR, while procurers benefit from competitive pricing during the PCP and may, where applicable, negotiate favourable conditions such as royalties or access rights to the final solutions developed.

As part of the **OMC**, suppliers will be invited to provide feedback on this proposed IPR approach, including:

- Potential barriers or risks.
- Alternative mechanisms or refinements that could improve market participation.

The questions included in the survey regarding IPR are entirely exploratory and non-binding. Their purpose is to gather structured feedback from potential suppliers on the feasibility and attractiveness of different IPR approaches. The insights collected during the OMC will inform the final strategy adopted in the PCP tender, with the aim of ensuring a balanced framework that fosters innovation, encourages broad market participation, and safeguards long-term public value. This dialogue with industry is essential to designing a PCP that is both competitive and appealing to innovative suppliers, while contributing to the development of a robust and sustainable innovation ecosystem.

9 Execution of the THERESA PCP

9.1 Overall timeline

The PCP procedure will follow the sequence below:

- May 2026 - Publication of the THERESA PCP Request for Tender.
- September 2026 - Deadline for submission of tenders.
- December 2026 - Publication of the Contract Award Notice in TED.
- January 2027 - Start of PCP Phase 1 (Solution Design).

9.2 PCP phases and duration

The THERESA PCP is organised into three sequential phases. Each phase represents an increasingly advanced level of technological development and testing. Following the evaluation of phase deliverables, only the highest-performing contractors will be invited to continue to the next phase. The structure of the PCP phases is summarised below.

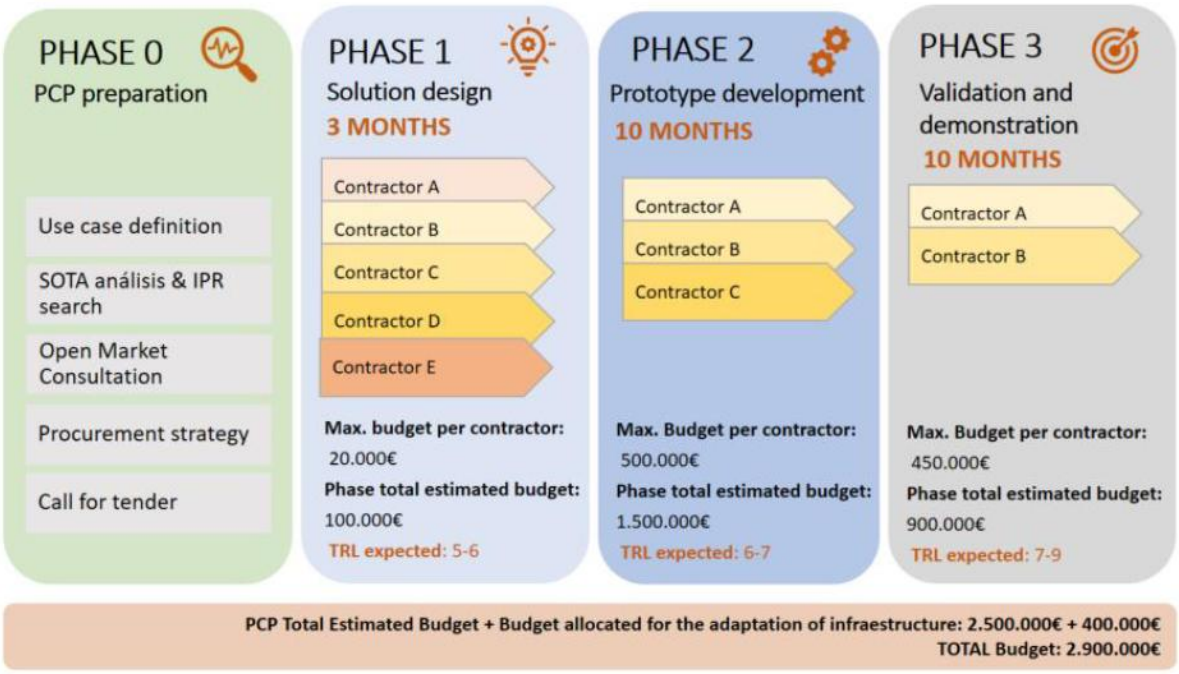

Figure 2. THERESA PCP´s phases

PCP Phase	Start	End	Duration	Number of Contractors Expected	Budget per Contractor
Phase 1 – Solution Design	Jan 2027	Mar 2027	3 months	5	20.000€
Phase 2 – Prototype Development	Jul 2027	Apr 2028	10 months	3	500.000€
Phase 3 – Field Validation	Aug 2028	May 2029	10 months	2	450.000€

Table 11. Tentative budget and duration per phase

9.3 Expected outputs of each phase

Phase 1: Solution design

- Development of the initial solution architecture.
- Feasibility analysis.
- Planning for prototype development.

Phase 2: Prototype development

- Construction and testing of prototypes.
- Performance characterisation in controlled conditions.
- Updated system architecture.

Phase 3: Field validation

- Deployment of 2 complete solutions. Each of them deployed and validated in a pair of European Hospitals.
- Validation under real hospital conditions
- Final performance evidence and reporting

Annexes

Annex I – THERESA use case

Context

Hospital wastewater (HWW) poses a significant environmental and health risk due to the presence of medicines, pharmaceuticals, pathogens and other hazardous substances. Traditional wastewater treatment systems employed by hospitals and municipal plants are often inadequate to effectively remove these contaminants.

Problem scope

Hospitals discharge substantial amounts of chemicals and microbial agents in their wastewater, including:

- Antibiotics.
- X-ray contrast agents.
- Disinfectants.
- Pharmaceuticals.

Many of these compounds resist normal wastewater treatment processes, contributing to environmental contamination and potential public health impacts.

Use case description

The use case focuses on an on-site treatment system capable of effectively removing toxic substances, infectious compounds, pharmaceutical residues and pathogens from hospital wastewater, thereby reducing environmental burdens and health risks at an affordable cost for health institutions.

AS IS situation

Due to the presence of medicines, pharmaceuticals, pathogens and hazardous substances in HWW, there are significant environmental and health risks for ecosystems and the public.

TO BE situation

With an improved wastewater treatment system:

- Discharges from hospitals have a reduced environmental impact.
- Toxic substances, infectious compounds, pharmaceutical residues and pathogens are significantly reduced before entering the municipal network or the environment.
- Risks to public health are minimised by ensuring the removal of disease-causing agents from hospital wastewater and reducing the

likelihood of waterborne transmission or contamination of drinking water sources.

Required functionalities

The on-site treatment solution is expected to:

- Channel hospital wastewater into a centralised treatment facility.
- Separate and/or treat highly soluble reagents (e.g. sodium azide) and other hazardous chemicals.
- Remove large solid debris and coarse materials from the wastewater.
- Operate stably despite high concentrations of disinfection agents.
- Treat persistent organic pollutants.
- Meet required wastewater discharge standards by effectively disinfecting HWW.
- Reduce nutrient concentrations (e.g. nitrogen and phosphorus).
- Filter and separate HWW through advanced treatment technologies.
- Ensure proper handling of any sludge generated.
- Include monitoring devices and sensors to measure key parameters (e.g. pH, temperature, dissolved oxygen, pollutant concentrations).
- Provide odour control measures.
- Enable, where regulations allow, non-potable reuse of treated HWW within the hospital (e.g. irrigation, toilet flushing, cooling towers).

Steps towards implementation

Identify all sources of HWW discharges within the hospital.

Determine the types of healthcare pollutants present at each identified discharge point.

Review national and EU regulations and guidelines governing HWW discharge.

Assess how innovative solutions can be integrated into the existing wastewater management system.

Train relevant staff members on operation, maintenance and monitoring procedures.

Perform regular sampling and analysis of treated wastewater and periodically assess overall system performance to identify optimisation opportunities.

Annex II – Information about participant hospitals

Operational and technical performance

Water use and flow information

- **HUVM (ES):** 2024 annual consumption 97,273 m³, 2025 YTD 99,021 m³. Monthly values range between 6,688–10,065 m³ in 2024.
- **CHV (ES):** Annual consumption 29,786 m³/year. Minimal seasonal variation.
- **WSS (PL):** Consumption 54,000 m³/year, monthly ~4,500 m³.
- **AZM (NL):** Approx. 160,000 m³/year, with significant summer increase due to cooling. Estimated sewage flow 100,000 m³/year.
- **FMS (Spain):** 2024 combined yearly consumption across three centres: ~260,500 m³/year including:

Hospital	m³/year	Comments
HUN	188,480 m³/year	Seasonal rises linked to irrigation in summer.
HVC	58,851 m³/year	
CU	13,163 m³/year	

Table 12. Water use and flow information per year

- **PERH (EE):** Annual consumption **86,970 m³**, peaks in Jan–Aug, lows in autumn.
- **ZAS (BE):** Combined yearly consumption across campuses : ~**220,789 m³** including:

Campus	m³/year
ZAS Campus Augustinus	26,129 m³/year
ZAS Campus Vincentius	39,239 m³/year
ZAS Campus Sint - Jozef	7,524 m³/year
ZAS Campus Palfijn	32,411 m³/year
ZAS Campus Middelheim	53,456 m³/year
ZAS Campus Cadix	21,791 m³/year
ZAS Campus Erasmus	3,056 m³/year
ZAS Campus Elisabeth	8,895 m³/year
ZAS Campus Hoge Beuken	8,742 m³/year
ZAS Campus PZ Stuivenberg	9,412 m³/year
ZAS Campus Joostens	10,134 m³/year

Table 13. ZAS Campuses water use and flow information per year

Average daily consumption

Hospital	m³/day	Comments
HUVM	215–335 m³/day	2024 data.
CHV	~82 m³/day	Derived from annual consumption.
WSS	~150 m³/day	
PERH	238 m³/day	
AZM	440 m³/day	
HUN	~715 m³/day	Combined (HUN main campus ~516 m³/day), derived from total annual consumption data.
ZAS	~605 m³/day	Average daily consumption derived from total annual consumption of campuses.

Table 14. Average daily consumption per hospital

Wastewater flow

- **Directly measured:** rarely measured; most hospitals **estimate wastewater flow≈ water consumption**.
- **Exceptions:**

Hospital	Campus	Estimate	Comments
AMZ		100,000 m³/year	~60% of water input (evaporation due to cooling).
WSS		150 m³/day	Estimation based on water consumption.
HUN			Currently does not measure wastewater but plans procurement for future monitoring.
ZAS	ZAS Campus Palfijn	127,4 m³/day	Based on 2025 measurements.
	ZAS Campus Hoge Beuken	247,31 m³/day	
	ZAS Campus Erasmus	28,57 m³/day	
	ZAS Campus Cadix	149,92 m³/day	
	ZAS Campus Vincentius	72, 0860 m³/day	

Table 15. Hospital wastewater flow

Seasonal or operational variations

Common findings:

- Minimal seasonal variation in most hospitals (CHV, WSS, PERH).
- Cooling-related summer increase in AZM.
- Irrigation-related summer increase in Navarra (for HUN).
- HUVM and ZAS show no clear seasonal trends based on 2024–2025 consumption charts.

Infrastructure and operational environment

Wastewater pathways and segregation:

Segregation of Streams

Stream	Typical Status Across Hospitals
Rainwater	Mixed or separate depending on building; **separate drainage exists** in Navarra, WSS, PERH. ZAS: Separation of rainwater at ZAS Cadix, ZAS Stuivenberg and ZAS Palfijn – rainwater used for toilets flushing
Laboratory wastewater	Often **not separated** (HUVM, WSS, PERH); **segregated in CHV and ZAS** except for campus Middelheim.
Laundry wastewater	Usually **outsourced**, hence no direct segregation.
Radioactive wastewater	**Segregated only in specific centres** (AZM, HUN) partial separation at ZAS.
Kitchen wastewater	Usually mixed; **grease traps** common (HUVM, PERH).
Septic/collection tanks	HUN, AZM and ZAS Middelheim have holding tanks for radioactive streams only.

Table 16. Hospital wastewater segregation streams

Final discharge points

Hospital	Final discharge points
HUVM	6 discharge points to municipal sewer.
CHV	1 main discharge point, with pre-screening.
WSS	4 discharge points to municipal sewer.
AZM	1main discharge point + two auxiliary points.
HUN	Several discharge connections depending on building (HUN, HVC, UC).
PERH	14 discharge channels converging at a municipal collector.
ZAS	+ 16 discharge points distributed across campuses.

Table 17. Final discharge points

Existing pre-treatment

Hospital	Existing pre-treatment
HUVM	Grease separator + sampling manhole + siphon manhole.
CHV	Mechanical coarse screening.
WSS	None.
AZM	Grease traps, plaster traps, amalgam separators; **no centralized pre-treatment**.
HUN	No general pre-treatment; only isolated systems (radioactive tanks, hazard collection tanks).
PERH	**3 grease traps**; otherwise no pre-treatment.
ZAS	Pre-treatment: amalgam separator, hydrocarbon separator, grease separators, mechanical coarse screening, septic tanks for hazard collection.

Table 18. Existing pre-treatment

Cross-connections

All hospitals report **no known cross-connections**.

Monitoring and control systems

Presence of monitoring devices

Hospital	Flow Meters	pH/Temp Sensors	BMS Integration	Water Quality Monitoring
HUVM	Yes (inlet via supplier billing)	Not specified	Not stated	Not stated
CHV	Yes (inlet)	Yes	BMS-ready	Full annual + quarterly analyses; Legionella & metals
WSS	No	No	No	None
AZM	Yes (inlet only)	Temp sensors on cooling discharge	Full BMS 24/7	Legionella only
HUN	Water inlet monitoring only	Chlorine monitoring	No integrated BMS	No wastewater monitoring
PERH	Inlet flowmeters	Temp/pressure	BMS data limited	Municipal quarterly wastewater tests
ZAS	Inlet and outlet flow meters	Temperature/pH sensors	No	Periodic water quality checks for Temp, pH, BOD, COD, total N, P, Suspended solids, metals content: As, Cd, Cr, Cu, Pb, Ni, Zn,Hg,Ag

Table 19. Monitoring and control systems

Remote Access Needs

Common themes:

- **Most hospitals prefer integration with Building Management System,** especially for alarms.
- **PERH prohibits external remote access** due to cybersecurity.

Operational capacity and barriers

Staffing and technical capacity

Hospital	Staffing and technical capacity
HUVM	Maintenance structure not detailed.
CHV	10 technical staff; basic checks feasible; some outsourcing.
WSS	All maintenance outsourced.
AZM	50 FTE facility staff; supervision available but work outsourced.
HUN	Large in-house team (12 mechanical/plumbing + other tech staff).
PERH	6 specialists; limited on-site interventions; monitoring is strong but constrained by BMS.
ZAS	Limited technical staff (FTEs), no skills and knowledge, supervision, maintenance and monitoring to be outsourced.

Table 20. Staffing and technical capacity

Common limitations

- Limited onsite operator hours (nights/weekends).
- Reliance on external contractors.
- Limited specialised wastewater expertise.

Operational barriers and acceptability

Space constraints

Hospital	Space constraints
HUVM	Multiple manholes, outdoor locations; general constraints not detailed.
CHV	Allocated area available (former WWTP).
WSS	Not specified in detail; space constraints likely.
AZM	**Severe outdoor space limitation: 6×8 m** near main sewage pit.

HUN	Space exists but **collector depth 6 m** is a challenge.
PERH	Extremely limited indoor space (toilet rooms 1.5–4 m²); outdoor installation requires municipal approval.
ZAS	Limited space, old buildings, differences between the campuses in terms of location, infrastructure, etc, multiple connection points to the sewer.

Table 21. Space constraints

Power, noise, safety aspects

- Electrical capacity often available but may require upgrades (HUN-Navarra).
- **Noise restrictions are critical** - especially HUN-Navarra and PERH (max 35–40 dB indoors).
- Hospitals emphasize **continuous access**, **no interruption to sewer flow**, and need for **bypass solutions**.

Chemical handling & odour

All hospitals highlight:

- Need to avoid harmful vapours.
- Need for odour control.
- Challenges handling physical waste/coarse materials (Navarra & PERH particularly).

Wastewater segregation & public health considerations

High-risk streams

- **Mixed in most hospitals.**
- **Radioactive wastewater:**
    - Segregated with holding tanks in *AZM* and *HUN and ZAS Campus Middleheim*.
    - Not separated elsewhere.

Infection control considerations

Risks mainly associated with:

- Physical waste (wipes, organic material).
- Potential accumulation of cytostatics/antibiotics.
- Need for watertight installations (HUN).

Space & site integration

Physical infrastructure constraints:

Space availability

- Most hospitals prefer **outdoor installation**, except where not allowed.
- Indoor space is generally **very limited** (especially PERH, AZM).

Access Constraints

Critical across hospitals:

- Delivery and installation must avoid blocking:
    - Emergency routes (AZM).
    - Patient transfer zones.
    - Residential areas (HUN).

Modularity Needs

- Most agree modularity is beneficial.
- CHV does **not require** modularity.
- PERH and ZAS emphasises modularity as a **strong advantage**.

Utilities

All hospitals have:

- Sewer connection.
- Water supply.
- Electrical systems (though may be limited or require cabling over long distances, e.g., HUN).

Summary of the hospital baseline characteristics

Across all hospitals:

Common Strengths

- Reliable water supply and consumption data
- Basic inlet flow metering
- Predictable wastewater volume
- Some in-house technical capacity

Common Limitations

- Almost no direct wastewater monitoring.
- Very limited wastewater segregation including laboratory and radioactive wastewater.
- Space constraints, especially indoors.
- Strict noise and safety requirements.
- Need for real-time alarms but restricted remote access (cybersecurity).

Implications for technology implementation

A future pre-treatment solution must be:

- Compact and modular with modules installable outdoors and indoors
- Low-noise (<35 dB in some cases).
- Highly sealed (especially for odour nuisance).
- Cybersecure and compatible with BMS (read-only or restricted integration).
- Capable of handling mixed hospital wastewater.
- Able to function with limited operator input and without disrupting 24/7 hospital service.

Annex III – How to prepare a good pitch for the OMC

This Annex explains how suppliers may effectively present their solutions within the framework of the THERESA OMC. It aims to enhance visibility among potential consortium partners and to support procurers in gaining a clearer understanding of existing approaches and technologies addressing the THERESA challenge.

Understand the audience

Before preparing a pitch, it is helpful to clarify the following aspects:

- Who is the intended audience?
- What are their **main priorities** (e.g. cost, speed, risk, return on investment, usability, scalability)?
- What **level of prior knowledge can be assumed** (e.g. sector expertise, awareness of the challenge, technical depth)?

The **language, level of detail and metrics** used should be adapted accordingly to match the audience.

When designing the slides, the pitch should aim to address:

- The **specific problem**, unmet need or challenge being targeted
- How the proposed solution addresses these needs and overcomes the identified challenges
- The **main value** proposition and how it compares with current standards or existing technologies
- The current maturity level of the solution and technology, including existing strengths and remaining gaps
- The type of support sought (e.g. funding, partnerships, end-users, data access)
- Whether the unmet needs can be addressed independently or require partners, and the intended role within a potential consortium (lead or contributing partner)

Tips: to do and to avoid

The following design principles are recommended throughout the presentation:

- Use **short and concise sentences.**
- Prioritise icons, visuals and diagrams over dense text
- Maintain a clear structure and coherent narrative flow
- Focus on outcomes rather than features alone
- Adopt a confident yet realistic tone
- Anticipate potential objections, gaps or limitations and outline possible mitigation approaches

The following should be avoided:

- Overloading the presentation with excessive technical detail
- Neglecting the business and operational impact
- Underestimating timelines or costs
- Presenting an unclear or weak role of the company within the proposed solution

Proposal for the slide design

The content of each slide may be adapted as needed, provided that all expected information is included. Pitch presentations will be uploaded to the THERESA's YouTube channel.

- Maximum slides allowed are FIVE.
- Maximum time for exposition will be **FIVE MINUTES.**

The following slide structure is suggested for the presentation:

1. What is the specific problem?

The presentation should start by clearly defining the specific problem or unmet need being addressed and explaining why it matters. This may include existing inefficiencies, unresolved challenges, risks or safety concerns.

2. The proposed solution is…

The proposed solution should be described in simple, outcome-focused terms, explaining what it is, what it replaces, improves or adds, and how it works at a high level.

3. Expected impact

The solution should be linked to its expected impact, including operational efficiency gains (such as time or productivity improvements), cost reductions or revenue gains, risk mitigation, regulatory compliance, and environmental benefits (e.g. reduced carbon footprint, lower pollutant releases or improved resource efficiency).

4. How is it going to work?

This section should describe the implementation approach and identify any missing components. It should outline the types of partners required, how the solution would be delivered and integrated, and the expected progress throughout the project, including key phases, a high-level timeline and key milestones.

5. Is it feasible?

The presentation should conclude by demonstrating feasibility and readiness, highlighting available resources (including roles and responsibilities),

prior experience or relevant case studies, the technology readiness level, and any vendor or partner support.

Annex IV – Protocol for bilateral meetings

Introduction

The present Annex IV constitutes the protocol for bilateral meetings between the procurers, the public buyers' group and suppliers, with a particular focus on the OMC phase of the project. It also sets out the compliance obligations that must be observed whenever procurers, public buyers and suppliers engage with one another.

Furthermore, it provides a **more detailed examination of the DOs and DON'Ts**, illustrating from a practical standpoint which information-sharing and communication practices are allowed or prohibited during the OMC, so that its objectives can be fulfilled without administrative, legal or compliance-related obstacles.

The aim of these bilateral meetings is to:

- Clarify and deepen the information received through the open OMC channels, specially through the THERESA OMC questionnaire.
- Better understand the capabilities, approaches and constraints of market suppliers.
- Refine the PCP design (scope, architecture, risk allocation, IPR, etc.), without providing any unfair advantage to individual suppliers.

In this regard, particular attention is devoted to ensuring, through specific measures, that all **information disclosed during the OMC is made accessible to any interested party**, thereby safeguarding a level playing field for the subsequent procurement phase and preventing any potential distortion of competition.

Legal framework and principles

All bilateral meetings are conducted in full compliance with the Treaty on the Functioning of the European Union (TFEU), in particular the principles of transparency, proportionality, equal treatment, non-discrimination and fair competition; **Directive 2014/24/EU, in particular Articles 40 and 41** on preliminary market consultations and measures to avoid distortion of competition the applicable regional contracting legislation of the Lead Procurer.

Participation in any OMC activity, including bilateral meetings, **does not**:

- Constitute a pre-selection of suppliers.
- Create any legitimate expectation or right to be awarded a contract.
- Give rise to any obligation for the Procurers to launch or award the PCP.

Eligibility and selection of participants

Bilateral meetings may only be held with organisations that:

- **Have formally participated in the OMC** (by submitting the THERESA OMC questionnaire).
- Are **active in fields relevant to the PCP challenge**.

The PBG will decide which organisations are invited to bilateral meetings, based on objective criteria, such as:

- Relevance of the role for the envisaged PCP solution (e.g. open platform providers, application/service providers, system integrators, potential coordinators).
- Experience in integrating solutions and working within ecosystems or open architectures.
- Innovative or distinctive features highlighted in their OMC contributions (e.g. different technical approaches, IPR models, business models).
- Representativeness of different market segments and geographical balance, where applicable.

Confidentiality and publication of information

The Procurers will treat the information received during bilateral meetings as follows:

Suppliers are responsible for clearly identifying, at the time of disclosure, which information is considered **confidential** and which is not, either in writing or orally. Where confidentiality is indicated orally, such designation shall be subsequently confirmed in writing, in order to ensure clarity on what must be identified as confidential.

Information explicitly identified as confidential and reasonably qualifying as such (e.g. trade secrets, sensitive technical details or confidential business strategies) will not be disclosed and will only be used internally for the purpose of understanding the market.

Information of general interest that **does not reveal confidential details may be summarised and published** in the THERESA OMC Summary Report, updated challenge description and requirements, and/or a public Q&A document published in English at https://theresa-pcp.eu/frequently-asked-questions/

Equal treatment and avoidance of undue advantage

To avoid any undue advantage and ensure a level playing field, the same general information regarding the OMC, including scope, budget, high-level requirements and timeline, will be made available to all interested suppliers through the OMC documentation, events and public Q&A, which will be available at https://theresa-pcp.eu/

Any clarification of general relevance that emerges during bilateral meetings will likewise be incorporated into the OMC documentation or the public Q&A, without identifying the supplier who raised the issue. Participation, or lack of participation, in bilateral meetings will not be considered as an award or selection criterion in the subsequent PCP tender.

If, despite these safeguards, a potential risk of distortion of competition is identified for a specific supplier, the procurers will implement proportionate

corrective measures to eliminate any undue advantage. Such measures may include, for example, providing additional disclosures to all bidders, in line with Article 41 of Directive 2014/24/EU.

Agenda for bilateral meetings

Bilateral meetings can be proposed by the PBG to specific market suppliers or requested by market suppliers that meet the eligibility criteria, **though the THERESA OMC questionnaire** between 6–24 February 2026.

A standard agenda will be used for all bilateral meetings with approximate time distribution such as:

Time	Action	Participant
2 min	Welcome and introductions	All participants
5 min	Reminder of the OMC objectives, this Protocol and the non-binding nature of the discussion	Procurers
15 min	Presentation from suppliers on their company and solution (based on the THERESA OMC questionnaire answers)	Suppliers
15 min	Questions from public buyers to suppliers	Buyers/Procurers
20 min	Questions from suppliers to public buyers	Suppliers
5 min	Summary of main takeaways and explanation of how the information will be used.	Procurers

Table 22. Standard bilateral meetings agenda

All information provided by suppliers to the buyers in the context of the PCP THERESA project, whether through the THERESA OMC questionnaire, during bilateral meetings, or via any other communication channel, will be anonymised, summarised, and published in English on the project's website. If any of the information shared at the meetings is **confidential** or could reveal sensitive information, **suppliers must clearly indicate this at the time of submission,** orally or in writing. Where confidentiality is indicated orally, this shall be confirmed in writing. Such information will be treated accordingly and will not be disclosed publicly.

All meetings will:

- Last approximately [30–90] minutes.
- Be conducted online.
- Be attended by at least two representatives of the procurers (one of them from the procurement/legal side) to ensure consistency and proper record-keeping.

Record-keeping

For each bilateral meeting, **the procurers** will keep a short-written record, which will be for internal use including:

- Date, time and format of the meeting.
- Names and roles of participants on both sides.
- Topics discussed and agreements.

A consolidated and **anonymised summary** of the insights gained from the bilateral meetings **should be presented separately.**

Allowed and not allowed topics

This section outlines the boundaries of the information and discussions that may take place during the OMC. It clarifies which topics can be legitimately addressed to support a better understanding of the PCP challenge and ensure an open, fair and well-informed consultation process, and which topics must be strictly avoided to prevent any risk of distorting competition or granting undue advantages to specific suppliers. Below are illustrative examples of allowed and non-allowed discussion areas.

What is discussed?

- Proprietary technology details.
- Specific cost estimates or pricing models.
- Commercial partnerships or business strategies.
- Detailed technical specifications.
- Regulatory challenges specific to the proposed solution.
- Concerns about the PCP process.

Non-allowed topics (examples):

- Conduct sales pitches, marketing activities or other **commercial solicitation** towards the PBG.
- Promote specific products or services with the aim of influencing future purchasing decisions.
- Provide individual guidance on how to optimise or structure a future tender submission.
- Discuss evaluation criteria, scoring methods, weighting, or selection thresholds.
- Grant any supplier competitive advantage over others.
- Validate or pre-approve specific solutions, technologies or approaches.
- Share confidential or commercially sensitive information about other suppliers.
- Commit the PBG to specific technical requirements, budgets, timelines or pilot sites.
- Negotiate contractual terms or future procurement conditions.

Template for bilateral meeting notes (internal)

Disclaimer: Any information explicitly identified as **"confidential"** by the supplier, whether orally or in writing, and reasonably qualifying as such (e.g. trade secrets,

sensitive technical details or confidential business strategies), **will not be disclosed** and will be used exclusively for internal purposes related to market understanding. Where confidentiality is indicated orally, such designation must be confirmed in writing.

CONTRACTOR NAME:

Meeting information			
Date:		**Location:**	
Time:		**Duration:**	
Meeting objectives:	• 1 • 2 • 3…		
Convened by:			
Attendees (BUYERS):			
• NAME – Position • NAME – Position • NAME – Position			
Attendees (PROCURERS):			
• NAME – Position • NAME – Position • NAME – Position			
• NAME – Position • NAME – Position • NAME – Position			
Attendees (SUPPLIERS):			
• NAME – Position and Company • NAME – Position and Company • NAME – Position and Company • NAME – Position and Company			
TOPICS ADDRESSED			
TOPIC 1 XXXXX			
TOPIC 2 XXXXX			
…			
COMMENTS			

Table 23. Template for bilateral meeting notes (internal)

Template for bilateral meeting notes (external)

Disclaimer: Any information explicitly identified as **"confidential"** by the supplier, whether orally or in writing, and reasonably qualifying as such (e.g. trade secrets, sensitive technical details or confidential business strategies), **will not be disclosed** and will be used exclusively for internal purposes related to market understanding. Where confidentiality is indicated orally, such designation must be confirmed in writing.

COMPANY NAME
• Company name • Company name
Summary
• Topic 1 … • Topic 2 …

Table 24. Template for bilateral meeting notes (external)

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