Procure 4Health

Open Market Consultation Document

(including Annexes)

Open Market Consultation for the future Pre-Commercial Procurement of R&D services concerning the preservation of fresh biological samples

July 2024

Funded by the European Union

GA n° 101057209

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Economic operators and other stakeholders are being informed that any information regarding the setup and execution of both the procurement process and the execution of any contract/framework agreement as a result of the procurement process as well as public summaries of the results of the PCP project, including information about key R&D results attained and lessons learnt by the procurers during the PCP, can be shared after consultation with the respective R&D provider by the PROCURE4HEALTH Consortium with(in) the context of the contract and consequently can be analysed, (re-)used and published by the PROCURE4HEALTH Consortium. Details should not be disclosed that would hinder application of the law, would be contrary to the public interest, would harm the legitimate business interests of the R&D providers involved in the PCP or could distort fair competition between the participating R&D providers or others on the market.

The PROCURE4HEALTH project receives funding under the European Union's Horizon Europe framework program for research and innovation under the grant agreement No 101057209. The EU is however not participating as a contracting authority in the procurement.

A Prior information notice, or PIN, has been published in TED to announce the Open Market Consultation on potential future procurement activity (notice publication number: 6662-2024).

The original language of this open market consultation is English.

Abbreviations and Acronyms

CET	Central European Time
COTS	Commercial Off-The-Shelf
EAFIP	European Assistance for Innovation Procurement
EC	European Commission
EU	European Union
FAIR	Findable, Accessible, Interoperable and Reusable
FRAND	Fair, Reasonable and Non-Discriminatory
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GPA	Government Procurement Agreement
HE	Horizon Europe
H&Sc	Health & Social Care
IPRs	Intellectual Property Rights
OMC	Open Market Consultation
PBG	Public Buyers Group
PCP	Pre-Commercial Procurement
PIN	Prior Information Notice
R&D	Research and Development
RFI	Request For Information
SMEs	Small and Medium Enterprises
SOTA	State Of The Art
TED	Tenders Electronic Daily
TRL	Technology Readiness Level
WTO	World Trade Organisation

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Key Definitions

Consortium	Group of public and/or private entities (including public buyers and supporting organisations) that are part of the PROCURE4HEALTH project. For more information: https://procure4health.eu/founding-members/
Contractor	A company or entity that has been awarded a contract under the PCP.
Lead Procurer	A Public Buyer who acts as a Procurer in the PCP and purchases the R&D services on behalf of itself and other Public Buyers (in this case, Servicio Andaluz de Salud).
Public Buyer	A public entity who purchases goods or services from the market and is subjected to the public procurement regulation.
Technology provider	A company or entity who develops and/or sells technology in the market.

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1 Purpose of the Open Market Consultation

1.1 Scope and main objectives

This document describes the objectives and rules applicable to the Open Market Consultation (OMC) of the project PROCURE4HEALTH for the future Pre-Commercial Procurement of Research & Development services concerning the preservation of fresh biological samples.

The OMC begins on the date of the publication of the Prior Information Notice (PIN) in the Tenders Electronic Daily (TED) and ends on the date indicated in this document unless the public buyers involved decide to terminate it prematurely.

Through this OMC, the Public Buyers Group (PBG) of PROCURE4HEALTH (identified in section 2), with Servicio Andaluz de Salud as lead procurer, aims to challenge the market to develop innovative solutions for advancing the preservation of biological samples for molecular biology studies. This initiative addresses the need for cost-efficient methods to preserve biological samples—ensuring the integrity and high yield of DNA, RNA, proteins, and metabolites—without requiring freezing and its associated infrastructure. These advancements are crucial for enhancing translational research, optimizing disease management, and improving patient outcomes in the context of precision medicine.

New molecular techniques in research (and increasingly in clinical practice) require the availability of biological material from patients preserved in a system that does not modify the nucleic acids, proteins or metabolites of the sample and that does not require freezing and the associated infrastructure. Frozen tissue is considered the best biological sample for current molecular biology techniques, but the costs of frozen storage are very high. The widespread method of storing patient samples is by fixation and embedding in paraffin, but this system does not allow to get the most out of patient samples. Therefore, there is a need to develop other techniques that would keep the sample as close as possible to the original state, at low costs.

In the end, patients are the ultimate to be affected, as their samples cannot be fully benefited from. Progress in translational research is also affected. It is important then to respond to this need so that the most modern and informative techniques can be applied to the diagnosis and treatment decision of patients in the context of precision medicine where multiple omics become predictors of response and prognosis. All of this results in an optimisation of disease management, savings in health system costs and improved patient survival and quality of life.

In this context, the purpose of the OMC is to inform technology providers and other relevant stakeholders about the needs of the PBG and to gather their input about the PROCURE4HEALTH challenge for developing innovative solutions tailored to facilitate the cost-efficient preservation of biological samples.

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Another objective of the OMC is to understand the technology providers' capabilities to satisfy the public buyers' needs and to obtain their input on the viability of the procurement plans and conditions as described in this document and annexes.

In sum, the objectives of this OMC are to:

1) Validate the findings of the State-Of-The-Art (SOTA) analysis and the viability of the set of technical and financial provisions.
2) Raise awareness of the industry and relevant stakeholders regarding the upcoming PCP.
3) Collect insights from the industry and relevant stakeholders (including users) to finetune the tender specifications.

This OMC is performed under the law of the lead procurer (Servicio Andaluz de Salud), which is Spanish law.

The contracting authorities involved in the PROCURE4HEALTH project are not legally bound in any way by the outcome of the OMC.

Starting an OMC does not mean that the PBG will start a tendering or purchasing procedure. If this OMC is followed by a tendering procedure and/or purchasing procedure, the PBG reserves the right to adjust and/or supplement the solution described in this document on every element. No rights can be derived from statements and/or communications during this OMC in any future tendering procedure and/or purchasing procedure.

The OMC is not part of any pre-qualification or selection process. No advantage or disadvantage will be given to any technology provider / group of technology providers to the detriment of others during the OMC and the sub-sequent competitive procedure for the award of contracts.

All information provided during the OMC and other background information will be published online in English.

Where appropriate, parts of the information received from market parties can be shared with the EC.

1.2 Who can participate?

The target groups of this OMC are technology providers, end users, research centers and universities. All interested parties are invited to take part in the OMC. However, please note that technology providers established in countries not eligible to participate in Horizon Europe Innovation Actions in any capacity cannot participate in the PCP procedure. Nevertheless, it is possible to form alliances of technology vendors (consortia).

Participation in the OMC is voluntary and non-binding and is at the own expense and risk of market operators. A market operator cannot charge any costs to the PBG for participation in the OMC or for (re-)use of its information in the context of a future procurement procedure.

Participation in this OMC is not a condition for submitting a tender in the subsequent procurement, does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process. The provided input in this OMC will not be used to evaluate future proposals.

1.3 Activities & timetable

The OMC will take place in the form of:

- An online event on 11 September 2024 (in English).
- A Request for Information (RfI) – a questionnaire using the EU Survey tool.
- Other activities as deemed necessary within the scope of the project.

The timetable of activities and required actions of the OMC is as follows:

Date	Event
5 January 2024	Publication of the general Prior Information Notice (PIN) on TED: https://ted.europa.eu/en/notice/-/detail/6662-2024
8 July 2024	Publication of the Prior Information Notice (PIN) on TED (specific for this challenge): https://ted.europa.eu/en/notice/-/detail/407805-2024 Publication of the OMC documents on the project's website: www.procure4health.eu Publication of the EU Survey questionnaire: https://ec.europa.eu/eusurvey/runner/preservation_samples
11 September 2024	OMC Event in English (online) (10:00 – 11:30 CET).
25 September 2024	Deadline to fill in the OMC questionnaire (17:00 CET).
10 October 2024	Publication of the OMC findings, including all questions and answers to the OMC questionnaire.
11 October 2024	Closure of the OMC.

Table 1: OMC Timetable

The PROCURE4HEALTH Consortium is entitled to adjust the planned activities and the timetable above and to include new activities at any time according to the needs and responses of the market. Furthermore, it may decide to terminate the OMC for its own

reasons at any time. In that case, the PROCURE4HEALTH Consortium will publish such modifications or termination on TED and the project's website (www.procure4health.eu).

The event celebrated within the framework of the OMC could be recorded. In that case, by attending the physical event you will consent to be recorded. By using your video and microphone during the webinars you will consent to be recorded. If you do not want your voice and image to be recorded during the webinars, you may ask your questions using the chat. The PROCURE4HEALTH Consortium shall use those records for the purpose of the project only.

In addition, please be aware that photos may be taken during the meetings. The PROCURE4HEALTH Consortium shall use those photos for the purpose of the project only.

1.4 Registration

Parties interested in participating in the OMC activities are requested to register here.

1.5 Procedure

The OMC starts on the date of its publication in TED and ends on the date set in the timetable, unless terminated earlier.

Interested parties are requested to register through the link provided above in order to participate in the events and receive additional information about the project. The questionnaire should be filled out before the deadline indicated in the timetable above.

The PROCURE4HEALTH Consortium will support interested parties throughout the whole OMC during the events and by answering questions through a Q&A document which will be published on the project's website.

Additional written contributions in the form of a Request For Information (RFI) questionnaire or other questionnaires (via the EU Survey platform) aiming to collect market information on innovative and commercial solutions may be requested.

The responses to the questionnaires should not contain any confidential information. As the questionnaire is intended to explore the market "as is", there are no wrong or right answers. The answers provided will be used as input for the procurement strategy and contract conditions.

After processing and analysing the answers, the PROCURE4HEALTH Consortium will disseminate the results to the widest possible audience. Nevertheless, all answers provided by market parties will be anonymized and treated as confidential. The PROCURE4HEALTH Consortium will therefore not provide information about specific answers from market operators. Only the general findings and a summary of the answers will be provided. The results of this OMC will be published on the project's website.

In case the information provided in this document and annexes needs further clarification, market operators may ask questions during the events, or via the contact email address (hello@procure4health.eu).

Market operators that wish to provide additional confidential information during the OMC can send an email to the email address indicated above. The information must be explicitly marked as confidential. Confidential information will not be included in the OMC report.

1.6 Annexes

The following annexes are part of this document:

- Annex I – Request for Information questionnaire.
- Annex II – Use case.
- Annex III – Market analysis report.

The annexes form an integral and inseparable part of this OMC document. In the event of any conflict between the provisions of this document and the annexes, the provisions of the OMC document shall prevail.

2 The Procure4Health project

2.1 Context and objectives

The PROCURE4HEALTH project aims to address the challenges faced by Health & Social Care (H&Sc) systems in the European Union through innovation procurement. Every year, over 250,000 public authorities in the EU spend around 14% of GDP (around €2 trillion per year) on the purchase of services, works and supplies, where Health & Social Care (H&Sc) represents approximately 10% the GDP[1]. The rising costs of H&Sc continue to strain global health systems, prompting the need for innovative solutions. The EC places a high priority on the digital transformation of H&Sc[2], fostering novel approaches and tools to guarantee the ongoing suitability of H&Sc systems. Reforms and innovative solutions are imperative for H&Sc systems to enhance resilience, accessibility, equity, sustainability [3], and effectiveness. In this context, innovation procurement has the vital role of stimulating innovation from the demand side.

Despite the potential benefits of innovation procurement, several obstacles hinder its widespread adoption across the EU. These barriers include the fragmentation of health systems, legal disparities, bureaucratic challenges, language barriers, and a reluctance among policymakers and H&Sc procurers to embrace innovation procurement. Procure4Health aims to overcome these challenges through the creation of a (wide coverage) network and consolidated database for knowledge exchange and sharing of best practices, and through the identification and prioritization of common needs (in a catalogue) for the preparation of concrete innovation procurement projects and action plans in the H&Sc sector.

PROCURE4HEALTH provides an appropriate environment for public and private procurers, as well as the wider H&Sc community, to effectively share knowledge, build capacities of procurers, define common needs and advance innovation procurement in the EU. PROCURE4HEALTH proposes a comprehensive methodology for establishing and running an H&Sc innovation procurers' network which follows established principles for community building and good experience exchange.

The primary objective of PROCURE4HEALTH is to establish and manage a network comprising H&Sc procurers. These procurers are tasked with deploying H&Sc innovations across the EU and associated countries. The aim is to identify common needs and develop effective innovation procurement strategies based on Europe-wide market consultations. These strategies, including PCP, PPI, or Innovation Partnerships, will be transformed into actionable plans for procuring research and development as well as innovative solutions,

[1] https://single-market-economy.ec.europa.eu/single-market/public-procurement_en
[2] European Commission (2018). *Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*. Brussels, 25.4.2018, COM(2018) 233 final.
[3] HCWH (2019). "Health Care's Climate Footprint: how the health sector contributes to the global climate crisis and opportunities for action". *Climate-smart health care series - Green Paper Number One.*

ultimately enhancing the services provided to patients and citizens. Hence, the solid objectives are:

2.2 PCP challenge and main requirements

The envisaged future PCP – i.e. a joint procurement of R&D services – is intended to be launched to reinforce public demand driven innovation in end-user services in the area of Health & Social Care. PCP has the potential to be an effective demand-side innovation action and a useful tool to close the gap between supply and demand for innovative solutions. Solutions are expected to achieve TRL 7-8.

The future PCP should deliver successful innovative and fully tested product(s) and/or service(s) that meet the common need of the PBG to procure research, develop innovative marketable solutions, speed up the time-to-market and provide best value for money.

The PBG aims to develop innovative solutions for implementing a sustainable and effective biological sample preservation system in the healthcare context that maintains the integrity of DNA, RNA, proteins, and metabolites without the need for freezing or its associated infrastructure. This solution should be cost-effective and ensure that biological samples remain as close as possible to their original state, enabling their use in advanced molecular biology techniques such as those required for precision medicine. Furthermore, it needs to comply with the specific functionalities described in Annex II.

2.3 The Pre-Commercial Procurement approach

This OMC concerns a future PCP of R&D services to be performed in their majority in the EU Member States or Associated Countries.

PCP is an approach that allows public procurers to buy R&D from several competing technology providers in parallel, to compare alternative solution approaches, and to identify the best value-for-money solutions that the market can deliver to address their needs. In PCP, there is a risk-benefit sharing under market conditions between the public procurer and the technology providers and a clear separation between the PCP and the deployment of commercial volumes of end-products.

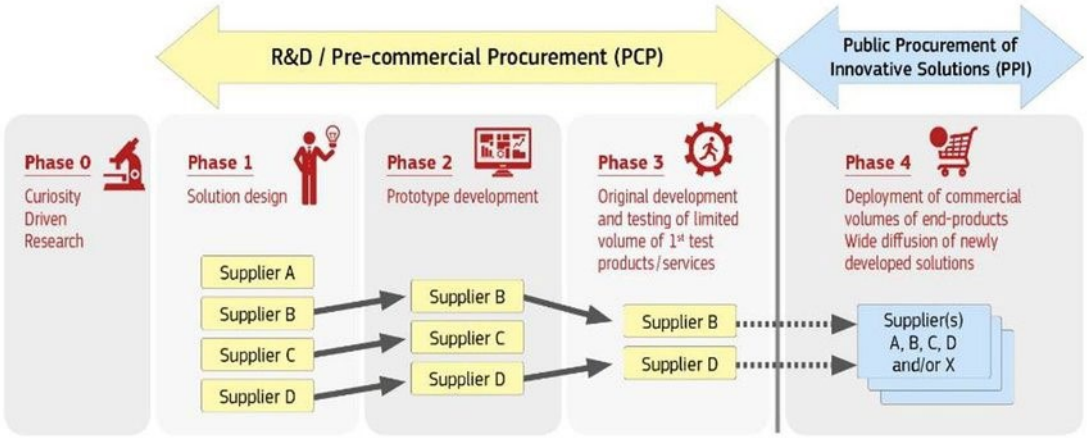

Figure 1: PCP and PPI, according to the European Commission (2016). Based on "Pre-commercial procurement: driving innovation to ensure sustainable high quality public services in Europe", COM(2007) 799 final.

Along with the R&D services, the PCP allows to purchase some products providing that the value thereof is **less than 50 % of the total value of the contract.**

The PCP tender will start with the publication of the contract notice along with the request for tenders, the framework agreement, and the phase contracts. After evaluating the offers submitted by the technology providers according to the rules established in the tender documents, the contracts will be awarded, and a contract award notice will be published. The process will be monitored to ensure sound deployment, integration and validation of the PCP.

The PCP procedure is composed of three phases of solution design, prototype implementation, and validation and demonstration of the solutions.

- **Phase 1. Solution design:** During this phase, the contractors will be asked to describe the solution providing the complete architecture and design thereof and verifying the technical, economic and organizational feasibility of their solution to address the PCP challenge.

- **Phase 2. Prototype implementation:** This phase concerns the development of the first prototypes of the solutions, which will be tested. Contractors will develop a first prototype based on the design documents delivered in the previous phase and test their solutions in lab conditions. Prototypes will be tested and verified to provide a measure of the technical performance of each solution in a controlled environment. During and at the end of the phase 2, the Public Buyers will request from the contractors a series of deliverables in order to evaluate their progress and the performed activities and obtained results.

- **Phase 3. Validation and demonstration of the solutions:** It will validate the final solutions (at least two) in diverse conditions, using the detailed scenarios and processes developed in the verification and validation strategy. During phase 3, a

feedback mechanism will be established between the Public Buyers Group and the selected contractors in order for the latter to receive requests for improvements directly from the end users. The Public Buyers will request from the contractors an Integration Report. Finally, a Field Acceptance Report related to the accomplishment that the two final solutions which have been deployed and that the validation tests have been successfully performed in a real operational environment will be requested.

After each phase, intermediate evaluations will be carried out to progressively select the best of the competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

The contractors will retain ownership of the Intellectual Property Rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential of the developed solutions.

Contracts implementation

During the implementation of the PROCURE4HEALTH PCP, effective tools will be used in order to monitor performance of the R&D suppliers and provide regular feedback during each phase. Each contractor will be assigned a main contact person (their supervisor) appointed by the procurers as the main point of contact.

More specifically the monitoring process will be divided in 3 set of activities:

- **Pre-monitoring:** A kick-off meeting per contractor will be scheduled at the beginning of each PCP phase and the selected contractors will be requested to present their implementation schedule for the PCP phase that they are entering in. During the same meeting, the supervisor will present the framework for the review. The objective is to establish a close and fruitful communication channel with the contractors, in order to ensure from the early beginning of the action that the project is implemented according to the needs of the buyers.

- **Monitoring:** Contract implementation will be monitored and reviewed against the expected outcomes for each phase. The intensity of monitoring and communication between the PBG and the contractors will increase from phase 1 to phase 3. For instance, regular meetings with the contractors by videocall or face-to-face, on-site visits to the contractors' locations to check and discuss the status of the work and progress, or any other suitable way. Ad-hoc meetings and on-site inspections are also possible in the event that the R&D development has halted or slowed down.

  The contractors are mandated to present monthly the current status of the work and describe the progress made. All the documentation generated by the contractors will be reviewed and the ideas and recommended areas to pursue will be highlighted in post-review activities.

- **Post-monitoring:** At the conclusion of the monitoring activities, the supervisor will provide written feedback for each contractor at each PCP phase. This feedback will generally consist of overall comments and remarks about the contractor's outcomes under review. Monitoring activities will be continued after the PCP is completed. Specifically, it will be checked whether the contractors are successfully commercializing the R&D results within the call-back period defined in the PCP framework agreement. If that is not the case, the PROCURE4HEALTH Consortium will ask the R&D suppliers to give licenses under FRAND terms to other third parties, or will ask to transfer back the ownership of results to the PBG.

2.4 The Public Buyers Group

The PROCURE4HEALTH Consortium brings together 18 public buyers from different EU Member States (Belgium, Denmark, Estonia, France, Greece, Italy, Norway, Poland, Portugal, Spain, Sweden, Turkey, United Kingdom). For the purpose of the PCP, the PBG will be represented by Sykehusinnkjop HF as lead procurer.

SERVICIO ANDALUZ DE SALUD (Spain)

Servicio Andaluz de Salud is responsible for the provision of healthcare to the population in the region (8,4 million citizens). It is a wide network based on high-quality, patient-centred, accessible care. It has more than 1,500 primary centres spread throughout the territory and grouped in Health Districts, the managerial unit at this level of care. The healthcare network also includes 52 hospitals with different complexities. Provision is free of charge at the point of care with the exception of part of the medication.

Servicio Andaluz de Salud has adopted corporate-wide information systems as a strategy to cope with ever increasing user mobility and a healthcare delivery model that involves many complex multidisciplinary professional teams. This, linked with the concept of integrated health and the evolving role of empowered patients in democratic societies, leads to the concept of the Single Health Record and the establishment of unified procedures.

SYKEHUSINNKJOP HF (Norway)

Sykehusinnkjop HF Hospital Procurement Trust operates as a central purchasing body for Norway's healthcare sector, collaborating with specialists and end-users nationwide. The trust, with six divisions and around 300 employees, provides specialized procurement services for the specialist health service. It emphasizes the principles of "the best agreement" to enhance financial flexibility, delivery capacity, and security of supply, contributing to future-oriented health services. Additionally, its strategic plan underscores precision and continuous improvement.

Aligned with the specialist health service's vision and core values, including respect, quality, and safety, Sykehusinnkjop HF prioritizes innovation, knowledge, commitment, and professionalism. The trust aims to be a flexible and solution-oriented entity at the forefront of market developments. It procures a range of healthcare essentials, such as IT equipment, pharmaceuticals, and medical-technical equipment, while actively promoting ethical and environmentally friendly purchasing practices. Finally, through partnerships with health regions, the trust collaborates closely to define and deliver services, ensuring alignment with regional needs and upholding responsible procurement practices.

ZESPOL OPIEKI ZDROWOTNEJ W SUCHEJ BESKIDZKIEJ (Poland)

The hospital in Sucha Beskidzka, established in 1982, stands as one of the region's largest and most advanced medical facilities. The Health Care Facility offers a comprehensive range of services, including primary healthcare, specialist outpatient care, inpatient treatment, emergency care, rehabilitation, long-term care, dialysis, and occupational medicine services. Additionally, the hospital has over 20 specialist clinics, 15 hospital wards, boasts more than 80 excellent doctors, and has served over a million satisfied patients.

RESEAU DES ACHETEURS HOSPITALIERS IDF - RESAH (France)

RESAH is a public interest group whose objective is to support the pooling and professionalization of purchasing and logistics for stakeholders operating in the health, medico-social, social, public and private non-profit sectors.

In order to achieve these objectives, RESAH acts within the framework of two areas of activity: the purchasing center whose purchasing volume reached 2 billion euros in 2022; and the resource and expertise with a responsible hospital buyer's desk, a training center, a publication activity and digitalization tools for the purchasing and logistics function.

The RESAH purchasing center offers more than 5,700 contracts concluded with 1,000 suppliers and falling within 11 purchasing families: medicines, medical devices, laboratory, biomedical, general equipment, general services, hotels, building and energy, transport and vehicles, IT, general services.

SKÅNE LANS LANDSTING (Sweden)

Region Skåne constitutes one of the 21 main administrative divisions (counties) in the country of Sweden, encompassing a total of 33 municipalities. Region Skåne, the governing body of the southernmost county in Sweden, holds autonomous authority and manages crucial sectors such as healthcare, trade and industry development, public transport, and cultural affairs, administering a populace numbering 1,402,425 citizens (as of 2021). Its headquarters are in Kristianstad, but it also has a presence in every municipality in Skåne. Simultaneously, Region Skåne oversees around 34,000 employees, primarily engaged in healthcare, including hospitals, primary healthcare units, and dental services. The region prioritizes an open and tolerant community, fostering creativity and innovation.

TURKIYE CUMHURIYETI SAGLIK BAKANLIGI (Türkiye)

The Turkish Ministry of Health is responsible for formulating and implementing health policies, planning and delivering healthcare services, and safeguarding patients' interests. Its duties encompass public health protection, disease risk reduction and prevention, health services administration, international public health risk prevention, health education and research development, and market regulation of medicines, cosmetics, and medical devices.

The ministry plays a pivotal role in managing the health system, formulating policies for health institutions nationwide, ensuring a balanced distribution of resources, and promoting equal, quality, and efficient healthcare services throughout the country. It collaborates internationally and across sectors, determines strategies, objectives, and plans, and exercises guidance, monitoring, evaluation, and supervision. In emergencies and disasters, the ministry plans and executes health plans, takes measures to eliminate regional differences in health service access, and directs relevant institutions and organizations to address factors impacting human health.

SERVICIO GALEGO DE SAÚDE (Spain)

The Galician Health Service (Servizo Galego de Saúde, SERGAS) is the public entity responsible for the health service and primary care activity in the Region of Galicia. It coordinates a network of 14 hospital centers, including 3 tertiary Care Hospital clusters (ranging from 1200 to 1500 beds each), 4 secondary care hospitals (ranging from 400 to 1200 beds), and 7 Countryside Hospitals (ranging from 100 to 300 beds each), along with over 450 primary care centers, covering the entire region. The strategic goals of SERGAS focus on optimizing integrated assistance mechanisms, ensuring citizens' rights, modernizing and humanizing the public health system, and promoting continuity of care through patient-centered organizations.

Under the Ministry of Health's supervision, SERGAS fulfills crucial functions, including providing healthcare through the Galician public healthcare network, distributing financial resources for care activities, governing and managing health centers, coordinating allocated resources, and implementing teaching and research programs. With a commitment to dynamic and patient-centered care, SERGAS plays a central role in the regional administration, overseeing and ensuring the delivery of quality healthcare services in Galicia.

NHS NATIONAL SERVICES SCOTLAND (United Kingdom)

NHS National Services Scotland has a crucial role in the Scottish healthcare system, functioning as a Non-Departmental Public Body under the Scottish Government's oversight. Committed to values such as customer focus, integrity, and excellence, it offers national strategic support services and expert advice to NHS Scotland. Its main activities focus on improving healthcare delivery, promoting efficiency, and supporting health and care transformation. NSS's strategic objectives include placing customers at the forefront, enhancing service value, improving operational processes, and fostering a positive work

environment. With a focus on remobilization and stakeholder feedback, NSS aims to prioritize efforts in enabling health and care transformation, supporting NHS Scotland with excellent services, and assisting organizations involved in health and care.

It provides services that support innovation and procurement in Scotland, including a Health Innovation Assessment Portal for stakeholders to submit their ideas and/or innovative products or technologies that could benefit Scotland's health and care services.

SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE (Portugal)

The Shared Services of the Ministry of Health (SPMS) is a legal entity operating under public law with a business-oriented character. Its primary mission is to provide shared services in procurement and logistics, financial management, human resources, and information and communication systems and technologies to entities within the health sector. It operates as a pivotal entity in centralizing, optimizing, and rationalizing the acquisition of goods and services in the National Health Service, playing a crucial role in enhancing efficiency and coordination.

SPMS's services encompass procurement and logistics strategy, financial management and accounting, human resources focusing on efficiency and automation, and information and communication systems and technologies. It plays a pivotal role in advancing digital health literacy and driving strategic initiatives, such as the National Strategic Telehealth Plan, to create more opportunities and improve healthcare services.

WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (Poland)

The Provincial Specialist Hospital in Olsztyn is a healthcare facility and a regional leader in innovative medical services. It is composed of numerous departments and treats over 27,000 patients while conducting 27,128 consultations annually. The hospital follows a patient-centric approach and continually invests in modernization.

The hospital actively engages in public procurement, emphasizing innovation, and has conducted around 16 tender procedures exceeding 215,000 euros, covering diverse needs from infrastructure to advanced medical equipment, including robotics.

AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (Italy)

The Regional Agency for Innovation and Purchasing (ARIA) supports and promotes development in the Region of Lombardy, with a strong emphasis on healthcare innovation. It supports more than 400 organizations, including healthcare authorities, hospitals, municipalities, and other public bodies across Lombardy and neighboring regions. In addition, it actively contributes to the digitization and innovation of public health services.

In 2020, ARIA launched and managed over 110 tenders, reaching a substantial value of 2.5 billion euros. Its impact extends beyond conventional healthcare services, encompassing over 5.8 million electronic health records, 14 million online visits booked, 33.5 million digitized reports, and 118 million electronic recipes. Through collaboration with the Lombardy Region,

ARIA is pioneering new standards, experimental models, and interoperability in healthcare, thereby shaping the future landscape of digital health services.

SERVICIO ARAGONÉS DE SALUD (Spain)

The Aragonese Health Service (SALUD) serves as the public health provider for the Region of Aragón, managing and coordinating the healthcare resources within the region. It integrates numerous centers, services, and establishments throughout the Region, strategically organized into eight sectors. These sectors encompass primary care, specialized care, socio-sanitary care, and mental health, each tailored to its specific geographical area. Beyond conventional healthcare, SALUD adopts a multidisciplinary approach, addressing a spectrum of health-related issues and actively incorporating societal concerns into its overarching mission.

SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (Estonia)

The North Estonia Medical Centre stands as a leading healthcare provider in the country. It functions as a regional hospital and holds competence to deliver specialized medical care. Its main objective is to provide high-quality specialized medical care and ambulance services, serve as a training base for healthcare professionals, and engage in healthcare-related study and research.

The Medical Centre boasts a workforce of over 4,800 individuals, including doctors, nurses, caregivers, and specialists. With more than 500 doctors and around 100 medical residents, the institution comprises 7 clinics and 32 specialist centers. Annually, the Medical Centre provides specialized medical care to approximately 144,000 patients, with over 24,500 receiving treatments on the hospital. Emergency medicine serves around 84,000 patients each year, offering emergency health services to an average of 230 patients per day.

5 YGIONOMIKI PERIFERIA THESSALIAS & STEREAS ELLADAS (Greece)

The 5th Regional Health Authority of Thessaly and Sterea Ellada, two administrative regions in Greece, is dedicated to planning, coordinating, supervising, and controlling the operations of Health Service Providers within its Health District. Furthermore, through its Health and Social Solidarity Organizations, the Authority focuses on providing essential information on primary and secondary healthcare, as well as insights on health initiatives, scientific events, educational, and research programs. Serving as a comprehensive hub, its platform also facilitates various opportunities, including requests for purchases or procurement.

It has actively participated in projects such as "Smart and Healthy Ageing through People Engaging in Supportive Systems – SHAPES," a European IA (Innovation Action) Research and Innovation Programme (€20,944,318.75). This initiative, involving 14 Member States, aimed to transform integrated Primary Health Care services delivery at national and European levels. Another notable project is "A Universal Cyber Security Toolkit for HealthCare Industry – SPHINX" (€4,999,435.00), focused on creating an integrated, intelligent cybersecurity tool

to protect the privacy and integrity of patients' medical data, enhance the security of Health IT systems, services, and infrastructures, and increase patients' trust in them.

REGION VASTERBOTTEN (Sweden)

The Region of Västerbotten assumes responsibility for delivering quality healthcare and medical services to all residents of Västerbotten County, funded through taxes, government grants, and patient fees. The region operates non-profitably, as mandated by the Health and Medical Services Act, with the overarching goal of ensuring good health and equitable care for everyone. It is organized into four areas of activity: Primary Care, Services, Hospital Care, and Dental Care. These services, including health centers and infirmaries, operate with a business-like approach with an annual budget exceeding SEK 9 billion.

The region is committed to enhancing the innovative capabilities of the Swedish healthcare system, ensuring the delivery of optimal care to the general public while using public resources efficiently and sustainably through active collaboration with employees, academia, industry, and various public actors at local, regional, and national levels.

VELINDRE NATIONAL HEALTH SERVICE TRUST (United Kingdom)

Velindre National Health Service Trust stands as one of the 12 legally mandated health organizations in Wales. It operates the Velindre Cancer Center providing specialist treatment, education, and R&D non-surgical tertiary oncology services to a population of 1.7 million in South East Wales. In addition to this role, the Trust manages the Welsh Blood and Transplant Services, extending its specialized services to a population of 3,3 million individuals all over Wales involving tasks like the collection and production of blood and its components, crucial for treating patients and supporting transplant programs.

Furthermore, the Trust hosts the NHS Wales Shared Services Partnership, which provides a wide range of support services such as procurement to NHS Wales, as well as the Health Technology Wales, a national body committed to enhancing the quality of healthcare in Wales by proactively identifying and adopting technological advancements and/or innovative care models.

REGION HOVEDSTADEN (Denmark)

The Region of Hovedstaden constitutes one of the 5 main regions in Denmark, encompassing a total of 29 municipalities, including the city of Copenhagen. Its governance is vested in a regional council comprising 41 elected members, overseeing a populace numbering 1,910,395 citizens (as of 2023). The responsibilities and activities of the Region of Hovedstaden range from healthcare services and innovation to international cooperation, as well as climate and environmental matters.

The Region of Hovedstaden places a pronounced emphasis on health research and innovation, fostering robust collaborations with enterprises, universities, and other stakeholders to establish the groundwork for future healthcare services, innovative treatments, technologies, and healthcare delivery. Additionally, it is crucial to highlight its

status as one of Denmark's largest purchasers, wielding a substantial procurement volume ranging between DKK 12-14 billion. The region strategically engages in procurement and tendering processes, guided by the overarching objective of "getting the most health for the money - for the benefit of the patients."

MERCURHOSP ASBL (Belgium)

MercurHosp ASBL constitutes a central purchasing body responsible for carrying out public procurement procedures on behalf of its members, with the latter ones retaining the right of participation or abstention from the aforementioned procedures. Its network of members consists of Belgian general, psychiatric, and non-acute hospitals, including other healthcare institutions (rest, care, rehabilitation homes, associations in favor of children, people with disabilities, etc.) directly or indirectly linked to them.

It is legally recognized as a non-profit organization, building up on the vision of promoting innovation and adding value to the healthcare sector in Belgium through professional procurement and international networking. Its main objective is to create a common structure that will ultimately provide a range of services necessary for the organization of hospital care based on contracts for services and supplies in all categories of purchases.

3 State-of-the-art analysis: preliminary results

This section presents the preliminary result of the market analysis and, in particular, the state-of-the-art (SOTA) analysis. The objective of this analysis was to identify existing technologies that can tackle the procurement challenge together with an analysis of the related patents and standards, and to estimate the TRL thereof.

The SOTA analysis performed within the PROCURE4HEALTH project uncovers a rich landscape of innovative solutions in the field of biological sample preservation and analysis. The patents highlight hypertonic solutions for preserving cells and extracellular components in naturally secreted body fluids, enhancing the potential for downstream analysis and diagnostics for a wide array of conditions including cancer, cardiovascular diseases, and infections. These solutions emphasize the importance of maintaining sample quality for accurate diagnostics.

Bioreactors configured for growing and analyzing tissues and organs represent another cutting-edge area, providing environments optimized for organ growth, monitoring, and eventual transplantation. Techniques for stabilizing biological samples using various compositions, including those with chelating agents and deep eutectic solvents, are pivotal in maintaining sample integrity under varying conditions.

Other notable methods include using non-crosslinking fixative solutions followed by cryoprotectants to preserve both morphology and biological components such as nucleic acids and proteins in biological samples. These methods offer robust and simple solutions for high-quality preservation without the labor-intensive steps associated with traditional methods. Additionally, methods for assessing biospecimen degradation through dynamic changes in protein biomarkers offer new ways to ensure the quality and reliability of biological samples over time.

Further innovations include advanced methods for controlled rate freezing and nucleation of biological materials, employing forced convective cooling with precise temperature and pressure control. This ensures rapid and uniform cooling, preserving the integrity of biological samples.

The scarcity of standards reveals both a potential gap and opportunities for innovation. For this moment, only one relevant standard has been identified, addressing the preservation of biological samples. It focuses on the competence and quality control of biobanks, which inherently includes aspects of the preservation, storage, and handling of biological materials to maintain their quality. However, it does not provide detailed procedures or requirements for the preservation of fresh biological samples specifically.

Overall, these patents reveal a future where biological sample preservation and analysis are significantly enhanced, ensuring high-quality, reliable data for medical diagnostics and research. The innovations span across methods for rapid freezing, genetic analysis, and

long-term stabilization, offering robust solutions for the healthcare and biotechnology sectors.

A wider market analysis report is included in Annex III.

4 Request for Information

The Request for Information survey is part of the OMC of the PROCURE4HEALTH project. It should provide the PROCURE4HEALTH Consortium with feedback from the market about the challenge concerning the preservation of fresh biological samples for molecular biology studies.

Technology providers are invited to answer all the questions of the survey (one survey per company). The results will be considered when drafting the tender documents for the future PCP.

The survey should be filled out online and submitted via the following link: https://ec.europa.eu/eusurvey/runner/preservation_samples

Please note that taking part in this survey is not a prerequisite for participation in the future PCP and does not give any advantage to any technology provider. All information provided in the questionnaire will be anonymized, summarized and published online in English on the project's website.

Your personal data will be collected, processed, stored and used by the PROCURE4HEALTH Consortium with the only purpose of gathering information from the market within the framework of the PROCURE4HEALTH project. Personal data will be treated as strictly confidential according to the General Data Protection Regulation (Regulation 2016/679 of the European Parliament and of the Council - GDPR). You may exercise your right to access your personal data and the right to rectify such data by contacting: hello@procure4health.eu.

Annex I – Request for Information questionnaire

QUESTIONS FOR TECHNOLOGY PROVIDERS	
PCP challenge and requirements	
1	Do you have any previous experience in Innovation Procurement processes (PCP, PPI, Innovation Partnership)? If yes, please elaborate.
2	What is your main business activity/experience related to the preservation of fresh biological samples?
3	Do you have any suggestions regarding the scope of the envisaged PCP?
4	If you were to develop the solution, could you indicate an estimated budget for the development and deployment of the solution? Please justify your answer.
5	If you were to develop the solution, could you indicate an estimated timetable for the development and deployment of the solution? Please justify your answer.
6	Do you have knowledge of any suitable technology or combination of technologies for the preservation of fresh biological samples? Yes / No. If yes, please elaborate.
7	Do you know any developments in the field of the preservation of fresh biological samples that PROCURE4HEALTH needs to take into account? Yes / No. If yes, which ones?
8	Do you foresee any barriers to implement a solution for the preservation of fresh biological samples? Yes / No / I do not know. If yes, please elaborate
9	Can you tackle all or part of the requirements of this challenge? Yes / No / I do not know yet. If yes, please explain. If I do not know yet, what additional information would you need?
10	Can you identify relevant functionalities that have not been described in the market consultation document? Yes / No If yes, please elaborate.
11	Can you provide any other recommendations regarding the preservation of fresh biological samples?
State-of-the-art (SOTA) analysis	

12	Do you think there is room for technological development beyond the state of the art? Please explain.
13	What kind of solutions or developments would you propose?
14	What value for the health care system do you estimate your solution might provide?
15	Do you know the TRL of those solutions/developments?
16	Can you identify any patents or standards that are relevant to the preservation of fresh biological samples?
17	What kind of standards and/or integration requirements do you think should be taken into account in the solution development?
Miscellaneous	
18	What information do you still need in order to make a good plan of action for the development and/or implementation of solutions suitable to address the preservation of fresh biological samples challenge?
19	Do you have specific requirements to achieve the functionalities that PROCURE4HEALTH should take into account? Yes / No. If yes, which ones?
20	How could you contribute to the preservation of fresh biological samples challenge? Please explain.
21	What are the risks associated to the development and implementation of a solution that tackles the functional needs of PROCURE4HEALTH?
22	In case the public buyers decide to follow a Public Procurement of Innovative solutions, would you agree on the possibility to have a Value Engineering* clause requiring contractors to present Value Engineering Change proposals for improvements and reduction of the Total Cost of Ownership during the term of the contract? Please explain your answer. **Value engineering is defined in this context as the sum of activities and actions aiming to ensure that the contractor fulfils its obligations such as to create added value for the public buyers. These activities and actions target innovative development, effective and/or efficient organisation of the project or similar.*
23	Do you have any suggestions and/or remarks?

Annex II – Use case

Preservation of fresh biological samples

Scope of the problem

New molecular techniques in research (and increasingly in clinical practice) require the availability of biological material from patients preserved in a system that does not modify the nucleic acids, proteins or metabolites of the sample and that does not require freezing and the associated infrastructure. Frozen tissue is the best biological sample for current molecular biology techniques, but the costs of frozen storage are very high. The widespread method of storing patient samples is by fixation and embedding in paraffin, but this system does not allow to get the most out of patient samples. Therefore, there is a need to develop other techniques that would keep the sample as close as possible to the original state (at low costs, preferably).

In the end, patients are the ultimate to be affected, as we cannot get the full benefit of their samples. Progress in translational research is also affected. It is important then to respond to this need so that the most modern and informative techniques can be applied to the diagnosis and treatment decision of patients in the context of precision medicine where multiple omics become predictors of response and prognosis. All of this results in an optimisation of disease management, savings in health system costs and improved patient survival and quality of life.

Description of the need

There is a lack of cost-efficient methods to preserve biological samples for molecular biology studies that require the use of intact DNA, RNA, proteins and metabolites, in high yield and of good quality. There are either alternatives on the market that improve the situation but do not solve it, or alternatives that would require a reconfiguration of sample collection flows and procedures in the Andalusian Public Health System.

Importance of addressing the need

There is a need for greater precision in the extraction of biological samples and for samples to be preserved as close to their original state as possible for the effective performance of molecular analyses with the techniques used in precision medicine. Addressing this need would, for example, reduce expenditure on current materials and preservation systems that, on top of that, do not even keep the sample in the desirable and needed state (i.e., similar to the original state). Moreover, responding to this need, we would have more useful samples for diagnosis and follow-up of patients and for research in the field of Precision and Predictive Medicine. State-of-the-art techniques such as spatial transcriptomics or epigenetic profiling, require intact and isolable DNA and RNA in appropriate quantities. In

addition, the use of surplus diagnostic samples would become more efficient as not as much sample would be needed, thus preserving a future use of it with new techniques that could emerge, and also optimises the analysis, being able to perform complex and massive profiling from the same amount of sample.

Use case

Frozen tissue is the best biological sample for current molecular biology techniques as high-quality and high-throughput nucleic acids and proteins can be extracted from them. The most common material that has been used so far is paraformaldehyde-fixed and paraffin-embedded tissue for two fundamental reasons: 1) due to ethical reasons, it is not always admissible to take invasive biopsies; and 2) many established clinical markers are immunohistochemical stains, so the repository of diagnostic samples is made in paraffin, which also does not require refrigeration. However, the quality and yield of nucleic acids and native proteins that current research requires are not achieved from tissues preserved in this way, despite the fact that the techniques have been tried to adapt to paraffin. Room temperature storage modalities are also being developed, but we still rely on freezing, so we estimate that pathology departments and biobanks would now need to store and distribute increasing quantities of frozen biological samples considering the increase in techniques such as sequencing for diagnosis and treatment selection.

Biological samples from patients can be broadly classified as tissue, blood or other fluids. These are sometimes processed to produce derivatives such as cells, nucleic acids or proteins, and then stored. Blood and fluids can also be processed to separate cellular components before freezing. It is this diversity of biological samples that must be collected and stored under optimal conditions.

The costs of frozen storage are very high, if we also consider that they require a room with access to autonomous safety power supplies, ambient refrigeration and emergency liquid nitrogen tanks. The need to find alternatives for storage at room temperature has been emphasized for quite some time, not only in terms of space but also administrative obstacles.

Massive analyses (genomic, transcriptomic, proteomic, metabolomic) that require nucleic acids, proteins and metabolites of the highest quality are already being used more, and not only tissues suitable for histological studies. Tissues preserved with paraformaldehyde have highly fragmented nucleic acids and are isolated with lower yield. This type of sample is valid for histology, immunohistochemistry, PR/RT-PCR, but not for studying the genome or transcriptome, for example. Increase in population and longevity, as well as the pathologies associated with it, will generate more and more specimens to be stored.

Keywords

- Fresh biological samples preservation
- Pathology departments
- Biobanks
- Molecular biology techniques

- Sample collection flow
- Sample collection costs
- Intact DNA, RNA, proteins and metabolites samples
- Precision medicine

SITUATION

AS IS NOW	WISH SITUATION
Frozen tissue is the best biological sample for current molecular biology techniques as high-quality and high-throughput nucleic acids and proteins can be extracted from them. The most common material that has been used so far is paraformaldehyde-fixed and paraffin-embedded tissue for two fundamental reasons: 1) due to ethical reasons, it is not always admissible to take invasive biopsies; and 2) many established clinical markers are immunohistochemical stains, so the repository of diagnostic samples is made in paraffin, which also does not require refrigeration. However, the quality and yield of nucleic acids and native proteins that current research requires are not achieved from tissues preserved in this way, despite the fact that the techniques have been tried to adapt to paraffin. Room temperature storage modalities are also being developed, but we still rely on freezing, so we estimate that pathology departments and biobanks would now need to store and distribute increasing quantities of frozen biological samples considering the increase in techniques such as sequencing for diagnosis and treatment selection.	We want to be precise in obtaining samples, so that with the minimum possible action we obtain everything we need from the patient. Currently, paraffin is used, but the innovation to be developed would be the generation of other techniques that keep the sample in the possible most similar state to the original (and that does not depend on being at -20º). Therefore, the challenge would be to adopt a method that preserves the sample and is useful both for the currently used techniques of histology, immunohistochemistry, etc., as well as for those that have been developed as Precision Medicine has evolved, and that are made with DNA, RNA, proteins and metabolites intact and isolated in high performance.

REQUIRED FUNCTIONALITIES

- A preservation method that maintains biological samples in a state as similar as possible to the original state.

- An effective method for preservation of biological samples without compromising the integrity of the molecular components (i.e., a method that preserves DNA, RNA, proteins and metabolites in high quality and yield).
- A method that facilitates the adaptability of the biological sample to molecular biology techniques used in precision medicine.
- An easy method to implement in surgical and clinical environments without the need for additional infrastructure.
- A method different from paraffin fixation and embedding.
- A method that does not require freezing.
- A cost-effective method.
- A method able to guarantee quality standards that ensure the suitability of samples for use in diagnosis and research.

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Annex III – Market analysis report

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