Procure 4Health

Market Consultation Report

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

October 2024

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

Abbreviations and Acronyms

CET	Central European Time
EC	European Commission
EU	European Union
GDPR	General Data Protection Regulation
HE	Horizon Europe
IPRs	Intellectual Property Rights
MDR	Medical Devices Regulation
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
TED	Tenders Electronic Daily
TRL	Technology Readiness Level
WTO	World Trade Organisation

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1 Purpose of the Open Market Consultation

1.1 Introduction

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

The OMC aimed, on one hand, to inform technology vendors regarding the potential future PCP. On the other hand, it intended to understand their capabilities to satisfy the procurers' needs and to obtain their input on the viability of the procurement plans and conditions as described in the OMC document and annexes.

The OMC was published through a Prior Information Notice (PIN) in the Tenders Electronic Daily (TED) on 8 July 2024. The rules and objectives of the PROCURE4HEALTH OMC, as well as the challenges, the potential public buyers and the PCP approach were described in the OMC Document with Annexes. This document was published the PROCURE4HEALTH website (www.procure4health.eu).

Market parties were also requested to fill out a questionnaire in the EU Survey. The deadline to fill out the questionnaire was 7 October2024. The intention of the questionnaire was to explore the market 'as-is', therefore there could not be wrong or right answers. The responses to the questionnaire could not contain any confidential information. The information obtained will be used as input for the procurement strategy and conditions.

The OMC was performed under the law of the Lead Procurer (Servicio Andaluz de Salud), which is Spanish law.

After processing the questions and responses of all suppliers, this document has the objective of communicating the results to the market. In this context, all information provided by technology vendors is treated as commercially sensitive and specific details will not be communicated to any supplier. Only the general findings are summarised and communicated in this report. This anonymised report (excluding the confidential information) will be published on 16 October 2024 on the PROCURE4HEALTH website (www.procure4health.eu).

By carrying out the OMC, the procurers do not commit to subsequently deploying a procurement procedure. Moreover, in case this OMC will be followed by a procurement procedure, the public procurers reserve the right to change any elements that define the desired solution. No rights can be derived from any statements made by the procurers during the OMC. Participation in the OMC is not a precondition for bidding in the future PCP.

The data collected, processed, stored and used by the PROCURE4HEALTH Consortium has the only purpose of implementing the PROCURE4HEALTH project and is handled according to the General Data Protection Regulation (Regulation 2016/679 of the European Parliament

and of the Council - GDPR). Participants may exercise their right to access their personal data and the right to rectify such data by contacting: (hello@procure4health.eu)

1.2 Activities & timetable

The OMC took 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.

The timetable for the OMC was set as follows:

Date	Event
8 July 2024	Publication of the Prior Information Notice (PIN) on TED.
8 July 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).
7 October 2024	Deadline for filling in the OMC questionnaire (17:00 CET).
16 October 2024	Publication of the OMC findings, including all questions and answers to the OMC questionnaire.
17 October 2024	Closure of the OMC.

Table 1: OMC Timetable

Parties interested in participating in the online event were requested to register through the Microsoft Teams invitation link which expired after the event. A total of 40 people participated in the event.

The webinar within the framework of the OMC was recorded. The video recording is available on the website of Procure4Health (https://procure4health.eu/omc-preservation-of-fresh-biological-samples/).

2 The OMC results

2.1 The OMC procedure and reporting

The OMC started on the date of its publication in the EU's Supplement to the Official Journal (TED) and ended on the date set in the timetable above.

Interested parties were requested to register in order to participate in the events and receive additional information of the project. Additional written contribution in the form of a Request For Information (RFI) questionnaire was requested through the EU Survey questionnaire. The responses to the questionnaire could not contain any confidential information. The questionnaire was 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.

The PROCURE4HEALTH Consortium supported interested parties throughout the whole OMC during the webinar, and by answering questions through a Q&A document which was published on the project's website.

Market operators who wished to provide additional confidential information during the OMC could send this to the email: hello@procure4health.eu. The information had to be clearly marked as confidential. Confidential information is not included in the OMC report.

The language of this market consultation is English.

2.2 Open Market Consultation report

After processing and analysing the answers, the PROCURE4HEALTH Consortium aims to disseminate the results to the widest possible audience through this OMC report. Nevertheless, all answers provided by market parties are anonymized. The PROCURE4HEALTH Consortium will therefore provide only the general findings and a summary of the answers obtained in the EU Survey questionnaire. The OMC Report is published on the website of PROCURE4HEALTH.

Based on the feedback provided in the EU Survey questionnaire, the respondents belong to start-ups, SMEs, private organisations and other groups as indicated in the figure below.

The participants who replied to the EU Survey questionnaire are from organisations in Germany, Spain, Italy, France and Türkiye.

		Answers	Ratio
Start-up		1	14.29 %
SME		4	57.14 %
Private organisation		1	14.29 %
Research center		0	0.00 %
End user		0	0.00 %
University		0	0.00 %
Other		1	14.29 %
No Answer		0	0.00 %

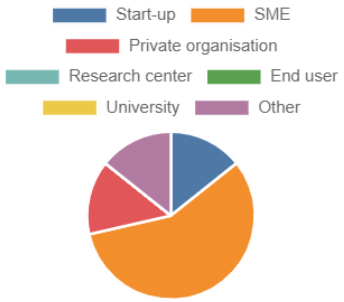

Figure 1.- Type of organisations who replied to the Request for Information using the EU Survey tool.

2.3 Summary of results

This section summarises the feedback provided to each of the 23 questions of the EU Survey under 3 topics: (1) The PCP challenge and requirements; (2) The State-Of-The-Art analysis; and (3) Miscellaneous.

2.3.1 The PCP challenge and requirements

1) Do you have any previous experience in Innovation Procurement processes (PCP, PPI, Innovation Partnership)?

Five respondents answered yes, and two respondents stated they have no experience in Innovation Procurement. A summary of the answers is provided below:

- One respondent mentioned that Innovation Procurement is a continuous process.
- One respondent contributed to the preservation of fresh biological samples challenge during an Open Market Consultation in Spain.
- One respondent reported having experience in two hospital projects in Seville, Spain, where they created devices to improve user experiences.
- One respondent indicated they participated as a technology provider in Innovation Procurement.
- One respondent managed two PCP projects under the coordination of a health information systems directorate, with their Ministry of Health participating as the lead coordinator. They also mentioned involvement in additional R&D projects.

		Answers	Ratio
Yes		5	71.43 %
No		2	28.57 %
No Answer		0	0.00 %

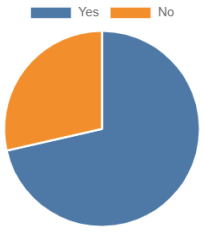

Figure 2.- Past involvement and experience with innovation procurement processes.

2) What is your main business activity/experience related with the preservation of fresh biological samples?

The responses indicate a range of activities and experiences related to the preservation of fresh biological samples. A summary of the answers is provided below:

- One respondent mentioned their foundation's involvement in the preservation of biological samples.
- One respondent stated that their primary mission is to develop complete solutions for the stabilization, storage, and shipping of biological samples at room temperature.
- One respondent described the development, validation, and patenting of an innovative histological fixative that outperforms traditional methods in preserving DNA, RNA, and proteins while complying with EU regulations.
- One respondent indicated the creation of a formaldehyde recipient designed to be easy to use and safe for respiratory exposure to medications.
- One respondent noted their focus on developing innovative solutions for diagnostics related to biological samples.
- One respondent explained that, in their region, the primary method for preserving fresh biological samples involves freezing and storing, with pathology practices utilizing techniques like paraffin embedding and other fixation methods. They also highlighted the role of biobanks in collecting, storing, and analyzing biological samples, especially in cancer research and genetic studies.
- One respondent mentioned leading a group of technological companies with expertise in thermomechanical devices and holding a patent for the preservation of biological materials through non-freezing supercooling, having conducted preliminary tests on various biological materials.

3) Do you have any suggestions regarding the scope of the envisaged PCP?

The responses indicate a variety of suggestions regarding the scope of the envisaged PCP, focusing on the need for universal, adaptable, and innovative solutions for the preservation of biological samples. Some respondents emphasized the importance of compliance with ethical standards and the integration of user-friendly technologies.

- One respondent stated they had no suggestions.
- One respondent suggested that the proposal should be universal and applicable to all types of biological samples, with a focus on medium to long-term shelf life.
- One respondent recommended including Glyoxal Acid Deprived solutions for improved structure preservation during the pre-analytical phase.

- One respondent indicated the development of a recipient that contains formaldehyde for preserving medical samples without freezing.
- One respondent mentioned they are working on a solution for fresh blood storage.
- One respondent suggested that the scope should focus on cost-effective and sustainable solutions, ensuring compliance with local and international ethical standards and being user-friendly for healthcare workers.
- One respondent noted that any technology developed should be synergistic, enhancing the capabilities of other existing technologies.

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.

The responses provided varied estimates for the budget required for the development and deployment of the solution. The estimates reflect differing scopes and technological approaches, indicating a range of financial commitments necessary for successful implementation. A summary of the answers is provided below:

- One respondent estimated a budget of €500,000.
- One respondent provided an estimate of €2,339,624 based on a detailed budget prepared for a Spanish call.
- One respondent noted that their product is an IVD CE-certified device that offers a cost-effective alternative to formaldehyde, helping to reduce expenses related to compliance and environmental management.
- One respondent estimated the budget at €25,000.
- One respondent indicated that raw estimates to validate their prototype would be around €1.5 million, including device validation and CE-IVD marking.
- One respondent suggested that an initial budget for a PCP project of this scale could be approximately €8-10 million, covering R&D, infrastructure upgrades, equipment, and training for healthcare personnel.
- One respondent indicated that total costs might range from €350,000 to €700,000, detailing specific expenses for personnel, materials, testing, and deployment.

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.

The responses varied widely in their estimated timelines for the development and deployment of the solution, reflecting different approaches and phases necessary for effective implementation. A summary of the answers is provided below:

- One respondent estimated a development timeline of 12 months.
- One respondent projected a timeframe of 3-4 years based on a detailed budget prepared for a Spanish call.

- One respondent mentioned that the validation of their product took ten years to complete.
- One respondent outlined a plan involving three milestones, taking approximately 9 months.
- One respondent estimated that development would last between 1.5 to 2 years.
- One respondent suggested a total estimated timeframe of approximately 24-36 months, structured into three phases: preparation (6-12 months), prototyping (8-12 months), and pilot testing (6-12 months).
- One respondent indicated that various phases of the work plan could last between 24 and 45 months, detailing specific durations for prototype engineering, testing, redesign, manufacturing, and deployment.

6) Do you have knowledge of any suitable technology or combination of technologies for the preservation of fresh biological samples? Please elaborate.

The responses highlighted a range of technologies and approaches relevant to the preservation of fresh biological samples. These included both established methods and emerging technologies that show potential for improving preservation practices. A summary of the answers is provided below:

- One respondent mentioned experience in tissue engineering and biotechnology.
- One respondent described their development of an IP-protected sample stabilization system based on lyophilization, which has demonstrated effectiveness for DNA and plasma stabilization.
- One respondent noted that their innovative fixative replaces formalin and improves the preservation of tissue structure and molecular integrity.
- One respondent indicated they have been investigating preservation technologies for six years.
- One respondent mentioned they have developed a prototype for preservation technology that is awaiting validation.
- One respondent referenced emerging room temperature storage methods using chemical preservatives that do not require freezing, showing promise for cost reduction and infrastructure needs.
- One respondent described a patented technology for preserving biological materials that avoids freezing by using supercooling, highlighting its advantages in maintaining tissue integrity and compatibility with other methods while being portable and energy-efficient.

		Answers	Ratio
Yes		7	100.00 %
No		0	0.00 %
No Answer		0	0.00 %

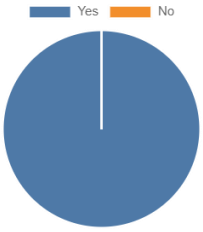

Figure 3.- Answers for the questions regarding the knowledge of any suitable technology or combination of technologies

7) Do you know any developments in the field of preservation of fresh biological samples that PROCURE4HEALTH needs to take into account? Please elaborate.

Respondents noted various developments in the field, from reagents to advanced molecular techniques, which might be illustrating for PROCURE4HEALTH. A summary of the answers is provided below:

- One respondent highlighted developments in stem cells and human cell preservation.
- Another mentioned a complete solution for biological sample preservation.
- One respondent emphasized an innovative fixative that improves DNA, RNA, and protein preservation.
- A respondent pointed out advancements in molecular techniques like spatial transcriptomics and metabolomics that require high-quality samples.
- One respondent referred to supercooling technology, applicable to both animal and plant biological samples.

		Answers	Ratio
Yes		6	85.71 %
No		1	14.29 %
No Answer		0	0.00 %

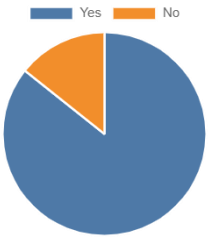

Figure 4.- Answers for the question regarding current developments in preservation of fresh biological samples.

8) Do you foresee any barriers to implement a solution for the preservation of fresh biological samples? Please elaborate.

Some respondents identified barriers to the implementation of new preservation technologies, while others did not foresee any issues. A summary of the answers is provided below:

- One respondent mentioned the reluctance to change and the need for validation efforts to shift technologies.

- A respondent noted barriers related to regulatory requirements and habits, emphasizing that new methods may not require significant operational changes.
- Another mentioned the cost of transitioning from traditional methods, such as paraffin embedding, and the need for regulatory approvals.
- One respondent highlighted the challenge of maintaining sample quality in diverse climates.
- Three respondents said they did not foresee any barriers.

		Answers	Ratio
Yes		4	57.14 %
No		3	42.86 %
I do not know		0	0.00 %
No Answer		0	0.00 %

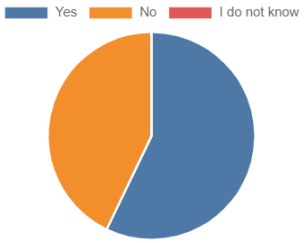

Figure 5.- Answers for the question regarding barriers in preservation of fresh biological samples.

9) Can you tackle all or part of the requirements of this challenge? How can you tackle them?

Respondents outlined their capabilities in addressing parts of the challenge, ranging from stabilization solutions to infrastructure and device development. A summary of the answers is provided below:

- One respondent mentioned competence in meeting the challenge.
- Another indicated they can stabilize DNA and plasma and are working on other biological materials.
- A respondent was unsure, noting the need for further information, but highlighted a validated solution for tissue and cell samples.
- One respondent mentioned establishing a development plan.
- A respondent shared their capacity to validate a preservation device.
- Another indicated their ability to provide IT infrastructure for storing and tracking samples, but noted that preservation technologies may require collaboration.
- One respondent stated their ability to engineer, prototype, and manufacture solutions.

		Answers	Ratio
Yes		6	85.71 %
No		0	0.00 %
I do not know yet		1	14.29 %
No Answer		0	0.00 %

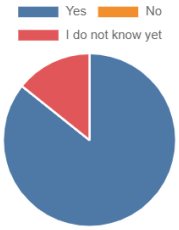

Figure 6.- Answers for the question regarding tackling all or part of the requirements of the challenge.

10) Can you identify relevant functionalities that have not been described in the market consultation document? Please elaborate.

Respondents provided additional insights into functionalities that could enhance preservation technologies. A summary of the answers is provided below:

- One respondent indicated there may be opportunities for improvement but noted they had not read the market consultation document.
- Another highlighted the danger of formaldehyde gas exposure and suggested designs to mitigate this.
- A respondent mentioned the integration of AI tools to predict sample degradation and real-time monitoring of storage conditions.
- One respondent suggested that devices should be portable, standardized, reliable, and traceable, offering specific characteristics to enhance preservation processes.
- Three respondents indicated no additional functionalities.

11) Can you provide any other recommendations regarding the preservation of fresh biological samples?

Respondents offered recommendations on addressing existing challenges in biological sample preservation, including the exploration of hybrid solutions and ensuring safety measures. A summary of the answers is provided below:

- One respondent recommended considering the practices of certain clinics.
- Another suggested that new solutions should address the limitations of current room-temperature stabilization technologies.
- A respondent emphasized the importance of safety in preservation solutions.
- One respondent recommended exploring hybrid preservation methods that combine room temperature and frozen storage.
- Another highlighted the need to minimize ionizing radiation, which deteriorates DNA and RNA, and stressed the importance of the full preservation chain from extraction to analysis.

2.3.2 The State-Of-The-Art analysis

1) Do you think there is room for technological development beyond the state of the art? Please explain.

The majority of respondents believe there is significant potential for further technological development. Several respondents emphasized the need for advancements, such as reinventing lyophilization to be effective for complex biological samples, which current methods fail to address adequately. One respondent highlighted the importance of improving the pre-analytical stage, as it could lead to more accurate biological tests and improved sequencing platforms. Another suggested exploring vacuum sealing as a novel preservation method. There was also mention of the need for miniaturization of sampling and simplification of storage conditions for blood. Additionally, one respondent suggested integrating IoT-based monitoring systems to track real-time storage conditions, while another mentioned the potential of supercooling technology, which would require engineering effort to optimize for biological samples.

2) What kind of solutions or developments would you propose?

Respondents proposed a range of solutions, including innovations in living cell preservation, complete off-the-shelf solutions for sample stabilization, and new reagents that can eliminate technical bottlenecks in genomic profiling and sequencing platforms. Some suggested practical solutions like containers for safely pouring formalin, minimizing the health risks to the operator. Another proposed the collection of blood samples to store, recover, and analyse fresh cells. Collaborative platforms for real-time data sharing between biobanks and healthcare facilities were also proposed. Additionally, one respondent focused on advancing supercooling technology, proposing a portable or fixed device that could cool samples well below their normal freezing point without freezing them. This supercooling technique, which involves controlling the air-sample interface and humidity, could preserve fresh biological samples at temperatures as low as -20°C without freezing.

3) What value for the health care system do you estimate your solution might provide?

One respondent pointed to the potential to rescue organ donation recipients through improved preservation techniques. Another highlighted contribution to biomedical research, improvements in clinical diagnosis, facilitation of clinical research, and economic, environmental, and space-saving advantages.

Other respondents focused on the broader social and economic impact. One respondent stated that their solution would lead to a significant social impact by improving the quality of diagnostic samples, leading to more reliable results. This, in turn, would help democratize the use of molecular diagnostic methods, reducing the overall cost of sequencing diagnostics and making advanced healthcare more accessible to a broader population.

The respondent also emphasized that adopting their solution, GAF®, would demonstrate a commitment to sustainability while enhancing an institution's reputation as an ethical, forward-thinking entity.

Another respondent suggested that their solution would improve the preservation of fresh samples without any harmful side effects for users. Improved cost-efficiency, better quality of care, and enhanced patient access to healthcare were cited as other potential benefits. One respondent argued that their solution would reduce the costs associated with frozen storage, enhance the quality of preserved samples, and allow for faster, more accurate diagnostics.

Respondents who proposed supercooling technology suggested that their solution could be implemented in both portable and fixed devices. This would improve the entire preservation chain, even allowing for the collection of samples at a patient's home in remote areas. The fixed version of the device would also save space and power while eliminating the need for chemicals, reducing risks of side contamination or chemical reactions, and simplifying sample handling compared to frozen samples.

4) Do you know the TRL of those solutions/developments?

Respondents provided different Technology Readiness Levels (TRLs) for their solutions. One respondent reported their solution to be at TRL 7-8, while another stated their development was at TRL 5-6. Two respondents mentioned TRL 4 for their technologies, with one specifying that biological materials could be supercooled and preserved for extended periods. Another respondent also reported their solution to be at TRL 7. Lastly, one respondent stated they did not know the TRL of their solution.

5) Can you identify any patents or standards that are relevant to the preservation of fresh biological samples?

Several respondents identified relevant patents and standards related to the preservation of biological samples. One mentioned that they had filed a European patent application (EP24382077.6) in January 2024. Another respondent referred to patents related to their Glyoxal Acid Free (GAF®) technology, which has been patented in Europe and the U.S. A third respondent mentioned that they were not aware of any patents directly relevant to their solution. However, they suggested that patents concerning cryopreservation technologies, sample transport containers, and preservation solutions would likely be relevant to this field. Additionally, one respondent highlighted the granted patent EP3096614, related to supercooling technology, which was issued on September 8, 2021.

List of Patents Mentioned:

1. EP24382077.6 (filed 2024)
2. GAF® patents (Europe, U.S.)
3. EP3096614 (supercooling, 2021)

6) What kind of standards and/or integration requirements do you think should be taken into account in the solution development?

One respondent stated that all known standards should be taken into account, while another emphasized that the solution should not change the users' workflow. They proposed that biological samples could be stored at room temperature cabinets after undergoing lyophilization, eliminating the need for ultra-low freezers. Another respondent stated that no specific standards were required for their solution.

Respondents emphasized the importance of adhering to established standards, particularly compliance with ISO standards relevant to laboratory practices, as well as ensuring data interoperability with existing healthcare systems (e.g., HL7 or FHIR for health data exchange). One respondent also mentioned the importance of compliance with electrical equipment standards and ISO 9001.

2.3.3 Miscellaneous

1) 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?

One respondent indicated that they needed a more detailed description of the demand or call for action and suggested a call to discuss these details further. Another stated that they did not require any additional information beyond access to the specific call details. Some respondents expressed the need for access to a lab in order to verify the effectiveness of their prototypes. Regulatory guidelines were also mentioned as important information for planning.

One respondent noted that a successful plan of action would require more information about the types of biological samples involved, existing storage technologies, and stakeholder needs. Additionally, understanding potential partnerships with research institutions or biotechnology companies would be beneficial. Another respondent suggested that it would be helpful to know if the members of the PROCUREMENT4HEALTH consortium would be able to conduct laboratory tests themselves to assess the quality of the preservation technologies.

2) Do you have specific requirements to achieve the functionalities that PROCURE4HEALTH should take into account? Please indicate the specific requirements:

Most respondents indicated that they did not have specific requirements. However, one respondent noted that any solution should support scalability and maintain sample integrity under different conditions. The respondent also stressed the importance of integrating the solution with existing health information systems to track and report data. Ensuring compatibility with current healthcare infrastructures was another key point mentioned by the respondent.

3) How could you contribute to the preservation of fresh biological samples challenge? Please explain.

Respondents indicated various ways they could contribute. Some focused on providing research and wholesale solutions for biological sample stabilization, while others emphasized their ability to offer superior tissue fixation technologies that preserve DNA, RNA, and proteins. One respondent suggested a safer method for pouring formalin over tissue samples, while another offered a prototype for blood cell storage. Others mentioned their capacity to leverage existing research expertise, collaborate with universities, and participate in pilot projects. Some respondents also highlighted their ability to engineer, prototype, and manufacture preservation solutions, ensuring they meet the required TRL levels.

4) What are the risks associated to the development and implementation of a solution that tackles the functional needs of PROCURE4HEALTH?

Several risks were identified by respondents, including the possibility of failing to stabilize specific biological samples, regulatory compliance challenges, and potential resistance from end-users due to unfamiliarity with new practices. Others mentioned technological obsolescence, difficulties in system integration, and typical R&D project risks, such as poor practical performance in operational environments or lack of user acceptance.

5) 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.*

Most respondents expressed openness to the idea of a Value Engineering clause. Some indicated that it was part of their daily business practices, while others sought further clarification on the implications of reducing total cost during the contract term. Several respondents agreed to redesign and create new prototypes if necessary, while others were unsure of the clause's specifics.

6) Do you have any suggestions and/or remarks?

Respondents generally had no additional suggestions or remarks. However, one respondent emphasized the importance of continuous training for personnel involved in sample preservation to ensure high standards of practice. Others declined to offer any further input.

3 The follow up PCP

PROCURE4HEALTH is preparing the operational ground for a Pre-Commercial Procurement (PCP) proposal concerning preservation of fresh biological samples. 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 the 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. Here are the required functionalities:

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

4 Conclusions

Based on the analysis of the responses to the 23 questions posed during the OMC for PROCURE4HEALTH, several key insights have emerged. The OMC revealed that the market is actively exploring and developing innovative solutions for the preservation of fresh biological samples. Respondents identified various technologies and approaches that are either at different stages of development or are already being tested and validated. These technologies include advanced lyophilization methods, room temperature stabilization techniques, supercooling, and chemical preservatives, all of which aim to improve the preservation of biological materials, reduce infrastructure costs, and maintain sample integrity over time.

Respondents highlighted the potential for further technological development beyond the current state of the art. Many cited the need for improvements in pre-analytical processes, particularly to optimize sample quality for advanced molecular techniques like sequencing. Several respondents also noted the benefits of integrating new technologies, such as IoT-based monitoring systems, to provide real-time data on storage conditions, which could enhance sample management and preservation.

Responses indicated a range of TRLs for the proposed solutions, with some technologies being in the early stages of development (TRL 3-4), while others were more advanced (TRL 7-8). This variation highlights the need for continued research, testing, and validation to bring these solutions closer to widespread implementation in healthcare settings.

Several respondents indicated their readiness to incorporate a Value Engineering clause within contracts, which would enable continuous improvements and cost optimizations throughout the project lifecycle. This approach is seen as beneficial, as it encourages contractors to develop more efficient and innovative solutions that can reduce the total cost of ownership over time. However, some respondents expressed a need for clarification on the specific expectations and conditions surrounding the application of such a clause.

Some respondents also pointed out potential barriers to implementing these solutions, including regulatory challenges, the cost of transitioning from traditional methods, and resistance to change within healthcare institutions. They expressed concern that end-users may be reluctant to adopt new technologies due to established workflows, infrastructure limitations, or the depreciation of existing equipment. Additionally, the need for extensive validation and demonstration efforts to ensure trust and acceptance of new technologies was highlighted as a critical factor in the success of these innovations.

Respondents also suggested that PROCURE4HEALTH consider the integration of AI-based tools for predicting sample degradation and real-time monitoring systems to ensure optimal storage conditions. Additionally, there were recommendations to collaborate with international biobanks and research centres to align with best practices and consider ethical, regulatory, and safety standards, particularly in relation to sample handling and data privacy.

Overall, the responses to the OMC demonstrate a clear demand for innovative solutions in the preservation of fresh biological samples. The market is poised for significant advancements, with technologies showing promising potential to improve the efficiency, cost-effectiveness, and safety of sample preservation methods. However, the successful implementation of these technologies will require addressing regulatory and operational barriers, fostering collaboration across stakeholders, and ensuring that solutions are adaptable to the needs and constraints of the healthcare sector.

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