Procure 4Health

Market Consultation Report

Results of the Open Market Consultation for the future Pre-Commercial Procurement of R&D services concerning home-based care and remote monitoring

July 2024

Funded by the European Union

GA n° 101057209

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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 home-based care and remote monitoring.

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 6 May 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 19 July 2024. 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 (Sykehusinnkjop HF), which is Norwegian 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 30 July 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 26 June 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
6 May 2024	Publication of the Prior Information Notice (PIN) on TED.
6 May 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/IntegratedCare
26 June 2024	OMC Event in English (online) (10:00 – 11:30 CET).
19 July 2024	Deadline for filling in the OMC questionnaire (17:00 CET).
30 July 2024	Publication of the OMC findings, including all questions and answers to the OMC questionnaire.
31 July 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 97 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 (OMC – Home-based care and remote monitoring – Procure4Health).

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, research centres, end users and other groups as indicated in the figure below.

The participants who replied to the EU Survey questionnaire are from organisations in Ireland, Germany, France, Spain, Sweden, Türkiye, United States, Netherlands, Poland and the United Kingdom.

		Answers	Ratio
Start-up		5	26.32 %
SME		6	31.58 %
Private organisation		3	15.79 %
Research center		2	10.53 %
End user		2	10.53 %
University		0	0.00 %
Other		1	5.26 %
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 18 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)?

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

- One respondent stated that they have successfully managed two PCP projects under the coordination of a governmental health information system directorate and have other R&D projects within their directorate.
- Another respondent indicated that their organization works through innovation procurement processes and collaborates with leading hospitals in various regions to develop advanced monitoring solutions for home and hospital care.
- A participant mentioned their involvement in a PCP project for integrated care solutions, having completed phase 2 and awaiting phase 3. They also participate in various local PPIs aimed at supporting care at home through technological solutions.
- One respondent shared their experience in the CAREMATRIX project, detailing their progression through multiple phases of the project, from solution design to prototype development and limited volume testing.
- Another participant reported their involvement in several innovation procurement processes, including dynamic procurement schemes for video-enabled care and virtual wards, as well as participation in various Horizon 2020 initiatives.
- A respondent mentioned being part of a consortium in the Rosia PCP and leading another consortium in the Carematrix PCP.

- One participant listed their participation in several PCPs, including ROSIA, Carematrix, MEDEA, and MEDP, and collaboration with various hospitals and health services.
- Another respondent highlighted their involvement in multiple innovation procurement processes, including a project to develop a web IT tool for a cancer survivor smart card and several public procurement initiatives focused on remote monitoring of older adults at home.
- A respondent indicated that two of their employees have previous experience in PCPs focusing on chronic condition management, although the company itself has not been involved in EU-related innovation procurement processes.
- One participant mentioned leading a PCP project and participating in two European PCP consortiums related to remote monitoring and rehabilitation, as well as involvement in another health service-promoted project.
- Another respondent noted their participation in various PCP projects such as CRANE, TiQuE, and InCareHeart, focused on developing new care models.
- A participant shared their work in several PCPs related to developing new care models.
- Another respondent indicated their involvement in several projects funded by Innovate UK and Scottish Enterprise, in collaboration with healthcare and academic organizations.
- One participant mentioned that one of their co-founders has extensive experience in innovation partnerships at the EU level and holds numerous patents.
- One respondent mentioned that their organization is cooperating with various hospitals, pharmaceutical companies, and health services.

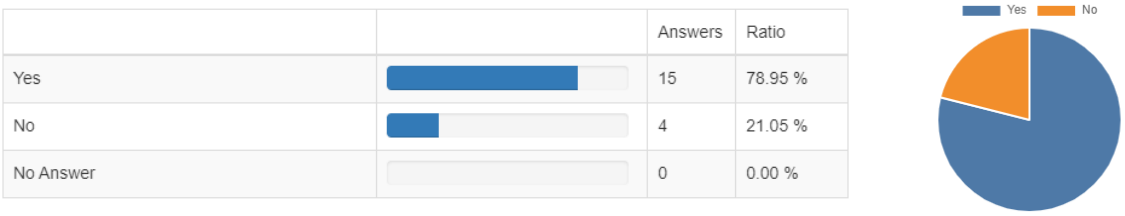

Figure 2.- Past involvement and experience with innovation procurement processes.

2) What is your main business activity/experience related with home based care and remote monitoring?

The respondents declared a wide array of business activities related to the PROCURE4HEALTH project, emphasizing their expertise in home-based care and remote monitoring. A summary of the answers is provided below:

- One respondent stated that their main business activity involves managing a comprehensive Home Health Care Services program under national health regulations. They provide medical and social support directly to patients in their homes, including medical care, rehabilitation, psychosocial support, hygiene

assistance, and daily activity help. Their goal is to facilitate patient recovery at home, reducing hospital admissions, and they adhere to national standards with teams like home care units, mobile health units, and outpatient clinics.

- Another respondent reported having deployed more than 7,000 sensors in 20 different countries for home-based and remote monitoring.
- A respondent indicated their primary business activities are software development for healthcare products and business consulting services. They create technological solutions for the healthcare field, designing applications and systems that comply with sector standards and regulations, and have developed a socio-health software platform, focused on optimizing resource use and providing personalized care.
- One respondent specializes in home-based care and remote monitoring solutions, offering a platform that includes features like automated workflows for patient monitoring, integration of health parameters, real-time data, advanced functionalities like risk classification, and robotic assistance. They aim to enhance patient care by supporting personalized healthcare plans and improving patient engagement.
- Another respondent operates a home hospital platform service providing advanced telemedicine solutions that extend clinical care beyond traditional settings. Their platform supports video-telemedicine, real-time health data monitoring, and remote medical team oversight, aiming to reduce hospital admissions and improve healthcare efficiency.
- A respondent offers a telemedicine platform that covers all features needed for holistic home-based care, including communication channels for patients and caregivers, gamified strategies for behaviour improvement, and multichannel remote monitoring that integrates data from various devices.
- One respondent is developing a remote monitoring device using AI algorithms for predicting COPD exacerbations, aiming to enable preventive treatment of COPD flare-ups.
- Another respondent mentioned their experience in home-based care and remote monitoring through telemedicine, telemonitoring, and telerehabilitation solutions. They have developed and commercialized an eHealth platform that supports various healthcare activities, including AI tools for consultation transcription and patient segmentation.
- A respondent is focused on developing algorithms for the detection and support of diagnosing rare diseases.
- One respondent operates as a technological centre specializing in AI, visual computing, and interaction, with a long history of R&D in digital health transformation projects. They have been involved in European projects related to home-based care and remote monitoring.
- Another respondent works on improving the diagnosis and treatment of hormonal pelvic conditions, developing a digital biomarker-based risk stratification platform with associated wearable solutions for personalized care at home.

- A respondent provides AI-backed telemonitoring solutions via a mobile app.
- One respondent supports 2 million patients at home annually, managing chronic conditions with services based on human and digital follow-up, remote monitoring, and personalized patient support through multidisciplinary expert teams.
- Another respondent develops telemedicine and remote monitoring platforms and has focused on this objective for over nine years.
- One respondent combines scientific and technological knowledge to develop new innovative concepts for functional assessment and contactless physiological monitoring, especially for chronic illnesses, older adults, and people with disabilities.
- A respondent mentioned their involvement in innovation processes and procurement.
- One respondent's primary eHealth business is telecare home services, with additional solutions for nurses' homes and hospitals.
- Another respondent focuses on advanced IoT solutions for healthcare, specializing in home-based care and remote monitoring for conditions like thoracic surgery, oncology, asthma, and COPD. They provide real-time data translation into actionable reports for doctors and patients.
- One respondent develops AI-driven Ambient Assisted Living systems, intelligent emergency call systems, and digital solutions like silent alarm systems and nurse call systems.

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

The following answers were provided:

- One respondent stated that the scope should consider integrating comprehensive electronic health records (EHR) systems, interoperability between different healthcare providers, and user-friendly interfaces for patients and healthcare professionals. They also emphasized the importance of cybersecurity and data privacy.
- Another respondent suggested confirming whether the solution will be piloted, including patient participation and social and health organization involvement. They also recommended introducing a data capture phase if there is no prior monitoring data for AI model training.
- A respondent proposed increasing twinning opportunities for healthcare organizations, focusing on independent clinical evaluations of eHealth systems, and tailoring the PCP to address specific needs identified by the Buyers Group. They also emphasized policy influence and advocacy, capacity building and knowledge sharing, and establishing clear metrics for measuring outcomes and impact.
- One suggestion was to include Meta Operating Systems for digital health, which would support European Health Data Spaces, IoT, Edge cloud, cognitive cloud technologies, and EU Sovereign data cloud using GAIA-X. They recommended expanding the scope to consider Meta Operating Systems for digital health.

- Another respondent advised being "device agnostic" to avoid issues with device obsolescence and scalability.
- One participant highlighted the importance of focusing on respiratory diseases, particularly COPD, which is the third leading cause of death worldwide, and the lack of current devices for monitoring and predicting flare-ups.
- A respondent emphasized the need for monitoring solutions that go beyond physiological variables to include aspects like stress, anxiety, depression, and isolation, especially for chronic patients. They suggested shifting the scope towards solutions that benefit patients and their caregivers.
- Another suggestion was to support diagnosis and treatment management for rare diseases with home-based software.
- One respondent proposed solutions to alleviate stress on primary health services, including therapy agents and assistive home services for remote monitoring.
- A participant recommended generating women's health data to understand the impact of sex-driven differences on health outcomes of chronic diseases.
- Another respondent suggested providing a clearer and more focused scope to help suppliers offer more effective solutions.
- One response highlighted the need to include treatments for respiratory diseases, diabetes, and other infusion therapies in the scope.
- One participant mentioned the importance of considering a human factor plan to address usability, acceptability, and interoperability issues.
- Another suggestion was to consider the functional capacity of patients, including those in nursing homes, and involve social services in the provided solution.
- A respondent emphasized focusing on interoperability, data security and privacy, scalability and flexibility, user-centric design, predictive analytics, environmental sustainability, comprehensive remote monitoring, and active collaboration with end users. They also recommended supporting the implementation phase with training and technical assistance.
- One participant advised focusing on start-ups in the process to foster innovation and support the European economy, as large companies are often slow on innovations.

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 to the budget estimation question for the PROCURE4HEALTH project varied widely, reflecting the complexity and scope of developing home-based care and remote monitoring solutions. Estimates ranged from 50,000 euros for the design phase to 4 million euros for comprehensive solutions. Several respondents provided detailed breakdowns, accounting for configuration, integration, licensing, and device costs, with one detailed estimate totalling 546,000 euros. Other estimates highlighted costs associated with clinical

trials, regulatory compliance, and ongoing support and maintenance. A summary of the answers is provided below:

- One respondent stated that the budget required for the development and deployment of a home-based care and remote monitoring solution should include comprehensive R&D, technology infrastructure, compatibility with existing healthcare systems, training healthcare providers, and ongoing support and maintenance. They emphasized the importance of integrating advanced technologies, robust cybersecurity measures, and considering the scale of deployment across national healthcare systems.
- One respondent provided an estimated budget of 1.5 million euros.
- One respondent detailed a budget estimate for the development and deployment of their solution, breaking it down as follows: configuration (39,000 euros), integration (117,000 euros), licensing fees (150,000 euros), and sensor device costs (240,000 euros), with a grand total of 546,000 euros. They justified the costs based on the complexity and necessary hours for each component.
- One respondent mentioned that their platform had already received multiple funding sources amounting to 5.3 million euros and is at TRL6. They estimated that each hospital needs to invest 50,000 to 100,000 euros for developing Standard Operating Procedures for Virtual Wards and Hospital at Home, and an additional 2.5 million euros for technology development and pilots for a Meta Operating System for Digital Health. They also noted that the community should invest up to 20 million euros in community open source work in this area.
- One respondent indicated they are raising 500,000 euros for clinical trials and expect a total of 3 million euros to enter the market in 4 years, with costs related to clinical trials and certification of a class II medical device.
- One respondent estimated a budget of 50,000 euros for the design phase, 800,000 to 1 million euros for implementation, and 500,000 to 600,000 euros for phase 3 validation in a controlled environment.
- One respondent suggested a budget of 1.1 million euros for developing a scalable solution to support patients with rare diseases within 24 months.
- One respondent estimated a budget of 4 million euros for a therapy agent and an assistive home service, breaking it down into 2.5 million euros for the therapy agent and 1.5 million euros for the assistive home service.
- One respondent stated that the budget depends on the expected product specified in the challenge brief but estimated 1.5 to 2 million euros based on previous PCPs.
- One respondent highlighted the challenge of estimating the budget due to numerous variables and activities involved but emphasized their experience in different markets and healthcare settings to inform future discussions.
- One respondent mentioned they have invested more than 1.5 million euros in development and over 8 years of work, offering their technology as Software as a Service.

- One respondent estimated a budget of 1.8 million euros, considering the technological challenge and compliance requirements for developing and validating the solution in a relevant environment.
- One respondent provided a budget range of 500,000 to 700,000 euros for labour, MDR, clinical tests, and market introduction for the first customer.
- One respondent estimated a budget of around 60,000 euros for concept definition, 600,000 euros for prototype development, and 1.5 million euros for the pilot phase, depending on the number of sites and patients to be piloted.
- One respondent detailed an estimated budget of 3.5 million euros for their QIoT solution, breaking it down into R&D (750,000 euros), regulatory compliance and certification (250,000 euros), hardware and infrastructure (600,000 euros), software development (400,000 euros), data security and privacy measures (200,000 euros), pilot programs and testing (300,000 euros), training and support (200,000 euros), marketing and awareness campaigns (200,000 euros), and project management and overheads (600,000 euros).
- One respondent estimated a budget of 1.8 million euros and a time-to-market of approximately 2 years for developing an AI-driven AAL-System for home-based care and remote monitoring, which includes various sensors to detect and analyse different events and measure vital parameters. They offered to provide detailed information, project description, work packages, and costs breakdown upon request.

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 respondents provided a diverse range of estimated timetables for the development and deployment of the proposed solutions. Some estimated a comprehensive timeline of up to 30 months, detailing phases such as design, prototyping, development, testing, and deployment. Others emphasized the variability of timelines, depending on factors like the level of customization, regulatory approvals, and clinical trials, with estimates ranging from 6 to 28 months. A few respondents outlined detailed project plans with specific phases and durations, while some highlighted the ability to deliver operational platforms within a shorter timeframe, emphasizing their competitive advantage. Overall, the responses illustrate a broad spectrum of approaches and timeframes, reflecting the complexity and variability inherent in developing and deploying healthcare solutions. A summary of the answers is provided below:

- One respondent stated that the preparation phase and call for tender phase would span approximately 15 months in total (12 months for preparation and 3 months for call for tender). Phase 1, encompassing concept design, solution architecture, and technical specifications, would take around 3 months. Phase 2, involving the development of prototype systems in two stages, would require approximately 8 months. Phase 3, dedicated to the development and testing of pilot systems, would extend over about 16 months.

- Another respondent estimated a range of 6 months to 18 months, depending on the level of customization and the need for additional CE Marking.
- One respondent provided a timetable with a 4-month design/co-creation phase, an 8-month development of a proof of concept (PoC), and a 14-month period to finish developments and deploy, totalling 26 months.
- A detailed 25-week (approximately 6-month) timetable was provided by one respondent, including project initiation and planning (weeks 1-4), configuration and integration development (weeks 5-17), and deployment and training (weeks 18-25).
- One respondent proposed a phased approach with six patient cohorts (e.g., cardio, respiratory, ambulatory care) and detailed timelines for each cohort's pilot deployment and scale-up, managed using AGILE methodologies over a period extending to May 2027.
- Another response included a timeline from 2023 to 2028, covering the improvement of device accuracy, development of AI models, clinical trials, optimization and design for manufacture, and the regulatory pathway.
- One participant estimated three phases: Phase 1 (2-4 months), Phase 2 (around 12 months), and Phase 3 (8-12 months), with additional time for permissions from ethical committees and regulatory agencies.
- A respondent expected 2 years for development and testing, followed by a 12-month deployment phase, initially in Poland, then expanding to Germany and France.
- One response projected 28 months to achieve TRL 7-8.
- Another respondent emphasized a need for 24-27 months to progress from TRL 2 to TRL 7, including a pilot study and reporting results.
- Some respondents highlighted the variability in timelines due to factors such as clinical studies, regulatory approvals, and access negotiations.
- One participant indicated their competitive advantage in offering a platform operational in less than 4 weeks, without integrations.
- An estimated timetable of 30 months was provided by one respondent, divided into 6 months for concept development, 12 months for prototype development, and 12 months for piloting.
- Another detailed response outlined a 24-month timetable divided into seven phases: research and planning (3 months), design and prototyping (3 months), development (6 months), testing and validation (3 months), regulatory compliance and certification (3 months), deployment and implementation (3 months), and monitoring and optimization (3 months).
- One participant stated that the R&D and time to market (TTM) would take approximately 2 years, including the development of system architecture, prototype sensors, data analysis algorithms, and AI models. They offered to provide detailed information upon request.

6) Do you have knowledge of any suitable technology or combination of technologies for home-based care and remote monitoring?

Respondents provided a diverse range of technologies and solutions suitable for home-based care and remote monitoring. They highlighted integrated electronic health records, interoperable healthcare solutions, AI-powered monitoring systems, wearable health tracking devices, telemedicine platforms, and mobile health applications. Specific technologies mentioned included a multi-use sensor platform for continuous monitoring, solutions designed for home-based care equivalent to institutional settings, and advanced remote patient care systems with automated workflows and robotic assistance. Additionally, respondents emphasized the importance of patient empowerment, comprehensive local support, integration with various medical devices, and the use of IoT, AI, cloud computing, and blockchain technologies to enhance patient care. They also discussed commercial platforms like Teladoc Health and Amwell and stressed the need for holistic IoT solutions that combine medical data with social care, security, and comfort. Overall, the responses reflect a strong focus on leveraging advanced technologies to improve the quality and efficiency of home-based care and remote monitoring services. A summary of the answers is provided below:

- One respondent stated that they are knowledgeable about various technologies suitable for home-based care and remote monitoring. These include integrated EHR systems, interoperable healthcare solutions, user-friendly interfaces, cybersecurity measures, and data privacy protocols. They also mentioned AI-powered monitoring systems, wearable devices for health tracking, telemedicine platforms, and mobile health applications as crucial technologies.
- Another respondent mentioned a wearable multi-use sensor platform for continuous or episodic monitoring linked to the cloud, with multiple regulatory clearances.
- A respondent described a solution designed for health and care at home, offering services equivalent to those provided in institutional settings through multidisciplinary teams, comprehensive risk assessment tools, automated processes, patient empowerment, and integration with various standards and certifications.
- Another respondent outlined their knowledge of suitable technologies for home-based care, proposing a solution with automated workflows, patient monitoring, risk classification, robotic assistance, patient interaction, and local support through various medical devices and a network of sister companies for local implementation.
- A respondent shared information about a "Hospital at Home" solution that provides remote patient care through virtual wards, leveraging video telemedicine, remote monitoring sensors, and a cloud-based dashboard for real-time patient management and virtual consultations.
- One respondent highlighted their technology suitable for monitoring exhaled breath and measuring specific biomarkers related to respiratory diseases like asthma, lung cancer, COVID-19, COPD, and food intolerance.

- A respondent mentioned their platform, which includes functionalities for remote consultations, monitoring, and integrated care services, and listed several commercial platforms for home-based care and remote monitoring, including tools for managing chronic conditions and AI-driven health analytics.
- Another respondent detailed a non-invasive wearable device for monitoring menstrual health through continuous data collection across the menstrual cycle, similar to ECG monitoring.
- One respondent emphasized their focus on empowering patients and caregivers to manage chronic conditions such as diabetes, heart failure, cancer, and multiple sclerosis.
- A respondent discussed telemonitoring solutions for CPAP, APAP, and BiPAP devices, diabetes management, and the importance of integrating human support with technology for effective patient care.
- Another respondent mentioned their platform's connectivity with over 20 brands of devices and wearables, enabling comprehensive data collection and monitoring.
- A respondent described their experience in developing technologies for functional assessment, mental health evaluation, contactless vital sign monitoring, and other health-related measurements at home.
- One respondent pointed out the importance of integrating various devices and data for a holistic IoT solution for home-based care, considering not only medical data but also social care, security, and comfort.
- Another respondent detailed their extensive knowledge in utilizing IoT devices, data analytics, AI, cloud computing, mobile applications, and blockchain technology for home-based care and remote monitoring.
- A respondent discussed their AI-driven AAL-System for home-based care and remote monitoring, using various sensors to collect vital and activity-related data, and developing AI models to analyse this data in real time for health-related event detection and prediction.

		Answers	Ratio
Yes		17	89.47 %
No		1	5.26 %
No Answer		1	5.26 %

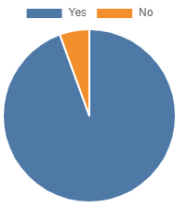

Figure 3.- Answers for the questions regarding the knowledge of any suitable technology or combination of technologies

7) Do you know any developments in the field of home-based care and remote monitoring that PROCURE4HEALTH needs to take into account?

Respondents provided a variety of insights on developments in home-based care and remote monitoring that PROCURE4HEALTH should consider. Key themes included the importance of integrated health information systems and platforms for data sharing and

collaboration, sensitive medical devices for real-time health data collection, and robust data security measures. Advancements in wearable technology, telemonitoring solutions, and AI-driven automation were highlighted for their potential to enhance remote patient care. Integration with EHR, reliable data transmission using 4G technology, and adherence to regulatory frameworks were also noted. Additionally, the significance of personalized care solutions, interoperability standards, and the integration of healthcare monitoring devices with smart home systems were mentioned. Specific projects and innovations, such as the development of an open digital health operating system and breakthroughs in breath analysis technology, were also cited as important considerations for PROCURE4HEALTH. A summary of the answers is provided below:

- One respondent emphasized the importance of integrated health information systems, sensitive medical devices for real-time data collection, strong encryption techniques for data security, and the role of advanced technologies like AI, IoT, and big data analytics in home health care.
- One respondent mentioned that many procurers in the PCP might already be familiar with relevant developments from participation in similar projects.
- One respondent highlighted advancements in wearable devices, telemonitoring solutions, robot intelligence and automation for risk classification and monitoring, integration with EHR systems, 4G integration for reliable data transmission, enhanced data security, interoperability standards, and virtual care platforms.
- One respondent discussed their current solution, BlueEye Virtual Ward, and a new project, DHOS, aimed at integrating various healthcare systems and supporting home hospital beds with advanced biometric sensors and predictive analytics.
- One respondent pointed out breakthroughs in breath analysis technology for respiratory disease monitoring.
- One respondent referenced CAREMATRIX as an example of a well-managed project relevant to PROCURE4HEALTH.
- One respondent shared their experience with implementing remote monitoring algorithms in hospitals, though not yet in home environments.
- One respondent mentioned the CAPTAIN project, which focuses on evaluating physical, emotional, and social health states, and the SHAPES EU project, which tested various digital health solutions.
- One respondent noted that digital technology adoption tends to be quicker among females compared to males.
- One respondent discussed digital solutions for diagnosing obstructive sleep apnea, remote monitoring connected to ventilators, and personalized diabetes care solutions using clinical data and patient preferences.
- One respondent highlighted the importance of integrating hybrid care models and devices that provide comprehensive information from home environments.
- One respondent mentioned the AI3Cord project, which assesses frailty at home using AI and IoT solutions.

- One respondent suggested considering social home telecare solutions and sensors for frailty assessment and management.
- One respondent listed key developments such as advanced wearable devices, telehealth and telemedicine platforms, AI and machine learning, interoperability standards, remote monitoring for chronic diseases, blockchain for data security, integration with smart home systems, and compliance with regulatory frameworks like the EU's MDR.

		Answers	Ratio
Yes		15	78.95 %
No		1	5.26 %
No Answer		3	15.79 %

Figure 4.- Answers for the question regarding current developments in home-based care and remote monitoring.

8) Do you foresee any barriers to implement a solution for home-based care and remote monitoring?

The responses to the question regarding barriers to implementing home-based care and remote monitoring solutions highlighted several key challenges. Participants pointed out regulatory challenges, data privacy concerns, resistance to change among healthcare professionals, and technological adoption issues, especially among the elderly. Other significant barriers included the need for data access and integration, organizational change, funding limitations, and the complexity of aligning new technologies with existing workflows. Additionally, technical challenges such as interoperability, reliable connectivity, and compliance with legal regulations were frequently mentioned. A summary of the answers is provided below:

- One respondent stated that barriers include regulatory challenges, data privacy concerns, resistance to change among healthcare professionals, and potential issues with technology adoption by patients, particularly the elderly or those with limited digital literacy.
- Another respondent identified main barriers as: 1) Access to data to train AI or ML models or validate any kind of model. 2) Data integration with public care and monitoring systems. 3) The impossibility of patients or professionals participating in the co-creation process. 4) Change management, specifically the rejection by professionals (health, admin, legal, IT...) and patients to do things differently.
- A respondent noted that 80% of the implementation barriers are related to aligning the technology with the work practices of medical staff, getting them to accept, get used to, and embrace new ways of working. The remaining 20% of the barriers are technical challenges. Key points include user adoption and training, patient engagement, communication and coordination, IT department acceptance,

interoperability issues, reliable connectivity, data privacy and security, financial constraints, regulatory and policy barriers, and infrastructure limitations.

- One respondent highlighted organizational change and the need for the development of standard operating procedures for home hospital solutions as the primary barrier, with additional secondary barriers related to technological integration, data security and privacy, patient and provider engagement, infrastructure and connectivity, regulatory and reimbursement challenges, cultural and organizational change, and technical support and maintenance.
- A respondent mentioned the low private funding interest in medtech and deeptech as a significant barrier preventing medical device companies from reaching the market soon.
- Another respondent emphasized that focusing solely on devices for remote monitoring could deviate efforts and budget, making validation more difficult. Additional barriers include the burden on physicians to monitor daily parameters, the long process and expense of obtaining certification under MDR, and compliance with the new AI Act.
- One respondent pointed out that the barriers will mainly be related to the accessibility to real data that characterizes different use cases.
- Another respondent noted challenges such as data privacy, integration, and rapidly changing regulations.
- A respondent identified navigating specific national healthcare reimbursement systems, the lack of a market access framework, medical device and privacy regulations, disparities in digital literacy and access to reliable Internet connectivity, and the need for training and supporting healthcare providers and patients.
- One respondent mentioned barriers such as acceptability and adherence by patients and professionals, integration with multiple healthcare medical records systems, multi-device integration, and compliance with legal regulations.
- Another respondent highlighted the importance of integrating and collaborating with the entire care ecosystem, including patients, informal caregivers, caregivers, social workers, and doctors.
- A respondent listed regulatory compliance, data security and privacy, interoperability issues, technology adoption, infrastructure limitations, cost and funding, technical support and maintenance, data management and analysis, patient engagement and compliance, healthcare provider workload, and reimbursement and incentives as barriers to implementing home-based care and remote monitoring solutions.
- One respondent mentioned bureaucracy, over-regulation in the EU, and lack of financing as barriers.
- Another respondent reiterated that barriers include regulatory challenges, data privacy concerns, resistance to change among healthcare professionals, and potential issues with technology adoption by patients, particularly the elderly or those with limited digital literacy.

		Answers	Ratio
Yes		15	78.95 %
No		3	15.79 %
I do not know		0	0.00 %
No Answer		1	5.26 %

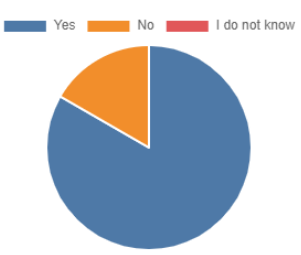

Figure 5.- Answers for the question regarding current developments in home-based care and remote monitoring.

9) Can you tackle all or part of the requirements of this challenge? How can you tackle them? What additional information would you need?

The responses to the challenge question reveal diverse approaches and capabilities among participants. A summary of the answers is provided below:

- One respondent stated that a shared mindset towards collaborative innovation is crucial. Larger companies are typically not interested in customization and prefer existing products, so demonstrating a joint development spirit is essential. Additionally, smaller companies should have core building blocks like sensors, alarming, and software for rapid innovation and continuous support.
- Another respondent mentioned that they have a comprehensive management software for home health care and remote monitoring. They maintain relationships with various companies and research centres to complete their solutions, addressing uncovered needs and offering multiple options for deployment.
- One participant affirmed their capability to tackle all requirements of the challenge with a comprehensive approach combining advanced technology, expert implementation, and robust support. They emphasized advanced remote monitoring, automated workflows, patient interaction, reliable devices, local support, seamless integration with EHR systems, and compliance with data security regulations.
- A respondent highlighted the importance of an integrated open ecosystem to solve diverse digital transformation requirements in healthcare. Their solution includes remote monitoring and alerting systems, patient engagement tools, and standards-based open digital health operating systems for interoperability and integration with existing healthcare records systems.
- Another participant mentioned their telemedicine platform as a basis for tackling the challenge.
- One response emphasized the need to find the right investor, noting that it takes time and networking. They suggested that new networks and people interested in deeptech would be helpful.

- A respondent with over two decades of experience in developing and commercializing medical devices stated they can tackle part of the challenge requirements, contributing mainly to research and innovation components and needing collaboration for full solution deployment.
- One participant mentioned that their internal development of intellectual property would provide the solution without costs for patients or clinics, with their clients being pharma/biotech companies.
- Another respondent highlighted the importance of compliance and data security in addressing the challenge.
- A participant emphasized the need for detailed information on MDRs, data protection laws, healthcare reimbursement policies, and the current healthcare infrastructure of the specific EU country. They also mentioned the importance of insights from various stakeholders to inform their approach.
- One response noted that their solution meets all needs except for care plans, which they plan to develop further based on discussions with partners and customers.
- Another respondent stressed the importance of UX and Human Factors design methodology for acceptance and adherence, involving relevant stakeholders from the beginning.
- A participant mentioned their home gateway solution, integrating various data sources, sensors for frailty management, an AI-based assistant, and alert generation. This solution should be developed for both home and nurses' home environments.
- One respondent detailed their innovative approach to home-based care and remote monitoring, including advanced technology integration, real-time monitoring, predictive analytics, interoperability, user-centric design, regulatory compliance, scalability, training and support, environmental sustainability, and pilot programs for validation.
- Another participant indicated that their current solutions address a large part of the challenge requirements, and they are conducting an R&D project to develop technologies and solutions for diagnosing and predicting various health and nursing care-related conditions.
- A respondent, the Ministry of the related country, expressed their capability to address both specific aspects and broader requirements of the challenge, leveraging their experience in managing complex healthcare projects and innovation procurement initiatives.

		Answers	Ratio
Yes		16	84.21 %
No		0	0.00 %
I do not know yet		2	10.53 %
No Answer		1	5.26 %

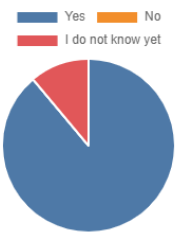

Figure 6.- Answers for the question regarding tackling all or part of the requirements of the challenge.

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

Participants highlighted several key areas for enhancement. They suggested integrating advanced features such as real-time data analytics for predictive healthcare, improved patient engagement tools, and expanded support for mental health monitoring. There was a call for better linkage between technology and healthcare providers, with more emphasis on automated workflows and advanced remote monitoring for patients with multiple chronic conditions. The incorporation of robust data analytics, telehealth capabilities, real-time alert systems, and enhanced security measures were also recommended. Additionally, respondents emphasized the need for comprehensive care plans managed by multidisciplinary teams, self-management tools, gamification for patient engagement, and personalized health predictions. Other suggestions included advanced data visualization, integration with wearable technology, and telehealth features, as well as social support functionalities and environmental monitoring to improve overall care delivery and patient outcomes. A summary of the answers is provided below:

- One respondent stated that additional functionalities could include real-time data analytics for predictive healthcare, enhanced patient engagement tools such as interactive dashboards, and support for mental health monitoring alongside physical health.
- Another respondent suggested that the linkage between technology and healthcare providers, including how they view and act on data, should be emphasized more.
- A third respondent identified several advanced functionalities for improving home-based care and remote monitoring. These include advanced remote monitoring that extends beyond basic vital signs to include metrics such as ECG readings and respiratory rates, as well as automated workflows that integrate with existing healthcare systems to manage patients with multiple chronic conditions. Enhanced patient interaction features, such as personalized health goals and educational resources, were also mentioned. Advanced data analytics for predictive insights and trend analysis, seamless telehealth capabilities for video consultations and remote diagnostics, and real-time alert systems with contextual recommendations were highlighted. Additionally, strengthening security measures with multi-factor authentication and compliance with international standards, designing scalable solutions to accommodate growing patient populations, and developing specialized modules for chronic disease management were suggested. The use of evolving machine learning algorithms to improve health predictions and recommendations and facilitating international collaboration with global health best practices were also recommended.
- Another respondent noted functionalities such as role definition and permission systems for managing video consultations, personal and common waiting rooms

for video consultations, and wearable video solutions for real-time remote consultations.

- It was also mentioned that comprehensive care plans managed by multidisciplinary teams should be considered, along with self-management tools and gamification to enhance patient engagement. Algorithms that analyse patient data and characteristics to offer a global vision and proactive interventions were suggested. Additionally, personalized health predictions and prognostic indicators, telecare services for patient security (especially for older individuals), and the inclusion of nurse home environments in requirements were recommended.
- Additional suggestions included advanced data visualization with interactive dashboards and customizable reports, integration with wearable technology to track additional health metrics, and telehealth integration for video consultations and remote diagnostics. Automated alerts and notifications for health metrics and medication reminders, AI-driven clinical decision support systems, and predictive modelling were also proposed. Social support features like community forums and caregiver access, comprehensive analytics for population health management and quality metrics tracking, and environmental monitoring integration (including air quality sensors and home safety monitoring) were emphasized as important enhancements.

11) Can you provide any other recommendations regarding home-based care and remote monitoring?

Respondents provided several recommendations for enhancing home-based care and remote monitoring. A summary of the answers is provided below:

- One respondent emphasized the need for solutions that can scale to accommodate a wide range of patient needs, from those requiring near ICU-level monitoring to stable patients with single chronic conditions. They also highlighted the importance of an interoperable, open data structure that ensures privacy and cybersecurity, and the ability to seamlessly link home care with hospital care within one electronic health record.
- Another respondent noted that aspects related to European initiatives, such as authentication through eIDAS and integration through Data Spaces, were not referenced in the document.
- Additional recommendations included enhancing patient education and support through comprehensive training programs and support hotlines. Ensuring data accuracy and quality by implementing regular device calibration and data verification processes was also suggested.
- Enhancing interoperability and integration by standardizing data formats, integrating home tests with clinical systems, and promoting continuous innovation through partnerships with technology companies and pilot programs were recommended.

- Focusing on holistic patient care by including support for integrative health practices and developing personalized care plans using data analytics and AI was advised. The creation of robust feedback mechanisms for both patients and healthcare providers was also suggested.
- Addressing social determinants of health by ensuring equitable access to technology and developing community support programs was highlighted. Promoting policy and reimbursement advocacy to encourage favourable reimbursement models was also recommended.
- Building patient communities through online forums and peer support was suggested, along with emphasizing automation in managing routine tasks and personalizing workflows based on patient needs. Advanced algorithms for evidence-based recommendations and international collaboration for continuous innovation were also recommended.
- Recommendations included leveraging sovereign cloud infrastructure to ensure local data storage and implementing robust cloud infrastructure for real-time access by clinicians. Advanced wearable technology and real-time biometric monitoring were suggested to improve patient compliance and care.
- Integrating video and telehealth solutions, customizing user-friendly software, and developing early intervention strategies were advised. Ensuring scalability and interoperability with existing systems, maintaining data security and compliance, and facilitating patient transfer information were also emphasized.
- The importance of avoiding expensive device orientations to support scalability, tailoring solutions to specific use cases, and focusing on simplicity for users was noted. Special attention to the needs of seniors, particularly those living alone or in rural areas, was also recommended.
- Recommendations for improving communication between patients and clinical professionals included developing tools like TOPFind for organizing and storing health-related resources and RecFIND for personalized recommendations.
- One respondent suggested specifying chronic conditions in the challenge brief to maintain focus and ensuring that the system is simple for both patients and professionals.
- It was recommended to establish robust training programs for healthcare providers and patients, create feedback loops for continuous improvement, and collaborate with telecommunication companies to ensure reliable connectivity for remote monitoring solutions.

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:

A summary of the answers is provided below:

- One respondent stated that there is potential for technological advancement beyond the current state, particularly in areas such as artificial intelligence, mobile health applications, wearable technologies, and telehealth, which could enhance the effectiveness of home-based healthcare services and improve patient care.
- Another respondent highlighted that while there is always room for improved measurements and technologies, the primary challenge lies in integrating these innovations into well-functioning systems that fit clinical workflows, emphasizing the need for shared and joint innovation processes.
- A participant mentioned that despite many technological proposals addressing different challenges, implementation remains a significant aspect requiring new approaches like "Implementation Research." This helps differentiate between technological demonstrations and innovative, implementable solutions.
- It was noted that significant room exists for technological development beyond the state of the art, with primary implementation barriers stemming from adjusting to new workflows and communication methods. Addressing these challenges involves engaging stakeholders, developing comprehensive implementation plans, providing continuous education, and fostering positive attitudes toward change.
- The need for advanced data analytics and machine learning was emphasized, including predictive analytics for identifying health trends, personalized medicine using large datasets, and enhancing remote monitoring devices with multi-parameter and non-invasive testing technologies.
- The integration of advanced wearable technology and home tests into unified monitoring platforms was also suggested, along with the development of intelligent automation and robotic assistance to adapt care plans in real-time and support daily activities.
- One respondent proposed extending the state of the art to include meta operating systems for digital health, such as RedZinc's Open Digital Health Operating System, to address interoperability issues and accelerate digital health transformation in Europe.
- The potential for AI applications in handling data origin and treatment, as well as defining use cases, was recognized as an area for growth.
- Development in breath analysis for non-invasive monitoring and diagnostics was highlighted as an emerging field with significant potential.
- Recommendations included incorporating machine learning for predicting patient deterioration, gamification for patient engagement, individualized therapy plans, and broader approaches integrating non-clinical care components and social services.
- The need for innovation, especially for underserved populations, to react quicker, save costs, and improve quality of life was emphasized.
- It was noted that large language models and IoT systems have room for development in areas such as behaviour characterization, anomaly detection, and identifying health condition biomarkers.

- The potential for comprehensive remote monitoring regimens to improve long-term health outcomes, particularly for women across different life stages, was mentioned.
- Advances in sensor technology, AI, machine learning, interoperability, user experience design, and high-speed internet connectivity were suggested as key areas for future development in home-based care and remote monitoring.
- One respondent emphasized that advancements are needed in sensor fusion, time-synchronized data processing, and AI technologies, and offered to provide meaningful information exchange on these topics.

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

Concerning the proposed solutions and developments, a summary of the answers is provided below:

- One respondent stated that their system, cleared by the FDA and soon to be CE marked, monitors vital signs for patients 12+ years in home or hospital settings. It includes alerts, can be cloud-based, and uses low-cost Android devices to reduce infrastructure costs.
- Another respondent emphasized the need for improved usability, proposing that solutions should dynamically adapt to users' needs, with AI playing a significant role.
- To enhance home-based care and remote monitoring, one respondent proposed several technological advancements, including advanced data analytics for predictive and personalized medicine, enhanced remote monitoring devices for multiple health parameters, integration with wearable technology and home tests, automation and robotics for daily activities and medical procedures, interactive platforms and online communities for patient engagement, improved 4G connectivity and strong authentication methods, advanced data security and privacy measures, and addressing implementation challenges by engaging stakeholders and fostering positive attitudes.
- One respondent proposed a Meta Operating System for digital health to support European Health Data Spaces, including support for keeping patients out of hospitals and enabling early discharge, hospital-at-home solutions, IoT sensors, European Electronic Health Record Exchange Format, cognitive cloud technologies, and EU sovereign data cloud.
- A telemedicine platform was proposed that integrates with various information systems for holistic patient management. This platform includes automated workflows, personalized alerts, and gamified systems to improve adherence.
- One respondent mentioned breath analysis as a potential solution.
- Another solution covered personalized therapy plans, patient engagement through gamification, adaptive content management, integration of non-clinical care components, GDPR compliance, and AI-based assistants for personalized feedback.

- One respondent proposed solutions focused on rare diseases, highlighting the need for better diagnostic processes, monitoring tools, and support for drug development and patient care.
- Virtual assistants, IoT-based services, AI tools for predicting high-risk conditions, decision support systems, and identification of biomarkers for neurological health conditions were suggested by another respondent.
- A remote monitoring device with an alerting system, combining personalized health programs with real-time professional support, was proposed by one respondent.
- Another respondent recommended AI and NLP-backed solutions for self-management support with clinical supervision.
- One respondent suggested solutions for sleep, ventilation, and diabetes management, including virtual interventions and a comprehensive platform for patient needs and progress monitoring.
- A proposal included devices that connect to a HUB for secure data transmission without requiring Wi-Fi.
- Non-invasive wearable sensors, fusion data algorithms for health profiles, predictive health tools, personalized health recommendations, senior-friendly interfaces, and customized alert criteria were recommended by one respondent.
- Another respondent proposed an IoT solution for home and nursing home environments, AI home assistants, and digitalized care plans.
- Sensor fusion, time-synchronized data processing, and AI were mentioned by one respondent as areas for further development.
- One respondent highlighted AI-supported medical diagnostic systems, remote patient monitoring through mobile health applications, and telehealth platforms, emphasizing the integration of wearable devices and sensors into home-based health monitoring systems.

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

A summary of the answers is provided below:

- One respondent stated that their solution would offer tremendous value by enabling more care to be delivered at home, increasing capacity without additional cost, and preventing admissions and readmissions, which would be a significant return on investment for hospitals.
- Another respondent highlighted that their solution would result in better resource utilization, earlier and more personalized care, reducing high-cost interventions, and creating a resilient system with better patient experiences. It also empowers patients by improving their health knowledge and involvement in their care, leading to improved quality of life and reduced medicalization.
- A respondent emphasized that their home-based care and remote monitoring solution improves patient outcomes, enhances efficiency, reduces costs, and increases patient engagement. Key benefits include early detection and

intervention, personalized care, automated workflows, remote monitoring, reduced hospital admissions, and improved patient service.

- Another respondent noted that their solution would reduce waiting lists, increase available beds through home hospitalization, reduce readmissions, improve operational efficiency, and generate cost savings. Additional benefits include personalized home care, patient empowerment, reduced infection risk, faster recovery, and a safer environment for recovery.
- One respondent detailed the impact of their virtual ward and digital health operating system, including the acceleration of integrated care, improved clinical care quality, validation through EU hospital pilots, better patient data access, reduced wait lists, and improved efficiency for clinicians.
- A respondent estimated significant value through patient empowerment, remote monitoring, reduced hospital stays and readmissions, standardized protocols, and improved care in underserved areas.
- Another respondent projected a market value for their COPD solution, estimating cost reductions of 3 billion USD in key EU countries with a 10% market share, focusing on serious patients.
- One respondent highlighted enhanced care coordination, reduced in-person visits, patient empowerment, predictive analytics, and cost savings through reduced readmissions as primary values of their solution.
- Another respondent aimed to shorten rare disease diagnosis time, increase diagnostic efficacy, reduce costs, and improve access to treatment and clinical trials, citing specific improvements for hereditary angioedema.
- A respondent emphasized the value of virtual assistance and AI for quick interventions, continuous monitoring through IoT, better chronic condition management, increased convenience, and cost-effectiveness by reducing emergency visits and hospital admissions.
- One respondent pointed out the need for an integrated view of chronic conditions to improve patient care, policy development, and support mental health, specifically addressing the under-researched area of women's health.
- Another respondent stressed the value of digital transformation in chronic condition management, leading to reduced hospital admissions and better stakeholder engagement.
- A respondent highlighted better decision-making, personalized care plans, enhanced patient outcomes, cost savings, improved efficiency, and increased patient satisfaction through continuous remote monitoring and real-time data transmission.
- Another respondent emphasized the value of a digital ecosystem for home care operations, cost savings, and improved patient data control, referencing their experience in Brazil.

- One respondent focused on early detection and prevention, personalized care plans, empowered patients, reduced hospital admissions and readmissions, improved chronic disease management, and increased access to medical services in hard-to-reach areas.
- A respondent underlined that digitalization of care, coordination, and patient self-care are crucial for a sustainable healthcare system.
- Another respondent pointed out that their solution offers early detection and intervention, enhanced efficiency, cost savings, increased access to care, empowered patients, data-driven decision-making, and enhanced patient satisfaction.
- One respondent estimated significant cost savings and reduced burden on healthcare personnel through early detection of neurodegenerative diseases and real-time health problem detection.
- A respondent emphasized the enhancement of home-based healthcare services, reducing dependency on hospitals, and enabling continuous tracking of patients' health status through remote monitoring technologies.

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

- One respondent stated that their solution is at TRL-9.
- Another respondent mentioned that by the end of their project, their solutions will have achieved a TRL ranging from TRL-7 to TRL-8.
- A participant reported that their BlueEye Cloud Platform is at TRL-9, with other components of their solution having the following TRLs: IoT Biometric Vital Sign Sensors (TRL-9), BlueEye Video (TRL-9), BlueEye Virtual Ward (TRL-6), BlueEye Care App (TRL-6), and DHLOS (TRL-4).
- One respondent indicated their solutions are at TRL-4 to TRL-5.
- A participant explained that any solution aiming for implementation in real settings should start from TRL-5 to TRL-6, as increasing the TRL significantly within the project duration (1-2 years) is not feasible.
- Another respondent mentioned their solution is at TRL-3.
- One participant specified the expected TRL progression due to the initiative: Virtual Assistant (TRL-5 to TRL-7), IoT services for Assistive Home (TRL-6 to TRL-8), DSS for Personal Care Plans (TRL-6 to TRL-8), and Biomarkers for Neurological Health Conditions (TRL-5 to TRL-7).
- A respondent noted their solution should be ranging between TRL-2 to TRL-7 given the scope of a PCP process.
- Another participant stated that their technology is already accessible to patients but faces challenges in widespread adoption due to reimbursement framework issues and lack of budget impact modelling.

- One respondent mentioned their digital health ecosystem is between TRL-8 and TRL-9.
- Two participants reported their solutions are between TRL-5 and TRL-8.
- Another respondent indicated their solution is at TRL-6.
- A respondent stated their existing solution is market-ready and successfully deployed, while their solution in development is in the prototype phase with MVP scheduled for 4Q2025 and GMA by 2Q2026.
- Another participant noted that the proposed solutions have different TRLs, with AI-supported medical diagnostic systems potentially having higher TRLs compared to monitoring systems integrated with wearable devices.

5) Can you identify any patents or standards that are relevant to home-based care and remote monitoring?

One respondent identified several relevant standards, including HL7/FHIR for exchanging electronic healthcare data, eIDAS for secure electronic interactions within the EU, GDPR for information privacy, NIS/2 for EU cybersecurity, ISO13485 for medical device quality management, and MDR for the regulation of medical devices in the EU. Another respondent listed specific patents and standards relevant to their HOPE@HOME solution, such as MobileHealthId for secure authentication and communication, dynamic procedures driven by Robot Intelligence (RI) and AI for personalized care, and methods for secure cross-border data sharing. Key standards for their solution include FHIR for data exchange, HL7 for healthcare data standards, ISO/IEEE 11073 for medical device communication, and GDPR for data protection and privacy.

One participant proposed several standards, including CyberEssentials, Esquema Nacional de Seguridad, ISO 13485:2016, ISO 14000 for environmental management, ISO 14971-2019 for medical device risk management, ISO 20000 for IT service management, ISO 27001 for information security, GDPR registration in Ireland and the UK, and CE marks for product compliance in the EEA. A respondent cited EP4054411A2 for a method of exhaled gas analysis and a universal portable breath content analyser. Another respondent emphasized the importance of HL7/FHIR for electronic health information exchange, noting the lack of widespread standards for how medical devices store and send data for remote monitoring.

One participant mentioned that their platform, currently classified as a medical device class I, is under review to be updated to class II-a. Another respondent identified several crucial standards and regulations, including GDPR, MDR, ISO 13485:2016, and HL7. They also mentioned key patents, such as US Patent No. 10,713,341 for a remote patient monitoring system by Philips Healthcare, US Patent No. 10,682,489 for a health monitoring system by Honeywell International, US Patent No. 10,478,447 for a remote health monitoring system using mobile devices by Apple Inc., and EP Patent No. 2,945,019 for a home-based health monitoring system by Siemens Healthcare.

One respondent referenced results from the PCP EQUILIN project, while another did not provide additional information beyond what the procurers had supplied. Another participant listed relevant patents and standards, including US Patent No. 10,997,701 for

remote patient monitoring systems and US Patent No. 10,676,458 for remote patient management methods. They also highlighted ISO 13485:2016, ISO/IEEE 11073, HL7 FHIR, HIPAA, GDPR, EN 60601-1-11, and IEC 62304 as critical standards for ensuring the safety, performance, and data protection of home healthcare devices and software.

One respondent offered to provide more details upon contact. Another participant mentioned numerous patents and standards relevant to home-based healthcare services and remote monitoring, including patents for telehealth platforms, wearable health monitoring devices, home-based medical imaging devices, and remote medical diagnostic devices. List of patents mentioned in the answers:

1. MobileHealthId (Authentication Method and Secure Communication)
2. Dynamic Procedures (RI/AI-Driven Dynamic Procedures)
3. Methods for Sharing Data Across Organizational and Geographic Borders
4. EP4054411A2 - Method of exhaled gas analysis and a universal portable breath content analyser
5. US Patent No. 10,713,341 - Remote Patient Monitoring and Engagement System (Philips Healthcare)
6. US Patent No. 10,682,489 - Health Monitoring System and Method (Honeywell International)
7. US Patent No. 10,478,447 - System and Method for Remote Health Monitoring Using Mobile Devices (Apple Inc.)
8. EP Patent No. 2,945,019 - Method and System for Home-Based Health Monitoring (Siemens Healthcare)
9. US Patent No. 10,997,701 - Remote Patient Monitoring Systems
10. US Patent No. 10,676,458 - Remote Patient Management Methods

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 the SDC 11073 standard, which governs medical device interoperability, should be a prerequisite. Another respondent emphasized the need to consider all previously described standards, along with their transposition to different countries where the solutions will be implemented or deployed in various phases.

A participant outlined the standards and integration requirements for the HOPE@HOME solution, highlighting the importance of an import-export module with predefined APIs for seamless data exchange. This module supports integration with existing health infrastructure, regional and national platforms, EHR systems, and laboratory information systems (LIS). The integration should extend to various medical devices and home tests, ensuring compliance with ISO/IEEE 11073. Additionally, adherence to data protection and privacy standards like GDPR and HIPAA, along with secure authentication methods such as MobileHealthId, is crucial. Interoperability standards like FHIR and HL7, dynamic procedures driven by RI/AI, and secure data sharing protocols across organizational and geographic borders are also important.

Another respondent mentioned the need for compliance with several standards, including CE marks, GDPR, ISO 27001, ISO 20000, ISO 14000, ISO 13485:2016, and ISO 14971:2019. They noted that their video calls are encrypted using AES-256, and they use the latest TLS versions with secure ciphers, along with regular penetration testing. Compliance with the MDR is also essential. They follow an open design approach for integration with hospital platforms, ensuring compatibility with various EPR systems through APIs like FHIR, OpenEHR, HL7, SSO, GAIA-X, P2SD+, EEHRxF, and TLS.

One participant suggested considering standards like HL7, FHIR, and Snomed for semantic interoperability. Another emphasized the importance of medical device development standards such as ISO 13485, ISO 14971, ISO 62304, ISO 60601, ISO 62366, ISO 10993, and ISO 14155.

A respondent noted that the medical devices market for remote monitoring is fragmented and highlighted the need for standards like HL7, FHIR, and WCAG for web content accessibility. Another participant stressed the importance of copyright protection for produced IP, compliance with ISO 13485 and ISO 27001, and conducting Freedom-to-Operate studies to avoid infringement of unlicensed IPR.

One respondent recommended considering clinical protocols for specific medical fields, FHIR for healthcare information exchange, the OMOP Common Data Model for standardizing observational data, the SymbloTe project for IoT device standards, and a single sign-on authentication system using PASETO tokens for secure access. Another mentioned the need for integration with national health records and hospital systems.

Some participants stated the importance of adapting to the particular needs of each project, considering the standards already indicated in the OMC document, and ensuring compliance with key standards such as HL7 FHIR, ISO 13485:2016, GDPR, HIPAA, ISO/IEEE 11073, and ISO 27001. They also suggested incorporating blockchain for secure data transactions and patient consent management.

Several respondents emphasized the necessity of considering medical device safety standards, data security and privacy standards, telehealth service standards, and compatibility requirements for integrating solutions with existing healthcare systems and infrastructures..

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 home-based care and remote monitoring challenge?**

   One respondent stated that understanding the funding amounts available for each phase would be beneficial. Another highlighted the need for well-defined use cases with objectives and key result outcomes (KROs), deadlines, and clear definitions of expected results in each phase. They also emphasized the importance of knowing if health professionals or patients will be available for the co-creation process, the scope of integration (such as sandbox or test environments), the availability of prior data, and support for ethics committee protocols if necessary. Additionally, setting limits to

prevent large companies from driving out SMEs through aggressive pricing was mentioned.

A participant outlined several key pieces of information needed to develop and implement the HOPE@HOME solution effectively. These include stakeholder requirements from healthcare providers, patients, and caregivers; technical specifications for interoperability standards and device integration; regulatory and compliance requirements; security protocols; operational workflow integration; user experience design; data sharing and integration; testing and validation plans; and implementation and support details.

Another respondent emphasized the need for understanding the project's full scope and scale, patient demographics, service providers, and coverage areas. They also mentioned the importance of defining roles and responsibilities of healthcare personnel, specific monitoring requirements, medical team management, logistics, software integration, budget and financing, and technical support requirements.

One respondent mentioned the need for detailed use case definitions. Another requested information on integration with healthcare backend information systems. Further details on time horizons, phases, case study handling, budget allocation, and specific environment requirements were also highlighted as necessary.

The scope of the call and budgetary details were identified as important by another respondent. Additionally, unmet needs, the current tech landscape, compliance and legal requirements, shared evaluation metrics across member states, and clinical and economic evidence requirements were pointed out as crucial information.

Understanding the care scenario, the number of patients and professionals on the platform, and the needs and requirements of the main stakeholders, including the target population, healthcare organizations, and informal caregivers, were noted by another respondent. They also emphasized the importance of understanding the expectations of the procurers regarding technology maturity, certification requirements, patient behavior, preferences, accessibility needs, and future implementation and support needs.

One respondent highlighted the need to know the number of health systems to be integrated and the number of users to be piloted. Another outlined the necessity of user requirements, regulatory guidelines (e.g., FDA, GDPR, HIPAA), technical specifications for hardware and software integration, data management protocols, infrastructure assessment, development and maintenance cost estimation, pilot testing and validation plans, stakeholder engagement strategies, and training programs for users.

One participant mentioned that their plan of action has been completed and they would appreciate support from the EU, inviting further contact. Another respondent expressed the need for new information about innovations, patient engagement levels, and common technical issues encountered in home-based care and remote monitoring implementations.

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

One respondent stated that the HOPE@HOME solution has several specific requirements for integration with PROCURE4HEALTH. These include an import-export module with predefined APIs for seamless integration with existing health infrastructure and device integration for efficient data transfer and management. The system must enable continuous remote monitoring and alerting, incorporating AI/RI-driven alerts for timely intervention. Automation of clinical workflows to improve efficiency and adapting to various diseases and conditions through customizable patient profiles and RI/AI decision support are also essential. Additionally, patient self-assessment and clinical planning should be empowered through user-friendly interfaces. Standards such as FHIR/HL7 compliance, GDPR compliance, data encryption, and secure communication protocols are critical. Advanced user dashboards and adherence to international standards like ISO/IEEE 11073 are also necessary to meet these requirements.

Another respondent highlighted the requirements for the BlueEye Virtual Ward solution, which include portable monitoring devices, a clinical dashboard, and access to healthcare professionals. They provided specific technical requirements for optimal platform performance, such as multimedia PCs or modern laptops with Intel Core i5 or higher processors, Windows operating systems, and internet browsers like Google Chrome or Microsoft Edge. Recommended internet connectivity is a minimum speed of 2 Mbps for video transmission and additional data monitoring. Integrated audio and video equipment, 27-inch monitors with HDMI connection capability, and printers for medical reports are also recommended.

One participant mentioned the need for timelines that facilitate the development of an algorithm as an objective marker of pain or bleeding in adolescents with dysmenorrhea, which includes obtaining ethical approvals and conducting biostatistical analyses.

Another respondent emphasized the importance of clinical validation and co-creation, suggesting that Phase 3 should include a pilot study covering a large and diverse cohort. They also mentioned considering the frailty index of the patients.

Additionally, a respondent stressed the need for interoperability, scalable cloud infrastructure, and a modular system architecture for flexibility and future expansion. They emphasized the importance of extensive real-world pilot testing and continuous feedback mechanisms to validate and refine the solution to meet clinical and regulatory standards effectively.

3) How could you contribute to the home-based care and remote monitoring challenge? Please explain:

The potential contributions from the market to the home-based care and remote monitoring challenge are outlined below:

- One respondent stated that their late-stage startup, with a technology and clinical focus, can contribute significantly through user-centric design expertise.

- Another respondent highlighted that their solution offers continuous real-time patient monitoring through wearable devices and home-based sensors, using AI/RI algorithms for predictive insights and alerts. They also mentioned improving clinical decision-making by automating workflows and supporting dynamic procedures with AI/RI intelligence, alongside creating personalized care plans and promoting patient self-management. The solution ensures integration with existing health infrastructure and compliance with international standards like FHIR and HL7, along with advanced data security and GDPR compliance. They offer customizable dashboards and user-friendly interfaces, aiming to reduce hospitalizations, optimize resources, and provide cost-effective healthcare delivery.
- Another participant stated that their solutions, including a virtual ward and a digital health operating system, facilitate home hospitalization, reduce waiting lists, prevent readmissions, and optimize patient management. They emphasized cost savings through reduced hospitalizations, improved patient comfort, and reduced infection risks. Their system supports integration across healthcare systems, enhancing interoperability and data accessibility. Their approach involves open design and extensive API support for seamless integration with electronic patient records, enhancing overall functionality and potential for strategic partnerships.
- One respondent expressed readiness to form a consortium to address all parts of the challenge once the scope and use cases are defined.
- Another mentioned their capability to provide versatile technology for non-invasive remote and portable analysis of breath to track respiratory and gut-health-related issues.
- One participant stated they could develop a module for monitoring rare disease treatments, facilitating specialist consultations, patient contact, and mental support.
- A technological centre respondent mentioned their expertise in applied research, data analytics, and AI, offering several proprietary software libraries for data analysis, real-world data capture, and predictive modelling.
- Another respondent highlighted their innovative technology and services to strengthen women's health equity by ensuring timely access to care and reducing healthcare costs.
- One participant mentioned their extensive experience in home-based care and remote monitoring, leveraging a mobile app for chronic condition management with an NLP assistant.
- Another highlighted their extensive experience and multidisciplinary expert teams, aiming to improve patient health and quality of life from therapy initiation to daily challenges, with a focus on respiratory disease, diabetes, and Parkinson's disease.
- One respondent emphasized their capability to create telemedicine and remote monitoring platforms quickly, adapting to specific needs with a short time to market.

- Another focused on user-centric design, patient engagement, AI and data analytics, advanced sensor technologies, and support for patient empowerment and informal caregivers.
- One participant mentioned their expertise in digitalizing care plans and coordinating social and health care systems.
- Another stated their capability to significantly contribute through advanced IoT technology, real-time monitoring, AI and predictive analytics, interoperability, data security, user-centric design, and scalable infrastructure.
- Another respondent offered to provide a solution and invited contact for further details.
- One participant emphasized their experience in developing and implementing digital health solutions, integrating advanced AI technologies, user-friendly interfaces, and robust data security, along with providing training and support for smooth adoption.

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

- One respondent highlighted risks including access to data for AI or ML model training, data integration with public systems, lack of patient/professional participation in co-creation, and resistance to change among professionals and patients.
- Another respondent identified major risks related to user adoption and implementation (80%), including resistance to change, training, communication, engagement, customization, and cultural barriers. Technical risks (20%) include interoperability, system reliability, cybersecurity, and scalability.
- Another respondent outlined risks with home hospital and virtual wards, such as technology reliability and accessibility, patient privacy and data breaches, patient recruitment, care coordination, and workflow disruptions.
- Additional risks mentioned included data management, patient/provider engagement, long development times, and high investment costs for medtech innovations.
- One response noted that patients with rare diseases (RDs) might need caregiver support to access the software.
- Risks associated with AI solutions included insufficient information for training and validation, data privacy challenges, and potential inconsistencies in deployed solutions.
- Another respondent mentioned the need for clear scope definition for functionalities like remote monitoring, automation, and patient assessment.
- Sustainability was cited as a significant risk due to rapid technological evolution and the importance of user engagement, retention, and product longevity.

- One participant listed risks such as data privacy and security, regulatory compliance, R&D costs, integration with existing systems, and user adoption.
- Concerns about professional conviction and enthusiasm for technology were also raised.
- Additional risks included technological validation deadlines, regulatory backlogs, cost overruns, usability issues, and integration with current workflows.
- A detailed risk register was provided, identifying risks such as non-compliance with regulations, data breaches, integration issues, low user adoption, technical failures, funding shortages, scalability, patient engagement, pilot testing issues, and continuous improvement.
- Regulatory challenges, data privacy, resistance to technology, and technical interoperability were also mentioned, along with concerns about over-reliance on technology and disparities in access.

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.*

One respondent indicated a positive stance on the inclusion of a Value Engineering clause, believing it would enhance the value and efficiency of their solutions. They argued that such a clause would promote ongoing improvements and reductions in the total cost of ownership, ultimately benefiting both the provider and public buyers by increasing quality and cost-effectiveness.

Another respondent agreed to the possibility of a Value Engineering clause, noting that it aligns with their practice of validating value creation through innovation. They emphasized that their approach includes an economic model for healthcare business managers, which quantifies economic value as part of their service co-creation process.

Some respondents expressed a need for further evaluation or discussion before providing a definitive answer. One mentioned a lack of experience with this clause and suggested that a detailed study would be necessary. Another respondent needed to consult with shareholders for a more informed decision, while others required additional information to understand the implications of the clause fully.

A few responses highlighted that the feasibility of the clause would depend on the specific conditions outlined in the tender documents. Despite this, there was general support for the idea, with some seeing it as beneficial for future product

commercialization and ensuring continuous improvement and cost reduction throughout the project.

Overall, there was a mix of enthusiasm and caution regarding the Value Engineering clause, with several respondents open to the concept but requiring more details to fully commit.

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

One respondent highlighted the importance of collaborating with research centers to address problems innovatively. They suggested that maintaining a close relationship with relevant organizations could enhance the proposal for the project, and further collaboration details would be confirmed once the tender details are known.

Another respondent provided a comprehensive set of suggestions for the PROCURE4HEALTH project, emphasizing several key areas. They recommended implementing comprehensive training programs tailored to different user groups to ensure proficiency with the new system. Engaging users early in the development process to gather feedback and ensure the solution meets their needs was also suggested. Improving design and functionality based on user feedback to make the platform intuitive, along with establishing a support system with helpdesks and regular check-ins, was considered crucial. Clear communication about the solution's benefits and functionalities was also advised.

In terms of technical integration and interoperability, the respondent emphasized ensuring seamless integration with existing health infrastructure and systems, focusing on interoperability with various devices and home tests. They also stressed the importance of implementing robust data security measures to protect patient information and comply with regulations like GDPR.

Customization and personalization were highlighted as important, with suggestions to offer customizable dashboards for different user groups and use AI-driven decision support to provide personalized care plans and recommendations. The respondent also recommended adopting Value Engineering to ensure continuous improvement and cost-efficiency, presenting proposals for enhancements and cost reductions. Establishing a feedback loop with users for iterative improvements and fostering collaborations with healthcare providers, technology companies, and research institutions were also suggested.

Additionally, the respondent underscored the need to maintain detailed documentation of processes, system functionalities, and user guidelines to aid training and troubleshooting. They advised focusing on user adoption and effective implementation, noting that the most significant challenges lie in how users adapt to new workflows and communication methods. Involving users early to help with implementation challenges and adopting an agile development approach due to the rapid pace of technological change were highlighted as critical steps.

Another respondent suggested supporting innovation in meta operating systems for digital health and European Health Data Spaces as a key focus for the project.

One respondent had no additional suggestions at the time but acknowledged the value of collaborating with various health solution providers and noted their extensive research experience in technologies related to health and personalized care.

Lastly, a respondent emphasized the importance of establishing clear communication and feedback mechanisms among all stakeholders to ensure that the developed solutions align with real-world needs. They also stressed considering scalability and flexibility in the design to accommodate future advancements and changing healthcare landscapes.

3 The follow up PCP

PROCURE4HEALTH is preparing the operational ground for a Pre-Commercial Procurement (PCP) proposal concerning home-based care and remote monitoring. 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 tailored to facilitate the transition from hospital-based to home and community-based care, emphasizing remote monitoring, AI-powered alerting systems, virtual assistants, and other advancements aimed at supporting patients with multiple chronic conditions across various medical specialties, thereby enhancing the sustainability and effectiveness of healthcare delivery. Here are the required functionalities:

- Remote monitoring and alerting system.
- Automation of clinical workflows.
- Adaption of systems to diseases, problems and (multiple chronic) conditions to be included in the patient profile definition.
- Patient own assessment and clinical planning.

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 engaged and prepared to tackle the complexities associated with home-based care and remote monitoring. Respondents collectively highlighted the importance of addressing technical, user adoption, and integration challenges to ensure the successful deployment of innovative solutions.

Responses indicated a consensus on the necessity of robust user adoption strategies, emphasizing comprehensive training programs tailored for different user groups, including healthcare providers, patients, and caregivers. Early involvement of users in the development process and maintaining clear communication channels were seen as critical to addressing implementation challenges and ensuring that the solutions meet real-world needs. The emphasis on user-centric design and ongoing support underscores the market's focus on creating intuitive and accessible solutions that facilitate smooth transitions and effective use.

Several companies indicated their readiness to incorporate a Value Engineering clause within contracts. They acknowledged that such a clause would facilitate continuous improvement and cost reduction throughout the project lifecycle. This approach is expected to enhance the overall value and efficiency of the solutions provided, benefiting both the providers and the public buyers by ensuring that the solutions not only meet but exceed expectations.

Some companies confirmed their commitment to fostering collaborations and partnerships. They expressed interest in working with research centres and other stakeholders to leverage expertise in areas such as anomaly detection, personalized recommendations, and risk prediction. These collaborations are seen as pivotal in advancing the technology and addressing specific challenges related to mental health, personalized care, and environmental risks.

Respondents also suggested that PROCURE4HEALTH consider supporting innovations related to meta operating systems for digital health and the European Health Data Spaces. This suggestion reflects a broader vision of integrating new technological and regulatory frameworks to enhance the effectiveness and scalability of home-based care solutions.

Overall, the responses received during the OMC underscore a collaborative and forward-thinking approach within the market. There is a strong emphasis on addressing the practical challenges of implementation, ensuring robust integration with existing systems, and maintaining a focus on user engagement and support. By leveraging the expertise and innovation present in the market, PROCURE4HEALTH can effectively address the complexities of home-based care and remote monitoring. The detailed insights and recommendations provided by the respondents will be instrumental in guiding the project towards successful outcomes, driving advancements in care delivery, and meeting the evolving needs of healthcare providers and patients.

Procure 4Health

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