HEALTHCHAIN

Co-funded by the European Union

Mirror Regions Call for SMEs

Annex 1: Challenges

Version no.1.0 (May 2024)

Co-funded by the European Union

HEALTHCHAIN

General details

GA number	GA 101094676
Project Acronym	HealthChain http://healthchain-i3.eu/
Project Title	Boosting value chains in Health at regional and EU level
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Project Duration	January 2023. – December 2025. (36 months)

Disclaimer

History of changes

Ver.	Date	Changes
1.0	28/05/2024	First public version

AITRIS

Automated imagery tool results for diagnostics and standardisation

A digital assistant that helps the radiologist in oncology analyse advanced imaging (CT, MRI, Mammography, Sonography), interpret them and write standardised radiology results.

Challenger

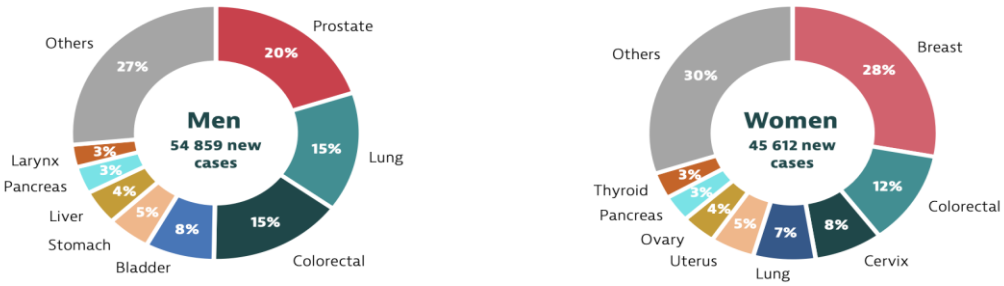
Medisprof Cancer Center is a private outpatient oncological hospital with two locations in Romania: Cluj-Napoca and Piatra Neamț. The clinic offers diagnostic and treatment services for all oncological localizations, in contract with the National Insurance Home. Founded in 2010 by Dr. Carolina Udrea, Medisprof started offering chemotherapy treatments in Cluj-Napoca, expanding its services in 2018. It is offering similar services in Cluj-Napoca and Piatra Neamț (2024), except for radiotherapy. With personnel of over 200, Medisprof offers laboratory tests, advanced imaging (CT, MRI, Mammography, Sonography), pulmonology, endoscopy, colonoscopy, radiotherapy, and chemotherapy treatments.

Medisprof is the only oncology healthcare provider in Romania with QOPI (Quality in Oncology Practice Initiative) certification from ASCO (American Society of Clinical Oncology) and strives to have a holistic approach, investing annually all its profit into developing quality services in Transylvania and Moldova. The group has a turnover of 10 million euros as of 2023.

Challenge description

According to estimates from the Joint Research Centre based on incidence trends from previous years, more than 100 000 new cancer cases were expected in Romania in 2022. Cancer incidence rates were expected to be lower than the EU averaged for both men and women. The main cancer sites expected among men were prostate expected in Romania in 2022. Cancer incidence rates were expected to be lower than the EU (20 %), lung (15 %) and colorectal (15 %) cancer, while among women breast cancer was expected to be the leading cancer site (28 %), followed by colorectal (12 %) and cervical (8 %). (source: Romania: Country Health Profile 2023).

Figure 5. More than 100 000 cancer cases in Romania were expected to be diagnosed in 2022



Age-standardised rate (all cancer): 674 per 100 000 population
EU average: 684 per 100 000 population

Age-standardised rate (all cancer): 428 per 100 000 population
EU average: 488 per 100 000 population

Notes: Non-melanoma skin cancer is excluded; uterus cancer does not include cancer of the cervix.
Source: ECIS – European Cancer Information System.

Cancer patients require periodic scans during their treatment to be able to adapt and monitor the therapy. Radiologists perform 4-5 imaging evaluations in a day, spending a lot of time interpreting the results, writing them in a descriptive/narrative way.

The RECIST (Response Evaluation Criteria in Solid Tumours) way of interpreting the results provides a simple and pragmatic methodology to evaluate the activity and efficacy of new cancer therapeutics in solid tumours, using validated and consistent criteria to assess changes in tumours. RECIST[1] is used in trials and considered insufficient in practice.

Only a few radiologists write the result in RECIST, and especially in clinical trials, the results interpreted in this way are not accepted by the surgeons and are hard to interpret by other doctors as well as by the patient.

The evaluation from one scan to another is more difficult to compare in the descriptive/narrative way.

Having the image interpretation in both ways native and RECIST would be considered as double the work for radiologists.

In conclusion, RECIST is insufficient, narrative is harder to build and follow-on (after 3 months).

By having a digital assistant that would help the radiologist analyse scans, interpret images and write standardised radiology results containing both RECIST and narrative, the clinic will:

- give radiologist support in interpreting the results
- decrease burnout in radiologists
- create an easier case follow-up/transfer between radiologists
- empower the patient, they will be able to see the progress of the treatment by themselves
- help oncologists get a clearer understanding to maintain/adjust treatment

Why we need to solve this problem:

- Insufficiently structured imaging interpretations in oncology patients, leading to suboptimal oncologist/radiotherapist decisions and quality of care
- Increased patient scrutiny on oncology quality of care (second opinion, AI usage)
- Increased number of investigations due to the increased number of patients and availability of equipment.

The cause of the problem:

- Lack of standardisation in radiology results presentation (RECIST based or not)
- Lack of recommended structuring of imaging interpretation in oncology

The insufficiently structured imaging interpretations in oncology patients lead to suboptimal oncologist/radiotherapist decisions and quality of care. The first patient profile is the lung cancer patient, to be followed by other patient profiles.

In 2022, Medisprof performed 8K scans out of which 823 investigations for lung cancer patients with an average of 2,4 investigations in a year/patient.

Challenge main objectives

The main objective is to develop a digital solution to reduce the time for radiologist interpretation, increase the satisfaction of oncologists and radiologists for imaging results that

[1] recist.eortc.org

will lead to better follow-up of patient journey for the management and decrease radiology subcontracting costs.

Solution functional requirements

The solution shall use the provided data (CT, MRI, Mammography, Sonography) to interpret images and write standardised radiology results to reduce the time of interpretation and help for a better follow-up.

Compulsory functional requirements

Image Processing: The digital assistant must be able to process advanced imaging data from various modalities including CT, MRI, mammography, and sonography.

Image Interpretation: the solution shall employ machine learning algorithms and advanced image analysis techniques to assist radiologists in interpreting complex oncological images accurately.

Lesion Detection: The digital assistant must be capable of identifying and highlighting suspicious lesions or abnormalities within the images.

Clinical Decision Support: It shall provide relevant clinical decision support based on evidence-based guidelines and best practices in oncological imaging.

Report Generation: It must be able to generate standardised radiology reports that comply with industry standards and include essential information such as lesion characteristics, location, size, and clinical recommendations.

Customization: The digital assistant shall allow radiologists to customise report templates, preferences, and workflow according to their specific needs and preferences.

Quality Assurance: It should include built-in quality assurance mechanisms to ensure the accuracy and reliability of image analysis and interpretation.

Continual Learning: The assistant should continuously learn from user interactions and feedback to improve its performance and accuracy over time.

Compliance and Security: It must adhere to strict data privacy regulations and security standards to protect patient information and maintain confidentiality.

Desirable functional requirements

Automated Segmentation: The assistant should be able to automatically segment different anatomical structures and lesions within the imaging data, reducing manual effort for the radiologist.

Quantitative Analysis: It should offer quantitative analysis tools to measure parameters such as tumour volume, density, and enhancement kinetics, providing additional insights for diagnosis and treatment planning.

Multi-Modal Fusion: The assistant should be capable of fusing information from multiple imaging modalities to provide a comprehensive assessment of the disease, leveraging the strengths of each modality.

Clinical Pathway Guidance: It could provide guidance on appropriate clinical pathways based on imaging findings, helping radiologists recommend further diagnostic tests or treatment options.

Outcome Prediction: Utilising machine learning algorithms, the assistant could assist in predicting patient outcomes based on imaging features and clinical data, aiding in prognostication and personalised treatment planning.

Integration with Clinical Decision Support Systems: It should seamlessly integrate with clinical decision support systems to provide access to relevant guidelines, research articles, and treatment protocols, supporting evidence-based decision-making.

Interactive Education: The assistant could offer interactive educational resources, such as case studies and tutorials, to help radiologists improve their skills in oncological imaging interpretation.

Natural Language Processing (NLP) for Report Generation: It could utilise NLP techniques to assist radiologists in generating comprehensive and structured radiology reports from their findings, enhancing efficiency and standardisation.

Image Annotation Tools: Providing tools for radiologists to annotate and mark regions of interest directly on the images could facilitate collaboration and communication with other healthcare professionals.

Continuous Performance Monitoring: The assistant should include mechanisms for monitoring its performance and soliciting feedback from users, allowing for iterative improvements and optimization.

Pilot scope

Type and number of targeted end-users

End-user type	Role	Number
Radiologist	*They have to provide requirements, use and validate the solution.*	*5*
Oncologist	*They have to provide requirements, use and validate the solution.*	*2*
Management	*Provide the CT scans*	*200*

Table 1. Targeted users

Language

Language Proficiency: Ensure that the digital assistant supports the primary language(s) spoken by the end-users. Use Romanian and English.

Pilot set up conditions

User Training and Support: Provide comprehensive training to radiologists and other healthcare professionals who will be using the digital assistant during the pilot. Offer ongoing

support and troubleshooting resources to address any technical issues or user concerns that may arise.

User Feedback Mechanisms: Establish mechanisms for collecting feedback from pilot participants, including surveys, focus groups, and direct communication channels. Gather insights on usability, effectiveness, and areas for improvement to inform iterative refinement of the digital assistant.

Evaluation Metrics: Define key performance indicators (KPIs) and evaluation metrics to assess the impact of the digital assistant on radiologists' workflow efficiency, diagnostic accuracy, report quality, and patient outcomes. Collect quantitative and qualitative data throughout the pilot period to measure progress and identify successes and challenges.

Ethical Considerations: Address ethical considerations related to the use of artificial intelligence in healthcare, such as transparency, accountability, and equitable access. Ensure that the pilot adheres to ethical guidelines and safeguards patient rights and welfare.

Communication and Stakeholder Engagement: Maintain open communication with stakeholders, including radiologists, referring physicians, administrators, and patients, to garner support for the pilot and address any concerns or misconceptions. Engage stakeholders in the planning, implementation, and evaluation processes to foster collaboration and buy-in.

Scalability and Sustainability: Consider the scalability and sustainability of the digital assistant beyond the pilot phase. Assess its potential for broader adoption across multiple healthcare facilities and develop a roadmap for long-term integration into routine clinical practice.

Ethical, legal or regulatory

An Ethics Committee of the Medisprof Cancer Center must previously validate the approach of the pilot. The solutions shall be fully GDPR compliant.

Data Privacy and Security: Implement robust data privacy and security measures to protect patient information and ensure compliance with regulatory requirements, such as GDPR. Encrypt data transmissions, restrict access to unauthorised users, and implement audit trails for accountability.

Technological

The systems and servers needed for running the pilot will be hosted by the Solver. The solution shall be able to exchange information (read and write data) with the systems of the Challenger.

Infrastructure Readiness: Ensure that the pilot site has the necessary infrastructure to support the implementation of the digital assistant, including compatible hardware and software systems, network connectivity, and secure data storage solutions.

Integration with Existing Systems: Integrate the digital assistant with the facility's existing systems, radiology systems, to facilitate seamless data exchange and workflow integration.

Data access

For the AI tool, training anonymised data will be extracted from the Challenger existing IT systems and provided to the Solver. This data will contain CT, MRI from lung cancer patients.

Expected impact and KPIs

Pilot satisfaction:

- Radiologist satisfaction >80%
- Oncologist satisfaction >80%
- Percentage of successful interpretation of radiology results >80%

Improved Efficiency: The digital assistant will streamline the workflow of radiologists by automating repetitive tasks, such as image analysis and report generation. This efficiency gain allows radiologists to focus more on complex cases and reduce burnout.

Enhanced Accuracy: By leveraging advanced machine learning algorithms and image analysis techniques, the digital assistant can assist radiologists in identifying subtle abnormalities and lesions in oncological imaging with higher accuracy. This can lead to earlier detection of cancerous lesions and improved patient outcomes.

Standardised Reporting: The digital assistant will facilitate the creation of standardised radiology reports, ensuring consistency and completeness in reporting across different radiologists and institutions. Standardised reports enable clearer communication with referring physicians and support evidence-based decision-making in patient care.

Advanced Data Analysis: With the capability to perform quantitative analysis and extract valuable insights from imaging data, the digital assistant enables radiologists to provide more comprehensive assessments of tumour characteristics, progression, and response to treatment. This aids in treatment planning and monitoring.

Facilitated Collaboration: The digital assistant fosters collaboration among multidisciplinary healthcare teams involved in oncology care. It provides a platform for sharing imaging data, analysis results, and treatment recommendations, facilitating informed discussions and consensus-building among team members.

Continual Learning and Improvement: Through continuous interaction with users and feedback collection, the digital assistant can adapt and improve its performance over time. It learns from user interactions, refines its algorithms, and incorporates new knowledge and best practices in oncological imaging interpretation.

Increased Accessibility: By providing access to advanced image analysis tools and decision support capabilities, the digital assistant extends the expertise of experienced radiologists to underserved regions or facilities with limited resources. This promotes equitable access to high-quality oncological care.

Patient-Centric Care: Ultimately, the digital assistant contributes to delivering more personalised and patient-centric oncology care. By supporting accurate diagnosis, treatment planning, and monitoring, it helps healthcare providers tailor interventions to individual patient needs, leading to better outcomes and improved quality of life for cancer patients.

Business opportunity

Market size

Internally, at the Medisprof this project would be replicable in 2 centres, with around 10 radiologists. Potential users are estimated at 6313 patients.

- The first target would be the cancer centres at national level (www.cdelacontrol.ro/medici)
- The second target would be the Imaging centres that perform imaging for oncology patients - a few national networks - Affidea, Medima, RMN Diagnostica.

The estimated prevalence rate of lung cancer per 100,000 people is approximately 14.000, for which the exact epidemiology remains unknown due to the absence of national records. (source Addressing the unmet need for a comprehensive lung cancer registry in Romania)

Adoption Plans

We plan on starting the pilot with lung cancer data, and then add all the other cancer data. We would like to be the golden standard for radiology in oncology standardised reports

iMOTION

Virtual assistant for voice-activated emotional state recognition in palliative care patients

Challenger

Los **Montalvos Hospital** (Palliative Care Unit, 1998) has been, for more than 20 years, the reference centre of the health system of Castilla y León (Spain) in charge of the integral socio-health care of advanced patients, providing training, assistance and research in palliative care. In addition to the Hospitalisation Unit, another important service is the Home Support Teams. The hospital has two teams, one for the rural area and the other for the urban area, which provide services 365 days/24 hours a day.

In addition, Los Montalvos Hospital count with the collaboration of ACPD (Association for the Development of Palliative Care in CyL), a non-profit association dedicated to the development, research and intervention in the field of PC. It is integrated in the PC Unit of the University Complex of Salamanca.

Challenge description

In recent years, the number of people with a limited life prognosis with an additional component of pain, suffering and dependency has increased notably. Around 308,475 people need palliative care in Spain (20,011 in Castilla y León), of which 126,640 (8,235 in Castilla y León) will require the intervention of specialised palliative care (PC) teams, although only 40% of them receive it. Although CYL is a pioneer in offering people with an advanced or terminal illness the support they need so they can continue to live in their chosen home while the disease progresses, this care process is always a challenge in Castilla y León, given its demographic and territorial reality. INTecum project (led by Gerencia Servicios Sociales JCYL) which has provided support to almost 600 (579) people, shows that 20% of people in need of personal support live alone.

The scaling up of PCs to rural areas requires the existence of effective, low-cost technological tools that allow patients to be monitored at home and remotely, anticipating their evolution in order to avoid situations that generate suffering in people.

It is necessary for both the patient and his or her family have a network from the beginning, when the patient is included in the Integrated Palliative Care Process, which, to be effective, must have a great capacity for flexibility and versatility according to the evolution of the illness and their emotional state. Despite the high prevalence of psychological symptomatology in advanced disease or at the end of life, specific assessment and intervention for these needs is lacking. Only 50% of patients (10% in 2014) with these needs receive the necessary psychological help to cope with their situation. Therefore, it is necessary to provide social and healthcare professionals in PC with tools for assessing the emotional state of the patient from the initial examination to enable them to act in a timely and appropriate manner in the intervention and to provide clinically validated and reliable monitoring of the patient's emotional evolution in order to prevent and anticipate the risk of emotional distress (ED).

Challenge main objectives

The main objective is to detect the emotional state of palliative care patients for the palliative care team professionals (the challenger) to consider it in the patients' personalised intervention plan, mainly at home. The expected benefit is to improve the psychosocial support of patients and enhance their emotional wellbeing and quality of life to prevent emotional distress.

A secondary objective is to validate, by the challenger, the use of a digital assistant capable of recognising these emotional states through voice recognition processing using NLP (Natural Language Processing) and DSP (Digital Signal Processing) techniques.

Solution functional requirements

Compulsory functional requirements

To comply with the objectives of the challenger the solution should address:

1. Identification of speech patterns through NLP (Natural Language Processing) and DSP (Digital Signal Processing) techniques in both the time and frequency domains, with the aim of discerning emotional states or moods in patients.
2. Use of technological tools such as personal assistant to recover the patient voice.
3. Provide an alert and reporting system to the PC team in order to be able to act in case of emergency or to prevent and anticipate (by monitoring the evolution of the historical data of the patient)

As compulsory requirements, the solution should meet:

1. Record the patient's conversation with the Palliative Care Professionals or relatives.
2. Identifies speech patterns through NLP (of the basic emotional states: fear, sadness, anger, joy, surprise and disgust) from the patient's conversations (what he/she says and how he/she expresses him/herself).
3. Allows the creation of rules based on speech patterns of the patient.
4. Provide an alert and reporting system to the Palliative Care Professionals to anticipate to Emotional Distress.
5. Allows to store and monitor the history of speech patterns as well as emotions.

Desirable functional requirements

1. The solution shall be adapted to patients' held devices like smartphones, tablets or personal assistants.
2. Provide feedback to patients on their emotional state.
3. Contain an interface easy to use and intuitive for patients and PC professional.

Pilot scope

Type and number of targeted end-users

The target population for this project are patients with chronic diseases or long-term illnesses in early stages of palliative care at home and inpatients in Castilla y León (Spain) and Socio-healthcare professionals (doctors, nurses, psychologists, social workers) from the Palliative Care Home Support Teams.

End-user type	Role	Number
PC Patients	Provide 100 (ideal) natural, unsimulated and unforced conversations with professionals	50
PC Home Support Professionals	Provide requirements, Manage the conversations with patients Identify basic emotions Use and validate the solution	2-3

Table 1. Targeted users

Language

The derivable should work under Spanish spoken pattern.

Other aspects

Another important aspect to consider is the possible drop-out of patients during the pilot due to the special characteristics of this group, which could affect the sample size.

Pilot set up conditions

The pilot setup conditions correspond to the objective of detecting the emotional state of palliative care patients by the Home Palliative Care Professionals.

During the pilot they will manage the conversations with patients in a natural, not forced way, and associate these conversations or parts of them, with one or more of the basic emotions.: fear, sadness, anger, joy, surprise, disgust or Neutral state. The conversation should be recorded in order to professionals can labelling emotions to identify speech patterns from the patient's conversations (what he/she says and how he/she expresses him/herself).

The pilot will be developed in a period of 12 months, including design, validation, testing and measuring of the impact of the co-created solution.

Ethical, legal or regulatory

As the sample is made up of **very vulnerable people**, the guidelines for research with this type of population will be followed.

Prior to the start of the pilot, the study protocol will be designed for approval by the Clinical Research Ethics Committee. This protocol will include:

- Study design to test the feasibility of the technology: The study will involve 50 patients and 2-3 professionals from Palliative Care Home Support Teams.
  An additional % will be recruited to ensure drop out replacement for patients
- Inclusion and exclusion criteria for participants. The study will target patients with long-term illnesses, cared for at home or in hospital settings.

The study will be conducted in accordance with the ethical principles that originate from the Declaration of Helsinki, and with the corresponding standards of good clinical practice, and current laws and regulations. In addition, participants' personal information will be kept confidential and will not be disclosed under any circumstances. In accordance with Organic Law 3/2018 on Personal Data Protection and guarantee of digital rights, which adapts Spanish legislation to the General Data Protection Regulation of the European Union, all patients will be notified (Patient Information Sheet) about their rights of access, modification, deletion and correction of data by requesting it to the corresponding researcher.

The iMOTION solution will apply the methodology "ethical artificial intelligence by design" in accordance with the Digital Rights Charter of the Spanish Government's Secretary of State for Digitalisation and Artificial Intelligence (SEDIA) of July 2021, which states that human-centred AI should guide any development framework that is built and thus demand that intelligent systems are not only explanatory, secure and robust, but also comply with European principles such as non-discrimination (bias), diversity and fairness and the protection of privacy.

Technological

A pilot implementation plan will be proposed, which will include:

- The installation of the equipment at homes/hospital, ensuring the quality and risk management of the experimentation.
- The elaboration of guidelines for the successful introduction of the technological and person support tools to maximise acceptance and satisfaction.
- the training of professionals and patients.
- From the technical point of view, possible incidences will be collected for the improvement of the system and a helpdesk will be set up to provide support.
- The systems and servers needed for running the pilot will be hosted by the Solver.
- The Solver will be responsible for the collection, management and analysis of the data during the study and for its destruction once the study is over.

Data access

No prior data is expected to be available, meaning all users will start as new users in the system.

Expected impact and KPIs

The solver solution should be used by the Palliative Care Home Support Teams. The solution should monitor the history of speech patterns as well as emotions each week so the professional can track the emotional state of patients between visits. Currently, to organize the visit the professional team, performs around 100 phone calls per week. (20-30 per days, 5 days a week).

Using iMOTION, the team expect to improve the service thanks to:

- A reduction in the number of weekly phone calls to appointment visits to patients due to emotional state: *at least in a 20%*
- A reduction of phone calls time duration cause the symptoms are known in advance: *at least in a 15%*

- A higher degree of satisfaction PC professionals in the use of the solution (SUS *System Usability Scale*[1]) at least 70 points.
- To achieve a high degree of patient's perception in the appropriateness of the service received by Palliative Care Home Support Teams to the improvement of their emotional well-being by using the application: Degree of satisfaction with PC service >5 (1-10).

Business opportunity

Market size

At the challenger organization, the primary end-beneficiaries of using iMOTION solution are around 200 patients with chronic diseases or long-term illnesses with a life-limiting prognosis attended by the 4-6 professionals (doctors, nurses, psychologists, social workers) of the Palliative Care Home Support Teams

iMOTION could also be extend to the psychosocial care teams (EAPS) from 8 hospitals (five of them in CYL that are part of the Northwest Commission) (Salamanca, Avila, Zamora, Valladolid, Burgos, Asturias, Pontevedra and La Coruña) and even to transfer it to National and European level (for example to North Portugal) if the experience is positive and provides useful results.

Beyond its use in palliative care, other future possible beneficiaries of iMOTION could be other vulnerable groups with psychosocial support needs.

Adoption Plans

If the pilot is successful, Hospital Los Montalvos intends to adopt the solution, by shared ownership of the solution and procure its maintenance.

Intellectual Property Rights

This section sets the rules for the evaluation, ownership, and exploitation of Intellectual and Industrial Property Rights.

Evaluation and Documentation: Each party shall evaluate and document in the Pilot Action Plan their respective contributions to the new solution. This assessment will consider each party's background knowledge, resources, and tasks undertaken in the co-creation pilot project, determining the ownership and rights of the resulting shared IP&IPR.

Intellectual Property (IP) Rights: The intellectual property rights developed or contributed by Hospital Los Montalvos are inalienable, reflecting the knowledge and resources provided by Hospital Los Montalvos, including work time, patient access, and real-environment validation. These rights will be set out in the relevant IP agreement.

Industrial Property Rights (IPR): Hospital Los Montalvos will opt-out of the commercial exploitation of the solution as it is not their objective, in exchange for certain compensations such as:

▪ Reduced overall cost in licensing and maintenance of the solution.

[1] System usability scale (SUS) is a simple, ten-item attitude Likert scale giving a global view of subjective assessments of usability.

- Allocated hours for corrective and evolutionary maintenance.
- Priority status for Hospital Los Montalvos in new developments.
- Collaboration by Hospital Los Montalvos in promoting the solution.

These rights will be set out in more detail in the relevant IPR agreement.

MoveBuddy

Intrinsically motivate obese children with an innovative and child-friendly digital solution that promotes long-term physical activity through gamification.

Challenger

Az groeninge is a dynamic general hospital located in Kortrijk (Belgium) with more than 1000 recognized beds. We are known for our advanced medical services and high-quality care. More than 2800 employees and approximately 260 hospital doctors strive every day to provide quality, safe, accessible, expert, and integrated care to every patient, with respect for everyone's individuality. To respond to the changing needs of the patient, the broadest possible medical offering is provided based on multidisciplinary and transmural collaboration with other healthcare institutions and primary care.

We do not shy away from innovative projects with clear added value for patient care. 'The greenhouse', an institute for clinical growth, was initiated because innovation, development, research, education and expertise are extremely important to az groeninge. A cluster of specialists who aim to build bridges for new trends, innovative treatments and quality.

Challenge description

Childhood obesity is a pressing health issue, with profound implications for individuals, and society at large. Beyond immediate impacts on self-esteem and quality of life, it significantly elevates the risk of chronic illnesses like diabetes and cardiovascular diseases, alongside psychosocial complications. This burdens healthcare systems with increased medical costs but also undermines societal productivity and well-being.

In Belgium alone, over 133400 children aged 2-18, representing approximately 5,8% of the population in this age group, are affected by obesity. (Belgische Kamer van Volksvertegenwoordigers, 2022) Currently, healthcare professionals rely on self-reporting or subjective observations when treating obese children, which is prone to biases and inaccuracies. In addition, healthcare professionals use generic approaches that may not be tailored to the specific requirements of individual children with obesity. This one-size-fits-all approach limits the effectiveness of interventions, as it fails to account for the diverse needs and preferences of each child.

Therefore, the solution must collect accurate data such as physical activity and sedentary behaviour (e.g. through an accelerometer). This includes steps taken, distance travelled, prolonged sitting time, sleep tracking, heartrate, intensity of the activity, … To avoid falsification of the values, it must be an accelerometer and not a regular pedometer.

The values can help identify patterns which can improve interventions to increase activity levels and promote healthier habits. Sleep plays a crucial role in overall health. Sometimes obesity can be associated with sleep disturbances. The tool should be equipped with sleep tracking capabilities to monitor duration, quality and disturbances. The tool would not only provide accurate data, allowing healthcare professionals to tailor interventions based on individualized insights and track progress. By integrating the measurement data into the electronic patient record, healthcare providers can monitor the child remotely and make

timely adjustments, which will most likely lead to more successful outcomes. This strategy improves the efficiency of the use of scarce hospital resources through tiered care. Children can be guided to the most appropriate level of intervention. Supervision in the hospital is reserved for children who require (renewed) intensive follow-up. Those who meet the exercise standards can receive guidance from regular sports clubs.

It is also important that the children are intrinsically motivated to exercise more through the tool due to the gamification aspect. By gamification they learn how to make the healthier choices and the pleasure of movement.

Challenge main objectives

The goal is to enhance the intrinsic motivation of children with obesity via gamification to consistently meet the daily exercise standard outlined by Flemish health recommendations for long-term physical activity. This entails at least 60 minutes of moderate to high-intensity exercise per day, aligning with both Flemish health guidelines and those set by the World Health Organization (WHO).

Solution functional requirements

Compulsory functional requirements

1. The solution (e.g. through an accelerometer) must accurately track and record children's daily physical activity levels: heartrate (steps taken, distance travelled, pace, intensity and duration of the activity, sleep-wake cycle, activity recognition or setting up the measurement of a certain activity (E.g. swimming, bicycling, running…):
   <100 counts per minute (cpm): sedentary,

   101-2295 cpm: moderately physically active,

   >2296 cpm: high physically active.

   (Evenson et al., 2008)
2. The tool must be child-friendly, engaging and age-appropriate interfaces to promote intrinsic motivation: catch the eye of children; attractive, easy to use, correct sizes and colours, safe…
3. It shall provide real-time feedback and progress tracking features for both children, parents and healthcare professionals to monitor adherence and empower to daily exercise goals. For example, if the daily exercise standard is not achieved during a certain period, the child and parent receive a reminder. If it persists, a notification is sent to the healthcare professional (HCP); physiotherapist or pediatrician. The real-time feedback mechanism allows children and parents to celebrate achievements, set goals, work collectively towards a healthier and more active lifestyle. It is vital for proactive intervention.
4. The solution must be capable of generating personalized intervention strategies for physical activity based on individualized insights derived from collected data. This data will be used for the gamification element in the wearable. The solution should be worn continuously to get the complete picture (24 hours a day). Therefore, it seems necessary to work with a wearable.
5. A user-friendly dashboard: easy interpretation of collected data and efficient consequence (E.g. Fail to meet daily exercise goal, actively encouraging more exercise through gamification, challenges…). Where the main users of the dashboard are the clinicians, nurses and physiotherapists.

6. The app should function on iOS and Android.
7. It should contain gamification elements to further stimulate children's engagement and motivation towards physical activity.
8. It should prioritize privacy and data security, adhering to relevant regulations and guidelines to safeguard sensitive health information.

Desirable functional requirements

1. The architecture should already take into account an integration with Electronic Patient file systems will be feasible: Klinisch Werkstation (KWS) or MyNexuzHealth. The integration with the system can be provided by using HL7.
2. It would be nice if the tool contains collaboration features to enable communication and coordination between HCP, parents and other children combatting obesity (by challenging each other...)
3. Scalability to accommodate a growing user base.
4. Ability to manually set activity zones by a healthcare professional based on exercise test results. (E.g. endurance (VO2 max), maximum heart rate...)

Pilot scope

Type and number of targeted end-users

End-user type	Role	Number
Children aged 6-9, 10-12, 13-15	They have to clarify their wishes, give ideas that would help them reach their activity goal on a long-term. They have to test and evaluate.	20
Parents (Equal numbers of mothers and fathers)	They have to provide requirements and feedback on the usability and effectiveness of the solution, offering insights to better meet de needs of children and families. After the requirements phase they need to evaluate and give suggestions to improve.	10
HCP: Pediatrician (3), Physiotherapist (3), dietician (2) and psychologist (2)	They have to provide requirements (specify needed data, needed interventions/consequences), recruit patients, use and validate the solution and	10

	preparatory steps for integration in the EPD.	

Language

Dutch – simple Children's language.

Children and parents will be recruited in the region of the hospital. Communication has to be done in their language (Dutch). Ability to communicate with young children should get specific attention.

Within the context of scale-up, it is useful to take preparatory steps to make the app also available in other languages (E.g. French or English).

Other aspects

It seems necessary to use an attractive wearable, with an accelerometer for reliably measuring children's physical activity levels.

This technology ensures accurate tracking and provides valuable data for assessing adherence to recommended exercise guidelines.

Additionally, establishing a link between the wearable device and a mobile app enhances real-time insights for both children and their parents, as well as HCP. This connectivity allows for immediate feedback on activity levels, progress tracking, and personalized intervention planning. Moreover, it fosters transparency and accountability, empowering children to take ownership of their health while facilitating communication between all stakeholders involved in supporting their physical activity goals. Integrating these features into the solution enhances its effectiveness and attractiveness, ultimately contributing to the success of the tool in promoting sustained motivation for physical activity among children with obesity.

Pilot set up conditions

Ethical, legal or regulatory

The Ethics Committee of az groeninge will previously validate the approach of the pilot. The solutions must be fully GDPR compliant to safeguard the privacy and confidentiality of participants' health information. Informed consents will be obtained from participants or their legal guardians.

Technological

The solution shall be able to exchange information (read and write data) preferably with the electronical patients records of az groeninge; Java - Klinisch Werkstation (launcher version 3.4.1) or MyNexuzHealth or makes the data available via another platform. Ideally this should be tested during the project.

The application should be hosted on the servers of the hospital.

The application should be compatible with the accelerometer support standards for data exchange and communication protocols to facilitate interoperability with wearable device platforms, enabling the collection and transmission of real-time physical activity data. Where the preference comes into one integrated system, where an application is seamlessly integrated with an wearable. On the other hand, it's also possible to make an open system where the application can receive data from any kind of hardware systems.

The solution shall address cybersecurity concerns to limit the risk of data breaches or unauthorized access to sensitive health information.

Authentication measures must be implemented to ensure secure access to the solution by authorized users, including children, parents, and healthcare professionals.

The solution should consider usability and accessibility requirements to ensure it is user-friendly for children, parents, and healthcare professionals with varying levels of technological literacy.

Data access

No prior data is expected to be available, meaning all users will start as new users in the system.

Expected impact and KPIs

The expected impact of the Movebuddy is an increased the percentage of children meeting daily exercise recommendations by the end of the pilot. Even more important is that children enjoy exercising, this can enhance a long-term effect and reduces prevalence and related costs of obesity-related health conditions.

Satisfaction rate among children, parents and HCP regarding the solutions effectiveness in motivating sustained physical activity.

It enables HCP to tailor interventions for children with obesity based on real-time data insights, leading to improved outcomes.

1. Percentage of children meeting daily exercise recommendations at least 5 days per week: 50% by the end of the pilot.
2. 40% of the children discovered the pleasure of exercise (PACES-S) (Chen, 2021), have a better quality of life and self-esteem (RSES) (Wood, 2021). Conduct surveys at baseline and end pilot.
3. User satisfaction is determined using the: USEQ scale (Domingos, 2022) and feedback session. 80% of the participants score 'very good' satisfaction (15-20).
4. Number of tailored interventions: track the personalized interventions prescribed by healthcare professionals based on insights derived from the solutions data analytics.

Business opportunity

Market size

- Internally, this project would be replicable in the pediatric services in az groeninge. Potential users are -estimated at least 60 children per year.

- At the national level there are approximately 133400 children (aged 2-18) with obesity in Belgium. Considering the potential adoption of the solution by various healthcare providers and organizations across the country, the market size could encompass thousands of children with obesity receiving treatment.
- The WHO European Childhood Obesity Surveillance Initiative (COSI) shows that there is a high and increasing prevalence of overweight and obesity of children and adolescents. One in three school-aged children live with overweight or obesity in the WHO European region. (World Health Organization, 2022)

The challenge of childhood obesity presents a significant opportunity for suppliers of innovative solutions, both within the organization and beyond. Other potential customers, such as healthcare providers, hospitals, public health agencies, schools, sport clubs may also benefit from implementing such solutions to address the growing epidemic of childhood obesity. With the scalability and adaptability of the solution, there is potential for widespread adoption across various healthcare settings, both nationally and internationally, contributing to improved outcomes for children with obesity on a global scale.

Adoption Plans

After a successful pilot, the solution will be scaled up to suggesting the solution to every child undergoing treatment for obesity. Additionally, other organisations will have the opportunity to adopt and integrate this tool in their treatment protocols, enabling the delivery of personalized sustainable care over a long term.

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OPER-ART

Addressing the uncertainty challenges of radiotherapy through personalised 3D molds used in radiotherapy and brachytherapy.

These personalised systems could improve treatment quality, outcomes, and patient comfort, reducing the use of health resources and increasing the well-being of patients and healthcare professionals.

Challenger

The University Hospital of Navarra (HUN) is the public reference centre in the Pamplona Area also being a general hospital for those demands that come from all over Navarra.

The HUN has just over a thousand beds and a total staff of nearly 6,500 professionals grouped into 43 clinical services. It records an annual volume of more than 40,000 admissions, 33,000 surgical interventions and more than 750,000 consultations.

The HUN defines itself as a centre committed to research and the promotion of innovation in healthcare. In the period 2011-2023, the HUN participates actively in research projects with funding from competitive calls and its professionals have published 898 scientific articles (JCR-Journal Citation Reports), with an impact factor of 2581. Likewise, in the last six years, 663 clinical trials have been conducted.

In concrete, Radiotherapy oncology service offers specialized radiation oncology treatments to patients of all ages and types of cancer.

Navarrabiomed-Fundación Miguel Servet will support with all administrative requirements and business support.

Challenge description

Radiotherapy (RT) is a treatment that consists of administering ionizing radiation to the tumour disease while sparing healthy organs. It is a widely used tool in the treatment of cancer: it is received by more than 60% of cancer patients and more than 40% of those who are cured. RT is designed specifically for each patient using medical imaging and planning systems specially tailored for this purpose.
The most common form of RT is External Beam RT (EBRT), which involves linear accelerators that emit radiation in a conformal and disease-targeted manner focused on extremely precise spots. For this, it is essential to use **immobilisation systems** so that patients are positioned in a reproducible way on a daily basis and the treatment is administered with adequate precision.
On the other hand, for the cancer lesions close to the skin where radiation is not adequately deposited, it is common to use **"bolus"**, a flexible accessory with an equivalent density to the human tissue, which is placed on the patient's surface and allows for improved dosimetry. However, commercially available boluses are not always properly adapted to the patient's body surface, which has a negative impact on the quality of treatment.
Another way of delivering RT is by brachytherapy, a procedure often performed in the operating theatre where the radioactive source is delivered close to the disease or inside the tumour itself, using different types of applicators depending on the anatomical location and characteristics of the disease. Nowadays, the **applicators and templates** used in

brachytherapy **are not customised commercial solutions, which can lead to suboptimal** treatment delivery and discomfort for patients.

The development and use of personalised systems for the techniques mentioned before will improve the quality of treatments, which will have an impact on cancer therapy outcomes. In addition, as the devices would be optimally adjusted to the patient's anatomy, the functionality and safety of treatments will be improved and can be performed more easily by professionals. Being tailored ergonomic applicators, this will improve patient comfort and experience. Additionally, it could replace the commercial non-adapted systems that are usually purchased, as new devices will be produced at the hospital on demand, which would mean a saving in expenditure and time together with a reduction in carbon footprint and costs derived from transport.
This project will comply with the Do Not Significant Harm (DNSH) principle by reusing the waste from the molds produced.

Challenge main objectives

The main objective is to co-create **a system for the personalised generation of 3D molds for use in radiotherapy tailored to each patient´s morphology.** This mold generating system would be used in the hospital. In the case of EBRT, this would involve the generation of customised bolus or immobilization elements. In the case of brachytherapy, the aim is to generate customised applicators or guides for interstitial brachytherapy.

The solution should allow bidirectional communication with radiotherapy treatment planning systems. It should allow the design of 3D molds adapted to the patient's anatomy and the dosimetric requirements of the treatment.

Solution functional requirements

Software tool designed to design/print 3D molds adapted to the patient's anatomy. It would be used in both external radiotherapy and brachytherapy.

Compulsory functional requirements

- **In external radiotherapy**: the 3D mold shall be used as a bolus material (tissue equivalent material) customized to the patient's surface. The thickness and shape would be defined in a planning system external to the application according to the dosimetric needs of each treatment.
    - The system would have to be able to use the DICOM[1] and DICOM RT[2] files of the planning system (*Eclipse*[3] and *Oncentra* from Varian and Elekta[4], respectively).
    - It will have visualization tools for the imported structures and specific tools for the manipulation, preparation and editing of the 3D mold corresponding to the bolus

[1] https://www.dicomstandard.org/

[2] https://dicom.nema.org/dicom/geninfo/brochure/rtaapm.htm

[3] https://www.varian.com/es/products/radiotherapy/treatment-planning/eclipse

[4] https://www.elekta.com/products/brachytherapy/oncentra-brachy/

(smoothing, trimming, suitability for the manufacturing process, marks, numbers, letters can be defined on the surface of the mold...).
- The solver must provide the printing material which shall be flexible, have a density equivalent to biological tissue (like water) and be biocompatible and meet legal requirements for contact with patients' skin.

- **In brachytherapy:** 3D molds shall be used as superficial applicators, intracavitary applicators and as needle insertion guides in interstitial implants.
  - The system would have to be able to use the DICOM and DICOM RT files of the planning system as inputs.
  - To have tools for the generation of surface applicators adapted to the external surface of the patient, of configurable thickness and size with the possibility of being displayed together to the patient's images and volumes.
  - Channels must be able to be generated within the applicators of specified diameter to insert the guide catheters of the radioactive source into them. These channels must be able to be generated automatically at a given distance between them and at a given distance from the patient's surface must meet the minimum curvature radius requirements configured by the user.
  - The channels must be able to be edited manually with the computer mouse.
  - Marks, numbers, letters shall be defined on the surface of the mold.
  - The solver must provide the impression material should be biocompatible and meet the legal requirements for contact with the mucosa of patients.

For external radiotherapy and brachytherapy, once the 3D molds are designed, they must be able to be exported manually to the planning system via DICOM RT, for dosimetric validation prior to manufacturing/printing.

The molds should have the minimum accuracy required for use as brachytherapy applicators. They should be made of flexible, rigid, or semi-rigid materials biocompatible with both the patient and the therapy and meet the legal requirements.

Desirable functional requirements

In External Radiotherapy: It would be of interest to be able to generate surface bolus without the need for medical CT (Computed Tomography). For example, through an optical surface reconstruction system.

In Brachitherapy: Auxiliary elements could be designed for commercial intracavitary applicators that facilitate the generation of interior channels for the insertion of needles or catheters, with straight or curved trajectories that can be graphically edited. The molds must be made of sterilizable and biocompatible material for contact with the patient's mucous membranes.

Pilot scope

Type and number of targeted end-users

End-user type	Role	Number
Radiation Oncologists	Recruit patients; provide requirements; validate solutions	4

Medical Physicists	Provide requirements; validate solutions	4
Radiation Therapists	Validate solutions	4
Patients	Better treatment	30

Table 1. Targeted users

Language

Spanish to ensure the co-design and implementation process with the end-users who usually do not speak English.

Other aspects

The best-fit solution may include the hardware and the material needed to accomplish the objectives.

Pilot set up conditions

Ethical, legal or regulatory

The pilot will be conducted with pseudonymized/anonymized data. If the solution incorporates optical reconstruction, patients will be informed of the image capture and will sign an informed consent form. In this case, an Ethics Committee of the Challenger must previously validate the approach of the pilot. The solutions shall be fully GDPR compliant. Once the proposal is made, the risks for data protection will be evaluated jointly with the IT. A data protection plan will be generated in accordance with the procedures.

The project will be evaluated by the *"Sección de Seguridad de la Información y Servicio al Usuario del Servicio Navarro de Salud"* to provide feed-back and approval of a detailed data management plan.

Technological

The system/computer required to run the software during the pilot should be available on the hospital facilities in stand-alone mode. It will exchange information with the radiotherapy planning systems via external storage media (USB flash drives or external hard drives).

Data access

The data will be provided to the Solver through previous data base from Oncology radiotherapist unit to develop, train and validate the solution, and from new patients during the recruitment to improve the accuracy of the solution, improving the treatments. The data

will be obtained from the Aria Network[5], a data management, planning and treatment platform for radiotherapy patients available at the HUN.

Expected impact and KPIs

For **External Radiotherapy:**

- Expected Impact: Better compliance with dosimetric objectives compared to traditional bolus systems. Reduction in millimeters of air between the bolus and the body surface measured in planning CT and treatment CBCT.
    a) Optimal < 1mm
    b) Acceptable: 1-2mm
    c) Could be improved but acceptable: 2-3mm
    d) Not acceptable: > 3mm
    KPI: 90% of cases in groups a,b,c.
- Expected Impact: Satisfaction on the part of radiophysicists in charge of planning and radiotherapy technicians through satisfaction questionnaires.
  KPI: >75% increase in professional satisfaction compared to previous processes measured by questionnaire.
- Expected Impact: workload reduction in mold design.

For **Braquitherapy:**

- Expected Impact: Better compliance with dosimetric objectives compared to traditional systems. Reduction in millimeters of air between the applicator and the body surface measured in planning CT.
    a) Optimal < 1mm
    b) Acceptable: 1-1.5mm
    c) Could be improved but acceptable: 1.5-2mm.
    d) Not acceptable: > 2mm
    KPI: 90% of cases in groups a,b,c.
- Expected Impact: Satisfaction on the part of the radiation oncologists who would handle the product and on the part of the radiation physicists in charge of planning.

KPI: >75% increase in professional satisfaction compared to previous processes measured by questionnaire.

- Expected Impact: reduction in mold manufacturing and design workload.

KPI: 50% reduction in mold development and design time.

- Expected Impact: assessment of toxicity comparatively with traditional brachytherapy systems.

[5] https://www.varian.com/products/software/digital-oncology/oncology-management-systems/aria-oncology-information-system

Business opportunity

Market size

The development and use of personalised systems for the techniques mentioned before will improve the quality of treatments, which will have an impact on cancer therapy outcomes. In addition, as the devices would be optimally adjusted to the patient's anatomy, the functionality and safety of treatments will be improved and can be performed more easily by professionals. Being tailored ergonomic applicators, this will improve patient comfort and experience. Additionally, it could replace the commercial non-adapted systems that are usually purchased, as new devices will be produced at the hospital on demand, which would mean a saving in expenditure and time together with a reduction in carbon footprint and costs derived from transport.
In total, we can estimate that in a first phase, approximately 100 patients per year could benefit from custom-designed personalized systems in HUN, but their potential reach could be much greater and could increase significantly in successive years, being used in other tumours.
On a national scale, this Solution could provide SMEs and the healthcare system with an innovative solution to provide better patient care, reduce upfront work for clinicians and doctors, and a new opportunity for companies to develop and improve new tools in new markets.

Adoption Plans

The solution we expect to achieve will improve radiotherapy treatments in different tumours, having a direct impact on the well-being of the population of Navarra. It will also lead to an improvement in the use of health and economic resources of the region.

If the result of the solution were satisfactory, and after the required feasibility study, we would propose to launch a Public Procurement of Innovative solutions (PPI) including during the process each necessary agent to achieve a successful implementation in the Health System.

The ultimate goal would be to adopt this solution in daily clinical practice.

TRIME

Multi-stage monitoring triage at home for Cardiovascular Diseases (CVDs)

Challenger

The **General Hospital of Pyrgos *ANDREAS PAPANDREOU*** was initially founded in 1886, and was fully rebuilt in 2004. The Hospital is located in the area of Syntriada, two kilometers outside the town of Pyrgos. extends over a plot of 80,000 m2, has a capacity of 280 beds.

The Hospital has 14 fully equipped operating theatres, a 25-bed Artificial Kidney Unit, a 9-bed Intensive Care Unit and a fully equipped X-Ray Diagnostic Department with CT Scanner servicing more 150000 citizens. The last years although the hospital is the main healthcare unit of the capital city Pyrgos and all surrounding towns, still faces continuous staff shortages leading to low care services delivery. Several departments remain to be low staffed, struggling to cope with the needs of the patients and all visitors seeking care attendance in the hospital. New contracts with external healthcare professionals provide short-term solutions. Facing this challenge, a more radical solution is suggested through shifting some care services at home, prior to visiting the hospital or especially supporting the outpatient monitoring at home, decreasing, in that way, the readmissions.

Challenge description

Remote home monitoring (RHM) models have been established to: 1) avoid unnecessary hospital admissions (appropriate care at the appropriate place), and 2) to efficiently monitor patients at home who either face chronic conditions (cardiovascular have the greatest prevalence and mortality rates) or had recently treatment / operation and have more critical monitoring needs.

Remote home monitoring (RHM) models have been established to: 1) avoid unnecessary hospital admissions (appropriate care at the appropriate place), and 2) to efficiently monitor patients at home who either face chronic conditions (cardiovascular have the greatest prevalence and mortality rates) or had recently treatment / operation and have more critical monitoring needs.

RHM of patients in rural communities is a rapidly developing modality to monitor rural patients. In cases of metropolitan hospitals like General Hospital of Pyrgos the need of remote triage can be most efficient in terms of resources utilization but also lifesaving in emergency cases with high severity.

More than 15% of patients that visit Emergency Rooms (ER) in the associated hospital, do not necessarily, require hospital level care, and can receive basic care at home. The limited resources of hospitals are continuously under challenge, due to insufficient healthcare facilities in neighbouring areas, and the rural geographical environment of the Prefecture of Ileias in the Western Greece, that needs to serve more than 150.000 inhabitants as targeted population.

Having an early needs analysis, during the early stage of this program, we concluded that >20 patients daily could avoid visiting the hospital, while > 1 out of 4 CVD patients that need regular monitoring could significantly improve their health condition and avoid high mortality rates

after post operations or severe incidents through remote monitoring and telecare @home. The Health-related Quality of Life (HRQoL)[1] scale will be used for the needs of the evaluation of the implemented solutions.

Targeted population

The proposed solution should facilitate healthcare professionals of the challenger organization to remotely monitor patients prior to admissions in the hospital (first-stage triage) and outpatients, once they have left from the hospital and need care services as part of a monitoring plan. The focus is especially on CVD patients (both diagnosed or people at risk of experiencing CVD) irrelevant of age or gender. CVD cases are the most common cases reported in the hospital and occupy most resources. Although, age is not an exclusive factor, most patients experiencing CVD are aged > 55 years old, hence all considerations regarding user-friendliness should be regarded.

Challenge main objectives

The main objective of this program is to develop a digital solution for the multi-stage monitoring triage at home for cardiovascular (CVD) patients, reducing hospital visits / re-admissions and improving citizens quality of life.

The solution is anticipated to facilitate healthcare professionals with tools to consult patients in need, remotely, and provide diagnosis and care where needed, based on real measurements reported on web systems. In fact, real measurements and relevant data should be collected by reliable equipment and transferred, in-real time, and be presented on a web system, that supports also the teleconsultation services.

Solution functional requirements

Compulsory functional requirements

The solution shall:

- Enable remote monitoring of patients experiencing basic post-operative or chronic conditions (e.g. atrial fibrillation) and need healthcare support at home.
- Enable direct communication between patients and the care professionals of the Hospital, through safe and encrypted communication protocols over proprietary servers and not commercial third-parties.
- Implement data access and analytics tools to collect, store, analyze, and visualize patient data generated during remote consultations and monitoring. This may include dashboards, reporting tools, and analytics software to track patient outcomes, identify trends, and make data-driven decisions to optimize the telecare program's effectiveness.
- Record and transfer in real-time ECG measurements and related biomarkers,
- Utilise telemetry systems for providing real measurements based on medical-grade equipment.
- Implement robust data security measures to protect patient confidentiality and comply with healthcare regulations. This includes encryption of data in transit and at

[1] Yin S, Njai R, Barker L, Siegel PZ, Liao Y. Summarizing health-related quality of life (HRQOL): development and testing of a one-factor model. Popul Health Metr. 2016 Jul 11;14:22. doi: 10.1186/s12963-016-0091-3. PMID: 27408606; PMCID: PMC4940947.

rest, access controls, authentication mechanisms, regular security audits, and compliance with relevant data protection standards.
- Include data aggregators for collecting and transmitting data in real-time.
- Include in the measurements all basic vital signs, plus ECG and stethoscope measurements for accurate diagnosis of CVD cases.
- Ensure robust non-centralized medical telecommunication infrastructure is in place to support video conferencing, telemonitoring, and other telehealth services (only military-grade and appropriate for protecting sensitive personal health data are allowed to be used).
- Provide basic medical records for all collected data to be stored and be shared.
- Enable all users to login from a web system consisted of the teleconsultation subsystem, and the telemetry subsystem, (Compulsory)
    - create different roles per user.
    - use strong encrypted user authentication protocols.
- Comply with all ethical, legal, regulatory, technological and data access requirements as described in sections 1.8.1, 1.8.2, 1.8.3.

Desirable functional requirements

The solution could:

- Support real-time threshold-based personalized services for providing classification of specific health conditions like CVD.
- Support personalised medical records and plans.
- Support both citizens with chronic needs and more emergency cases where they require prompt care delivery (more frequent condition for high volume admissions in hospitals e.g. sudden heart pain).
- Include Notifications system, for emergency alerts.
- Consider inclusivity both for seniors and younger patients, ensuring that the proposed system is user-friendly even for the least ICT experienced users and all diagnostic equipment is wireless for advanced ease-of-use.
- Analyse the impact of remote home monitoring models against care delivery in hospitals and other traditional healthcare settings.

Pilot scope

Type and number of targeted end-users

End-user type	Role	Number
Healthcare professionals	*They have to provide requirements, recruit patients, use and validate the solution*	4
End-Users	They will make use of the telemedicine solution and the diagnosing equipment remotely.	>30

Language

All communication, surveys, solution implementation, forms and reporting from the side of healthcare professionals and end users will be in Greek. The system / solution will also need to be in Greek.

Other aspects

- All diagnosing equipment needs to be medical-grade, and CE certified.
- For the needs of the pilot stage, the solution provider should use at least three sets of devices that can be used by the healthcare professionals and their patients. Each set should include at least a data aggregator, a screen for supporting the teleconsultations, a body temperature thermometer, a blood pressure monitor, a stethoscope, an ECG, and a glucose meter. The hospital can provide their available equipment to the awarded company. If such equipment happens to be invalid for the purposes of the pilot, the awarded SME must commit to provide the appropriate devices for the pilot, which will be returned to the company immediately after.
- Measurements should be in real-time (store-and-forward approaches are out of the scope of the present project).

Pilot set up conditions

The pilot implementation is expected to last approximately 4-6 months, adequate time to identify opportunities, identify missing requirements that have not been identified, give the time to citizens and professionals to meet these new solutions (awareness stage) and an early training to professionals.

The monitored patients at home should reach >8-14 patients monthly. A trained nurse will assist in delivering care once each case has been diagnosed with telemetry nodes.

Exact performance indexes will be defined during the first two months of the project, so these can keep track of the progress and performance of the delivered services.

Ethical, legal or regulatory

- Ensure that the telecare program complies with General Data Protection Regulation (GDPR) or relevant privacy laws in Greece. Patients' personal health information must be securely handled and only accessed by authorized personnel.
- Obtain informed consent from patients participating in the pilot program. Patients should be fully informed about the nature of the telecare services, how their data will be used, and any potential risks or benefits.
- Ensure that healthcare professionals of General hospital of Pyrgos, providing telecare services are properly licensed and credentialed in accordance with state or national regulations. This may include physicians, nurses, therapists, and other healthcare providers.
- Develop clear protocols for handling emergencies and urgent situations during telecare consultations. Ensure that patients have access to local emergency services and that healthcare providers can quickly escalate care if needed.
- Ensure compliance with regulatory requirements and guidelines governing telehealth services, data privacy, security, and healthcare practice standards.

Technological

The solution shall:

- Be hosted on servers physically located within the geographic region of the pilot.
- Implement secure technology platforms and encryption protocols to protect patient data during telecare consultations. Regularly assess and update cybersecurity measures to mitigate the risk of data breaches or cyberattacks.
- Implement mechanisms for evaluating the effectiveness and outcomes of the telecare pilot program. Monitor patient satisfaction, clinical outcomes, and adherence to ethical and regulatory standards to inform future implementation and expansion efforts.
- The solution should be fully functional as web standalone SaaS.

Data access

- No prior data is expected to be available, meaning all users will start as new users in the system.

Expected impact and KPIs

The selected solution is expected to:

- Provide patients with home-based monitoring, clinical care, and support, hence reducing unnecessary transfers > 15%,
- Off-load burden from primary care practices. Reduction in the number of physical visits of patients to the hospital by 15%.
- Facilitate and increase the number of remote examinations by >10% for a more frequent and accurate monitoring and diagnosis.
- Increase in the quality of life of remote patients, using the Health-related Quality of Life (HRQoL) scale, during the total intervention period.
- Decrease the cost of healthcare for patients > 15%.

Business opportunity

Market size

- This project could be replicable, beyond the challenger hospital to 3 more hospitals (public and private) in the Region of Western Greece, as the needs are similar changing in volume. University Hospital of Rio accommodates > 1000 admissions per shift, servicing a broad population of > 300K citizens.
- At the national level there are >10 hospitals with expressed similar needs that could further employ the triage system prior to admissions and in conjunction with the remote monitoring to reduce both unneeded admissions but also monitor outpatients remotely. It is expected that for a medium-scale hospital up to 40-50 patients could be monitored remotely. The monitored conditions can be extended beyond CVD to several other cases, using the suggested technologies.

Adoption Plans

In Doctorshello, we consider the remote monitoring of chronic patients a high priority service that needs to be supported by suitable technologies/ trained staff. Upon successful completion and pilot implementation of the selected solution in the Challenger hospital, we aim to assist

and scale up the solution and explore new opportunities for collaborations and market adoption.