HEALTHCHAIN

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HealthChain Call for SMEs

Annex 1: Challenges

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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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Disclaimer

History of changes

Ver.	Date	Changes
1.0	29/05/2024	First public version

K-control

Interdialysis potassium level intensive monitoring

The Regional Health Service of Murcia (Servicio Murciano de Salud-SMS) provides healthcare to 1.47 million inhabitants (about 3.09% of the whole Spanish population). It integrates 11 hospitals, with 3,651 beds and more than 400 primary care centres. It is noteworthy that the Region of Murcia has been chosen by technological partners as a convenient living lab. Being a single-province region, political and administrative decision-making would be faster, which saves time, money and resources. The Region of Murcia owns the award of Reference site 2 stars in EIP AHA (European Innovation Partnership on Active & Healthy Ageing).

The Murcian Health Service has extensive experience in demand-driven co-creation, associated or not with innovative public procurement. Not in vain, SMS has obtained national and international awards such as the First International Prize in the category of “Outstanding Innovation Procurement in ICT” of the Procura+ 2021 awards for the 'InDemand' project or the Technology and Health Foundation Award for the *Best Technological Innovation in Health Driven by an Autonomous Community 2022* to the "InDemand" project.

Challenge description

Hyperkalaemia (HK) is an important cause of morbidity and mortality as it can generate life-threatening arrhythmias. The urgent approach to acute HP is an emergency frequently attended to in medical and nursing wards, and requires an extraordinary consumption of resources (pharmacological, care in emergency departments, hospital admissions and intensive care units, sessions of extra dialysis).

The HP rate worldwide is 2,8 cases per 100-person-year. In the general population, up to 3,2% of hospitalized patients may have potassium levels above normal. Its prevalence increases in patients with chronic kidney disease (CKD), in diabetics, cardiac patients, in the elderly and in patients taking drugs that prevent the renal elimination of potassium, such as blockers of the renin-angiotensin aldosterone axis, which are widely used. The population with advanced CKD and on dialysis is the one with the highest risk for HK. In haemodialysis (HD) up to 26.4% of patients have potassium levels above 5,1 mEq/L.

A low-potassium diet is a fundamental pillar in the treatment of chronic HK. Relying on potassium content tables of foods and recipe books, patients can prepare their daily menus in order to avoid an increase that could be life-threatening before the next dialysis.

However, this is a difficult effort to fulfil since:

- In Spain (and especially in Murcia), there is a deep root in the traditional Mediterranean diet rich in fruit and vegetables, and therefore rich in potassium.
- purification therapy in HD lasts around 4 hours and is performed intermittently every 2 or 3 days, so potassium accumulates between dialysis, especially when it comes to a long time.
- Demotivation of these patients is high as they are subjected to daily restrictions and live in ignorance of the effectiveness of their dietary actions.
- It involves confrontations with caregivers and health personnel in less compliant patients.
- It considerably worsens the patient's quality of life and limits social relationships by having to restrict eating.

- Potassium monitoring in the chronic HD population is carried out by pre-dialysis blood collection and in accordance with the Spanish Nephrology Society's recommendations at least once a month in stable chronic patients.

There is, therefore, an unmet need to monitor potassium levels more intensively in HD patients.

Challenge main objectives

- Optimize management of HK.
- Engage the patient in the low potassium diet and promote self-empowerment.
- Reduce the rate of complications due to HK.

Solution functional requirements

Compulsory functional requirements

- Reliable and non-invasive measurement of potassium in the patient's daily life.
- User's environment will be a dashboard for healthcare professionals and a mobile user-friendly app for patients.
- The solution will be hosted in the cloud and managed by the company with all the guarantees of privacy and security.
- It must be easy-to-use, through a gamified solution that manages information, recommendations and achievements.
- It must store patient data in order to show their progress.
- The solution will send automatically personalised recommendations to patients, according to guidelines.
- It will allow automating of responses to patients depending on the query.
- It will facilitate synchronous and asynchronous contact through chats and video conferencing.
- It will allow the administration of questionnaires and scales that the patient can complete autonomously and generate a tree of automatic recommendations.
- The healthcare team will manage the monitoring and be able to modify the rules and responses to the needs remotely.

Desirable functional requirements

- It would show patients information about the potassium content of foods.
- It would be able to record the food eaten by the patient and count its potassium content.
- To be interactive through an assistant who would reinforce the patient and reward their progress.
- Possibility of translation to avoid language barriers.
- The solution would apply Artificial Intelligence embedded in the workflow manager to alert of possible problems at the 'process' level not perceived by the actors or nodes.
- We want technology to help in the adherence and sharing with third parties of good practices in potassium monitoring management, as well as community resources in a sustainable and cost-efficient way for SMS.
- If blood glucose and TCO2 could be determined at the same time, intensive potassium monitoring could help characterize the behaviour of this cation, its circadian cycle, as well as its exact relationship with the patient's daily diet.

Pilot scope

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

It will include at least 30 patients, who will test the solution for 6 months.

The healthcare professionals' team will be composed by different profiles and specialities. The main professional actors in the pilot will be nurses and nephrologists from a dialysis unit.

Type and number of targeted end-users:

End-user type	Role	Number
Patients	With different skills and condition's level	At least 30
Nurses	Closer patient´s follow up and main interlocutor with patients.	5
Nephrologists	Leading the design and compliance of the plan	At least 2

Table 1. Target users

Language

- The solution must be in Spanish. Other languages would be desirable (English, French, German, Arabian).

Other aspects

- Synchronous and asynchronous contact through chats and video conferencing.
- Possibility of synchronization with other devices such as a smart watch for reducing the digital gap, with autonomy >5 days, allowing personalized alerts and recommendations to be displayed to patients.

Pilot set-up conditions

The pilot set-up conditions are based on three pillars: a data processing contract, the use of standards as HL7 or FHIR, and an agile and short integration with the corporative system during the pilot, focused on validating a Minimum Viable Product (MVP).

Ethical, legal or regulatory

The Entity undertakes to process the personal data to which it has access as a result of the execution of the contract, observing the principles required by the legislation on data protection, in particular those relating to data quality, data security and duty of secrecy, as well as in accordance with the specific instructions received from the data controller, not using the data for any purpose other than the provision of services described in the object of the contract. Likewise, it undertakes to observe professional secrecy, maintaining absolute confidentiality and confidentiality on any data it may come to know on the occasion of compliance with the contract, in accordance with the level of protection established in the European data protection Regulation (EU 2016/679)of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data and Organic Law 3/2018 of 5 December, on the Protection of Personal Data and guarantee of digital rights, not communicating to any third party the data provided by the data controller. The data controller will determine whether, at the end of the services provided

by the data processor, the personal data should be destroyed, returned to the data controller or handed over, where appropriate, to a new data processor. The destruction of the data shall not proceed when there is a legal provision obliging their conservation, in which case they shall be returned to the data controller, who shall guarantee their conservation for as long as such obligation persists. This obligation will continue even after the end of their relationship with the person in charge. The Entity will ensure and be responsible for its employees and / or collaborators receive the data only to the extent that it is necessary to their knowledge for the provision of the object of the contract. In the event that the Entity uses the data for purposes other than those stipulated, communicates them or uses them in breach of the instructions set out in this contract, it shall be liable for the infringements set out in Articles 70 et seq. of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, in which it has incurred.

Technological

The user identification will be then provided through the OAuth standard. The solution may notify SMS systems about certain events and situations. Ideally via ´HL7´ messaging, but web services could also be an option. This information may include registration status, activity, progress and periodic (summarized) clinical information. The IT systems needed for running the solution will be hosted by the solver. If the complexity of the connections is too high or the personal data could be at risk, these systems could be hosted in local servers of the SMS. This will be established in a technical session at the beginning of the project. Anyway, the solver will provide mechanisms to guarantee that the Servicio Murciano de Salud can exploit the data. Data No prior Challenger data is expected to be available, meaning all users will start as new users in the system. The repository of documents and resources to be shared with the end users will be supplied and / or validated by the SMS.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs

To define the expected impact, a control group could be compared with an intervention group in which potassium was intensively monitored.

We will quantify in each group:

- Episodes of HK above 5.5 meq/L (reference value above normal in our laboratory).
- Episodes of moderate-severe HK defined by potassium above 6 meq/L.
- Number and type of complications associated with HK: emergency care, hospital admissions, ICU admissions, sudden deaths from unknown causes in a long period of dialysis.
- Number and type of intervention performed in relation to HK: dietary adjustment, dialysis adjustment, blood glucose correction, correction of acidosis, increase in potassium binders, urgent dialysis, and admission to ICU.
- Decrease in the use of potassium binders.

Finally, a quality-of-life questionnaire will be carried out before and after the intervention.

In 2022, 129 admissions with HK and 35 urgent assistances for severe HK were registered at the Reina Sofía Hospital.

Expected impact in one year:

- Reduction of more than 10% in HK episodes.
- Reduction of at least 20% in episodes of severe HK and/or the need for urgent dialysis.
- Any improvement in the reduction of long-term mortality from unrelated causes in HD patients.
- Quality of life of patients and their relatives before / after, valued through the SF12 short questionnaire. Goal: 20% improvement.
- Decreased need for potassium binders.
- Improved efficiency by reducing the healthcare resources used and lowering morbidity and mortality measured by the significant decrease of:
    - days of hospitalization, stays in the emergency room.
    - the number of dialysis performed by HK in chronic patients.
    - pharmaceutical prescriptions of potassium binders.

Business opportunity

Market size

The need of a more intensive and non-invasive way to monitor interdialysis potassium level is a universal pending task and its trend is growing year by year. The HK rate worldwide is 2,8 cases per 100-person-year. In the general population, up to 3,2% of hospitalized patients may have potassium levels above normal. Its prevalence increases in patients with CKD, diabetics, cardiac patients, in the elderly and in patients taking drugs that prevent the renal elimination of potassium, such as blockers of the renin-angiotensin aldosterone axis, which are widely used. The population with advanced CKD and on dialysis is the one with the highest risk for HK. In HD, up to 26.4% of patients have potassium levels above 5,1 mEq/L.

This new solution could be easily expanded to other healthcare systems after a hypothetical success in this pilot, which would be based on less complications and optimization of costs.

The challenger group offers their cooperation in the following:

- Advice on business model.
- In case of success of the pilot experience, the SMS undertakes to manage the possible resulting solutions in the volume to be determined, through the appropriate legal means, in particular as provided by the contractual regulations.
- Dissemination of results with the support of clinicians and patient associations, in order to make patient organizations aware of the solution at national and international level.
- Collaboration with a study of cost saving based on the published evidence, as well as with its publication and dissemination.
- Identification and contact with other potential customers.
- Advice on collaboration with the pharmaceutical industry by shortening treatment evaluation times in collaborative clinical trials.

Adoption plans

If the pilot is successful, SMS intends to adopt the solution, by a shared ownership of the solution co-created 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 SMS are inalienable, reflecting the knowledge and resources provided by SMS, including work time, patient access, and real-world validation. Usage of such intellectual property by other parties shall require a formal licensing agreement with mutually agreed terms.

Industrial Property Rights (IPR): SMS may opt-out of the commercial exploitation of the solution due to its lack of capacity in this area. In such a case, the exploitation rights will defer to the two companies, subject to compensations to SMS. These compensations will be based on the IP generated during the K-control project, where SMS will have an active role in the validation of the technology, and they are defined as the following future benefits: Reduced overall cost in licensing and maintenance of the solution.

- Allocated hours for corrective and evolutionary maintenance.
- Priority status for SMS in incident handling.
- Priority status for new developments related with the software developed by the follower SME.
- Collaboration by SMS in promoting the solution, including identifying customer networks and assisting in presentations.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	**CREATSENS HEALTH S.L.**
DESCRIPTION OF THE SME	renalyse Renalyse (CreatSens Health S.L.) is a biotech company that focuses its activity on the development of medical platforms and devices to improve the quality of life of patients by monitoring different relevant biochemical parameters. The company was established in September 2017, being a spin-off of the Universitat Rovira i Virgili (URV) in Tarragona. During these years, through many scientific publications, awards, and media appearances, Renalyse has demonstrated a great capacity to solve a market need. The company aims to provide unique screen-printed-based electrochemical sensor solutions that help patients and healthcare professionals to better manage the information generated in primary care centers, doctor's offices, or at the patient's home. For that, Renalyse centers its activity on developing novel healthcare platforms that aim to improve people's well-being by enabling decentralized analysis of relevant biochemical parameters in the blood to enable prediction, early detection, and prevention of serious diseases at home. There is a high level of experience among Renalyse team members in the field of business management, research and development, electronics, and implementation of quality system and regulatory. The activities in the Healthchain project are suitable for Renalyse, especially for the challenge K-control, as the aim is to increase the capacity of healthcare organization through the introduction of a new POC device and deliver solutions for doctors for a better management of their patients.
WEBSITE URL	http://www.renalyse.com

Table 2. Leading SME general information

Solution proposed:

Kontrol-IT: Pilot test for the Uncertainty Reduction Tool in ambulatory monitoring of interdialysis potassium

Kontrol-IT will be a point-of-care tool that allows rapid and affordable monitoring of Chronic Kidney Disease (CKD) via measuring the potassium ion from the patient's home or while in the dialysis machine. The core patented technology consists of a **chemical sensor integrated into a single system**, combining blood sampling, sensor calibration and sample measurement. Data will then be sent to a database through wireless technology to an application. The application will include content on dietary recommendations for CKD patients with special attention in potassium content from the diet. The information will help patients to know exactly the potassium they will ingest and ideally contain resources to reduce potassium content in foods. Based on the potassium intake data that the patient fills in into the app and the comparison with the potassium values determined by the device, the app should reinforce the patient's achievements in a gamification environment, In the event that potassium approaches the limits, the app will be able to provide reminders regarding the limitations in the intake of those foods with a higher potassium content. In any case, the application will only be able to estimate the potassium content according to food and portion ingested as a guideline and according to general recommendations.

Kontrol-IT is a disruptive solution, significantly size-reduced, with high accuracy, affordable, that will compete with current alternatives.

The solution includes a **self-calibration system** which simplifies the interaction device-user as patients will only need to introduce their blood to the system. Our capsules have a microfluidic system that can move the fluids inside to auto-calibrate the sensor. **For the first time, an appropriate self-management CKD diagnostic tool will be available in the day-to-day life of the patient to guide the choice of their daily menu in order to mitigate uncertainty.**

In a CKD situation, patients must follow strict indications regarding their diet and medication. By measuring the parameter several times per week, doctors will know exactly their patients' habits and its relationship with the diet, to try to establish dietary modifications, needs in potassium binders or changes in dialysis schedule in each case.

Kontrol-IT allows greater knowledge between diet and potassium levels to improve outpatient care, patient quality of life, reduction of hyperkalaemia episodes, and enables significant savings in the healthcare system as well as decreasing hospital congestion. The solution will create a patient-physician channel in which patients are more attended and monitored from their homes/residencies.

Current stage of development

CreatSens Health S.L is preparing for the final product fabrication, and it is especially focused on the industrial scalability of the microfluidic piece with the calibrators. The electronic part, including the pump for the microfluidics, is being tested and it is expected to study the viability for a scalable fabrication. The chemical sensor for potassium detection has already been validated with real blood samples (N=700) from dialysis patients and CreatSens will have an alpha app version ready to start the project in September 2024. It is expected to have a full functional KIT (sensoring + electronics + alpha app), ready for its optimization during the KONTROL-IT development.

Work to be done by the leading SME

The project will be divided into four phases that contribute to the clinical validation of the KONTROL-IT platform as described below:

WP 1	**Design of the study (M1-M4)**
Activities	1.1 Design of the Clinical study: establish with the medical team which information will be collected from the patients, number of patients, repetitions, and periodicity. 1.2 Clinical Committee protocol: Servicio Murciano de Salud (SMS). 1.3 Patients' recruitment: information for the patients following all the clinical and ethical guidelines. 1.4 Patients' education on the platform: trainings on how to use the device and the platform and support with educational contents. 1.5 Usability study & KPI: consensus of indicators for measuring the impact of the solution.
Milestones	*M3: Protocol for the clinical trial signed.*

WP 2	Software (M1-M12)
Activities	3.1 Software adaptation to the study: together with the medical team and the patients the software will be adapted to collect all the information needed for the study in a simple and visual way. 3.2 Iterations of software, data and visualization: several iterations of the software and in situ study of the trial will be done to assess the adoption of the end user and the usefulness to the specialist. 3.3 Medical recommendations based on the study: the final outputs of the study will be incorporated as medical recommendations in the RENALYSE software upon medical validation of the results.
Milestones	*M4: Software ready for this specific study (M4).* *M5: Improved software with feedback from the study (M12).*

WP 3	Clinical Trial (M5-M10)
Activities	4.1 Potassium measurement: measurement of the potassium levels in blood from all the participants according to the procedure established during the design of the study. 4.2 User experience: all the other information introduced by the patient to the software (diet, other medical parameters e.g. sugar, blood pressure, etc.) will be constantly evaluated to perform recommendations and iterate the software according to the results.
Milestones	*There are no milestones in this phase.*

WP 4	Validation of the solution (M5-M12)
Activities	5.1. Data collection: results will be collected during all the clinical trial to iterate the software and incorporate immediate feedback to adapt it to the needs of the patients and the medical team. 5.2 Data analysis: the final results will be analysed statistically and also from a medical perspective to further improve the software interface, the user experience and the medical management.
Milestones	*M6: Report of the study with the chemical results, the user experience and the medical recommendations (M12).*

	WORKING PACKAGES	PRE-PROJECT			PROJECT START											
		-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12
1	**Design of the study**															
1.1	Design of the Clinical study															
1.2	Clinical Committee protocol					M3										
1.3	Patients' recruitment															
1.4	Patients' education on the platform															
1.5	Usability study & KPI															
2	**Software**															
2.1	Software adaptation to the study							M4								
2.2	Iterations of software, data and visualization															
2.3	Medical recomendations based on the study															M5
3	**Clinical trial**															
3.1	Potassium measurement															
3.2	User experience															
4	**Validation of the solution**															
4.1	Data recopilation															
4.2	Data analysis															M6

Figure 1. Kontrol-IT Gantt Chart

Follower SME

Scope of work performed by the follower SME

The consortium detected a specific profile that will perfectly fit with the development of the K-control Challenge:

Medical software provider: That Follower SME profile must have previous experience in the development of medical software based on IEC 62304:2006 or knowledge in the compliance and/or implementation of the ISO 13485 applied to software and app development. It is also highly valuated to have previous knowledge in the development of diet recommendations for Chronic Kidney patients. It is expected to be part of the development of the app and diet protocols for the K-control Challenge with the final goal of enhancing/ complementing KONTROL-IT's tool, to improve patient education on healthy diet awareness and adding new information between potassium levels and patient diet for the clinician.

Main tasks for the Follower SME to address the K-control Challenge are:

- Improve Renalyse's app to integrate potassium values with symptomatology, diet, weight and lifestyle information though a machine learning algorithm.
- Co-create with Renalyse (Leading SME) and SMS (Healthcare organisation), for the development of a device that provides cutting-edge information on potassium for both the patient and the doctor. For the patient, the device can be an educational tool to help guide daily dietary choices. For the physician, intensive inter-dialysis potassium monitoring will increase knowledge about inter-dialysis potassium variations and their relationship to the patient's diet.
- Design an alarm protocol system for several CKD patient's profile.
- Create an easy-to-use interface for elderly people that will be validated during the clinical trial through a usability study.
- Develop a security protocol for patient's clinical data transferring and storaging.

PASPADOC

A new holistic way to capacitate patients who suffer chronic pain

The Regional Health Service of Murcia (Servicio Murciano de Salud-SMS) provides healthcare to 1.47 million inhabitants (about 3.09% of the whole Spanish population). It integrates 11 hospitals, with 3,651 beds and more than 400 primary care centers. It is noteworthy that the Region of Murcia has been chosen by technological partners as a convenient living lab. Being a single-province region, political and administrative decision-making would be faster, which saves time, money and resources. The Region of Murcia owns the award of Reference site 2 stars in EIP AHA (European Innovation Partnership on Active & Healthy Ageing).

The Murcian Health Service has extensive experience in demand-driven co-creation, associated or not with innovative public procurement. Not in vain, SMS has obtained national and international awards such as the First International Prize in the category of "*Outstanding Innovation Procurement in ICT*" of the Procura+ 2021 awards for the 'InDemand' project or the Technology & Health Foundation Award for the *Best Technological Innovation in Health Driven by an Autonomous Community 2022* to the "InDemand" project.

Challenge description

The current health system has difficulties in carrying out efficient activity in patients with chronic painful pathologies. Due to the system structure, patients with chronic pain find themselves left aside as a result of the lack of accessibility, care and follow-up. On many occasions they create false expectations of healing with tests and referrals that distort the patient's perception, preventing their empowerment and self-care, which decreases quality of life.

Currently, the indicators of first visit and follow-up in hospital care and referrals through consultations from Primary Care are not relevant to evaluate the efficiency of treatments in patients with chronic pain. The patient is seen by a hospital specialist that refers them again to the Primary Care team with a new treatment, which is again ineffective, and the Primary Care doctor once again consults another specialist to look for new solutions. In all referrals, with their waiting times due to the overload of the healthcare system, caused, in turn, by the prevalence of chronic processes, the patient is left in a care limbo, waiting...

The waiting lists for services that deal with musculoskeletal problems (Traumatology, Rehabilitation and Rheumatology) add up to 30% of the total list of waiting times of the Murcian Health Service and they increase year after year, without an efficient staff management to balance activity/demand. Notably, surgical indications for chronic processes occur due to an increase in user demand once it has been considered that the conservative treatments do not achieve the expected benefit and even though it will not be achieved with surgical treatment either. The surgical indication is very striking conditions such as fibromyalgia. The objective would be to treat the processes by indication and not by escalation (RD 605 indicators, surgery, outpatient consultations and evidence).

In this sense, we highlight the following needs for chronic pain patients:

- Longitudinal and comprehensive patient follow-up.
- Holistic treatment.

- Continuous remote assistance, avoiding unnecessary in-person consultations.
- Linkage with the patient that facilitates quality care in their process.
- Empowerment of the patient that allows them to manage their pain using all available tools, both pharmacological and non-pharmacological.
- Unified therapeutic plan that not only focuses on a false promise of healing, but also focuses on achieving your best functional state, making you understand key aspects such as diet, activity, sleep, emotional management and medication with the aim of improving the patient's quality of life.

Challenge main objectives

- A more efficient management of chronic pain from Healthcare Organization point of view.
- Improve accessibility and follow-up of patients with chronic pain.
- Promote self-empowerment among patients with chronic pain.

Solution functional requirements

Compulsory functional requirements

- The solution must offer the patient a quick access route to healthcare.
- User's environment will be a dashboard for professionals (nurses of the call centre, family doctor and hospital healthcare professionals) and a responsive mobile app for patients.
- The solution will be hosted in the cloud and managed by the company with all the guarantees of privacy and security.
- The tool will provide the operator with indicators that are relevant to detect changes in health status that allow them to make changes to the therapeutic plan.
- The solution may request care with other healthcare services depending on the needs detected (Nursing, physiotherapy, doctor, social worker, etc.).
- The operator will be able to modify the indications within the limits of the treatment plan.
- Automation of responses to patients depending on the query.
- The tool will have standardized support health resources (recommendations on healthy habits, emotion management, relaxation, etc.).
- The tool will allow the registration and exploitation of data.
- A ´dashboard´ view for health professionals where they can exploit all the information and ability to manage all patients and detect abnormal situations or suggest changes, being able to configure a system of alerts to avoid them.
- It´s also needed a dashboard for the patient, showing them the path to their empowerment with the strengths and needs, motivating him /her through rewards and gamification of tasks.
- Synchronous and asynchronous contact through chats and video conferencing.
- It will allow the administration of questionnaires and scales that the patient can complete autonomously and generate a tree of automatic recommendations.
- SMS will provide a nursing team that integrates the management of all these needs remotely.

Desirable functional requirements

- Possibility of translation to avoid language barriers.
- The patient will receive information about their follow-up from a professional who knows their situation and it will be reflected in the patient's history.

- Possibility of synchronization with other devices such as a smart watch that reduces the digital divide, with autonomy >5 days, allowing the registration of the agreed physiological parameters and with voice recognition.
- It will allow the monitoring of certain physiological parameters (HR, BP, RR, circadian rhythm, activity, etc.).
- The solution will be able to apply Artificial Intelligence (AI) embedded in the workflow manager to alert of possible problems at the 'process' level not perceived by the actors or nodes.
- We want technology to help in the adherence and sharing with third parties of good practices in chronic pain management, as well as community resources in a sustainable and cost-efficient way for SMS.

Pilot scope

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

It will include at least 30 patients, who will test the solution for 6 months.

The healthcare professionals' team will be composed by different profiles and specialities. The main professional actors in the pilot will be nurses, physicians from Primary Care, rehabilitation, and physiotherapists.

Type and number of targeted end-users:

End-user type	Role	Number
Patients	With different skills and conditions	At least 30
Nurses	Close patient´s follow-up, bridging the gap between patients and SMS resources.	5
Rehabilitation physician	Leading the design and compliance of the plan	1
Physiotherapist	Leading the compliance of the plan	1
Primary Care physician	Recruitment and monitoring of the patients	1

Table 3. Targeted users

Language

- The solution must be in Spanish. Other languages would be desirable (English, French, German, Arabian).

Pilot set-up conditions

The pilot set-up conditions are based on three pillars: a data processing contract, the use of standards as HL7 or FHIR, and an agile and short integration with the corporative system during the pilot, focused on validating a Minimum Viable Product (MVP).

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protection, in particular those relating to data quality, data security and duty of secrecy, as well as in accordance with the specific instructions received from the data controller, not using the data for any purpose other than the provision of services described in the object of the contract. Likewise, it undertakes to observe professional secrecy, maintaining absolute confidentiality and confidentiality on any data it may come to know on the occasion of compliance with the contract, in accordance with the level of protection established in the European data protection Regulation (EU 2016/679)of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data and Organic Law 3/2018 of 5 December, on the Protection of Personal Data and guarantee of digital rights, not communicating to any third party the data provided by the data controller. The data controller will determine whether, at the end of the services provided by the data processor, the personal data should be destroyed, returned to the data controller or handed over, where appropriate, to a new data processor. The destruction of the data shall not proceed when there is a legal provision obliging their conservation, in which case they shall be returned to the data controller, who shall guarantee their conservation for as long as such obligation persists. This obligation will continue even after the end of their relationship with the person in charge. The Entity will ensure and be responsible for its employees and / or collaborators receive the data only to the extent that it is necessary to their knowledge for the provision of the object of the contract. In the event that the Entity uses the data for purposes other than those stipulated, communicates them or uses them in breach of the instructions set out in this contract, it shall be liable for the infringements set out in Articles 70 et seq. of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, in which it has incurred.

Technological

The user identification will be then provided through the OAuth standard. The solution may notify SMS systems about certain events and situations. Ideally via ´HL7´ messaging, but web services could also be an option. This information may include registration status, activity, progress and periodic (summarized) clinical information. The IT systems needed for running the solution will be hosted by the solver. If the complexity of the connections is too high or the personal data could be at risk, these systems could be hosted in local servers of the SMS. This will be established in a technical session at the beginning of the project. Anyway, the solver will provide mechanisms to guarantee that the Servicio Murciano de Salud can exploit the data. Data No prior Challenger data is expected to be available, meaning all users will start as new users in the system. The repository of documents and resources to be shared with the end users will be supplied and / or validated by the SMS.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs

The expected impact is:

- a decrease in the perception of pain (measured using pain scales),
- a decrease in the need for medications with consequent reduction in side effects,
- increase in self-care,
- improvement in accessibility to the health system,
- reduction in the number of visits (primary care, emergencies, etc.),
- reduction in the number of hospital admissions caused by exacerbation of the disease,

- increase in their quality of life.

KPIs are divided into three categories:

Health

We will measure this aspect with quality-of-life questionnaires administered to the patient both prior to the pilot and afterwards, as well.

- Quality of life before / after valued through the SF12 short questionnaire. Goal: 20% improvement. Satisfaction:

A control cohort could be created to establish differences.

Satisfaction

We will determine the impact on satisfaction through validated satisfaction questionnaires, such as the System Usability Scale (SUS), both in terms of users as well as the professionals who work with the solution.

- Tool satisfaction survey segmented by user roles (patient, neurologist and nurse) using the Customer Satisfaction Score (CSAT).): Goal: CSAT >8 (out of 10) in each user group (role).
- Patient experience through the Net Promoter Score (NPS). Goal: NPS >+50

Usability measured by System Usability Scale (SUS). Goal: SUS >80 Efficiency

Regarding the healthcare impact, we will measure the efficiency of the solution based on the reduction of tests, referrals and in-person consultations, as well as savings on medication pre-registration. We could compare the different variables before and after inclusion in the pilot and even establish a cohort control.

Business opportunity

Market size

In the Region of Murcia chronic pain is responsible for more than 30% of the total waiting list, as the rest of the region in Spain. This new solution could be easily expanded to all the other healthcare systems after a hypothetical success in this pilot, based on demonstrated cost savings achieved.

The challenger group offers their cooperation in the following:

- Advice on business model.
- In case of success of the pilot experience, the SMS undertakes to manage the possible resulting solutions in the volume to be determined, through the appropriate legal means, in particular as provided by the contractual regulations.
- Dissemination of results with the support of clinicians and patient associations, in order to make patient organizations aware of the solution at national and international level.
- Collaboration with a study of cost saving based on the published evidence, as well as with its publication and dissemination.
- Identification and contact with other potential customers.
- Advice on collaboration with the pharmaceutical industry by shortening treatment evaluation times in collaborative clinical trials.

Adoption plans

If the pilot is successful, SMS intends to adopt the solution, by a shared ownership of the solution co-created 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 SMS are inalienable, reflecting the knowledge and resources provided by SMS, including work time, patient access, and real-world validation. Usage of such intellectual property by other parties shall require a formal licensing agreement with mutually agreed terms.

Industrial Property Rights (IPR): SMS may opt-out of the commercial exploitation of the solution due to its lack of capacity in this area. In such a case, the exploitation rights will defer to the two companies, subject to compensations to SMS. These compensations will be based on SMS relinquishing approximately 20% of royalties to both companies and shall include:

- Reduced overall cost in licensing and maintenance of the solution.
- Allocated hours for corrective and evolutionary maintenance.
- Priority status for SMS in incident handling and new developments.
- Collaboration by SMS in promoting the solution, including identifying customer networks and assisting in presentations.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	INVESTIGACIÓN Y DESARROLLO INFORMÁTICO EIKON S.L. – IDI EIKON
DESCRIPTION OF THE SME	IDI EIKON is a software development Spanish SME operating in European markets and created in 1989. Its e-Health Business Unit provides a wide service portfolio to local, regional, national and European socio-sanitary and healthcare organizations (HCO). To do so, we rely on AdsuM++, IDI EIKON's 100% proprietary development. AdsuM++ operates as a Meta-Platform allowing to design and implement different types of services on top of it. AdsuM++ offers project co-ordination and co-creation roles as well as care protocol designers, IT engineers, AI experts and support profiles. IDI EIKON recurrent R&D activity expands AdsuM++ modules, features and capability along time. Currently, AdsuM++ is being used by HCOs in Primary (as a daily practice tool, TRL9) and Secondary (within Research Studies and Observatories, TRL8-9) use cases in Spain, Italy and United Kingdom. IDI EIKON has wide experience in participating and co-ordinating different European Projects, also focusing in validating different technical proposals. INCA Project included the participation of Servicio Murciano de Salud, partner in HealthChain. In addition, IDI EIKON has already participated in different co-creation processes with private partners and HCOs which resulted in successful commercial products, now being marketed jointly with different stakeholders. IDI EIKON provides extensive expertise in: • Care protocols and individualised care pathways design and implementation (inflammatory diseases, infectious diseases, rare diseases and chronic conditions) • Multi-disciplinary care co-ordination and patient-centric care models • Patient-reported outcomes • New Artificial Intelligence (AI) models supporting clinicians (predictive models) and patients (self-care guidance) • Integration and interoperability with third party systems

WEBSITE URL	http://www.idieikon.com http://www.idieikon.com/adsum

Table 4. Leading SME general information

Solution proposed:

PALDOC: Chronic Pain Liquid Care Platform

IDI EIKON will contribute an AdsuM++ value-based healthcare Meta-Platform licence ("in the market", TRL9) supporting PALDOC to:

- Implement HCO's innovative care protocols and procedures on whatever condition/pathology in the need of providing a "proactively monitored patient journey" along time.

- Ensuring care protocols allow multidisciplinary groups (MDG) active participation, considering not only different clinical profiles but an active patient (and informal caregiver) profile participating from the care process.

- Using those validated instruments that can add value to measure patient's achievements in self-managing chronic pain attending the following areas:
  - Patient's pain intensity (i.e. VAS)
  - Patient's holistic characterization
  - Patient's functional quality of life (i.e. EQ5D)

- Offering easy-to-use interfaces for patients, running in any Internet-connected device and using pictograms to simplify interactions, where possible.

- Focusing on Health Outcomes achievements from multiple perspectives.

- Introducing Data Analysis capabilities based on deterministic business rules and in AI Large Multimodels Models (LMM) that provide counsel and guidance [this component is on a TRL8-9 maturity level, as adaptations and training of the AI model is to be tailored to PASPADOC needs]
  - To clinical providers: detecting patterns that deviate from Care Protocol control goals, "triggering" manual adaptations of care plan.
  - To patients: providing "always on" interfaces to ask for guidance and resources on managing chronic pain.

- Standardizing data collected from third parties, clinical providers records or patient-reported data, in order to ensure powerful data exploitation options afterwards, in primary use cases (detecting how to improve care models) and in secondary use cases (enabling new research studies).

- Providing intermediate Care Pathway Management interfaces, so designed processes can be:
  - Easily modelled

- Progressive extended
- Flexibly adapted, when evidence demands so
- Seamlessly integrated with other IT systems
- Independently managed by HCO without dependencies on IDI EIKON

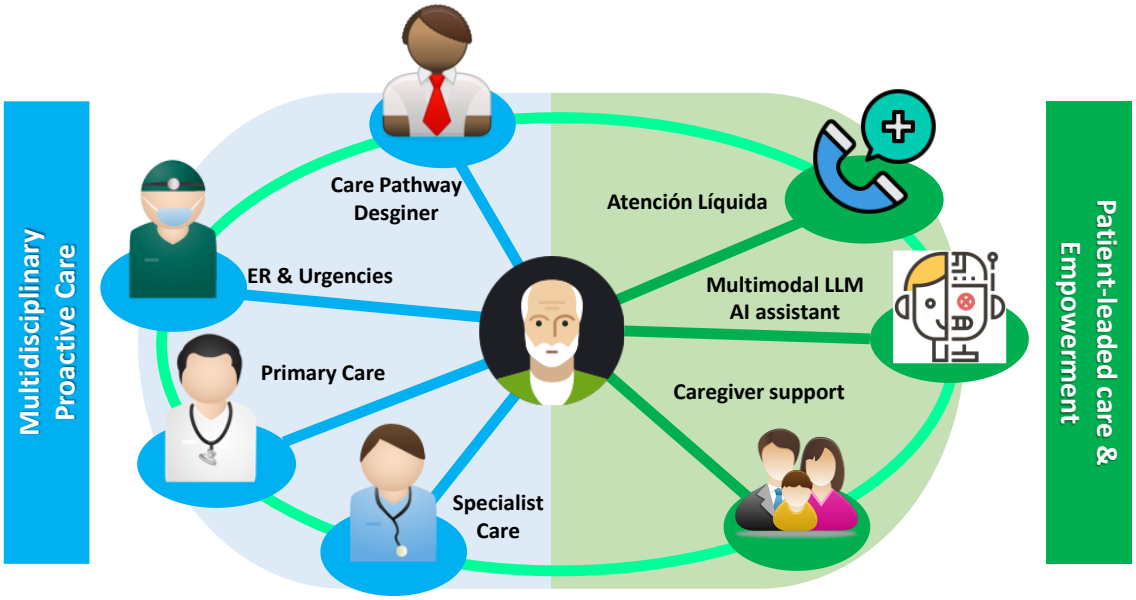

Figure 2. PALDOC Integrated Care Paradigm

PALDOC provides products, services, content, education, guidance and a baseline technology. This might help in improving standards of care. Meta-platforms like PALDOC are the way of the future for the enterprising in healthcare with tremendous untapped potential.

- **Meta-platform capacity**: provides a TRL9 set of modules co-creators use to model its own service portfolio. New services are available as soon as co-creators define them, and can be real-time-changed, addressing wrong-design scenarios without stopping a project. This provides an incredibly powerful asset to co-creation teams, not tied by IT developers to "play" its creative role and to change its mind as many times as needed.

- **Test disruptive technologies "on the fly"**: add new services to your pilot if you want to. Test new HTML5 Web-RTC synchronous communication features. Train your own AI assistant to support users, relying on your Health Resources repositories. Transform every record into normalized data codified in SNOMED-CT, OMOP or ICD ontologies. PALDOC regularly delivers new features, as AdsuM++ platform liberates them. PALDOC may use them to expand pilot impact.

- **Born to interoperate**: integration is 100% guaranteed, even in pilot stages. Reusing available data boosts PALDOC potential to unsuspected thresholds.

- **Scale up without limits**: from pilot to production, from one HCO to an entire region, from one clinical condition to multi-morbidity scenarios, from local data repositories to European Observatories aggregating invaluable data.

- **Hybrid business models**: when moving to post-pilot phases different architecture setups might be considered. Clinician interfaces might be hosted at SMS premises, but Patient interfaces will need to be available in Internet. PALDOC supports this "hybrid architecture" model ensuring all security policies from HCO are observed.

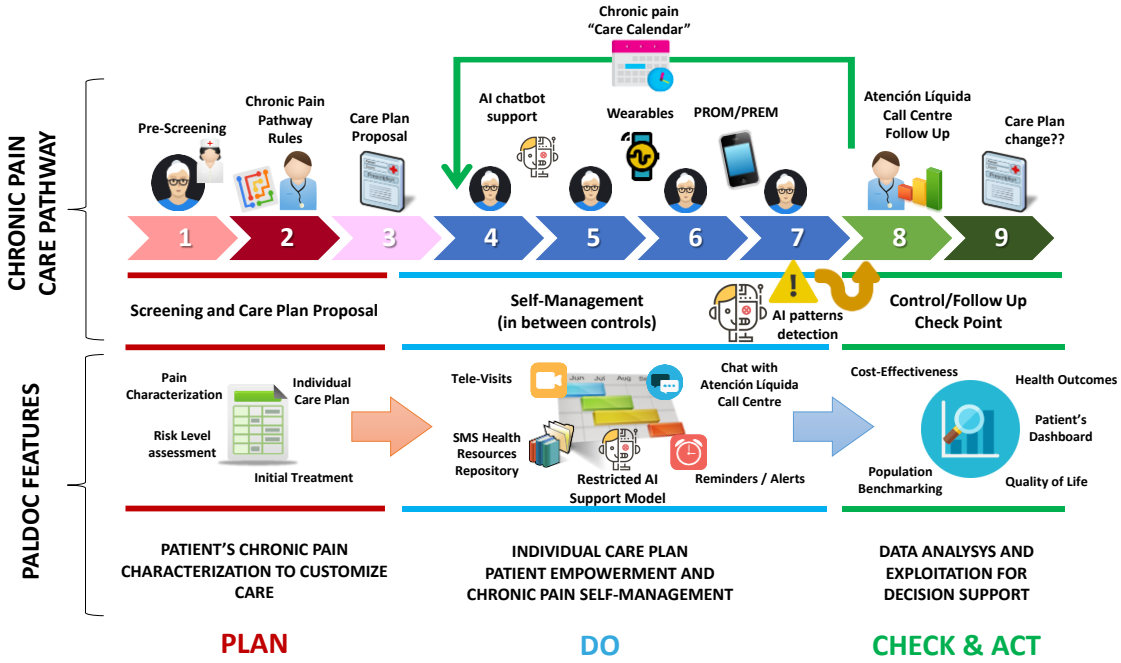

Figure 3. PALDOC Chronic Pain Service Outline

Work to be done by the leading SME

WP1 – Co-creation process coordination

Here IDI EIKON (Leading SME) will manage the co-creation design process, by planning a set of requirements' capture meetings with the SMS in between month 1 and 8 (T1.1). Then, co-creation follow-up meetings will be held to track PALDOC development progresses, readdressing wrong designs and validating releases with end users (T1.2). Follow up activities will be tracked since month 9 (T1.2) and co-creation business agreements exploration will start on month 15 (T1.3).

WP1 Milestones:

- M1 (month 8): PALDOC Chronic Pain Care Pathway final design document.
- M5 (month 18): PALDOC post-pilot exploitation agreement signed.

WP2 – PALDOC infrastructure set-up

IDI EIKON will handle all technical works to ensure the cloud-based infrastructure (T2.1 – T2.2) hosting PALDOC and interoperability mechanisms with SMS IT systems (T2.3) are up and running before pilot activities kick-off.

WP2 Milestone:

- M2 (month 9): PALDOC infrastructure deployment completed.

WP3 – PALDOC tailored features development

Relying on the final design document produced by WP1, PALDOC Development Team will manage the works to customize PALDOC Platform modules. Based on the inputs from WP1, PALDOC AI assistants will be trained leveraging on available Health Resources repositories (T3.1, T3.4), Wearable and Medical devices data will be integrated as an additional data source (T3.2) and synchronous communication tools in between patients and care providers using videoconferencing will be fine-tuned (T3.3).

WP4 – Pilot Deployment

Pilot activities will be kicked-off in month 14 and will run up to month 18. Process will start with end users' recruitment (T4.1) with SMS support for this process (inclusion criteria, consent forms, ethical committees…). Regular monitoring activities will happen (T4.2), including support to end users and follow-up coordination within the co-creation team.

WP4 Milestone:

- M3 (month 14): PALDOC pilot deployment report.

WP5 – Impact Evaluation

Measuring impact is a key part of PALDOC solution. In order to do so, we will perform a "before pilot" measurement for the KPI set proposed (T5.1), covering project impact, health outcomes achieved and satisfaction/usability dimensions. Final set of KPIs will be agreed within WP1 Co-Creation Process Coordination. An additional "after pilot" evaluation of KPIs (T5.2) will happen in month 18, and a final Impact Evaluation Report will be generated.

WP5 Milestone:

- M4 (month 18): PALDOC Impact Evaluation Report.

WP6 – Business model, dissemination and communication

All tasks related with post-pilot exploitation, scalability and new stakeholders/promoters' engagement will be addressed here (T6.1 – T6.2). To do so, we will rely on HealthChain project support resources and Follower SME contributions.

month	mar-24	abr-24	may-24	jun-24	jul-24	ago-24	sep-24	oct-24	nov-24	dic-24	ene-25	feb-25	mar-25	abr-25	may-25	jun-25	jul-25	ago-25
WORK PACKAGE / TASK	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**	**M8**	**M9**	**M10**	**M11**	**M12**	**M13**	**M14**	**M15**	**M16**	**M17**	**M18**
WP1: co-creation process coordination																		
T1.1 - SMS co-creation meetings								**m1**										
T1.2 - Co-creation follow-up meetings																		
T1.3 - PALDOC exploitation agreements																		**m5**
WP2: PALDOC infrastructure set up																		
T2.1 - Cloud-based architecture set up																		
T2.2 - Architecture deployment									**m2**									
T2.3 - PALDOC - SMS Interoperability mechanisms																		
WP3: PALDOC tailored features development																		
T3.1 - AI assistant training																		
T3.2 - Wearables data integration in PALDOC																		
T3.3 - Video-conferencing in PALDOC																		
T3.4 - Health resources repository publication																		
WP4: Pilot deployment																		
T4.1 - Users recruiting																		
T4.2 - PALDOC Chronic Pain Care Pathway usage support														**m3**				
WP5: Impact evaluation																		
T5.1 - "Before" pilot KPI measurements																		
T5.2 - "After" pilot KPI measurements																		**m4**
WP6: Business Model, Dissemination and Communication																		
T6.1 - Post-pilot business modelling																		
T6.2 - Dissemination and Communication																		

Figure 4. PALDOC Gantt Chart

Follower SME

Scope of work performed by the follower SME

IDI EIKON is a software development, interoperability expert and value-based healthcare models provider company that contributes a licence on its Care Pathways Management platform (AdsuM++) as the basis supporting almost all requirements (mandatory and desirable) included in PASPADOC challenge.

Additional adaptations of AdsuM++ agreed in the initial co-creation process with the SMS can be addressed by IDI EIKON's IT Team (participants, roles and experience of this team is detailed in the previous section of this document).

However, IDI EIKON is looking for an SME that can provide the following services:

- **Ability to provide (or generate) additional Health Resources related to Chronic Pain that might be integrated in PALDOC repositories and used to train PALDOC AI assistant.** To be integrated in WP3 (T3.4):
    - Empowering patient's ability to self-manage their chronic pain condition is a key goal in PALDOC. To do so, an AI-based personal assistant will be offered to patients. This AI will need specific materials and advice on how to deal with Chronic Pain on a daily basis. We are looking for a Follower SME that can support us in validating the available content and materials from the PALDOC HCO while contributing new resources and materials for training the AI-based assistant. Specific expertise in generating "patient friendly" documentation will be appreciated.

- **Active participation from co-creation follow-up meetings, contributing new ideas and validating previous decisions.** To be integrated in WP1 (T1.2).

- **Contribution to develop an Internet of Things layer (IoT) for PALDOC, where Wearable devices and their data (preferably obtained from the Follower SME own "data concentrators") are integrated into AdsuM++.** To be integrated in WP3 (T3.2):
    - PALDOC has a beyond-pilot sustainability goal. Leveraging on partners that can provide added value to our proposal will help us in extending PALDOC across Europe. We do think that ensuring interoperability with providers that are already offering their own Wearables devices and related platforms in the market can contribute to PALDOC expansion. We do foresee to integrate in PALDOC platform data measured by wearable devices that provide insights on chronic pain management (sleep quality, walking activity, falls and similar KPIs) so this data can be used to trigger specific alerts and advice, by fusing it with other PALDOC inputs. We do foresee to pick up this data directly from the data concentrator platform collecting data from individual devices, in order to reach a seamlessly integration we can widely reuse in different implementation scenarios.

- **Contribution to develop an Internet of Things layer (IoT) for PALDOC, where medical devices and their data (preferably obtained from the Follower SME own "data concentrators") are integrated into AdsuM++.** To be integrated in WP3 (T3.2):
    - Continuing efforts planned for wearable devices, we also do foresee to integrate in PALDOC platform data measured by medical devices that provide insights on chronic pain management (neurostimulators, drug pumps and similar devices) so

this data can be used to trigger specific alerts and advice, by fusing it with other PALDOC inputs. We do foresee to pick up this data directly from the data concentrator platform collecting data from individual devices, in order to reach a seamlessly integration we can widely reuse in different implementation scenarios. Medical devices and related management platform should be EC certified and classified accordingly under EU Medical Device Regulation.

Reabilitar@mente

Effectiveness of cognitive rehabilitation programs for hospitalized elderly people. The aim is implementing cognitive rehabilitation programs to improve orientation, memory, and functional independence concomitant with a complementing rehabilitation nursing interventions in the area of functionality.

Decree-Law no. 30/2011 of 2 March created the Centro Hospitalar e Universitário de Coimbra, E.P.E., a Public Institution. The Centro Hospitalar e Universitário de Coimbra, E.P.E. (CHUC) comprises the following hospitals: Hospitais da Universidade de Coimbra (HUC), Hospital Geral (HG), Hospital Pediátrico (HP), Maternidade Bissaya Barreto (MBB), Maternidade Daniel de Matos (MDD) and Hospital Sobral Cid (HSC).

CHUC's mission is to provide high quality, differentiated healthcare in a context of training, teaching, research, scientific knowledge, and innovation, and to be a national and international benchmark in areas considered to be centres of excellence.

According to its vision, CHUC is an open organisation, made up of a network of hospital units, services and technologies structured and integrated to provide society with humanised, complete, close, reliable, and transparent care with a positive impact on the community, guaranteeing efficiency and overall sustainability in the medium and long term.

It has a workforce of more than 8,000, around 1,700 acute beds, and in the first half of 2023 there were 1,3687 emergency appointments, 2,6745 patients discharged, 2,597 patients operated on, and 62,353 Day Hospital sessions.

In any hospital, the Internal Medicine Service is considered a fundamental valence and the "pillar" of the organisation, as it integrates knowledge built up and dispersed by the different specialties or subspecialties that were born from it.

Internal Medicine is a core speciality in the health system, it is versatile and is defined as a speciality that is more about patients than diseases.

Internal Medicine intervenes at all levels of health and disease, namely:

- Health promotion
- Disease prevention
- Diagnosis
- Therapy
- Follow-up
- Coordination with other hospital specialities and primary care

Challenge description

At Centro Hospitalar e Universitário de Coimbra, 70% of medical admissions and 73% of medical hospital days belong to patients over 65. However, it has been recognised that the hospital response is not adequate for this population, with long stays in hospital and progressive functional and cognitive decline.

Associated with the aging process are cognitive changes that cause disabilities and limitations, such as reduced mobility, decision-making, memory loss, difficulty in managing daily routines, among others.

Maintaining cognitive health is a fundamental premise for preventing cognitive impairment and delaying the onset of dementia, dependency, and the person's (in)ability to take care of themselves. Cognitive rehabilitation is considered to be a therapeutic process that aims to systematically recover, compensate, and promote neurocognitive skills, based on the assumption of the brain's plastic capacity. It is in this context that the reciprocal relationship between the person and the environment is established, and therefore the possibility of the application of a Cognitive Rehabilitation Program having an impact on brain plasticity.

On the other hand, the interest in the relationship between the specific needs of the elderly and the usefulness of technologies in meeting them is evident in the growing number of studies on the use and acceptance of technologies by this segment of the population.

Currently, some studies have shown that cognitive stimulation combined with new technologies causes positive changes in the memory of the elderly, as well as instructing them in useful technological skills to facilitate daily activities and can even bring social benefits.

In this context, and given the challenges that aging faces today, there is a need to design and implement a cognitive rehabilitation program in a hospital setting in partnership with new technologies, particularly in internal medicine services.

It seems also important to be possible to use these technologies after discharge and monitor the effects of a cognitive rehabilitation program at a cognitive level, as well as the repercussions at a functional level as a contribution to improving the person's quality of life.

Challenge main objectives

There is evidence that one of the predictors of functional decline during hospitalization is cognitive impairment. With this in mind, the aim is to develop a rehabilitation program that includes exercises in the areas of cognitive rehabilitation, on topics related to each person's personal tastes, as well as some occupational activities from their current and past life.

Solution functional requirements

Compulsory functional requirements

The application of cognitive rehabilitation, using new technologies, should consider:

- A low degree of difficulty in interpretation, given that the vast majority of patients have a low level of education, and can't read or write.
- A low level of ICT/digital literacy
- Visual impairment
- Difficulties to hear.
- Mobility limitations, namely the inability to get out of bed.

Therefore, the solution shall:

- Provide engaging content for cognitive rehabilitation considering the above-described characteristics of the targeted population.
- Provide feedback on patients' performance, so that the patients can self-assess and improve.
- Include an accessible and friendly UX/UI adapted to the characteristics of the targeted population such as (but not limited to) prioritizing images over texts, possibility to increase font sizes, audible support for people with hearing loss, among others.
- The solution shall be adapted to patients' held devices like smartphones, tablets, laptops and/or smartTVs.

Desirable functional requirements

The solution could be adapted to the socio-economic and socio-cultural level of the patient, considering factors such as jobs and hobbies.

The solution could combine both physical and cognitive rehabilitation.

The solution could be adapted for later use of the patient at home, after hospitalisation.

It would be desirable to combine movement and reasoning in the same exercises.

Possibility of monitoring each patient results over time.

Pilot scope

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

It will be expected to test the solution for 6 months.

The healthcare professional's teams will be composed by nurses (leading by rehabilitation nurses).

The target population for this project is all elderly people admitted to internal medicine wards with altered functional independence, orientation, and memory. The sample will be selected according to the voluntary participation.

End-user type	Role	Number
Nurses (rehabilitation)	Provide requirements, use, and validate the solution.	3
Patients	Validate the solution	50

Table 5. Targeted users

Language

- The language will be in Portuguese, simple language, using images, symbols, and sounds.

Pilot set-up conditions

The pilot setup conditions correspond to the objectives of exploring and testing a program for the cognitive rehabilitation of the hospitalized elderly people.

The cognitive rehabilitation programme will consist of helping people to improve the performance of their activities of daily living, providing autonomy and independence.

It should incorporate specific exercises to develop the basic areas of mental function: attention, language, memory, visual-spatial ability, and association of ideas.

The exercises should be applied through any medium capable of representing everyday situations in which the person is encouraged to concentrate, interact, reason, and make decisions, understand speech, and express feelings and thoughts.

Ethical, legal, or regulatory

All CHUC employees, as well as the general public, including companies that collaborate with CHUC, are governed by the Privacy and Data Protection Policy (Publication of 11.08.2022, Board of Directors), which explains the terms under which CHUC processes the personal data of its users, as well as the rights they may exercise, in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council - General Data Protection Regulation (GDPR) - and other applicable national legislation on privacy and data protection.

In addition to Privacy and Data Protection, all CHUC managers and employees must consider the Code of Ethical Conduct (Publication of 22.09.2022, Board of Directors.

The pilot should have the approval of the Ethics Committee of the hospital and the inform consent of the patient or caregiver.

Technological

It must be usable on a tablet or smartTV. In the case of combining movement and image, specific software will have to be install/developed for this, and possibly access to cameras.

Expected impact and KPIs

With the implementation of cognitive rehabilitation programmes for hospitalised patients over 65 years of age, the expected impact is to:

- Reduce the cognitive decline of the elderly during hospitalisation using innovative technologies in cognitive stimulation.
- Improve the functionality of hospitalised elderly people.
- Improve the quality of life and patient experience/satisfaction for the over-65s.

To measure the results, we can use:

- Maintain or increase the FIM [1] score.
- Maintain or increase the MoCA [2] score.
- Maintain or increase the Quality of Life [3] score.
- Levels of satisfaction with care >5 (1-10).

Business opportunity

Market size

CHUC's Internal Medicine Service preferably serves the population of the catchment area assigned to it by the hospital referral networks (Centre Region of the country).

The solution developed as part of the pilot could be replicated in the other internal medicine departments (a total of six more). In addition, we believe it would be useful to implement it in other contexts, particularly in other medical speciality services. It will also have applicability in

[1] FIM (Functional Independence Measure). Aims to diagnose the degree of functional capacity/disability of adults and the elderly, assessing the person's performance and the need for care required to carry out a series of motor and cognitive tasks of daily living. The maximum total is 126 points and indicates total independence and the minimum is 18 points and indicates total dependence.

[2] MoCA (Montreal Cognitive Assessment). Is a brief screening tool for mild cognitive impairment. This instrument assesses different cognitive domains: executive function; visual-3spatial ability; memory; attention, concentration and working memory; language; and temporal and spatial orientation. The maximum score is 30 (points).

[3] SF-36 v2 (MOS Short Form Health Survey 36 Item v2. Measuring and assessing the health status of populations and individuals with or without disease; monitoring patients with multiple conditions, comparing patients with different conditions and comparing the health status of patients with that of the general population.

other contexts, given that the rate of elderly people admitted to the institution is quite substantial.

Adoption plans

The department of internal medicine and medical specialities is the largest in the hospital. And in general, the elderly population fills a large number of hospital beds.

If the pilot is successful, CHUC intends to adopt the solution, by shared ownership the solution co-created and procure its maintenance.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	NEUROINOVA, Lda
DESCRIPTION OF THE SME	Neuroinova is a SME dedicated to R&D of technologies in the field of cognitive diagnosis, monitoring and rehabilitation. It is specialised in the field of cognitive health, developing innovative services based on the implementation of technologies on common clinical processes. The systems and technological products that it develops are focused on two fundamental aspects: 1) in the increase of the ability and quality of work of highly specialised health professionals (e.g. neuropsychologists, physical therapists, occupational therapists) and 2) improving patient access to early diagnosis and supervised interventions in the area of cognition and consequently their participation in the therapeutic path. The company currently assures the whole chain of technical-scientific development and marketing of technology-based medical devices COGWEB® (Web-based cognitive training) and Brain on Track® (Cognitive monitoring system). These products are directly marketed to the end customer (full-stack services) or through licensing to institutions or individuals after a specific training process.
WEBSITE URL	www.neuroinova.com/

Table 6. Leading SME general information

Solution proposed:

Cognitive Vitality Training 2.0: CogniViTra 2.0

The existing COGWEB solution will be enhanced to incorporate a range of new functionalities aimed at facilitating functional rehabilitation and adaptation for patients during hospitalization and discharge - CogniViTra2.0. This upgraded system will specifically target individuals facing cognitive health risks even after leaving the hospital. The proposed cognitive 5 training programme includes the possibility of prescription of simple motor tasks, and it is adapted to the needs and tastes of each patient. This solution will have a series of additional features to meet the needs of a population in-hospital recovery and can be subsequently used at home, within a perspective of continuity of care and prevention of dementia and cognitive deficits. To increase adherence and make the system more meaningful for users, cognitive rehabilitation tasks will focus on topics related to each person's personal preferences, as well as some occupational activities from their current and past life.

The COGWEB® (a cognitive training program previously developed by our team) is composed of several exercises, with different levels, aimed at training different cognitive functions, such as attention, memory, language, executive functions, among others, that the professional uses to create training plans adapted to the needs and characteristics of each patient. As it is an online platform, it is available from any computer or tablet with internet access, without the need to install any software.

CogniViTra2.0 is based on products and services that the team has been successfully implementing on the market for many years, representing an evolution of those products and services to meet the growing needs of patients and healthcare professionals. The characteristics of our current solution, together with the features we propose to develop within this project, enables:

- Flexible and personalized creation of intervention plans tailored to the user's characteristics, adjusting the type of cognitive training exercises, their degree of difficulty and the type of content.
- Deliver engaging content tailored for cognitive rehabilitation, considering the unique characteristics of the targeted population.
- To define the type of response (mouse, touch, or motor) to cognitive exercises.
- Prescription of simple motor tasks.
- Cognitive and physical training tasks to be carried out both during hospitalization and after discharge, at home.
- It is adapted for use by people with low levels of education and digital literacy.
- It remains usable post-discharge and facilitates ongoing monitoring.
- Continuous monitoring by accessing patient performance records and graphs.

If widely adopted, the described solution could have a significant impact on the Centro Hospitalar e Universitário de Coimbra response promoting continuity of care and intervening in the prevention of dementia and cognitive deficits of the population. CogniViTra2.0 aims to extend the capacity of healthcare professionals to support people in need of cognitive stimulation by providing a solution that allows them to follow-up more people simultaneously. It aims to address the demand from patients for increased session hours, surpassing the limitations imposed by the availability of care resources, including human and physical infrastructures. By doing so, it contributes to significantly reducing the delivery costs of healthcare services. Furthermore, it has demonstrated the potential to enhance professional productivity by up to 50%. Interactions with care professionals have indicated that CogniViTra2.0 enables effective monitoring and simultaneous care for more patients, suggesting a cost ratio below 1. Additionally, the solution's adaptability to different contexts ensures its effectiveness across diverse patient populations, making it a valuable asset for the hospital striving to provide comprehensive and patient-centered care. Neuroinova complies with the standards defined by the GDPR and ISO 13485, so all security and confidentiality issues are assured.

Work to be done by the leading SME

CogniViTra 2.0 is structured into four distinct Work Packages (WPs), each with specific objectives and tasks distributed across the project's 12-month timeline. The leading SME will develop the following tasks within each WP:

- **WP1**, "Project Management & Coordination," focuses on ensuring seamless collaboration, and the tasks to be done are related to efficient project management, risk mitigation, financial oversight, and quality control.

- **WP2**, "Prototype development" is dedicated to developing and integrating the new features of the solution while optimizing the current features. This task aims to develop the CogniViTra 2.0 prototype to be tested in a laboratory environment and then in a clinical setting. Initially, the task will focus on developing non-functional prototypes of the final service that will be validated by target groups to consolidate the functionalities to be implemented; in particular, those related to implicit and explicit interaction mechanisms. After conceptual validation, the necessary applications will be implemented. This includes the definition of requirements for the solution for cognitive training, the development and integration and the product testing and re-engineering.
- **WP3**, "Pilot Deployment and Validation" encompasses tasks such as ethical approval, privacy protection plan, user recruitment, usability tests and pilot deployment; In this WP it will be initiate the ethical approval process, that comprehends preparing and submitting all necessary documentation for pilot deployment, as well as implementing an all-encompassing user recruitment strategy designed to target participants who meet the inclusion and exclusion criteria outlined for pilot studies. This WP also includes the deployment of the pilot study, using the proposed solution, for a total of 50 users.
- **WP4**, "Dissemination, Business, and Exploitation Strategy" is committed to developing a robust dissemination plan, business strategy, and exploitation roadmap to ensure the project's research results reach a wide audience and pave the way for successful commercialization and sustainability.

Follower SME

Scope of work performed by the follower SME

The specific tasks and activities allocated to complement the development of the innovative solution proposed are focused in technical and clinical features. As stated before, it is of great importance that a health solution is accessible, intuitively usable and adapted to the target population, namely elderly individuals with limited levels of digital literacy that might also have cognitive deficits. Usability and user experience will be considered in the co-creation process and will be applied using different methodologies, and we believe it would be valuable to involve a partner with experience in designing user interfaces for digital health platforms, to develop tasks aimed at optimizing and improving CogniViTra2.0 interfaces.

The tasks to be carried out by the Follower SME would be mainly focused on:

- Visual design, to create adapted and aesthetic interfaces; Interaction design, to ensure optimized interactions with interface elements, including navigation and feedback mechanisms.
- Accessibility, to guarantee that the interfaces are adapted to be used by people with low digital literacy and with disabilities, including requirements about colour contrast, fonts.
- Responsive design, to assure that the interfaces adapt to different types of screens providing a consistent user experience across platforms.
- Usability testing, participating in the evaluation of the effectiveness and usability of the interface design.
- Documentation, namely creating design specifications, style guides and other relevant documentation.
- Incorporation of assessment scales and respective evolution charts.
- Creation of info videos on topics related to active ageing (contributing to increased health literacy).

RecoMed

Boost medication safety in Plastic Surgery and Burns department!

Decree-Law no. 30/2011 of 2 March created, the Centro Hospitalar e Universitário de Coimbra, E.P.E., a Public Institution. The Centro Hospitalar e Universitário de Coimbra, E.P.E. (CHUC) comprises the following hospitals: Hospitais da Universidade de Coimbra (HUC), Hospital Geral (HG), Hospital Pediátrico (HP), Maternidade Bissaya Barreto (MBB), Maternidade Daniel de Matos (MDD) and Hospital Sobral Cid (HSC).

CHUC's mission is to provide high quality, differentiated healthcare in a context of training, teaching, research, scientific knowledge, and innovation, and to be a national and international benchmark in areas considered to be centres of excellence.

According to its vision, CHUC is an open organisation, made up of a network of hospital units, services and technologies structured and integrated to provide society with humanised, complete, close, reliable, and transparent care with a positive impact on the community, guaranteeing efficiency and overall sustainability in the medium and long term.

It has a workforce of more than 8,000, around 1,700 acute beds, and in the first half of 2023 there were 1,3687 emergency appointments, 2,6745 patients discharged, 2,597 patients operated on, and 62,353 Day Hospital sessions.

Plastic Surgery is an extremely wide-ranging speciality, ensuring the diagnosis and treatment of multiple pathologies such as burns and their squeal; skin and soft tissue tumours and their squeal; breast reconstruction; pharyngeal-laryngeal reconstructions; scalp reconstructions (particularly in cochlear implant exposures); oesophageal reconstructions; traumatology and its squeal (including the prevention and treatment of pressure ulcers); hand surgery; peripheral nerves and brachial plexus; congenital anomalies of the head and neck, trunk, genitals and limbs; gender reassignment surgery (including breast surgery, penis and vulvo-vaginal reconstructions); lymphatic surgery; body contouring surgery after bariatric surgery and aesthetic surgery. Plastic Surgery has an interface with all areas of surgery: from Gynaecology to Urology, including Head and Neck Surgery, Neurosurgery, Otorhinolaryngology, Thoracic Surgery, Dermatology, Orthopaedics and Paediatric Surgery.

Genetically, it is linked to the Burn Unit with which it shares clinical staff, and this is a perfect solution for the burn patient as it allows for continuity of care and the transmission of all clinical information and relevant patient characteristics.

The types of care provided by the service are the traditional ones for a surgical service, i.e.:

- Hospitalisation: 25 beds.
- Operating Theatre: access to the Peripheral Operating Theatre on a daily basis and some operating times in the Central Operating Theatre (1 operating time per week). Operating Theatre in the Paediatric Hospital (1 operating time per month).
- Ambulatory Surgery: operating times in the Ambulatory Surgery Unit (two days from 8.30am to 2pm - general anaesthesia - and one day from 2pm to 6pm - local anaesthesia).
- Outpatient Consultation: 2 offices - Consultation daily.

Challenge description

The hospital is a large and complex set of services where care is provided to promote the health of the population. An individual's visit to a health institution, either for a routine consultation, a scheduled intervention, or an acute situation, most often leads to changes in medication. It

has been described that failures in communication between transitions of care can lead to discrepancies and confusion in the usual medication.

Lack of communication during patient transition is the reason for 50% of medication-related errors and about 20% of adverse drug reactions (Institute for HealthCare Improvement, 2006).

This situation can lead to re-admissions, morbidity and mortality and increased health costs. The sustainability of resources, particularly in the health area, is a growing concern and medication reconciliation is one of the accessible and available tools to reduce the risk of these events, but also to reduce and/or minimize their consequences.

The National Plan for Patient Safety 2015-2020 (D.R. 2ª série - nº 28/2015, of February 10) and the current National Plan for Patient Safety 2021-2026 (D.R., 2ª nº 187/2021, of September 24) recognize its importance, including medication reconciliation in their objectives and setting targets for achievement.

Medication reconciliation is a formal and systematic process in which different healthcare professionals work together to obtain and evaluate the patient's medication list with the doctor's admission, transfer, or discharge prescriptions. It consists of obtaining and checking a complete and accurate list of the medicines that each patient is currently taking. This list is compared with the medicines that have been prescribed and where discrepancies are identified, these are discussed with the prescriber and the reasons for these changes are documented. When the patient is transferred, a current and accurate list of medicines is provided to the person who will be taking over the patient's care.

In CHUC's Plastic Surgery and Burns service, after the hospital implemented the electronic medical record, there is no therapeutic reconciliation process that implements the recommendations of the Directorate-General for Health (Norma 018/2016. Reconciliação da Medicação. Direção Geral de Saúde). The application for this project aims to respond with a digital solution that allows this process to be implemented.

Challenge main objectives

The main objective is to improve, with a digital solution integrated into the patient's electronic record, the accessibility and updating of the medication list of patients admitted to this clinical service, avoiding communication errors and negative consequences in terms of patient safety, with the aim, whenever possible, of active participation by the patient themselves, empowering them to better manage their medication.

The aim is to ensure accurate and complete knowledge of a patient's medication information in order to prevent medication-related incidents at all transition points in healthcare interfaces (Institute for HealthCare Improvement, 2006).

The end result will be the communication of the updated medication list to the next care provider or to the patient/caregiver.

Solution functional requirements

Compulsory functional requirements

The system to be implemented must respond to the following needs / propositions:

- Obtaining and verifying: the complete and accurate list of medicines that each patient is currently taking.
- Comparison: of the list of medicines that the patient is taking in relation to the medicines that have been prescribed.

- Documentation: where discrepancies are identified, these are discussed with the prescriber and the reasons for the changes are documented,
- Final document: when the patient is transferred, a current and accurate list of medicines (including the reasons for changes) is provided to the person who will be taking over the patient's care.

Therefore, the solution shall:

- Acquire the full list of medicines the patient is currently taking.
- Compare this list with the medicines that have been prescribed in hospital.
- Identify discrepancies.
- Emit a document with discrepancies, so that the prescriber can analyse and decide.
- To be able to export a final document, to be given to the patient, with the therapeutic list to follow, updated and exact (and with the possibility of including reasons for changes, as well as a field for free-text comments).
- Be integrated and communicate within national and hospital's medical records and hospital pharmacy systems.
- Be eased to use.

Desirable functional requirements

The solution could release alerts when occur discrepancies.

Pilot scope

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

It will be expected to test the solution for 6 months.

The healthcare professional's teams will be composed especially with pharmacists and physicians.

End-user type	Role	Number
Pharmacists	Provide requirements, use, and validate the solution.	3
Physicians	Provide requirements, use, and validate the solution.	6
Patients	Beneficiaries (all the pilots will be developed based on different patients' medicine lists)	50

Table 7. Targeted users

Language

- The solution must be in Portuguese. There are no special language requirements for iteration with the end users in addition to those related to the description of the drugs.

Pilot set-up conditions

The pilot setup conditions correspond to the objective of capturing lists of medicines that patient is currently taken, comparing this list with what has been prescribed, identifying, and signalizing the discrepancies and creating a document to be provided to patient or caregiver.

All the information must be managed around the clinical and pharmaceutical informatics system.

Ethical, legal, or regulatory

All CHUC employees, as well as the general public, including companies that collaborate with CHUC, are governed by the Privacy and Data Protection Policy (Publication of 11.08.2022, Board of Directors), which explains the terms under which CHUC processes the personal data of its users, as well as the rights they may exercise, in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council - General Data Protection Regulation (GDPR) - and other applicable national legislation on privacy and data protection.

In addition to Privacy and Data Protection, all CHUC managers and employees must take into account the Code of Ethical Conduct (Publication of 22.09.2022, Board of Directors)

Technological

The solution needs to communicate with the actual IT systems.

Data access

The tool to be developed need to extract data from the hospital existing IT system about name, dose, method of administration and schedule medicines and then bring measurements and output to the system.

Expected impact and KPIs.

With the creation and implementation of this tool, we aim to obtain benefits centred on the patient and on the efficiency of the hospital system:

- Increasing safety, reducing errors related to inappropriate medication.
- Managing the economic resources spent on medication.
- And, indirectly, increasing the satisfaction levels of healthcare professionals and patients/carers.

As a process indicator:

- 75% of admissions/discharges of patients with medication reconciliation.

Business opportunity

Market size

As mentioned earlier in this document, CHUC is a large healthcare organisation with a high volume of production. It is concerned with providing quality and patient-centred care.

CHUC has many departments and services providing care in different areas and specialities, and the problem of therapeutic reconciliation is a cross-cutting issue.

Therefore, the solution developed as part of this pilot can be replicated in all of the hospital's care centres.

Taking the first half of 2023 into account, the figures are as follows: there were 134,687 emergency attendances, 26,745 patients discharged, 25,497 patients operated on, 62,353 Day Hospital sessions.

Adoption plans

If the pilot is successful, CHUC intends to adopt the solution, by shared ownership the solution co-created and procure its maintenance.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	VirtualCare
DESCRIPTION OF THE SME	VirtualCare is an SME that excels in developing and applying IT and biomedical solutions to elevate healthcare. The company implements innovative technologies across Portuguese hospitals to streamline healthcare delivery and patient care. Adding to the previous summary, VirtualCare is currently involved in various clinical areas across 23 Portuguese hospitals, showcasing our diverse expertise in healthcare innovation: • Women and Child Health: We manage processes related to women's and children's health (gynaecology, pregnancy, childcare, breastfeeding, breast cancer), which includes interoperability with health entities' Information Systems (IS) at the time of childbirth or analysis. Our integrations extend to SClinico, medical equipment and IS related to pregnancy, the DGS to produce obstetric indicators, and EUSOMA in the context of breast cancer. We also focus on dematerialising clinical processes (emergency, hospitalization, consultation, childbirth, and surgeries). • Adverse Reaction Management: We handle adverse reactions to medications, allergies, and incidents with medical devices, including detection in clinical records using AI, integration with SClinico, INFARMED, and other IS, and follow-up in hospitals and health centres. This also includes processes to correct the mislabelling of patients mistakenly marked as allergic to beta-lactams. • Other systems include applications for Acute Pain and Difficult Airway Management, Hemodialysis, and Antipsychotic Management. This diversified portfolio demonstrates VirtualCare's commitment to enhancing healthcare quality and efficiency through innovative IT and biomedical solutions.
WEBSITE URL	www.virtualcare.pt

Table 8. Leading SME general information

Solution proposed:

MediRecon: Medication Reconciliation and Management System

MediRecon is a digital solution designed to address the challenges associated with medication management and reconciliation for patients admitted to the Plastic Surgery and Burns department at the Centro Hospitalar e Universitário de Coimbra, E.P.E. (CHUC). By seamlessly integrating with the hospital's electronic medical record system, MediRecon aims to streamline the process of obtaining and updating patients' medication lists, ultimately reducing medication-related errors and significantly improving patient safety.

Key Features:

1. **Medication List Acquisition:** MediRecon will have channels to gather a complete inventory of each patient's current medications from multiple sources, including electronic health records and pharmacy databases. This ensures accurate and up-to-date information about every patient's medication regimen.
2. **Prescription Compatibility Check:** The system will cross-reference the acquired medication list against the prescribed medications for each patient, identifying potential discrepancies or conflicts that may lead to adverse drug reactions or other issues.
3. **Discrepancy Resolution:** Upon detecting discrepancies, MediRecon will generate a report outlining the identified inconsistencies and recommended solutions. This documentation will facilitate communication between healthcare providers and enable timely interventions to rectify medication errors.
4. **Integration with Hospital Systems:** As a standalone application, MediRecon can integrate with the hospital's health records and pharmacy systems, allowing for real-time updates and synchronization of patient medication information. Create interoperability resources compatible with international standards (eg., FHIR, ATC and IDMP).
5. **Alert Notifications:** MediRecon will provide alerts to healthcare professionals when potential discrepancies are detected, enabling prompt action to protect patient safety. This solution can use the existing hospital alert system to send the alert.
6. **User-Friendly Interface:** Designed with usability in mind, MediRecon offers an intuitive platform accessible to healthcare professionals. In cases where an interface is already available, MediRecon services will be available through an API to be integrated in an existing system.
7. **Pilot Testing and Validation:** Prior to full implementation, MediRecon will undergo rigorous testing and validation during a pilot project involving a diverse team of stakeholders, including pharmacists, physicians, and nurses.
8. **Database Harmonization:** To enhance the safety and efficiency of patient care, MediRecon will include a centralized component specifically designed to collect and manage adverse drug reactions (ADRs) recorded across various systems at CHUC. This component will be able to integrate ADR data from multiple sources, including electronic medical records and pharmacy management systems. By centralizing ADR information, the system will provide healthcare professionals with a comprehensive view of each patient's reaction history, facilitating more informed decision-making and improving the response time to potential adverse events.

The system proposed has several internal components and is integrated with typical hospital information systems.

Existing Hospital Information Systems to integrate with:

- ADT (Admission-Discharge-Transfer): SONHO from SPMS

- EPR (Electronic Patient Record): SClinico from SPMS
- External Prescription: PEM from SPMS
- Internal Prescription: SGICM from Glintt
- Plastic Surgery Patient Data: B-ICU from B-Simple
- User Authentication: Active Directory from Microsoft

Internal components:

- ReconMed Smart Engine
- Interoperability engine and APIs
- Graphical User Interface for ReconMed
- Adverse Drug Reactions Component
- Drugs Knowledge Base
- Audit Trail
- Storage component

Work to be done by the leading SME

The Leading SME will execute the following activities during the 12-month project:

1. Technical Requirements of Data and Information Sources:

- Identify and consolidate various sources of drug information critical for gathering comprehensive data. This may include databases, hospital records, and other relevant digital and offline sources. We also need to define the owners of such sources of information and if they are willing to exchange information.
- Establish data quality standards to ensure that the information collected is reliable, timely, and accurate.
- Define the data elements needed from each source.

2. Interoperability development:

- Develop methods to ensure seamless interoperability among the selected data sources. This includes adopting standard data formats and protocols for data exchange and integration.
- Create a prioritized ranking system based on the importance and urgency of each data source to streamline processes and focus on critical data first.

3. Functional Requirements:

- Define the workflows intended for usage of the system in order it can obtain, verifying, and updating a complete and accurate list of medications for each patient.
- Implement a comparison feature to cross-verify the current medication list with the prescriptions issued within the hospital.
- Ensure that when a patient is transferred, the next care provider or the patient/caregiver receives a current, accurate medication list with explanations for any changes.

4. Data Aggregation and Intelligence Development:

- Integrate data from various sources to build an intelligence system that can analyse and present actionable insights.
- Develop algorithms and/or methods to detect discrepancies and potential medication errors automatically.

5. Pilot and Implementation Strategy:

- Conduct a pilot to design, validate, and test the solution, measuring its impact and effectiveness.
- Involve pharmacists, physicians, and patients in testing and refining the solution to ensure it meets the needs of all stakeholders.
- Compliance and Ethical & Legal Considerations:
- Adhere to ethical standards and data protection regulations such as GDPR, ensuring that all personal and medical data is processed with the utmost privacy and security.
- Ensure that data is only seen and analysed by authorized healthcare practitioners or patients.

6. Desired Outcomes and Impact Measurement:

- The solution should increase patient safety by reducing medication errors, manage resources efficiently, and improve satisfaction levels among healthcare professionals and patients.

Activity	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
1	x	x										
2		x	x	x	x	x	x					
3	x	x	x									
4			x	x	x	x	x	x	x			
5						x	x	x	x	x	x	x
6										x	x	x

Figure 5. MediRecon Gantt Chart

Follower SME

Scope of work performed by the follower SME

The primary objective of the Follower SME is to ensure that the MediRecon system is fully prepared and compliant with regulatory requirements for certification as a medical device.

This includes achieving compliance with relevant international standards and obtaining necessary certifications that demonstrate safety and efficacy.

Scope of Work:

1. **Regulatory Strategy Development:**
Develop a comprehensive strategy for medical device certification, including identifying the specific standards and regulations applicable to the MediRecon system.

Collaborate with regulatory experts to ensure all requirements are understood and integrated into the development and testing processes.

2. **Documentation Preparation:**
Prepare all necessary documentation required for certification, such as the Device Master Record (DMR), risk management files, and clinical evaluation reports.

Ensure that all documentation is maintained up to date with the latest product specifications and test results.

3. **Quality Management System (QMS) Implementation:**
Assist in the implementation of a Quality Management System compliant with ISO 13485, focusing on the development, production, and post-market surveillance of medical devices.

Train the project team on QMS processes and requirements to ensure consistent compliance throughout the product's lifecycle.

4. **Testing and Validation:**
Oversee the execution of comprehensive testing protocols to validate the safety, functionality, and performance of the MediRecon system under various conditions.

Document all test results and ensure they meet the criteria set by regulatory bodies for medical device certification.

5. **Audit and Inspection Preparation:**
Prepare and support the MediRecon team for audits and inspections conducted by regulatory authorities or certification bodies.

Address any findings or feedback from these audits promptly to maintain the timeline for certification.

6. **Certification Submission and Liaison:**
Coordinate the submission of all necessary applications and documents to the appropriate regulatory bodies.

Act as the primary liaison between the MediRecon project team and regulatory agencies, ensuring clear communication and swift resolution of any issues that arise during the certification process.

7. **Expected Outcomes:**
Successful preparation and submission of the MediRecon system for medical device certification.

Establishment of a robust Quality Management System that supports continuous compliance and quality assurance.

Achievement of certification, facilitating the legal marketing and widespread adoption of the MediRecon system in healthcare settings.

HIPRO - hip surgery patient reported outcome.

Improving patients' safety and empowerment after fast-tracking hip surgery.

Surgical Hospital Rožna dolina, Ljubljana, Slovenija is a small surgical hospital, privately own but public financed, with approximately 7000 surgical procedures performed per year. Surgery is mainly oriented to orthopaedic and general surgery. About 700 hip procedures are performed per year.

Challenge description

Hip preservation surgery is rapidly advancing. Patients are after hip surgery in some institutions discharged from hospital as soon as two days. After discharge may acute problems patient may present (hip dislocation, fracture, infection). After discharge, their first visit to surgeon is usually scheduled fourteen days after surgery. Between discharge and first post-surgery visit to doctor they are in the hands of their family. In early postoperative period they are without proper medical follow-up. self- assessment and communication with the surgeon would be beneficial for patients' follow-up. In the context of healthcare and surgical outcomes, PRO stands for "Patient Reported Outcomes." PROs are assessments or measures that capture information directly from patients about their health and well-being. They provide valuable insights into how patients perceive the impact of surgical procedures or medical treatments on their quality of life, symptoms, and overall satisfaction. Patient-reported outcome (PRO) measures are becoming an integral part of measuring treatment effectiveness. There are several Patient Reported Outcome (PRO) measures that are commonly used to assess outcomes after hip surgery (see resources. These PRO instruments are designed to capture the patient's perspective on their hip function, pain, and overall well-being following hip surgery. Yet they are in paper form and for elderly usually difficult to fill out. The current way of monitoring patients after fast-tracking hip surgery does not meet the expectations of patient and physicians.

The targeted group of patients for this challenge are elderly patients undergoing fast track hip surgery who are discharged from hospital after one or two days, though similar problems can be seen in other medical conditions, requiring surgical treatment. The telephone consultation service is insufficient to cover the demand and care of this patients after fast discharge from hospital, as it is difficult to assess full range of possible malfunctions and patient is usually invited to visit a physician.

Challenge main objectives

The main objective is to improve patient safety after fast-track surgery and discharge from hospital (and therefore improving their quality of life). As a secondary objective the Challenger also wants to learn the acceptance of tailored medical mobile solutions in elderly and to learn how to easily integrate 3rd party mobile solutions through its corporate IT (windows based) system.

Solution functional requirements

Compulsory functional requirements

- The solution shall be user friendly and adapted to digital literacy levels of the targeted patients (e.g. Elderly). The content shall be easy to digest by the patients by, for example using pictograms rather than text that captures the patient's perspective on their hip function, pain, and overall well-being following hip surgery.
- The solution shall allow information exchange between patients and their surgeon:
  - patient would choose from several templates to create the message, depending on the message type.
  - Health care professionals should be able to send the same message to patient.
- Calendar management: so, patients and physician can easily add or review patients' medical condition.
- Alert surgeon and family physician and family member that a relevant event or incidence needs their attention configurable through their channels of communication (smart phone, e-mail, etc.)
- Usable and intuitive for patients
- Tailor made mobile phone medical application for patients after fast-tracking hip surgery should be user friendly and based on pictograms rather than on classic text survey. To emphasize the basic idea an example is made from e-mojis. Here's a simplified part and creative representation:
  - Pain Assessment:
    - 😖 (Severe pain)
    - 😣 (Moderate pain)
    - 😐 (Mild pain)
    - 😊 (No pain)
  - Function Assessment:
    - 🚶 (Walking difficulty)
    - 🏃 (Able to run)
    - 🏋️ (Able to lift weights)
    - 🤸 (Able to perform sports)
  - Deformity Assessment:

  etc.

- Optimised for multi-device access.
- Including a survey to access quality of life indicator.
- When the user starts there will be available an application for local patients developed by Solver that incorporates, among others, user authentication. The new medical application must be called through authentication application, so user identification takes place under maximal safety conditions.
- The Solver application will be available for Android and iOS.

Desirable functional requirements

- Facilitate access to informative resources for self-empowerment, like documents, and videos. Including on a survey to assess quality of life indicator and to request and collect the patient outcomes over time.
- Medication management. Possibility that doctors incorporate and modify prescriptions.

- Connection with 3rd party devices like smart bands or watches to track day activity and sleep patterns.
- Information summaries and analytics on the available data to empower patients and facilitate better disease management by the patients themselves, in collaboration with their doctor.

Pilot scope

After beta version of application is prepared, 30 patients undergoing fast track hip surgery will enrol in the pilot together with two orthopaedic surgeons.

Language

- The application must be available in English and in Slovene language as the targeted population is not fluent in English.

Other aspects

- Patient must be owner of smart mobile device (smart phone).

Pilot set-up conditions

Ethical, legal, or regulatory

The approach of the pilot must be previously validated by an Ethics Committee of Medical faculty or National medical ethical board. The Committee will pay special attention to the collection of informed consents of patients by solver and the protection of personal data, observing the requirements established by the European data protection Regulation and Slovenian law.

If considered necessary, the Solver will be asked to anonymise the data according to mechanism established by the Challenger. At any case, the Solver cannot exploit or make the data for different purposes than the ones agreed with the Challenger and after pilot end, all copies of the data must be transferred back to the Challenger or deleted.

Technological

The systems and servers needed for running the piloted application will be hosted by the Solver. For safety reasons and data protection the Solver should have back up servers. Technological requirements will be established in a technical session at the beginning of the project.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs.

- Reduction in the number of physical visits of patients: a) to the doctor office at least 10% and b) to emergency room at least 20%.
- Quality of life indicator VR-12 (*see resources*). Increase of an average one point per month of usage, with a maximum 10 points during the total survey period.

Business opportunity

Market size

At the level of hospital organisation this project will be available in two hospitals with more than 20 orthopaedic surgeons. At the national level there are more than 20 hospitals with the orthopaedic units.

Presented application can be extended in a standard way with the same technology to many other pathologies, inside and outside starting hospital, with great possibility of growth.

Adoption plans

We plan to procure and scale up the solution in our organisation if the pilot is successful.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	ZenLab d.o.o.
DESCRIPTION OF THE SME	ZenLab is a software development company specialized in Enterprise System Integration, Business Process Management, Service Oriented Architecture, E-Commerce, Custom Software Development supporting digital transformation within any kind of industry or business. Within the health sector ZenLab is concentrated in finding ways to save time for clinicians and administration, so they can devote more time to real needs of the patient, starting with patient admission, treatment time, patient discharge and post treatment period.
WEBSITE URL	https://www.zenlab.eu/

Table 9. Leading SME general information

Solution proposed:

MobileCare+: Enhancing Post-Op Resilience in Fast-Track Hip Surgery

MobileCare+ is designed to revolutionize post-operative care for elderly patients following fast-track hip surgery (FTHS). This solution demonstrates significant potential in enhancing the integration of new knowledge by leveraging advanced technologies and methodologies. The main characteristics and components of MobileCare+ include a patient-centric mobile app, an HL7 FHIR big data infrastructure, a user interface for clinicians, a robust privacy and security pillar, and an advanced Language Model (LLM) pipeline for the collection of Patient-Reported Outcomes (PROs). Languages supported: English and Slovenian.

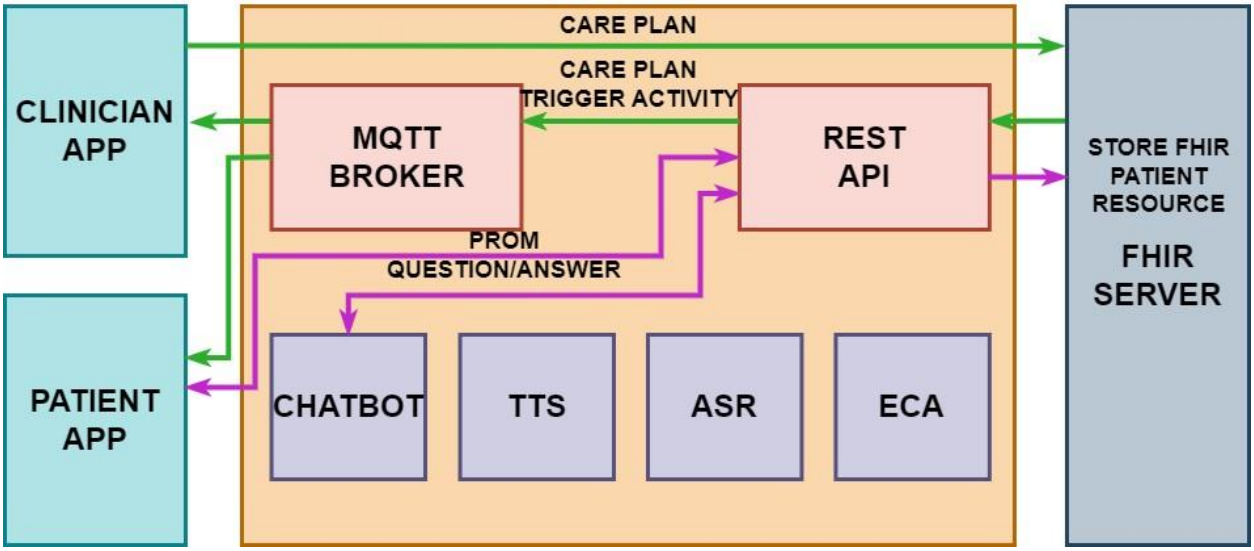

Figure 6. MobileCare+ architecture diagram

Components of the MobileCare+:

- **Mobile App for Patients (MobileCare+):** The mobile app serves as a patient-centred platform, featuring a chatbot companion that guides users through their post-operative journey. It facilitates automated follow-ups and collects valuable patient-reported data through conversational surveys. The app prioritizes user-friendliness, with pictograms for simplified information, multi-device access, and customizable communication templates. Graphical mock-ups will illustrate the user interface and will help us design the seamless navigation experience during co-creation.
- **HL7 FHIR Big Data Infrastructure:** The HL7 FHIR infrastructure ensures seamless data flow between the mobile app and hospital systems. It enables real-time interoperability with Electronic Health Records (EHR) and facilitates the aggregation of patient data for insightful analytics. Concepts such as CDS Hooks Enable Personalization and Automation of Care Plans.
- **User Interface for Clinicians:** A dedicated user interface empowers clinicians by providing real-time access to patient data and analytics. This component will be brought to TRL6 through mock-ups depicting the interface design and functionalities during co-creation.
- **Privacy and Security Pillar:** The privacy and security pillar is a cornerstone of MobileCare+, ensuring the confidentiality and integrity of patient health data. Technologies such as KeyClocak, Solver and SAPL will be used for authentication and authorization.
- **LLM Pipeline for PRO Collection:** The Language Model (LLM) pipeline supports the collection of PROs using standardized surveys and natural language processing. Mock-ups and visual representations showcase the algorithm's capabilities in extracting symptoms through medical named-entity-recognition. The setup and validation strategy for the algorithm are outlined in response to potential challenges with analytics.

Work to be done by the leading SME

WP1 focuses on requirements and design. Task T1.1 studies healthcare routines and digital interventions, establishing initial use cases with stakeholders reported in D1: Domain Landscape and Initial Study Protocol. T1.2 delivers the initial study initiation package, including feasibility details, data flow, security, privacy requirements, and recruitment strategy. Collaborating with T1.3 and T1.4, the final study protocol is approved by ethics committees by M7. T1.3 identifies unmet needs and engages stakeholders through participatory design, setting up a co-creation methodology. T1.4 transforms outcomes into technical and functional requirements. Results are documented in D2: Platform's Requirements & Conceptual Architecture.

WP2 focuses on the development of the app for patients. Task T2.1 focuses on designing modules for patient monitoring, integrating mechanisms for collecting Patient-Reported Outcomes (PROs), chatbots, and Language Models (LLMs) for non-invasive data collection. Task T2.2 develops modules for presenting medical information, enhancing patient, caregiver, and professional empowerment. Task T2.3 concentrates on the Mobile Health Application for patients (iOS + Android), integrating smart-band functionalities. The outcomes contribute to MobileCare+'s Alpha version (i.e. D3) for co-creation refinement in collaboration with WP4, leading to the Beta Version (i.e. D4), ready for validation in the clinical feasibility study.

WP3 focuses on developing a deployable solution and back-end functionalities for seamless integration into clinical routines. T3.1 defines a common, semantically interoperable data model based on HL7 FHIR standards. T3.2 deploys advanced security and privacy mechanisms, including cryptographic tools and access controls. T3.3 delivers a backend for physicians' data access, personalization and automation (using CDS hooks) of care workflow (messages, alerts, activities. medication), and communication. T3.4 sets up the decentralized ecosystem, integrating outcomes into MobileCare+'s Alpha and Beta versions (D3, D4).

WP4 focuses on co-creation and real-world evaluation of MobileCare+. T4.1 manages study recruitment, executes a Living Lab co-creation until M12 (D5 report), and T4.2 assesses feasibility (D6 report). T4.2 analyses results through mixed methods, evaluating technical suitability, user experience, and acceptability. Gender and sex-related differences in toolkit usage will be assessed, providing insights for refinement.

WP5 aims to ensure timely and high-quality project results through technical and administrative coordination, along with ethical monitoring. It implements an effective dissemination and communication strategy aligned with the HealthChain Consortium. At M4, a project handbook, encompassing management and communication strategies, will be delivered. The final report at M18 will assess MobileCare+ against non-technical and non-clinical Key Performance Indicators (KPIs), summarizing all activities.

Follower SME

Scope of work performed by the follower SME

The follower SME contributions are divided into Work Packages:

WP1: Focus on requirements and design, participatory design, jointly setting up a co-creation methodology, technical and functional requirements and conceptual architecture.

WP2: Focus on development of the app for patients in corelation with the functionalities supported by the system developed by ZenLab, Developing the modules for presenting medical information, enhancing patient, caregiver, and professional empowerment.

Mobile Health Application for patients (iOS + Android), integrating smart-band functionalities.

WP3: Focus on developing a backend for physicians' data access, personalization and automation (using CDS hooks) of care workflow (messages, alerts, activities. medication), and communication., advanced security and privacy mechanisms, including cryptographic tools and access controls, on top of the ZenLab architecture.

WP4: Focus on co-creation and real-world evaluation of MobileCare+. T4.1 manages study recruitment, executes a Living Lab co-creation until M12 (D5 report), and T4.2 assesses feasibility (D6 report). T4.2 analyses results through mixed methods, evaluating technical suitability, user experience, and acceptability. Gender and sex-related differences in toolkit usage will be assessed, providing insights for refinement.

WP5: Focus on Quality assurance, administrative coordination and ethical monitoring. Implementation of the dissemination and communication strategy aligned with the HealthChain Consortium.

MEPRO - Smart mobile phone application for self-assessment of mental distress

Improving patients' safety by assessing mental distress after surgery.

Surgical Hospital Rožna dolina, Ljubljana, Slovenija is a small surgical hospital, privately own but public financed, with approximately 7000 surgical procedures performed per year. Surgery is mainly oriented to orthopaedic and general surgery.

Challenge description

Mental distress - in this context-levels of mental, physical, and emotional stress can be high before and after surgery (common causes of stress include anything that results in pain, including illness and surgery)- can be alert or sign that patient has medical problems after discharge from hospital and he or she for various reasons does not want to speak about them with family, relatives, or physician. Detecting mental distress in individuals can be challenging because it often involves subjective experiences and emotions. However, there are several signs and indicators that may suggest someone is experiencing mental distress. It's important to note that these signs can vary from person to person, and some individuals may hide their distress, so it's not always easy to detect. There are some pre-screening systems for mental health distress designed to identify individuals who may be at risk for mental health issues or distress. These systems are often used in various settings, including healthcare, education, workplaces, and community organisations, to help assess and support individuals who may need mental health intervention.

According to research conducted by Surgical hospital Rožna dolina, there is no user-friendly mental distress self-assessment mobile phone application in the market that satisfies the demands of hospital (we call patient-oriented view): tailored to be connected with possible medical conditions and in Slovene language.

Although mental distress assessments are typically complex and require detailed evaluation by medical healthcare professionals, mobile version for self-assessment may be the first important step to alert family, relatives, or physicians that patient has medical problems (he or she is not willing to talk about).

Main group of patients: all adult patients discharged from hospital after general or orthopaedic surgery.

An indicator of the quality of life perceived by the patient is the VR-12 (see resources), validated method to measure general perception of quality of life.

Challenge main objectives

The main objective is to improve patient self-assessment and safety after discharge from hospital (and quality of life). As a secondary objective the Challenger also wants to learn the acceptance of tailored medical mobile solutions in elderly and to learn how to easily integrate 3rd party mobile solutions through its corporate IT system. After assessing the mental distress, the application should put the patient in contact with physician or member of family.

Solution functional requirements

Compulsory functional requirements

- The solution shall be user friendly for low digital literacy levels. The content shall be easy to digest by the patients, for example, using pictograms rather than text that captures patient's perspective on their mental condition after surgery.
- The solution shall allow Information exchange between patients and their surgeon.
  - Patient would choose from several templates to create the message, depending on the message type.
  - Doctors should be able to send the same message to patient.
- Calendar management: so, patients and physician can easily add or review patients' medical condition.
- Alert surgeon and family physician and family member that a change in mental condition needs their attention configurable through their channels of communication (smart phone, e-mail, etc.)
- Usable and intuitive for patients.
- When the user starts there will be available an application for local patients developed by Solver that incorporates, among others, user authentication. The new medical application must be called through authentication application, so user identification takes place under maximal safety conditions.
- The Solver application will be available for Android and iOS.

Desirable functional requirements

- Use of AI to recognize facial expression.
- Facilitate access to informative resources for self-empowerment, like documents, and videos. Including on a survey to assess quality of life indicator.
- Medication management. Possibility that doctors incorporate and modify prescriptions.
- Connection with 3rd party devices like smart bands or watches to track day activity and sleep patterns.
- Information summaries and analytics on the available data to empower patients and facilitate better disease management by the patients themselves, in collaboration with their doctor.
- Optimised for multi-device access.
- Including on a survey to assess quality of life indicator (VR-12) and to request and collect the patient outcomes over time.

Pilot scope

After beta version of application is prepared, 30 patients who underwent general or orthopaedic surgery will enrol in the pilot together with two physicians.

Language

- The application must be available in English and in Slovene language as the targeted population is not fluent in English.

Other aspects

- Patient must be owner of smart mobile device (smart phone).

Pilot set-up conditions

Ethical, legal, or regulatory

The approach of the pilot must be previously validated by an Ethics Committee of Medical faculty or National medical ethical board. The Committee will pay special attention to the collection of informed consents of patients by the Solver and the protection of personal data, observing the requirements established by the European data protection Regulation and Slovenian law.

If considered necessary, the Solver will be asked to anonymise the data according to mechanism established by the Challenger. At any case, the Solver cannot exploit or make the data for different purposes than the ones agreed with the Challenger and after pilot end, all copies of the data must be transferred back to the Challenger or deleted.

Technological

The systems and servers needed for running the piloted application will be hosted by the Solver. For safety reasons and data protection the Solver should have back up servers. Technological requirements will be established in a technical session at the beginning of the project.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs.

- Reduction in the number of physical visits of patients: a) to the doctor office at least 10% and b) to emergency room at least 20%.
- Quality of life indicator VR-12 (see resources). Increase of an average one point per month of usage, with a maximum 10 points during the total survey period.

Business opportunity

Market size

At the level of hospital organisation this project will be available in two hospitals with more than 20000 surgical discharges per year. At the national level there are more than 20 hospitals with the surgical units.

Presented application can be extended in a standard way with the same technology to many other pathologies, inside and outside starting hospital, with great possibility of growth.

Adoption plans

We plan to procure and scale up the solution in our organisation if the pilot is successful.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	DITA d.o.o.
DESCRIPTION OF THE SME	DITA was established in 2024 as a spin-off company, by dr. Izidor Mlakar and dr. Bojan Musil with the goal of developing health care solutions that will support a digital transformation of healthcare organizations and the healthcare sector.
WEBSITE URL	www.dita.si

Table 10. Leading SME general information

Solution proposed:

COMPASS: Comprehensive Monitoring and Post-surgical Support System for Physical and Mental Wellbeing.

COMPASS is a comprehensive framework designed to collect digital biomarkers non-intrusively and assess individuals for the risk of mental distress. This innovative system comprises three key components: the mPatient App for patients, the Risk Assessment Model, and the mClinician App for healthcare providers. Real-world data is sourced from diary recordings, physiological biomarkers obtained from smart wearables, and validated instruments like PHQ-9, GAD7, EQ5D 3L, and VR-12. The Risk Assessment Model, serving as the central component, employs (X)AI techniques and traditional AI approaches to analyse data patterns and create personalized risk profiles. Machine learning-based predictive models for mental health will be developed and statistically validated by clinicians.

The mPatient App, brought from TRL4 to TRL7, offers a user-friendly mobile interface presenting data in easily digestible visualizations. It tracks mood swings, well-being, rehabilitation progress, upcoming appointments, and aids in managing physical and mental states. The app includes features such as eConsent, Diary & Care Plan, Message for patient-doctor communication, Knowledge Bank for mental health information, and a Virtual Assistant providing personalized support.

The mClinician App, a web-based solution, aids clinicians in decision-making and optimizing physical visits by providing a back-end interface as a decision support tool. It integrates real-world data collected by the mPatient App, enhancing overall patient care and communication.

The micro-service-based infrastructure supporting these components consists of Apache Camel and Apache ActiveMQ Artemis. Apache Camel facilitates external access to AI and data services, serving as a connection between components, while Apache ActiveMQ Artemis, an MQTT broker, handles internal and external communication. The architecture, verified at TRL7, incorporates REST API implemented with Java and Swagger UI for documentation and testing.

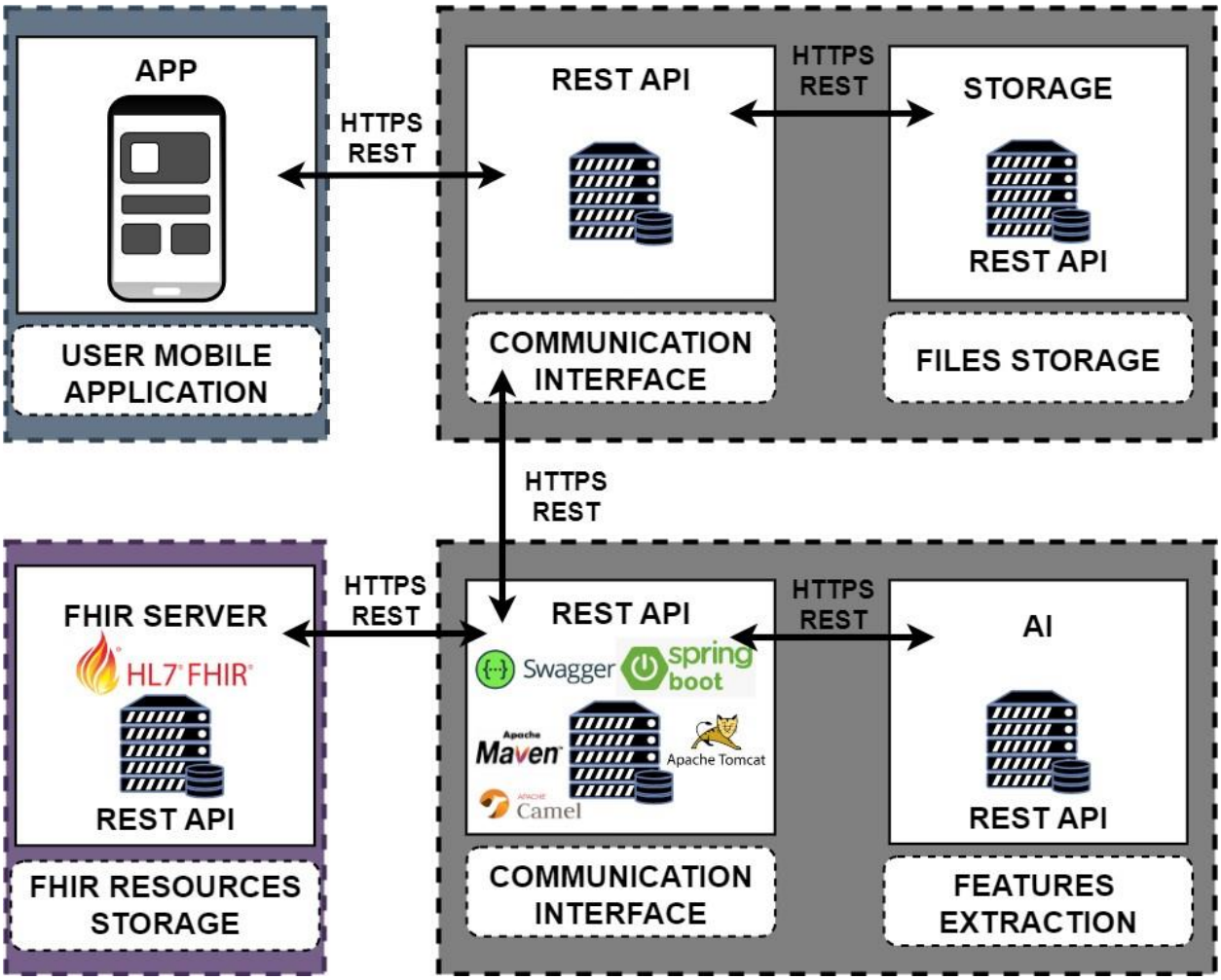

Figure 7. Solution overview diagram

In summary, COMPASS combines advanced technologies, including AI and machine learning, with user-friendly interfaces in the mPatient and mClinician Apps. This holistic approach aims to transform mental health monitoring, empowering both patients and clinicians with real-time data, personalized support, and efficient decision-making tools. The micro-service infrastructure ensures seamless communication and data operations across the entire system.

Work to be done by the leading SME

WP1. Project management and Awareness and Impact building focuses on crucial project management objectives: effective monitoring, adherence to plans, interfacing with EU services, ensuring quality, and risk management. WP1 ensures coordinated efforts, quality assurance, and strategic communication, crucial for successful project implementation.

WP2. Requirements elicitation and design of the study protocols focuses on providing initial understanding on mental health monitoring, post-surgery well-being, and digital intervention practices. Employing the PRISMA methodology, T2.1 analyses existing knowledge, while T2.2 defines use cases with a Patient and Public Involvement (PPI) approach. T2.3 identifies technical requirements and ensures compliance with privacy and security regulations. Outputs include D1 – Requirements, Use Cases, and Studies (M6), encapsulating

stakeholders' needs, COMPASS users, use cases, technical requirements, the initial architecture, and the study initiation package. This comprehensive approach aligns the project with real-world needs and regulatory standards.

WP3. COMPASS Platform Development aims to establish an advanced multimodal sensor network and data model. The goal is to capture features essential for monitoring mental health parameters, empowering patients through educational materials and direct patient-doctor communication. T3.1 focuses on Reference Platform Architecture and Open APIs Specifications, aligning with relevant models (Rest, ReEIF & FIWARE). T3.2 concentrates on developing mHealth & mClinician Apps, emphasizing user interfaces and integrating third-party devices. T3.3, the Risk Assessment Model, delves into knowledge discovery using AI/ML models and comprises of: (i) feature extraction using graph similarity techniques; (ii) feature enrichment, (iii) linking mental health risk prediction and proposing interventions (from the educational library), by employing diverse ML. T3.4 ensures Integration, Data & Security assurance, delivering the COMPASS platform with major releases. Outputs include Technical Architecture (M9), Prototype version for Living Labs (M10), and Beta version (M15) for validation in clinical studies, summarized in D2, at M15.

WP4. Co-creation, Evaluation and Demonstration in Real-World Conditions focuses on Co-creation, Evaluation, and Demonstration in Real-World Conditions. It aims to organize, deploy, and operate living labs, and evaluating the feasibility of the COMPASS solution based on predefined KPIs in real-world pilots. T4.1 ensures Actor & Community Engagement, fostering recruitment success through community-building activities. T4.2 deploys COMPASS Living Labs & Proof-of-Concept, refining technologies through co-creation, leading to a Beta Version. T4.3 coordinates Pilot Roll-out, following study initiation package guidelines, and T4.4 evaluates Pilot Outcome, monitoring technical suitability, GDPR compliance, and KPI results. Outcomes include a Public Engagement Strategy (M10), Evaluation of Living Labs outcomes (M15), and COMPASS Framework and sustainability assessment (M18), summarized in D3.

Follower SME

Scope of work performed by the follower SME

We propose that the Follower SME gets involved in the next tasks:

WP1. Project management and Awareness and Impact building

In collaboration with the leading SME, the follower SME should concentrate effort in:

a) Quality assurance, administrative coordination and ethical monitoring.

b) Implementation of the dissemination and communication strategy.

WP2. Requirements elicitation and design of the study protocols

Technical requirements analyse for the Application (resources needed):

a) Focus on requirements and participatory design.

b) Functional requirements and conceptual architecture.

c) Requirements for IoS and Adroid marketplace distribution.

WP3. COMPASS Platform Development

While the system of the solution will be developed by DITA, we propose that the follower SME will concentrate their effort in:

a) Development of the Application for physicians; backend portal, personalization and automation of care workflow: messages, alerts, activities, privacy control.

b) Development of the patient application, based on the multimodal sensor network and data model system developed by the leading SME.

c) Integration with third-party devices.

d) Ios and Android application store distribution.

e) Joint integration, Data & Security assurance.

WP4. Co-creation, Evaluation, and Demonstration in Real-World Conditions

With the main effort dedicated to:

a) Setting up a co-creation methodology.

b) Support the organisation, deployment and operation of living labs.

c) Community Engagement.

d) Coordinate the pilot Roll-out.

e) Evaluating Pilot Outcomes, monitoring technical suitability, GDPR compliance, and KPI results.

FallPredict

Real-time patient monitoring during independent movements in the Hospital.

KBC Rijeka is one of five clinical hospital centres in Croatia. It is a regional hospital centre covering three counties, providing medical care for approximately 600,000 inhabitants. Consists of 18 clinics, 6 clinical institutes, 6 independent institutes, 2 independent departments and the hospital pharmacy. KBC Rijeka employs more than 3.400 employees, 312 biomedical, and health researchers. The hospital performs activities of health care and diagnostic activities in the field of medicine with more than 3 mill. medical services. KBC Rijeka is a clinical partner for several higher education institutions (HEIs) such as The Faculty of Medicine Rijeka, The Faculty of Health Studies, and The Faculty of Dental Medicine.

Challenge description

Currently, prevention efforts rely heavily on manual supervision by healthcare staff. However, taking into account the number of medical staff (74 nurses working in shifts and 8 caregivers) in the Clinic for cardiovascular diseases and number of beds 53 and 8 special chairs for one day hospital stay (therapy and diagnostic procedures), it's not feasible that each patient is monitored all the time. Although tenders are announced and scholarships are approved, we are faced with an insufficient number of nurses.

To provide continuous and better supervision or assistance for patients who need to go for a walk, use the restroom, etc. implementing a solution that allows for remote monitoring of patients during unassisted movements during hospital stay can bring several significant benefits. It enhances patient safety, reduces the risk of falls and injuries, optimizes staff resources, and improves overall operational efficiency. The hospital benefits from increased patient satisfaction, reduced incidents of adverse events, and a more proactive approach to patient care.

Additionally, the solution contributes to a positive impact on key performance indicators, such as fall incidence rates, patient engagement in physical activities, and overall healthcare quality measures.

In the Clinic for Cardiovascular Diseases of KBCRI, around 20 falls of patients occur in a year. Of all these falls about 15% are serious one with severe injures like bone fractures. With this solution, this number can be reduced, but also if a fall happens nurses will be immediately alerted which can reduce the pain and suffering of the patients as the reaction of medical staff can be quick.

The solution would improve patient hospital experience as their mobility and independence within the hospital environment wouldn't be limited only to their room and bed. It should be noted that only patients who will give approval will wear wearable sensors for fall detection.

Furthermore, in recent years, fall risk assessment has gained prominence with the realization that falls require significant medical attention and can pose significant financial burdens.

Challenge main objectives

The main objective of the challenge is to enhance patient safety by providing a solution that can detect potential falls in real-time. The solution aims to minimize the risk of injuries

resulting from falls and improve the response time of healthcare providers, while at the same time, patients can preserve their mobility and independence within the hospital environment.

Solution functional requirements

Compulsory functional requirements

- The solution shall support and include patient held devices, for example, wearable sensors on the patient or their clothing (e.g. wrist, leg, slippers) to accurately detect changes in posture and movement.
- Wearable sensor for fall detection should be designed with careful consideration of various factors to ensure optimal usability, effectiveness, and user comfort. Following requirements must be achieved:
  - Compact design and lightweight - allowing patients to wear it comfortably without hindering their movements.
  - Comfort and Skin-Friendly Materials: Use soft and hypoallergenic materials to prevent irritation and ensure comfort during prolonged wear.
  - Water Resistance: Sensor should be water-resistant.
  - Battery Life: Sensor should be able to work normally without re-charging or changing batteries for 30 days.
  - Sensor should support wireless connectivity (e.g., Bluetooth) with monitoring system that will be placed in the room for nurses or smartphones of nurses.
  - Language mode: the software should have a possibility to choose the Croatian language.
- The system must have an immediate alerting mechanism that notifies healthcare providers when a potential fall is detected in real-time. Also, it must show the exact location of the patient at the time of alert.
- The system should provide a user-friendly interface for healthcare providers to view real-time data, alerts, and patient information related to fall detection.
- The system should be able to monitor several patients at the same time.

Desirable functional requirements

- It would be good if the sensor can also track number of the steps in certain time interval (6 minutes intervals) by the patients as this data can be used to determine if the patient is feeling healthier and can be discharged from the hospital ("6-minute walk test").

Pilot scope

End-user type	Role	Number
Medical staff (Cardiologists and nurses)	They have to provide requirements, recruit patients, use and validate the solution.	10
Patients	Participate in the pilot and validate the solution.	20

Table 11. Targeted users

Language

- Solution and the whole pilot, including the communication with the end-users will be conducted in Croatian language.

Other aspects

- Solver needs to provide KBCRI with the wearable sensors for fall detection of patients. KBCRI estimates that 5 wearable sensors would be sufficient to conduct the pilots, but other agreements could be reached.

Pilot set-up conditions

Ethical, legal, or regulatory

An Ethics Committee of the KBCRI must previously validate the approach of the pilot. The solution shall be fully GDPR compliant. Solver should familiarize with the Croatian national law and all relevant legal or other documents that regulate healthcare system and IT sector in Croatia as well as European union. The hospital will not take the responsibility or obligation to perform legal/administrative/technical corrections or advises to selected Solvers or options. Solver will be responsible for the innovative solution/product that is not in line with all legal conditions that arrange the healthcare system in EU and/or Croatia.

Technological

The technical solutions are focused on the use of wearables like sensors in smart watch or bracelet devices, to help determine if fall has occurred, and if that statement is true, alert medical personnel about the incident, location of the fall and identification of the patient. Every patient wears a device identified to his/her name, the device is via WIFI connected to the hospital network and registered in the database. On the central console computer, hospital personnel watch the status of every patient in real time. If the fall occurs the smart watch registers the changes in values in its gyroscope and acceleration sensors and sends the alert of possible incident and location of the fall to the central console computer, as well as to the mobile version of the monitoring application on the phone of selected personnel. As the device is registered to the exact patient, in monitoring application we also know the identification of the patient that is subjected to the possible fall incident. Every device is in local hospital network (central console monitoring stations, smart watches, mobile phones, central database server) so the communication between the devices is ensured. As for requirements for this project there are hardware and software parts of the development. As for hardware, central computer monitoring station, mobile phones, smart watches, wireless access points and server is required. For software part, the development of monitoring applications, API (application programming interface) for communication with smart watch sensors, and database management system is needed. Manny commercial smart watches (Samsung, Huawei, Apple watch, etc.) already have fall detection functionality built in as feature, as well as functionality of sending fall detection alarm to predefined locations, so there is no need for developing complex algorithm for measuring data from the sensors, but it is needed to develop monitoring applications that can receive data from communication protocols used by smart watches.

The system doesn't need to be interoperable with our current IS, but if applicable than it should have the possibility to communicate to our HIS over HL7 (Health layer 7) protocol. As for technical solution, we need device on patient that monitors the possible fall in real time, and if fall occurs alarms the personnel of the possible fall. Specified system should be standalone application on local network, but with built in mechanism for communication with other systems in the future over HL7 protocol (sending and receiving HL7 messages).

Data access

Solution will work as a separate system and no data will be extracted from organisational systems, or any other for this solution. The Confidentiality Agreement will be signed between KBCRI and the chosen supplier/solver (SME) of the innovative solution.

Expected impact and KPIs.

To provide continuous and better supervision or assistance for patients who needs to go for a walk, use the restroom, etc. implementing a solution that allows for remote monitoring of patients during unassisted movements during hospital stay at Clinic for cardiovascular diseases can bring several significant benefits. It enhances patient safety, reduces the risk of falls and injuries, optimizes staff resources, and improves overall operational efficiency. The hospital benefits from increased patient satisfaction, reduced incidents of adverse events, and a more proactive approach to patient care.

Additionally, the solution contributes to a positive impact on key performance indicators, such as fall incidence rates, patient engagement in physical activities, and overall healthcare quality measures.

- **Reduce number of fall incidence rate by 10%.** In the Clinic for Cardiovascular Diseases of KBCRI, around 20 falls of patients occur in a year. The goal is to compare patients who will have wearable sensor with group of patients who won't (both groups will be of similar age/health condition) in certain period of time.
- **Reduction in Fall-Related Injuries**: Compare the severity and types of injuries in falls of the patients who have wearable sensor and patients who don't. Goal is to compare if the quick reaction of the medical staff (they receive alert by the solution) can reduce severity of injuries.
- **Patient Satisfaction**: Administer patient satisfaction surveys on the patients who participated in testing (e.g. if they feel better and safer wearing it, does it impact their comfort during the stay, did they feel that the system respected their privacy, did the fall monitoring system impact their ability to engage in daily activities, etc.). Goal is to analyse scores and feedback to assess satisfaction levels. The aim is to have at least 20 patient surveys received and have 60% of positive answers. Likert scale will be used for rating.[4] The satisfaction of the medical staff who will participate in the pilot will be also measured by the survey. The aim is to have 60% of positive answers (Likert scale will be used for rating).

Business opportunity

Market size

- *Internally, the KBCRI is* a regional hospital centre covering three counties, providing medical care for approximately 600,000 inhabitants. Consists of 18 clinics, 6 clinical institutes, 6 independent institutes, 2 independent departments and has the total capacity is 1069 patient beds. More than 45,000 patients are hospitalized annually at the Rijeka Clinical Hospital Center and about 300,000 patient days are realized. This solution can be replicated in other clinics in the KBCRI who have hospitalized patients that are the target group (elderly or frail patients).
- At the national level in Croatia there are thirteen (13) Clinical institutions which include five (5) main Clinical Hospital Centres, there are twenty-two (22) General Hospitals and twenty-eight (28) Special hospitals. There are also a number of private hospitals which are not included in this calculation. According to the last available data (2022.), there were 22.717 beds in Croatian hospitals and 658.189 patients were treated. The market size estimates indicate the potential for substantial revenue and positive impact on

[4] https://www.questionpro.com/blog/what-is-likert-scale/#:~:text=Definition%3A%20A%20Likert%20scale%20is,%2C%20product%2C%20or%20target%20market

patient safety across the Croatian healthcare landscape if the solution proves to be efficient and effective.

Adoption plans

If the pilot project will be successful, our internal decision-making body will decide about the acquisition of the innovative solutions. There is no commitment for KBCRI to adopt or purchase the innovation if successful.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	Full name: Sparky solution d.o.o. Short name: Sparky
DESCRIPTION OF THE SME	Sparky is a data science company based in Croatia, focused on helping organisations leverage the power of their data to gain insights and create value. They are specialized in building custom data solutions, including end-to-end data science services. Sparky's offerings encompass data ingestion, preparation, big data technologies, machine learning, data visualization, and the creation of custom data products. They cater to various industries, including health, finance, telecommunications, media, and sports, providing solutions that enhance customer experience, predictive maintenance, and overall service quality using IoT, big data technologies, and advanced data science techniques. Sparky also offers consulting services and custom data science training for their clients, emphasizing their goal to make data science workflows more accessible to end users and clients. They already have several PoC project in EU market for health industry (development of data science application based on AI and advance analytics).
WEBSITE URL	https://sparky.science

Table 12. Leading SME general information

Solution proposed:

StabilityGuard: Advanced fall prevention system

Our proposal is to jointly co-develop "StabilityGuard", a sophisticated system designed to prevent and detect falls, in conjunction with the KBC Rijeka and the Follower SME which will be awarded through the HealthChain Call for SMEs. By employing state-of-the-art technology to monitor, forecast, and promptly address fall incidents, this system aims to paradigm shift patient safety in healthcare settings. The innovation of StabilityGuard resides in its ability to incorporate novel insights from the domains of healthcare, machine learning, and wearable technology. Through the utilization of real-time data analysis and predictive algorithms, StabilityGuard empowers healthcare providers to proactively avert mishaps, thereby signifying a substantial advancement in the provision of patient care and safety.

Key elements

- **Wearable sensors:** which are discreetly integrated into wristbands (or other bands approved by co-creation organisations), are utilized to continuously monitor the

movements and vital signs of patients. In the prototype phase, preliminary accuracy and comfort tests are being conducted.

- **Monitoring dashboard:** Healthcare providers are able to monitor real-time data from all patients using a centralized dashboard. This dashboard employs intuitive visuals to emphasize any anomalous patterns or potential fall risks. Upon completion of the design phase and UI mock-ups, development is prepared to commence.
- **AI model:** Advance AI model built on sample dataset used for prediction of fall incidents based on provided data. This will add additional insights that will help professionals improve their monitoring process. Upon completion, Ai model is integrated into Monitoring dashboard.
- **Alert system:** Staff are promptly notified by the system in the event of a detected fall or high-risk circumstance, facilitating an expeditious response. It contains provisions for escalation and, if required, communication with emergency services. Upon completion of the phase, integration with the interface and wearable sensors is being done.

In order to implement the analytics component, specifically the algorithm for fall prediction, our configuration entails assembling a heterogeneous dataset from the ubiquitous sensors across a range of conditions.

Included in the validation strategy are:

- Cross-validation is a machine learning approach that verifies the algorithm's performance across various subsets of data.
- Real-world pilot testing involves the implementation of the system among a controlled cohort of patients in order to collect feedback and make algorithmic refinements.
- Performance metrics involve the assessment of the algorithm's specificity, sensitivity, and accuracy in the detection and prediction of falls.

By implementing this all-encompassing strategy, StabilityGuard surpasses the benchmarks set for effectiveness and innovation in healthcare fall detection and prevention.

Work to be done by the leading SME

1. Project coordination and risk management: Sparky will arrange and oversee the kick-off meeting to establish the project's scope and objectives, as well as plan frequent progress meetings to support decision-making and monitor project advancement. Sparky will detect potential dangers at an early stage of the project's lifespan and create strong measures to counteract these risks. This will encompass both technical and operational hazards, guaranteeing thorough coverage.

2. Technological development: Sparky will take charge of creating and enhancing interfaces that are easy to use and meet the requirements of different users, including healthcare professionals and patients. Also, the goal is to create the fundamental StabilityGuard system, integrating an efficient alarm mechanism to promptly inform personnel of potential fall hazards in real-time. Sparky will construct and enhance a sophisticated AI model that utilizes the given data to precisely forecast occurrences of falls. This process entails the careful selection of appropriate algorithms, training the model using a wide range of data sets, and seamlessly integrating it into the StabilityGuard system.

3. Testing and evaluation: Sparky will deploy the StabilityGuard system in a controlled setting to assess its functioning and ease of use. Also, it will guarantee the efficient functioning of the system in various healthcare environments. Evaluation of the performance data will be done,

in relation to predetermined KPIs to determine the efficiency and dependability of the system. This analysis will provide guidance for additional optimizations and changes.

4. Stakeholder engagement and feedback: Sparky will organize extensive workshops including crucial stakeholders, to collect vital requirements and design suggestions. It will also collect and incorporate feedback from participants in a systematic manner during the pilot period to improve the system, with a specific focus on boosting user satisfaction and system performance.

5. Compliance and regulatory adherence: Sparky will oversee and guarantee adherence to all pertinent health data protection requirements, such as GDPR. Also, it will facilitate the preparation steps for the acquisition of essential regulatory approvals and certifications that are vital for implementing medical technologies in healthcare environments.

6. Maintenance and ongoing support: Sparky will create a strategy for continuous maintenance and updates of the StabilityGuard system to guarantee its efficiency and security against new threats. It will deliver extensive training and assistance to end-users, guaranteeing that healthcare providers possess the necessary skills to utilize the system proficiently.

Follower SME

Scope of work performed by the follower SME

1. Project management and compliance: Follower SME will provide assistance in project management by actively engaging in meetings and contributing to decision-making processes. This entails collaborating with Sparky and other partners to guarantee the timely achievement of all project milestones. It will offer specialized knowledge and guidance regarding adherence to healthcare regulations and standards. The follower SME will guarantee that the StabilityGuard system complies with all pertinent local and international regulatory prerequisites, such as GDPR, hence enhancing the project's credibility and feasibility.

2. Technological support and system enhancement: Follower SME will enforce efficient data management policies to guarantee that the data gathered by StabilityGuard is handled, kept, and utilized in accordance with the most stringent data protection and privacy regulations. It will strengthen the security framework of the StabilityGuard system to protect sensitive patient data from unauthorized access and potential cyber threats. It will also. aid in the seamless integration of the StabilityGuard and its components into pre-existing healthcare IT ecosystems. This involves assuring interoperability with EHR systems and other platforms for managing healthcare.

3. Solution validation: Follower SME will perform thorough testing of the StabilityGuard system, with a specific emphasis on usability, security, and performance, to verify that the system fulfills all given requirements. It will conduct periodic quality assurance audits to protect the system's integrity. Revise the risk management plan as required, taking into account the results of these evaluations and any additional hazards discovered during the testing stage.

4. Engagement and training: Follower SME will organize supplementary stakeholder engagement activities to obtain wider input and feedback on system development. This entails coordinating workshops and meetings in addition to those led by Sparky in order to guarantee thorough engagement of all stakeholders. It will also create customized training resources based on feedback to address the individual requirements of users. Assist in conducting training sessions to ensure that healthcare personnel and patients acquire the necessary skills to effectively utilize the StabilityGuard system.

MediLink

Facilitating communication between specialists and family doctors in remote areas.

KBC Rijeka is one of five clinical hospital centres in Croatia. It is a regional hospital centre covering three counties, providing medical care for approximately 600,000 inhabitants. Consists of 18 clinics, 6 clinical institutes, 6 independent institutes, 2 independent departments and the hospital pharmacy. KBC Rijeka employs more than 3.400 employees, 312 biomedical, and health researchers. The hospital performs activities of health care and diagnostic activities in the field of medicine with more than 3 mill. medical services. KBC Rijeka is a clinical partner for several higher education institutions (HEIs) such as The Faculty of Medicine Rijeka, The Faculty of Health Studies, and The Faculty of Dental Medicine.

Challenge description

KBCRI Rijeka is the main clinical centre for the Primorsko-Goranska region. This region, due to its geographical location, has a lot of remote areas that include settlements in the surrounding mountain areas as well as the islands in the northern Adriatic Sea. Some of these areas as up to several hours drive from the KBCRI, which represents a significant problem for the local population when they need to visit a specialist. KBCRI already has agreements with some of the Health Centres in remote areas for the so-called “dislocated infirmary” where specialists from the KBCRI visit these remote health centres (usually two times a month) to provide services. One of the aims of the KBCRI Strategy 2021 – 2025. is to further develop these “dislocated infirmary” as well as to enhance cooperation with family doctors in individual and long-distance cooperation (telemedicine).

A remote telemedicine platform, portal, or application that would facilitate communication between specialists (cardiologists in KBCRI) and family doctors who are treating patients in remote areas would directly contribute to the objective stated in the KBCRI Strategy 2021 – 2025.

Furthermore, Heart failure (HF) remains a major medical problem in Croatia and represents a heavy economic burden for hospitals In Croatia. Diseases of the circulatory system are in first place as a cause of death (39.1%). Among the first 10 causes is ischemic heart disease with 12.2%. At the age >65 years, diseases of the circulatory system cause a mortality rate of 42%. When talking about Heart Failure and knowing that the prevalence is 1-2% in adult population worldwide, there are 31.000 to 62.000 people living with Heart Failure in Croatia. Detecting HF patients before their health deteriorates or needs hospitalization would be of great value for patients and the KBCRI.

Improved communication among specialist and primary care has the potential to improve patients’ access to specialized care, enhance the efficiency of patient referrals, reduce delays in treatment, and ultimately contribute to better health outcomes for residents in remote areas of the Primorsko-Goranska region.

Challenge main objectives

The main objective of the challenge is to establish a comprehensive and efficient telemedicine system that connects cardiologists from the hospital in Rijeka with family doctors in remote areas of the Primorsko-Goranska region. This solution aims to enhance access to specialized

cardiac care in remote locations, improve collaboration between healthcare professionals, and ultimately contribute to better health outcomes for patients with cardiovascular conditions.

Solution functional requirements

Compulsory functional requirements

- The solution shall be a platform, portal, or application. It must provide secure communication for real-time video conferencing, secure messaging, and collaborative discussions between specialists, patient, and family doctors. By talking with the family doctor and the patient at the same time, we can better and better learn more about the patient's condition, the way of treatment so far and how to improve the patient's condition, reduce hospitalizations and reduce the need to come to the hospital from distant places. Family medicine doctors have a way to send a referral to the computer system under the name of consultation and thus receive a specialist (cardiologist) report in writing based on an audio-video examination.
- The solution shall have an intuitive and user-friendly interface to ensure ease of use for both specialists and family doctors.
- The system should work as an individual solution and will not be integrated with existing hospital or health centre IT systems.
- The solution shall be scalable to accommodate potential increases in user numbers (so that several different video calls can be done at the same time).
- Language mode: the software should have a possibility to choose the Croatian language.
- The solution shall have the option to send/receive sound data (e.g. family doctor can use a digital stethoscope to record the heart or lungs of the patient and send it to the specialist to assess a patient who is not physically present). This will be the digital way of patient physical examination. The solution shall include an interface for collaboration between two or more remote locations, exchange of medical documentation (HIS,PACS,LIS), as well input for digital transmission of health and vital signs of the patient on the remote location (remote stethoscope, remote thermometer, etc.).
    - Inclusion of data gathered from stethoscope and thermometer is a must, and this functionality's must be integrated in the solution.
    - The solution must ensure integration of third-party medical equipment in that application (stethoscope, thermometer), and compliance with health communication standards (HL7, DICOM) for exchange of medical data records over digital source.

Pilot scope

End-user type	Role	Number
Cardiologists from the KBCRI	They have to provide requirements, recruit family doctors, use and validate the solution.	5
Primary care doctors (family doctors) in the branches of the Primorsko-Goranska Healthcare Center	They have to provide requirements, recruit patients, use and validate the solution.	5
Patients	Participate in the pilot and validate the solution.	25

Table 13. Targeted users

Language

- Solution and the whole pilot, including the communication with the end-users will be conducted in Croatian language.

Pilot set-up conditions

Ethical, legal, or regulatory

An Ethics Committee of the KBCRI must previously validate the approach of the pilot. The solution shall be fully GDPR compliant. Solver should familiarize with the Croatian national law and all relevant legal or other documents that regulate healthcare system and IT sector in Croatia as well as European union. The hospital will not take the responsibility or obligation to perform legal/administrative/technical corrections or advises to selected Solvers or options. Solver will be responsible for the innovative solution/product that is not in line with all legal conditions that arrange the healthcare system in EU and/or Croatia.

Technological

As for technical solution, the best secure practice is to use some form of teleconferencing systems available for communication between the nodes (remote locations). Teleconferencing systems use specialized SIP and H.323 communication protocols that are robust and ultimately secure, as well as compatible with today standards in video quality (HD, 4k, 8K). The communication can be peer to peer, or over telemedicine network, but both communication options must be available out of the box. The teleconferencing systems already comes with HD/4K cameras, as well with daisy chain microphones and speakers, but there must be one other input source to the teleconferencing system, and that is computer with custom application designed for interaction between doctor and patients. On that application. On hardware side, requirements are teleconferencing systems with cameras speakers and microphones, network devices, input computers, large LCD screens and remote stethoscope and thermometers.

System needs to be scalable; it needs to have peer to peer communication between the remote nodes and needs to have capabilities for data sharing between the remote nodes. Communication must be in audio and video format of the highest standard (minimum HD quality), and data sharing for medical equipment between nodes must be assured by the software. Medical equipment that must be compatible and integrated in the system is remote stethoscope and remote thermometer.

Data access

Solution will work as a separate system and no data will be extracted from organisational systems, or any other for this solution. After such audio video consultation, the specialist and the family doctor will be able to make conclusion regarding patients' health. The medical report will be written and visible in digital form as a specialist report or consultation. Also, the Ethic Committee should give the agreement. The Confidentiality Agreement will be signed between KBCRI and the chosen supplier of the innovative solution.

Expected impact and KPIs.

The solution has the potential to improve access to specialized care, enhance the efficiency of patient referrals, reduce delays in treatment, and ultimately contribute to better health outcomes for residents in remote areas of the Primorsko-Goranska region.

- Number of successful specialist -family doctor communications facilitated through MediLink. Goal is to have more than twenty-five (25) successful specialist-family doctor communications facilitated through MediLink.
- Enhance the efficiency of patient referrals and reduce unnecessary expenses for the patients and hospital. Goals is to reduce number of patients that after the teleconsultations will have to come to the hospital by at least 7%. The KPI will be measured by determining the percentage of patients who participated in the trials and did not need to physically visit the hospital from the total number. (Total number of patient who didn't need to visit hospital due to the solution / Total number of patients in the trials *100).
- Patient and doctors' satisfaction: Administer patient satisfaction surveys on the patients who participated in testing (e.g. how satisfied were they with this kind of service, did the teleconsultation saved them time and money compared to physically traveling to the hospital, were they comfortable discussing their health concerns through the teleconsultation platform, how would you improve it, etc.). Goals is to analyse scores and feedback to assess satisfaction levels. The aim is to have at least 20 patient surveys received and have 60% of positive answers (Likert scale[5] will be used for rating). Also, the satisfaction of the doctors involved in the trials will be assessed to receive feedback and make improvements if possible. The satisfaction of the doctors who will participate in the pilot will be also measured by the survey. The aim is to have 60% of positive answers (Likert scale will be used for rating).

Business opportunity

Market size

- Internally, KBCRI Rijeka is the only clinical centre for the Primorsko-Goranska region. This region, due to its geographical location, has a lot of remote areas that include settlements in the surrounding mountain areas as well as the islands in the northern Adriatic Sea. Some of these areas are up to several hours drive from the KBCRI, which represents a significant problem for the local population when they need to visit a specialist. KBCRI already has agreements with some of the Health Centres in remote areas for the so-called "dislocated infirmaries" where specialists from the KBCRI visit these remote health centres (usually two times a month) to provide services. One of the aims of the KBCRI Strategy 2021 – 2025. is to further develop these "dislocated infirmaries" as well as to enhance cooperation with family doctors in individual and long-distance cooperation. Therefore, there is a significant potential to expand and replicate this solution outside Clinic for Cardiovascular diseases, as there are other clinics (Clinic for Cardiovascular diseases is one of the 18 clinics in KBCRI) that are also cooperating with the Health centre of Primorsko-Goranska county and their branches through the "dislocated infirmaries".
- There is also significant potential at the national level in Croatia as many Health centres in Croatia are dealing with lack of specialists (especially smaller and remote places like islands and rural areas). According to the Croatian Ministry of Health, there are currently 63 Health centres in Croatia (not including branches of County Health Centres) and most of them would have benefited from this solution as well as their patients. Furthermore, this solution can be also adapted to the communication between doctors in different hospitals/clinical centres (not only specialists with family doctors).

[5] https://www.questionpro.com/blog/what-is-likert-scale/#:~:text=Definition%3A%20A%20Likert%20scale%20is,%2C%20product%2C%20or%20target%20market

Adoption plans

If the pilot project will be successful, our internal decision-making body will decide about the acquisition of the innovative solutions. There is no commitment for KBCRI to adopt or purchase the innovation if successful.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	Bit4bytes d.o.o.
DESCRIPTION OF THE SME	Bit4bytes is a versatile Design and Development Agency, comprising a creative team of developers, designers, and strategists committed to guiding companies across platforms and places with agile design and digital experiences. Our expertise extends to crafting innovative solutions for the healthcare industry, including a platform designed for elder care with monitoring and smart devices integration.
WEBSITE URL	www.bit4bytes.com

Table 14. Leading SME general information

Solution proposed:

Bit4Health (B4H)

Introducing an advanced healthcare communication platform designed to deliver specialized cardiac care, this solution focuses on enhancing remote consultations, collaboration, and patient outcomes. Here are the key features:

- **Comprehensive Telehealth Platform**

The solution is a secure and user-friendly platform offering real-time video conferencing, secure messaging, and collaborative discussions between specialists, patients, and family doctors.

It facilitates simultaneous consultations with family doctors and patients, providing insights into the patient's medical history, ongoing treatment, and potential improvements to optimize care.

- **Intuitive Interface**

Boasting an intuitive and user-friendly interface, the platform ensures ease of use for both specialists and family doctors, promoting seamless communication and collaboration.

- **Independent Solution**

Designed as a standalone system, the platform operates independently, eliminating the need for integration with existing hospital or health center IT systems. This ensures a flexible and efficient solution.

- **Scalability**

The solution is scalable to accommodate a growing user base, allowing multiple concurrent video calls to take place. This ensures flexibility and adaptability to evolving healthcare needs.

- **Collaboration Interface**

A built-in interface facilitates collaboration between remote locations, enabling the exchange of medical documentation (HIS, PACS, LIS).

- **Data Integration and Standards Compliance**

Ensures inclusion of data gathered from stethoscopes and thermometers, seamlessly integrating these functionalities into the solution.

Supports the integration of third-party medical equipment, such as stethoscopes and thermometers, and complies with health communication standards (HL7, DICOM) for secure exchange of medical data records over digital sources.

This healthcare communication platform aims to bridge the gap in specialized cardiac care, promoting collaboration, accessibility, and improved health outcomes for patients in remote locations.

Work to be done by the leading SME

- **Analysis**: Identify and document the specific requirements and objectives of the pilot project.
- **Design**: Design prototype based on the specific requirements and objectives.
- **Development**: Development based on a designed and specified prototype.
- **Delivery**: Deployment of the solution within the real environment.
- **Support**: Completion of user training sessions to ensure healthcare staff are proficient in using the solution. Support while using the solution, fixing bugs, and maintaining the solution.

Task/month	1	2	3	4	5	6	7	8	9	10	11	12
Analysis with the user												
Design protoype												
Development												
Delivery												
Support												

Table 15. Bit4Health Gantt Chart

Follower SME

Scope of work performed by the follower SME

1. **Functional Testing:**

Verifies that the communication platform performs its intended functions accurately and efficiently.

2. **Usability Testing:**

Evaluates the communication platform's user interface (UI) and user experience (UX) to ensure it is intuitive and user-friendly for healthcare professionals.

Involves conducting tests with end-users to gather feedback on navigation, workflow efficiency, and overall satisfaction.

3. **Performance Testing:**

Assesses the communication platform’s performance under various conditions, including peak usage, to ensure it can handle the expected workload without slowdowns or crashes.

Measures factors such as response time, throughput, and resource utilization to identify any performance bottlenecks.

4. **Security Testing:**

Focuses on identifying vulnerabilities and ensuring the communication platform's resistance to unauthorized access, data breaches, and cyber threats.

DIGICARE - AWARE

We need a solution to create more awareness amongst healthcare professionals about the necessity and possibilities of remote patient monitoring and the Virtual Care Center and to also activate them to make more use of remote patient monitoring. The goal is to scale up remote patient monitoring to further realize transformation of healthcare to make it futureproof. We want to contribute to a culture change.

Rijnstate is a teaching hospital in the Netherlands and offers inpatient and outpatient services in 28 medical specialties, as well as emergency care, with a special focus on oncology, immunology, vascular care, and vulnerable elderly. Approximately 5,500 employees work at Rijnstate. Together they focus on the 450,000 residents in the service area. This makes them one of the largest healthcare providers in the Netherlands and the largest employer in the region.

Rijnstate wants to be at the forefront of innovation. That is why we are constantly working on ways to noticeably improve ourselves and our services. And if we believe that something can indeed lead to better care, then we really go for it. We want to realize innovations that are tangible, so we focus on evidence development of innovations in daily clinical practice. To make our care increasingly pleasant, flexible, and effective on all fronts. On a very human level. In other words: for you.

Challenge description

Creating awareness on remote patient monitoring

Rijnstate has already implemented the means for remote patient monitoring, which means that care is only given physically in the hospital if necessary and at the home setting when possible. Rijnstate has a Virtual Care Center for this, which is a department of specialized nurses who are responsible for the remote patient monitoring. Remote patient monitoring is necessary to keep healthcare accessible with the growing demand for healthcare and the decreasing number of healthcare professionals.

We need to create more awareness amongst healthcare professionals about the possibilities of remote patient monitoring and the Virtual Care Center to achieve upscaling this kind of care transformation for more patients, by more healthcare professionals and for more patient populations. We are continuously increasing the number of care pathways with remote patient monitoring, but so far only a relatively small group of healthcare professionals makes use of this. To really transform healthcare, we need the majority of healthcare professionals to understand the necessity and know the possibilities. The question is how we can reach and encourage a large group of healthcare professionals (Rijnstate has ~3500 healthcare professionals).

What is the difficulty to scale up?

There are a variety of reasons for the limited awareness (of the added value of) or use of remote patient monitoring. For some healthcare professionals it might be unfamiliarity with the possibilities and/or with the added value (for patients or themselves). For others it might be fear of change, high workload, limited digital skills, limited financial compensation. Often there is insufficient time to invest in a new innovation, neither for the implementation nor for the adoption of innovations such as remote patient monitoring.

What solution do we want?

This challenge requires a solution to create awareness about the added value and possibilities of remote patient monitoring among healthcare professionals in a clear and attractive way for which limited time investment is needed. The goal is to create awareness to increase motivation and use of remote patient monitoring for their patient population(s). The solution needs to include information about the necessity and the possibilities, and it needs to activate them to start/increase using remote patient monitoring. It should be encouraging to a large group of healthcare professionals of distinct roles and various levels of knowledge and (digital) skills. Most importantly, it should be suitable for healthcare professionals who are experiencing a remarkably high workload and tight working schedules.

The goal

A solution to create awareness to increase motivation and use of remote patient monitoring is essential for upscaling to contribute to transforming healthcare to make it futureproof. What we need is a culture change. We can use a creative solution to get there.

If we find a solution, then there will be a lot of potential to expand it to create awareness of other innovations and digital tools. This can have a significant impact.

Challenge main objectives

The main objective is to scale up remote patient monitoring for more patients, by more healthcare professionals and for more patient populations to transform healthcare to make it futureproof. To achieve this, we need to create more awareness amongst a larger group of healthcare professionals in Rijnstate about the necessity and the possibilities of remote patient monitoring and the Virtual Care Center. We need to encourage and activate them to start/increase using remote patient monitoring. We want to achieve a culture change.

Solution functional requirements

Compulsory functional requirements

- The solution shall take little time for healthcare professionals to use. It shall be suitable for healthcare professionals who are experiencing an extremely high workload and tight working schedules.
    - This could mean that the solution shall be brought to healthcare professionals (e.g., at their departments or computers) instead of asking the healthcare professional to go somewhere for the solution.
    - This also means that the solution shall be flexible regarding availability. It shall not be at set times, because many healthcare professionals do not have breaks at predefined times.
- The solution shall be applicable to a large group of healthcare professionals. Rijnstate has ~3500 healthcare professionals and we want to reach as many as possible. It doesn't have to reach all healthcare professionals at once, it can be phased.
- The solution shall be appealing to distinct roles of healthcare professionals (physicians, nurses, doctor's assistants, team managers). These are mostly practical people, so the solution should also be practical.
- The solution shall be appealing to various levels of knowledge (of remote patient monitoring) and (digital) skills.
- The solution shall be able to give information about the necessity and possibilities of remote patient monitoring but shall also have an element to activate healthcare

professionals to start using remote patient monitoring (a call to action). It must contain an adoption plan, which also addresses existing fears about this new way of working.
- The solution shall be proven effective (not necessarily in healthcare organizations).
- The solution shall be scalable to other innovations or digital tools.
- It shall be clear from the start what it will cost to scale up the solution after the pilot.

Desirable functional requirements

- The solution shall be tailored to the Rijnstate corporate identity if applicable.

Pilot scope

In the pilot we can start with the solution at two departments: one inpatient and one outpatient department.

End-user type	Role	Number
Healthcare professionals of an inpatient department (physicians, nurses, doctor's assistants, team managers)	Target group of the solution	*Depending on the department*
Healthcare professionals of an outpatient department (physicians, nurses, doctor's assistants, team managers)	Target group of the solution	*Depending on the department*

Table 16. Targeted users

Language

- The solution and the pilot must be in Dutch for the target group.

Pilot set-up conditions

Ethical, legal, or regulatory

- The solution must be fully GDPR compliant.
- The privacy and security of the solution must be approved by the Compliance & Risk department of the hospital.

Technological

- The solution (if it is a digital solution) shall be stand-alone, independent of the hospital's existing systems.
- The solution (if it is a digital solution) shall be approved by the IT-department.

Other

- The solution must be in line with the Rijnstate corporate identity and approved by the Communication department.

Expected impact and KPIs.

- Increase in the use of remote patient monitoring for existing care pathways, expressed by an (irregular) increase in patient inclusions.
- Increase in the number of requests to implement remote patient monitoring for care pathways that do not contain remote patient monitoring yet.
- A participation percentage of at least 50% of the targeted departments.
- User satisfaction of the solution: on average a positive result.

The expected impact and KPIs can be further detailed before the start of the pilot, depending on the solution. The “before”-situation to further specify the expected increases can be measured before the start of the solution.

Business opportunity

Market size

There is potential to extend the solution to create awareness of other innovations and digital tools within the hospital. Rijnstate is an innovative hospital, so creating awareness and activating a large group of healthcare professionals will always be applicable and necessary.

In addition to the use within Rijnstate, there could also be an opportunity for a supplier of the solution to scale it to the region (e.g. primary care), other hospitals (e.g. start within the mProve network of 7 hospitals or regional hospitals) and other large companies (if the solution is not health-specific). The problem of how to activate a large group of people into adapting an innovation is broadly applicable.

Adoption plans

If the solution is successful, we plan to scale up the solution to use for creating awareness for other innovations and digital tools.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	Buro StrakZ
DESCRIPTION OF THE SME	Buro StrakZ focuses its work on the future of healthcare and is the expert on the theme of healthcare technology and digital skills. Buro StrakZ's focus is on healthcare professionals. How do they demonstrate agility and willingness to change? What competencies do they need to tackle the challenges in healthcare and continue to provide high-quality and innovative warm care? We make learning and innovation fun and effective with various training courses and products.
WEBSITE URL	www.burostrakz.nl

Table 17. Leading SME general information

Solution proposed:

Let's get digital!

Rijnstate needs a solution to create more awareness amongst healthcare professionals about the necessity and possibilities of remote patient monitoring and the Virtual Care Center and to also motivate and activate them to make more use of remote patient monitoring. The goal is to scale up remote patient monitoring to further realize transformation of healthcare to make it futureproof. We want to contribute to a culture change. Rijnstate is **not** looking for a new technical solution. It's all about a cultural change to digital healthcare.

Buro StrakZ will organize creative sessions to thoroughly explore what healthcare professionals need, what success factors of change management need improvement and which solutions can contribute to the goal. As a result, a program of solutions to further scale up remote patient monitoring will be created and implemented.

Work to be done by the leading SME

We go through various steps to arrive at an effective program to further scale up digital care. Our goal is a program that is scalable for other programs about digital healthcare and other hospitals.

- **Presentation of current approach.** Insight into the current approach and the interventions that have already been done and to what results they have led.

  Result: view of initial situation.

- **Working session on the success factors**. A presentation for those involved about the success factors of involving employees in digitization. An analysis is made of these success factors in the Rijnstate hospital. In addition, the implementation tips from the book 'Een tikje blauw en een kloddertje roze' are examined.

Result: this, together with the success factors in the working method, leads to a strength-weakness analysis.

- **Peeking at the neighbours, exploring other hospitals**. Buro StrakZ explores other hospitals for effective elements and solutions. This is done through online interviews. Buro StrakZ processes this in a short advisory report. Brainstorm employees supplemented with wise neighbours. Based on the strength-weakness analysis, Buro StrakZ prepares a number of brainstorming questions. During a session with a varied group from the hospital, an out-of-the-box working method is supervised. Participants are challenged to come up with unusual solutions to existing challenges. After a reversal method, this leads to more realistic, feasible ideas.

  Result: a wall of ideas.

- **Processing brainstorming solutions**. In a small committee, the solutions devised are analysed and it is explored which solutions can contribute to the desired goal. The results from the preliminary exploration are included in this.

  Result: chosen ideas for a communication plan.

- **Program design**. The program is developed together with the project group and the devised solutions are designed and prepared.

  Result: this leads to an action plan.

- **Testing solutions with stakeholders**. The plans are presented in a session with stakeholders. Participants may provide feedback and ask questions.

  Result: feedback.

- **Session processing feedback**. The feedback is processed into an action plan by the project group led by the project leader.

  Result: new plan.

- **Designing solutions and shaping communication campaign**. Everything is prepared for the start of the program.

  Result: communication campaign

- **Baseline measurement of the use of digital care**. A baseline measurement is taken to explore the starting point. How many departments currently provide digital care to how many patients?

  Result: baseline assessment.

- **Implementing solutions**. The implementation of the program is starting. Ambassadors are deployed in the workplace for this purpose. They are briefed in advance.

  Result: kick-off and implementation.

- **Evaluating solutions**. After 1 week, 1 month and 3 months, an interim evaluation of the program takes place and adjustments are made if necessary.

  Result: evaluation and steering information.

- **Final measurement**. After the agreed pilot period, we take a new measurement to measure objective results.

  Result: rapport.

- **Coaching project leader and innovator**. Use of coaching hours during this entire process.

Result: knowledge and feedback.

Follower SME

Scope of work performed by the follower SME

For the role of follower SME, we are looking for a design company. Due to the way that the solution of the leading SME (Buro Strakz) is set up, it's not known yet what should be designed. The result of the solution of Buro StrakZ will be a program of solutions, which can take different forms. This means that we need a follower SME who is versatile and flexible in their design skills. We will need multiple solutions, which could be both online and offline and could for example range from an old-school poster to an out-of-the-box innovative design.

The goal of the designs will be to make healthcare professionals enthusiastic about monitoring@home, to contribute to a culture change. So, it is important that the follower SME is experienced in change communication and understands user experience. They should also be experienced with internal communication since this is very different from external communication.

Moreover, what is important to realise is that the content will be produced by the leading SME together with Rijnstate. So, the follower SME has a more executive role and is not the one who comes up with e.g. a communication strategy or the contents of a campaign. That is why we are looking for a design company and not a communication company.

Requirements:

- Demonstrable designing specialist(s) (we would like to see examples of previous experience in the proposal).
- Experience within healthcare.
- Knowledge of internal change communication (not only external change communication).
- Knowledge of user experience.
- Innovative, versatile and flexible with a broad range of (digital) design skills.
- Sustainable solution.
- The content that will be created must be owned by Rijnstate. That means all content should be made freely available to Rijnstate, during and after HealthChain, and Rijnstate must receive the rights for the source data.
- The solution must be accessible.
- The solution must be in accordance with Rijnstate's corporate identity and policy.
- The solution must be in line with current initiatives for internal communication and the content that has been devised by Rijnstate and the leading SME.
- The solution can be both online and offline.
- The material that is used must be royalty-free in The Netherlands.
- The solution has to be fully compliant with the GDPR, ISO27001, NEN 7510, NEN 7512 and NEN 7513.
- Servers used for data storing have to physically be located within Europe (also back-up servers).

- Any privacy, security and technical aspects of the solution have to be approved by the Compliance & Risk department and Information & Medical Technology department of Rijnstate.
- All proposed solutions must be approved by Rijnstate in terms of feasibility and all aspects mentioned above before development, especially in case of online solutions.

DELSIS (Determine the Extent of Lifestyle Support to Increase Self-management)

We need an efficient way to determine the extent of lifestyle support that a patient needs to stimulate their self-management. Where one might only need a hyperlink to a website, the other might need a full coaching program. With the right extent of support, unnecessary demand for healthcare can be reduced, which is essential to keep healthcare accessible in the future.

Rijnstate is a teaching hospital in the Netherlands and offers inpatient and outpatient services in 28 medical specialties, as well as emergency care, with a special focus on oncology, immunology, vascular care, and vulnerable elderly. Approximately 5,500 employees work at Rijnstate. Together they focus on the 450,000 residents in the service area. This makes them one of the largest healthcare providers in the Netherlands and the largest employer in the region.

Rijnstate wants to be at the forefront of innovation. That is why we are constantly working on ways to noticeably improve ourselves and our services. indeed, we believe that something can indeed lead to better care, then we really go for it. We want to realize innovations that are tangible, so we focus on evidence development of innovations in daily clinical practice. To make our care increasingly pleasant, flexible, and effective on all fronts. On a very human level. In other words: for you.

Challenge description

Increasing patients' self-management

Because of the growing demand for healthcare and the decreasing number of healthcare professionals, transformation is necessary to guarantee accessible and affordable healthcare in the future. This means, among other things, moving hospital care to the home setting and increasing patients' self-management. In other words, facilitating patients to be able to longer and better take care of themselves at home and only get professional care (physically or at a distance) when it is necessary. An important aspect of self-management is to promote a healthy lifestyle, e.g., healthy nutrition and physical activity.

What is the difficulty?

Rijnstate already started various initiatives to increase patients' self-management, such as education as part of remote patient monitoring and a lifestyle front office ("Gezondheidsplein"), in which lifestyle coaches, nurses and physicians help patients to improve their health and prevent (worsening of) diseases. An important part is to find the right way of supporting a patient, one that meets the needs of that particular person. One patient might prefer a hyperlink to a website with the right information, while the other might need a full coaching program. There are plenty of support possibilities, but we lack an efficient way to determine *the extent* of lifestyle support that a patient requires.

If patients receive too little guidance, then their self-management will not increase, and patients will need more professional care than strictly necessary. If patients receive too much guidance (e.g., many patients are unnecessarily referred to the lifestyle front office), then there is also too much demand for professional care than strictly necessary, which is not an efficient

use of healthcare staff. To keep healthcare accessible in the future, we need to find a way to support patients in a way that is tailored to the patient's needs.

What solution do we want?

We want a tool or method to determine the extent of lifestyle support that a patient needs. We do not have capacity to manually determine this for each patient in a conversation with a healthcare professional, so we need a digital tool, or a method combined with our existing digital tools that can facilitate this. The extent of support will mostly depend on the level of (digital) health literacy. It has to be a solution that is easy to use for patients of all levels of health literacy and digital skills. The solution should not contain the lifestyle support itself, because we already have existing methods. It should only contain the triage to determine the extent of support that is needed.

The goal

The goal is to assess the extent of lifestyle support patients need in order to tailor the way the support is given. In this way, we want to increase patients' motivation to improve their lifestyle and self-management. This should contribute to decrease/prevent further increase of the demand for healthcare, which is essential to guarantee accessible and affordable healthcare in the future.

Challenge main objectives

The main objective is to improve patients' self-management by providing the right extent of lifestyle support that fits patients' needs. We need a solution to automatically determine the *extent* of support that is needed, so not the content of the support but the support process. By increasing self-management, we aim to decrease unnecessary healthcare demand in order to guarantee access to healthcare in the future.

Solution functional requirements

Compulsory functional requirements

- The solution shall determine the extent of lifestyle support that a patient needs. It should not include the lifestyle support itself or advise about the content (i.e. an intervention), because that is already in place.
- The solution shall be easy to use for patients of all levels of (digital) health literacy.
- The solution shall include a way to measure the level of (digital) health literacy. Other and more detailed factors to determine the extent of support have to be further determined during the preparation of the pilot.
- The results of the solution (assessment) shall be easy to view and interpret for healthcare professionals (e.g., lifestyle coaches), so that they can then provide the patient with tailored lifestyle support.
- The solution shall be accessible for patients both at home and in the hospital, e.g. via a smartphone or laptop.
- The solution shall be proven effective in healthcare.
- The solution shall be available in Dutch.

Desirable functional requirements

- Preferably, the solution will be embedded in an existing system, so that patients will not have to log in to another system for this purpose (this would be in the long term, after a successful pilot).
- If applicable, the solution shall be tailored to the Rijnstate corporate identity.

Pilot scope

The project will be divided into three phases:

1. Exploration phase: establish what is necessary to determine the extent of lifestyle support that patients need. E.g. which questionnaires and data sources are required.
2. Pilot with test data.
3. Only if pilot with test data is successful: pilot with patient data.

Type and number of targeted end-users:

End-user type	Role	Number
Phase 2: Test "patients"	They will use the solution.	TBD
Phase 3: Real patients		50
Healthcare professionals (nurses, physicians)	They will provide requirements, validate the solution, and prescribe the solution to patients.	*Depending on the department*
Lifestyle coaches	They will provide requirements and validate the solution.	2

Table 18. Targeted users

Language

- The solution and the pilot have to be in Dutch.

Pilot set-up conditions

Ethical, legal, or regulatory

- The solution has to be fully GDPR compliant.
- The solution has to comply with ISO27001, NEN 7510, NEN 7512 and NEN 7513.
- Servers used for data storing have to physically be located within Europe.
- The privacy and security of the solution has to be approved by the Compliance & Risk department of the hospital.
- The suppliers and Rijnstate shall agree on a service level agreement before the pilot starts.

Technological

- The solution has to be compliant with the existing hospital architecture, for if an integration within an existing system is required/desirable after the pilot. In the pilot, the solution can be stand-alone.
- The solution has to be approved by the IT-department.
- More detailed technological requirements will follow when the solution and its place in the hospital infrastructure is further defined.

Data access

- The solution shall only use data provided by the patient. It shall not need data from e.g. the electronic medical record.

Other

- The solution has to be in line with the Rijnstate corporate identity and approved by the Communication department.
- From the start a rough estimate of the costs to scale up the solution after the pilot should be clear. This is to prevent the situation in which after the pilot it could turn out not feasible to carry the structural costs for scale up.

Expected impact and KPIs.

For the pilot, the expected impact is mostly measured by the user satisfaction. It will not be possible to measure a difference in self-management, because self-management includes more aspects than only (the extend of) lifestyle support.

A difference in healthcare demand is also hard to measure because this is also dependent on various factors outside the solution.

So, the KPIs for the pilot will include:

- Patients' satisfaction of the use of the solution: on average at minimum 7/10.
- Patients' satisfaction of the extent of lifestyle support received: on average at minimum 7/10.
- Healthcare professionals' satisfaction of the solution: on average at minimum 7/10.
- Lifestyle coaches' satisfaction of the triage that the solution provides: on average at minimum 8/10.

The expected impact and KPIs can be further detailed before the start of the pilot, depending on the solution.

Business opportunity

Market size

Internally at Rijnstate, the solution could after a successful pilot be expanded to be used by all departments for which patients' self-management should be increased. This is intended to be a hospital-wide solution since all patients can benefit from a healthy lifestyle and preventing (worsening of) diseases.

In addition, the solution could also be expanded to the region (e.g. primary care, social domain, or municipalities), other hospitals (e.g. start within the mProve network of 7 hospitals or regional hospitals) and other countries. The topic of healthy lifestyle and prevention is getting more and more attention and priority in society, so a tool to determine the extent of support that people need for this is broadly applicable.

Adoption plans

If the solution is successful, we plan to scale up the solution to be used at more departments and eventually for all patients for whom it is relevant (hospital-wide). A possible side effect or further development might also be that the result of the solution could be used in consults as advice to what should be discussed by the healthcare professional with the patient and on which level this should be.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	Health Coins B.V.
DESCRIPTION OF THE SME	Health Coins B.V. (est. 2015 in the Netherlands) is aimed at making the healthy choice of the participants immediately interesting and attractive. We do this by using technology with a unique mix of reward, insight, gamification and social engagement.
WEBSITE URL	www.healthcoin.nl

Table 19. Leading SME general information

Solution proposed:

LAT – Lifestyle Assessment Tool

This project aims to develop a method to assess the extent of lifestyle support patients of the Rijnstate hospital require in order to tailor the support to a patient's needs. It does this by combining filled in questionnaires with environmental (Geographical Information System – GIS) data and the available lifestyle interventions of Rijnstate and partners of Rijnstate.

With this solution, individual patients are assessed on their level of knowledge about vitality and their ability to self-manage, which is used to quickly determine the appropriate extent of support. The healthcare professionals who work for the Gezondheidsplein (lifestyle front office) at Rijnstate will be able to manage a bigger caseload with qualitative good triage. This can result in decrease for the need for Rijnstate to hire more lifestyle coaches to analyse all patients that are in need to improve their lifestyle.

The solution will be safe, secure and scalable for all the persons in need of a healthier lifestyle.

A questionnaire is used to determine what extent of support is best for the patient to achieve a healthy lifestyle, e.g. self-managed, one-time consult of a lifestyle coach, coaching program, etc. The questionnaire consists of 20 to 30 statements about the current lifestyle, the needs, the goals and level of (health) literacy. The patient will also be invited to answer questions about their motivation towards a healthy lifestyle. Which strategy will be most effective will highly depend on the underlying motivational convictions that a person has. The questionnaire will deliver an individual score and (after review by a healthcare professional) a triage outcome to achieve and maintain a healthy lifestyle.

In the example below you will find a statement where the participant is invited to indicate the match with this statement (0 is 'absolutely not' and 10 is 'very accurate').

Figure 8. Questionnaire example

The tool will match the strategies of lifestyle interventions of Rijnstate and their Gezondheidsplein to the patients who fill in the questionnaire. The outcome of the questionnaire is an individual score which gives an indication of the level of accompaniment that a person needs in combination with the best intervention available that fits the needs and the goals of the individual. The output for the staff is a selection of triage outcomes. The rules for the selection of the triage outcome are programmed into business rules (like questions 5-8 that score below 5 are red flags for extra consult with a doctor). The tool can select the best possible triage outcomes that are derived from descriptions of the intervention. It uses AI based upon Large Language Models to generate triage outcomes.

These triage outcomes are to be approved by healthcare professionals. After that the participant will receive their triage outcome.

As shown in the illustration below, there are three possible triage outcomes for this patient.

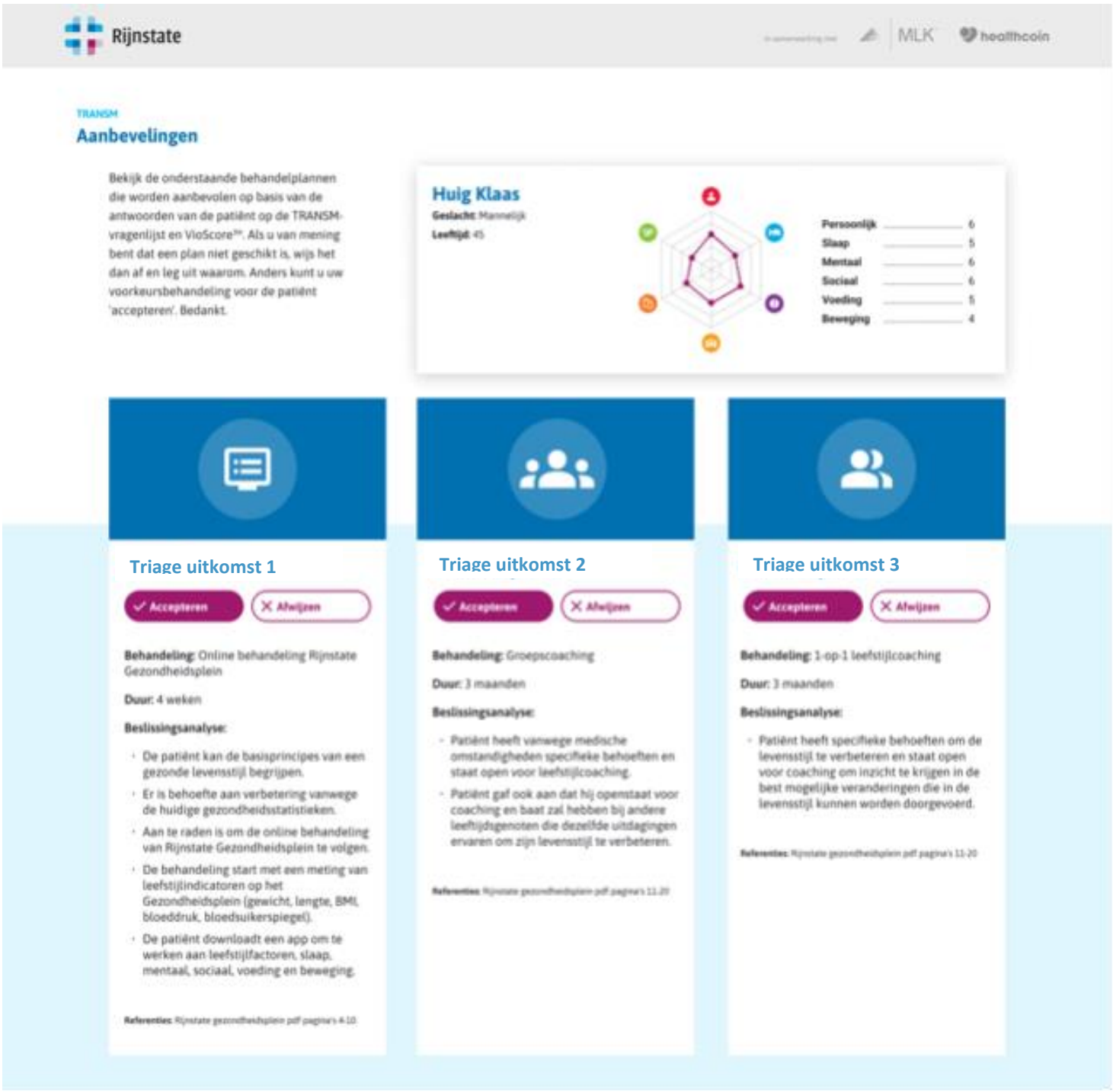

Figure 9. Triage outcomes example

Apart from the lifestyle assessment process being more objective and accessible to everyone, the tool also can connect with lifestyle interventions and apps to directly invite participants to onboard and work on their lifestyle. In this way there is a direct way of supporting a healthy lifestyle for those who feel stimulated to start.

In the separate environment for healthcare professionals there is a well-documented view on the 'caseload': which participants filled in the questionnaire? Who are waiting for approval?

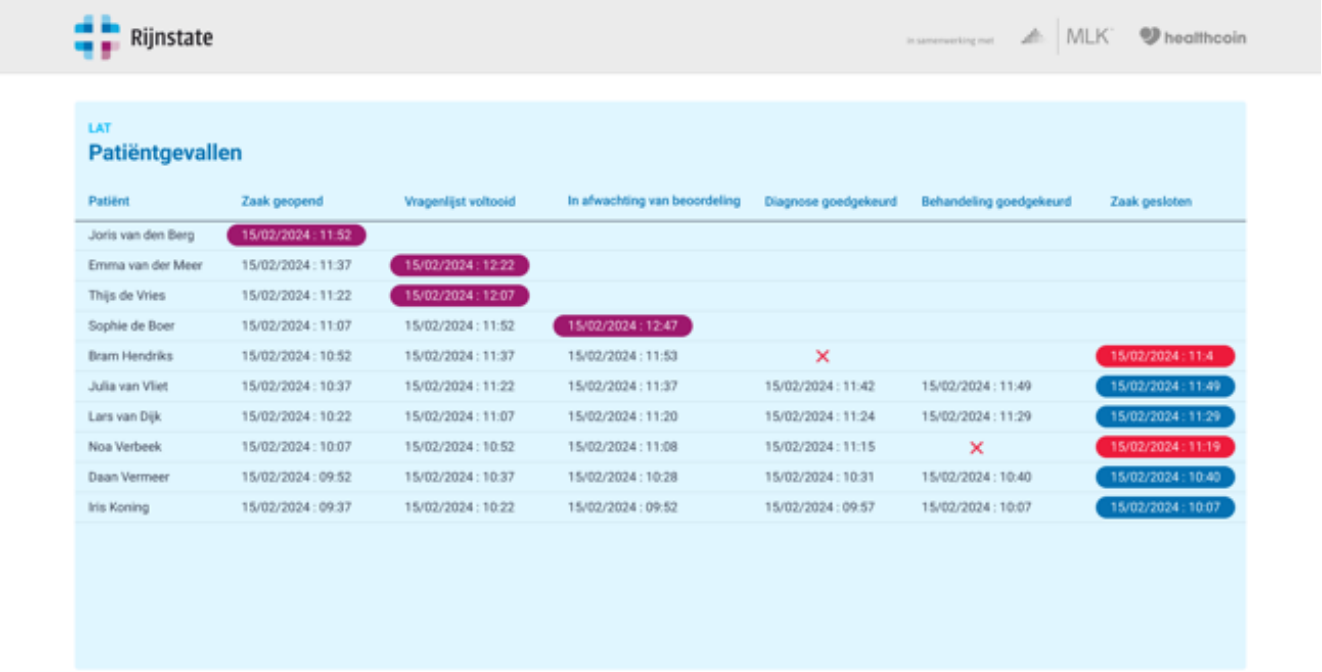

Figure 10. Application dashboard

Work to be done by the leading SME

Health Coins, as the leading SME, will implement the following activities during the solution co-creation and pilot (September 2024 to August 2025):

1. Planning, goal and KPI's, project team with roles – output: **project plan.**
2. Customer journey + legal check – output: **customer journey** (2x for patient and for healthcare professional).
3. Development framework – output: **framework**. Interviews with healthcare professionals to develop:
    a. Decision tree - Questionnaire development – testing
    b. Categories of questions
    c. Personas of patients. This is relevant to adapt the triage tool to certain characteristics of patients to make it more engaging. E.g. younger persons get a different use of words than older persons.
4. Triage outcomes – output: **information for tool to take into consideration for the triage outcomes.** Collect information about the triage outcomes and Rijnstate offers and match them with the questionnaire results to determine the business rules.
5. Communication – output: **mails/info/help info** in the tool.

- Development of mails/information for patients and healthcare professionals with instructions.
- Selection of pilot group.

6. Implementation in tool MyLifeKit – output: **working demo** on website URL.
    a. Communication with patients / healthcare professionals
    b. Testing within project team
    c. After successful tests – pilot group is invited to fill in the questionnaires (50 participants)
    d. Evaluation
7. Evaluation: KPI evaluation (questionnaire) + (when positive) Scale up strategy – output: **evaluation report**

The interactions we are expecting to have:

- Project leader Rijnstate: once every two to four weeks a project update session. During the 12 months project around 15-20 interactions (1 hour per interaction).
- Healthcare professionals/lifestyle coaches: interview sessions + information briefings to inform about the process and how to fill in the satisfaction score at the end of the pilot. During the project 10-15 interactions (1 or 2 hours per interaction).
- Users/patients: 50 patients filling in the LAT and the satisfaction score (1 hour per patient).

Technological needs:

- The LAT can be filled in on the device of the patient or it can be filled in on a device within Rijnstate hospital.
- The environment in LAT for the professionals is a secure website that is accessible through a computer/laptop/tablet at Rijnstate.
- No technological requirements for the devices are needed.

Follower SME

Scope of work performed by the follower SME

Tasks

For the role of follower SME, we are looking for a company who can contribute to the successful use of the leading SME's solution and/or can help to scale up the solution.

Since we would like to receive a broad range of good proposals, we formulated three possible contributions that a follower SME could have to the project.

We are looking for an SME who could contribute to **one or more tasks** as described below:

1) Patient engagement

In order to make a success of the triage tool, we need a way to motivate patients to make use of it, that is to fill in the questionnaire(s). That means that we could use the help of a party who has expertise in the healthcare sector with the adoption of software or self-management solutions for patients. The follower SME should not build the software itself, which the leading SME will do, but they should know how to maximise patient engagement.

Questions to be answered:

- In what way should patients be approached to make them want to use the triage tool as a first step to improve their lifestyle?
- Where in a patient journey can questionnaires about lifestyle and self-management (the teachable moment) be best integrated for patients to participate?
- What motivates patients to open and use the triage tool?
- Are people more likely to use the triage tool on their own device or physically at the hospital either with or without support (for example from a volunteer) or in a more (innovative) interactive way?
- What keeps patients motivated to complete the questionnaire in the triage tool or which aspects lead to incomplete questionnaires?
- How can we make the tool accessible to patients with different digital- and health literacy skills?
- How can we make the use of the triage tool a positive experience for patients?

The product of the follower SME should be a concrete advise to improve patient engagement and/or should be a design that we can incorporate in the triage tool or the process in which the triage tool will be used. The goal will be to motivate patients to use the triage tool as a first step to improve their lifestyle. This way we want to maximise the outcomes of the triage tool and improve the user experience of patients.

2) Adaptation of triage tool (content) to cultural diversity

Question to be answered:

- How can we make the triage tool accessible to patients from multiple cultural backgrounds?

It will not only ask to translate the tool, but also to adapt it to the culture specific challenges concerning a triage tool or lifestyle content. This is both relevant for the variety of patients

within Rijnstate and to make the triage tool of the leading SME scalable to other (international) organisations.

The product of the follower SME should be a concrete advise to adapt the tool and the content of the questionnaire to people with different cultural backgrounds with at least two target groups involved to adjust the content.

3) Exploration market possibilities for triage tools

It would also be interesting to know how other triage tools for lifestyle on the market in the healthcare sector have been implemented and used, and to incorporate their lessons learned into our solution. The follower SME could be the one that gives advise based on experience with similar solutions as the leading SME's triage tool to make it more successful and/or scalable.

Questions to be answered:

- What does the market for AI-based triage tools look like in European countries participating in HealthChain?
- Are there other healthcare organisations interested in a triage tool for lifestyle support assessment?
- What is the state of the art of performing triage for lifestyle support?
- What are the problems or challenges in the current way for triage for lifestyle solution?
- Are there other suppliers for AI-based triage tools and if so, what products are currently used?

The product of the follower SME should be a market report for the market of AI-based triage tools containing some advice to incorporate lessons learned in the solution for Rijnstate and possibilities to scale-up the solution to other European countries.

Requirements

General requirements:

- Experience within healthcare.
- Any content that would be created must be owned by Rijnstate. That means all content should be made freely available to Rijnstate, during and after HealthChain, and Rijnstate must receive the rights for the source data.
- The solution must be created in collaboration with Rijnstate's Marketing & Communication department.
- Any designs must be in accordance with Rijnstate's corporate identity and policy.
- The solution must be in line with current initiatives for communication and the triage content that has been devised by Rijnstate and the leading SME.
- Any material that is used must be royalty-free in The Netherlands.
- The solution has to be fully compliant with the GDPR, ISO27001, NEN 7510, NEN 7512 and NEN 7513.
- Any servers used for data storing have to physically be located within Europe (also back-up servers).
- Any privacy, security and technical aspects of the solution have to be approved by the Compliance & Risk department and Information & Medical Technology department of Rijnstate.

- All proposed solutions must be approved by Rijnstate in terms of feasibility and all aspects mentioned above before development, especially in case of online solutions.

Additional requirements task 1:

- Experience with maximising patient engagement (we would like to see examples of previous experience in the proposal).
- Expertise in user (patient) experience, including users with limited digital or health literacy skills.
- Experience with motivating people to use a triage tool, complete a questionnaire or use software.

Additional requirements task 2:

- Experience in adapting software/information to apply to cultural differences, both between countries as within countries (we would like to see examples of previous experience in the proposal).

Additional requirements task 3:

- Experience with market research within healthcare (we would like to see examples of previous experience in the proposal).
- Experience with triage tools for lifestyle support assessment, e.g. level of health literacy, level of self-management, etc.