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FAST TRACK TO INNOVATION PROCUREMENT

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PITCH

Development of a Sustainable and Patient-Friendly Home-based Capillary Blood Sampling Device for Improved Healthcare Access. An ideal capillary sampling device should be semi-autonomous and allow for automated capillary blood sampling with a single, painless action. Furthermore, the product should not produce a lot of waste. As a gained advance, home-based sampling reduces waiting time and eliminates travel distance for patients.

ORGANISATION DESCRIPTION

Erasmus Medical Centre, located in Rotterdam, the Netherlands, is an international leading academic hospital with a mission for a healthy population and to pursue excellence in healthcare through research and teaching. Erasmus MC is a public organisation. In 2021 Erasmus MC had 659,317 outpatient visits. Erasmus MC posted a financial result of €46 million in 2021. Sustainability is visibly on the move at Erasmus MC and the subject is gaining broader support. For example, several Green Teams have been set up in the departments.

CHALLENGE DESCRIPTION

Currently, patients are required to travel to the hospital for blood sampling, which sometimes requires the assistance of family or friends. Outpatient travel represents a substantial portion of patients' travel distances. By enabling home-based blood sampling, patients will have the flexibility to draw blood at their convenience. This reduces productivity loss associated with time away from work, and reduces unnecessary travel.

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In-hospital blood sampling affects a wide range of patients, including those who require frequent monitoring of blood levels for chronic diseases, oncology patients undergoing treatment, and patients requiring blood tests for other medical reasons. Given that approximately 60% of the Dutch population is diagnosed with at least one chronic disease, a painless home-based blood sampling device has the potential to improve the healthcare experience for a significant proportion of the population.

Our motivation to solve this is to improve the healthcare experience for patients by implementing a painless home-based blood sampling device. By introducing this innovative solution, we aim to address several key challenges associated with in-hospital blood sampling.

Furthermore, hospital visits for blood sampling can have a negative impact on patients' well-being, as the need for in-hospital follow-up visitations can evoke distress and anxiety. By shifting the sampling process to the comfort of their homes and allowing patients to draw blood outside office hours, patients can experience a sense of control. This could reduce the stress associated with hospital visits. This flexibility empowers patients to take an active role in their healthcare process by providing them with the option to collect blood samples at a time that suits their schedule best. Returning the samples to a laboratory for analyses can simple be done by regular post mail. By eliminating the need for unnecessary travel, home-based capillary blood sampling can not only enhance patient convenience but also have a positive impact on the environment by reducing fuel emissions.

By overcoming the barriers associated with in-hospital blood sampling and introducing a painless home-based alternative, we can revolutionize the way blood samples are collected. Our motivation is driven by the desire to improve patient outcomes, enhance well-being, increase convenience and patient involvement, and reduce the environmental impact of unnecessary travel.

FIGURE 2: PATIENT JOURNEY

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CHALLENGE MAIN OBJECTIVES

Our main objective is to enhance patient satisfaction by enabling patients to draw blood within the comfort of their own homes, ensuring a painless experience, and promote environmental sustainability. By providing patients with the convenience of conducting blood sampling at home, we aim to improve overall patient experience, increase compliance with necessary testing, and ultimately contribute to better healthcare outcomes.

SOLUTION FUNCTIONAL REQUIREMENTS

The ideal requirements for a home-based blood sampling device focusses around factors such as painlessness, ease of use, safety, and limited waste production. One innovative approach to blood sampling that addresses these requirements is the use of microneedles. In comparison to traditional capillary sampling methods, this technique significantly reduces the level of pain experienced by patients. We envision a sustainable solution based on this established technique of capillary sampling by painless microneedles.

Compulsory functional requirements

A potential solution could be a handheld device designed for insertion into the skin of the upper arm, similar to existing devices currently in use. However, this device would incorporate **advanced microfluidic technology**, which serves two primary purposes: reducing the amount of blood required for sampling and reducing overall waste production. By using microfluidic principles, the device optimises the blood collection process, ensuring accurate sample acquisition with minimal discomfort to the patient. Of note: capillary sampling results in adequate sample volumes to allow for testing on numerous relevant items, such as tumormarkers for various cancer types.

Additionally, the device could feature a container that is specifically designed to fit within the **dimensions of European mailboxes**. This consideration enables convenience for patients by enabling them to receive the device directly at their homes. European mailboxes have a minimum dimension of 25 x 3.2 cm. The smaller package size also results in reduced shipping costs, as regular mail services are typically less expensive than package delivery services. Ultimately, this improvement in accessibility and cost-effectiveness contributes to improved patient satisfaction and better health outcomes.

To fulfil the functional requirements of a **painless and easy-to-use** blood sampling device, the design should prioritize user-friendly features. The device should have clear and intuitive instructions for insertion and blood collection, ensuring that patients can easily perform the procedure independently. Additionally, it should incorporate safety mechanisms to prevent accidental needle injuries and ensure the proper disposal of used microneedles, guaranteeing user safety and minimizing the risk of contamination.

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In terms of **waste reduction**, the device should be designed to minimize the overall volume of consumables required for blood sampling. This includes the microfluidic components, collection containers, and any other disposable elements. By optimizing the design, the device can reduce waste while still maintaining the accuracy and reliability of the blood sampling process.

Furthermore, the device should be **compatible with standard laboratory procedures** to facilitate seamless integration with existing diagnostic workflows. This allows for easy transfer of collected blood samples to testing facilities, ensuring accurate and reliable analysis of patient samples.

To ensure the successful implementation and adoption of the home-based blood sampling device, training and educational materials should be provided to patients. These resources should clearly explain the steps involved in using the device, address any concerns or questions, and emphasize the benefits of home-based blood sampling in terms of convenience, reduced healthcare visits, and improved patient satisfaction.

In conclusion, the functional requirements of an ideal home-based blood sampling device revolve around painless and easy-to-use features, safety, and limited waste production. Leveraging microneedle technology, the device minimizes patient discomfort while incorporating microfluidic advancements to optimize blood collection. By considering package size and compatibility with European mailboxes, the device becomes more accessible and cost-effective. Furthermore, prioritizing user-friendly design, safety mechanisms, waste reduction, and seamless integration with laboratory procedures ensures a comprehensive and efficient solution.

Desirable functional requirements

The following requirements would provide added value but could be included or excluded based on the supplier's budget and time constraints:

Integration with Mobile Applications: Developing a companion mobile application that works in conjunction with the blood sampling device would enable patients to track their test results, receive reminders for future tests, and access educational resources. Integration with mobile applications can enhance patient engagement and provide a more holistic user experience.

Sample Quality Assurance: Implementing built-in mechanisms to ensure sample quality, such as detecting insufficient blood volume, would help patients obtain reliable and accurate test results. This requirement would increase the confidence in the home-based blood sampling process.

Depending on total volume of collected blood, but more importantly on stability of the tested item for a few days allowing time between drawing and analysing, the number of relevant

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test items can ideally even be expanded resulting in even more potential applications of this device in health care.

Multi-Language Support: Providing support for multiple languages in the device's user interface and accompanying materials would provide the diverse needs of patients from different language backgrounds. This requirement promotes inclusivity and accessibility.

PILOT SCOPE

For the pilot, we plan to include a diverse group of end-users consisting of patients who require regular blood sampling. The pilot will involve approximately 100 participants, representing a broad range of age groups and medical conditions. The primary language of communication and documentation during the pilot will be Dutch. The participants will be selected from various healthcare facilities and will receive the necessary training and support to ensure proper use of the home-based blood sampling device. For the pilot, we plan to test only for blood tests that are well-established in capillary sampling to allow for adequate reliability assessment.

Type and number of targeted end-users

End-user type	Role	Number
Healthcare professionals	They have to recruit patients, ordering, collection, processing, and interpretation of blood samples	5
Patients who require regular blood testing	Use the device	100
Laboratory	**Processing and analysing the collected blood samples, comparing to venepuncture samples to assess the reliability**	**##**

TABLE 1: TYPE AND NUMBER OF TARGETED END-USERS

Language

During the pilot implementation, there is a language requirement for iteration with the end-users, as the patients involved are Dutch. Effective communication and understanding are crucial for a successful pilot program. For the development of the sampling device itself, a non-Dutch speaking company would also be fitting. For the development of the

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communication material in Dutch, the researchers of Erasmus MC would naturally be closely involved.

Other aspects

The focus will primarily be on evaluating the reliability, usability, effectiveness, and patient satisfaction with the home-based blood sampling device itself. The effort and investment during the pilot will primarily involve the development, manufacturing, and distribution of the devices. Data collection and analysis, as well as gathering feedback from the participants, will also be important aspects of the pilot, contributing to the overall effort and investment required.

PILOT SET-UP CONDITIONS

Legal and Regulatory Compliance: The proposed solution must comply with all applicable laws, regulations, and standards related to healthcare, data privacy, and medical devices. This includes adherence to data protection regulations (such as GDPR), medical device regulations (such as FDA approval or CE marking), and any other relevant legal requirements in our jurisdiction.

Ethical, legal or regulatory

The pilot implementation approach and procedures must be reviewed and approved by the Medical Ethics Committee Rotterdam before starting the pilot. This ensures that the pilot adheres to ethical guidelines, respects participant rights, and protects their privacy and well-being.

All participating patients must provide informed consent before their involvement in the pilot. This includes clear and comprehensive information about the purpose, procedures, risks, benefits, and data handling practices associated with the home-based blood sampling device. Informed consent ensures that participants are aware of their rights and can make voluntary decisions regarding their participation.

Technological

To ensure systems interoperability, authentication measures, and other related requirements during the pilot, the following considerations should be considered:

Reliability of Sampling: The home-based blood sampling device should consistently and accurately collect blood samples to ensure reliable test results. The device should be designed to minimize errors, such as incomplete or incorrect sampling, and provide clear indications or feedback to users to ensure proper sample collection. Reliability in sampling

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is crucial to ensure the accuracy of diagnostic tests and maintain the trust of both patients and healthcare providers in the home-based blood sampling process.

Interoperability with Existing Systems: The home-based blood sampling device and associated software should be designed to seamlessly integrate and exchange information with existing healthcare systems, such as laboratory information systems. This enables efficient data exchange, sharing of test results, and collaboration with healthcare providers.

EXPECTED IMPACTS AND KPIS

- Improve patient satisfaction by at least 15% with the use of our capillary sampling device, compared to standard of care blood withdrawal by venepuncture.
- An indicator towards achieving our objective of decreasing hospital visits for blood sampling would be the percentage reduction in patients visiting healthcare facilities solely for this purpose, which should be reduced by at least 10%, compared to the standard of care in-hospital venepuncture

BUSINESS OPPORTUNITY

Market size

The challenge of improving patient satisfaction through home-based blood sampling presents a significant opportunity for a supplier of innovative solutions. This need is not only relevant for the Challenger organisation but also has relevance for other potential hospitals or medical laboratories. The estimation of the market size:

Internal Level:

Home-based sampling can be used in several departments within our hospital.

The number of patients benefiting from home-based blood sampling within our hospital can be estimated based on the patient population. In 2022, Erasmus MC conducted around 600 blood withdrawals a day. Capillary samples are suitable for almost all blood samples except blood culture testing and most coagulation tests.

National Level:

The proposed home-based capillary sampling device has the potential to benefit a wide range of patients in the Netherlands. As approximately 60% of the Dutch population is

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diagnosed with at least one chronic disease, the device can benefit a significant portion of the population. This includes patients with diabetes mellitus, cardiovascular disease, chronic kidney disease, thyroid disease, and oncological patients. These patients require frequent blood sampling, which can be burdensome and time-consuming. Along with chronic diseases, part of the surveillance of patients diagnosed with several types of cancer (testicular, colorectal or prostate) requires multiple blood samplings per year. The device can be especially beneficial for elderly patients and those living in rural or remote areas, who may find it difficult to travel to hospitals.

Adoption plans

If the pilot of the home-based blood sampling solution proves to be successful and meets the desired objectives, the adoption plans for scaling up the solution within our organisation can be developed.

By developing implementation plans, hospitals can effectively scale up the home-based blood sampling solution if the pilot is successful. These plans will address the various aspects of procurement, implementation, training, management change, infrastructure, and ensuring a smooth and successful integration of the solution into healthcare practices.

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