First project summary

May 2025

Context and overall objectives

RealCare is a cutting-edge research initiative focused on developing and validating next-generation point-of-care (PoC) systems that detect essential biomarkers in human biofluids in real-time. These systems are designed to be compact, energy-efficient, and integrated with extended reality interfaces, with a specific emphasis on cancer and cardiac diseases in demanding clinical settings. RealCare's approach includes advanced biomarker detection technologies, such as microfluidics and new generations of microneedles, label-free electrochemical biosensors using 2D materials, optical sensors utilizing CRISPR, biological amplifiers combined with fluorescent microscopy, and scalable SPR with energy-efficient electronic readouts, AI data processing, and wireless communication units. Additionally, RealCare will design portable, interoperable, and adaptable PoC systems that integrate the biomarker detection technology with vital sign monitoring, including advanced data analytics and AI methods. The initiative also focuses on developing intuitive extended reality interfaces, such as augmented and virtual reality, to visualize biomarker data in realtime and facilitate rapid medical decision-making in integrated in-care environments and workflows. Rigorous clinical validation studies will be conducted in relevant clinical settings, including the surgery room, ICU, and patient's home, to ensure accuracy, reliability, usability, and impact on patient outcomes. RealCare places special attention on including a diverse patient population in their studies to validate the effectiveness of the developed systems. Data quality, interoperability, and medical data protection are key considerations in RealCare's strategy. Based on our unique PoC technological platform and our strong, multidisciplinary consortium partnership, we propose promising lab-tomarket paths with the potential for significant societal impact.

Work performed and main achievements

Objective 1 Real-time PoC technology validation and medical expertise integration

- Clinical trial STING is started to investigate the presence of biomarkers during lung cancer surgery.
- Two point-of-care technologies are developed to measure patient with cardiovascular disease: (1) measurement of lactate, pH and CRP in ISF using microneedles and sensors; (2) speckle plethysmography for contactless monitoring of heart rate, heart rate variability, blood pressure and oxygenation saturation.
- Prospective observational study design is proposed to investigate if exosomes are biomarkers for heart transplantation failure.

Objective 2 **Develop and validate a real-time PoC system for detecting ctDNA, nucleosomes and exosomes in arterial blood using innovative optical sensing methods**

- Two different markers are identified for lung cancer detection: (1) ctDNA and (2) exosomes. For both biomarkers new technology will be developed. For ctDNA CRISPR technology in combination with microfluidics will be investigated, while for exosomes the development of a bio-amplification device, SPR and AFM are currently developed.

Objective 3 **Develop a real-time multi-modal sensor technological platform**

- For measuring the health condition of cardiovascular patients, it was decided not to measure pancreatic stone protein.
- With the microneedle patches designs were made to be able to measure pH, lactate, CRP and NT-proBNP.
- For the optical sensing approach, a prototype has been made that enable contactless measurements of vital signs. The optimal camera position was found.

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Objective 4 **Development of minimally-invasive polymer-collectors for quasi-continuous sampling of ISF**

- A microneedle patch is developed and instead of measuring outside the patch, focus is shift to measure inside the needle to avoid the delay in transport of biomarkers (lactate, pH).
- A prototype has been made that integrate microneedles in combination with ISF collection.

Objective 5 **Development of a system integration platform with interoperability with other consumer wearables and fixed hospital data infrastructure**

- An overview of the integration of the different sensors into a platform has been made.
- Specification of the different sensors are also made.

Objective 6 **Develop advanced data analytics methods and algorithms for real-time disease digital fingerprints and user-friendly extended reality interfaces**

- Baseline datasets are found to validate the initial analytics models for the cancer use case.

Objective 7 **Establish an effective strategy for open science, open data, and intellectual property**

- An independent ethical advisor was appointed.