Topic idea submitted to IHI - Reference Number: TI_001235

Are you submitting the idea: ☑ in your personal capacity? □ on behalf of an organisation?

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea: Advanced Health Prevention through Biomarker Measurement with Wearable Devices

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field: Diagnosis and treatment are generally triggered by the onset of symptoms, while imperceptible changes in biomarkers can indicate the onset of a health condition before symptoms are observed. This project addresses this gap in health preservation through the continuous preventive monitoring of biomarkers using wearable or implantable devices and a centralised monitoring system, allowing for A) the early detection, prevention and treatment of diseases and B) a better understanding of the determinants of health.

These challenges affect various stakeholders:

*Patients: The availability of good medical care is variable, but implementing a centralised monitoring system can help address this issue and empower EU citizens to take control of their health.

*Public Health Systems: Delayed patient treatments result in higher long-term costs due to increased disease prevalence and the need for more intensive treatments. The availability of extensive early biomarker information is helpful to design optimal prevention policies across Europe.

*Healthcare Providers: Limited access to real-time data hampers their ability to make informed, timely decisions, reducing the overall effectiveness of prophylaxis. A centralised automated patient monitoring system helps alleviate the burden on healthcare professionals.

*Technology Developers: The absence of regulatory framework, data standardisation, prioritised medical requirements and market potential hampers their desire to develop new biomarker measurement capabilities or monitoring platforms.

By addressing these challenges, the project aims to shift the healthcare paradigm from reactive to preventative, benefiting all stakeholders through improved health outcomes, cost savings, and

enhanced patient engagement.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO1: contribute towards a better understanding of the determinants of health and priority disease areas"

"SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treat- ment and management of diseases, meeting the needs of endusers

"SO3: demonstrate the feasibility of people-centered, integrate health care solutions"]

Please select the keywords that are most relevant to your idea:

["Prevention"

"Detection"

"Digital health"

"Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

The primary objectives of the idea are:

* to enhance the understanding of key health determinants by collecting data during pathogenesis across diverse populations and develop new evaluation methodologies, possibly AI-based;

*to integrate the efforts across healthcare, technology, and public health sectors, to design a coherent set of biomarker sensors, unified medical information system, data-driven prevention and treatment strategies and regulatory frameworks;

*to provide patients with means to proactively manage their health;

*to facilitate the early detection and personalised intervention for priority diseases such as cardiovascular diseases, diabetes, and cancer;

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific <u>objectives</u>, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

IHI general objectives: 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

The project is expected to significantly impact the EU innovation ecosystem by enabling the iterative development, implementation and long-term improvement of large-scale, cross-sectoral technologies focusing on early disease detection and personalised prevention. It opens a range of incidental opportunities (e.g. personalised adjustable dietary supplement).

The project aims to develop safe, effective, and people-centred solutions that demonstrate the feasibility of integrating innovative healthcare technologies into existing systems and that support strategic EU health goals, including Europe's Beating Cancer Plan.

The expected outcomes include improved patient health preservation, reduced healthcare costs, and strengthened leadership in health innovation.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

Collaboration through a cross-sectoral and multidisciplinary public-private partnership is essential to this project because it integrates diverse expertise and resources necessary for success. The development of continuous biomarker monitoring devices requires the convergence of multiple industries—pharmaceuticals, biotech, medical devices, health ICT—to create comprehensive, effective solutions. Each sector contributes unique capabilities: biotech and pharma provide insights into biomarkers, medical devices enable real-time monitoring, and health ICT facilitates data integration and analysis.

Collaboration between private industry and public partners is equally critical. Academia and healthcare practitioners contribute cutting-edge research and clinical expertise, ensuring the innovations are scientifically sound and clinically relevant. Patient involvement ensures the solutions are user-centred, while regulators ensure safety and compliance. This partnership accelerates innovation, ensures real-world applicability, and fosters the adoption of new health technologies across Europe, addressing public health needs effectively and efficiently.

Why is the contribution of industry needed to achieve the expected impacts?

Contribution of industry: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.

The contribution of industry is crucial to achieving the expected impacts because large companies bring essential resources and expertise that drive innovation and scalability. These companies possess the infrastructure and experience required to translate scientific discoveries into market-ready products efficiently. Additionally, their involvement ensures that the innovations are designed with industry standards and market needs in mind, facilitating faster adoption and integration into healthcare systems. The industry's commitment enables a more significant, far-reaching impact on public health across Europe. This partnership accelerates progress toward meeting strategic health objectives and ensures that the resulting innovations are both practical and scalable.