

All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Expected impacts to be achieved by this topic

The following impacts are expected:

- Patients benefit from preventive treatment or early disease intervention before onset of symptoms.
- Prevention and early diagnosis of disease, combined with better understanding of the mechanisms involved, leading to the development of more cost-effective interventions and strategies.
- Increased availability of validated biomarkers for disease interception and diagnosis, tested in real-world settings.
- Advanced analytics/artificial intelligence supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.

Expected outcomes

R&I actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for disease(s) of high unmet public health need selected by the applicants:¹

- Patients will receive more timely personalised interventions (prevention, early treatment to avoid complications, etc) to reduce morbidity and mortality from major diseases, improving the lives of citizens.
- Healthcare professionals have access to a screening platform and clinically validated biomarkers for identifying people at risk of disease to facilitate the selection of the most appropriate preventative action.
- Researchers have new biomarkers for prediction and prevention to allow for the development of safer and more effective personalised interventions tailored to the individual's characteristics.
- Healthcare systems will benefit from reliable evidence to target effective, preventative therapeutic interventions to those citizens who will benefit most from them.

Scope

As the population of the European Union ages, the rising burden of disease is a major challenge to the sustainability and resilience of healthcare systems. The identification of individuals at risk of developing an illness so that they can receive an appropriate treatment before the disease develops is an important factor to address this problem. However, for many health conditions, we lack full understanding of the underlying

¹ **Unmet public health needs** are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life...) and/or the number of people affected by it. For example, Alzheimer's disease.

mechanisms, including the predisposition to disease and how environmental and genetic factors affect the occurrence of the disease.

Projects funded under this topic should address this challenge by developing an open platform for screening individuals with the aim of identifying people at risk of disease. Applicants should clearly identify a disease(s) of unmet public health need, and specify the initial biomarkers to identify people at risk that will be used within the project (e.g. genetic, metabolic, digital and imaging biomarkers, lifestyle/environmental, family inherited disease, and/or combinations of these) and explain their choices with relevant evidence where possible. By the end of the project, the screening platform should be able to be used for population screening and decision-making including selection of the most appropriate intervention(s) and new technology development.

In particular, for the selected disease(s), the project(s) funded under this topic are expected to:

- Set up a comprehensive interdisciplinary collaboration of the clinical research, industrial, public health, and health technologies communities to develop the screening platform and generate the evidence base for general population screening. This platform should be built to operate in an open-source environment allowing interoperability with applications from different providers, and build on clearly identified existing initiatives where relevant, while aiming at facilitating reusability (for example, a modular structure to enable flexibility and customisation to support new developments). The ethics considerations of operating such a platform must be considered and relevant guidelines for digital biomarker design and development should be followed as appropriate.
- Clinically validate and assess the utility of the screening platform and biomarkers² to identify people at risk by designing and implementing a large-scale general population cohort screening study in several representative European countries.
- Design and clinically validate innovative assay technologies for disease risk identification, including digital technologies with data capture/analysis.
- Deliver digital tools for more effective and efficient management and execution of screening programmes and improved disease prevention. Artificial intelligence (AI) tools should be robust and explainable where relevant.
- Publish the relevant methods, standard operating procedures (SOPs), algorithms, standards and guidelines to allow the platform to be used more broadly and for diagnostics and therapies to be developed.
- Develop a plan/roadmap based on solid evidence to facilitate the regulatory qualification of the biomarkers identified and used within the project, and seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice).
- Develop and optimise relevant clinical practice guidelines through systematic evidence and outcome review, while addressing factors influencing uptake of these biomarkers in clinical practice.

² Biomarkers are biological characteristics, which can be molecular, anatomical, physiological, or biochemical. These characteristics can be measured and evaluated objectively. They act as indicators of a normal or a pathogenic biological process. They allow the assessment of the pharmacological response to a therapeutic intervention. A biomarker shows a specific physical trait or a measurable biologically-produced change in the body that is linked to a disease or a particular health condition. A biomarker may be used to assess or detect a specific disease as early as possible (diagnostic biomarker), the risk of developing a disease (susceptibility/risk biomarker), the evolution of a disease (prognostic biomarker) – but it can also predict response to a given treatment including potential toxicity (predictive biomarker).

- Raise awareness of disease prevention and provide training and education to relevant healthcare professionals, patients and family members. These training materials should be made available for use after the project ends.

A key objective is to facilitate changing healthcare practice, so applicants will need to demonstrate that their outputs can be taken up by healthcare systems and take steps to facilitate this.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

Why the expected outcomes can only be achieved by an IHI project

To develop novel biomarker combinations and implement them in a broadly applicable screening platform requires significant cross-sectoral expertise including from patients, healthcare professionals, biomarker specialists, machine learning experts, academic researchers, SMEs, and the pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together in the collaborative environment provided by an IHI project to achieve the objectives of this topic.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply³.

³ See section 4.2.3.2 of this second amended Work Programme