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, leads 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 R&I, resulting in wider availability of personalised health interventions to end-users.

Expected outcomes

Proposals 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 earlier or more timely interventions (prevention, early treatment to avoid complications, etc) to reduce morbidity and mortality from major diseases, improving lives of citizens.

- Health care 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 EU ages, the rising burden of disease is an important 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 mechanisms,

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[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.

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 who are not yet diagnosed with a disease with the aim of identifying people at risk. Applicants should clearly identify disease(s) of unmet public health need,[1] 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, family inherited disease) and explain their choices with empirical 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 open to devices from different vendors and build on clearly identified existing initiatives where relevant.

- Clinically validate and assess the utility of the screening platform and biomarkers to identify people at risk by designing and implementing a large-scale general population cohort screening study in several 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. AI tools should be 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 to facilitate the eventual regulatory qualification of the biomarkers used within the project.

- Develop and optimize relevant clinical practice guidelines through systematic evidence and outcome review.

- Raise awareness of disease prevention and provide training and education to relevant health care 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 should also reserve resources to synergise with other relevant initiatives, including other projects funded under this topic.

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, health care professionals, biomarker specialists, machine learning experts, academic researchers, SMEs, 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

IHI estimates that an IHI financial contribution of around EUR 10 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. *NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.*

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

[To be determined: The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" [apply][do not apply][2].]

Glossary

Biomarkers	Biomarkers are biological characteristics, which can be molecular, anatomic, physiologic, 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).
Unmet public health needs	**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.

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[2] See section 4.2.3.2 of this amended Work Programme