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 2: Development and proof of principle of new clinical applications of theranostics solutions

Expected impacts to be achieved by this topic

- Improved availability of effective treatments for patients based on multi-modal theranostics[1] solutions.
- Stronger resilience and improved strategic autonomy of Europe's health systems, for example, by implementing new manufacturing capabilities for medical radioisotopes and radiopharmaceuticals (in accordance with the EU SAMIRA[2] action plan).
- Depending on the disease area of the application, contributing to the objectives of Europe's Beating Cancer Plan and to the Horizon Europe Mission on Cancer.

Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must contribute to at least three of the following outcomes:

- Patients will benefit from increased treatment efficacy, reduction of time to treat, fewer side effects, and reduced duration of hospitalisation.
- Healthcare professionals benefit from education, training on theranostic treatment approaches, recommendations, and clinical guidelines on the most appropriate use of theranostic solutions.
- European healthcare systems benefit from a broader spectrum of theranostic treatments and improved cost-effectiveness and affordability of theranostic solutions due to scale effects and more robust European supply chains.
- Technology developers, healthcare professionals and patients benefit from increased information on the sensitivity, quantification, stratification and staging of diseases.

Scope

Multi-modal theranostics solutions, currently dominated by radionuclide-based therapy and companion diagnostics are emerging as safe, personalised, and effective approaches for the treatment of several diseases. However, use of such therapies is limited to a few specialised centres with the need to increase clinical treatment capacities, and to widen the arsenal of theranostics, possibly including novel non-nuclear approaches, e.g., enabled by nanotechnologies.

To address this challenge, project(s) funded under this topic should aim at developing new, or innovative combinations of existing, multi-modal theranostics solutions including radiopharmaceuticals and/or non-radioactive theranostics solutions. Applicants should clearly identify a disease(s) of unmet public health

[1] Theranostics refers to the pairing of diagnostic biomarkers with therapeutic agents that share a specific target in diseased cells or tissues.
[2] The SAMIRA action plan is the EU's first comprehensive plan for action to support a safe, high quality and reliable use of radiological and nuclear technology in healthcare.

need, (e.g., oncology, neurology and/or advanced multi-disease conditions) and explain their choice with relevant evidence where possible.

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

- Develop innovative theranostics solutions and consider conducting proof of concept clinical trials to demonstrate the added value of the proposed theranostics solutions for patients.
- Develop tools for the quantification of the chosen disease(s) through development of novel modalities to ensure proper planning and monitoring of patients care, which may include imaging, artificial intelligence and pathology models.
- Facilitate the development of tools to increase European theranostics manufacturing capabilities and treatment capacities, including guidance on quality assurance and improving logistics of supply at the EU level.
- Develop education & training materials on the deployment of multi-modal theranostics solutions and their integration in clinical settings including recommendations for the organisation and composition of disease-specific medical expert boards.

In addition, applicants are expected to consider the potential regulatory impact of the results and as relevant develop a strategy/plan for generating appropriate evidence as well as engage with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification advice).

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

Theranostics solutions require a highly multidisciplinary team of specialists for their clinical application and integration in a patient treatment workflow. Furthermore, the production of theranostics pharmaceuticals, based on radionuclides or nanomedicine products, involves and requires specialised knowledge and expertise. Therefore, a cross-sectorial collaboration is necessary for clinical deployment of theranostics solutions between academia, healthcare professionals as well as the health industry sectors which for instance contribute with the production of therapeutic reagents and the development of imaging technologies. It is recommended to include regulators in all steps during development and related planning.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 25 000 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 12 000 000 would allow a proposal to address these outcomes appropriately. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.*** 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

[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]