

**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 theranostic solutions**

### **Expected impacts to be achieved by this topic**

- Improved availability of effective treatments for patients based on multi-modal theranostic<sup>1</sup> 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<sup>2</sup> action plan).
- Depending on the disease area of the application, contributing to the objectives of Europe's Beating Cancer Plan and 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 theranostic 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, the 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 theranostic solutions including radiopharmaceuticals and/or non-radioactive theranostic solutions. Applicants should clearly identify a disease(s) of unmet public health need,

<sup>1</sup> Theranostics refers to the pairing of diagnostic biomarkers with therapeutic agents that share a specific target in diseased cells or tissues.

<sup>2</sup> 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.

(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 theranostic solutions and consider conducting early phase clinical trial(s) as proof of concept(s) to demonstrate the added value of the proposed theranostic solutions for patients;
- develop tools for the quantification of the chosen disease(s) through the development of novel modalities to ensure proper planning and monitoring of patient care, which may include imaging, artificial intelligence and pathology models;
- facilitate the development of tools to increase European theranostic manufacturing capabilities and treatment capacities, including guidance on quality assurance and improving logistics of supply at the EU level;
- develop education and training materials on the deployment of multi-modal theranostic 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 if relevant develop a strategy/plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification/scientific advice).

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

Theranostic solutions require a highly multidisciplinary team of specialists for their clinical application and integration in a patient treatment workflow. Furthermore, the production of theranostic 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 theranostic solutions between academia, healthcare professionals as well as the health industry sectors which for instance contribute with the production of diagnostic and therapeutic agents 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 of up to EUR 25 000 000.

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. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by in-kind contributions to operational activities (IKOP), financial contributions (FC), or in-kind contributions to additional activities (IKAA) from private members and/or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA. See call conditions for further information.

### **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 call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

INDICATIVE TEXT