Topic 3: Personalized oncology: Innovative people centred, multi-modal therapies against cancer

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.

Expected impacts to be achieved by this topic

In addition to contributing to the Europe's Beating Cancer Plan, the Mission on Cancer, the EU Industrial and Pharmaceutical Strategy, and implementation of the Sustainable Development Goals s of the United Nations, the work supported under this topic will help to achieve several of the expected impacts from IHI JU specific objective 2: Integrate fragmented health Research & Innovation (R&I) efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users.

By more specifically:

- Breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative people-centred, integrated health care solutions that can seamlessly be introduced in health care systems.
- Fostering development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation.
- Better and faster integration of future products, services and tools along the health care pathway responding to patients' specific needs leading to improved health outcomes and patient well-being.

Moreover, the work supported under this topic will also contribute to some expected impacts from IHI JU Specific Objective 3: Demonstrate the feasibility of people-centred, integrated health care solutions

- Patients benefit from treatment and care better adapted to their needs through improved diagnostics prognosis and monitoring their quality of life while on and beyond treatment.
- Integrated health care solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and healthcare providers through an inclusive approach.
- Successful implementation of digital solutions supporting people-centred care.

Expected outcomes

Platform, standards and regulatory

- A versatile and dynamically evolving platform for R&I collaboration across sectors, between academia and industry partners with a focus on the early stages of applied clinical research on cancer.
- Cancer health care pathway standards to enable personalized treatment and joint registries.
- Demonstration of how the benefits of health technology convergence can be harnessed in line with all relevant regulatory frameworks in Europe.

Improved multi-modal therapy

- Health innovations in cancer therapy through development, testing and validation of multi-modal therapeutic approaches including novel or emerging technical and clinical concepts and potentially supported by in vitro diagnostics.
- Personalized therapeutic options for cancer patients to improve outcomes.
- Improved active monitoring and adaptation of therapy through the patient journey, involving early-response biomarkers and evaluation of their predictive power and correlation to clinical outcomes.

Scope

Different treatment modalities are available for various cancers, however, the differing biology of cancers as well as the differing efficacy of treatment modalities dictate rather patient-specific approaches. Multi-modal therapies have been shown to be of high value in this respect and there is a strong need to increase the therapeutic arsenal of such multi-modal therapies and to tailor the treatment approach to the individual patient.

The aim of this call topic is biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, in vitro diagnostics, co-morbidities, clinical and real-world data.

Proposals should facilitate the development of new health technologies and integrate them with (possibly adapted) current therapy concepts, to create and explore multi-modal therapies personalized to the needs of the individual patient. Applicant consortia should pursue different therapeutic strategies and combine at least two cancer treating modalities[1] (supported by a sound scientific rationale in the application).

The proposed R&I activities should include development of research protocols for multi-modal therapies expected to have a significant potential to create patient benefits. These protocols should

[1] Pharma-, nanotech-, radio- or other therapeutic approaches (e.g.: small molecules, hormone-, cell-, or immuno-therapy, drug delivery systems and nanoparticles, adaptive radiation therapy with guided dose optimization, altered dose fractionation schemes including hypo-fractionation, ablation and radio-surgical concepts based on photon or charged particle radiation including FLASH ((irradiation at ultra-high dose rates, several orders of magnitude higher than conventional dose rates), theranostics and radiopharmaceuticals).

be explored via early clinical studies with sufficient sample size and statistical power to assess safety and efficacy and demonstrate feasibility of the chosen multi-modal approach.

Depending on the specific therapies to be studied and combined, the R&I activities should consider the clinical decision-making process aspect among the various disciplines involved and also include evaluation of aspects such as the sequencing, timing and dosing of therapies to maximize treatment effects with minimal toxicity and normal tissue complications. It is expected that the use of prognostic and predictive biomarkers and the combination of diagnostic tools to plan and adapt treatment and evaluate treatment and follow up of the patients will be a key component of the proposed integrated health care solutions.

To overcome the barriers to cross-sectoral collaboration, proposals need to consider methodologies and standards for the combination of various technologies into integrated health care solutions Furthermore, proposals should also consider the design and conduct of clinical studies of multi-modal therapies and methods to evaluate their safety and clinical benefits.

Proposals should include a description of how data will be generated, captured and stored, and how it will be used and sustained to promote collaboration among stakeholders.

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

Rapid scientific and technical progress in medicinal products, diagnostics, medical devices, and complementary services have created the potential for significant improvements in health care. However, the opportunities for developing integrated, interoperable health care solutions can only be fully harnessed if barriers to cross-sectoral collaboration and to collaboration with patients and health care professionals are overcome.

To realize the potential synergistic effects of biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, in vitro diagnostics, co-morbidities, clinical and real-world data, it will be necessary for different industry sectors to come together and exchange knowledge and experience, and to find optimal combinations of the various solutions they can provide. Moreover, this cross-sectorial collaboration must be extended to academia and health care providers to leverage innovative clinical concepts that they can offer, and to ensure the clinical relevance of technical and scientific innovations. IHI JU provides a unique opportunity to break the existing silos to enable faster development of people-centred, safe, effective, cost-effective and affordable health solutions.

Indicative budget

Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants, the rest being covered by financial contribution received from IHI JU (see call conditions for further information).

Indicative duration of the actions

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

Dissemination and exploitation obligations

To be determined