

Topic idea submitted to IHI - Reference Number: TI_001173

Are you submitting the idea:

- in your personal capacity?
 on behalf of an organisation?

Please select from the list below the type of stakeholders your organization represents:

Small& medium enterprise (SME)

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Novel nuclear theranostics for personalised cancer diagnosis and care

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:

While significant progress has been made in cancer treatment, current therapies are unable to address the ongoing unmet need with cancer diagnoses and deaths still growing within the EU. Many different treatment modalities are available; however, the wide variation in cancer biology and treatment efficacy requires patient-specific, molecular approaches to find the optimal combination for each patient.

The specific challenge to be solved by this topic is to provide personalised anti-cancer care with theranostic solutions using radiopharmaceuticals. Radiopharmaceuticals combine a radioisotope with a targeting molecule (antibody, peptide, small molecule, etc) that binds to cancer-specific biomarkers. Theranostics takes this one step further, developing matched pairs of diagnostic and therapeutic radiopharmaceuticals targeting the same biomarker, giving precise overlap between imaging and treatment. This allows the clinician to tailor treatment for each patient based on their specific biomarker expression and tumour uptake as measured by the diagnostic imaging.

The recent growth in nuclear theranostics has been driven by advances in related areas such as cancer imaging data and equipment, biomarker identification/validation, introduction of novel radioisotopes, and increasing clinical experience with medical radionuclides. Despite this promise, several barriers hinder the development of fully-personalised theranostics. These include limited radionuclide supply (especially in Europe), poor translatability of current pre-clinical models, missing clinical data for personalised dosimetry and clinical usage, unclear regulatory path, and low knowledge in the medical community about how to use these treatments.

Proposals should address these barriers to provide fully-integrated anti-cancer nuclear theranostic solutions ready for fast incorporation into the healthcare system.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing 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"
"SO3: demonstrate the feasibility of people-centered, integrate health care solutions"]

Please select the keywords that are most relevant to your idea:

["Non-communicable diseases"
"Oncology"
"Diagnosis"
"Treatment"
"Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

This topic's objective is to develop novel theranostics, integrating molecular imaging and molecular therapy along the healthcare pathway to give fully personalized oncology care. By tailoring treatment from the matching diagnostics, we can give the right drug to the right patient at the right dose, allowing us to better respond to their specific needs, improving health outcomes and well-being throughout the patient journey. These objectives contribute to Europe's Beating Cancer Plan, the Mission on Cancer, and IHI SO2 & SO3.

A key objective is to foster collaboration, breaking down silos between public or private research organisations, hospitals, and medtech/biotech/pharma industry, aligning with IHI SO2. We aim to upskill clinical staff across disciplines about theranostics, contributing to the SAMIRA Action plan objectives, and strengthen EU manufacture and supply of medical radionuclides in line with EU Industrial and Pharmaceutical Strategy and SAMIRA Action Plan, improving accessibility and affordability of these healthcare solutions.

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

IHI general objectives: 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

- Health innovations in cancer care through development, testing and validation of multi-disciplinary nuclear theranostic approaches, including novel or emerging technical and clinical concepts.
- Fostering the development of personalised therapeutic options for cancer patients to improve outcomes, including shared information and integration of various specialised clinicians as well as shared decision-making for treatment and care.
- Improved active monitoring and adaptation of therapy throughout the patient journey due to integration of imaging diagnostics and targeted therapy, giving evidence-based decision making and

more involvement of patients in the cancer patient journey.

- Proven collaboration framework to provide a platform for R&I across sectors, between academia and industry with a focus on the early stages of applied clinical research on cancer.
- Increasing the competitiveness of European health industries and strengthening EUs position as global leaders in radionuclide supply and clinical development.
- Improved accessibility and affordability of effective cancer diagnostics and care for all EU citizens.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

While significant progress has been made in cancer treatment, current therapies are unable to address the ongoing unmet need with cancer diagnoses and deaths still growing within the EU. Many different treatment modalities are available; however, the wide variation in cancer biology and treatment efficacy requires patient-specific, molecular approaches to find the optimal combination for each patient.

The specific challenge to be solved by this topic is to provide personalised anti-cancer care with theranostic solutions using radiopharmaceuticals. Radiopharmaceuticals combine a radioisotope with a targeting molecule (antibody, peptide, small molecule, etc) that binds to cancer-specific biomarkers. Theranostics takes this one step further, developing matched pairs of diagnostic and therapeutic radiopharmaceuticals targeting the same biomarker, giving precise overlap between imaging and treatment. This allows the clinician to tailor treatment for each patient based on their specific biomarker expression and tumour uptake as measured by the diagnostic imaging.

The recent growth in nuclear theranostics has been driven by advances in related areas such as cancer imaging data and equipment, biomarker identification/validation, introduction of novel radioisotopes, and increasing clinical experience with medical radionuclides. Despite this promise, several barriers hinder the development of fully-personalised theranostics. These include limited radionuclide supply (especially in Europe), poor translatability of current pre-clinical models, missing clinical data for personalised dosimetry and clinical usage, unclear regulatory path, and low knowledge in the medical community about how to use these treatments.

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Why is the contribution of industry needed to achieve the expected impacts?

***Contribution of industry:** Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.*

Radionuclides are recognised as having a high market potential (current market €85mn, CAGR 12%) and many industry members of the IHI-affiliated partners are working within the radionuclide/theranostic space. However, the barriers to entry mentioned in the scope above are slowing development and preventing wider uptake of these treatments, reducing market size and potential income for all players.

In particular, these issues are found at all stages of the value chain, from manufacture and supply through pre-clinical and clinical development, to barriers to uptake in the clinic, and include complex technical issues beyond just proving efficacy and safety of the chosen solutions. These can not be

addressed by public partners, and the inclusion of industry partners in the project is necessary to address issues along the full value chain. Expertise is required from medtech manufacturers or equipment suppliers, pre-clinical and clinical CROs, digital health, data science, biotech, and pharmaceutical companies.