



Personalised oncology: innovative people centred, multi-modal therapies against cancer

IHI call 1 – topic 3

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Before we start...

- We are recording this webinar and it will be published on the IHI website.
- We will also publish the presentation slides and participant list on the webinar web page.
- 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.

Today's webinar

- **Will cover:**

- Introduction to IHI programme
- IHI Call 1 Topic 3:
 - Challenge, need for public-private collaborative research
 - Scope, outcomes & impacts, budget
- Proposal submission, evaluation & preparation tips

- **Will not cover** rules and procedures

- The webinar on **rules and procedures** is at:
www.youtube.com/watch?v=qriw3AbEP-M
- **Preparing proposal budgets** webinar:
Monday 27 June | 14:30-16:00
Register at: <https://europa.eu/!PfGJf7>



Innovative Health Initiative

EU's new **partnership in health** between:

- the **European Union** represented by the European Commission
- &
- **Healthcare industry associations:**
 - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
 - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
 - **EuropaBio** (biotechnology industry)
 - **MedTech Europe** (medical technology industry)

IHI's general objectives

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need
- Make Europe's health industries globally **competitive**.

Strategic Research & Innovation Agenda

Focus

- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

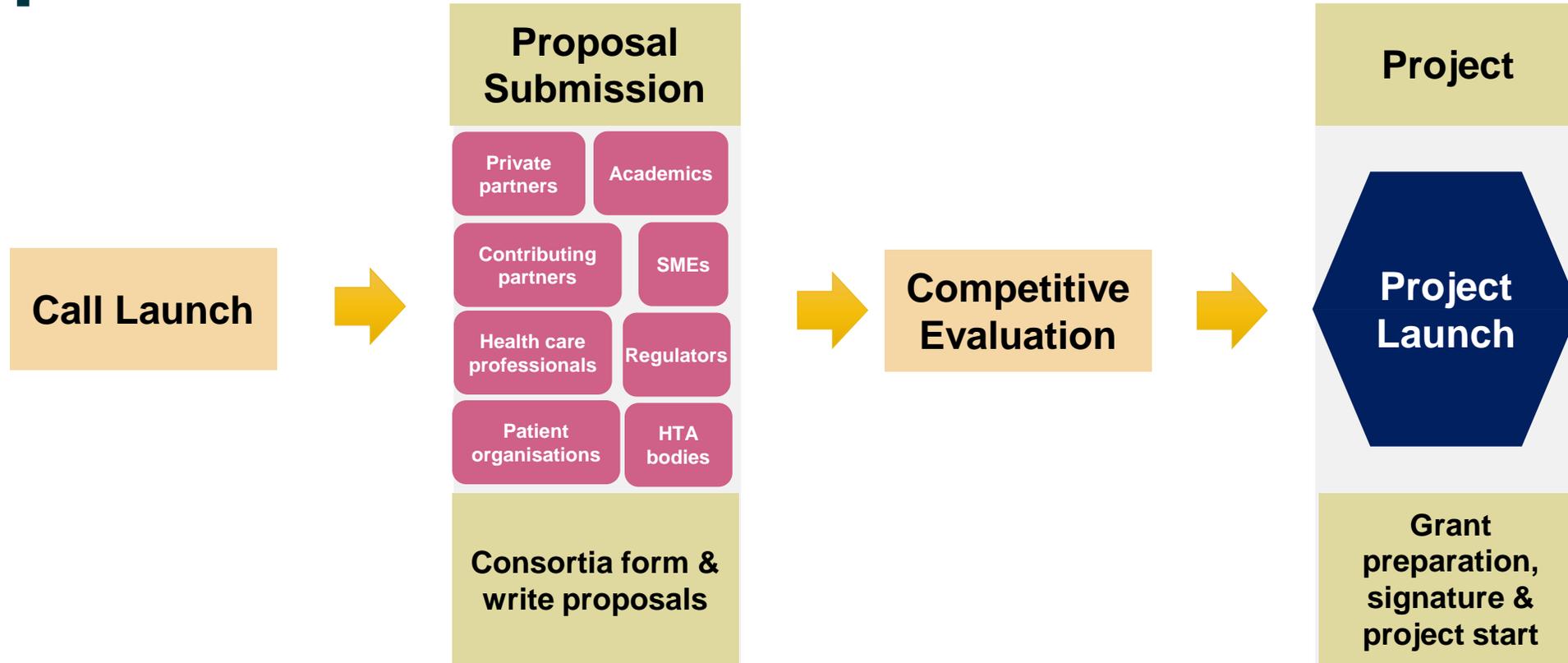
Goal

- Lay foundations for development of **safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level



How does IHI work? single-stage procedure





Personalised oncology: innovative people centred, multi-modal therapies against cancer

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The challenge

- Different treatment modalities are available for various cancers
- Multi-modal therapies shown to be of high value
- The differing biology of cancers as well as the differing efficacy of treatment modalities show the need of patient-specific approaches
- Strong need to increase the therapeutic arsenal of such multi-modal therapies and to tailor the treatment approach to the individual patient.



Need for public-private, cross-sector collaboration

The development of integrated, interoperable health care solutions can only be fully harnessed if barriers to cross-sectoral collaboration and to collaboration between the following partners are overcome:

- **Patients** to ensure people centred approach
- **Different industry sectors** in health to exchange knowledge and experience and find optimal combinations of solutions.
- **Academia and healthcare providers** to leverage innovative clinical concepts and ensure the clinical relevance of technical and scientific innovations.



Scope of the topic

The aim of this call topic is **biomarker-guided multi-modal precision oncology**.

- Proposals should facilitate **the development of new health technologies** and integrate them with current therapy concepts, to create and explore **multi-modal therapies**.
Applicant consortia should pursue different therapeutic strategies and **combine at least two cancer treating modalities** (supported by a sound scientific rationale in the application).
- The proposed activities should include development of **research protocols** for multi-modal therapies to 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.

Scope of the topic

Depending on the specific therapies to be studied and combined, the activities should consider:

- The **clinical decision-making process** aspect among the various disciplines involved.
- The evaluation of aspects such as the **sequencing, timing and dosing** of therapies to maximise treatment effects with minimal toxicity and normal tissue complications.
- The use of **prognostic and predictive biomarkers** and the combination of **diagnostic tools** to plan and adapt treatment and evaluate treatment and the follow up of patients (key component of the proposed integrated healthcare solutions).
- **Methodologies and standards** for the combination of various technologies into integrated healthcare solutions.
- **The design and conduct** of clinical studies of multi-modal therapies and **methods to evaluate** their safety and clinical benefits



Expected outcomes

Platform, standards and regulatory

- **A 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 healthcare pathway standards** to enable personalised 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 and potentially supported by in vitro diagnostics.
- **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** through the patient journey, involving early-response biomarkers and evaluation of their predictive power, as well as **more involvement of patients in the cancer patient journey**.

Expected impact

- **Breaking down fragmentation** between various disciplines of medicine and technological areas.
- **Fostering the development** of safe and effective innovative health technologies.
- Better and faster **integration of future products, services and tools** along the healthcare pathway responding to patients' specific needs.
- **Patients benefit from treatment and care** better adapted to their needs through improved diagnostics, prognosis and monitoring their quality of life.
- **Integrated health care solutions**, including those based on the use of digital solutions.

Budget & Duration

BUDGET

- Applicant consortia will be competing for the maximum financial contribution from IHI up to **EUR 40 000 000**.
- IHI estimates that an IHI financial contribution of around **EUR 10 000 000 to EUR 20 000 000** would allow a proposal to address these outcomes appropriately.
- Applicant consortia shall 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.

DURATION

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

Simplified example budget

| Participant type | Total costs | Requested IHI funding | In-kind contributions (IKOP, IKAA, FCs) |
|---|-------------------|-----------------------------|--|
| 'Public' partners (Universities, hospitals, SMEs, patient orgs, regulators.....) | 20 million | 20 million | 0 |
| Private members & Contributing partners | 20 million | 0 | 20 million |
| Total | 40 million | 20 million (50%) | 20 million (50%) |

Dissemination, exploitation and communication

- Crucial to ensure **take up of project results** after the funding ends.
 - **Long term impact**
- In your proposal, you must:
 - Describe the activities that are planned
 - Describe the target group(s) addressed
 - Reserve sufficient resources for these activities



Proposal Submission & Evaluation

Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.
- **Part B** of the proposal is the **narrative part** that includes three sections:
 - Excellence
 - Impact
 - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**
- **Annexes:**
 - Participant type
 - Budget details
 - Clinical studies template

Evaluation Criteria (1/2)

● Excellence

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

● Impact

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
- Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
 - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.



- Tips for applicants

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
 - www.ihl.europa.eu/apply-funding/open-calls
 - www.ihl.europa.eu/apply-funding/future-opportunities
- Form your consortium **early**
 - Always think “public-private partnership“
 - Include partners bringing **in-kind contributions**
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results



Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts, webinar & brokerage event participants:**

- ihi-calls-2022.b2match.io/components/20715

- Use EU Funding & Tenders portal **partner search tool:**

- <https://europa.eu/!QU87Nx>

- Get in touch with your **IHI national contact point:**

- <https://europa.eu/!D7jyMy>

- Network on social media:

- www.twitter.com/IHIEurope

- be.linkedin.com/company/innovative-health-initiative

