

**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: Patient-generated evidence to improve outcomes, support decision making, and accelerate innovation**

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

The following impacts are expected:

- Enable the added value of people-centred integrated healthcare solutions<sup>1</sup> to be assessed according to criteria that matter to patients and citizens, using patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs).
- Facilitate the development and implementation of integrated healthcare solutions based on patient input including PROMs, PPI, and PREMs. These solutions should better respond to the needs and preferences of patients and citizens and support an inclusive approach.
- Enable the smart use of patient input and patient-generated evidence to facilitate the faster market entry of patient-centric and cost-effective advanced integrated healthcare solutions<sup>1</sup>, and also spur further innovation by improving return on research and innovation investments.
- Use patient input gathered via m-health, e-health and other technologies to gain improved insights into the real-life behaviour of, and challenges faced by, patients of all ages with complex, chronic diseases and co-morbidities.

### **Expected outcomes**

Research and innovation (R&I) actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for the use cases selected:

- Decision makers have new methods for the integration of PROMs, PPI, and PREMs and other people-generated information into regulatory and health technology assessment (HTA) evaluation processes for integrated healthcare solutions.
- Patients of all ages have access to novel integrated healthcare solutions<sup>1</sup> that are developed using structured patient input and better respond to their needs and preferences.
- Researchers have new methodological approaches to elicit and integrate patient preferences into the conception, development, and implementation of integrated healthcare solutions<sup>1</sup>.
- Researchers have wider access to interoperable, quality patient input and patient-generated data, respecting the FAIR (findable, accessible, interoperable, reusable) principles, facilitating the research and development of integrated healthcare solutions.

<sup>1</sup> Integrated healthcare solutions are innovative solutions integrating various technologies, coupled with complementary tools and services.

- Researchers are provided with new outcomes, outcome measures and the time horizon over which value should be assessed to develop appropriate tools and methods for the collection and analysis of PROMs, PPI, and PREMs.

## Scope

The amount of health data generated by citizens themselves is rapidly increasing. Such data includes patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs), as well as other digital health data/digital biomarkers. While the potential for these data to be harnessed to improve individual healthcare is enormous, these data are often fragmented among multiple providers, so that neither the citizen, nor the healthcare ecosystem have a comprehensive overview, and therefore it is very challenging to fully use these data to provide reliable evidence for decision-makers, and to improve health outcomes.

Research and innovation (R&I) actions to be supported under this topic will aim to address this challenge by:

- Developing a framework to integrate patient input and patient-generated data for use in decision making (regulatory, health economic evaluation, reimbursement, healthcare programme design, tailored prescription of therapies, and technology development), benefit-risk evaluation and value assessment of integrated healthcare solutions.<sup>1</sup> Applicants should build on existing frameworks where appropriate and appropriately address ethics considerations.
- Implement several use cases to support and demonstrate the use of the framework, focusing on using patient input and patient-generated evidence to address challenges that are not adequately addressed by other initiatives. These use cases should demonstrate the value of using patient input (PROMs, PPI, PREMs) and patient generated data (digital health data/digital biomarkers) along the healthcare continuum, including showcasing improvements to data interoperability, healthcare workflows and processes, disease prevention, and care, including home-based care. These use cases should also act as examples of best practice for future use of the framework.
- Facilitating multi-stakeholder access to patient inputs and patient-generated health data such that actionable harmonised data can be used for quality decision making.
- Comparing/contrasting the properties of the three types of patient input (PROMs, PPI, PREMs), identify differences and opportunities for integrated/complementary use.
- Developing an approach or approaches to integrating PROMs, PPI, and PREMs data into the design of core outcomes sets, end-to-end patient treatment pathways, clinical decision support systems, and treatment guidelines. The core outcome sets used within the project should be made available more widely where possible.

Applicants are expected to seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice) and consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

As the cost of healthcare continues to rise, integrated healthcare solutions<sup>1</sup> offer possibilities for delivering better patient outcomes more efficiently. However, the infrastructure for developing effective solutions at scale and for evaluating novel 'high-value' care products, programmes, and services is fragmented.

While patient input is critical to developing these person-centred integrated care solutions, to date, coordination among different types of product and service providers has been mostly on an as-needed basis.

There has been little incentive for these diverse research disciplines and different types of product and service providers to coordinate their efforts to develop systematic approaches to the use of patient-generated data.

Such patient input can be derived from multiple sources, which have different theoretical foundations and are at different levels of methodological maturity. Different types of patient input, although complementary, require different skill sets that are often not found within a single institution. Only a pre-competitive collaboration that brings together patients, healthcare professionals, industry sponsors, researchers, programme designers, and programme evaluators, can ensure the effective implementation of patient input in the design, evaluation, and implementation of effective innovated integrated care strategies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 14 000 000 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 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**

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" do not apply<sup>2</sup>.

<sup>2</sup> See section 4.2.3.2 of this second amended Work Programme.