

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 1: Support healthcare system resilience through a focus on persistency in the treatment of chronic diseases

Expected outcomes

The main outcome of this research collaboration is to better understand why significant advances in technology in recent years have not contributed to widespread improvements in healthcare systems, which still struggle to keep more than 50 % of people on chronic disease treatment for longer than 12 months. The goal is to develop and pilot innovative and multi-stakeholder approaches leveraging social innovation activities and scalable technology to improve the health outcomes of people living with chronic diseases by supporting treatment persistency with a particular focus on diabetes, obesity, and cardiovascular disease. Persistency is part of drug adherence and is defined as the length of time between starting treatment and the last dose which immediately precedes discontinuation of medication.

Although novel treatments are becoming more available with major improvements in convenience and efficacy, poor persistency to treatment is still a major challenge in the healthcare system. Insights from pilots under this topic will be shared with relevant stakeholders of the healthcare ecosystem to improve outcomes for people living with chronic diseases. The pilots should include cardiometabolic diseases, such as diabetes, obesity, and cardiovascular disease. Other chronic diseases may be considered in this collaboration if they contribute to the overall understanding of barriers and opportunities. Moreover, it is not the goal to develop new technologies and/or pharmaceutical drugs during the course of the project, but rather to address how insights and new approaches can be applied in clinical practice and implemented in guidelines and recommendations.

The action under this topic must contribute to all of the following outcomes:

- map and share insights from existing projects, pilots and datasets to get to a shared understanding of what the barriers and opportunities in the respective healthcare systems are in order to improve persistency and health outcomes for people living with chronic diseases;
- develop and implement new/ revised collaborative models between public and private organisations with the aim of improving persistency and health outcomes;
- generate clinical and scientific evidence to demonstrate results in order to show the value of these new approaches and technologies;
- integrate new insights into the treatment regimen in close collaboration with people living with chronic diseases to improve disease outcomes;
- develop a consistent methodology/framework for measuring persistency using real-world data;
- develop recommendations and consensus reports with relevant healthcare stakeholders;
- optimise communication between healthcare systems and patients to improve persistency.

Scope

The scope of this topic is to improve treatment persistency among people living with chronic diseases. According to the [MEDI-VOICE](#) project funded by the European Commission, non-adherence to medication accounted for approximately 200 000 deaths annually in the European Union, and according to a World Health Organisation (WHO) report from 2003, around 50 % of people living with a chronic disease do not adhere to the prescribed medication. From a recent analysis by Kvarnström et al (2018) [1], the major barriers for adherence to medication range from a lack of disease knowledge by the patient to logistical barriers like availability of medication and price (see list below), ultimately leading to discontinuation of medication.

The major categories of barriers identified are:

- patient specific, e.g. lack of knowledge, lack of routines, poor health literacy, gender, transition from paediatric to adult care, socioeconomic background;
- disease specific, e.g. lack of symptoms, lack of improvement, illness fatigue;
- treatment specific, e.g. side effects, complexity in dosages, inconvenience;
- healthcare and system specific, e.g., poor communication among stakeholders including e.g. physicians, patients, pharmacies, insurance providers, service providers, policy makers;
- social and culture specific, e.g. stigmas, religious belief, other alternatives;
- logistic and finance specific, e.g., price, renewal of prescription.

To address these barriers, this topic is expected to focus on the healthcare- and system-specific categories. The barriers to persistency identified in the list above are strongly interlinked, and in an effort to better understand the healthcare ecosystem in relation to persistency, it is the goal to especially explore the interface between the patient and healthcare providers. It is well-described that a lack of timely and accurate interaction/communication between patient and healthcare provider is key. Patients may lack education about their disease(s) and when support is minimal and there is insufficient patient counselling available, it can leave the patient with unanswered questions which might lead to discontinuation of their medication. In addition, social components, in particular health inequalities including stigma and financial barriers, will also be in focus.

In this topic we propose a strong public-private coalition to help define and drive new models for collaboration across the healthcare ecosystem to improve persistency. This is to the benefit of patients as well as healthcare system sustainability by leveraging scalable technology that may hold the key to improving healthcare at the same time as providing it to many more individuals projected to have chronic diseases. A key component to successful implementation will be the patient voice and user experience.

It is planned to:

- share experiences and insights from existing pilots in specific healthcare environments and disease areas;
- use both observational and diverse clinical research methodologies to demonstrate impact, including health economics and outcomes research;
- drive fit-for-purpose studies to secure the evidence needed to maximise impact – particularly moving from test to scale;
- foster close collaboration between industry and academia within this field to ensure fast and feasible execution in real-world settings;

- build internal understanding & competencies within persistency to inform drug, study and service development;
- build training programmes for healthcare stakeholders;
- analyse how the new learnings/insights might be implemented in clinical treatment guidelines.

Expected impacts

The action under this topic is expected to achieve the following impacts and contribute to the following EU policies/initiatives:

- improving outcomes for patients with chronic diseases by supporting them to stay on the recommended and most efficient treatment, reducing symptoms and side-effects in the best way;
- less co-morbidities for patients on chronic disease treatment;
- reducing inefficiencies and costs in healthcare systems.

These impacts are in alignment with objective 2 and 3 in the IHI JU.

Results from the IMI BEAMER project are expected to be taken into account and incorporated. The action resulting from this topic is expected to reach out and work together with other initiatives, e.g. IMI Gravitare Health and those funded through the [Horizon Health](#) call on “Ensuring access to innovative, sustainable and high-quality health care”. Data collection will be in agreement with recommendations from the European Health Data Space (EHDS).

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

Persistency in chronic disease care is one of the major known cost drivers in the healthcare system. Addressing the underlying barriers and potential improvements requires co-development by a number of different players in the healthcare system. It also requires a neutral platform to discuss solutions and insights to co-create and adopt solutions. It is expected that this is a multidisciplinary and cross-sectorial collaboration between pharma and technology companies, service and platform providers, insurance providers, healthcare professionals and patients.

Pre-identified industry consortium and contributing partners

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following pharmaceutical and medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Abbott
- Eli Lilly
- Menarini
- Novo Nordisk (Lead)
- Pfizer
- Sanofi
- Servier

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e., beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged

that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall as project leader facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 11 300 000.

This budget is expected to cover four pilots in different disease areas (including diabetes, obesity, and cardiovascular disease) in different geographies and healthcare systems. It is expected that infrastructure for data collection, de-identification, harmonisation, user interfaces, apps, and other relevant tools will have to be set up and customised. Also, the number of required stakeholders and parties for this collaboration is large and will require a solid governance setup and well-functioning stakeholder management.

- The indicative in-kind and financial contribution from industry beneficiaries is EUR 11 300 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The pre-identified industry consortium and contributing partner(s) expect to contribute to the IHI JU project by providing the following expertise and assets:

- results and insights from existing pilots and studies;
- real-world evidence (RWE) and clinical trial data;
- expertise in medical & science, data collection, epidemiology, evidence generation, publication support, digital health, market access, patient voice, health economics and outcomes research;
- data platforms, digital tools, apps, remote monitoring technology.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partner(s).

This may require mobilising the following expertise and/or resources:

- access to relevant data on persistency and treatments, such as access to electronic health records and public data;
- expertise in patient journey, clinical practice, and chronic disease management, health economics and outcomes research and health technology assessment within relevant disease areas.

At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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' do not apply.

References

1. Kvarnström K, et al. Barriers and facilitators to medication adherence: a qualitative study with general practitioners. *BMJ Open*. 2018