

**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: Improving clinical management of heart disease from early detection to treatment**

### **Expected outcomes**

Actions under this topic must contribute to the following outcomes, ultimately contributing to reducing the burden of heart disease:

- Health care systems and patients benefit from the development of integrated solutions for improving critical aspects in the overall care pathway (primary, ambulatory and hospital care) for heart disease.
- Health care systems and patients will benefit from the development or optimisation of innovative technologies leading to personalised, patient-centric solutions for the early detection, diagnosis or treatment of heart disease.
- Patients benefit from proposed strategies tailored to their needs for improved outcomes in heart disease.
- Healthcare professionals benefit from the deployment of solutions for improved diagnostic procedures, referral programs or clinical workflows as well as targeted training for relevant clinical staff where appropriate.

### **Scope**

Heart disease includes structural heart disease (SHD), coronary artery disease (CAD), heart failure (HF) and heart arrhythmias, which are common, devastating, and heterogeneous medical conditions causing a high burden in Europe and worldwide<sup>12</sup> [1][2]. It is estimated that SHD affects 14 million people in Europe alone, while, worldwide, HF affects more than 64 million [1], atrial fibrillation more than 37 million [2] and 244.1 million people were living with CAD in 2020<sup>2</sup>. The impact of these diseases is significant both in terms of the health-related quality of life of patients and caregivers, and the large economic burden, amounting to over 280 billion euro in the EU for cardiovascular disease (CVD [3]). In Europe, the prevalence of these conditions is expected to rise due to the ageing population and the lifestyle of citizens and, thus, the economic burden will also increase dramatically in the next decades with the costs for health care accounting for the largest part [3][4][5].

However, despite the importance of SHD, CAD, HF and heart arrhythmias, disease management and long-term outcomes remain heterogeneous [6] due to the lack of comprehensive access to detection, diagnosis and care. The care of people with heart disease is also highly complex, with a multitude of diagnostic procedures and multidisciplinary therapeutic approaches available, including pharmaceutical, minimally invasive and surgical interventions, disease-modifying therapies, and cardiac rehabilitation. Moreover, means for early diagnosis are often suboptimal, thus novel approaches should be explored to provide sustainable and scalable solutions [7].

Critically, improved early detection, diagnosis, referral and patient stratification linked to optimised clinical workflows and clinical decision making hold the promise of faster, personalised treatments. However, to achieve their successful implementation, there is the need for substantial cross-sectorial

<sup>1</sup> [About Structural Heart Diseases | SHD Coalition](#)

<sup>2</sup> [2022 Heart Disease & Stroke Statistical Update Fact Sheet Global Burden of Disease](#)

research and innovation and better integration of the different steps of care from primary to hospital care for an optimised disease management in more efficient healthcare settings.

Projects funded under this topic should address all or any of the following heart diseases: SHD, CAD, HF, and heart arrhythmias.

Applicants are expected to assemble a suitable cross-sectoral public-private partnership to propose activities to address the following objectives in heart disease. In this context, applicants may consider identifying and addressing only some critical aspects of the patients' journey, or of specific care settings with the aim to contribute to the overall care pathway improvement.

- Improve the efficiency of primary care, ambulatory or hospital care, considering how to optimise the patient pathway from one to the other and the transition among the teams in each care setting.
- Improve patient outcomes through earlier detection, better diagnosis, monitoring and/or treatment. This may include the development or deployment of innovative technologies or package solutions for early detection and diagnosis, or to seamlessly both treat and monitor (e.g. personalised imaging technologies, personalised sensing technologies, artificial intelligence (AI)-powered clinical decision tools, digital imaging, diagnostics' technologies).
- Develop and implement measures and digital tools to enhance efficiency and optimise patient outcomes in primary and hospital care (e.g. reducing hospitalisations, disease burden and/or length of stay), and ensure a continuum between early detection, diagnostic and therapeutic approaches by guiding patients faster to the selection of the best treatment modality. For example, via procedural automation, non-invasive testing, improved access to data, integrated pathways dashboards, and AI-powered clinical decision making.
- Develop personalised, patient-centric solutions in diagnosis and treatment to improve patients' healthcare experience, considering the needs of specific populations, such as children, elderly patients, cardio-oncology patients, or patients with co-morbidities.
- Adequate consideration should be given to the sustainability and scalability of the proposed solutions.
- Explore management strategies combining access to medical teams specialising in heart disease and social interventions to address population inequalities in outcomes. Also consider the heterogeneity of the healthcare system in Europe and generate evidence applicable across the diversity of European realities.
- Conduct an initial health economic study (such as cost-effectiveness analyses, budget impact models etc) of the proposed interventions on the healthcare system.
- Patients and health care professionals should be engaged in all stages of the project from conceptualisation and throughout the implementation (e.g. in raising public awareness, education of patients, helping with the improvement of the referral pathway and the pathway to treatment, developing targeted training for relevant clinical staff).
- Consider the potential regulatory impact of the results and as relevant develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g., national competent authorities, the European Medicines Agency (EMA) Innovation Task Force, qualification advice).

Applicants should also reserve resources to synergise with other relevant initiatives, including other projects funded under this topic and those resulting from IHI Call 2 topic 1<sup>3</sup> and IHI Call 5 topic 3<sup>4</sup>, as well as with other European research initiatives and infrastructures such as the European Partnership on Transforming Health and Care Systems (THCS), the Healthier together – EU non-communicable diseases (NCD) initiative, among others.

<sup>3</sup> <https://www.ih.europa.eu/apply-funding/ih-call-2>

<sup>4</sup> <https://www.ih.europa.eu/apply-funding/ih-call-5>

## Expected impacts

Actions under this topic are expected to achieve the following impacts:

- Patients benefit from personalised patient-centred healthcare from early detection to treatment, and improved patient outcomes and experience due to advanced detection, diagnostic, decision-making and disease management throughout the continuum of care.
- Healthcare professionals benefit from novel diagnostic procedures and optimised clinical workflows, which lead to improved clinical outcomes for heart disease.
- Healthcare systems benefit from organisational solutions and an efficient transition through the different stages along the whole continuum of the care pathway for heart disease.
- Companies develop and offer advanced, robust and scalable solutions that leverage innovative technologies, tools and services allowing for integration with other existing workflows to effectively and efficiently support healthcare professionals and health systems in achieving their goals.

Actions are also expected to contribute to the following EU policies/initiatives:

- European Partnership on Transforming Health and Care Systems (THCS)
- Healthier together – EU non-communicable diseases (NCD) initiative
- The European Commission proposal for a European Health Data Space (EHDS).

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

The complexity of clinical care for SHD, CAD, HF and heart arrhythmia patients calls for the involvement of different industry sectors involved in diagnosis, data analytics, clinical decision-making, and pharmaceutical and non-pharmaceutical interventions. Beyond industry, it requires bringing together researchers, hospitals, medical staff, patients and patient organisations. The IHI framework provides the ideal setting to create a fruitful collaboration and leveraging of resources and know-how of all these stakeholders and deliver the expected outcomes from this topic.

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 25 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 12 500 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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 and costs for the action-related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). While 45 % is the threshold for eligibility, applicant consortia are strongly advised to aim for 50 % to provide a margin e.g. for unforeseen changes during the project lifetime. IKOP and FCs may be contributed by the constituent and affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document "call text" published on the IHI website).

## 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 call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

## References

- [1] Savarese G, Becher PM. Global burden of heart failure: a comprehensive and updated review of epidemiology. *Cardiovasc Res.* 2023 Jan 18;118(17):3272-3287
- [2] Lina Wang, Feng Ze, et al. Trends of global burden of atrial fibrillation/flutter from Global Burden of Disease Study 2017. *Heart* 2021;107:881-887.
- [3] Cardiovascular disease cost the European Union economy €282bn in 2021 — Nuffield Department of Population Health (ox.ac.uk).
- [4] d'Arcy, Joanna L., et al. Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. *European heart journal* 37.47 (2016): 3515-3522.
- [5] Hessel FP. Overview of the socio-economic consequences of heart failure. *Cardiovasc Diagn Ther.* 2021 Feb; 11(1): 254–262.
- [6] Lawson CA, Zaccardi F, Squire I, et al. 20-year Trends in Cause-Specific Heart Failure Outcomes by Sex, Socioeconomic Status, and Place of Diagnosis: A Population-Based Study. *Lancet Public Health* 2019;4:e406-20. 10.1016/S2468-2667(19)30108-2
- [7] Luise Gaede MD, Marta Sitges MD, Johnson Neil, Eleonara Selvi, William Woan, Richard Derks, Helge Möllmann. European heart health survey 2019. *Clinical Cardiology*, Vol.43, Issue 12.