

**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 : A city-based approach to reducing cardiovascular mortality in Europe

### Expected outcomes

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

- **Patients and citizens** will benefit from better preventive measures, earlier detection and diagnosis, better outcomes for disease management, and access to innovative and effective treatments for cardiovascular disease (CVD), as needed,
- **Healthcare providers** will benefit from updated, evidence-based guidelines on CVD management and more efficient clinical pathways. They will gain clarity on what best practice in health management and CVD prevention means in European cities,
- **Healthcare system decision makers** will have better evidence and tools to implement appropriate CVD prevention strategies, including digital therapies allowing its introduction in clinical practice and adoption by all segments of society.
- **Health technology assessment bodies, payers and regulators** will benefit from better information on real-life use of cardiovascular medicinal products, the benefit-risk profile of medical devices and value of CVD prevention in cities/urban areas (note: a city/urban area is expected to have a population of at least 50.000 in its urban centre, in line with the OECD-EC (Organisation for Economic Co-operation and Development – European Commission) definition of a city<sup>1,2</sup>).
- **Researchers, including industry stakeholders, and clinical investigators** will benefit from models and findings that will help future program implementation in other cities in Europe and beyond.

### Scope

Cardiovascular Diseases (CVD), the world's leading cause of mortality, are responsible for over 18 million deaths annually, with a staggering cost of EUR 282 billion in 2021 [1]. The CVD risk has been acknowledged by WHO's Sustainable Development Goal (SDG) 3.4 aiming to reduce heart disease rates by one-third by 2030<sup>3</sup>. Trends in the total population of EU27 and UK from 1961 to 2018 show a decline in the share of population living in rural areas over the total population, while towns and cities experienced a smooth and constant increase. Europe's level of urbanisation was 75% in 2022<sup>4</sup> is expected to increase to approximately 83.7% in 2050<sup>2</sup>. In cities, CVD risks are amplified by factors like pollution, scarcity of green spaces and stressful lifestyles. The trend towards urbanisation often lead to significant healthcare disparities and worsening of CVD outcomes especially among underserved communities. Thus, an improvement on the management of CVD in cities would be of significant benefit for the great majority the European citizens living in an urban context.

The focus of this topic is on identifying and creating scalable models, interventions, and practices to enhance the overall efficiency and effectiveness of CVD management based on existing (e.g.

<sup>1</sup> OECD-EC. "[Cities in Europe: The new OECD-EC definition](#)". 2012.

<sup>2</sup> European Commission, "[Urbanisation in Europe](#)," last updated July 2020.

<sup>3</sup> WHO, "[Noncommunicable diseases \(who.int\)](#)". September 2023.

<sup>4</sup> <https://data.worldbank.org/>

[Cardio4Cities](#)) [2] or new pilots in up to 5 cities, to build evidence for replication across Europe in different socio-economic conditions.

The action funded under this topic will consider primary and secondary prevention strategies, early detection, timely diagnosis and treatment (healthcare delivery), lifestyle changes (personal responsibility), and living environment (community responsibility).

Against this objective, the future action is expected to deliver:

- Models and/or good practices (including governance structure, funding/financing models, etc.) and roadmaps on cost effective approaches to improve cardiovascular (CV) health management that can be replicated across Europe.
- Recommendations for updating European guidelines and standards on CVD management (including primary, secondary prevention and treatment)
- A stronger definition and improved selection of performance indicators on CV mortality, patient outcomes and economic impact of interventions.
- Harmonized data standards for measurement of performance and impact (including PROMs<sup>5</sup>, PREMs<sup>6</sup>, Patient Preference, Clinical Outcome Assessments etc.).
- An easy-to-use digital platform (ideally based on existing solutions to ensure interoperability) and high-quality data that enable a data driven approach to CVD risk management.
- New solutions including digital and telehealth for early detection and monitoring of CVD patients.
- Recommendations on enhancing patient use of and access to technology and digital therapies (telemedicine, wearables, clinical mobile apps...).
- A platform, network, or another support mechanism for exchange of good practice, learnings, and experience, to support further deployment of successful approaches across Europe and beyond.
- Recommendations on improving living conditions to support the goal of decreasing impact of cardiovascular diseases.

To address this challenge, the action funded under this topic should:

- Select up to 5 cities to serve as pilot use cases. These cities should be representative of the European context (in particular on size and population) to allow broader implementation across regions/countries, different cultural and/or economic distributions. Indicatively, each pilot city (or another urban administrative entity) is expected to have a population of at least 50.000 in its urban centre, in line with the OECD-EC definition of a city.
- Conduct a gap analysis of existing cardiovascular disease screening and diagnostics, clinical pathways and public health policies to guide the development of scalable models and best practices to fill these gaps, also considering broader European application (for example, set targets, define actions, strengthen enablers). The identified solutions for improvement should be based on data-driven insights to identify multi-sectorial interventions that improve the management of CVD risk factors (such as hypertension, diabetes, low-density lipoprotein cholesterol) and preventing these risks from developing. They should also consider the entire continuum of care (detect, treat, control). Applicants are expected to consider all applicable legislative and regulatory constraints and their possible impact on the implementation and

<sup>5</sup> PROM: Patient Reported Outcome Measurements

<sup>6</sup> PREM: Patient Reported Experience Measurements

results of the project. End-users (including citizens, patients, healthcare professionals and providers, health technology developers among others) should be included from the start in the co-creation to ensure future buy-in and implementation.

- Collaborate with patients to develop strategies and guidance for effective CV health awareness campaigns.
- Collaborate with healthcare professionals to review and adapt guidance on CVD prevention and management.
- Set up sustainable platforms and other support mechanisms for deployment of the models (sharing best practice between pilot cities and across regions)
- Pilot novel and/or improved early detection and diagnostic solutions, patient management strategies, (including improved patient support, remote patient management, patient flows), and initiatives to maintain workforce engagement.
- Explore potential funding tools to complement healthcare systems funding for managing cardiovascular health (including bonds, insurance, crowdsourcing, etc.) to implement the models.
- Leverage existing and newly created sources of multimodal data for decision making and management of CVD (collecting, connecting, standardising, processing and analysing)
- Design and deploy communication and awareness-raising campaigns, including training and capacity building for health workers to effectively address various population groups affected by CVD.

Applicants should consider synergies with relevant initiatives at National level and with other European health initiatives such as the European Innovation Partnership on Active and Healthy Ageing,<sup>7</sup> Reference site collaborative Network,<sup>8</sup> and Urban Health Cluster,<sup>9</sup> to maximise the potential for creating models that can be applied in various urban settings to improve cardiovascular health. This collaborative approach underscores the potential for cross-applicability of health solutions in addressing chronic diseases.

The action should also consider learnings and synergies with other IMI and IHI initiatives such as H2O, EHDEN, BigData@Heart, iCARE4CVD, among others.

Applicants are expected to 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, EMA Innovation Task Force, qualification advice).

## Expected impacts

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

- Decrease the CVD burden in European cities by the reduction of CV events, disability, and mortality.
- Enable future clinical pathways leading to improved patient outcomes.

<sup>7</sup> European Commission, "[The European Innovation Partnership on Active and Healthy Ageing \(EIP on AHA\)](#)." Accessed March 2024.

<sup>8</sup> Reference Site Collaboration Network, "[Home - RSCN](#)." Accessed March 2024.

<sup>9</sup> Urban Health Cluster, "[Urban Health Cluster | The first European Cluster to improve and safeguard health and well-being of citizens, leaving none behind](#)." Accessed March 2024.

- Reduce the pressure of patients flow in the healthcare system via innovative diagnostic/detection solutions.
- Strengthen the definition, standardization and selection of performance indicators on CVD mortality, patient outcomes and economic impact of interventions, and thus help future clinical pathways and intervention implementation studies.
- Optimise healthcare expenditure to tackle the financial strain of CVD, amounting to €282 billion annually in the EU [3]. The emphasis is on prioritizing spending for maximum efficiency and value, balancing the costs of advanced interventions with their long-term benefits.
- Strengthen public awareness initiatives and incorporate improved diagnostic methods to enhance early detection and treatment of CVD to reduce premature CVD deaths and support preventive healthcare measures.
- Strengthen patient input to treatment pathways, disease monitoring and scientific guideline enhancement.
- Contribute to European policy on Active and Healthy Aging and align with the European Commission's proposal for the European Health Data Space (EHDS).<sup>10</sup>

These impacts are in alignment with specific objectives 3 and 2 of IHI JU<sup>11</sup>.

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

This action requires collaboration among multiple public and private sectors and stakeholders due to the multifaceted nature of urban CVD challenges. The economic viability is also a key consideration and require multiple parties to come together for economy of scale by having all actors working together collaboratively in a consortium and not in a fragmented manner, as well as for solutions to be adoptable by, and beneficial for, European health systems.

Pharmaceutical companies, biotech firms, medical device manufacturers, and health ICT sectors must join forces and collaborate to create an integrated approach to CVD management. Collaboration between private (industry) and public partners (city management, academia, healthcare practitioners, community, patients, payers) is key for ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs and future expectations.

The public-private partnership model ensures that industry innovations are effectively translated into practical health solutions, considering regulatory standards and real-world applicability.

### **Pre-identified industry consortium**

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 with regard to such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry

<sup>10</sup> European Commission, "[Green Paper on Ageing](#)," January 2021; European Commission, "[Proposal for a regulation - The European Health Data Space](#)," May 2022

<sup>11</sup> [https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

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 15 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**
- The indicative in-kind contribution from industry beneficiaries is EUR 15 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

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 72 months.

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

### Contribution of the pre-identified industry consortium

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

- Ongoing pilots (including models, management, or coordination platforms)
- Data from prospective observational studies
- Necessary health interventions: medical devices (e.g. wearables), diagnostics, medicines
- Support to the organisations of meetings, workshops, conferences and setting up the coordination and dissemination platform (including IT systems where appropriate)
- Expertise in the field of R&D in relevant science fields, clinical development, medical and regulatory affairs, medical education, health economics, data management, communication.

### Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and expected outcomes of the topic, considering the expected contribution from the pre-identified industry consortium.

This may require mobilising the following expertise in:

- Clinical practice in CVD in both primary and secondary care
- Clinical investigators/researchers in CVD
- Health economics and outcomes

- Economic modelling and financial tools
- Data and knowledge management
- Artificial Intelligence
- Communication and awareness raising campaigns.
- Healthcare systems organisations.
- Complex project management.
- Telehealth and remote patient management.
- Health impact of living conditions/urbanism.

Key resources might include : data, data platforms, diagnostic and monitoring tools, education and training infrastructure, communication platforms (including social media and other).

Key stakeholders to be involved include (not limited to): public health and research institutions, learned societies, hospitals, health providers, health systems managers, medical associations, patient organisations, community leaders. Connectivity with competent authorities responsible for planning and deployment of programmes targeted by the action is a must (in advisory role or as participants in the action).

At the second stage, the consortium selected at the first stage and the predefined industry consortium 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] Kotseva K, Gerlier L, Sidelnikov E, Kutikova L, Lamotte M, Amarenco P, Annemans L. Patient and caregiver productivity loss and indirect costs associated with cardiovascular events in Europe. *Eur J Prev Cardiol.* 2019 Jul;26(11):1150-1157. doi: 10.1177/2047487319834770. Epub 2019 Apr 6. PMID: 30955367.
- [2] Reiker et al., "[Population health impact and economic evaluation of the CARDIO4Cities approach to improve urban hypertension management,](#)" *Plos Global Public Health.* April 2023.
- [3] Luengo-Fernandez et al, "[Economic burden of cardiovascular diseases in the European Union: a population-based cost study.](#)" *National Library of Medicine.* December 2023.

### Glossary

Acronym	Meaning
CVD	Cardiovascular Disease
EHDS	European Health Data Space
EC	European Commission
EU	European Union
IHI JU	Innovative Health Initiative Joint Undertaking

IMI	Innovative Medicines Initiative
OECD	Organisation for Economic Co-operation and Development
PROMs	Patient Reported Outcome Measures
PREMs	Patient Reported Experience Measures
SDG	Sustainable Development Goal
UK	United Kingdom
WHO	World Health Organization

INDICATIVE TEXT