A city-based approach to reducing cardiovascular mortality in Europe

IHI call 8 – Topic 1

Kalliopi Christoforidi, Scientific Project Officer 18/06/2024 • Online



Before we start...

- We are recording this session and it will be published on the IHI website. We will also publish the presentation slides.
- The call will be launched shortly and all links and details of how to apply will be published on the IHI website and the Funding and Tenders Portal.
- If you want to ask a question please use the chat function on the right corner of your screen.



Today's webinar

• Will cover:

- Introduction to IHI programme
- IHI call 8 topic 1 presented by lead of the pre-identified industry consortium
- Proposal submission & evaluation
- Tips for writing a successful proposal

• Will not cover

rules and procedures



Innovative Health Initiative

EU 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)











European Union

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.



IHI projects are...

Created via open and competitive calls for proposals

Cross sectorial public private partnerships leveraging:

- Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

• Public funding via European Commission (Horizon Europe)



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



https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda



A city-based approach to reducing cardiovascular mortality in Europe

IHI call 8 – topic 1

Franck Perraudin 18.06.2024 • Online



ASCVD* is a major driver of heart attacks and strokes. It is also a major contributor to cardiovascular death - #1 killer worldwide









Deaths due to cardiovascular diseases per year rising to 24 million in 2030 CV deaths are due to heart attacks and strokes, or ASCVD

Recurrent CV events are **preventable**

Costs to healthcare system by **2030**

World Health Organization. Cardiovascular diseases (CVDs). Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) [Last accessed: March 2022]. McClellan M, Brown N, Califf RM, Warner JJ. Call to Action: Urgent Challenges in Cardiovascular Disease: A Presidential Advisory from the American Heart Association. Circulation. 2019;139(9):E44–E54. World Health Organization. WHO Cardiovascular diseases –Programme. Available from: https://www.who.int/health-topics/cardiovascular-diseases/#tab=tab_1 [Last accessed: March 2022]. The Global Economic Burden of Non-communicable Diseases. https://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf. Accessed March 21st, 2022



ASCVD* - Atherosclerotic Cardiovascular Disease

Cardiovascular burden in Europe: #1 public health issue

For the first time in 50 years EU countries have reported an increase in premature CVD deaths. These adverse trends have been attributed to an insufficient awareness of CVD, limited and geographically varied investment in cardiovascular prevention and treatment and the rising prevalence of obesity (with that of diabetes, hypertension, dyslipidemia and atherosclerosis).¹

The avoidable death rates for working age adults from cardiovascular disease accounted for **65.5%** of the age-standardized avoidable cardiovascular mortality rate and more than **60 million potential years of life are lost** in Europe annually.^{2, 3}



Source: https://ehnheart.org/eu-action-on-cvd.html

- 1. EU Action on CVD (ehnheart.org)
- 2. Trends in Avoidable Mortality from Cardiovascular Disease in the European Union (Ise.ac.uk)
- 3. Late-Breaking Science: New data highlight the huge economic burden of CVD in Europe (escardio.org)

4. 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.

In 2021, CVD cost the EU €282 billion⁴

€155B (55%) in healthcare costs

€47B (17%) in productivity losses

€79B (28%) in the costs of informal care of people with CVD



The challenge

Cardiovascular Diseases (CVD), the world's leading cause of mortality, are responsible for over 18 million death annually, with a staggering cost of EUR 282 billion in 2021, €155B (55%) in healthcare costs, €47B (17%) in productivity losses, and €79B (28%) in the costs of informal care of people with CVD¹

- 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.
- 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, while towns and cities experienced a smooth and constant increase. In 2022, Europe's level of urbanisation was 75%, it is expected to increase to 83.7% by 2050².
- CVD risks are amplified in cities by factors such as pollution, scarcity of green spaces and stressful lifestyles. The trend towards urbanisation often leads to significant healthcare disparities and worsening of CVD outcomes especially among underserved and disadvantaged communities.



^{1.} OECD-EC. "Cities in Europe: The new OECD-EC definition". 2012.

^{2.} European Commission, "Urbanisation in Europe," last updated July 2020.

Need for public-private, cross-sector collaboration

The public-private partnership model ensures that industry innovations are effectively translated into practical health solutions

- The **multifaceted and complex nature of urban CVD challenges** required collaboration among multiple public and private sectors and stakeholders.
- Economic viability is a key consideration and requires multiple parties to come together for economy of scale, by having all actors working together in a consortium and not in a fragmented manner, as well as for solutions to be adoptable, and beneficial for, EU health systems.
- Pharmaceutical companies, biotech firms, medical device manufacturers, and health ICT sectors must 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.



Scope of the topic

• 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. <u>Cardio4Cities</u>) or new pilots **in up to 5 cities**, to build evidence for replication across Europe in different socio-economic conditions.

• These pilots should propose a good coverage of different geographies and contexts in Europe and deliver scalable solutions be used for other cities. 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).



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, and clarity on what best practice examples 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).
- 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.

innovative

Expected impact - 1/2

The action under this topic is expected to achieve all the following impact and contribut3 to the following EU policies/initiatives:

- Conduct a gap analysis of existing cardiovascular disease screening and diagnostics, also high-stress lifestyles (nutrition, physical activity) socioeconomic disparities
- 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.
- 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 €282B annually in the EU (1). 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.



Expected impact – 2/2

The action under this topic is expected to achieve all the following impact and contribut3 to the following EU policies/initiatives:

- Strengthen patient and citizen input to treatment pathways, disease monitoring and scientific guideline enhancement.
- Contribute to the European policy on Active and Healthy Aging, aligning with the European Commission's proposal for the European Health Data Space (EHDS) (2). to implement the EHDS by providing FAIR data aligned with the EHDS requirements.
- Start building a system for continual impact assessment and provide early evidence on the impact and effectiveness of the applied recommendations.
- Use learnings and outcomes to synergize with other IHI and IMI initiatives

These impacts are in alignment with specific objectives 3 and 2 of IHI JU (3).



^{1.} Luengo-Fernandez et al, "Economic burden of cardiovascular diseases in the European Union: a population-based cost study." National Library of Medicine. December 2023.

^{2.} European Commission, "Green Paper on Ageing," January 2021; European Commission, "Proposal for a regulation - The European Health Data Space." May 2022

^{3. &}lt;u>https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf</u>

Expected contributions of the industry consortium

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'):

- Menarini
- Novartis AG (Lead)
- Novo Nordisk
- Servier
- Siemens Healthineers
- Huawei

Note: 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 beneficiaries shall as project leader facilitate an efficient drafting and negotiation of project content and required agreements.



Expected contributions of the applicants

Expertise and resources expected to be brought into the project by pre-identified industry consortium:

- 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.



Key Facts

Budget

- The maximum financial contribution from the IHI JU is up to EUR 15 000 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 15 000 000.
- 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).
- Duration
 - 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.





Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS





S MedTech Europe from diagnosis to cure





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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
- Annex:
 - Participant type



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

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.



Evaluation Criteria (2/2)

Quality and efficiency of the implementation

- Quality and effectiveness of the outline of the work plan
- 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
 - <u>www.ihi.europa.eu/apply-funding/future-opportunities</u>
- Form your consortium early
 - Already think "public-private partnership"
- 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

See our <u>guide for applicants and project consortia on regulatory considerations</u> <u>for IMI and IHI projects</u> for useful advice on regulatory issues to consider when preparing your proposal



Finding project partners

You'll need to build or join a consortium!

- Network with your contacts & IHI Call days participants:
- https://ihi-call-days.ihi.b2match.io/
- 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:
 - <u>www.twitter.com/IHIEurope</u>
 - <u>be.linkedin.com/company/innovative-health-initiative</u>





Thank you for your attention

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#IHICallDays











10:30-11:30 Novel endpoints for osteoarthritis by applying big data analytics



14:30-15:30 Modelling regulatory sandbox mechanisms and enabling their deployment



15:30-16:30 Patient-centred clinical-study endpoints derived using digital health technologies



etnia







V2 Vaccines Europe





How to book your meetings via the B2Match platform

Book your meetings in 4 easy steps

- 1. Make yourself available
- 2. Look for partner on the participants tab
- 3. Select date, time, attendees (up to eight per meeting), add message
- 4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: <u>https://europa.eu/!fnJFFM</u>



Questions time

If you want to ask a question please use the chat function on the right corner of your

screen



