# Cardiovascular diseases - improved prediction, prevention, diagnosis, and monitoring

IHI call 2 – topic 1

Kalliopi Christoforidi, scientific project officer, IHI
22.06.2022 • Online

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# Before we start…

- We are recording this webinar and it will be published on the IHI website.
- We will also publish the presentation slides and participant list on the webinar web page.
- 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.

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# Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI Call 2 Topic 1 presented by lead industry pre-identified consortium
  - Proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover** rules and procedures
  - The webinar on rules and procedures is at: www.youtube.com/watch?v=qriw3AbEP-M

- **Webinar on how to complete the financial part of the proposal**
  - Monday 27 June, 14:30
    Registration: https://bit.ly/39LB8K6

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# Innovative Health Initiative

EU's new **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)

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COCIR Advancing Healthcare | efpia | EuropaBio The European Association for Bioindustries | MedTech Europe from diagnosis to cure | Vaccines Europe | Co-funded by the 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**.

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# 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

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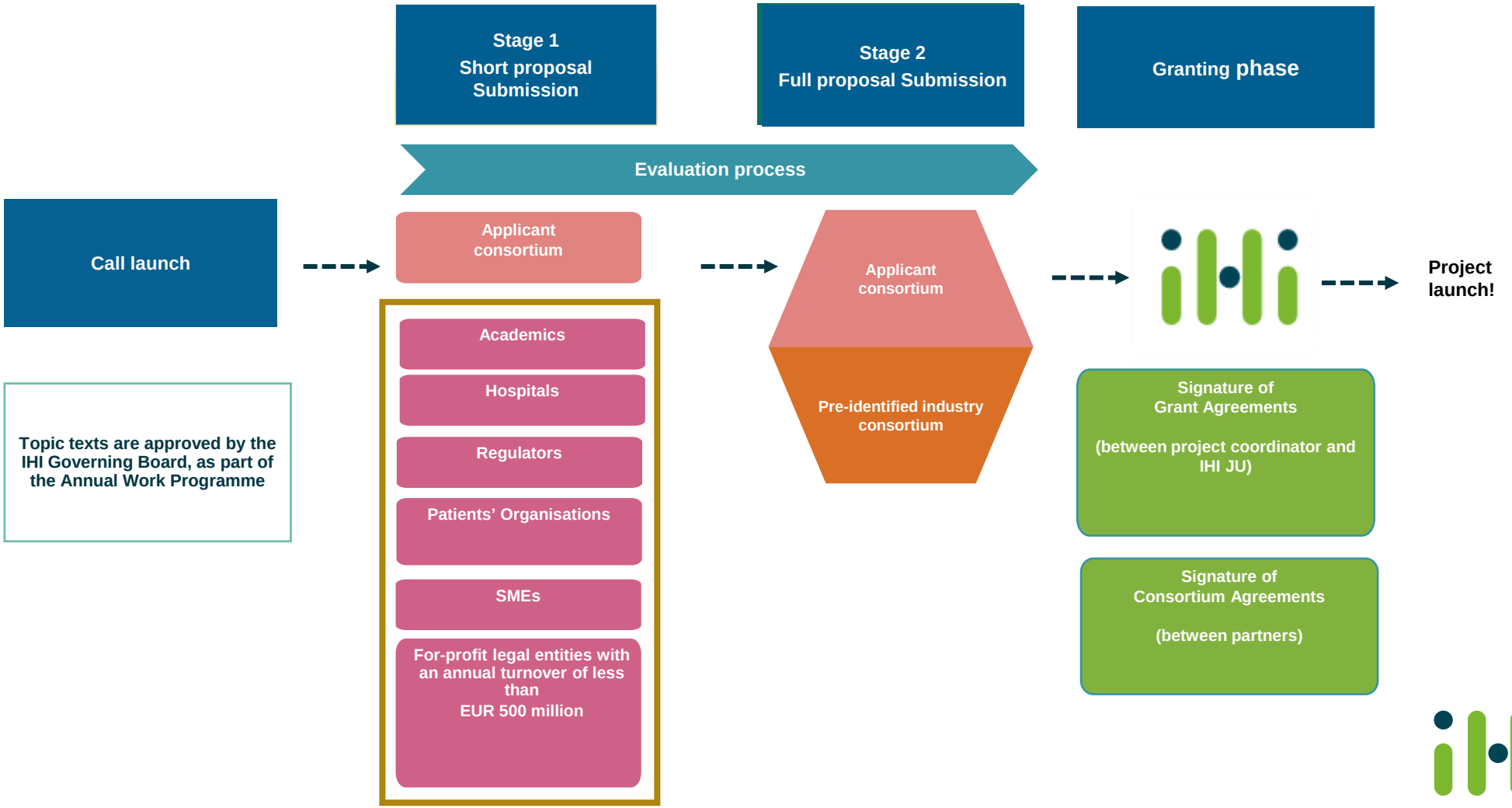
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

# Two –stage calls – How does it work?

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# Cardiovascular diseases - improved prediction, prevention, diagnosis, and monitoring

## IHI call 2 – topic 1

Gerard Kornelis Hovingh, Novo Nordisk
22.06.2022 • Online

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# Proposal Submission & Evaluation

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# 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

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# 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.

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# Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

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# Tips for applicants

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# Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - www.ihi.europa.eu/apply-funding/open-calls
- 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

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# Finding project partners

**You'll need to build or join a consortium!**

- Network with **your contacts**
- Network with **fellow webinar participants**
- 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:
  - www.twitter.com/IHIEurope
  - be.linkedin.com/company/innovative-health-initiative

www.ihi.europa.eu/apply-funding/find-partners

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Thank you for your attention

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COCIR Advancing Healthcare

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Kees Hovingh
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# The challenge

- Cardiovascular disease is one of the leading causes of morbidity and mortality
- 60 mill people in EU live with CVD, annual cost of 210 bill EUR

Currently a “one size fits all approach” is the standard



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Source: www.waghostwriter.com/staff_name/kent-golf-academy/

# The aim

- Need a better risk classification
- Need a better identification
- Need a better understanding of the
  - natural progression of disease
  - impact of interventions beyond simply ”counting the events”, which invariably comes with delay

- This will result in:

***Smarter design, development, and evaluation of novel therapies***

Which serves the ultimate aim:

The right intervention for the right individual at the right time

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# Need for public-private, cross-sector collaboration

- **Combine multitude of databases** of clinical academic institutions (large cohorts of patients with multimodality imaging for example), research institutes (data about genetic risk markers; genome wide variation), large pharmaceutical companies (intervention studies, plasma and genetic biobanks), medical device manufacturers (large numbers of datasets from device treatment data, proteomics data, specific novel biomarker tests), and healthcare wearables (large datasets on biometrics)
- Concerted action needed for **sustainable data collection** that explores news ways of leveraging existing ‘open access’ databases and subsequent analysis by different stakeholders with a multitude of areas of expertise working in aggregated task forces. Close collaboration with payers, patients, and regulators.
- **Interchange of knowledge and experience** is needed to change behaviours in a clinical practice with empowered patients (e.g. through PROMs and PREMs), supported by interest organisations within the area of public health
- Cross-sectorial collaboration can help to recognise and appropriately **address** sex, race and cultural **biases and disparities in the healthcare delivery process** of CVD management and enable novel ways to deliver people-centred, safe, effective, cost-effective, and affordable **health solutions**



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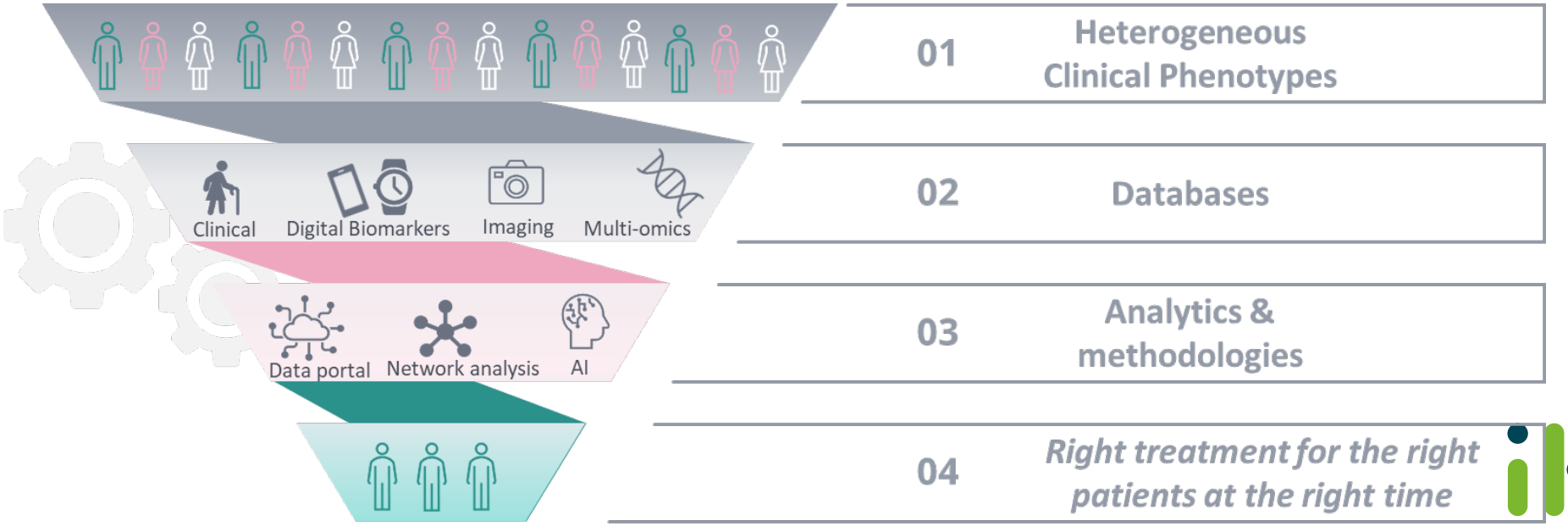
# Scope of the topic

- Identify risk factors
- Focus on initial drivers
- The continuum ranging from early development to secondary prevention
- Patient empowerment (wearables, biometric data)
- Sustainable models for assessing future interventions

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# Some examples

ESC European Society of Cardiology

European Heart Journal (2022) **43**, 1569–1577
https://doi.org/10.1093/eurheartj/ehac055

CLINICAL RESEARCH
*Ischaemic heart disease*

## Targeted proteomics improves cardiovascular risk prediction in secondary prevention

ORIGINAL ARTICLE

## Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation

Marco V. Perez, M.D., Kenneth W. Mahaffey, M.D., Haley Hedlin, Ph.D., John S. Rumsfeld, M.D., Ph.D., Ariadna Garcia, M.S., Todd Ferris, M.D., Vidhya Balasubramanian, M.S., Andrea M. Russo, M.D., Amol Rajmane, M.D., Lauren Cheung, M.D., Grace Hung, M.S., Justin Lee, M.P.H., et al., for the Apple Heart Study Investigators*



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# Expected outcomes

- Identify hurdles and solutions towards **right treatment for the right patient at the right time**
- Identify **risk factors** and **predictive/prognostic models**
- Build **sustainable database** (proteomics, genomics, transcriptomics, biometrics, imaging, behaviour)
- Platform for **scientific dialogue** and educational environment with KOLs, HTAs and regulators, politicians, policy makers, and CV interest groups
- Support building a CVD **patient community** in EU
- Increase **holistic** understanding across drugs, devices, data, digital, diagnostics
- Drive **prevention** of cardiometabolic complications
- Pave the way for more **sustainable clinical trials** and evidence models for CVD
- Better and **earlier treatment options** in clinical practice



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# Expected impact

- **Increased accuracy of diagnosis and efficacy of treatment**
  - Individualised sub-phenotype-risk approach & risk-focused targeted therapy
- **Empowered and encouraged patients**
  - Take control over their health by accessing an integrated overview
  - Including biometric data from wearables and their health information
  - More informed dialogue with their healthcare provider(s)
- **Early diagnosis** of CVDs
  - Better understanding of the mechanisms involved
  - More cost-effective strategies
  - Identification of new care pathways



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# Expected contributions of the applicants

- Identification of and **access to relevant data sources** (devices, intake forms, diagnostic and exploratory tests) for ASCVD, CKD, T1D, and HF
- **Plan for data capture**, storage, and sharing, e.g. integration into a federated database
- Increase **understanding of early disease**
- Generate & validate a **risk model**
- **Include social, ethical, regulatory aspects**, through real-word evidence and wearables
- Develop **model for** short- and long-term **economic consequences**
- Develop **decision tool** for physicians
- Integrated **PROM**
- Explore possibilities for **novel methods** of clinical development and trial execution

**IHI funding for applicant consortium: 11 179 000 EUR**



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# Expected (in-kind) contributions of the industry consortium

- Data: data from clinical trials, biobank data, real world data, wearables and other smart devices, algorithms, identification of risk, sensor technology, telecommunication, data management/hospital information system, AI, mobile technology
- Expertise: medical expertise, bioinformatics, data science, public health, patient input, clinical and regulatory expertise, early identification from wearables
- Technology: such as wearable devices, mobile technology, telecommunication technology and other smart devices that will enable the recording of new data.
- Identify hurdles and solutions towards right treatment for the right patient at the right time

**Partners: Novo Nordisk (“Lead”), Becton Dickinson, Evotec, Fresenius, Huawei, Philips, Roche Diagnostics, Astra Zeneca, Lilly, Amgen, JDRF**

**In-kind contribution: 11 179 000 EUR**



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# Budget

- Maximum financial contribution from IHI up to **EUR 11 179 000**
- Indicative in-kind contribution from industry partners: **EUR 8 979 000**
- Indicative in-kind and financial contribution from IHI JU contributing partners is **EUR 2 200 000**
- Indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.

# Duration

- Indicative duration: **48 months**
- The predefined industry consortium and contributing partner may jointly agree on a different duration when submitting the full proposal

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Thank you for your attention

ihi.europa.eu

*[For two-stage calls:* ***Do NOT include the contact details of the industry partner(s).*** *Potential applicants should not contact industry people directly.*
***All questions*** *should go through the* ***IHI Programme Office****]*

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