Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence

IHI call 6 – topic 2

Colm CARROLL
16.01.2024 • Online

innovative health initiative

Before we start…

- We are **recording this webinar.** The recording and slides will be published on the IHI website and the B2Match platform.

- The call **has been launched** and all links and details of how to apply have been published on the IHI website and the Funding and Tenders Portal.
  https://www.ihi.europa.eu/apply-funding/open-calls
  https://europa.eu/!qCgKGR

innovative health initiative

Today’s webinar

Will cover:

- Introduction to IHI programme
- IHI Call Topic:
  - Challenge, need for public-private collaborative research
  - Scope, outcomes & impacts
- Proposal submission & evaluation
- Tips for writing a successful proposal

Will not cover rules & procedures

- This webinar is on the IHI website:
  - www.ihi.europa.eu/news-events/events/ihi-call-days-calls-6-7

innovative health initiative

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)

innovative health initiative

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**.

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

IHI projects are…

Created via **open & competitive calls** for proposals

Cross sectorial public private partnerships leveraging:

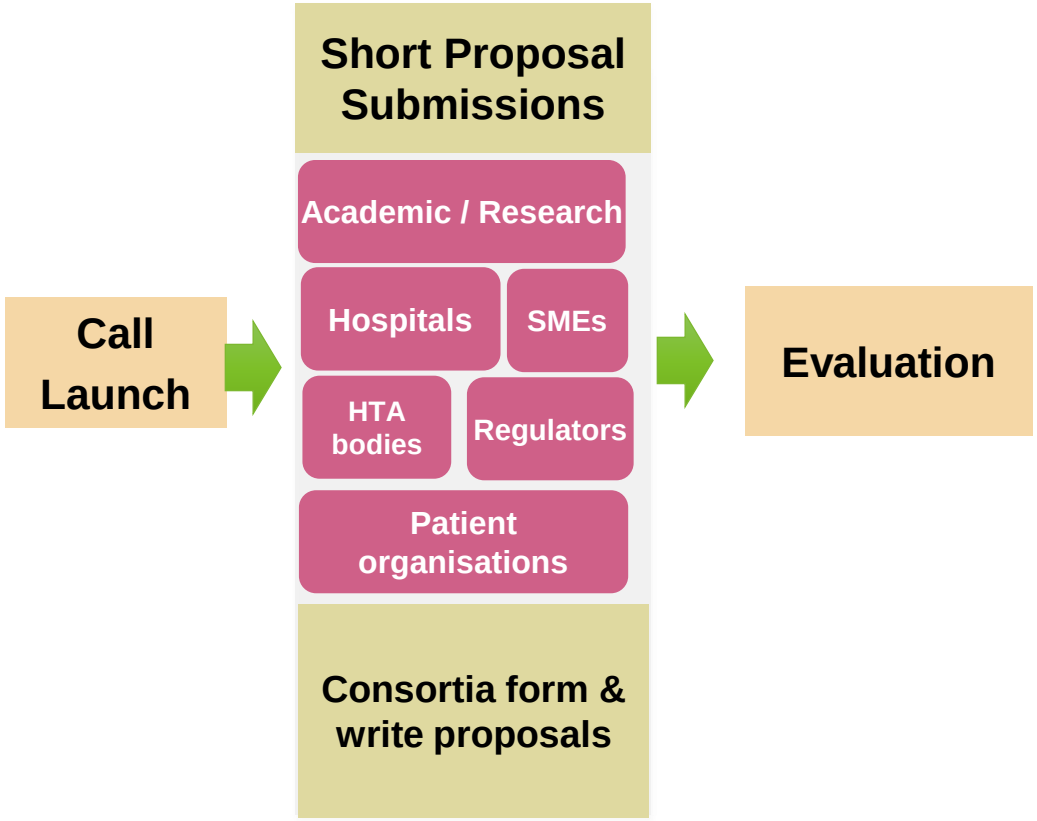
- **Contributions from industrial partners** (*COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)*
- if relevant, contributions from contributing partners

and

- **Public funding** via European Commission

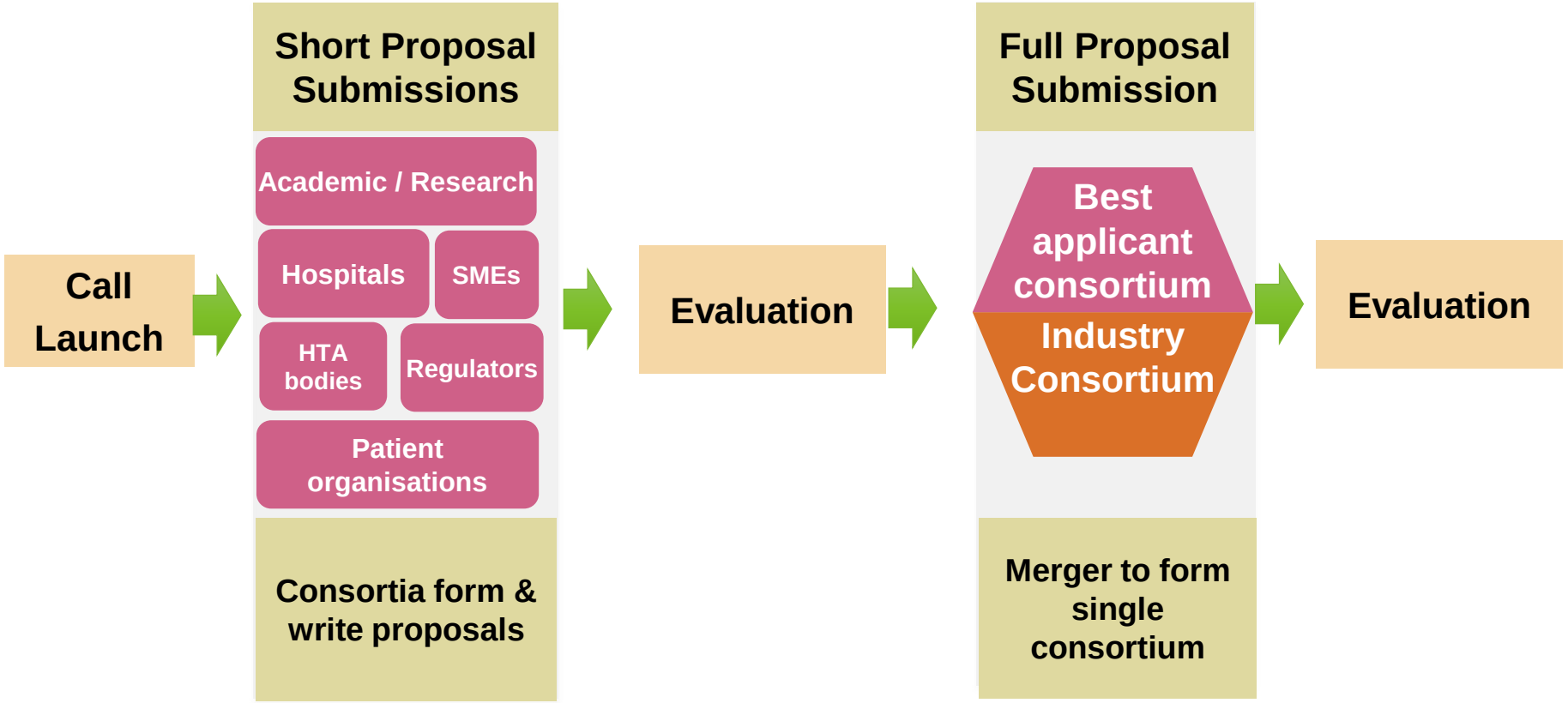
innovative health initiative

How IHI works: 2-stage calls



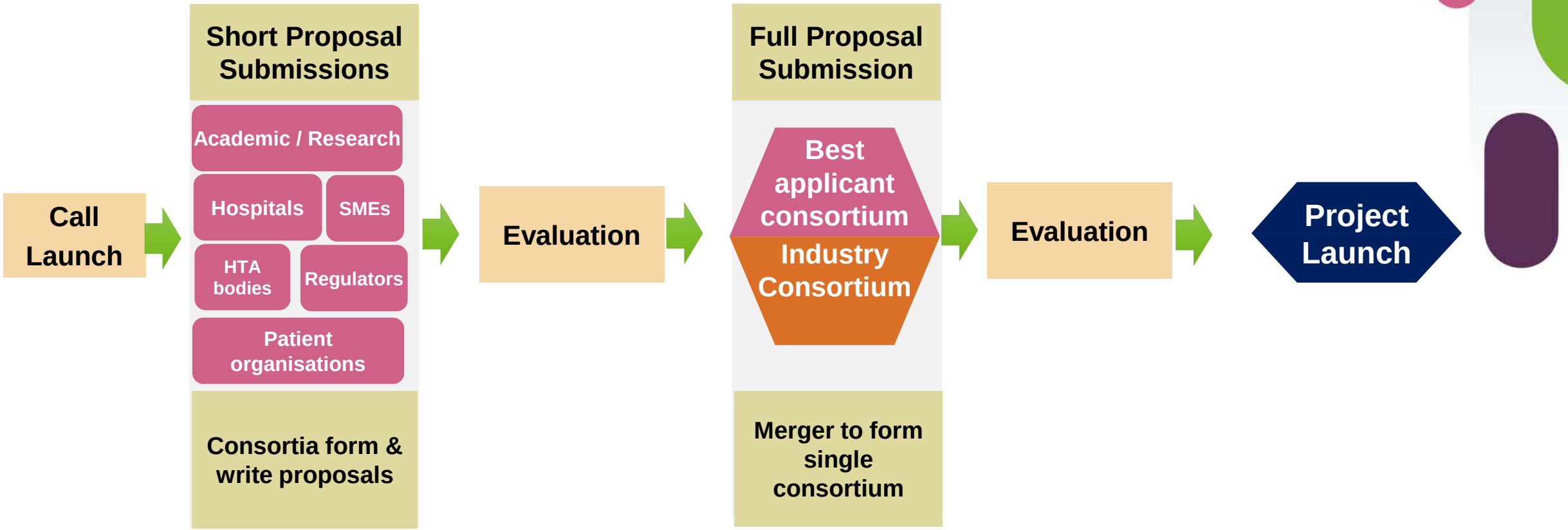
innovative health initiative

How IHI works: 2-stage calls



innovative health initiative

How IHI works: 2-stage calls



innovative health initiative

Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence

IHI call 6 – topic 2

Emel MASHAKI CEYHAN
16.01.2024 • Online

innovative health initiative

Need for public-private, cross-sector collaboration

Public-private, cross-sector collaboration will provide:

- **Access to Varied Data Sources:**
  - Public-private collaboration enables access to diverse data sources such as national/regional databases, healthcare providers, clinical sites, and industry-specific data, especially use cases.
- **Alignment with Regulatory Expectations:**
  - Collaboration with regulatory authorities, HTA bodies, and payers ensures that the developed guidance aligns with existing regulatory frameworks and addresses their expectations, facilitating acceptance and adoption.
- **Stakeholder Engagement:**
  - Public-private collaboration facilitates engagement with a diverse range of stakeholders, ensuring that the practical guidance reflects the needs, perspectives, and concerns of all relevant parties involved in RWD/RWE utilization.

innovative health initiative

The challenge

Development of Practical Guidance for Real-World Data/Evidence in HC Decision-Making

- Lack of structured, evidence-based, and practical guidance for the use of RWD/RWE in regulatory, HTA, and payer decision-making.
- Custom-made and non-standardized RWD/RWE submissions that require significant expertise and effort from sponsors and decision-makers.
- Variations in regulatory frameworks for medicinal products and medical devices, leading to different experiences and needs among stakeholders.

innovative health initiative

Scope of the topic

Step 0: Mapping of RWE/D landscape

Mapping of existing methodologies guidelines, practices and relevant projects .

Step 1: Analyze Previous Use Cases

In-depth study of a broad range of use cases where RWD/RWE has been previously assessed for decision-making.

Step 2: Development of Methodology

Based on the findings from the use case analysis, develop a draft of the methodology document and recommendations.

Step 3: Pilots

Conduct pilots to test the draft guidance in various contexts.

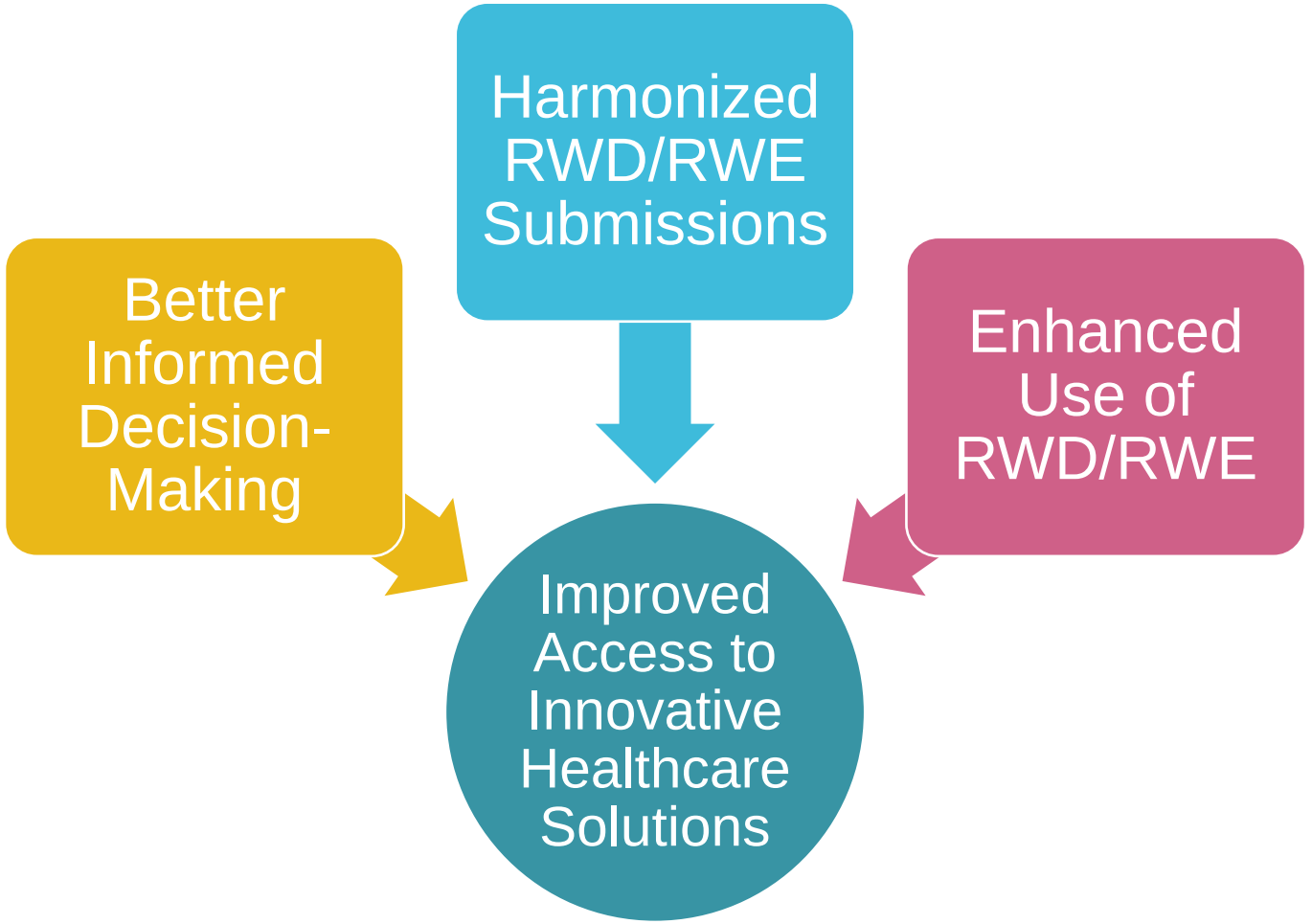
Step 4: Finalize the practical guidance

- Gather feedback and learnings from the pilots to refine and finalize the practical guidance document.
- Draft dissemination and training plans

Completed in the 1st year

innovative health initiative

Expected impact



innovative health initiative

Expected outcomes

Evidence based practical guidance for sponsors on the use of RWE/RWD

- Industry, sponsors, and other stakeholders have access to structured, evidence-based and practical guidance and recommendations on the use of real-world data / real world evidence (RWD/RWE).

- focus on medicinal products, medical devices, and therapeutic products that combine a medicinal product with a medical device (drug-device combinations).

- Regulators, HTA bodies and payers will receive more structured and consistent RWD/RWE submissions to inform their decision making.

innovative health initiative

Expected (in-kind) contributions of the industry consortium

The expected (in-kind) contributions of the industry consortium include the following:

- **Industry Expertise:** Real-world evidence, clinical development, benefit-risk evaluation, regulatory affairs, health technology assessment (HTA), health economics, and market access for medicinal products, medical devices, and combination products

- **Previously Assessed Use Cases**

- **Synergies with Existing Initiatives:** to advance RWD/RWD in EU such as the GetReal Institute, REDDIE, Real4Reg, RWE4Decisions, etc...It should also be aligned with the ambitions and guidelines set out for the European Health Data Space (EHDS).

innovative health initiative

Expected contributions of the applicants

comprehensive expertise in:

- **RWD/RWE incl. data science**, standards & guidance;
- access, linkage, and use of RWD and/or synthetic data to evaluate medicinal products, medical devices, and combinations;
- technical, legal and ethical requirements to **access and use patient data** in EU
- knowledge of medicinal product and/or medical device **development regulations**;
- **interacting with regulatory authorities**, national competent authorities, HTA bodies, notified bodies and payers;
- **consumer-directed communications** and/or patient advocacy (social media reach and expertise in health sector communications);
- **managing multi-stakeholder** cross-sectoral projects; citizens and/or patient representatives real-world data sources (healthcare providers, clinical sites, contract research organisations (CROs), vendors, national/regional databases);
- previous **use cases** that can be used **evaluate existing methodologies, guidelines**, and practices for the use of RWD/RWE in healthcare decision making.

innovative health initiative

Budget

- The maximum financial contribution from the IHI JU is up to **EUR 13 300 000**.
- The indicative in-kind and financial contribution from industry beneficiaries is **EUR 13 300 000.**

Duration

The indicative duration of the action is **60 months.**

innovative health initiative

Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Proposal submission & evaluation

innovative health initiative

Proposal Template

- **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 3 sections:
  - Excellence
  - Impact
  - Implementation

  Read instructions** in proposal template **very carefully

- **Annex:**
  - Participant type

innovative health initiative

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.

innovative health initiative

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.

innovative health initiative

Tips for applicants

innovative health initiative

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

innovative health initiative

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:
  - www.twitter.com/IHIEurope
  - be.linkedin.com/company/innovative-health-initiative

innovative health initiative

#IHICallDays

innovative health initiative

Call 6

- **15 Jan** **14:30** Rules & procedures: two-stage calls
- **16 Jan** **10:30** RWD / RWE in decision-making
- **16 Jan** **14:30** Treatment persistency

Pitches Info sesions

Call 7

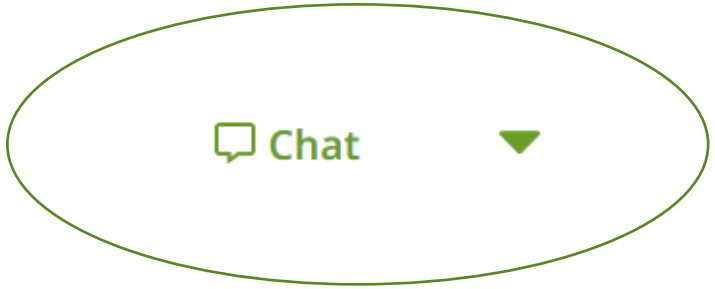
- **10 Jan** **10:30** Management of heart disease
- **10 Jan** **14:30** Optimised hospital workflows
- **11 Jan** **10:30** Rules & procedures: single-stage calls
- **11 Jan** **14:30** Clinical validation of biomarkers
- **12 Jan** **14:30** Single-stage calls: financial aspects
- **23 Jan** **14:30** Management of heart disease
- **24 Jan** **14:30** Optimised hospital workflows
- **25 Jan** **14:30** Clinical validation of biomarkers

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe

Co-funded by the European Union

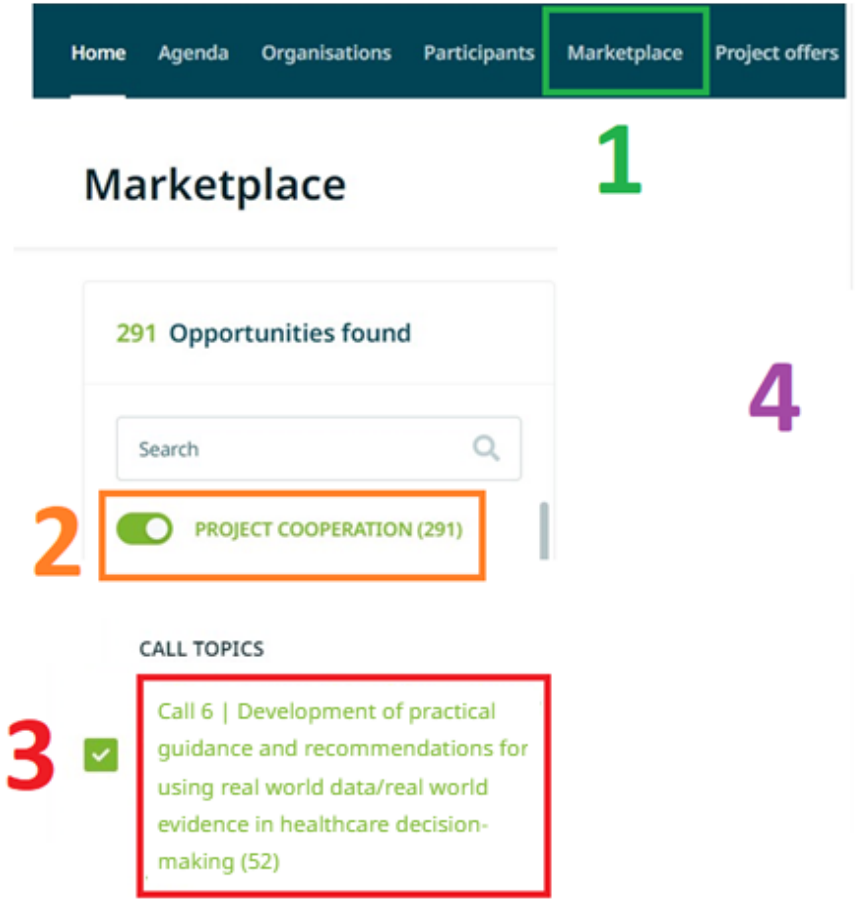
Questions

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



innovative health initiative

Marketplace



4

PROJECT COOPERATION — Updated on January 15, 2024

Multistakeholder Project Management, Communication, Data Governance

ARTTIC Innovation is a German consultancy with more than 35 years' experience in public funding and project management and more than 18 years in supporting innovations from large international public-private partnerships in the life sciences.

PROJECT COOPERATION — Updated on January 12, 2024

User-Centered Healthcare Processes Expertise - Analysis, Interoperability, P...

I have a strong interest in joining a project with my academic expertise. My background stands at the interesection of social and technical science.

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION — Updated on January 12, 2024

Mental Health in Chronic Disease: Streamlining Prevention and Treatment

We aim to tackle the high prevalence and impact of mental health conditions in people with chronic conditions associated with an increased risk for mental health burdens such as epilepsy. The focus is on developing, implementing, and evaluating screening, monitoring, and decision support tools to increase the patients' disease management and reduce the workload for the health care professional....

innovative health initiative

Matchmaking: Meet via B2Match

Book your meetings

1. Make yourself available using **meetings tab**
2. Find/meet partners on the **participants tab**
3. Enter meeting details, add a message.
4. **Send the request**

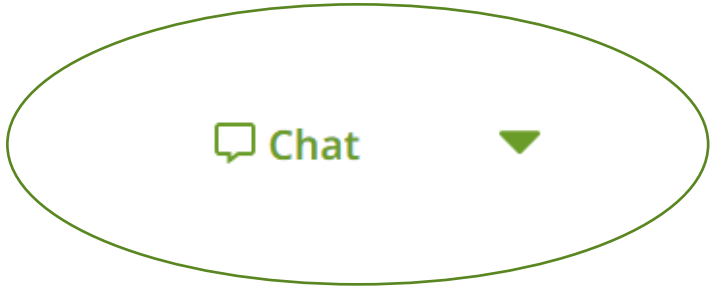
Step by Step guide

https://europa.eu/!fnJFFM

innovative health initiative

Questions

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



innovative health initiative

innovative health initiative

Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union