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

IHI call 6 – topic 2
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://www.ihi.europa.eu/apply-funding/open-calls)
  [https://europa.eu/!qCgKGR](https://europa.eu/!qCgKGR)
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

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)
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 & 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
How IHI works: 2-stage calls

Call Launch → Short Proposal Submissions → Evaluation

- Academic / Research
- Hospitals
- SMEs
- HTA bodies
- Regulators
- Patient organisations
- Consortia form & write proposals
How IHI works: 2-stage calls

1. **Call Launch**
   - **Short Proposal Submissions**
     - Academic / Research
     - Hospitals
     - SMEs
     - HTA bodies
     - Regulators
     - Patient organisations
   - Consortia form & write proposals
   - **Evaluation**

2. **Full Proposal Submission**
   - Best applicant consortium Industry Consortium
   - Merger to form single consortium
   - **Evaluation**
How IHI works: 2-stage calls

1. **Call Launch**
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2. **Evaluation**
   - Full Proposal Submission
     - Best applicant consortium
     - Industry Consortium
   - Merger to form single consortium

3. **Evaluation**
   - **Project Launch**
Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence

IHI call 6 – topic 2
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.
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.
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
Expected impact

- Better Informed Decision-Making
- Improved Access to Innovative Healthcare Solutions
- Harmonized RWD/RWE Submissions
- Enhanced Use of RWD/RWE
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.
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).
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.
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**.
Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS
Proposal submission & evaluation
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
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 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
  ● 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
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/](https://ihi-call-days.ihi.b2match.io/)
- Use EU Funding & Tenders portal **partner search tool:**
  - [https://europa.eu/!QU87Nx](https://europa.eu/!QU87Nx)
- Get in touch with your **IHI national contact point:**
  - [https://europa.eu/!D7jyMy](https://europa.eu/!D7jyMy)
- Network on social media:
  - [www.twitter.com/IHIEurope](http://www.twitter.com/IHIEurope)
  - [be.linkedin.com/company/innovative-health-initiative](http://be.linkedin.com/company/innovative-health-initiative)
#IHICallDays

**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

**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
Questions

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

1. Marketplace

2. 291 Opportunities found
   - Search

3. CALL TOPICS
   - Call 6 | Development of practical guidance and recommendations for using real world data/real world evidence in healthcare decision-making (52)

4. PROJECT COOPERATION
   - 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.

   - 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 intersection of social and technical science.
     - What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

   - 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...
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
Questions

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Thank you for your attention