Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union

IHI call 2 – topic 2

Nathalie Seigneuret, senior scientific project manager, IHI
16.06.2022 • 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 2 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

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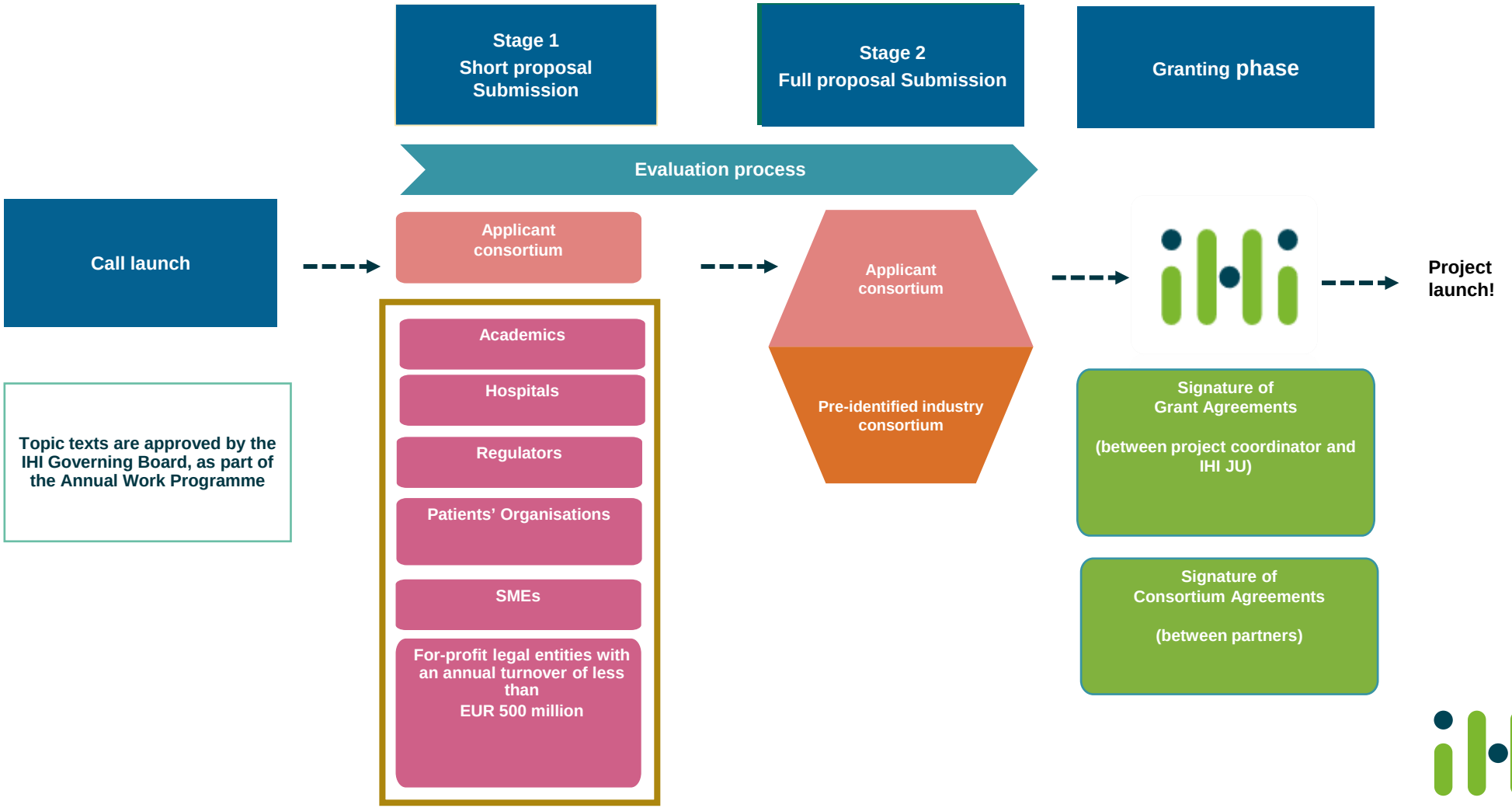
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

Two –stage calls – How does it work?



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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

efpia

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The challenge

Patients with unmet medical needs in Europe experience delay in access to valuable innovation

EU losing attraction for early clinical trials investments

European Clinical Excellence hub struggling to keep the pace of other regions globally

Early Feasibility Studies (EFS) not taken up in the EU

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Need for public-private, cross-sector collaboration

Experience from other regions
shows the potential of Public-Private collaboration and the potential of EFS ‘standardization’ in terms of uptake of EFS

Cross-sectorial collaboration a must
to ensure a harmonized understanding of best practice and one comprehensive methodology for EFS

The value of involving partners with relevant expertise:
regulators, HCPs, patients, SMEs, start-ups, research, academia, biostatisticians, legal experts, ethicists

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Scope of the topic

Set a tested and trialed EU methodology to promote the uptake of Early Feasibility Studies in the EU:

Blueprints, guidelines, templates

in line with EU regulations

Stakeholder network

Connected through an EU online portal

Use-cases (pilots)*

To test and validate the methodology

** Use-cases can and should ideally cover solutions across disease areas, with diverse technologies (medtech, digital, combination products, diagnostics…)*

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Expected outcomes

The EU methodology for EFS in the EU, stakeholder network and online portal will contribute to:

Patients: engaged from the start

EU-wide and national **regulators**, **HTA bodies**, **Notified Bodies**: Earlier knowledge, better plan, uniform approaches.

Healthcare professionals, medical societies, hospitals and researchers: Improved clinical excellence, stronger disease understanding, earlier quality data.

Health technology developers, incl SMEs: Controlled opportunity to test and assess early on, better informed development phase.

Expected contributions of the applicants

- **Expertise from:** regulators, healthcare professionals, patients and patient representatives, health technology developers and SMEs, HTA bodies, research organisations, academia, biostatisticians, legal experts, ethicists.

  - To co-create a comprehensive EU Methodology
  - To facilitate an active and sustainable stakeholder network
  - To develop an online portal with ‘all you need to know and do’ when conducting an EFS in the EU.
  - To run use-case where appropriate and relevant

IHI funding for applicant consortium: 10.7 Million EUR

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Expected (in-kind) contributions of the industry consortium

- Legal, ethics & compliance, regulatory, R&D, and clinical expertise to feed into the development of the EU Methodology and online portal.
- Propose potentially breakthrough technologies across disease areas to test the EFS methodology and inform any further adaptations (use-cases)
- Project management, dissemination and communication.

In-kind contribution: 10.7 Million EUR

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Budget

INDUSTRY:
10.7 Mill EUR In-kind

21.4 Million EUR

EU:
Matching 10.7 Mill EUR
For ‘public’ consortium

Industry consortium: Edwards, Abbott, Medtronic, WL Gore, Philips, Syntes (Johnson and Johnson)

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Indicative Duration: 48 months

Ongoing communication & dissemination

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The value of joining the innovative PPP

Contribute to implementing IHI Strategic Research Agenda

Improve patient access & understanding of disease

Improve quality of clinical evidence and attract clinical excellence

Facilitated running of EFS use-cases where relevant

Facilitate conduct of EFS and attract innovation

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Thank you for your attention

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