Modelling regulatory sandbox mechanisms and enabling their deployment to support breakthrough innovation

IHI call 8 – topic 3

Nathalie Seigneuret, senior scientific project manager
20.06.2024 • Online

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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.

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Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 8 topic 3 presented by lead of the pre-identified industry consortium
  - Proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover**
  - rules and procedures - Presentation & Recording

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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)

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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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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)

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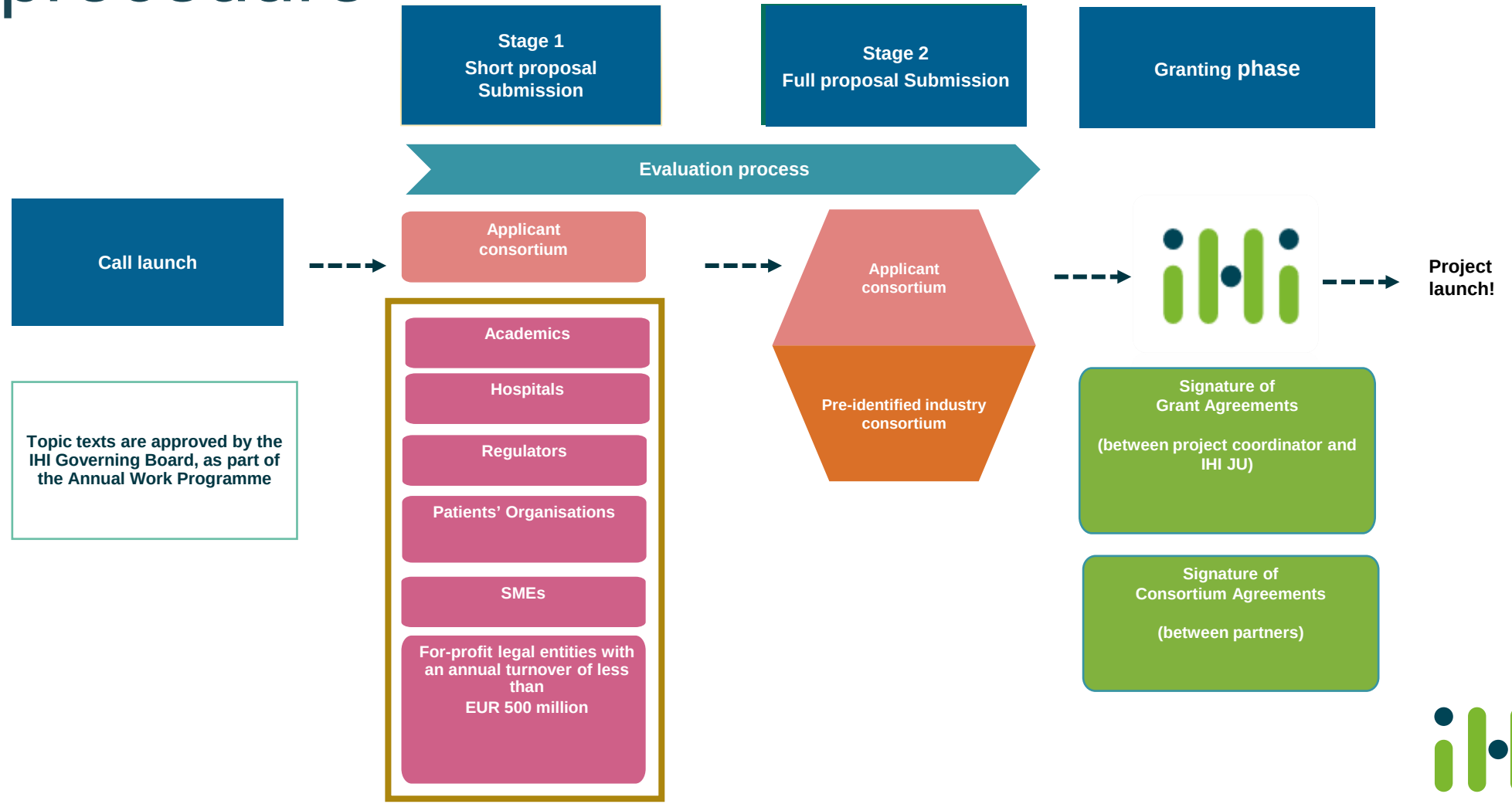
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure



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Modelling regulatory sandbox mechanisms and enabling their deployment to support breakthrough innovation

IHI call 8 – topic 3

Francois Hebraud (Roche) & Magdalini Papadaki (MSD)
20.06.2024 • Online

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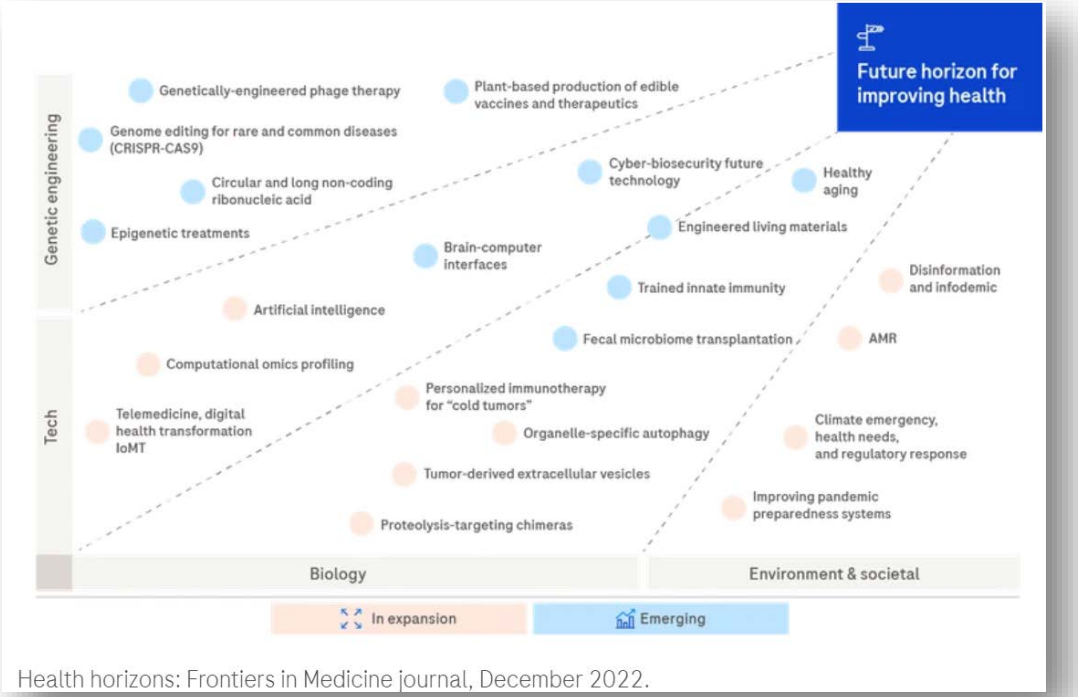
The current pace of discovery of healthcare innovations is outpacing the ability of regulatory science and evaluation frameworks to keep up

Collective tidal wave of biomedical innovations



Health horizons: Frontiers in Medicine journal, December 2022.

Novel Regulatory Decision-making tools

Advanced Manufacturing

Novel Standards Development

Different Global Regulatory frameworks & timelines

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What is a regulatory sandbox?

Regulatory sandboxes an important future-proofing element in the legislative proposal

Allow the testing of novel solutions in a controlled environment for a limited amount of time under the supervision of regulators

Entail a shared learning objective for innovators and regulators

Helps to inform future regulation through experimentation and evidence generation

Minimise the risks of regulating ex-ante innovative and novel approaches prematurely or inappropriately

Facilitate the more efficient or rapid subsequent adaptation of the legislation

Remark: Artificial intelligence (AI) Act creates an opportunity for regulatory sandboxes focused on case studies for AI-enabled medical devices

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The challenge

Translating provisions into an effective new regulatory tool

A mechanism still new to the healthcare and pharmaceutical sector:

- What is the spectrum of possible healthcare innovations which could benefit from a regulatory sandbox?
- How do their nature inform the construct?
- Which features and practices should be built in the mechanism to make it effective?
- How do regulatory sandbox connect with other stakeholders in the ecosystem beyond regulators & developers (HTA bodies, Payers, Clinicians and Patients) to foster the uptake of innovation developed within a regulatory sandbox?

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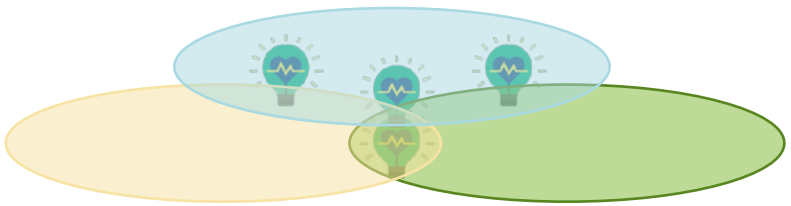
Need for public-private, cross-sector collaboration

Healthcare Innovation is complex endeavor that cannot be tackled in isolation

Regulatory challenges will arise

Innovation happens at the interface of disciplines



Engagement across sectors and multi-disciplinary collaboration are essential

- Innovators from the academic sector and from the various developer organisations (including biotech and start-ups)
- Regulatory science and oversight are at the heart of regulatory sandboxes
- Downstream decisions makers and solution recipients

=> help to build trust which is essential to ensure the adoption of the resulting mechanisms and future outputs

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Scope of the topic 1/3

The project could be approached as a methodological simulation to contribute to the progression and successful implementation of regulatory sandboxes for healthcare innovations

- The objective of the project is to deliver recommendations for the architecture of the regulatory sandbox & the focus remains in the space of regulatory activities of healthcare innovations
- There is no pre-identified type of healthcare innovation ; diversity of cases will be needed to model the sandbox mechanism
- Cultivate a more progressive thinking to accompany the final adoption of healthcare innovations evaluated in a regulatory sandbox context

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Scope of the topic 2/3

Scan

- Identify a number of healthcare innovation case studies
- understand how a regulatory sandbox could be used to solve further-defined challenges at an existing regulation level
- cases could draw from the past, present and from horizon scanning activities

Analyse

- Anticipating consequences for health technology development under a regulatory sandbox
- Proactively identifying any guardrails and mitigation measures

Develop

- Mapping out conceptual elements and operationalisation features of future sandbox mechanisms based on existing experiences
- Modelling how to operationalise the sandbox

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Scope of the topic 3/3

Additional considerations:

- Part of the topic entails modelling a regulatory sandbox. The proposal should therefore consider good practices for designing and evaluating the necessary operating models
- The project outcomes could also offer directions for the translation of the resulting recommendations into digital tools and systems deemed necessary for the functioning of regulatory sandboxes
- Applicants will have to explore key aspects across the life-cycle of healthcare innovations with the objective of accompanying their ultimate adoption

A shared objective should also include

- Developing a regulatory strategy and interaction plan for generating appropriate evidence & engagement
- Identifying aspects that can be leveraged by existing regulatory tools, as well as the limiting aspects and the flexibilities that would be required under a regulatory sandbox to achieve the timely development and access of healthcare innovations.

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Expected outcomes

An **horizon scanning** for potential sandbox candidates including how sandboxes provide an additional tool to existing frameworks, and identified examples to model the process

Analysis of how regulatory sandboxes can drive science and health technology innovation in an evolving environment

Recommendations for end-to-end operations of regulatory sandboxes to inform healthcare innovation developers, regulators, and other decision makers

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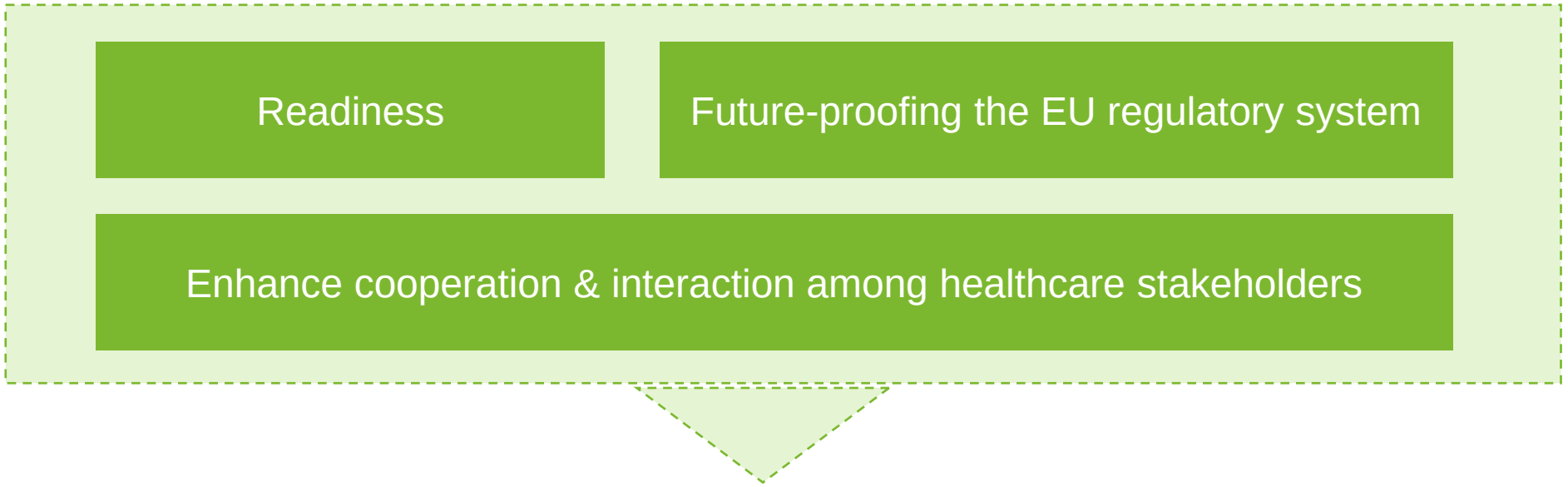
Expected impacts



Expected contributions of the industry consortium

The pre-identified industry consortium expects to contribute by providing the following expertise and assets in healthcare innovation :

- R&D including Manufacturing/CMC, Clinical Development, Regulatory, Legal and IP
- Access to patient including HTA/Pricing and Reimbursement, Medical & Health Affairs and Communication;
- Input on impact on decision-making;
- Risk assessment and risk management expertise;
- Organizational design (design thinking);
- Cases simulation

Expected contributions of the applicants

Expertise and resources expected to be brought into the project

This may require mobilising the following expertise and/or resources:

- Project management expertise in running cross-sectorial projects;
- Broad expertise in R&D of healthcare innovation;
- Simulation
- Organizational design
- Regulatory and legal expertise are core to a number of activities ranging from
  - the fitness check evaluation
  - development
  - simulation and design of the regulatory sandbox operating principles;
- Healthcare professionals and patient perspectives,
- HTA and payer perspective;
- Horizon scanning & adoption of innovation
- Risk management to inform the anticipated consequences of the use of regulatory sandboxes (e.g. via scenario design) and contribute to defining mitigation solutions;
- IT and digital expertise.

Applicants are also expected to propose **case studies.** The pre-identified industry consortium would also propose case studies, to be aligned and decided by the full consortium
at the second stage when preparing the full proposal.

Key Facts

Budget

- The maximum financial contribution from the IHI JU is up to **EUR 5 200 000**
- The indicative in-kind and financial contribution from industry beneficiaries is **EUR 4 261 096**
  - Include the allocation of EUR 100 000 financial contribution (FC) from industry beneficiaries to be decided by the full consortium at the second stage when preparing the full proposal

Duration

- The indicative duration of the action is **36 months**

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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

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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 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.

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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/future-opportunities
- 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 **guide for applicants and project consortia on regulatory considerations for IMI and IHI projects** for useful advice on regulatory issues to consider when preparing your proposal

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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

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Call 8

21 June

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

Online event

COCIR Advancing Healthcare · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

Register now

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: https://europa.eu/!fnJFFM

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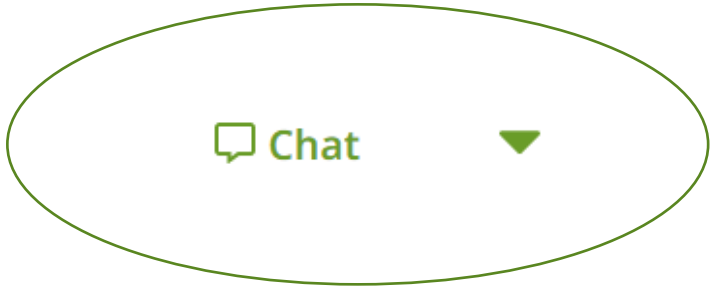
Questions time

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



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