Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment

IHI call 4 – topic 1

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Before we start…

- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.
- All information regarding future IHI call topics is indicative and subject to change.

Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment

IHI call 4 – topic 1

Salomé Koussoroplis, Scientific Project Officer, IHI
19.01.23 • Online

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Today’s session

- **Will cover**:
  - Introduction to IHI programme
  - IHI Call 4 Topic 1 presented by lead industry pre-identified consortium
  - Information on proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover** rules and procedures
  - The webinar on rules and procedures will be organised at a later stage

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)

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

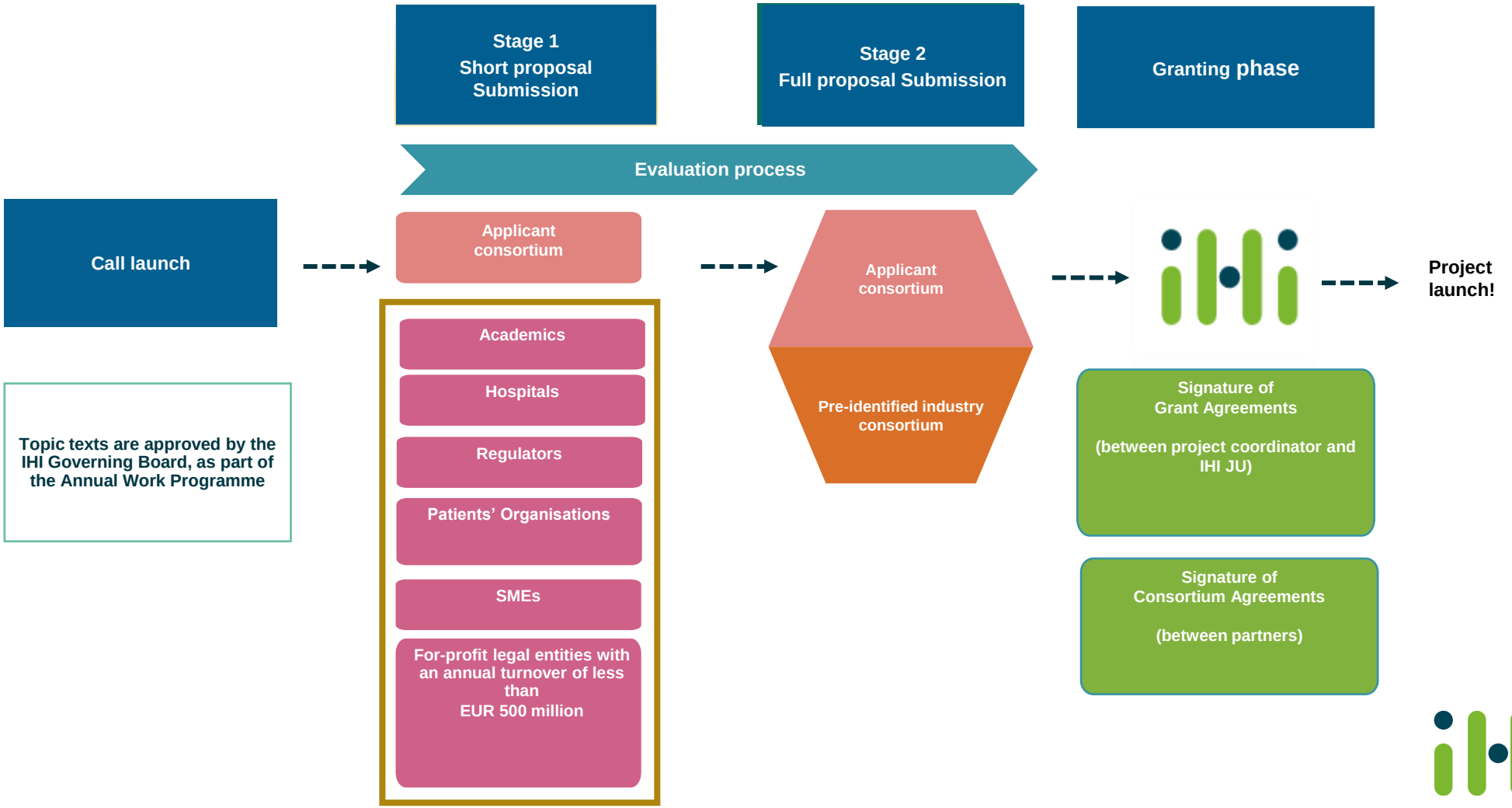
Goal

- 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

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

Two –stage calls – How does it work?



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Expanding Translational Knowledge in Minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment

IHI call 4 – topic 1

Majken Dalgaard
19.01.2023 • Online

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The challenge

- The development of in vitro models for human safety assessment is challenging due to complex biological responses in various organ systems
- Legal obligation to replace, reduce and refine use of animals in research, including a specific focus on restricting the use of the non-human primates (NHPs) unless scientifically justified
- New drug modalities are often designed to engage human targets with high specificity, which is the rationale for selecting NHPs in the safety testing
- Replacing NHPs with minipigs in the safety testing of new therapeutic modalities is difficult due to lack of translational knowledge pigs versus NHP and humans

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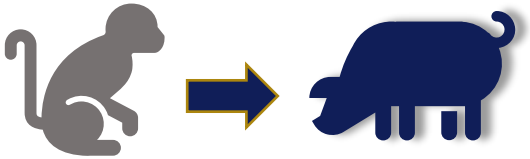
Objectives



Key Objectives

- To advance biomedical R&D by generating background scientific data to turn minipigs into a viable and feasible alternative to NHP in key therapeutic areas with special focus on translatability human versus minipig in nonclinical safety assessment

- To characterise the (mini)pig for use in R&D of new therapeutics and innovative medical technologies. The knowledge generated in this project may facilitate innovative health solutions, improve disease understanding and human predictions

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Need for public-private, cross-sector collaboration

Cross- sectoral collaboration a must

to implement and develop up-to-date species, specific technologies, provide high quality data, ensure best practise and sustainable solutions

Interchange of knowledge and expertise

to transfer translational knowledge/technology/bioinformatics between species

The value of involving partners with relevant expertise

Regulators, SMEs, start-ups, research, academia

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Scope of the topic

- Compile and publish existing historical safety data in minipig biomedical R&D and discuss data with regulators
- Evaluate the translatability of minipigs in human risk assessment following treatment with biologicals and new therapeutic modalities and discuss future perspectives of the minipigs with regulatory agencies
- Minipigs multi-omics and imaging
- Characterise and validate genetically modified pig models
- iPig: Digital technologies, clinical data collection and AI
- Further characterise minipig immune system and validate reagents, assays, and biomarkers for immunologic investigations
- Project management: Compile, digitalise, publish existing and newly produced data

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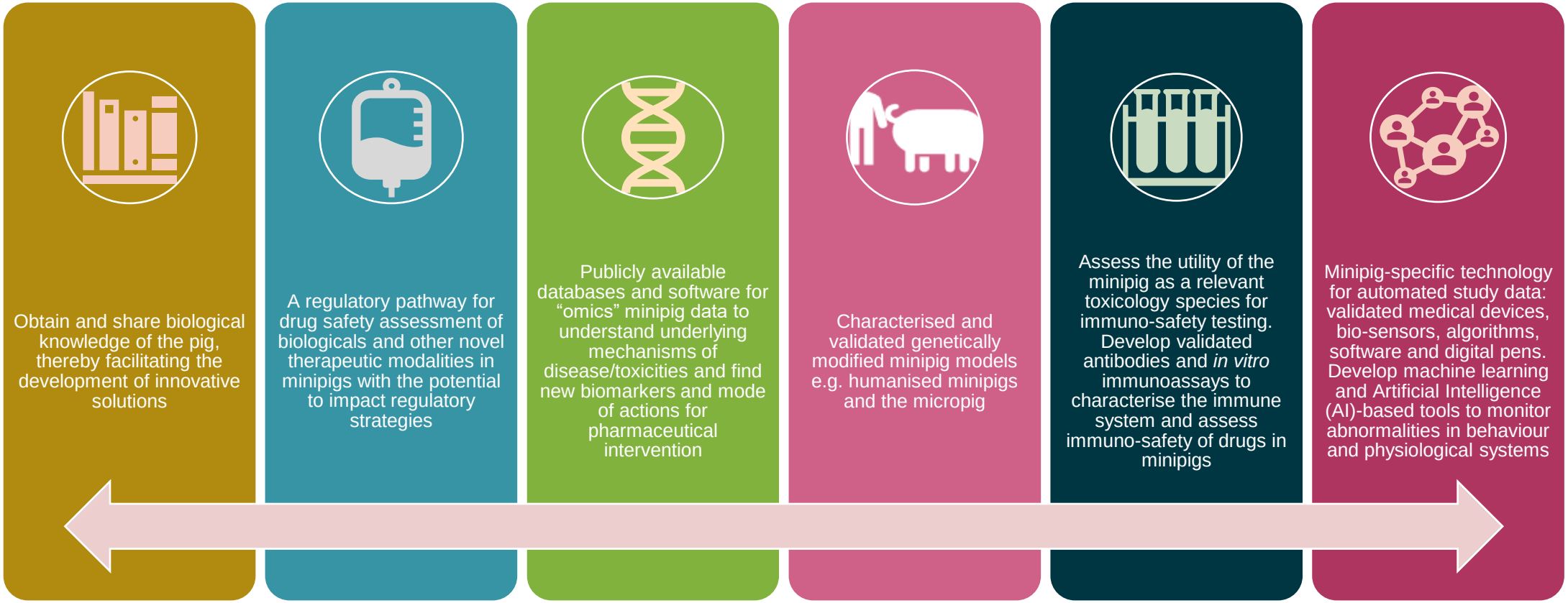
Expected outcome



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Expected impact

By closing the current translational knowledge gaps

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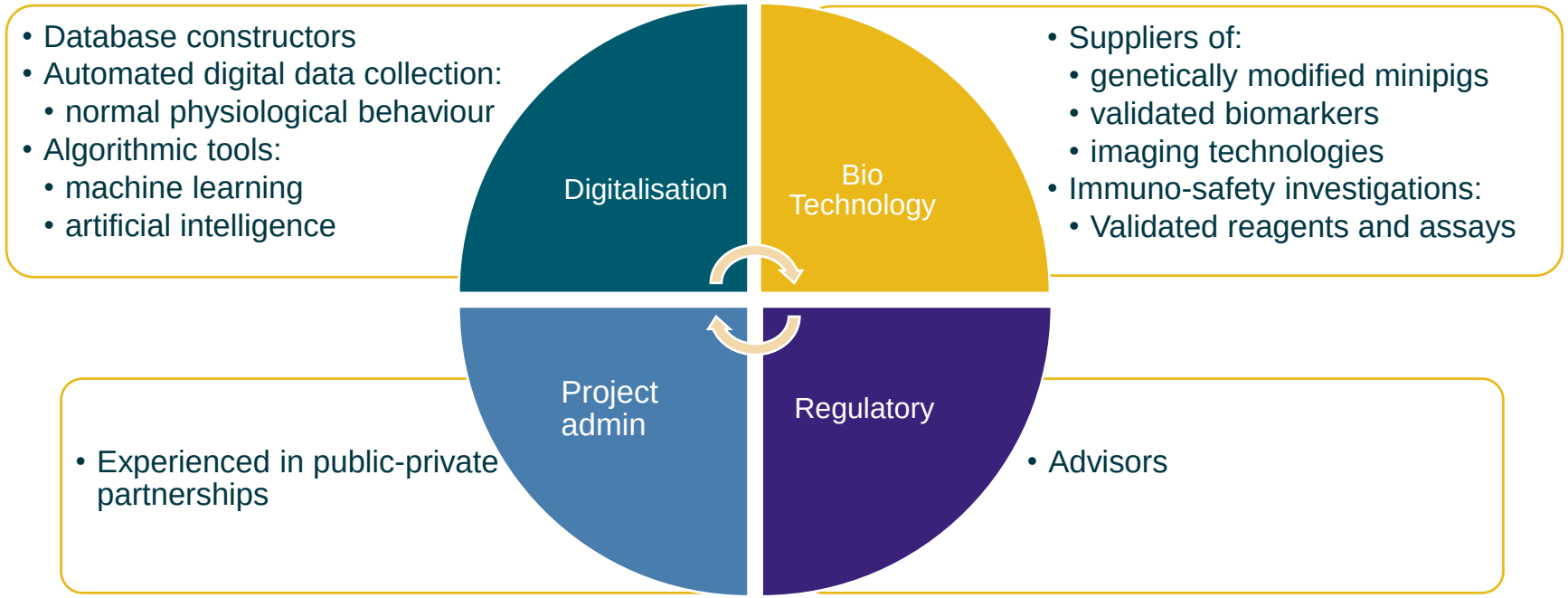
Expected contributions of the applicants



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Expected (in-kind) contributions of the industry consortium

- Experimental settings: Pharmaceutical drug candidates, drug products, animal units, experimental equipment, laboratories
- Data: access to standard toxicology and clinical safety endpoints, historical data, gene expression, immunosafety biomarkers and assays
- Expertise: nonclinical expertise, data science, regulatory expertise, immunosafety, “omics” evaluation, disease models, devices
- Technology: Standard for Exchange of Nonclinical (SEND) databases and SEND visualisation systems, implants, device software

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Budget

Total indicative budget of nearly 18 Mill EUR

- Pharmaceutical/vaccine companies: Novo Nordisk (lead), Novartis, Roche, Lundbeck, Pfizer, Merck KGaA, Sanofi, Bayer, Boehringer Ingelheim, Bristol Myers Squibb
- Other companies: LabCorp, Charles River, VeriSim Life
- Patient organisation: JDRF

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Duration

Indicative duration 60 month

Final decision will be taken by the private-public consortium

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Thank you for your attention

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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.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the outline of the work plan.
  - Capacity 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
  - www.ihi.europa.eu/apply-funding/future-opportunities
- Form your consortium **early**
  - Always 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 & 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

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

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 or organisation 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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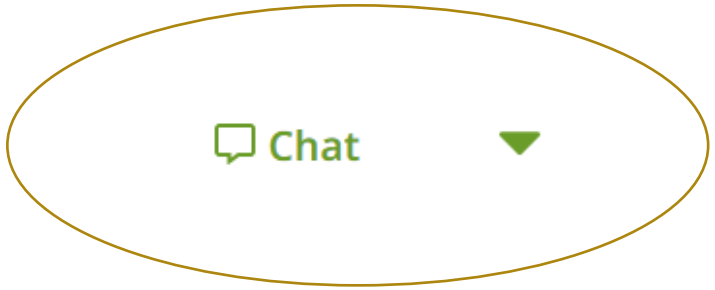
Questions time

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



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