Inclusive clinical studies for equitable access to clinical research in Europe

IHI call 4 – topic 3

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Important disclaimer

Please be aware that the call topics are still under consultation with the States' Representatives Group and the Science and Innovation Panel (IHI advisory bodies).

All information regarding future IHI call topics is indicative and subject to change until call launch.

You will find the final authorised version of the topic text on the Funding and Tenders Portal at call launch.

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Before we start…

- We are recording this webinar and it will be published on the IHI website and and B2Match platform.
- We will also publish the presentation slides

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Inclusive clinical studies for equitable access to clinical research in Europe

IHI call 4 – topic 3

Nathalie Seigneuret
21.06.2023 • Online

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Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI Call 4 Topic 3 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 IHI website and B2Match platform

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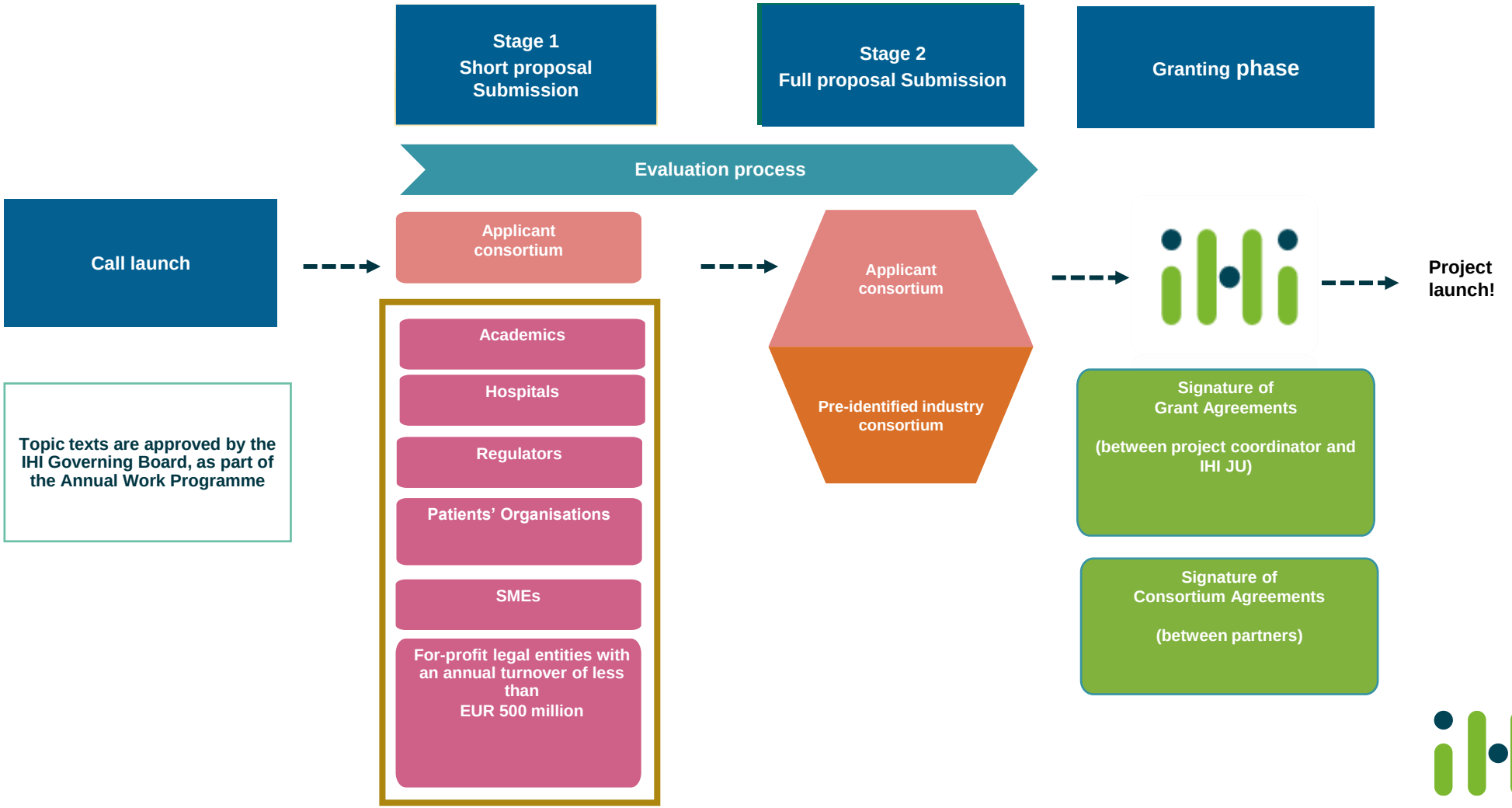
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

Two –stage calls – How does it work?



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Inclusive clinical studies for equitable access to clinical research in Europe

IHI call 4 – topic 3

Ambily Banerjee
21.03.2023• Online

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The overarching challenge

A lack of representativeness in our trials to reflect the patients that use the products

- **Patient recruitment and retention remains a leading challenge** in the efficient completion of clinical studies, including studies on medicinal products, medical devices, or IVDs.
- There is still only limited diversity within recruited patient populations.
- **The under-representation of diverse populations** (due for instance to their race and ethnicity, gender, age, socio-economic status, geographical location**) creates knowledge gaps about the risks and benefits** of health technologies for these specific populations.
- This topic aims to **develop a multi-faceted approach to overcome the multifactorial barriers associated with the recruitment and retention of underserved patient populations** in clinical studies and to contribute to transforming the way clinical studies are conducted in Europe.

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Need for public-private, cross-sector collaboration

Insufficient participation of underserved patient populations in clinical studies poses a complex challenge that the entire health industry faces.

IHI offers a **non-competitive, neutral setting** enabling the sharing of expertise and experiences towards a common goal.

An important paradigm change is needed to succeed in better including under-represented populations, requiring collaboration among stakeholders: patients, caregivers, academia, healthcare practitioners, clinical investigators, industry, sponsors, contract research organisations, regulators, health technology assessment bodies. payers, social scientists, and ethicists etc.

A **cross-sectoral and multidisciplinary public-private approach** is the only way to harness the insights from key stakeholders, consider all perspectives and adjust the trajectory in real time.

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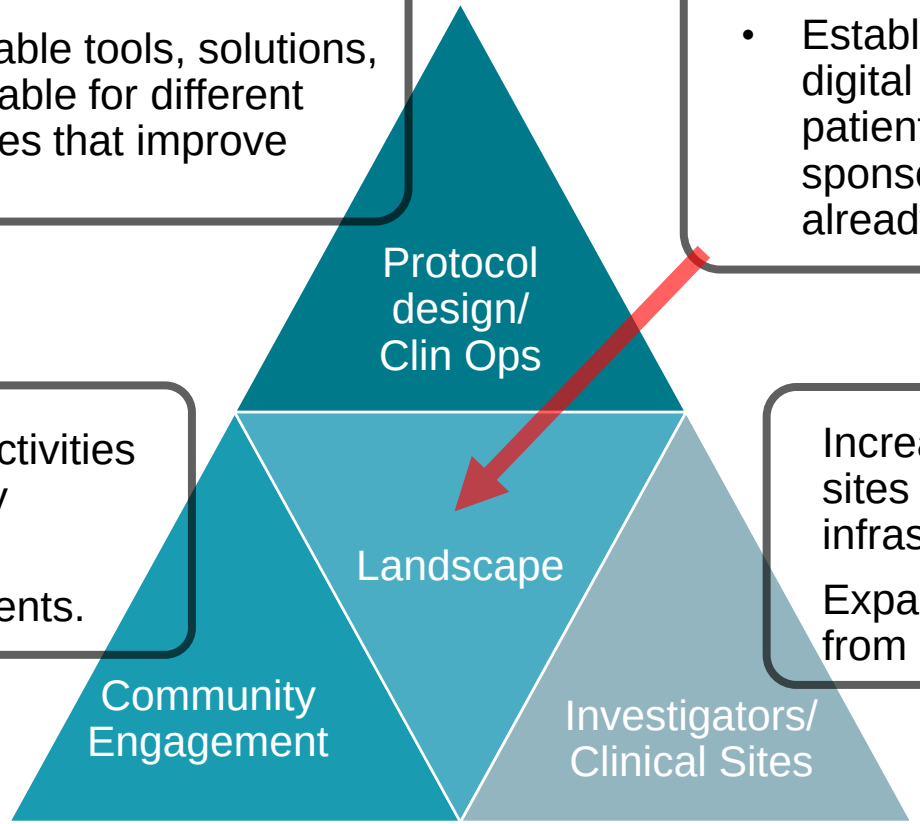
Scope – SUMMARY: 4 key pillars within the scope

To improve inclusivity by improving the Clinical Trial infrastructure sustainably, in all trials

- Establish criteria for measuring ‘representativeness’.
- Develop a set of suitable tools, solutions, and strategies applicable for different types of clinical studies that improve representativeness.

- Agree definition of “underserved”.
- Establish a sustainable patient-centric digital platform connecting the patients, patient support organisations, regulators, sponsors, and sites; by making use of the already existing resources (such as CTIS).



- Develop targeted activities to foster community engagement.
- Build trust with patients.

Increase the number of community-based sites (especially in geographies where the infrastructure is currently lacking)

Expand the pool of investigators and site staff from under-represented communities.

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Scope

Landscape

- **Agree a definition of "underserved" population in Europe with regulators**, that include populations facing socio-economic, systemic, or cultural barriers that prevent equitable access to clinical studies. This could include gender, age, race, ethnicity, refugees, homeless, disabled populations.
- Estimate the **current participation of diverse study populations** in clinical studies differentiated by success in recruitment and retention
- **Define and develop country- and social- and culture- specific understanding** of factors driving under-representation and underserved populations in Europe.
- **Establish a sustainable patient-centric digital platform** connecting the patients, patient support organisations, sponsors, and investigators at different sites (including in community settings, hospitals, primary physicians, etc). To ensure patient engagement, the platform should use lay language and make use of existing resources such as Clinical Trials.gov information; Patient Support information developed by patient organisations, or Clinical Trials Information System (CTIS). This is important to ensure that the patient/community engagement activities undertaken lead to patients being directed to use the platform, leading to an improvement in participation of diverse patients. The needs of underserved populations with access barriers to digital platforms should be considered.
- Define the **governance structure and maintenance/ownership** of the platform.
- Understand the interface between international, regional, and local approaches.

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Scope

Community engagement

- Raise awareness, develop educational activities and inclusive toolkits to **increase knowledge and trust of target populations towards clinical studies** to overcome recruitment, participation, retention challenges and to enable early patient engagement.

- Develop **targeted activities to foster community engagement** and build trust with patients.

- **Establish connection** between different stakeholders in the community e.g., researchers, industry stakeholders, patients, caregivers, investigators, and healthcare providers.

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Scope

Investigators/clinical sites

- Build new site capabilities and develop training activities to **increase the number of community-based sites** and to **expand the pool of investigators, including investigators from under-represented communities and naïve investigators**, to set them up in geographies where the infrastructure is missing.

- Create the necessary support mechanisms and define specialised training e.g., **cultural competency training, naïve investigator training**, etc. through existing clinical networks, medical institutions, patient organisations and community-based organisations.
- Existing resources such as Clinical Trials Transformation Initiative (CTTI), or other projects such as IMI Connect 4 Children [c4c], EUPATI, can be leveraged.

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Scope

Protocol design and clinical operations

- **Establish criteria for measuring 'representativeness'**, i.e. patients enrolled in the trial represent the prevalence of the disease in different sub-populations. For example:
  - Representation: Age, Sex, Gender, Race, Ethnicity (measured against prevalence)
  - Inclusion: Socioeconomic Status, Rural vs. Urban access, Sexual Orientation, Disability, Payer Status (private vs public), Pregnancy/lactation status, etc.
- **Identify and assess existing tools and solutions for patient recruitment** and retention.
- Identify and review aspects of study design such as narrow eligibility criteria, methodological approaches, logistical and other patient-related factors that could limit broader patient and communities' engagement.
- Develop **a set of suitable tools, solutions, and strategies applicable** for different types of clinical studies including studies with medicinal products, medical devices, or IVDs.
- **Explore and validate approaches that improve access**, participation, recruitment, and retention of diverse patient populations.

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Scope

Test solutions in use-cases

- The pilot use-cases will be determined during the project based on the **availability of cases from sponsor companies** and in discussion with the consortium, in one or more disease areas of choice.

- The proposed disease areas should constitute an unmet public health need and a significant burden to patients, health care systems and society. Furthermore, the proposed areas should be representative to allow broad implementation across diverse disease areas, type of clinical studies including clinical research on medical products, clinical investigations for medical devices and performance studies for IVDs.

- The purpose of the pilot use-cases is to **test tools and solutions for patient recruitment and retention**, assess the **functionality of the digital platform**, and test the improvements brought by the digital platform on patient recruitment and retention.

- Applicants are expected to consider the potential regulatory impact of the results and as relevant develop a strategy/plan for generating appropriate evidence as well as engage with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification advice).

- In their proposals, applicants should leverage and build on existing tools & solutions and best practice experiences that have already been developed at national European and / or international level, including tools developed in IMI/IHI projects.

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Expected outcomes

Strengthen through use-cases, the tools and solutions used to recruit a diverse and representative patient population, supported by a community-informed approach.

- **Patients will benefit from:**
  - A easy-to-use- digital platform, built with input from patients, enabling easier access to trials
  - Access to community based sites, which could reduce burden of travelling to a clinical trial site
- **Investigators/sites will benefit from:**
  - Cultural competency and educational training to better engage with diverse populations
  - Increased pipeline of investigators/site staff from underserved communities
- **Sponsors will benefit from:**
  - More generalisable results, leading to better innovations and greater trust in industry
  - A toolbox of new approaches, tools, solutions to increase patient recruitment and retention, to better design and conduct clinical studies
- **Regulators and health technology assessment bodies will benefit from:**
  - A better benefit-risk profile across the patient populations for use in clinical practices.
  - Better understanding of underserved/underrepresented populations and harmonisation of data standards (across demographic descriptors) across Europe

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Expected impact

The following impacts are expected:

- **Enhanced representativeness** of underserved populations in clinical studies across Europe
- **Awareness and understanding** of what diversity, under-represented and underserved communities look like in geographies across Europe including **barriers and gaps to recruitment and retention** in different clinical studies
- **Increased study data reliability and genetic diversity** by including different demographic groups, thereby **enhancing patient trust** in the evidence generated.
- More patients benefit from **increased access to improved innovative health technologies** including medicinal products, medical devices that meet the specific needs and profiles of all patient populations.
- Promoting implementation of **new tools, solutions, approaches, or process models** that will reduce the burden of clinical studies and facilitate and increase diverse patient populations' access to clinical studies.

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Expected contributions of Industry consortium

- **Expertise** in legal, ethics and compliance, regulatory, diversity, equity and inclusion (DEI) in clinical research / study design at **a local and regional level**.
- At a minimum **three use-cases (in selected disease areas)** are expected to be used as “pilots” to test the infrastructure that will be established during the project.
- Contribution to the elaboration of **educational programme and training materials** for investigator training
- Capability to **enable the platform to be used widely** (and adopted as a single solution) by a variety of stakeholders
- Leverage synergy with the **existing IMI/IHI initiatives and TransCelerate** collaborations across industry.

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Expected contributions of the applicants

- **Project management** expertise in running cross-sectorial projects
- Partners with expertise in **building a patient-centric digital platform** that connects various health ecosystem stakeholders, for e.g., patients, patient support organisations, sites, CROs, sponsors, registries
- Partners who have **strong relationship with patient representatives/patient organisations** to gather patient insights and ensure patient-centricity at all levels of the project
- Public health experts, social scientists, behavioural scientists, to **help change behaviours and mindsets**.
- Knowledge on the **regulatory aspects** (including Good Clinical Practices) of drug/ medical device development
- Experience with **localised epidemiology data** (i.e., incidence/prevalence) overlayed by demographics and/or local ethnopharmacology
- Expertise in **gathering patient insights** for clinical studies – such as input to protocol design, user acceptance testing of the platform, etc.
- Experience with consumer-directed communications and/or interactions and/or patient advocacy (social media reach and **expertise in health sector communications** preferred).
- Expertise in **cultural competency training** delivery to the sites and **onboarding naïve investigator** sites
- Knowledge of **the existing clinical studies and site databases** in Europe

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Budget and Duration

BUDGET

€28 million from Pharma **(in-kind)**

€28 million from IHI

TOTAL = €56 million

DURATION

6 years

Funding expected Sept 2024

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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 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 & 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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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/!FkjV9n

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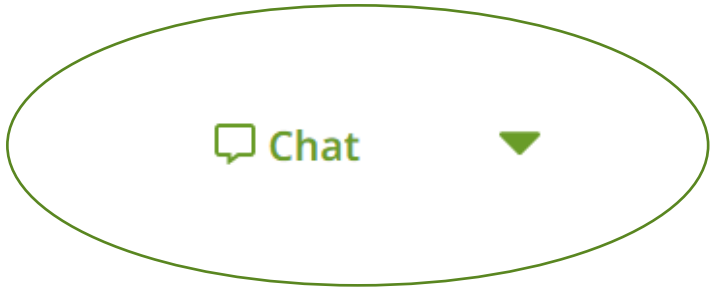
Questions time

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



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#IHICallDays

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Call 4

19 June	**16:00-17:30**	IHI rules & procedures
20 June	**10:00-11:00**	Expanding translational knowledge in minipigs
20 June	**14:00-15:00**	Patient-centric blood sample collection
21 June	**10:00-11:00**	Inclusive clinical studies
21 June	**15:30-16:30**	Improving trials for rare diseases
22 June	**14:00-15:00**	Safe & sustainable by design packaging & devices
22 June	**16:00-17:00**	Sustainable circular development and manufacture

Online event

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe

Co-funded by the European Union

Register now

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Call 5

26 June	15:00-16:30	IHI rules & procedures
27 June	10:00-12:10	Non-animal approaches for health technologies
27 June	14:00-16:10	Theranostics solutions
28 June	14:00-16:10	Stroke management
29 June	10:00-12:10	Synthetic data generation
29 June	14:00-15:30	The financial part of the proposal

Online event

Register now

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Thank you for your attention

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