



Welcome to the  
Innovative Health Initiative  
kick-off & brokering event  
Brussels, 14/06/2022



# Session 3 - How can you participate in IHI calls?

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- Call conditions and rules for participation

Desmond Barry  
14.06.2022 • Brussels

# Outline

1. Participation rules
2. Entities eligible to participate
3. Entities eligible for funding
4. Funding rules
5. Intellectual Property Rights
6. From Call to grant award
7. Call timelines
8. Points to remember

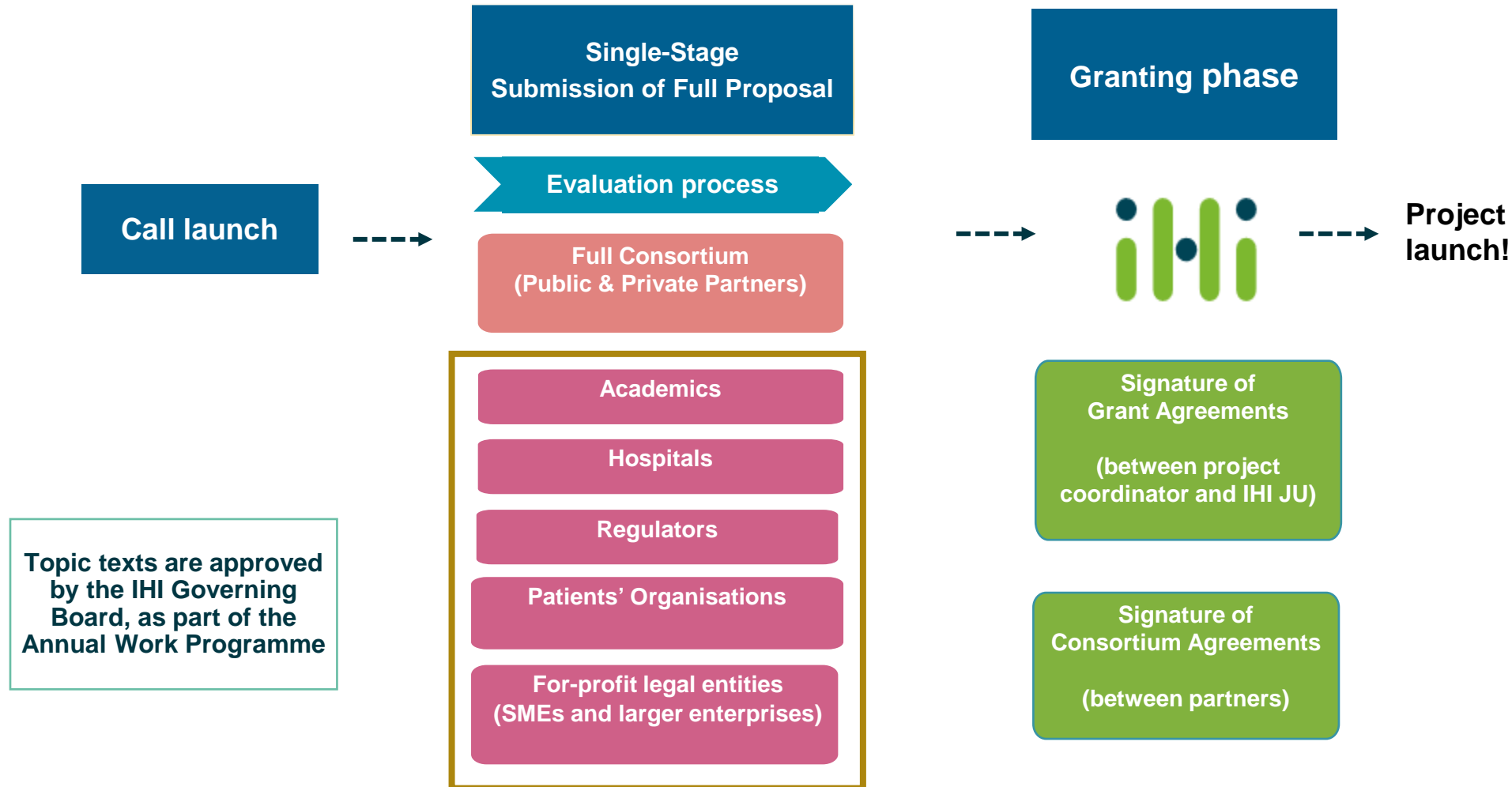


- 1. Participation rules

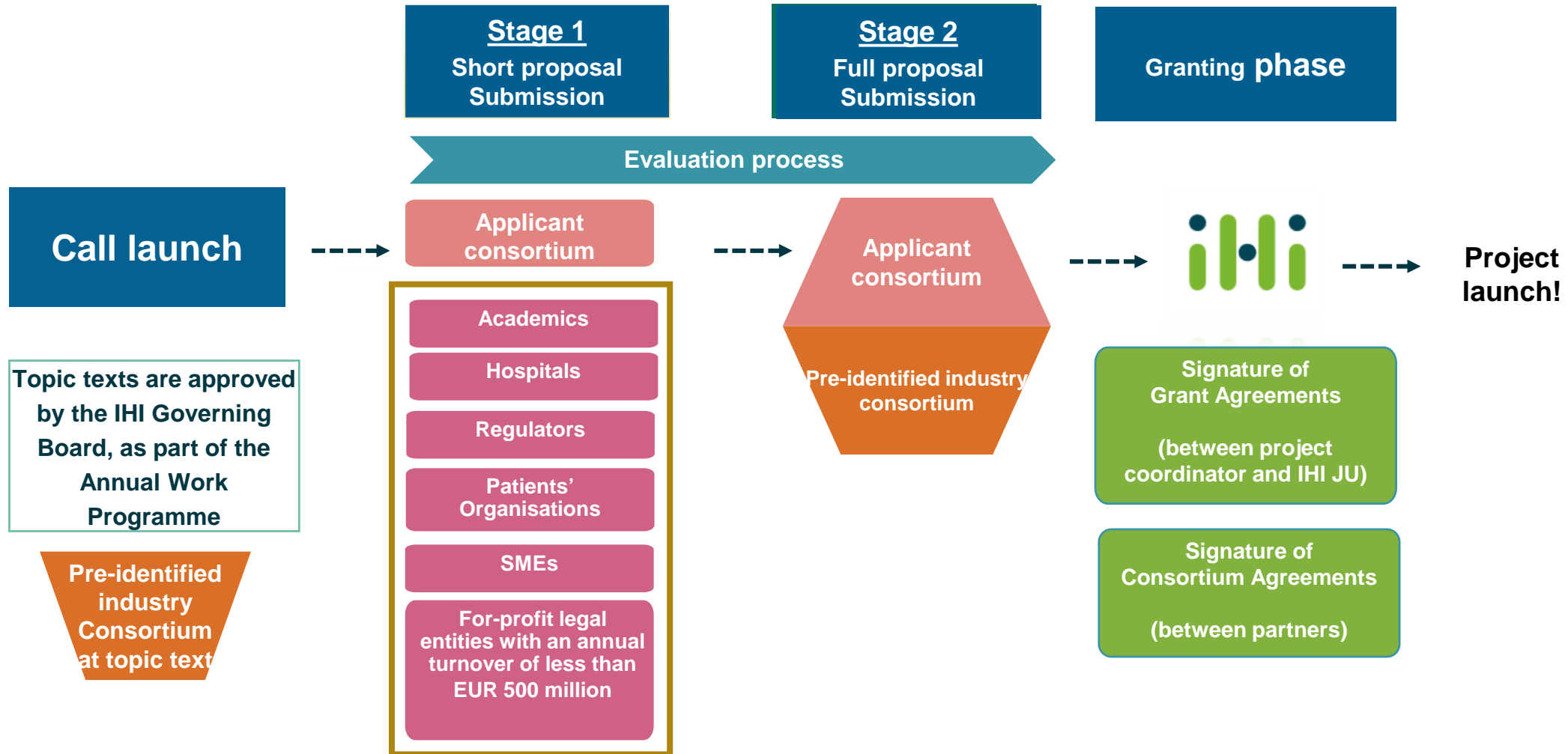
# Two types of consortia envisaged (Type of Calls)

- **Single-stage calls:**
  - ✓ open
  - ✓ public and private actors self assemble and compete for funding
- **Two-stage Calls:**
  - ✓ applicant consortia must submit a 'short proposal (SP)' for the stage 1 evaluation.
  - ✓ SPs must involve all applicant organisations requesting JU funding.
  - ✓ the first ranked applicant consortium will be invited to prepare and submit a 'full proposal (FP)' for the stage 2 evaluation together with the 'pre-identified industry consortium'

# How does IHI work? single-stage procedure



# How does IHI work? two-stage procedure





# Conditions for Call 1 single-stage



- **Single-stage**
  - ✓ All evaluated proposals will be ranked in one single list.
  - ✓ Proposals above the threshold will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget.
- For topic(s) involve clinical studies, applicants should submit the **essential information for clinical studies** annex (admissibility condition)
- **Indicative contribution:** For each topic, the maximum JU contribution is set in the call text
- **Plan for Dissemination, Exploitation and Communication Activities (PDECA)**  
It must be included in 2nd stage Full proposals



# Conditions for Call 2 two-stage

- First ranked applicant consortium will be invited to prepare and submit a 'full proposal (FP)' for the stage 2 evaluation together with the 'pre-identified industry consortium'.
- For topic(s) involve clinical studies, applicants should submit the **essential information for clinical studies** annex (admissibility condition) **in the second stage**
- **Indicative contribution:** For each topic, the maximum JU contribution and the estimated industry contributions are set in the call text
- **Hearings:** If necessary, at stage 1 hearings might be organised with applicants during panel meetings. After submission deadline, coordinators will be informed about the possible date for the hearing
- **Plan for Dissemination, Exploitation and Communication Activities (PDECA):** It must be included in 2nd stage Full proposals

Contacts/discussions about a given topic between potential applicant consortia and members of the pre-identified industry consortium **are prohibited throughout the procedure** until the results of the first stage evaluation.



- 2. Entities eligible to participate

# Attracting stakeholders

**Any legal entity, regardless its place of establishment, carrying out work relevant to the Call objectives may be part of applicant consortia**

**But... not all participating entities are eligible for funding**

# Eligibility

## Consortium composition (collaborative projects)

- at least **one independent legal entity** established in a **Member State**, and
- at least **two other independent legal entities** each established either in a **different Member State** or an **Associated Country**.

### EU COUNTRIES

- Member States (MS) including their outermost regions
- The Overseas Countries & Territories linked to the MS.

### NON-EU COUNTRIES

- Countries associated to Horizon Europe (AC)
- Low and middle income countries: See [HE Programme Guide](#).



### COUNTRIES ASSOCIATED TO HORIZON EUROPE

- Association agreements produce legal effects
- Transitional arrangements
- UK is treated as an associated country throughout the process - Grant agreements can only be signed if the association has come into force.
- Switzerland is currently not covered by the transitional arrangement.

# EU restrictive measures

## Special rules apply for entities from certain countries

- Given the invasion of Ukraine by Russia and the involvement of Belarus:
  - Legal entities established in Russia, Belarus, or in non-government controlled territories of Ukraine are **not eligible to participate** in any capacity



- 3. Entities eligible for funding

# Eligibility rules: funding



Any legal entity established in a Member State, Associated Country or Low and Middle Income Countries

See Horizon Europe programme guide

**NEW**



Third country to Horizon Europe legal entities are normally not eligible for receiving IHI funding

exceptional funding (recommended by experts evaluators) when it considers that their participation is essential





# Eligibility for funding in single-stage Calls



# Eligibility for funding in two-stage Calls



Non-profit organisations

For-profit legal entities  
(SME and larger enterprises with an annual turnover of less than EUR 500 million)



NOT eligible for funding:

- Pre-identified Industry Consortium
- For-profit company:

(a) with an annual turnover of EUR 500 million or more  
(b) directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.



4. Funding rules

# IHI JU Specific types of Beneficiaries

## Private member

Any legal entity established under public or private law (including constituents and/or affiliates) that is member of one of the Industry Associations.

**Constituent entities** means the entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes.

**Affiliated entity** means the entity that has a capital or legal link with a beneficiary (which is in this case a private member or a private member constituent entity)

**Contributing Partner** legal entities interested in supporting IHI JU's objectives in their specific areas of research, without becoming a member; it participates in the Consortium and provides in kind or financial contributions but is not providing in-kind contributions to additional activities (IKAA)



# Industry contributions

## In-kind contributions to operational activities (IKOP)

- Eligible costs incurred in implementing the action.
- **Non-EU IKOP** refers to in kind contribution incurred outside of the 27 EU Member States and Associated countries to Horizon [Europe](#)

## In-kind contributions to additional activities (IKAA)

Costs for implementing additional activities (not project task and therefore not IKOP)

- ✓ *Programme-specific* (i.e. uptake of results from IHI/IMI)
- ✓ *Project-specific* (i.e. dissemination, sustainability or exploitation of IHI JU project results)

## Financial Contribution (FC)

- Financial transfer (cash contributions) by private industry members, their constituent or affiliated entities and by contributing partners to:
  - ✓ project beneficiary(ies) supporting the eligible costs incurred in implementing the IHI projects, or
  - ✓ the IHI JU [directly](#) (to increase a given project funding)

# Contribution types

- **IKOP** - In-kind contributions to OPerational activities

Eligible costs incurred in implementing an IHI project

Can be Non-EU IKOP or EU IKOP

- **FC** - Financial contributions

Cash contributions to project beneficiary(ies) from the same consortium to support eligible costs for project implementation

- **IKAA** - In-kind contributions to Additional Activities

Costs for implementing additional activities **NEW**, no IKAA in IMI2

Private members

Contributing Partners



*Private members, their constituents or affiliated entities can contribute IKOP, IKAA and FC.*

*Contributing partners can contribute IKOP and FC, not IKAA.*

# 45% Eligibility Criterion

- Costs related to contributions (IKOP, IKAA and/or Financial contribution) provided by IHI JU private members and IHI JU Contributing partners, their constituent entities and affiliated entities if any, shall amount to at least **45% of the sum of [total project eligible costs plus IKAA]**.
- **Reminder: Contributing Partners can not provide IKAA**
- Coordinator of (full) proposal must submit a Declaration to confirm that the required 45% contributions will be provided



IKOP + IKAA + FC must be  $\geq$  45% of (Project eligible costs + IKAA)

**If the 45% Industry contribution is not secured collectively by the private member participants, the proposal will be declared ineligible and therefore will not be evaluated**

IHI JU office will verify the 45% contributions prior to the GA signature

# Key thresholds

- **Non-EU IKOP  $\leq$  20% total IKOP** of private members and contributing partners at Programme level

Project level: also 20% limitation unless otherwise specified in call text

Call 1 and 2: limit set to 100% non-EU

- **IKAA  $\leq$  40% total (IKOP + IKAA)** of private members at Programme level

Project level: also 40% limitation by analogy

If more than 40%, private member to liaise with Industry responsible office to ensure good monitoring



# One single funding rate per project

**One project = One rate**

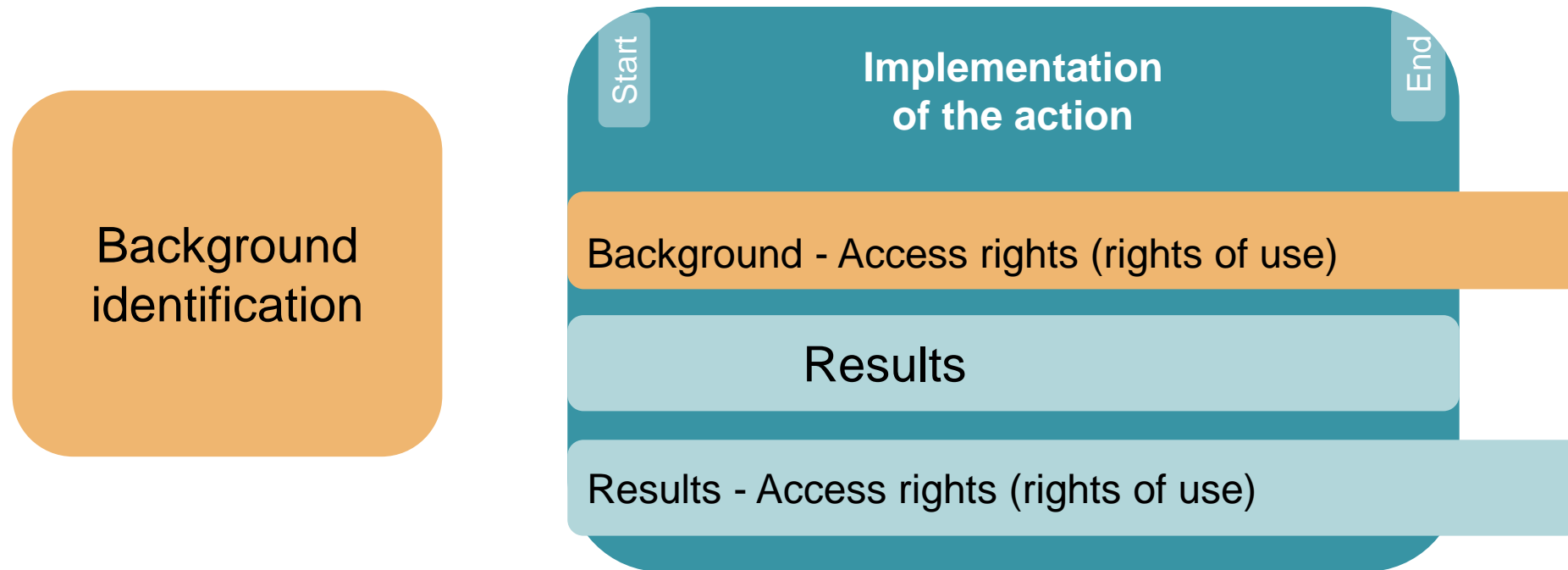
**For all beneficiaries and all activities**

- **100% of the direct eligible costs**
- **Indirect costs: 25% flat rate**



## 5. Intellectual Property Rights (‘IPR’) in IHI

# Snapshot of key IP concepts for IHI Actions



**Background:** As defined in the MGA (Article 16.1), “Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

- (a) held by the beneficiaries before they acceded to the Agreement and
- (b) needed to implement the action or exploit the results”.

**Results:** any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights

**Access Rights:** define who and when can use Background and Results

# IPR in IHI compared to IMI2

- Horizon Europe ('HE') legal basis applies (no specific derogations for IHI JU, unlike IMI2).
- IHI IPR rules derived from:
  - Horizon Europe Model Grant Agreement ('MGA') Article 16;
  - supplemented by specific rules identified in HE MGA Annex 5 and;
  - where relevant, the applicable call conditions.
- IHI JU maintains right to object to transfers of ownership of results or to grants of exclusive licences.
- Results Ownership List ('ROL') to be submitted at project end as part of final periodic report listing all results and ownership of them (including joint ownership structures).
- Emphasis on Exploitation and Open Science:
  - HE MGA integrates Open Science dissemination model;
  - Affordable Access Provisions can, when provided for in the call conditions, introduce additional exploitation obligations for relevant IHI topics;
  - Unexploited project results can be matched with interested parties via the Horizon Results platform.

## **Some notable Access Rights changes from IMI2 JU to IHI JU\***

- Access Rights are now consistent with Horizon Europe MGA;
- No third party access rights after project end for research use of results.

\* Project IPR specificities to be agreed amongst all parties and detailed in the project Consortium Agreement



- 6. From Call to grant award

# New features in the Horizon Europe proposal template

## NEW FIELDS IN PART A

- Researchers table – needed to follow up researchers careers (HE indicator)
- Role of participating organisation
- Self-declaration on **gender equality plan**
- Ethics self-assessment
- Security questionnaire (**NEW!** in all HE proposals)
- Information on participants' previous activities related to the call

# IHI Proposal template

## SHORT PROPOSAL (20 pages)

- **PART A** does not require a budget table but only the total requested EU contribution
- **PART B** narrative part that includes three sections that each correspond to an evaluation criterion
- **Compulsory** IHI annex on the type of participants (enables IHI to meet its reporting obligations)

## FULL PROPOSAL (50 pages)

- **PART A** requires a budget table
- **PART B** narrative part that includes three sections that each correspond to an evaluation criterion
- **Compulsory** IHI annex - type of participants (enables IHI to meet its reporting obligations)
- **Compulsory** IHI annex - Declaration of in-kind contribution commitment
- **Optional** IHI annex In-kind contributions to additional activities (IKAA)
- **Optional/ Compulsory** HE annex - Essential information for clinical studies (depending on the topic)
- **Optional** HE annex - Ethics



# Evaluation criteria and thresholds

- Minimum of 3 independent experts
- Each proposal evaluated 'as it is', not as 'what could be'
- Sub-criteria listed in evaluation form

Criteria	Threshold
Excellence	3/5
Impact	3/5
Implementation	3/5
<b>TOTAL</b>	<b>10/15</b>



# Agreements for IHI Actions



## *IHI Grant Agreement*

- The new Horizon Europe Model Grant Agreement 'HE MGA' includes 44 articles, as well as specific Annexes.
- IHI JU follows HE MGA with IHI JU specificities reflected in Annex 5.
- It is e-signed between IHI JU and Coordinator only. **Other beneficiaries e-sign Accession Forms.**

## *Consortium Agreement for IHI Actions*

- Contractual arrangement between all participants to set out their rights and obligations, especially governance, liability and IPR.
- IHI JU is not a party/signatory.
- Shall comply with the **HE MGA.**
- To be fully agreed/finalised before the signature of the GA.
- To be adapted to the specific needs of each IHI JU action! **Templates** online.



7. Timelines

# Call 1 – single stage – Indicative timelines



# Call 2 - two-stage – Indicative timelines

end June 2022	• Launch of the Call
end-September 2022	• Call Submission Deadline - Short Proposals (SP)
October 2022	• Scientific evaluation - SPs
end-November 2022	• Information to the applicants - evaluation outcome
end-February 2023	• Submission Deadline - Full Proposal (FP)
March 2023	• Scientific evaluation - FPs
April 2023	• Evaluation Outcome letters to the applicants
July 2023	• Grant Agreement Preparation (GAP) and GA signature



## 8. Points to remember

# Points to remember

- Read all the call-relevant material: [www.ihl.europa.eu](http://www.ihl.europa.eu)
- Begin forming your consortium early. Read the topic text. Check the IHI website and F&TP.
- Ensure that all information is explicitly described in order to allow the expert-evaluators to assess against the evaluation subcriteria. **Respect the page limit.**
- Use the proposal structure / template - pay special attention on how to complete your ethics self-assessment.
- Plan the 45% In kind contribution. This is the responsibility of the entire consortium.
- Complete accurately the researchers table (Proposal Part A) and ensure a gender balance. This might impact the proposal ranking in case of equal scores
- Coordinator must be financially viable
- Contact the IHI Office (NOT industry topic writers): [infodesk@ihl.europa.eu](mailto:infodesk@ihl.europa.eu)

# Your contact points

## At the IHI Programme Office

General queries: [applicants@ihi.europa.eu](mailto:applicants@ihi.europa.eu)

## State Representative Group (SRG)

The main States Representatives appointed to IHI JU SRG (the main delegates, but not the alternates) are on our website here:

<https://www.ihi.europa.eu/about-ihi/who-we-are/states-representatives-group>.

# Do you want to be an expert-evaluator?

- IHI JU (and the whole EU research family) are always looking for new, competent experts in diverse fields
- Create or update your expert profile via <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert>
- E-mail [experts@ihi.europa.eu](mailto:experts@ihi.europa.eu) mentioning your expert profile number (format EX20XX1234567)





- Opportunities for SMEs

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# Why do we want SMEs in IHI projects?

- SMEs can act as a **key interface** between latest academic discoveries and implementation in industry
- SMEs can **rapidly adapt** to meet the needs of IHI projects
- With a commercial focus, SMEs can drive projects to achieve **high impact results**
- By developing products & services, SMEs can ensure the results of IHI projects are **widely available after the funding ends**
- Help create a favourable ecosystem for **SME innovation and growth.**

# Why should SMEs join IHI projects?

- IHI projects are focused on translating results from research into **real world products & services** – an opportunity for SMEs
- SMEs can fine-tune their offering with the actual **end-user researchers**
- Collaboration with large medtech & pharmaceutical companies allows access to whole healthcare value chain & the **building of research and business networks**
- **Enhancing reputation and visibility.** IHI project achievements often get recognised and promoted at an international level
- Funding: **100% of costs reimbursed**

# Wearable & smartphone data platform

- SME **The Hyve** developed a platform for **remote patient monitoring** using **wearable devices, smartphone sensors and apps** in collaboration with King's College London in the RADAR-CNS project.
- Key pillar of The Hyve's **commercial offer**:  
<https://www.thehyve.nl/focus-areas/digital-measures>
- Now **generating new business** facilitating >45 additional studies:
  - Depression, MS, Alzheimer's Disease, Parkinson's Disease, Autism, Infectious diseases.
  - Over 40 000 study participants. Over EUR 30 million investment.

# K4DD - Sierra Sensors

- **Molecular Affinity Screening System** developed by SME Sierra Sensors using input from pharma partners.
- Measures target-ligand binding kinetics in high-throughput format

- Acquired by  **BRUKER**



<https://www.bruker.com/en/products-and-solutions/surface-plasmon-resonance.html>

# SME as project coordinator



The MELLODDY project is **developing privacy preserving machine learning** technology for **drug discovery**. SME **Owkin** is the **coordinator**.

- *“The impact of the MELLODDY project on Owkin has been massive. We have grown from 30 to 150 personnel, MELLODDY was central to that.”*
- *“In the project, we developed our technology with companies who are also our customers. We’ve demonstrated to them that our technology works at scale, adds value and meets their high demands.”*



**Mathieu Galtier**, Chief Product Officer at Owkin





# Possibilities for SME participation in IHI Calls 1 & 2

# Call 1

- **Topic 1 (Neurodegenerative diseases)**
  - Health data platforms
  - Advanced analytical and workflow tools
- **Topic 2 (Cancer imaging)**
  - Innovative features of **AI/ML-enabled tools** used for diagnosis, prognosis, therapy planning, intervention, and follow up of cancer patients
- **Topic 3 (Personalised oncology)**
  - Diagnostic tools, biomarker analysis
  - Clinical study monitoring
- **Topic 4 (Heterogeneous health data)**
  - Health data platforms & analytical tools
  - Tools focussed on the needs of patients
  - Clinical (and other) decision support systems





# Call 2

- **Topic 1 (Cardiovascular diseases)**

- Expertise in AI and software
- Expertise in devices and digital health

- **Topic 2 (Early Feasibility Studies)**

- Participation of SMEs is encouraged with the aim of ensuring a wide applicability of the methodology and valorising innovations of SMEs for the benefit of citizens. Moreover, SMEs, particularly those with expertise in **legal, regulatory and ethical matters**, are encouraged to join the consortium to support the development of relevant criteria for the methodology.

# Q&A

Slido: #IHbrokeraage

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