



Iniciativa de Salud Innovadora

IHI – Innovative Health Initiative JU

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WHAT IS IHI?



IHI IS EUROPE'S NEW PARTNERSHIP FOR HEALTH

IHI is a **collaboration** between the EU and the biopharmaceutical, biotechnology, digital health and medical technology sectors, as well as academics, patients, regulators and other healthcare professionals.

FROM IMI TO IHI



IHI will build on the extensive experience of **IMI's 14 years and almost 200 projects** to build an interdisciplinary, sustainable, patient-centric health research partnership to help transform patients' lives.

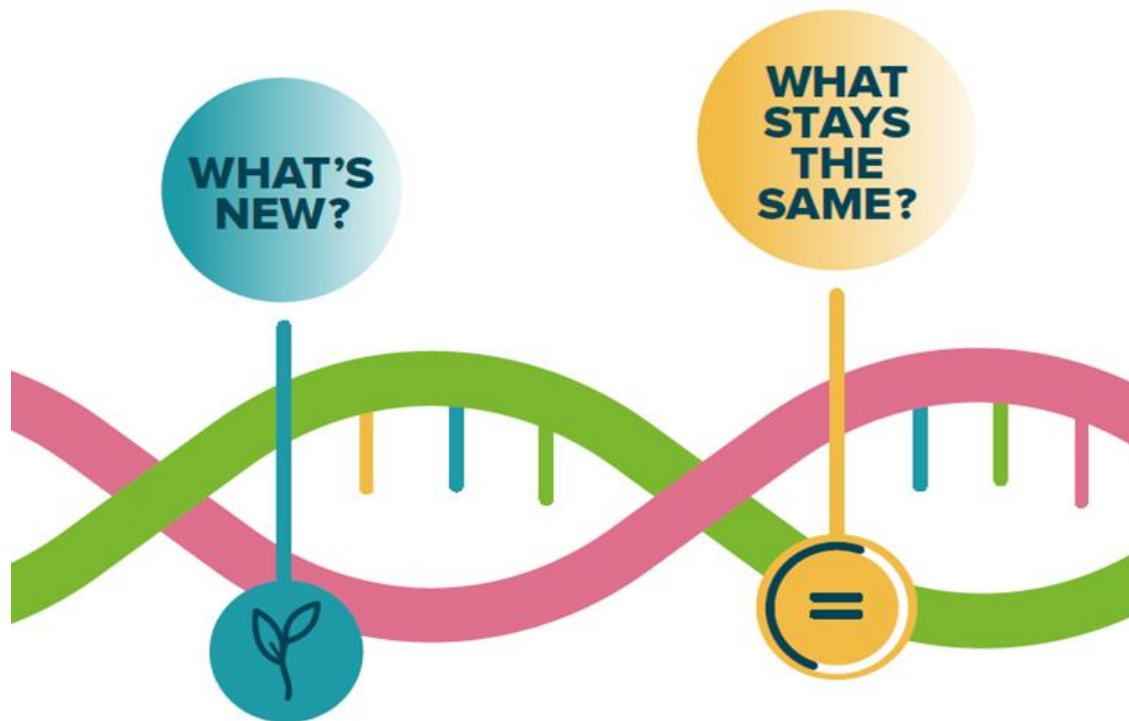
IHI PARTNERS



The industry members that make up the new partnership are:

COCIR
EFPIA
EuropaBio
MedTech Europe
Vaccines Europe

The public member in the partnership is the European Union, represented by the **European Commission**




- The way we're governed will change.
- The scope of the partnership is broader than IMI as it will cover the **entire continuum of care**.
- There will be new, specific objectives that align with the EU's latest health policy strategies.

- **Funding comes equally** from the public and industry partners.
- Calls for proposals will be **open and competitive**.
- Projects started under IMI will be managed by IHI.

- A new Strategic Research and Innovation Agenda
- The Science and Innovation Panel
- One and two stage calls

Private members






- IMI1: Only EFPIA 
- IMI2: EFPIA and **Associated Partners**
- IHI: 5 Industry Trade Associations and **Contributing Partners:**



MedTech Europe
from diagnosis to cure



IHI Private members (PM)

Industry Trade Associations	Represents	Mission/Vision
	Pharmaceutical industry	To create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.
	Medical imaging, radiotherapy, health ICT and electromedical industries	Our industry provides safe and high quality products and services, which contribute to reducing health inequalities and enhance cost efficiency in healthcare systems. COCIR's key objective is to promote free worldwide trade of innovative medical technology while maintaining the competitiveness of the European medical imaging, radiotherapy, electromedical and health ICT industries.
	Medical Technology industry	Make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path.
	Vaccine industry	To support broad access to immunisation, enabling better protection of the health of individuals and the wider community throughout life, with both existing vaccines and those in development.
	Biotech industry	Committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy.

abbvie

Almirall
Solutions with you in mind

AMGEN

AstraZeneca



Boehringer
Ingelheim

Bristol-Myers Squibb

Chiesi
People and ideas for innovation in healthcare

ESTEVE

genzyme

GRÜNENTHAL

gsk
GlaxoSmithKline
Vaccines

Janssen
PHARMACEUTICAL COMPANIES
of Johnson & Johnson

Lilly

Lundbeck

MERCK

novo nordisk

NOVARTIS

ORION

Pfizer

Roche

SANOFI

sigma-tau

SERVIER

ucb Pharma

zoetis

innovative
health
initiative

cytiva disc SwiftPharma.

bioForum FREGET GLASER & ASSOCIÉS Trinomab

olon UNION THERAPEUTICS

BIO DEUTSCHLAND boc DEUTSCHE INDUSTRIEVEREINIGUNG BIOTECHNOLOGIE

SOVIET BIOTECHNOLOGIES FINNISH BIOTECHNOLOGIES Holland BIO scienceINDUSTRIES

Swiss Biotech Association ALEXION AstraZeneca Rare Disease abbvie

BiOMARIN CSL Behring Biotherapies for Life GILEAD

IPSEN Lilly MSD Be well

MERCK NOVARTIS Pfizer

PTC sobi Takeda

uniQure VERTEX regenold

SFLIPHARMA VVCLS

ACCURAY aidence

BARCO

Carestream

Elekta

@saote

HOLOGIC

IBM

PHILIPS

SIEMENS Healthineers

ASSOCIATIONS

ABHI

bvltg

Ferit

HealthTech Finland

TIP GÖR DER

AGFA HealthCare

Alcon

BAYER

CMR SURGICAL

EOS imaging

FUJIFILM

HUAWEI

KONICA MINOLTA

SAMSUNG

UNITED IMAGING

.AGORIA

CONFINDUSTRIA Dispositivi Medici

FME

snitem

zvei

AGFA

Apple

Canon CANON MEDICAL

Dedalus

Epic

GE HealthCare

Iba

LUXIUM

SERVIER

aparmed

ETOSZ

FMed

Medtech

3M

Abbott

Agilent Technologies

AIDIAN

Alcon

ALMAC

Ambu

Ansell

APPLE INC.

APOLLON BIOTECK

Artirex

ASARI

ASCENIA

ASP

AtriCure

AVANOS

B BRAUN

BAUSCH + LOMB

BAXTER

BAYER MEDICAL CARE

BD

BECKMAN COULTER

Binding Site

BIO-RAD

BIOCARTIS

BIOMERIEUX

BioSystems

BIOTRONIK

bioWest

Boston Scientific

Cardinal Health

Cepheid

CERUS

IMI2 AP: Associated Partners (AP)

IHI: Contributing Partners (CP)



BILL & MELINDA
GATES *foundation*



In total,

38 Associated Partners (IMI2)

Full list on IMI website <https://www.imi.europa.eu/get-involved/associated-partners>

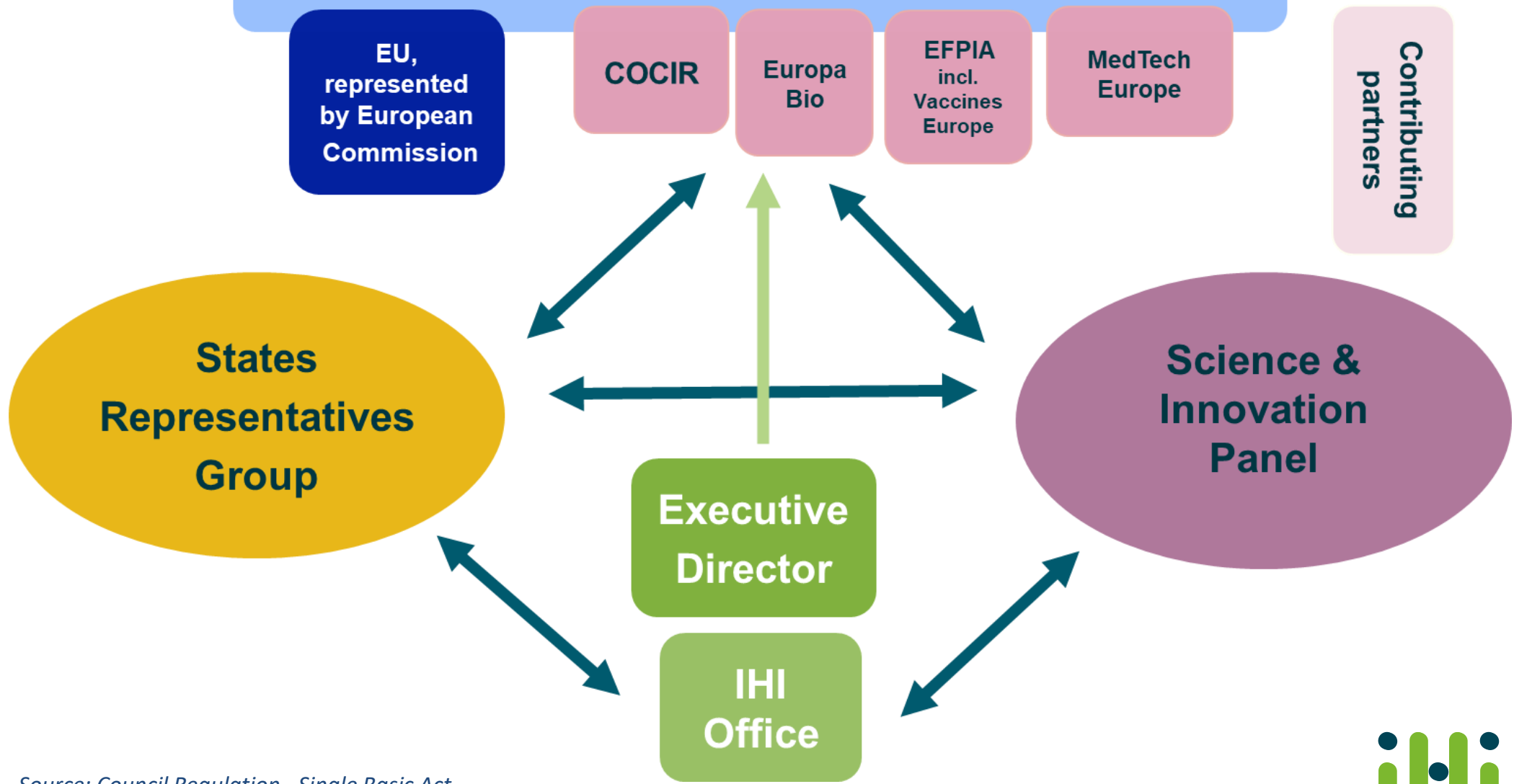
29 Contributing Partners (IHI)





- Governanza

GOVERNING BOARD



Source: Council Regulation - Single Basic Act



- Objetivos y Agenda Estrategica

IHI: Agenda estratégica

Enfoque

- Metodologías **interdisciplinarias** para facilitar la creación de nuevos productos y servicios para **prevenir, interceptar, diagnosticar, tratar y controlar** enfermedades y promover la recuperación de manera más eficiente.

Objetivo

- Facilitar el desarrollo de productos o soluciones **más seguros y eficaces** que respondan a necesidades no cubiertas y puedan ser implementados en los sistemas sanitarios

IHI: Objetivos Generales

- contribuir a la **creación de un ecosistema** de investigación e innovación sanitarias **que facilite la traducción** de los conocimientos científicos en **innovaciones**;
- fomentar el desarrollo de **innovaciones seguras**, eficaces, **centradas en las personas** y eficientes que respondan a **necesidades estratégicas de salud pública no satisfechas**, mostrando, la **integración viable** de productos o servicios de asistencia sanitaria con una idoneidad demostrada para ser **adoptados por los sistemas de asistencia sanitaria**;
- impulsar la innovación sanitaria intersectorial en favor de una **industria sanitaria europea competitiva** a escala mundial.

Specific objectives

- a. **Mejorar el conocimiento de los factores que afectan a nuestra salud** y el desarrollo y tratamiento de ciertas enfermedades

- b. **Integrar los esfuerzos fragmentados de investigación e innovación en salud** haciendo que los varios sectores sanitarios y otras partes interesadas colaboren. Esto favorecerá el Desarrollo de herramientas, datos, plataformas, tecnologías y procesos para facilitar la prevención, el diagnóstico, el tratamiento y el control de enfermedades en **áreas de salud pública no cubiertas**

Specific objectives

- c. **Demostrar la viabilidad de soluciones sanitarias integradas** que se basen en diversas tecnologías de diferentes sectores y aborden las necesidades de las personas que las utilizarán, como pacientes y profesionales sanitarios.
- d. **Aprovechar mejor las oportunidades para recopilar datos de salud** y utilizarlos en investigación y atención, todo ello respetando la legislación de privacidad pertinente.
- e. **Desarrollar formas de evaluar el valor de las soluciones innovadoras e integradas** de salud para pacientes, cuidadores, profesionales y organizaciones médicas y otras partes interesadas.

Innovative Health Initiative launches first five projects

<https://www.ihl.europa.eu/news-events/newsroom/innovative-health-initiative-launches-first-five-projects>

Meet IHI's very
first projects!



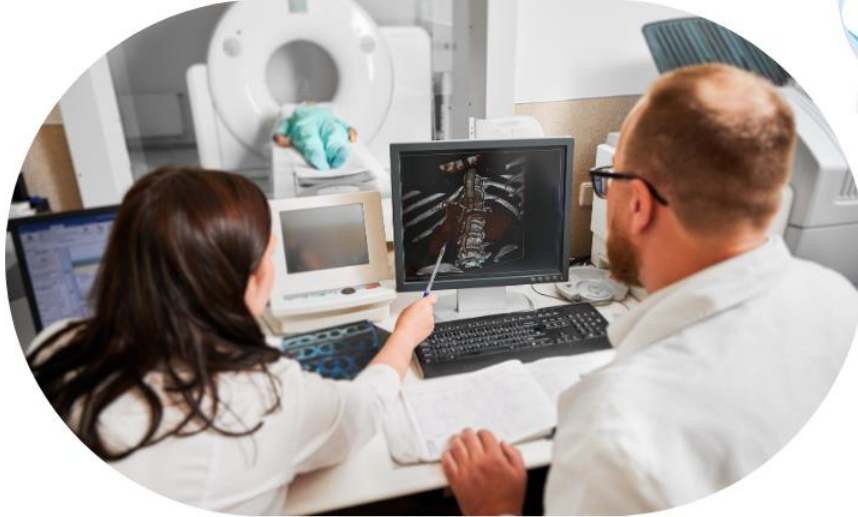
Addressing **cancer and neurodegenerative diseases**, and bringing on board sectors as diverse as pharmaceuticals, medical technology, big data, and imaging, **the new projects** exemplify our cross-sector partnership!





GUIDE.MRD

Better blood tests to determine who needs additional cancer treatment – and who doesn't



IDERHA

An open, big data platform to
advance lung cancer research,
diagnosis and care



CLAIMS

Creating a diagnostic platform that offers a holistic view of people with multiple sclerosis



PROMINENT

A coherent approach to the care of people with Alzheimer's disease and other health problems



IMAGIO

A miniaturised approach for more precise cancer treatments, with limited side effects

Partners of IMAGIO

Consortium



MedTech

PHILIPS
PROFOUND
NANOVI
Gremse-IT
SAINT-GOBAIN
Flash Pathology

Clinical research

Radboudumc
UMC Utrecht
VU UNIVERSITY AMSTERDAM
LUMC
UNIKLINIK KÖLN
Maastricht UMC+
Fondazione IRCCS Istituto Nazionale dei Tumori
NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

Pharma

Janssen
Pfizer
ImaginAb
THERMOSOME

Technical research

TU Delft
UNIVERSITY OF TURKU
UNIVERSITY OF TWENTE
EBERHARD KARLS UNIVERSITÄT TÜBINGEN
ETH zürich

Patient organizations

Longkanker Nederland
European Cancer Patient Coalition
SIOP Europe the European Society for Paediatric Oncology
Nederlandse Leverpatiënten Vereniging
Lever



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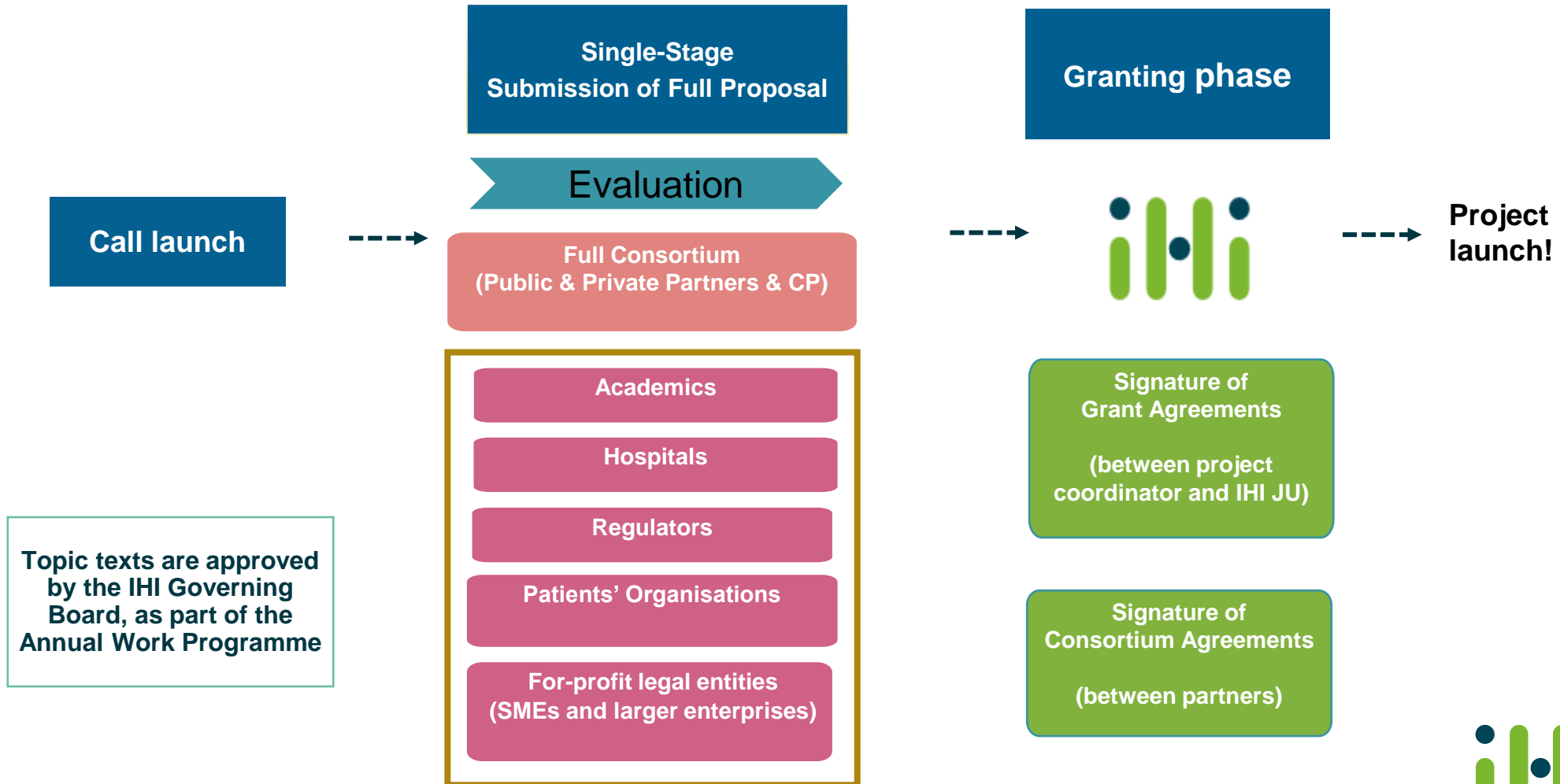
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Tipos de convocatoria

Single-stage / Two-stage



Convocatoria IHI-single-stage



#IHICallDays

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

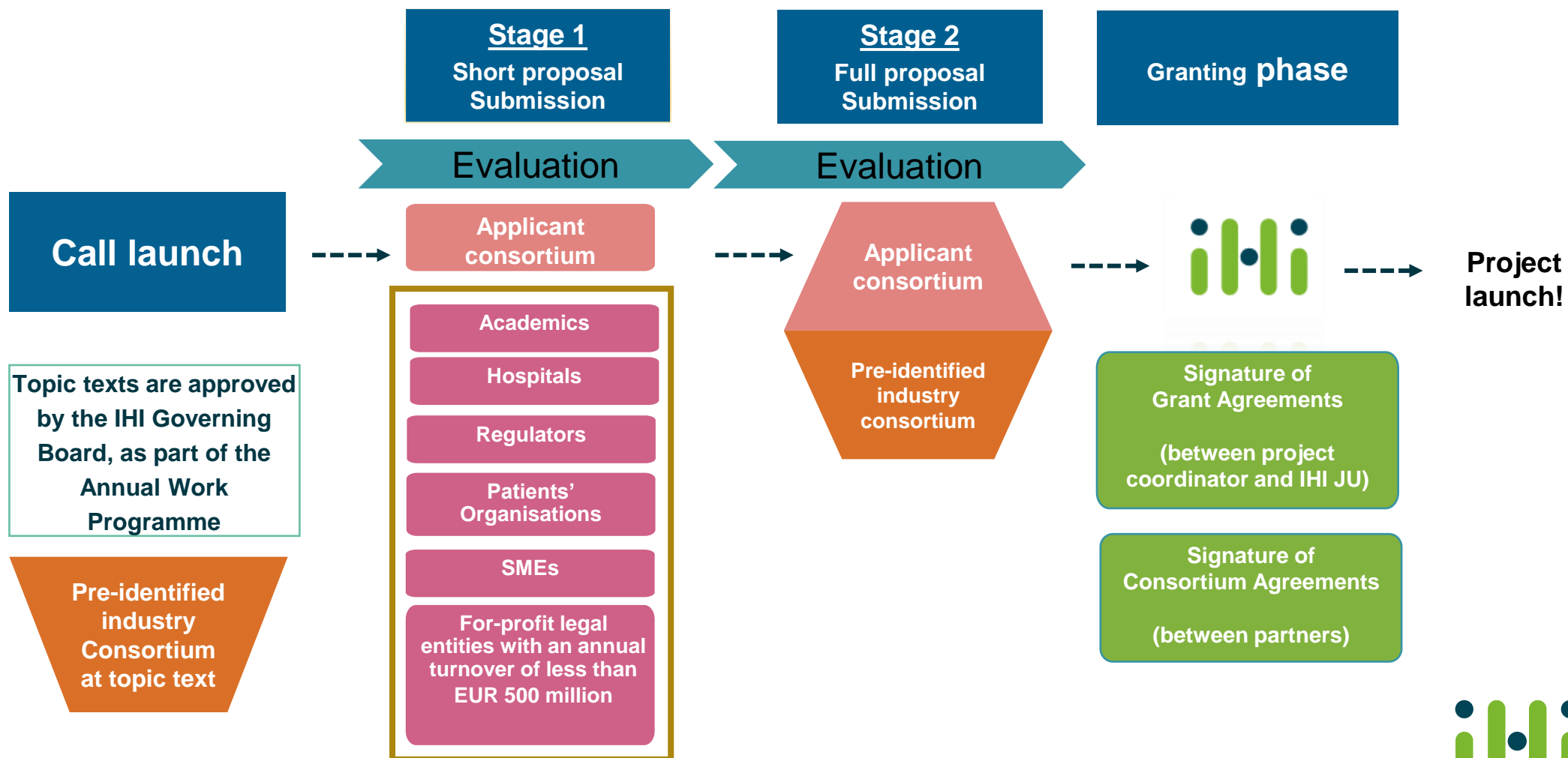
Register now



Call 5 - single stage – Timelines



Convocatoria IHI-two-stage



#IHICallDays

Call 4



Online event

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

[Register now](#)



Call 4 - two-stage – Timelines

Early June 2023*	• Publication of draft topics
27 July 2023	• Launch of the Call
08 November 2023	• Call Submission Deadline - Short Proposals (SP)
November-December 2023	• Scientific evaluation – SP
End January 2024	• Evaluation Outcome letters to the applicants
23 April 2024	• Submission Deadline - Full Proposal (FP)
May 2024	• Scientific evaluation - FP
End of June 2024	• Evaluation Outcome letters to the applicants
End of September 2024	• Grant Agreement Preparation (GAP) and GA signature

* Two draft topics (minipigs and microsampling) were already published on October 2022

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- IHI project proposals
Eligibility

Eligibility

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 and Territories (OCTs) 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 applicants are treated as beneficiaries during the application process and as associated partners throughout the project implementation unless the association has come into force.
- Switzerland is currently not covered by the transitional arrangement.





- IHI project proposals
Eligibility (for Funding)

General eligibility rules for funding



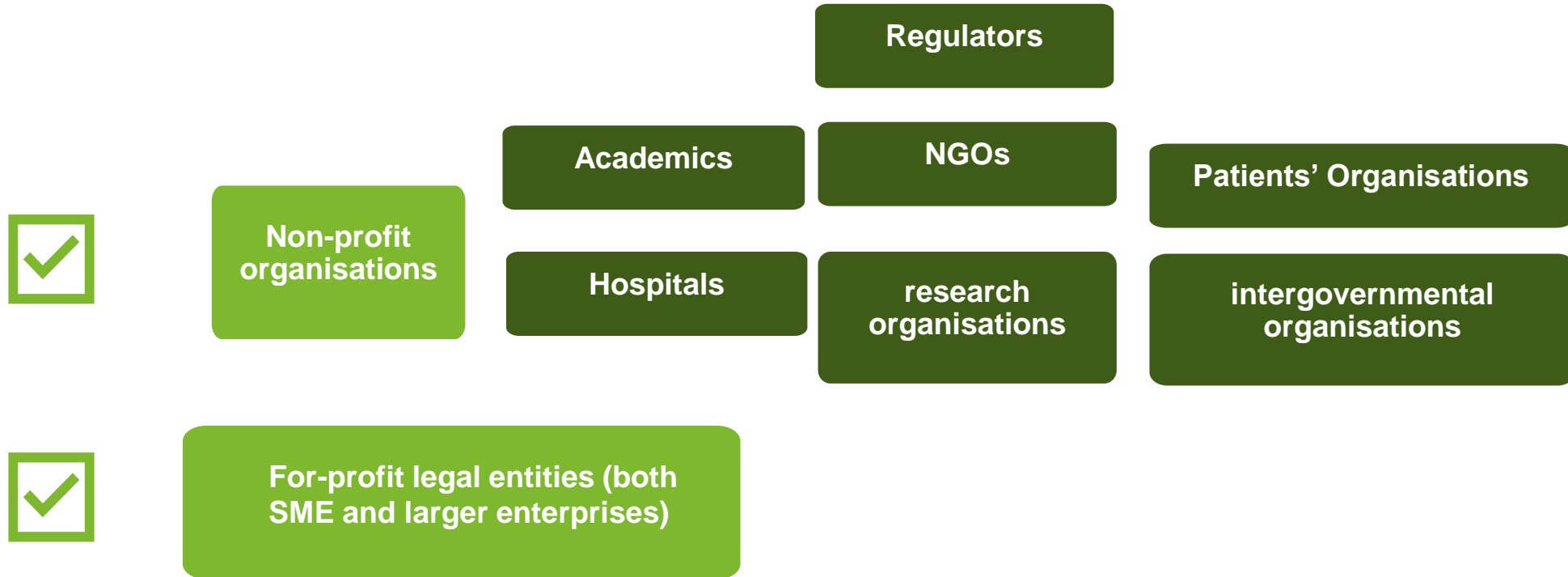
Any legal entity established in a Member State, Associated Country or Low and Middle Income Countries



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

exceptional funding (recommended by expert 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

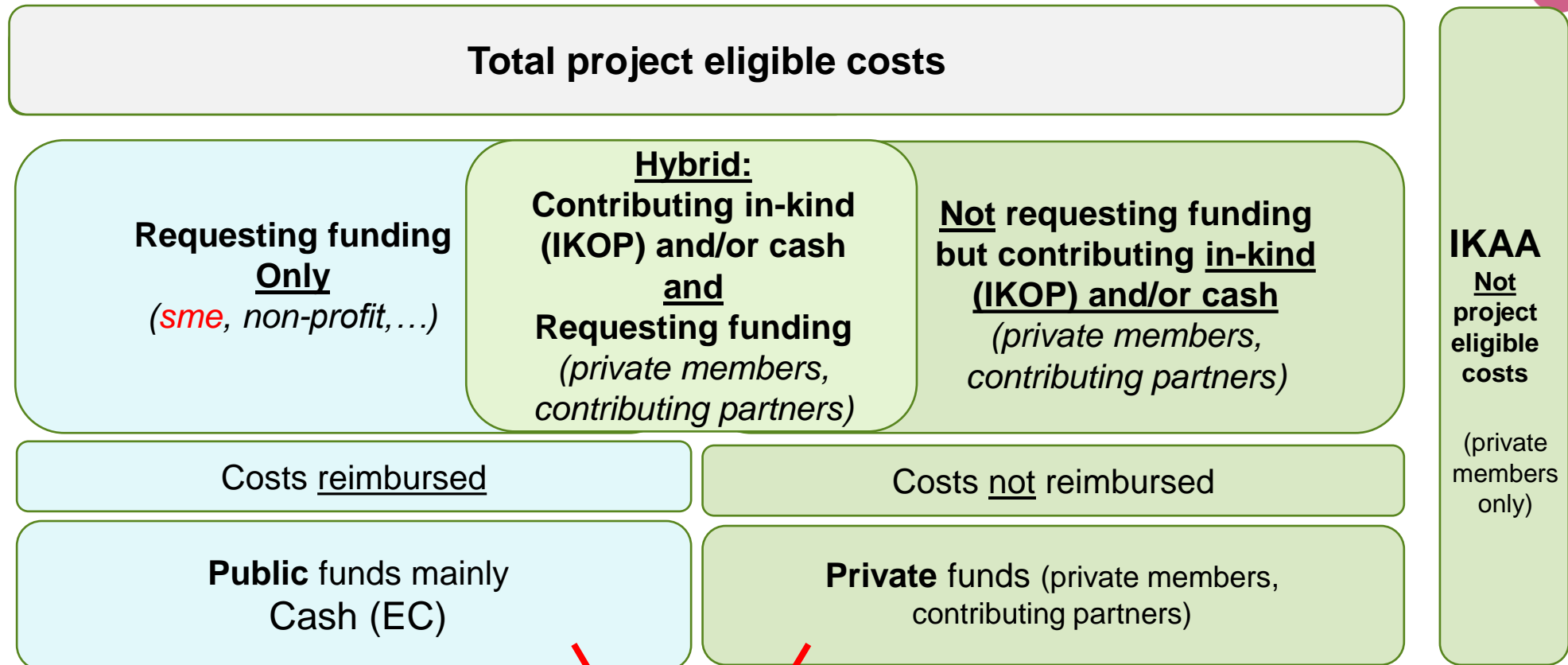
(b) directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.





- IHI project proposals
Financial part

Estimated eligible costs



Co-funding principle



Budget table

For private members and contributing partners

Only for private members

N o.	Name of beneficiary	Co untry	Rol e	Per son nel costs	Subcontr acting costs	Purchase costs			Internally invoiced goods and services (Unit costs)	Indirect costs	Total eligible costs	Funding rate	Maximum EU contribution to eligible costs	Requested EU contribution to eligible costs	Income generated by the action	Financial contributions	IKOP In-kind contributions for operational activities	Non-EU IKOP	Own resources	Total estimated income	IKAA In-kind contributions for additional activities
						Travel and subsistence	Equipment	Other goods, works and services													

Estimated eligible costs

Estimated EU contribution and other sources of financing

IHI's specificities

For all applicants





- Types of contribution and contributors

IHI Private members (PM)

- **Four** Industry trade associations (EFPIA includes Vaccines Europe subgroup)



- “Constituent entities”: members of these associations







- Affiliated entities of the above entities (financial or legal link)



Contributing Partners (CP)

- Any legal entities interested in supporting IHI JU's strategic and specific objectives in their specific areas of research without becoming full members
- Application by submitting a letter to IHI Governing Board (GB) before the call deadline
 - CP to be approved by the IHI GB
- CP in IHI Call 1: AB Science, icoMetrix, Combinostics, LGC Clinical diagnostics,...
- More information on contributing partners on [IHI website](#)

IHI specific budget items

	Private members	Contributing Partners
• IKOP - In-kind contributions to OPerational activities		
• FC - Financial contributions		
• IKAA - In-kind contributions to Additional Activities		

Not Private members or Contributing partners → Cannot contribute IKOP, IKAA and FC

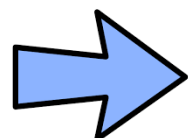


One key threshold

Min 45% contribution

*“Private members, their constituents or affiliated entities and contributing partners must contribute at least **45%** of the action’s eligible costs and costs for additional activities”*

$(IKOP + FC + IKAA) \geq 45\%$ of action’s (eligible costs + IKAA)



[Annex on budget](#) verifies automatically if your proposal reaches 45%

If threshold not reached collectively → (full) proposal NOT evaluated

Min 45% contribution

- Coordinator of the proposal must submit a Declaration (Annex) to confirm that the required 45% contribution will be provided
- 45% can be reached with only one or two contribution type (e.g only with IKOP)
- Only private members and contributing partners can contribute to the 45%

(during GAP, IHI office checks if private members are indeed members and if contributing partners have been approved by the IHI GB).
- 45% must be maintained during project implementation
 - Prudent approach recommended for proposals: aim for 50%

Simplified budget example: Single-stage

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	15 million	100%	15 million	0
Private members & contributing partners (requested funding = 0)	15 million	100%	0	15 million
Private members & contributing partners (<u>'Hybrid'</u>)	10 million	100%	5 million	5 million
Total	40 million	100%	20 million (50%) Public funds	20 million (50%) Private funds

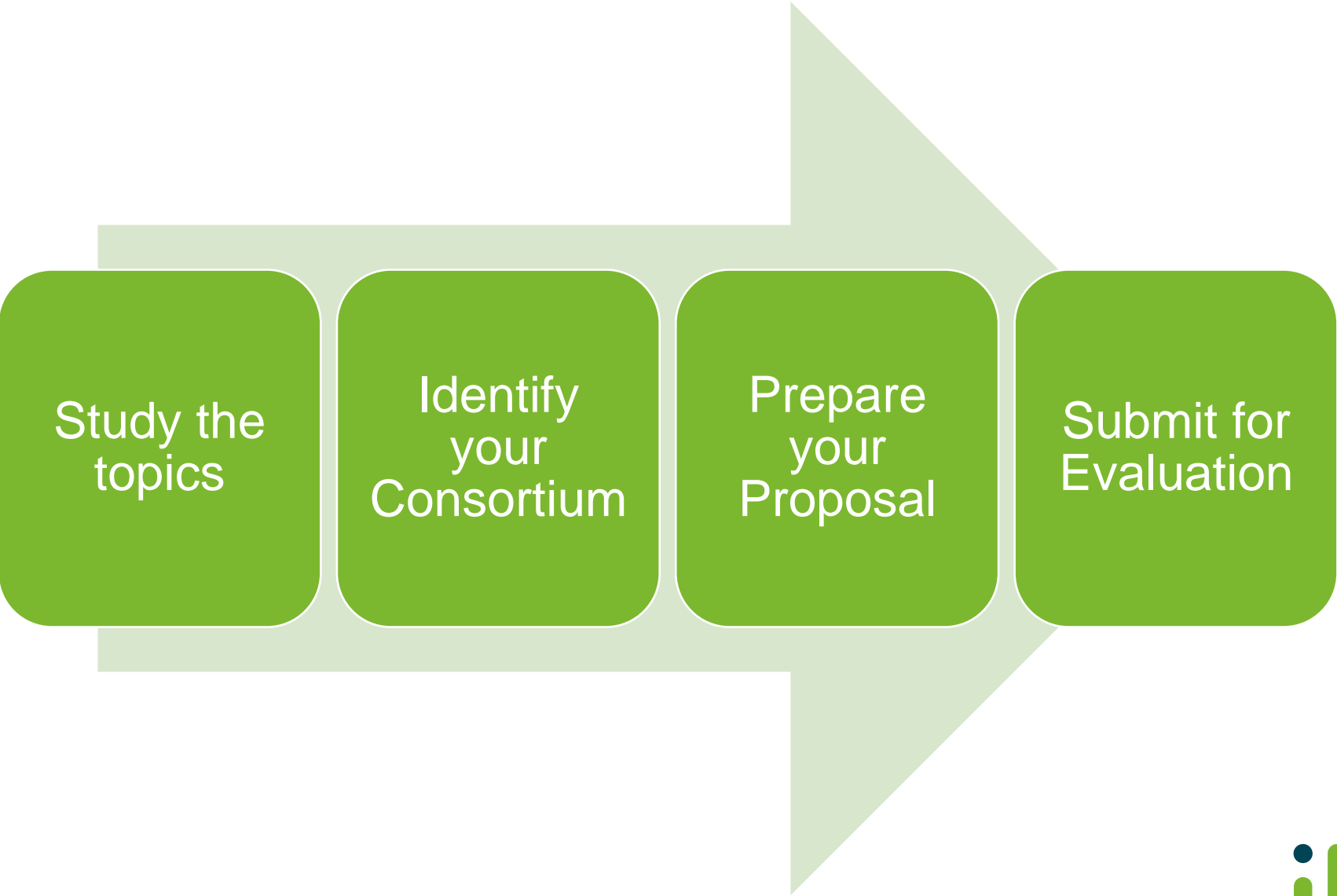
Simplified budget example: Two-stage

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	20 million	100%	20 million	0
Pre-identified Private members and Contributing partners (not eligible for funding)	20 million	100%	0	20 million
Total	40 million	100%	20 million (50%) Public funds	20 million (50%) Private funds



Submission and Evaluation





Plantilla de Propuesta - 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
- **Annexes:**
 - IHI JU annex: Type of participants
 - IHI JU annex: Declaration of in-kind contribution commitment
 - IHI JU annex: In-kind contributions to additional activities (IKAA)
 - Annex: Essential information for clinical studies

➤ **Read instructions** in the proposal template **very carefully**





Standard evaluation process



Evaluation criteria and thresholds

- 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
TOTAL	10/15

Evaluation criteria – Tips

Excellence:

- Address all the objectives of the topic text (unless written otherwise). You should not pick and choose or you will be penalized.
- Clearly describe how your methodology has incorporated knowledge from various stakeholders. This is NOT about the consortium composition but about the knowledge build into the methodology

Impact

- Please provide meaningful and MEASURABLE estimates when it comes to your project's contribution to impacts. We often see unrealistic impacts with no justification

Implementation

- Prepare clear graphs, focus on the overall structure of your project, your WPs and their overall objectives.
- Short Proposal? Reflect and leave some space to describe how your consortium will fit with the industry consortium: aka read the topic text and what the industry is bringing to the project and show you have taken this into consideration.

- 
- Información adicional

Points to remember

- Read all the call-relevant material: www.ihl.europa.eu (Topic text, Guide for Applicants, IHI FAQs, IHI Proposal Templates, Evaluation Forms, Annotated Model Grant Agreement, SRIA)
- Begin forming your consortium early. Check the IHI website and F&TP. [Check the IHI Call Days website.](#)
- Ensure that all information is explicitly described in order to allow the expert-evaluators to assess against the evaluation subcriteria. **Respect the page limit!**
- Plan the **45% In kind contribution and aim at 50%**. This is the responsibility of the entire consortium.
- **Coordinator must be financially viable – check in advance**

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 mentioning your expert profile number (format EX20XX1234567)

Your contact points

At the IHI Programme Office

General queries: applicants@ihi.europa.eu

IHI Office: infodesk@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>.



Gracias! Preguntas?

