

Iniciativa de Salud Innovadora

Jornada Informativa – Convocatorias 3 y 4



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 - Reglas de participación y elegibilidad
 - Presupuesto de Proyectos en IHI
 - Preparación de propuestas y proceso de evaluación
 - Información adicional

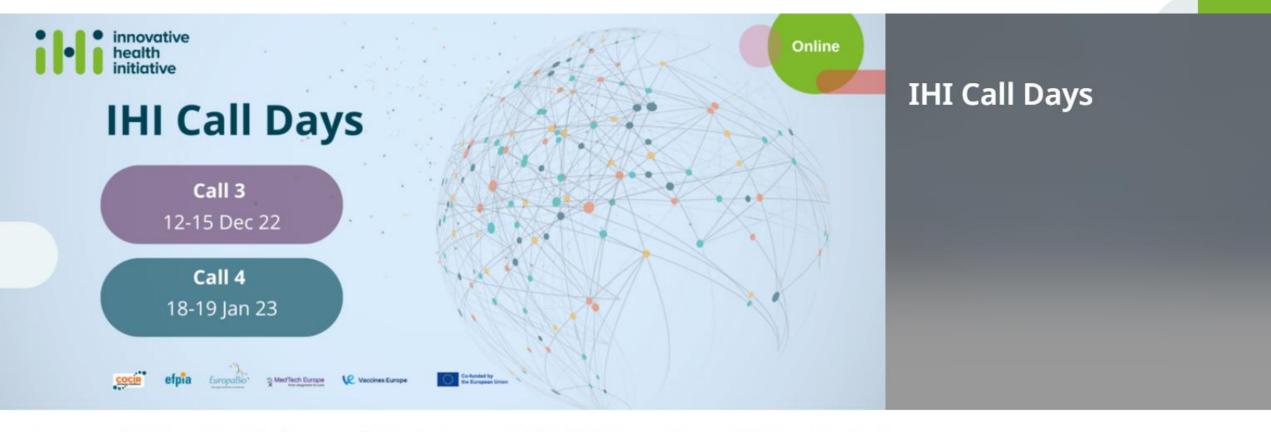


IHI: Objetivos Generales

- 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.



Save the date!



Home Matchmaking Platform Marketplace Call 3 - Pitching General FAQ Contact



3^a Convocatoria IHI (single stage) – borrador 24/12/2022

- <u>Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need</u>
- <u>Topic 2</u>: <u>Patient-generated evidence</u> to improve outcomes, support decision making, and accelerate innovation
- <u>Topic 3: Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiency</u>
- <u>Topic 4: Strengthening the European translational research ecosystem for advanced therapy medicinal products (ATMPs) for rare diseases</u>
- <u>Topic 5: Digital health technologies for the prevention and personalised</u> management of **mental disorders** and their long-term health consequences



4^a Convocatoria IHI (two stage) - borrador 24/12/2022

- Topic 1: **Expanding translational knowledge in minipigs**: a path to reduce and replace non-human primates in non-clinical safety assessment
- <u>Topic 2: Patient-centric blood sample collection</u> to enable decentralised <u>clinical trials and improve access to healthcare</u>



Tipos de convocatoria

Single-stage / Two-stage



Convocatoria IHI-single-stage

Single-Stage
Submission of Full Proposal

Evaluation process

Call launch

Full Consortium (Public & Private Partners)

Topic texts are approved by the IHI Governing Board, as part of the Annual Work Programme Academics

Hospitals

Regulators

Patients' Organisations

For-profit legal entities (SMEs and larger enterprises)

Granting phase



Project launch!

Signature of Grant Agreements

(between project coordinator and IHI JU)

Signature of Consortium Agreements

(between partners)

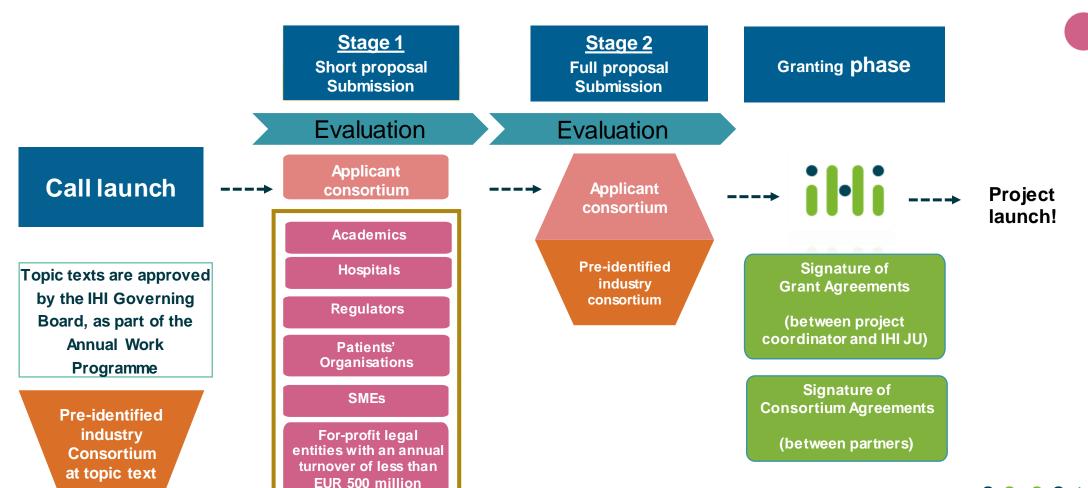


Condiciones Convocatoria 3, single-stage

- For each topic:
 - ✓ 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) involving 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



Convocatoria IHI-two-stage





Condiciones Convocatoria 4, 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

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

Plazos estimados



Call 3 – single stage – Indicative timelines

mid-December 2022

Launch of the Call

mid-March 2023

Call Submission Deadline - Full Proposals (FP)

March-April 2023

Scientific evaluation

June 2023

• Information to the applicants - evaluation outcome

September 2023

Grant Agreement Preparation (GAP) and GA signature



Call 4 - two-stage - Indicative timelines

mid-January 2023 Launch of the Call end-April 2023 Call Submission Deadline - Short Proposals (SP) April-May 2023 Scientific evaluation - SPs mid-July 2023 • Information to the applicants - evaluation outcome mid-October 2023 Submission Deadline - Full Proposal (FP) October-November 2023 Scientific evaluation - FPs December 2023 • Evaluation Outcome letters to the applicants Grant Agreement Preparation (GAP) and GA March 2024 signature



Cómo preparar tu propuesta [info]

Webinars on IHI rules and procedures

- **Rules and procedures,** Friday 10 June | 10:30-12:00 Click here for the <u>recording</u> and the <u>presentation</u>
- **Preparing the financial part of the proposal,** Monday 27 June | 14:30-16:00 Click here for the <u>recording</u> and the <u>presentation</u>

- <u>IHI Call Days for Calls 3 and 4</u>: [12-15/12/2022] y [18-19/01/2023]
- Sesiones informativas sobre reglas, procedimientos y presupuestos de propuestas
- Sesiones informativas sobre los Call Topics
- Sesiones de matchmaking y pitching temáticos



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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



Consortium Composition

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.

- 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.



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



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IHI project proposals Financial part



Cómo preparar tu propuesta [info]

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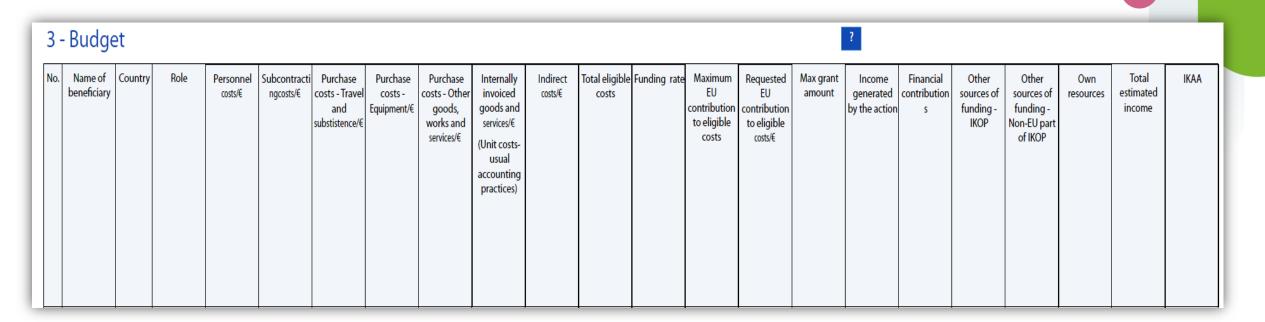


Budget table

		Prepare Budget table?				
Single stage proposa	l	Yes				
Two-stage call	Short proposal	No Only total requested EU contribution for the project should be specified				
	Full proposal	Yes				



Budget Table

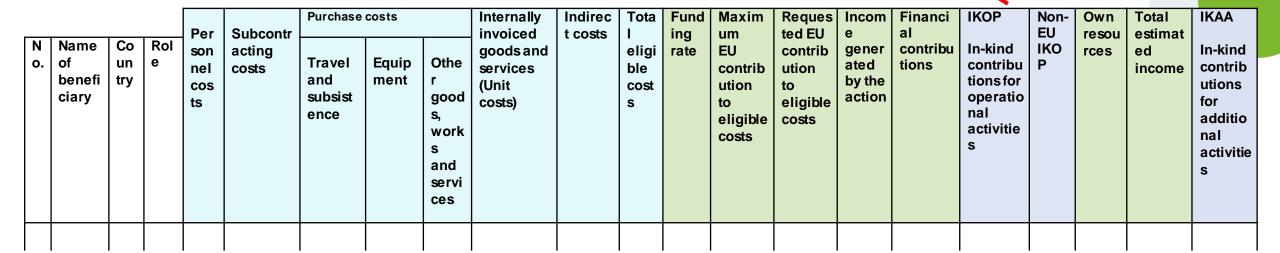




Budget table

For private members and contributing partners

Only for private members



Estimated eligible costs

Estimated EU contribution and other sources of financing

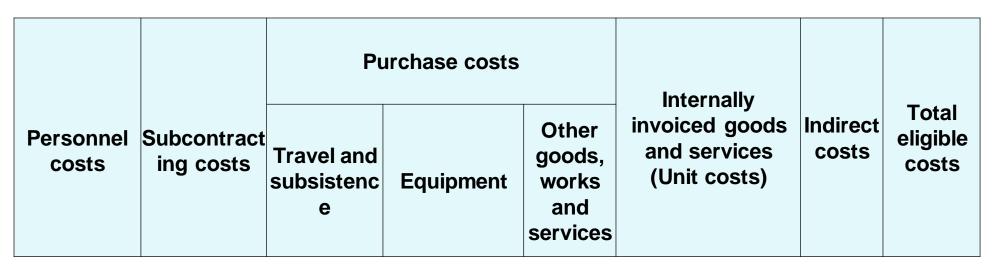
IHI's specificities



For all applicants

Estimated eligible costs

Types of costs categories





actual/real, recorded in the accounts, foreseen in the budget, necessary for the action, documented/auditable, etc.



Only eligible costs can be reimbursed or be considered as in-kind contribution (IKOP)



Estimated eligible costs

Total project eligible costs

Incurred by entities

Requesting funding Only

(sme, non-profit,...)

Hybrid:

Contributing in-kind (IKOP) and/or cash and

Requesting funding

(private members, contributing partners)

Not requesting funding but contributing in-kind (IKOP) and/or cash

(private members, contributing partners)

Costs reimbursed

Costs not reimbursed

Costs covered by

Public funds mainly Cash (EC)

Private funds (private members, contributing partners)







Not project eligible costs

(private members only)

Budget table

			Per	Subcontr	Purchase	costs		Internally invoiced	Indirec t costs	Tota I	Fund ing	Maxim um	Reques ted EU	Incom e	Financi al	IKOP	Non- EU	Own resou	Total estimat	IKAA
N o.	Name of benefi ciary	Co un try	son nel cos ts	acting costs	Travel and subsist ence	Equip ment	Othe r good s, work s and services	goods and services (Unit costs)		eligi ble cost s	rate	EU contrib ution to eligible costs	contrib ution to eligible costs	gener ated by the action	contribu tions	In-kind contribu tions for operatio nal activitie s	IKO	rces	ed income	In-kind contrib utions for additio nal activitie s

Estimated eligible costs

Estimated EU contribution and other sources of financing

IHI's specificities



For all applicants

How are participants costs covered?



- Reimbursed by IHI (= EU contribution)?
- > Covered with own resources?
- Covered by financial contributions received (other than from IHI)? (e.g. from private members, contributing partners)?

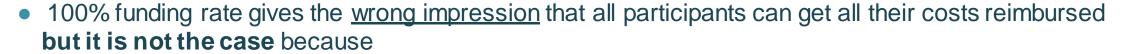
Several scenarios possible:

- Can be with only one source of financing (e.g. only EU contribution)
- Can be with a combination (e.g: EU + FC)
- Can be none (e.g: the entity not eligible for funding, or providing only IKOP)



The Funding Rate confusion

Funding rate	Maximum EU contribution	Requested EU contribution
Always 100% (Automatic)	= Funding rate x total eligible costs	Amount of IHI funding requested to reimburse part/all project eligible costs
For all entities, even for entities not eligible for funding!	(<u>Automatic</u>)	(To encode manually)



- Private members and contributing partners should bring at least 45% contribution to the project
- Some participants <u>are not eligible</u> for funding
 (e.g. in two-stage calls: pre-identified industry consortium members)



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 ('Hybrid')	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		



Costs covered by financial contributions (FC)

- Amount expected to be received for the project, other than the EU contribution
- Includes FC received by Private Members or Contributing Partners
- Beneficiaries receiving a FC must ensure that the part of costs covered by the FC are manually deducted from the requested EU contribution (no double funding allowed)
- In Proposal part b (table 3.1k): Financial contributions to be explained:
 - private member/contributing partner paying the FC,
 - the FC amount,
 - the beneficiary receiving the FC and
 - the concerned project activities



Costs covered with own resources

- Amount expected of own resources the participant plans to use for the implementation of the project
- When total project eligible costs not entirely covered by EU contribution or financial contribution or both
- Always zero for private members and contributing partners (own resources = IKOP)



Simple example of sources of financing

Type of participant	Total eligible costs	Requested EU contribution	Financial contributions	Own resources
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators)	20 million	10 million	5 million	5 million

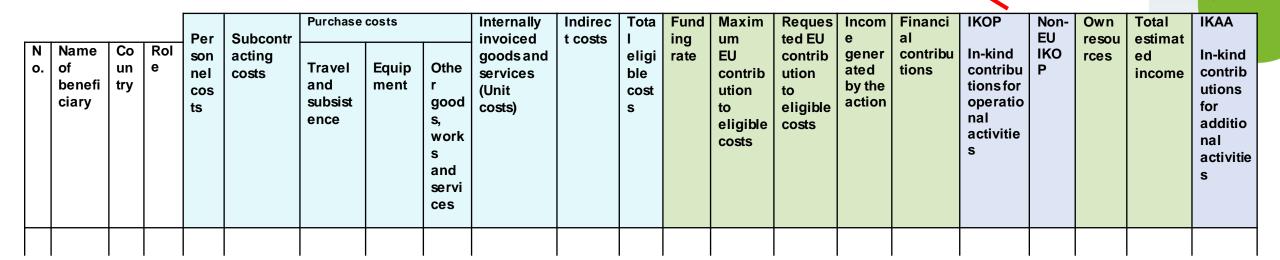
- Check that all costs are 'covered' but no profit
 - > Total eligible costs = (requested EU + financial contributions + own resources)



Budget Table

For private members and contributing partners

Only for private members



Estimated eligible costs

Estimated EU contribution and other sources of financing

IHI's specificities



"Private Members"

- = "private members, their constituent or affiliated entities"
 - Private members: industry trade associations (EFPIA, inc. Vaccines Europe, COCIR, MedTech, EuropaBio)
 - Constituent entity: member of one industry trade association (pays membership fees)
 - Affiliated entity: 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 Partners (CP)

- Any organisation that wants to contribute to the IHI objectives without becoming a full member can apply
- Application: via '<u>letter of endorsement</u>' to IHI Governing Board (GB).
- In letter: commit a certain contribution to a certain topic
- To be approved by the IHI GB





Contribution types

Private Members Contributing Partners







FC - Financial contributions
 Cash contributions to project beneficiary(ies) from the same





IKAA - In-kind contributions to Additional Activities
 Costs for implementing additional activities

consortium to support eligible costs for project implementation







Key Financial Thresholds



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].
- Coordinator of (full) proposal must submit a Declaration to confirm that the required 45% contributions will be provided

IKOP + IKAA + FC must be ≥ 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



Other thresholds

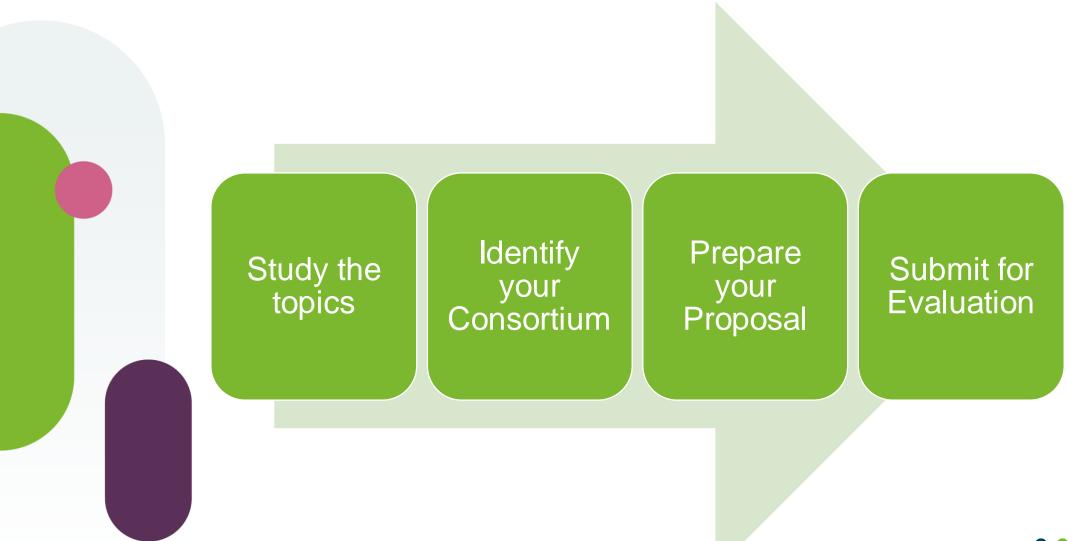
- Non-EU IKOP ≤ 20% total IKOP of private members and contributing partners at <u>Programme level</u>
 - Also 20% limitation at project level, unless otherwise specified in call text
- IKAA ≤ 40% total (IKOP + IKAA) of private members at <u>Programme</u> level
 - Project level: also 40% limitation by analogy

Exceptions? Private member to liaise with Industry responsible office to ensure good monitoring



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

Receipt of proposals

Individual evaluation

Consensus group Panel review

Finalisation

Admissibility/eligibility check

Allocation of proposals to evaluators

Experts assess proposals individually.

Minimum of three experts per proposal (but often more than three).

All individual experts discuss together to agree on a **common position**, including comments and scores for each proposal.

The panel of experts reach an **agreement** on the scores and comments for all proposals within a call, checking **consistency** across the evaluations.

if necessary, resolve cases where evaluators were unable to agree.

Rank the proposals with the same score

The Commission/Agency reviews the results of the experts' evaluation and puts together the **final** ranking list.



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* (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, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

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.
- Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

Evaluation Criteria* (2/2)

- Quality and efficiency of the implementation
 - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
 - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.







Preparación (1/2)

- Lee todo el material disponible:
 - Topic text
 - Guide for Applicants, IHI FAQs
 - IHI Proposal Templates, Evaluation Forms
 - Annotated Model Grant Agreement
- Asegurate de proveer toda la informacion requerida en el texto de la convocatoria y en la plantilla de propuesta para facilitar a los expertos la evaluación de en base a los criterios de evaluación.
- Ten en cuenta los objetivos y filosofía de IHI's: SRIA



Preparación (2/2)

- Identifica y afianza tu consorcio cuanto antes
 - Piensa en "public-private partnership"
 - Incluye miembros aportando in-kind contributions
- Participa en los IHI Days [3,4], preparate para el evento revisando los webinars de las primeras convocatorias.
- Dudas? Contacta con la Oficina de IHI: infodesk@ihi.europa.eu



Ayudanos!

Participa como Evaluador

- IHI, y todos los programas de investigacion de la UE, buscan continuamente nuevos expertos con experiencia en diferentes areas.
- Crea o actualiza tu perfil en el <u>Funding and Tenders Portal</u>
- Informanos via <u>experts@ihi.europa.eu</u>, indicando tu numero de identificacion (EX012345*)

Ayudanos a definir nuevas convocatorias

Puedes propones tus ideas <u>aqui!</u>



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?











