

Guide for Applicants

Manual for Submission, Evaluation and Grant Award

IHI JU Calls for Proposals

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Horizon Europe

Disclaimer

This guide is designed to assist applicants in preparing and submitting their proposal. It is based on the rules and conditions set out in the IHI JU Work Programme and the Horizon Europe Model Grant Agreement, which are accessible through the Funding & Tenders Portal and the IHI JU website.

This guide does not supersede those documents, which are legally binding.

This guide may be subject to modifications during the implementation of the IHI programme.

Chronology and list of reviews

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Abbreviations and definitions

Acronym	Meaning
3A	Affordability, availability and accessibility
CFS	Certificate on financial statements
COCIR	European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries
CoI	Conflict of interest
EC	European Commission
ECA	European Court of Auditors
ED	IHI JU Executive Director
EFPIA	European Federation of Pharmaceutical Industries and Associations
ESR	Evaluation summary report
EU	European Union
EUR	Euro currency
EuropaBio	European Association for Bioindustries
FC	Financial contribution
FP	Full proposal
FSIGN	Person in the organisation authorised to sign financial statements in the EC IT tool
GAP	Grant agreement preparation
GB	IHI JU Governing Board
HE	Horizon Europe
IER	Individual evaluation report
IHI JU	Innovative Health Initiative Joint Undertaking
IKAA	In-kind contributions to additional activities
IKOP	In-kind contributions to operational activities
JUs	Joint Undertakings
LEAR	Legal entity appointed representative
LSIGN	Person in the organisation authorised to sign grant agreements in the EC IT tool
MedTech Europe	European trade association for the medical technology industry
MGA	Model grant agreement
OLAF	European Anti-Fraud Office (<i>Office Européen de Lutte Antifraude</i>)
PPP	Public-private partnership
RIA	Research and Innovation Action
RtO	Right to object
SBA	Single Basic Act
SIP	Science and Innovation Panel
SMEs	Small and medium-sized enterprises
SP	Short proposal
SRG	States' Representatives Group
SRIA	Strategic Research and Innovation Agenda
Vaccines Europe	Specialised vaccines group within the EFPIA
WP	Work Programme

Main definitions

Additional activities: Activities that contribute to IHI JU's objectives, are carried out in the European Union (EU) or countries associated to Horizon Europe, are not funded by IHI JU or any other EU funding programme. Additional activities can be either project-specific (when they contribute towards the achievement of the objectives of an IHI JU project, or the dissemination, sustainability or exploitation of IHI JU project results), or programme-specific (when they contribute to the uptake of results from an IHI/IMI2 project(s) or have a significant added value for the Union). Project-specific additional activities are not project tasks (i.e. not IKOP).

Affiliated entities: Entities with a legal or capital link with the beneficiary, which is neither limited to the action nor established for the sole purpose of the action implementation. Affiliated entities implement parts of the action and are allowed to charge costs directly to the grant. **Affordability, availability and accessibility:** Obligation laying on the participants which must, during the lifetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly available and accessible, at fair and reasonable conditions (Article 125(3) SBA).

Applicant: Legal entity submitting an application for a call for proposals.

Associated partners: Entities that implement action tasks but without requesting EU funding, nor contributing in-kind contributions.

Associated countries: Third countries associated to Horizon Europe.

See list of countries https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

and the relevant updates here: https://ec.europa.eu/info/news/updates-association-third-countries-horizon-europe_en

Award criteria: Sometimes also referred to as 'evaluation criteria'. All proposals are evaluated based on three criteria: excellence; impact; and quality and efficiency of the implementation. The work programme will lay down further details of the application of the award criteria and specify weightings and thresholds.

Background: 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. For more information, please see the HE Model Grant Agreement and in particular Annex 5.

Beneficiaries: A legal person, other than the IHI JU, which is a signatory of the Grant Agreement (either directly or through an accession form).

Call for proposals: A procedure to invite applicants to submit project proposals with the objective of receiving funds from the European Union.

Call publication: The act of publishing calls for project proposals on the Funding and Tenders Portal.

Consensus discussion: A meeting of the experts who participated in the individual evaluation to discuss the scores awarded and prepare comments. Experts attempt to agree on a consensus score for each of the criteria that have been evaluated and comments which justify the scores and are suitable for feedback to the proposal coordinator. Scores and comments are set out in a consensus report. The meetings are moderated by an IHI JU representative and are usually held in Brussels or remotely.

Consortium agreement: An internal agreement between members of a consortium establishing their rights and obligations with respect to the implementation of an action in compliance with the grant agreement. For IHI JU projects, the consortium agreement should be finalised before the GA signature.

Constituent entities: Entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes. In the context of the IHI JU, constituent entities are the members of the industry trade associations COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe.

Contributing partner: Any country, international organisation, or legal entity other than a member of the IHI JU, or a constituent entity of a member or an affiliated entity of either, that supports the IHI JU's objectives in its specific area of research and whose application to become a contributing partner has been approved by the IHI JU Governing Board.

Coordinator: A beneficiary of the consortium responsible for managing the project, submitting reports and deliverables, and acting as intermediary for all contacts with the EU Granting Authority.

Council Regulation (EU) 2021/2085 or 'Single Basic Act' (SBA): The act establishing the Joint Undertakings (including IHI) under the Horizon Europe programme.

Electronic submission: Project proposals for Horizon Europe calls are prepared and submitted electronically via the Funding & Tenders Portal by the coordinator of the project consortium. The electronic submission service is accessed by selecting an open topic in the Funding & Tenders Portal call service.

Eligibility criteria: Criteria used to determine whether a proposal meets the requirements to become eligible for a European Union grant.

Ethics appraisal procedure: The ethics appraisal procedure concerns all activities funded in Horizon Europe and includes the ethics review procedure, conducted before the start of the project, as well as the ethics checks and audits.

Evaluation procedure: Methodology under which the evaluation is performed for a specific call for proposals.

Evaluation review procedure: A coordinator may request an evaluation review procedure if they believe the evaluation has not been carried out in accordance with the procedures set out in the rules for participation, the relevant work programme, or the call for proposals. The review only covers the procedural aspects of the evaluation, and not the merits of the proposal.

Evaluation summary report: The official document containing the evaluators' score of a proposal evaluated for the granting authority.

Evaluation threshold: The minimum evaluation scores that a Horizon Europe project proposal must receive in order to be ranked. The default thresholds are a score of at least 3 out of 5 for each individual criterion, and a score of at least 10 out of 15 for the sum of the individual scores. The thresholds are applied to unweighted scores. Different thresholds may be specified in the conditions of the call for proposals. Proposals scoring below any of the thresholds will be rejected.

Exclusion criteria: Experts check on the exclusion criteria which reflect if applicant is or not excluded and the reasons for exclusion (see section 5.3.6.3).

Funding & Tenders Portal: The entry point (the Single Electronic Data Interchange Area) for participants and experts in funding programmes and tenders managed by the European Commission and other EU bodies.

Grant: direct financial contributions, by way of donation, from the EU budget in order to finance any of the following: a) an action intended to help achieve an EU policy objective; b) the functioning of a body which pursues an aim of general EU interest or has an objective forming part of, and supporting, an EU policy ('operating grants').

Grant agreement: A contract concluded between the IHI JU and the beneficiaries under which the parties receive rights and obligations (e.g. the right to the Union's financial contribution and the obligation to carry out the research and development work). It consists of the basic text and annexes.

Horizon Europe: The EU's key funding programme for research and innovation. See https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en.

Independent observers: With a view to ensuring a high degree of transparency, IHI JU appoints independent experts to act as observers of the evaluation process from the point of view of its working and execution. Their role is to give independent advice to IHI JU on the conduct and fairness of all phases of the evaluation sessions.

Individual evaluation report: At the end of the evaluation process, each expert should produce an individual evaluation report for each proposal, with justifications for all scores given.

In-kind contributions to operational activities (IKOP): Contributions by the IHI JU private members, their constituent or affiliated entities and by contributing partners, consisting of the eligible costs incurred by them for implementing the action, less the contribution of the IHI JU to those costs.

In-kind contributions to additional activities (IKAA): Contributions incurred by the IHI JU private members, their constituent or affiliated entities, consisting of costs for implementing additional activities.

Legal entity: Any natural person, or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

Legal entity appointed representative (LEAR): Person appointed to be the legal representative of a legal entity participating in EU funding programmes. The LEAR is usually an administrative staff member of the central administrative department of the organisation. The LEAR provides the Commission with up-to-date legal and financial data, including the people in the organisation authorised to sign grant agreements (LSIGNs) and financial statements (FSIGNs); and commits to keep the information up to date, enabling future use for grants and other transactions between the entity and the Commission research (and other) programmes. The LEAR can delegate some of their tasks to account administrators.

Legal representative: A natural person who has been empowered (directly or indirectly) by a legal entity to enter into legal commitments on its behalf.

Legal signatory (LSIGN): A role in the Funding & Tenders Portal giving special access rights for paperless grant management in Horizon Europe. LSIGNs have full read/write access to the e-forms for grant management and are authorised to electronically sign grant agreements and amendments. LSIGNs are assigned in the Funding & Tenders Portal by the Legal Entity Appointed Representative (LEAR) of the organisation (or one of their account administrators).

Member State: A state that is party to treaties of the European Union and thereby subject to the privileges and obligations of European Union membership.

Model grant agreement: The compulsory form of a grant agreement. It consists of a core text (determining the basics of a project) and several annexes.

Non-profit legal entity: A legal entity which by its legal form is non-profitmaking, or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

Panel report: a report including lists and scores of all evaluated proposals in an indicative budget line for the IHI JU records.

Participant identification code (PIC): a nine-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes.

Participant register: A central database of organisations (legal entities) participating in EU funding programmes. Each organisation has a participant identification code (PIC) that is used as the unique identifier in all interactions in any proposals or grants in which the organisation is involved.

Participants: Entities participating in the action as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors, or recipients of financial support to third parties.

Private member: A legal entity that is a member of the IHI JU other than the Union. The private members of IHI JU are the industry trade associations COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe.

Public-private partnership: A partnership where private sector partners and the European Union commit to jointly support the development and implementation of a research and innovation programme or activities.

Ranking: Proposals are ranked on the basis of the evaluation results. The selection is made on the basis of that ranking.

Research and Innovation Action (RIA): An action primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service, or solution. For this purpose, they may include basic and applied research, technology development and integration, and testing and validation of a small-scale prototype in a laboratory or simulated environment. Projects may contain closely connected but limited demonstration or pilot activities aiming to show technical feasibility in a near-to-operational environment.

Reserve list: Due to budgetary constraints, it may not be possible to support all proposals that have been evaluated positively. Proposals on a reserve list will only be financed if funds become available.

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.

Right to object: right of the IHI JU to object to transfers of ownership or to the exclusive licensing of results. This objection may be raised if: a) the transfer/exclusive license is to a legal entity established in a non-EU country not associated with Horizon Europe, and b) the IHI JU considers that the transfer or exclusive licence is not in line with EU interests (Annex 5 Horizon Europe Model Grant Agreement). This right may be also exercised to object over results generated by beneficiaries not receiving funding (Article 24(3) of the SBA).

Score: Proposals for projects to be funded under Horizon Europe are evaluated on the basis of selection criteria (financial and operational capacity) and award criteria (excellence, impact, efficiency of implementation). Unless otherwise specified in the conditions of the call for proposals, each of the award criteria is scored between 0 and 5. The total score is calculated as a weighted sum of the scores for each criterion. The default is equal weight for all criteria. Other weightings may be specified in the conditions of the call for proposals.

Single-stage submission scheme: A scheme in which there is a single proposal submission and evaluation phase and there is no pre-defined industry consortium. The applicant consortium composition may include any

legal entities, including private members and/or contributing partners and their constituent and affiliated entities who will ensure the 45 % eligibility criterion is fulfilled.

Submission: The formal act of submitting a proposal to IHI JU.

Third Country: any country outside the EU which is not associated to Horizon Europe.

Topic: IHI JU calls for proposals (as defined in the annual work programme) are subdivided into topics. A topic defines a specific research and innovation subject or area for which applicants are invited to submit proposals. The description of a topic comprises the specific scope and expected impact of the projects to be funded, and also the type of project, evaluation criteria and deadline for submission of proposals.

Two-stage submission scheme: A scheme in which applicants must submit a short proposal (SP) for the stage 1 evaluation. SPs must involve all applicant organisations requesting JU funding. At the end of the stage 1 evaluation, under each topic, only the applicant consortium of the first ranked SP will be invited to prepare and submit a full proposal (FP) for the stage 2 evaluation together with the pre-identified industry consortium for the topic.

Work Programme: The document adopted by IHI JU for the implementation of the IHI JU specific programme in accordance with Articles 23 and 25 of the SBA, and detailing call topics and associated modalities.

Reference documents

This section contains reference documents relating to calls for proposals launched under the IHI programme. Applicants are invited to read the following materials before preparing and submitting their proposal.

The reference documents are also available on the [IHI website](#) and in the [EU Funding and Tenders Portal](#) (IHI JU dedicated Call area).

IHI-specific documents

[Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations \(EC\) No 219/2007, \(EU\) No 557/2014, \(EU\) No 558/2014, \(EU\) No 559/2014, \(EU\) No 560/2014, \(EU\) No 561/2014 and \(EU\) No 642/2014 \(in short Single Basic Act 'SBA' or Council Regulation \(EU\) 2021/2085\).](#)

[IHI JU Annual Work Programme \(AWP\)](#)

[Strategic Research and Innovation Agenda \(SRIA\)](#)

[IHI JU guidelines for in-kind contributions to additional activities \(IKAA\)](#)

Evaluation form (single and two-stage calls)

[IHI JU evaluation form for Research and Innovation Actions \(single and two-stage calls\)](#)

Application forms for submitting proposals

The following templates and annexes are available to download in the submission system. Applicants can also consult the relevant documents via the links provided below.

Research and Innovation Actions – single-stage and second stage of two-stage procedure

Proposal template - Part A of the proposal is generated by the IT system in the submission environment (for more information see the HE Part A template [here](#)). In Part A of the proposal applicants insert general information on their proposal (e.g. proposal acronym), details on the participants, on the budget, information on Ethics and Security, as well as other type of questions (e.g. information on clinical studies). Please note that **only** Part A of this template is applicable for this call. For Part B, see point below.

[IHI JU proposal template \(RIA/FP\) - Part B](#)

[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](#)

If applicable, any additional supporting documentation related to ethics and/or security issues.
Research and Innovation Actions – first stage in a two-stage procedure

Research and Innovation Actions – first stage of two-stage procedure

Proposal template - Part A of the proposal is generated by the IT system in the submission environment (for more information see the HE Part A template [here](#)). In Part A of the proposal applicants insert general information on their proposal (e.g. proposal acronym), details on the participants and the overall proposal budget. Please note that **only** Part A of this template is applicable for this call. For Part B, see point below.

[IHI JU proposal template \(RIA/SP\) - Part B](#)

[IHI JU annex: Type of participants](#)

Horizon Europe Reference documents

[Horizon Europe Main Work Programme 2021–2022 – 13. general annexes](#)

[Horizon Europe Programme Guide¹](#)

[Horizon Europe Framework Programme and Rules for Participation Regulation 2021/695](#)

[HE Specific Programme Decision 2021/764](#)

[EU Financial Regulation](#)

[Rules for legal entity validation, LEAR appointment and financial capacity assessment](#)

[Funding & Tenders Portal online manual](#)

[Funding & Tenders Portal terms and conditions](#)

[Funding & Tenders Portal privacy statement](#)

Model Grant Agreement

[EU Grants AGA — Annotated Model Grant Agreement](#)

[Horizon Europe General Model Grant Agreement MGA v1.1 of 15 April 2022 \(or subsequent versions\)](#)

NOTE: In this document, the term ‘private member’ refers to both the private members of IHI JU and their constituent or affiliated entities.

¹ Applicants are invited to read the Horizon Europe Programme Guide which provides detailed guidance on the political priorities of Horizon Europe such as gender equality and inclusiveness, the social sciences and humanities (SSH), social innovation, ethics and integrity, security, dissemination and exploitation of research results, the do no significant harm principle, open science, etc. Specific guidance is also provided in the proposal template Part B.

1 Introduction

On 30 November 2021, Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe came into force. This Regulation established the Innovative Health Initiative Joint Undertaking (IHI JU) and repealed - among others - Regulation (EU) 557/2014 establishing the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU)².

IHI JU works by bringing together diverse stakeholders public and private (universities, companies large and small, patient organisations and other health stakeholders) in collaborative projects that address disease areas where there is a high burden on patients and/or society. IHI JU focuses on cross-sectoral projects involving the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area to respond to unmet public health needs.

The members of IHI JU are the European Union, represented by the European Commission, and the European life science industry, represented by the industry associations COCIR³, EFPIA (including Vaccines Europe)⁴, EuropaBio⁵ and MedTech Europe⁶.

More information can be found on the IHI JU website: <https://www.ih.europa.eu/about-ih/who-we-are>

This guide for applicants aims to assist applicants in the preparation and submission of proposals in response to calls launched by IHI JU. Its purpose is to explain the procedure to be followed by applicants and how the evaluation, selection, award and review procedures are performed by IHI JU.

It also highlights IHI JU's specificities, provides clarifications where needed, and directs potential applicants to the appropriate sources of information on preparing and submitting proposals in response to IHI JU calls.

All information concerning IHI JU Calls is published on [IHI JU website](#) and in the [Funding and Tenders Portal](#) (under "**Search Funding & Tenders**" / "**Grants**" / "**Horizon Europe**"). The electronic submission system also has an online wizard that guides the applicants step-by-step through the preparation of their proposal.

If you have any questions on IHI JU calls, please send them to infodesk@ih.europa.eu.

IT-related questions concerning the submission tool/portal need to be addressed directly to the IT Helpdesk of the Funding and Tenders Portal:

<https://ec.europa.eu/info/fundingtenders/opportunities/portal/screen/support/helpdesks/contact-form>. The help desk can also be reached via e-mail (EC-FUNDING-TENDER-SERVICE-DESK@ec.europa.eu) or by phone (+32 2 299 22 22).

² According to Article 174 of Regulation (EU) 2021/2085, the IHI JU is the legal and universal successor of the IMI2 JU. Consequently, as of 30 November 2021, the IHI JU has taken over all IMI2 JU's rights and obligations and is now responsible for managing the IMI2 programme

³ COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See <https://www.cocir.org/>

⁴ EFPIA is the European Federation of Pharmaceutical Industries and Associations. See <https://www.efpia.eu/>

⁵ EuropaBio is the European association representing corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 2600 biotech companies, 2300 out of them are SMEs. See <https://www.europabio.org/>

⁶ MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. See <https://www.medtecheurope.org/>

2 Types of actions funded under IHI

Most IHI JU calls for proposals are for Research and Innovation Actions (RIA). These actions are in line with the IHI JU partnership’s objectives and should focus on the pre-competitive area, thereby creating a safe space for efficient collaboration between companies active in different health technologies. The majority of the projects funded by the Joint Undertaking should be cross sectoral in order to reflect the integrative nature of the IHI JU. As such they should help to break down the silos between health industry sectors and strengthen industry-academia collaborations.

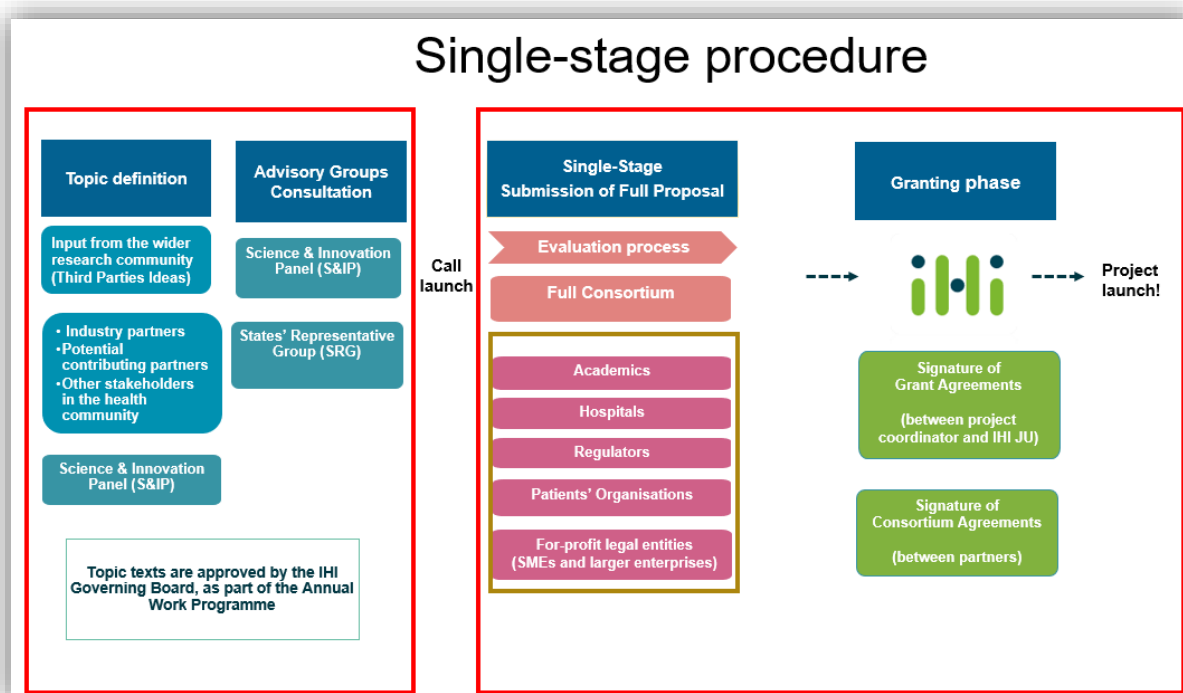
These activities are always to be put in context within the general framework of the priorities set out in the IHI JU Strategic Research and Innovation Agenda (SRIA) (see <https://www.ihj.europa.eu/about-ihj/research-and-innovation-agenda>).

2.1 Single and two-stage calls for proposals

IHI JU uses two types of submission schemes: single-stage and two-stage calls.

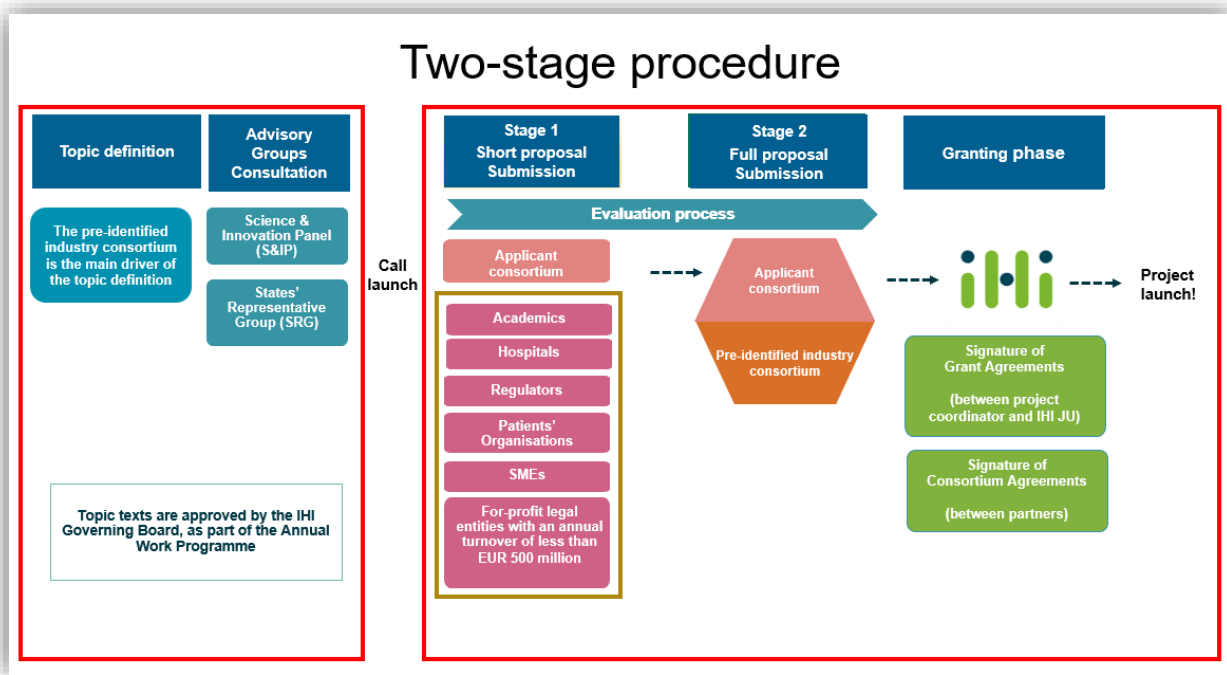
For **single-stage calls**, applicant consortia may consist of different stakeholders such as academia, SMEs, large companies, regulators, etc. Applicant consortia will be assessed on the basis of the required expertise to reach the objectives of the submitted proposals, taking into consideration any specific requirement described in the call topic text, including the public-private partnership requirement. Therefore, applicants might need to involve participants from different health sectors to meet the specific objectives.

A **single-stage submission** implies a single submission and evaluation process, without a pre-defined industry consortium. Applicants must therefore submit a full proposal which includes one or several private members, their constituent or affiliated entities and/or contributing partners. To meet the eligibility criteria, applicants must ensure already at proposal stage that the collective contribution to be provided by the private members, their constituent or affiliated entities and/or contributing partners amounts at least to 45 % of the proposal’s eligible costs and the costs of any related additional activities. After the evaluation, proposals above threshold may be invited for grant preparation according to the ranked list and within the available budget.



Under a **two-stage call**, applicants must submit a short proposal for the stage 1 evaluation. All applicants requesting JU funding must be part of the short proposal. At the end of the stage 1 evaluation, under each topic, only the applicant consortium of the first ranked short proposal is invited to prepare and submit a full proposal for the stage 2 evaluation together with the 'pre-identified industry consortium' (the main driver of the topic definition) for the relevant topic (see IHI two-stage procedure below).

Full proposals to be submitted for stage 2 shall include one or several private members, their constituent or affiliated entities and/or contributing partners. To fulfil the eligibility criteria, applicants must also ensure at the full proposal stage that the collective contribution to be provided by the private members amounts at least to 45 % of the proposal's eligible costs and the costs of any related additional activities.



⚠ The full proposal must be consistent with the short proposal, taking into account the stage 1 evaluation outcome, and may not differ substantially apart from integration of the 'pre-defined industry consortium'.

2.2 Entities eligible to participate

A distinction must be made between legal entities eligible to participate, and legal entities eligible to receive funding from IHI JU.

2.2.1 Participation: any legal entity

Any legal entity, regardless of its place of establishment, including legal entities from non-associated third countries or international organisations, is eligible to participate (whether it is eligible for funding or not).

In order for a consortium to be considered eligible, it should include:

- at least one independent legal entity established in a Member State; and
- at least two other independent legal entities, each established in different Member States or associated countries.

For more information on the eligibility conditions, consult the [Horizon Europe Work Programme 2021-2022](#), and for up-to-date information on the current list of associated countries and low and middle income countries see the [list of participating countries in Horizon Europe](#). Participants must register in the [participant register](#) before submitting their application, to get a participant identification code (PIC) and be validated by the Central Validation Service (REA Validation) before signing the grant agreement. For the validation, they will be asked to upload the necessary documents showing their legal status and place of establishment during the grant preparation stage. A validated PIC is not a prerequisite for applying.

More information regarding the participant register is available here:

Participants register user's guide: <https://ec.europa.eu/research/participants/data/support/manual/urf.pdf>

Rules on legal entity validation, LEAR appointment and financial capacity assessment:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/rules-lev-lear-fca_en.pdf

2.3 Entities eligible for IHI JU funding

Eligibility for IHI JU funding mainly depends on the place of establishment and the legal status of a legal entity, but it also depends on the type of IHI call and some IHI specificities, which are addressed in this section.

2.3.1 General principles

Any independent legal entity is [eligible for EU funding](#) if established in one of the eligible countries⁷, i.e.:

- the **Member States** of the European Union, including their outermost regions and the Overseas Countries and Territories (OCTs);
- Horizon Europe **associated countries**;
- **low- and middle-income countries** identified in the Horizon Europe [Programme](#).

In practice, EU funding primarily supports the participation in projects of organisations like universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies (companies with a turnover below EUR 500 million).

⁷ See [List of participating countries in Horizon Europe](#) and Horizon Europe Work Programme 2021-2022 General Annexes https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-13-general-annexes_horizon-2021-2022_en.pdf

Depending on the type of call for proposals, larger companies may also be eligible to receive EU funding. Details of who can receive funding is detailed in the sections below.

Legal entities that are established in a **third country to Horizon Europe** are normally not eligible for receiving IHI funding and if they wish to be part of an applicant consortium, they should participate in IHI JU project at their own costs. Nevertheless, following a specific, reasoned request from the applicant consortium, IHI JU may decide (on the basis of the external evaluators' recommendation) to exceptionally grant them funding if it considers that their participation is essential for implementing the proposed project. Further information can be found [here](#).

2.3.2 Rules for funding per type of call

For single-stage calls, the general common principles described in section 2.3.1 above apply.

In two-stage calls, the general common principles described above apply, but the following entities are **not eligible for funding**:

- the pre-identified industry consortium (legal entities identified by IHI JU as participating in the specific topic);
- any legal entities which is:
 - a for-profit legal entity with an annual turnover of EUR 500 million or more;
 - a for-profit legal entity directly or indirectly controlling/or being controlled by for-profit legal entities with an annual turnover of EUR 500 million or more.

2.3.3 Types of legal entities

The consortium composition could consist of public (non-profit) and private (for-profit) legal entities.

An IHI project may involve:

- research/higher or secondary education organisations (private or public)
- small & medium enterprises (SMEs) and larger companies (for-profit legal entities)
- non-governmental organisations (NGOs)
- healthcare professional organisations / healthcare providers
- patient / citizen organisations
- regulatory bodies
- notified bodies
- health technology assessment bodies (HTAs)
- healthcare payers
- charities and foundations
- public authorities

Definitions of the types of stakeholders that could join consortia under the IHI programme can be found [here](#).

Public bodies and non-profit organisations

Public bodies and non-profit organisations are eligible for funding in both single-stage and two-stage calls as long as the general common principles specified in section 2.3.1 above are fulfilled.

For-profit organisations: SMEs, mid-size and large companies

There are 3 types of for-profit companies:

- Small and medium-sized enterprises (SMEs)
SMEs, including start-ups, are defined in the [EU recommendation 2003/361](#) and the 2020 SME user guide. The main factors determining whether an enterprise is an SME are:
 - staff headcount
 - either turnover or balance sheet total

Company size	Staff headcount	Turnover	or	Balance sheet total
Medium	< 250	≤ €50m		≤ €43m
Small	< 50	≤ €10m		≤ €10m
Micro	< 10	≤ €2m		≤ €2m

- Mid-size companies: Companies with an annual turnover of less than EUR 500 million, or companies that directly or indirectly controlling or being controlled by for-profit legal entities with an annual turnover of less than EUR 500 million.
- Large companies (for-profit legal entity): Companies with an annual turnover of EUR 500 million or more, or companies directly or indirectly controlling or being controlled by for-profit legal entities with an annual turnover of EUR 500 million or more.

In single-stage calls, all for-profit companies are eligible for funding if the general common principles specified in section 2.3.1 are fulfilled.

In two-stage calls, the same applies for SMEs and mid-sized companies but large companies are not eligible for funding.

2.3.4 Private members, contributing partners and proposal eligibility

This section refers to IHI-specific types of beneficiaries, defining their roles, their contribution types and their impact on the eligibility of a (full) proposal.

2.3.4.1 Private Members

The **private members** of IHI JU are the private industry associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe.

At the level of the consortia implementing IHI JU projects, the private members include both the above-mentioned industry associations, as well as the members of these associations ('constituent entities') and the entities affiliated to these members ('affiliated entities').

Private members, their constituents and affiliated entities can contribute three types of contribution to consortia implementing IHI JU projects:

- **in-kind contributions to operational activities (IKOP)** consist of the eligible costs for implementing the action;
- **in-kind contributions to additional activities (IKAA)** consist of costs for implementing additional activities;
- **financial contribution (FC)** consists of cash contributions to project beneficiary(ies) (or directly to IHI JU) to support the eligible costs incurred by the project beneficiary(ies) concerned in implementing the IHI action.

For detailed explanations of each of these types of contribution see section 3.2.1.3.1 *Composition of the budget table*.

In single-stage calls, private members are eligible for funding if the general common principles specified in section 2.3.1 are fulfilled.

In two-stage calls, the same rule applies, however, private members of the pre-identified industry consortium are not eligible for funding.

2.3.4.2 Contributing partners

Organisations that want to support specific areas of research without becoming full members of IHI can apply to become contributing partners of IHI JU.

The '**contributing partner**' category was created with the goal of opening up IHI JU to a wide range of health stakeholders who may want to invest in IHI JU without becoming full members. As the name suggests, contributing partners invest their own resources (which can be researchers' time, laboratories, data) or cash in a specific IHI project or projects. Their contributions work in a similar way to contributions by private members.

The contributing partner category builds on the associated partner status created under the Innovative Medicines Initiative 2 (IMI2) programme, the forerunner to IHI JU.

More information on how to become a contributing partner is available on the IHI JU website:

<https://www.ih.europa.eu/shape-our-future-research/become-contributing-partner>

Contributing partners can contribute IKOP and FC to a project, but not IKAA. IKAA can only be contributed by private members. In addition, contributing partners cannot contribute FC directly to IHI JU.

For detailed explanations of each of these types of contribution see section 3.2.1.3.1 *Composition of the budget table*. Pre-identified private members and contributing partners

In two-stage calls, the pre-identified private members and their constituent entities (pre-identified industry consortium) and the contributing partners are the main drivers of the topic definition and they identify their in-kind contributions through expertise and assets. The pre-identified private members and contributing partners are listed in the topic text (overall contribution and not per partner) and they are not eligible for funding.

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

2.3.4.3 Additional eligibility criterion for IHI JU (full) proposals on the proportion of industry / contributing partner contributions to the project

There is one IHI-specific eligibility criterion at the level of the consortium for the eligibility of the proposal in order to be evaluated.

Applicant consortia must ensure that at least 45 % of the action's eligible costs and costs for action-related additional activities are provided by contributions (IKOP, FC, ICAA) from private members, their constituent or affiliated entities, and by contributing partners (collectively the 'industry consortium participants').

While private members may contribute any of those contribution types, contributing partners may only contribute IKOP and FC, not ICAA.

The 45 % threshold can be reached by providing one, two or three of these contribution types.

While the minimum threshold for proposals to be considered eligible is set at 45%, consortia are encouraged to aim at having 50% of the action's eligible costs and costs for action-related additional activities provided by the industry consortium participants.

This eligibility condition must be fulfilled by single-stage proposals, and full proposals submitted at stage two of a two-stage call, in order for the proposal to be evaluated.

IHI JU office will perform an additional check before signing the grant agreement where will verify that the 45% rule has been fulfilled and the parties providing the contributions are private members and contributing partners that have been approved by IHI Governing Board.

If the 45 % contribution (IKOP + ICAA + FC) is not secured collectively by the industry consortium participants, the proposal will be declared ineligible and therefore will not be evaluated.

2.3.4.4 Table summarising eligibility rules for receiving IHI funding

IHI Funding Eligibility Rules (Summary)					
	Type of organisation	Single-stage call	Two-stage call		
Established in a Member State, a country associated to Horizon Europe, or a low- and middle-income country	Public bodies and non-profit organisations (academic institution, hospital, NGO, research organisation, regulator, patient organisation, intergovernmental organisation)		Eligible	Eligible	
	For-profit SME and larger enterprises	turnover of less than EUR 500 million (*)	Eligible	Eligible	
		turnover of EUR 500 million or more (**) (large company)	Eligible	<u>Not eligible</u>	
	Private member (COCIR, EFPIA (including Vaccines Europe) , EuropaBio and MedTech Europe).	Pre-identified in two-stage call text		N/A	<u>Not eligible</u>
		NOT Pre-identified	For-profit organisation with turnover of less than EUR 500 million (*)	Eligible	Eligible
			For-profit organisation with turnover of EUR 500 million or more (**) (large company)		<u>Not eligible</u>
	Contributing partners	Pre-identified in two-stage call text		N/A	<u>Not eligible</u>
		NOT Pre-identified	For-profit organisation with turnover of less than EUR 500 million (*)	Eligible	Eligible
			For-profit organisation with turnover of EUR 500 million or more (**) (large company)		<u>Not eligible</u>
	Associated Partners		<u>Not eligible</u>	<u>Not eligible</u>	
NOT established in a Member State, a country associated to Horizon Europe or a low- and middle-income country	Any legal entity	<u>Not eligible</u> (***)	<u>Not eligible</u> (***)		

(*) or directly or indirectly controlling/or being controlled by for-profit legal entities with an annual turnover of less than EUR 500 million.

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

(***) Entities that are not established in a Member State, a country Associated to Horizon Europe or in one of the low- and middle-income countries are in principle not eligible for funding. Nevertheless, following a specific request from the applicant consortium, IHI JU may decide (on the basis of a recommendation from the external evaluators) to exceptionally grant them funding if it considers that their participation is essential for implementing the proposed project.

2.4 Types of IHI participants

This section provides a summary of the types of participants that could join consortia under the IHI JU programme. More information can be found in the Horizon Europe General Model Grant Agreement (MGA v1.1 of 15 April 2022 or subsequent versions).

2.4.1 Beneficiaries

Beneficiaries are any legal entities signing the grant agreement.

They can be:

- Public bodies or non-profit organisations (academic institutions, hospitals, public bodies, NGOs, research organisations, regulators, patients organisations, intergovernmental organisations, etc.);
- for-profit organisation (SMEs and larger companies under certain conditions);
- private members;
- contributing partners.

The consortium must agree on which of the beneficiaries should become the coordinator. The coordinator is responsible for managing the project, submitting reports and deliverables, and acting as intermediary for all contacts with the EU granting authority.

The beneficiaries, as signatories of the grant agreement, are fully responsible towards the granting authority for implementing it and for complying with all its obligations.

They must implement the agreement to the best of their abilities, in good faith, and in accordance with all the obligations and terms and conditions it sets out.

The beneficiaries must implement the action as described in Part B of the proposal and in compliance with the provisions of the agreement, the call conditions and all legal obligations under applicable EU, international and national law (see article 11 of the grant agreement). They must have the appropriate resources to implement the action under their own responsibility. If they rely on affiliated entities (see Article 8) or other participants (see Article 9), they retain sole responsibility towards the granting authority and the other beneficiaries of the consortium.

Beneficiaries are jointly responsible for the technical implementation of the action. If one of the beneficiaries fails to implement their part of the action, the other beneficiaries must ensure that this part is implemented by someone else (without being entitled to an increase of the maximum grant amount and subject to an amendment; see Article 39). The financial responsibility of each beneficiary in case of recoveries is governed by Article 22 on the payments and recoveries and the calculation of amounts due. The beneficiaries (and their action) must remain eligible to participate in the IHI JU programme for the entire duration of the action. Costs and contributions will be eligible only as long as the beneficiary and the action are eligible.

2.4.2 Affiliated entities to beneficiaries

Affiliated entities (the new Horizon Europe terminology for the former 'linked third parties' under Horizon 2020) are entities with a legal link to the beneficiaries which implement parts of the action and are allowed to charge costs directly to the grant.

They do not sign or become party to the grant agreement, but they are part of the consortium and often play an important role. They are therefore de facto treated like beneficiaries (*i.e. they have their own financial statement, must provide their own certificate on financial statements (CFS), must contribute to the technical report, must submit deliverables, etc*). Annotations in the AGA which refer to beneficiaries usually also apply to affiliated entities (just like the provisions of the MGA themselves; *see also MGA Preamble*).

At the level of the consortium, affiliated entities to private members need to be mentioned separately, both in the budget and description of tasks

2.4.3 Associated partners

With Horizon Europe, a new type of participant has been introduced (new for 2021-2027), the so-called **associated partners**. Entities that do not request funding or are not eligible for funding may participate in an action as Associated Partners. They may implement action tasks but without receiving EU funding nor claiming contributions.

The associated partners do not sign or become party to the grant agreement but may implement important parts of the action. Therefore, the grant agreement mentions them and defines their role (rights and obligations).

Characteristics of implementation by associated partners:

- An associated partner participates at its own costs (does not receive EU funding).
- An associated partner performs action tasks directly.
- Associated partners do NOT sign the GA (and are therefore not beneficiaries).
- The consortium (or in case a link exists with a specific beneficiary, the beneficiary) remains responsible towards the granting authority for the action tasks performed by associated partners.

For more information, consult the MGA, Article 9.

Associated partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one) and do NOT need to comply with the eligibility conditions for funding (but they may be eligible, and just choose to participate without funding).

Associated partners must be listed in Article 9.1, and their tasks must be mentioned in the proposal Part B. Applicants may include the total estimated costs of their associated partners in the budget for their proposal (*i.e. under the headings 'Other sources of financing': 'Financial contributions' and 'Own resources'*) but this is for information purposes only. The information is not transferred to the grant as the associated partners are not required to report on their costs.

The consortium is responsible for the proper implementation of the tasks performed by associated partners (*proper quality, timely delivery, etc*).

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interests), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record keeping) also apply to the associated partners. The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA),

etc.) can exercise their rights also towards the associated partners. It is thus advisable to embed the above-mentioned obligations either in a side agreement between the beneficiaries and the associated partners or in the consortium agreement.

2.4.4 Third parties giving in-kind contributions to the action

Beneficiaries may use in-kind contributions provided by third parties (i.e. personnel, equipment, other goods, works and services, etc), if necessary to implement the action (see art. 9.2 HE GA).

Examples: *A civil servant working as a professor in a public university is also working on the action. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary may charge these costs to the grant, even if they are paid by a third party (the ministry/government).*

In-kind contributions refer to cases where a third party makes available some of its resources to a beneficiary, either for free (i.e. without any payment) or against payment. The beneficiary must declare the corresponding costs under the budget category it would use if they were its own costs (e.g. 'Personnel costs for seconded persons', 'Equipment costs', 'Costs for other goods, works and services', etc), as actual or unit cost, depending on the rules of the budget category). The costs for the in-kind contributions are eligible and may be charged by the beneficiaries which use them. The eligibility conditions for such costs are set out in Article 6 of the MGA.

Third parties giving in-kind contributions do not implement any action tasks. In-kind contributions and the third parties contributing should be mentioned in Part B of the proposal. The costs are included in the budget as part of the beneficiaries' eligible costs.

If in-kind contributions are charged to the grant, the beneficiaries must ensure that that the bodies mentioned in Article 25 (e.g. granting authority; the European Court of Auditors (ECA); the European Public Prosecutor's Office (EPPO), the European Anti-Fraud Office (OLAF)) have the right to carry out checks, reviews, audits, and investigations also on the third parties.

2.4.5 Subcontractors

Subcontractors may participate in the action, if necessary for the implementation.

Subcontractors must implement their action tasks in accordance with Article 11. The costs for the subcontracted tasks (invoiced price from the subcontractor) are eligible and may be charged by the beneficiaries, under the conditions set out in Article 6. The costs will be included in the budget as part of the beneficiaries' costs. The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (recordkeeping) also apply to the subcontractors.

The beneficiaries are responsible for the proper implementation of the subcontracted action tasks by the subcontractors (*proper quality, timely delivery, etc*). They must moreover ensure that they comply with certain obligations as described in the HE MGA.

Examples: Subcontractors participate in the action to develop and maintain the project website, to run specific testing and analysis of an assay, medical writers for communication material, if described in the proposal Part B (and Annex 1 of the Description of Action if the proposal is selected for funding) as an action task.

2.4.6 Table summarising types of participants

This table gives an overview of the different kinds of IHI JU grant participants and indicates cost eligibility (not exhaustive):

Type of Participants (Summary)					
TYPE	Works on 'action tasks'?	What is eligible for the beneficiary / affiliated entity?	Must be indicated in the Part B of the proposal?	Conditions for participation	GA article
Beneficiaries (including private members and contributing partners)	YES	Costs	YES	Must be eligible (if requesting funding)	Art. 7
Affiliated entities (including those of private members and contributing partners)	YES	Costs	YES	Must have a capital or legal link with a beneficiary and fulfill the same eligibility conditions	Art. 8
Associated partners	YES	/	YES	No specific conditions (APs do not receive funding)	Art. 9.1
Third parties contributing to the project	Participate in the action as contributors	Costs	YES	/	Art. 9.2
Subcontractors	YES	Invoiced price	NO (only subcontracted tasks must be indicated)	Must be best value for money or lowest price and no conflict of interest	Art. 9.3
Third parties receiving financial support	Participate in the action as recipients	Amount of support given	YES	According to the conditions in Annex 1 GA	Art. 9.4

SUMMARY

The **coordinator** is responsible for managing the project, submitting reports and deliverables and acting as intermediary for all contacts with the EU granting authority.

The **other beneficiaries** must implement their part of the project and contribute to the grant administration (*preparing the grant, reporting, etc.*).

The roles should be attributed according to the level of participation in the project. The main participants should participate as **beneficiaries** or **affiliated entities** (linked third parties in FP7, H2020, IMI1 JU and IMI2 JU

grants). Other entities can participate as associated partners, subcontractors, third parties giving in-kind contributions, etc.

Associated partners and **third parties giving in-kind contributions** normally do not get any part of the grant money and will therefore have to organise other funding sources (*bear their own costs, internal reallocation of funding inside the consortium, find investors, etc.*).

Subcontracting should normally constitute a limited part of the project and will need to be justified (give reasons). Tasks may NOT be subcontracted inside the consortium (between beneficiaries or affiliated entities).

The consortium participants are **jointly responsible** for implementing the project activities (in accordance with their proposal/description of the action). If a project is not finished (or badly implemented), the grant money may have to be reduced.

3 Preparation and submission of a proposal in a nutshell

Proposals must be created and submitted by a contact person of the coordinating organisation via the Electronic Submission System of the [Funding & Tenders Portal](#) (accessible via the topic page of the call), using the forms and templates provided there.

- The **timelines (deadlines for the proposals submissions)** are clearly indicated both on the IHI JU website and on the calls pages in the Funding and Tenders Portal in the format: date (day/month/year), time (hh:mm:ss Brussels time/CET).
- Each call is clearly indicated both on the IHI JU website and the calls pages in the Funding and Tenders Portal and the participants are invited to carefully check this information in order to assess which call/topic they are interested in
- Clear information on the type of call; whether **single-stage (full proposal – FP) or two-stages (short proposal – SP - for stage 1)** is also provided both on the IHI JU website and on the calls' pages in the Funding and Tenders Portal. Under a **two-stage submission scheme**, you must submit a short proposal for the stage 1 evaluation. All applicants requesting JU funding must be part of the short proposal. At the end of stage 1 evaluation, under each topic, only the applicant consortium of the first ranked short proposal will be invited to prepare and submit a full proposal for the stage 2 evaluation together with the 'pre-identified industry consortium' for the relevant topic.
- **Admissibility and eligibility criteria** are indicated for each call in the IHI JU Work Programme. There are some differences between the IHI JU Calls and the general/standard HE calls.
- The **evaluation thresholds** are listed in the respective IHI JU Work Programme, which is part of the calls' documents and available on both the IHI JU website and the calls pages in the Funding and Tenders Portal.
- **The evaluation criteria** for each call are presented in detail in the IHI JU Work Programme and applicants are invited to check each year the respective Work Programme. An evaluation form is also provided in the calls' documents in case applicants would like to self-check their proposal.
- **Templates for the proposals (Part B) including annexes** are provided in the calls' pages in the Funding and Tenders Portal (they can be downloaded from the portal once the coordinator has created a draft proposal). They contain clear indications/instructions on how to fill in the various sections. Applicants are advised to carefully read the instructions and follow them. To help applicants, model templates (pdf format for information only) are also provided both in the portal and the IHI JU website.
- **A proposal may consist of several documents/parts.** Applicants are invited to carefully check that when submitting the proposal (full proposal vs short proposal), all documents/parts/information required are

correctly included. Failure to submit all the documents/parts/ information may render the proposal inadmissible/ineligible.

- Proposals must be **complete** and contain all the requested information and all required annexes and supporting documents (see reference documents section for the proposal templates and annexes).
- The **funding rates in IHI JU** grants: For all beneficiaries and all activities, the funding rate is 100 % of the eligible costs, while for indirect costs a flat rate of 25% applies.

Indicative timetable for evaluation and grant agreement:

	Information on the outcome of the evaluation (single stage, or first stage of a two-stages)	Information on the outcome of the evaluation (second stage of a two- stages)	Indicative date for the signing of grant agreement
Single-stage	Maximum 5 months from the submission deadline at the first stage.	NA	Maximum 8 months from the submission deadline
Two-stage *	Maximum 5 months from the submission deadline at the first stage.	Maximum 5 months from the submission deadline at the second stage.	Maximum 8 months from the submission deadline at the second stage.

*For two-stage calls, the applicants will be informed of the results of the first stage (SP results) at the latest 6 weeks before the deadline for the second stage submission (FP submission).

Important information

Check regularly the Funding & Tenders Portal call page for updated information on the call.

Make sure all participants are registered in the Participant Register and have their 9-digit participant identification code (PIC).

You can submit your proposal several times before the deadline, to make updates or changes. As long as the call has not been closed, the newly submitted version will overwrite the previous one. Once the deadline has passed, no further additions or resubmissions are accepted, unless we ask you to clarify any obvious clerical errors on your part.

Submit your proposal as early as possible and at least 48 hours before the deadline in order to avoid any last-minute technical issue. There is no reason to delay the submission for confidentiality concerns as the system does not allow any access to the proposals before the call deadline.

In case of technical problems with the Submission System, please contact [IT Helpdesk](#) via their online contact form or call them on +32 229 92222 if you need immediate assistance.

For questions related to the call/topic you are applying for, please contact the IHI office at applicants@ihi.europa.eu


3.1 How to find partners for your application

As early as practicable, the IHI JU office publishes on the IHI website draft information on future call topics, ahead of the official call launch and its publication on the Funding and Tenders portal. This is to give potential applicants additional time to see if a topic could be relevant to them, assess how their involvement would be valuable, and start to find or build a consortium.

It is important that potential applicants building a consortium analyse the information in the call text, in particular the scope, and determine what and how their organisation, and other organisations that they intend to include in the applicant consortium, could contribute to the project in terms of skills, expertise, resources, and experience to fulfil the requirements as in the topic text.

The most effective way of getting into or building a consortium is to use your existing professional and personal contacts. There are also other ways to search for partners:

- Use the [Partner Search function](#) of the Participant & Tenders Portal. This function allows you to look for experienced partners who already have ongoing projects, or to browse in the database of registered organisations. You can search by keyword/geographical area/funding type, etc. Search results include complete organisation profiles with lists of funded projects and the option to contact representatives of the organisation. If you have selected your area of interest via the topic search, you may publish your interest in one or more of the open/forthcoming topics of a call on the Portal. All your published interests will be visible on your organisation's page too.
- Participate in the webinars for applicants and brokerage events organised by IHI JU. These are advertised on the IHI website and are also a good opportunity to network and identify potential partners.
- Participate in conferences, brokerage events, info days organised by the EU or networks in the Member States (National Contact Points or Desks, Enterprise Europe Network, as well as their own network).
- Use social media to advertise your interest in a call topic.

 IHI JU cannot help individual organisations to find partners – our calls for proposals are competitive and providing personal assistance to some organisations would undermine the principle of equal treatment and fairness.

3.2 Proposal submission

Developing a proposal for an IHI call topic takes time. It is important that applicants allocate appropriate time prior to the deadline for proposal writing and development.

Setting up a proposal (principal) steps:

- the initiation and framing of the scientific outline;
- formulation of a consortium with the expertise required;
- writing the proposal, ensuring it addresses the evaluation criteria: excellence – impact – quality and efficiency of the implementation;
- consolidating the administrative sections of the proposal such as IHI specific annexes, ethical issues and partners info;
- submitting the **complete** proposal.

Proposals are submitted using the application forms available in the Submission System.

Proposals must be **complete** and contain all the requested information and all required annexes and supporting documents.

The coordinator is the key actor in the (administrative) preparation of an IHI proposal. All participants can contribute to the parts, but it is the person from the coordinating organisation who created the application who finalises and submits the application and eventually signs the grant agreement if the proposal is selected for funding. The coordinator should have the mandate of all participants to submit the application (explicit agreement to participate).

When submitting the proposal, the coordinator will have to confirm that they have the mandate to act for all applicants. Moreover, they will have to confirm that the information in the application is correct and complete and that all participants comply with the conditions for receiving EU funding (especially eligibility, financial and operational capacity, exclusion, etc.). Before signing the grant, each participant will have to confirm this again by signing a declaration of honour. Proposals not complying with these requirements will be rejected. We advise you to read the Proposal Submission Service User Manual (available on the Funding & Tenders Portal) while preparing your proposal.

The electronic submission system is an online wizard that guides you step-by-step through the preparation of your proposal. The submission process consists of 6 steps:

Step 1: Logging in to the portal.

Step 2: Select the call, topic and type of action in the portal

Step 3: Create a draft proposal: Title, acronym, summary, main organisation and contact details.

Step 4: Manage your parties and contact details: Add your partner organisations and contact details.

Step 5: Edit and complete the web forms for proposal part A and upload proposal part B.

Step 6: Submit the proposal.

3.2.1 Instructions for completing Part A

The submission form is accessed via the call submission link in the Funding & Tenders Portal. The electronic form has 5 sections:

- General information
- Participants
- Budget
- Ethics and Security
- Other questions

These need to be completed before a submission can take place. Many fields are mandatory and are marked in red if left empty; failure to fill in any mandatory field will block submission.

A list of all participants in the proposal must be created by the coordinator. Please make sure that all participants are previously registered in the participant register and have their 9-digit participant identification code (PIC).

For technical details on how to fill in Part A, we advise you to read the [Proposal Submission Service User Manual](#) (available on the Funding & Tenders Portal) while preparing your proposal.

3.2.1.1 General Information

This section contains information about the proposal acronym, title, duration, keywords and abstract. The abstract should provide a clear understanding of the objectives of the proposal and how they will be achieved. Please note that if your proposal is funded, the abstract will be published. It must therefore be short and precise and should not contain confidential information. This section also contains general declarations related to the proposal and participation in Horizon Europe, which must be filled in by the proposal coordinator.

3.2.1.2 Participants

This section contains the administrative information of all organisations participating in the proposal. In addition, for each participating organisation, you must provide the following information:

- List of researchers involved in the proposal, i.e. those engaged in the conception or creation of new knowledge, improvement or development of concepts, theories, models, techniques, instrumentation, software or operational methods. People involved in the project in non-research roles do not need to be included.
- Role of participating organisation in the project (multiple choice is allowed).
- List of up to 5 publications, widely used datasets, software, goods, services, or any other achievements relevant to the call content.
- List of up to 5 relevant previous projects or activities, connected to the subject of this proposal.
- Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.
- Whether the organisation has a gender equality plan. Please note that if the proposal is selected, public bodies, higher education establishments and research organisations (from Member States and associated countries) will need to have a gender equality plan before grant agreement signature.

Complete accurately the researchers table (Proposal Part A) and ensure a gender balance.

This might impact the proposal ranking in case of equal scores.

3.2.1.3 Estimated budget

This section explains in detail the different elements composing the budget table of a (full) project proposal. It also highlights the different thresholds to pay attention to when planning an estimated budget and provides concrete examples of budget tables for different consortium compositions and types of call.

The budget table will be made available to the independent experts evaluating the (full) proposal.

The budget table and the description of resources in Part B should be aligned.

With the exception of obvious clerical errors, in case of inconsistencies between the budget table and the description of resources in Part B, the figures entered in the budget table will prevail.

3.2.1.3.1 Composition of the budget table

The budget table needs to be filled in for proposals to single-stage calls and for full proposals to the second stage of two-stage calls.

The budget table is composed of the elements below.

3 - Budget																						
No.	Name of beneficiary	Country	Role	Personnel costs/€	Subcontracting costs/€	Purchase costs - Travel and subsistence/€	Purchase costs - Equipment/€	Purchase costs - Other goods, works and services/€	Internally invoiced goods and services/€ (Unit costs-usual accounting practices)	Indirect costs/€	Total eligible costs	Funding rate	Maximum EU contribution to eligible costs	Requested EU contribution to eligible costs/€	Max grant amount	Income generated by the action	Financial contributions	Other sources of funding - IKOP	Other sources of funding - Non-EU part of IKOP	Own resources	Total estimated income	IKAA

There is no budget table for short proposals in the first stage of two-stage calls. There, only the total requested EU contribution for the proposal should be specified.

3 - Budget	
Total requested EU contribution for the proposal	0

All elements of the budget table are explained below.

Personnel costs (A)

The following types of personnel costs are allowed:

- Actual or unit costs for employees or equivalent (salaries and social security contributions, taxes and other costs linked to the remuneration, if they arise from national law or the employment contract or equivalent appointing act).
- Actual costs for natural persons under direct contract other than an employment contract.
- Actual costs for seconded persons by a third party against payment. (Example: a project team member who is employed by a third party outside the project. The third party is reimbursed by the participant, and the participant charges these costs to the project.)
- Unit costs for the work of SME owners for the action (i.e. owners of beneficiaries that are small and medium-sized enterprises not receiving a salary) or natural person beneficiaries (i.e. beneficiaries that are natural persons not receiving a salary).

Subcontracting costs (B)

This budget category covers costs for subcontracted action tasks, i.e. service contracts for parts of the project that are not implemented by the beneficiary itself, but by a subcontractor.

A subcontracting cost is eligible if it corresponds to the amount invoiced by the subcontractor, fulfils the general eligibility conditions and if the subcontractor is selected following the beneficiary's usual purchasing

practices — provided these ensure subcontracts with best value for money (or if appropriate the lowest price) and that there is no conflict of interests.

Only limited parts of the action may be subcontracted. Limited parts means that subcontracting remains proportionate both in terms of share of subcontracted action tasks as well as in terms of share in the eligible cost.

Subcontracting between participants and with affiliated entities is not allowed.

The tasks to be subcontracted and the estimated cost for each subcontract must be set out in the proposal Part B, and the total estimated costs of subcontracting per beneficiary must be set out in the budget.

Subcontracts are normally wide in scope (implementation of a part of the project, i.e. action tasks). If a contract covers only individual equipment or consumables, this will be considered as a purchase (see Article 6.2.C.2 and C.3).

Purchase costs (C)

Purchase costs are eligible if they fulfil the general eligibility conditions and are bought using the beneficiary's usual purchasing practices — provided these ensure purchases with best value for money (or if appropriate the lowest price) and that there is no conflict of interests.

The following types of purchase costs are allowed:

- C.1. Travel, accommodation and subsistence (Article 6.2.C.1);
- C.2 Equipment, infrastructure or other assets (Article 6.2.C.2);
- C.3 Other goods, works and services, if necessary to implement the action (see Article 6.2.C.3).

Purchase contracts are normally limited in scope. If a contract covers the implementation of action tasks, this will be considered as a case of subcontracting.

Internally invoiced goods and services (D)

'Internally invoiced goods and services' means goods or services which are provided within the beneficiary's organisation directly for the action and which the beneficiary values on the basis of its usual cost accounting practices. Costs of internally invoiced goods and services must be declared as unit costs in accordance with usual cost accounting practices.

Indirect costs (E)

The financing of indirect costs is calculated automatically by the system as a flat rate of 25 % of the total eligible costs (categories A-D, except subcontracting costs and cost for internally invoiced goods and services, if any).

Total eligible costs (H)

Total of all project eligible costs (sum of categories A-E). Calculated automatically.

Costs are eligible if they fulfil the eligibility criteria (Article 6.1 and 6.2 of the MGA).

Details of eligible costs can be found in the call conditions, the Model Grant Agreement and the related guidance (in particular, the [EU Grants AGA Annotated Grant Agreement](#)).

Funding rate (U)

The funding rate is automatically set to 100 % for all consortium applicants.

As a result, participants that are not eligible for receiving funding still have a 100 % funding rate (e.g. large companies in two-stage calls).

Maximum EU contribution to eligible costs (L = U x H)

The maximum EU contribution is automatically calculated by multiplying the total costs of the legal entity with its funding rate.

The maximum EU contribution is a positive amount for all consortium applicants (even the ones that are not eligible for funding) as the funding rate is automatically set to 100 %.

Requested EU contribution to eligible costs

The amount that a legal entity requests as EU contribution (i.e. IHI funding) to reimburse a part or all of its project eligible costs. This amount can be equal to or lower than the maximum EU contribution (L).

The 'requested EU contribution' has to be filled in manually and therefore it needs to be updated if changes are made in any of the cost categories (A-E). The requested EU contribution cannot be higher than the maximum EU contribution.

If a participant is not eligible for funding, it should ensure that no EU contribution is requested even though the tool allows it (as the funding rate is set to 100 % for all participants).

Eligibility criteria for receiving IHI funding are detailed in section 2.3.

Eligibility for receiving IHI funding depends on the place of establishment of the participant, on the type of call and on the legal entity status (e.g. SME, non-profit, etc.) encoded in the participant register.

It is therefore crucial that each participant provides its legal and financial information in the participant register before the grant signature.

Max grant amount

This amount is automatically calculated by the tool and corresponds to the sum of budgeted eligible costs.

Income generated by the action

The expected income generated by the action (revenues), during its duration.

Financial contributions (FC)

The financial contributions the legal entity expects to receive, other than the EU funding. It includes FC received by private members, their constituent entities or affiliated entities and/or by contributing partners.

Eligible costs covered by the FC received should be included in the total eligible costs of the beneficiary that is receiving the FC.

Beneficiaries that are the recipients of a FC must also ensure that the part of costs covered by FC are manually deducted from the EU requested contribution.

The proposal Part B of the (full) project proposal contains a table (table 3.1k) in which applicants must specify: the company name of the private member/contributing partner paying the FC; the FC amount; the name of the beneficiary receiving the FC; and the project activities the beneficiary will carry out with the received FC.

This category can also include financial contribution(s) that an associated partner expects to receive for the implementation of the project.

Other sources of funding – in-kind contributions to operational activities (IKOP)

IKOP consists of eligible costs incurred by IHI private members, their constituent or affiliated entities and by contributing partners for implementing the action, less the requested EU contribution to those eligible costs.

IKOP = total eligible costs – reimbursed costs

IKOP provided by private members/contributing partners are subject to the same HE rights and obligations (eligibility criteria rules, reporting rules, etc) as any other beneficiary signing the grant agreement.

In single-stage calls, private members and contributing partners are entitled to receive funding if they are established in a Member State, a country associated to Horizon Europe or low- and middle-income countries. If they decide to request the reimbursement of some project eligible costs (i.e. request EU funding), their IKOP shall equal their project eligible costs minus their reimbursed costs. This needs to be calculated manually (i.e. is not automatically calculated by the tool in the budget table).

In two-stage calls, private members and contributing partners may be eligible for funding or not (see section 2.3 on eligibility criteria). In any case, if private members/contributing partners are pre-identified in the call text of a two-stage call, they are not eligible to receive EU funding. As a result, IKOP always equals project eligible costs for these beneficiaries.

In the budget table, the column 'IKOP' can only be filled in by private members, contributing partners, or their affiliated entities. This category should always be zero for all other types of beneficiaries and for associated partners.

The column 'IKOP' should include all IKOP, i.e. both EU and non-EU IKOP. Those concepts are explained in the section below.

Non-EU IKOP

In-kind contributions to operational activities can be provided from within the European Union or outside the European Union.

'Non-EU IKOP' refers to eligible costs for project activities carried out in third countries **outside of** the 27 EU Member States and

Associated countries to Horizon Europe⁸.

The non-EU criteria takes into account where the underlying activities are carried out, not where the company incurring the related costs is established.

⁸ See the '[List of Participating Countries in Horizon Europe](https://ec.europa.eu/info/news/updates-association-third-countries-horizon-europe_en)' For up-to-date information on the current list of Associated countries see here: https://ec.europa.eu/info/news/updates-association-third-countries-horizon-europe_en .

Examples

Costs incurred by a US-based private member or contributing partner carrying out activities for the project in Germany are considered EU IKOP.

Costs incurred by a German-based private member or contributing partner carrying out activities for the project in the US are considered non-EU IKOP.

Only IKOP can be non-EU. Financial contributions are always considered as EU and IKAA must be EU.

Non-EU contributions cannot exceed 20 % of the overall IKOP at programme level.

The IHI JU may establish in the call conditions a different maximum percentage of non-EU in kind contributions applicable to individual projects (e.g. for Calls 1 and 2, launched in 2022, the limit of non-EU IKOP for projects has been set to 100 %).

In the budget table, the column 'Non-EU IKOP' is included in the column 'total IKOP'.

The proposal Part B of the (full) project proposal contains a table (Table 3.1I) in which the consortium needs to specify the company name of the private member/contributing partner contributing non-EU IKOP, the amount of non-EU IKOP, and the project activities to be carried out outside the EU and HE associated countries.

Own resources

The amount of expected own resources the legal entity plans to use for the implementation of the action. A legal entity uses its own resources when its total project eligible costs are not entirely covered by IHI funding and/or by other sources of financing.

This category should always be zero for private members, their constituent entities or affiliated entities and for contributing partners.

Total estimated income

Calculated automatically as the sum of the requested grant amount, income generated by the project, financial contributions, IKOP and own resources. The amount should match the total estimated project costs when there is no associated partner in the applicant consortium.

In-kind contributions to additional activities (IKAA)

Contributions incurred by IHI JU private members, their constituent or affiliated entities, consisting of costs for implementing additional activities.

Only IHI JU private members can contribute IKAA. Contributing partners can only contribute IKOP and FC, not IKAA.

IKAA can be programme-specific or project-specific. For the preparation of a (full) proposal, only project-specific IKAA is relevant.

Project-specific IKAA consists of additional activities contributing towards

- the achievement of the objectives of IHI JU funded projects, or
- the dissemination, sustainability, or exploitation of IHI JU project results.

Additional activities are not project tasks (i.e. not IKOP). It is up to the applicant consortium to decide what is IKOP and what is IKAA for their respective proposal. Activities identified as IKAA in one IHI proposal cannot be identified as IKAA or as IKOP in another IHI proposal.

Additional activities must contribute to IHI JU's objectives and/or tasks (as defined in Article 115 and 116 of the Regulation)⁹ but must not be funded by the IHI JU or any other EU funding programme.

Additional activities must be carried out in the EU or in Horizon Europe associated countries.

The IKAA of a project should normally not exceed 40 % of the sum of IKOP and IKAA provided by IHI private members to the project. If IHI private members want to contribute more IKAA than 40 %, they should inform their relevant industry office accordingly so that it can be closely monitored.

The IKAA planned for a specific (full) project proposal in a single-stage call or in the second stage of a two-stage call should be detailed in the [annex on in-kind contributions to additional activities \('IKAA'\)](#), following the step-by-step [instructions to fill-in this annex](#).

Detailed information on IKAA can also be found in the '[IHI JU Guidelines for in-kind contributions to additional activities \(IKAA\)](#)' 3.3.3.2 Thresholds in the budget table

While preparing the budget table, the consortium has to ensure the following thresholds are respected.

Industry contribution threshold of minimum 45 %

In order for their (full) project proposal to be eligible, applicant consortia should ensure that at least 45 % of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members, their constituent or affiliated entities, and/or from contributing partners.

(IKOP + FC + IKAA) ≥ 45% of (action's eligible costs + action-related IKAA)

While private members can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA.

The 45 % threshold can be reached by providing any of these types of contribution (e.g. only with IKOP).

This threshold is an eligibility criterion. If it is not reached collectively by private members and/or contributing partners of a (full) proposal, the proposal will NOT be evaluated.

- The coordinator of a (full) proposal must submit a Declaration to confirm that the required 45% contributions will be provided (see section 3.2.2.2 Annex: Declaration of in-kind contribution commitment)

IKAA threshold of maximum 40 %

The total IKAA provided by private members, their constituent entities and affiliated entities should not exceed 40 % of private members' total in-kind contribution (IKAA + IKOP) at overall IHI JU programme level. The overall limitation of 40 % of IKAA at IHI JU programme level includes both programme-specific IKAA and project-specific IKAA.

For proposals, the same limitation of 40 % is recommended but it is not compulsory. In case IKAA exceeds the 40 % threshold for a proposal, the private member(s) should inform the relevant industry association office so the overall IKAA threshold at programme level – which cannot exceed 40 % – can be properly followed-up and monitored by the industry.

⁹ IHI JU's general and specific objectives are also listed on IHI website: <https://www.ih.europa.eu/about-ih/mission-and-objectives>;

Non-EU IKOP threshold of maximum 20%

Non-EU IKOP cannot exceed 20 % of the overall IKOP at programme level.

IHI JU may establish in the call conditions a different maximum percentage of non-EU in kind contributions applicable to individual projects (e.g. for calls 1 and 2, launched in 2022, the limit of non-EU IKOP for projects has been set to 100 %).

However, it is recommended that non-EU IKOP provided by private members and contributing partners not exceed 20% of their total contribution (IKOP + IKA + FC) to the concerned proposals.

If non-EU IKOP exceeds the 20 % threshold for a proposal, the private member(s) and contributing partner(s) should inform the relevant industry association office so that the overall non-EU IKOP threshold at programme level – which cannot exceed 20 % – can be properly followed-up and monitored.

3.2.1.3.2 Budget table examples

The following examples are tailored to IHI and give applicants detailed information on how to build their estimated budget.

For the purpose of these examples:

- Only the most relevant columns from the budget table are considered.
- It is considered that the applicant consortium includes legal entities based in at least 3 different Member States, fulfilling therefore the eligibility conditions for participation (see section 2.2 on entities eligible to participate).
- It is considered that all legal entities are established in a Member State, associated country or low- and middle-income country, fulfilling therefore the general eligibility condition for receiving funding (see section 2.3 on entities eligible for funding).

A. Proposal for single-stage call

In a single-stage Call, any legal entity established in a Member State, associated country or low- and middle-income country is eligible to receive funding.

No.	Participant name	Total eligible costs (H)	Requested EU contribution to eligible costs (M)	Financial contributions (FC)	IKOP (S)=(H)-(M)	Including Non-EU IKOP (T)	Own resources (R)	Total estimated income (M+FC+S+R)	IKAA (P)
1	Private member	6 000 000	2 500 000	0	3 500 000	1 000 000	0	6 000 000	2 050 000
2	Private member	2 000 000	0	0	2 000 000	0	0	2 000 000	0
3	Private member	1 500 000	750 000	0	750 000	200 000	0	1 500 000	2 450 000
3.1	Affiliated entity	500 000	200 000	0	300 000	100 000	0	500 000	50 000
4	Contributing partner	1 000 000	500 000	0	500 000	0	0	1 000 000	0
5	Non-profit organisation	9 250 000	7 000 000	2 100 000	0	0	150 000	9 250 000	0
6	For-profit SME	1 150 000	1 150 000	0	0	0	0	1 150 000	0
6.1	Affiliated entity	250 000	250 000	0	0	0	0	250 000	0
7	For-profit large company	1 100 000	800 000	0	0	0	300 000	1 100 000	0
	TOTAL	22 750 000	13 150 000	2 100 000	7 050 000	1 300 000	450 000	22 750 000	4 550 000

Key data

Total eligible costs (H) + total IKAA (P)	= EUR 27 300 000
Minimum 45 % industry contribution to be reached for the proposal to be eligible	= EUR 12 285 000 (45 % x 27 300 000)
Total industry contribution IKOP (S) + FC + IKAA (P)	= EUR 13 700 000 (EUR 7 050 000 + EUR 2 100 000 + EUR 4 550 000)
Percentage of industry contribution	= 50.18 % (13 700 000 / 27 300 000)

The budget table is correctly balanced.

Total eligible costs (H) of EUR 22 750 000 equals total estimated income, which is made of total requested EU contribution (M) + total own resources (R) + total IKOP (S) + total FC received (FC).

The budget table fulfils the necessary thresholds.

Minimum 45 % industry contribution: Total Industry contribution of EUR 13 700 000 (IKOP+IKAA+FC) is **≥45** % of (total eligible costs (H) + total IKAA (P)). In the above example, it is 50.18 %.

Note: This example illustrates all types of contributions (IKOP, IKAA, FC), but it is not obligatory for a proposal to have all types of contribution as long as the 45 % is secured.

Maximum 40 % IKAA: $IKAA (P) \leq 40 \% \text{ of } (IKOP (S) + IKAA (P))$. In the above example, it is 39.22 %.

Maximum 20 % non-EU: $Non-EU IKOP (T) \leq 20 \% \text{ of } IKOP (S)$. In the above example, it is 18.44 %.

Explanations per participant

Depending on your participant type, you can go directly to the explanation relating to your participant number.

Participants 1, 2 and 3: IHI private members

- Private members are eligible for funding as we consider in this example that they are all established in a Member State, associated country or low- and middle-income country. However, only Participants 1 and 3 are requesting IHI funding. Participant 2 may not be interested in receiving EU funding because it needs to maximise its IKOP for the purpose of reaching the 45% threshold.
- Private members can provide all types of industry contribution: IKOP, FC and IKAA. They can provide either one, two or three of these contribution types (e.g. a private member can contribute only IKAA).
- Private members' total contribution to the project is $IKOP + FC + IKAA$.
- $IKOP (S)$ are eligible costs incurred to implement the project (H), minus the funding requested to IHI to partially reimburse these eligible costs (M).
- Eligible costs included in $IKOP$ can be incurred in the EU or HE associated countries (= EU $IKOP$) or outside the EU or HE associated countries (= non-EU $IKOP$). Non-EU $IKOP (T)$ is the part of eligible costs included in the total $IKOP (S)$ that is planned to be incurred outside the EU or HE associated countries.
- Private members can pay FC to other beneficiaries eligible for funding from the same consortium. Financial contributions (FC) are declared by the beneficiary(ies) receiving the FC, not by the company that is paying it.
- Only eligible costs incurred by private members can be reimbursed by IHI, if requested. Costs for additional activities cannot be reimbursed by IHI.
- The column (R) for own contributions is not applicable for private members (i.e. it must be zero).
- $IKAA (P)$ are costs for additional activities (i.e. not $IKOP$). This category is only applicable for private members, their constituent entities or affiliated entities.

Participant 3.1: Affiliated entity of private member 3

- The affiliated entity 3.1 is legally linked to the private member 3.
- The information specified above for Participants 1, 2 and 3 is also applicable for the affiliated entity 3.1.

Participant 4: IHI contributing partner

- Contributing partners are eligible for funding as we consider in this example that they are all established in a Member State, associated country or low- and middle-income country.
- Contributing partners can provide $IKOP$ and FC (either one or the other or both), but not $IKAA$.
- Contributing partners' total contribution to the project is $IKOP + FC$.
- $IKOP (S)$ are eligible costs incurred to implement the project (H), minus the funding requested to IHI to partially reimburse these eligible costs (M).

- Eligible costs included in IKOP can be incurred in the EU or HE associated countries (= EU IKOP) or outside the EU or HE associated countries (= non-EU IKOP). Non-EU IKOP (T) is the part of eligible costs included in the total IKOP (S) that is planned to be incurred outside the EU or HE associated countries.
- Contributing partner can pay FC to other beneficiaries eligible for funding from the same consortium. Financial contributions (FC) are declared by the beneficiary(ies) receiving the FC, not by the contributing partner that is paying it.
- The column (R) for own contributions and (P) for IKAA are not applicable for contributing partners (i.e. they must be zero).

Participants 5, 6, 6.1 and 7: non-profit organisation, for-profit SME and its affiliated entity, as well as for-profit large company

- In single-stage calls, any legal entity is eligible for funding if established in a Member State, associated country or low- and middle-income country. We consider this to be the case for Participants 5, 6 and 7 in this example.
- Total eligible costs to implement the action (H) are either reimbursed by IHI funding (M) and/or by financial contribution (FC) paid by private member(s)/contributing partner(s) and/or by the beneficiary itself with its own resources (R). In this example, participant 5 receives a financial contribution of EUR 2 100 000.
- For each FC, it should be specified in the proposal Part B (table 3.1k): the company name of the private member/contributing partner paying the FC, the FC amount, the name of the beneficiary receiving the FC and the project activities to be carried out by the beneficiary with the received FC.
- Participant 5 cannot request IHI funding for costs already covered by the financial contribution. As a result, the amount of 2 100 000 must be deducted from the EU contribution (M) requested by Participant 5. Additionally, the FC is to cover some of its eligible costs to implement the project. As a result, the amount of EUR 2 100 000 must be specified in its total eligible costs (H).
- Eligible costs that are not reimbursed (either by IHI or by financial contribution received from private members/contributing partners or by both) are costs to be covered by the participant's own resources. In this example, while Participants 5 and 7 are eligible to get reimbursed 100 % of their eligible cost, they make the choice not to request the maximum EU contribution allowed and plan to bring instead some of their own resources to the project (EUR 150 000 for Participant 5 and EUR 300 000 for Participant 7).
- The columns IKOP (S), Non-EU IKOP (T) and IKAA (P) are not applicable for beneficiaries that are not private members/contributing partners. As a result, their values must be zero for Participants 5, 6, 6.1 and 7.

B. Short proposal for stage 1 of two-stage call

In a two-stage call, private members and contributing partners are pre-identified in the call text and their guaranteed contribution in term of IKOP, FC and IKAA representing at least 45 % of the project proposal's total eligible costs and costs for project-specific additional activities determines the maximum amount of EU funding available for the project proposal.

In the first stage of a two-stage call, the pre-identified private members and their constituent entities (the 'pre-identified industry consortium') and the contributing partners are not involved and are not eligible for funding. The other applicant organisations requesting funding should prepare and submit a short proposal, considering the call text and the maximum amount available of EU funding.

In the short proposal, there is no estimated budget table, just a total amount to be specified as the requested EU contribution for the concerned proposal.

In a two-stage call, legal entities have to be established in a Member State, associated country or low- and middle-income country in order to be eligible for funding. Moreover, the following entities are not eligible for funding:

- Pre-identified private members and contributing partners (legal entities identified in the call text by the IHI JU as participating in the specific topic);
- Any for-profit company:
 - with an annual turnover of EUR 500 million or more;
 - directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.

C. Full proposal for stage 2 of two-stage call

Once a short project proposal has been selected, the pre-identified private members and contributing partners join the rest of the applicant consortium in the second stage of the two-stage call to prepare the full project proposal.

No.	Participant name	Total eligible costs (H)	Requested EU contribution to eligible costs (M)	Financial contributions (FC)	IKOP (S)=(H)-(M)	Including Non-EU IKOP (T)	Own resources (R)	Total estimated income (M+FC+S+R)	IKAA (P)
1	Public body	7 250 000	6 000 000	1 250 000	0	0	0	7 250 000	0
2	Non-profit organisation	1 500 000	1 500 000	0	0	0	0	1 500 000	0
2.1	Affiliated entity	3 500 000	3 500 000	0	0	0	0	3 500 000	0
3	For-profit SME	5 150 000	4 300 000	0	0	0	850 000	5 150 000	0
4	For-profit large company	1 500 000	0	0	0	0	1 500 000	1 500 000	0
4.1	Affiliated entity	2 000 000	0	0	0	0	2 000 000	2 000 000	0
5	Associated Partner	0	0	70 000	0	0	100 000	170 000	0
6	Private member (Pre-identified)	5 300 000	0	0	5 300 000	1 000 000	0	5 300 000	2 500 000
7	Private member (Pre-identified)	3 700 000	0	0	3 700 000	200 000	0	3 700 000	2 000 000
8	Contributing Partner (Pre-identified)	2 600 000	0	0	2 600 000	0	0	2 600 000	0
	TOTAL	32 500 000	15 300 000	1 320 000	11 600 000	1 200 000	4 450 000	32 670 000	4 500 000

Key data

Total eligible costs (H) + total IKAA (P)	= EUR 37 000 000
Minimum 45 % industry contribution to be reached for the proposal to be eligible	= EUR 16 650 000 (45 % x EUR 37 000 000)
Total industry contribution IKOP (S) + FC + IKAA (P)	= EUR 17 350 000 (EUR 11 600 000 + EUR 1 250 000 + EUR 4 500 000)
Percentage of industry contribution	= 46.89 % (17 350 000 / 37 000 000)

The budget table is correctly balanced.

Total eligible costs (H) of EUR 32 500 000 equal total estimated income minus the estimated income from the associated partner, participant 5 (EUR 32 670 000 – EUR 170 000).

The budget table fulfils the necessary thresholds.

Minimum 45 % industry contribution: Total industry contribution (IKOP+IKAA+FC) is **≥45 %** of EUR 37 000 000 (total eligible costs (H) + total IKAA (P)). In the above example, it is 46.89 %.

Note: This example illustrates all types of contributions (IKOP, IKAA, FC), but it is not obligatory for a proposal to have all types of contribution as long as the 45 % is secured.

Maximum 40 % IKAA: IKAA (P) of EUR 4 500 000 is ≤ 40 % of EUR 16 100 000 (IKOP (S) +IKAA (P)). In the above example, it is 27.95 %.

Maximum 20 % non-EU: Non-EU IKOP (T) is ≤ 20 % of IKOP (S). In the above example, it is 10.34 %.

Explanations per participant:

Depending on your participant type, you can go directly to the explanation relating to your organisation.

Participants 1, 2, 2.2 and 3: Public bodies, non-profit organisations and their affiliated entities, as well as for-profit SMEs

- In two-stage calls, these legal entities are eligible for funding if established in a Member State, associated country or low- and middle-income country. We consider this to be the case in this example.
- The eligible costs of those beneficiaries to implement the action (H) are either reimbursed by EU funding (M) and/or by financial contribution paid (FC) by private member(s)/contributing partner(s) and/or by their own resources (i.e. at their own costs). In this example, private member(s)/contributing partner(s) are paying a financial contribution (FC) of EUR 1 250 000 to Participant 1.
- For each FC, it should be specified in the proposal Part B (table 3.1k): the company name of the private member/contributing partner paying the FC, the FC amount, the name of the beneficiary receiving the FC and the project activities to be carried out by the beneficiary with the FC received.
- Participant 1 cannot request IHI funding for costs already covered by the financial contribution. As a result, EUR 1 250 000 must be deducted from the EU contribution (M) requested by Participant 1. Additionally, the FC is to cover some of its eligible costs to implement the project. As a result, costs corresponding to the FC must be specified in the eligible costs (H) of Participant 1.
- Eligible costs that are not reimbursed (either by IHI or by financial contribution received from private members/contributing partners or by both) are costs to be covered by the participant's own resources. In

this example, while participant 3 is eligible to get reimbursed 100 % of its eligible cost, it makes the choice not to request the maximum EU contribution allowed and plans to bring instead some of its own resources to the project (EUR 850 000).

- The columns IKOP (S), Non-EU IKOP (T) and IKAA (P) are not applicable for beneficiaries that are not private members/contributing partners. As a result, their values must be zero for Participants 1, 2, 2.1 and 3.

Participant 4: For-profit large company

- In a two-stage call, this type of entity is not eligible to receive EU funding. As a result, the requested EU contribution must always be zero.
- All estimated costs planned by this entity to implement the project are to be covered by its own resources (R).
- The columns IKOP (S), Non-EU IKOP (T) and IKAA (P) are not applicable for beneficiaries that are not private members/contributing partners. As a result, their values must be zero for Participant 4.
- This applies to both Participant 4 and its affiliated entity 4.1.

Participant 5: Associated partner

- Associated partners are not requesting EU funding (even though they may be eligible for funding) and participate at their own costs.
- Cost incurred by associated partners cannot be declared as eligible costs. As a result, column (H) must always be zero.
- Applicants may include the total estimated costs of their associated partners in the budget for their proposal (i.e. under the 'Financial contributions' and 'Own resources' headings) but this is for information purposes only. The information is not transferred to the grant as the associated partners are not required to report on their costs.
- In the example above, the Participant 5 plans to receive a financial contribution of EUR 70 000 from an external financing source (i.e. other than IHI or a private member/contributing partner) and plans to incur EUR 100 000 of costs (covered with its own resources) for working on the implementation of the project.
- The columns IKOP (S), Non-EU IKOP (T) and IKAA (P) are not applicable for associated partners. As a result, their values must be zero for Participant 5.

Participants 6 and 7: Pre-identified private members

- Pre-identified private members are not eligible for funding. As a result, their requested EU contribution (M) is equal to zero.
- (Pre-identified) private members can provide all types of industry contribution: IKOP, FC and IKAA. They can provide either one, two or three of these contribution types (e.g. a private member can contribute only IKAA).
- The pre-identified private members' total contribution to the project is IKOP + FC + IKAA.
- IKOP (S) is always equal to eligible costs incurred to implement the project (H) as the funding requested (M) is always equal to zero for pre-identified private members.
- Eligible costs included in IKOP can be incurred in the EU or HE associated countries (= EU IKOP) or outside the EU or HE associated countries (= non-EU IKOP). Non-EU IKOP (T) is the part of eligible costs included in the total IKOP (S) that is planned to be incurred outside the EU or HE associated countries.

- (Pre-identified) private members can pay FC to other beneficiaries eligible for funding from the same consortium. Financial contributions (FC) are declared by the beneficiary(ies) receiving the FC, not by the company that is paying it.
- The column (R) for own contribution is not applicable for (pre-identified) private members (i.e. must be zero).
- ICAA (P) are costs for additional activities (i.e. not IKOP). This category is only applicable for (pre-identified) private members, their constituent entities or affiliated entities.

Participant 8: Pre-identified contributing partner

- Pre-identified contributing partners are not eligible for funding. As a result, their requested EU contribution (M) is equal to zero.
- (Pre-identified) contributing partners can provide IKOP and FC (either one or the other or both) but not ICAA.
- The (pre-identified) contributing partners' total contribution to the project is IKOP + FC.
- IKOP (S) is always equal to eligible costs incurred to implement the project (H) as the funding requested (M) is always equal to zero for pre-identified contributing partners.
- Eligible costs included in IKOP can be incurred in the EU or HE associated countries (= EU IKOP) or outside the EU or HE associated countries (= non-EU IKOP). Non-EU IKOP (T) is the part of eligible costs included in the total IKOP (S) that is planned to be incurred outside the EU or HE associated countries.
- (Pre-identified) contributing partners can pay FC to other beneficiaries eligible for funding from the same consortium. Financial contributions (FC) are declared by the beneficiary(ies) receiving the FC, not by the company that is paying it.
- The column (R) for own contribution and (P) for ICAA are not applicable for (pre-identified) contributing partners (i.e. must be zero).

3.2.1.4 Ethics and security

The ethics issues table contains a list of elements to identify any ethics issues in the proposed work. It must be completed even if there are no ethics issues. If you answer YES to any of the questions, you are requested to complete an ethics self-assessment and provide information on:

- ethical dimension of the objectives, methodology and likely impact;
- compliance with ethical principles and relevant legislation.

For more information on security and on each of the ethics issues and how to address them, see section 6 and 7.

3.2.1.5 Proposal including clinical studies

This section applies ONLY to full proposals to be submitted under single-stage calls and the second stage of two-stage calls. Applicants have to answer whether there are clinical studies¹⁰ included in the work plan. If the answer is YES, applicants are strongly encouraged to provide details of their clinical studies in a dedicated

¹⁰ Clinical study means any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

annex that must be uploaded in the submission environment (Annexes). The information on clinical studies annex can be found at:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

3.2.2 Instructions for writing Part B

Part B is the Technical Description of the proposal, which needs to be prepared using the Word template downloaded from the Submission System. Once finished, it must be uploaded as a PDF file.

Please be aware of the formatting conditions indicated in the template, which must be respected.

Unless specified otherwise in the conditions set out in the IHI JU Work Programme (WP) for the call you have applied for, the page limit is 20 pages for short proposals and 50 pages for full proposals. The page limit will be applied automatically by the system; excess pages will be automatically made invisible and will not be taken into consideration by the experts. Experts will also be instructed to ignore hyperlinks to information that is specifically designed to expand the proposal, thus circumventing the page limit.

The IHI JU follows the Horizon Europe proposal templates that consist of 3 fundamental sections: Excellence, Impact and Implementation. However please read carefully the instructions of the proposal templates since there are differences in the certain sections compared to the Horizon Europe requirements to reflect the public-private partnership (PPP) nature of the IHI programme and the collaboration among all relevant stakeholders.

Brief explanations of the different sections of the Part B are given below, however, detailed guidance can be found in the proposal templates themselves (see reference documents section for the relevant links).

Section 1 – Excellence

The excellence part includes the project's objectives, ambition, and the suggested methodology.

For information on policy considerations to be covered under the proposal's methodology (gender dimension, 'do not significantly harm' principle, social sciences and humanities, and open science), please see the Horizon Europe Programme Guide (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf).

During the first stage of a two-stage call, the applicant consortium is expected, when developing their methodology and proposed activities, to take into account the expected contribution of the pre-identified industry consortium and contributing partners which will join at stage 2 to form the full consortium.

Section 2 – Impact

This section includes 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. In addition, for single-stage calls and the second stage of two-stage calls, it includes the measures to maximise impact with regards to dissemination, exploitation and communication.

Section 3 – Quality and efficiency of the implementation

Applicants should present how the project is going to meet its objectives via a detailed work plan. Applicants should also take into consideration any associated risks, the effort assigned to work packages, the role of each participant, and the overall expertise of the consortium.

In addition to the Horizon Europe requirements, the implementation section was adapted for IHI by including tables to capture the financial contribution (FC), in-kind contributions to additional activities (IKAA) and non-EU part of the in-kind contributions for operational activities (IKOP).

3.2.2.1 Annex: Type of participants

The '*type of participants*' is an IHI-specific annex. The excel template can be found [here](#) and the instructions on how to fill in this template can be found [here](#).

This is a compulsory annex and it must be uploaded as separate document in the submission system. This annex is applicable to single-stage and two-stage calls.

3.2.2.2 Annex: Declaration of in-kind contribution commitment

The '*Declaration of in-kind contribution commitment*' is an IHI-specific annex. The word document template can be found [here](#).

This is a compulsory annex and it must be uploaded as separate document in the submission system. This annex is applicable to all single-stage calls.

3.2.2.3 Annex: In-kind contributions to additional activities (IKAA)

The '*In-kind contributions to additional activities (IKAA)*' is an IHI-specific annex. The excel template can be found [here](#) and the instructions on how to fill in this template can be found [here](#).

This is an optional annex and it is applicable to all single-stages calls and the second stage of two-stage calls.

3.2.2.4 Annex: Essential information for clinical studies

The *information on clinical studies* is a Horizon Europe annex.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in a dedicated annex.

The information on clinical studies annex can be found [here](#):

The annex is applicable only for single-stage calls and the second stage of two-stage calls.

3.2.2.5 Annex: Ethics

This is a HE annex. The ethics self-assessment should be included in proposal part A. However, in calls where several serious ethics issues are expected, the character limit in this section of proposal part A may not be sufficient for participants to give all necessary information. In these cases, participants may include additional information in an annex to proposal part B.

This is an optional annex and it is applicable to all single-stage calls and the second stage of two-stage calls.

3.3 After proposal submission

At submission, the application package is combined into one document, sealed and an e-receipt is generated (with date and time of submission).

All contact people at the coordinating organisation will receive an e-mail after the submission. If you have not received this e-mail, the application has not been submitted. Please try again or contact the [IT Helpdesk](#).

3.3.1 Access by IHI JU

IHI JU does not have access to the proposals until the call deadline has passed. However, in order to plan the evaluation process, we will ask you for permission to access to certain information prior to the deadline:

- call title and topic for which the proposal is submitted;
- title of your application, proposal abstract, keywords;
- PICs of the participating organisations.

A warning will inform you that the granting authority will be accessing this information and will give you the opportunity to refuse access.

Applicants must be informed that, at the end of the call evaluation, the IHI JU may provide the States' Representatives Group (SRG) and the Science and Innovation Panel (SIP), the IHI JU advisory bodies, with the following information on the proposals submitted:

- Proposal: number, acronym, title, status (eligible Y/N and selected Y/N), duration;
- Participant: role (Coordinator Y/N), country, legal name, PIC, organisation type, URL, total cost, requested JU contribution, IKOP, IKAA, FC;
- Ranking list;
- Evaluation summary reports.

This will allow the SRG and the SIP to efficiently follow up the implementation of the programme, including the outcome of the calls and projects, in accordance with Articles 20(12), 21(7) and 124(4) of the SBA).

This information will be treated confidentially.

3.3.2 Withdrawing a proposal

Before the call deadline, the coordinator can withdraw a proposal in the Submission System. After the call deadline, withdrawal has to be requested via the [IT Helpdesk](#) contact form in the Funding & Tenders Portal.

Once withdrawn, the new status will be shown on the My Proposals page (and you can delete the application with the Delete button).

3.3.3 Multiple proposals

If the coordinator submits a number of similar proposals, the Granting Authority may ask them to choose one or more of them to be withdrawn.

3.3.4 Complaints about failed submission

If you think that submission of your proposal failed and this was due to a technical error on the portal side, you may lodge a complaint through the [IT Helpdesk](#). The complaint must be filed within 4 **calendar days** after call closure. You will receive an acknowledgement of receipt the same or next working day.

What else to do? You should secure a PDF version of the part B and annexes of your application holding a time stamp before the call deadline (file attributes listing the date and time of creation and last modification), as well as proof of the alleged failure (screenshots). You may be requested by the IT Helpdesk to provide these items.

The EC services will check the IT logs (application log files and access log files of the Commission IT systems involved) and see if they show a technical problem on the portal side which prevented you from submitting (or resubmitting) the proposal.

You will be notified about the outcome as soon as possible.

If your complaint is justified, the files you provided to the IT Helpdesk will be used as your proposal and sent for evaluation. If you didn't provide any files, the last version recorded in the IT system will be used.

4 Proposal admissibility and eligibility

4.1 Admissibility criteria

Once you have submitted a proposal, IHI JU will check it for admissibility (i.e. if it is complete and properly put together).

The admissibility conditions are described in the General Annexes (Annex A) of the Horizon Europe Work Programme.

They are generally the same across all EU programmes. The proposal must:

- be submitted through the online Submission System before the call deadline;
- be complete —application form correctly filled out, all sections of Parts A and B completed, all annexes and supporting documents provided;
- be readable, accessible and printable. Furthermore, the proposal should respect the page limit set out in the application form. Excess pages will be automatically made illegible and will not be taken into consideration by the evaluators.

In case of an 'obvious clerical error' (*e.g. omission to submit evidence or information on a non-substantial element of the proposal*), we may first ask you to provide the missing information or supporting documents. Please note that if the missing information or document would substantially change the proposal, it will not be taken into account.

4.2 Eligibility criteria

For admissible proposals, IHI JU will check its eligibility (i.e. if it fulfils the eligibility conditions). For more information see section 2.2.

4.3 Proposal page limit

Unless stated otherwise in the WP applicable to a specific call, in the first stage of a two-stage submission and evaluation process, the page limit for the short proposal is maximum 20 pages.

In a single-stage call / the second stage of a two-stage call, the page limit for the full proposal is maximum 50 pages.

The proposal should respect the page limit set out in the application form. Excess pages will be automatically made illegible and will not be taken into consideration by the evaluators.

4.4 Outcome of the admissibility & eligibility check

If the proposal is considered inadmissible or ineligible, we will inform the coordinator (via a '**proposal rejection letter**' sent through the electronic exchange system), together with the reasons why and how to appeal.

For complaints procedures against such rejections, see section 5.3.7 - Complaints.

5 Evaluation of proposals

5.1 Independent experts and observers

If your proposal is admissible and eligible (or if admissibility and/or eligibility cannot immediately be determined), it will pass to the evaluation phase. All proposal submitted under a call (or within a coherent part of the call, i.e. a topic) are evaluated together.

In order to ensure that only proposals of the highest quality are selected for funding, IHI JU relies on **independent experts** ('evaluators') for the evaluation of proposals. IHI JU appoints evaluators for each topic in a call from the EU database of external experts. When selecting evaluators, IHI JU looks for a high level of skills, experience and knowledge in the relevant areas, e.g. scientific area, project management, innovation, exploitation, dissemination and communication.

Provided the above condition can be satisfied, a balanced composition of the evaluation panels in the following criteria will be also taken into account:

- gender¹¹;
- geographical diversity;
- experience in the private and public sectors;
- an appropriate turnover of independent experts from year to year.

Proposals are evaluated by at least three experts (in many cases, five or more).

The names of the independent experts specifically assigned to IHI JU calls are not made public. However, their names will be included in the general lists of independent experts who have participated in the Horizon Europe programme, which are published every year (name, nationality and fields of expertise) in the Funding & Tenders Portal.

The evaluation process may be followed by one or more external experts acting as **independent observers**. Observers are contracted to check the functioning and execution of the overall process, verify compliance with the procedures, and provide IHI JU with independent advice on:

- the conduct and fairness of all phases of the evaluation process;
- how evaluators apply award criteria;
- how to improve the procedure.

Observers, however, do not express views on the proposals or on the evaluators' scientific opinions. Therefore, it is not necessary that they have specific expertise in the area of the topics being evaluated. In fact, selecting observers without specific expertise on the topics under review may be an advantage to avoid

¹¹ Commission Decision [2000/407/EC](#) of 19 June 2000 relating to gender balance within the committees and expert groups

possible conflicts between their individual opinions on the outcome of the scientific evaluation and their assessment of the evaluation process.

In order to follow the remote evaluation phase, observers are given access to the evaluation system (as observer role only) and to all communications between IHI JU and the evaluation experts. Observers attend the consensus and panel review meetings during the proposal evaluation process, liaising with the IHI JU staff members involved in the evaluation, and may contact some or all the evaluation experts to collect their opinions on the evaluation.

After each evaluation session, the observers set out their findings and recommendations in a report to IHI JU, which is made public on the IHI website together with the IHI JU's responses to the observers' recommendations.

5.2 Conflicts of interest

Independent experts must adhere to a code of conduct in their contract, which includes obligations of impartiality and confidentiality. Experts who have a conflict of interest will be excluded from the evaluation.

In case a potential Col is spotted or brought to the attention of IHI JU, the JU reserves any right to take the final decision on the case and to take the appropriate measures.

IHI JU considers that a conflict of interest exists if an expert:

- was involved in the preparation of a proposal;
- benefits directly or indirectly if a proposal is accepted;
- has a close family or personal relationship with any person representing an applicant;
- is a director, trustee or partner or is in any way involved in the management of an applicant;
- is employed or contracted by one of the applicants or any named subcontractors;
- is a member of governance body or an advisory group set up by the IHI JU to advise on the preparation of IHI Annual Work Plan in an area related to the call;
- is a HE National Contact Point (NCP) or is directly working for the Enterprise Europe Network;
- is a member of a Horizon Europe programme committee.

Such an expert may, however, exceptionally be invited to take part in the evaluation session, if all of the following apply:

- the expert works in a different department/laboratory/institute from where the action is to be carried out;
- the bodies operate with a high degree of autonomy;
- such a role is justified by the requirement to appoint the best available experts and by the limited size of the pool of qualified experts (and this is documented).

IHI JU will however decide whether a conflict of interest exists — taking account of the objective circumstances, available information and related risks — when an expert:

- was employed by one of the applicants in the last three years;
- is involved in a contract or grant agreement, grant decision, membership of management structures (e.g. member of management or advisory board etc.) or research collaboration with an applicant or a fellow researcher, or had been so in the last three years;
- is in any other situation that could cast doubt on their ability to participate in the evaluation of the proposal impartially, or that could reasonably appear to do so in the eyes of an external third party.

A conflict of interest of an expert may require the expert to refrain from assessing one single proposal or the entire set proposals submitted for a give topic or call. For more detailed information, please refer to the Horizon Europe Expert Model Contract and in particular its Annex 1 Code of Conduct: https://ec.europa.eu/research/participants/data/ref/h2020/experts_manual/h2020-experts-mono-contract_en.pdf.

5.3 Evaluation process

The evaluation process has three phases:

Phase 1 — individual evaluation

Phase 2 — consensus group

Phase 3 — panel review

Before starting the evaluation process, the evaluators are briefed on:

- the evaluation process and procedures (including award criteria);
- the content of the topics under consideration;
- the terms of their contract (e.g. confidentiality, impartiality, conflicts of interest, completing tasks and approving reports, penalties for non-compliance);
- the need to evaluate proposals as they were submitted, rather than their potential should certain changes be made.

Proposals are evaluated and scored against selection and award criteria - excellence, impact, and quality and efficiency of implementation. The standard evaluation criteria and thresholds are described in detail in the Work Programme that all applicants should read carefully.

The [evaluation form](#) that experts use to evaluate proposals are available on the IHI website and in the Funding and Tenders portal for each call.

Experts score each **award criterion** on a scale **from 0 to 5** (half point scores may be given):

- 0 – Proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.
- 1 – Poor. The criterion is inadequately addressed or there are serious inherent weaknesses.
- 2 – Fair. The proposal broadly addresses the criterion, but there are significant weaknesses.
- 3 – Good. The proposal addresses the criterion well, but a number of shortcomings are present.
- 4 – Very good. The proposal addresses the criterion very well, but a small number of shortcomings are present.
- 5 – Excellent. The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

The maximum overall score is thus 15 (3x5).

In Horizon Europe, there is no scope for recommending improvements to proposals (including improvements on the budget). In particular, proposals with an inflated budget, taking into account cost efficiency considerations, should receive a lower score. However, experts may identify shortcomings, and formulate remarks which may be of assistance to the consortium if the proposal proceeds to the next stage (i.e. stage 2 and grant preparation).

Proposals will be evaluated on their own merit, and not their potential should certain changes be made. Proposals with an inflated budget are likely to receive a lower score.

5.3.1 Phase 1 — individual evaluation

During the individual evaluation for a given topic, the evaluators work individually. Each evaluator gives a score for each criterion, with explanatory comments, and prepares an 'individual evaluation report' (IER).

They also should indicate if the proposal


- is out of scope, i.e. it falls entirely outside the scope of the part of the call topic which they are evaluating;
- involves security issues that will need further scrutiny.

5.3.2 Phase 2 — consensus group

After the individual evaluation for a given topic, all evaluators who have evaluated the proposal will get together in a 'consensus group', to agree on a common position on comments and scores.

The consensus group will have an impartial moderator coming from the IHI JU staff who will seek a consensus and will ensure that each proposal is evaluated fairly and according to the award criteria.

A rapporteur (normally one of the evaluators, or an external expert contracted as dedicated rapporteur), will draft the consensus report of the proposal, after the consensus group's agreement on the comments and scores. If the consensus group cannot reach a common view, the consensus report will set out both the majority view and the dissenting views.

 In some cases we may ask additional experts to examine the proposal, to establish whether a clear majority view exists.

5.3.3 Phase 3 — panel review

After the consensus phase, the evaluation panel will review all the proposals under each topic (or within a call, or part of a call, when specifically mentioned in the WP/call) to:

- make sure that the consensus groups have been consistent in their evaluations;
- if necessary, propose a new set of marks or revise comments;
- resolve cases where evaluators were unable to reach a consensus.
- There will be no panel review:
 - if the IHI JU WP/call provides for an exception;
 - if there are sufficient funds to support all the proposals that passed the relevant thresholds;
 - if the same consensus group has examined all the proposals. In this case, their final review will be done together with the consensus reports. This is considered to constitute the panel review.

In IHI JU, the consensus group (phase 2) and panel review (phase 3) are normally merged in one meeting when the same consensus group has examined all the proposals submitted for a given topic of the call and there is a separate budget per topic.

If a panel review takes place, it is guided by a 'panel chairperson' (normally an IHI JU staff member) who must ensure fair and equal treatment of the proposals. A rapporteur (who may also be the chair) may be appointed to draft the panel's report.

As part of the panel deliberations, IHI JU may organise **hearings with the applicants** to:

- clarify the proposals and help the panel establish their final assessment and scores;
- improve the experts' understanding of the proposal.

The call documents will indicate if hearings may be organised.

Following the submission of the proposals, if hearings will be organised, IHI JU will inform applicant consortia and will provide them with details in relation to the hearing through the coordinator contact person indicated in the submitted proposals.

Hearings are held if deemed necessary by the evaluation panel, in particular:

- in stage 1 of a two-stage evaluation, invitations to hearings may be sent to the coordinators of up to the four highest-scored short proposals;
- in stage 2 of a two-stage evaluation, an invitation to a hearing may be sent to the coordinator of full proposal;
- in a single-stage evaluation, invitations to hearings may be sent to all the proposals that have passed the individual thresholds (even if they fell short of the overall threshold).

In these instances, the consortia coordinator will be provided beforehand with a list of questions.

Hearings may not be used to modify proposals or add missing information. You may only provide explanations and clarifications in response to questions provided by the panel in advance. You may choose not to attend the hearing and to reply only in writing.

Hearings may be held remotely via web-conference or by telephone, or on site in Brussels.

The 'panel report' includes:

- the 'evaluation summary report' (ESR) for each proposal, based on the consensus report, including comments and scores, and taking into account the panel's deliberations and any new scores or comments considered necessary;
- the 'panel ranked list' of proposals passing all thresholds, along with a final score.
- **For each group of proposals with the same score**, starting with the group achieving the highest score and continuing in descending order:
 - Proposals that address **aspects of the call that have not otherwise been covered** by more highly ranked proposals will be considered to have the highest priority.
 - The proposals identified under 1), if any, will themselves be prioritised according to the scores they have been awarded for '**Excellence**'. When these scores are equal, priority will be based on scores for '**Impact**'.
 - If necessary, the **gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the research and/or innovation activities, and who are included in the researchers table in the proposal**, will be used as a factor for prioritisation.
 - **Complete accurately the researchers table and ensure a gender balance.**
 - If necessary, any further prioritisation will be based on geographical diversity, defined as the number of Member States or associated countries represented in the proposal that are not otherwise receiving funds from projects higher up the ranking list (and if equal in number, then by budget).

- If a distinction still cannot be made, the panel may decide to further prioritise by considering other factors related to the objectives of the call, or to Horizon Europe in general. These may include, for example, enhancing the quality of the project portfolio through synergies between projects or, where relevant and feasible, involving SMEs. These factors will be documented in the panel report.
- The method described in 1), 2), 3) and 4) will then be applied to the remaining equally-ranked proposals in the group.

5.3.4 Outcome of the evaluation: IHI JU ranked list

The proposals that passed the thresholds will be ranked according to the results of the evaluation. The IHI JU Governing Board will issue a decision approving the evaluation results after the evaluation is completed in a single-stage procedure, and after the evaluation of short proposals and the evaluation of full proposals is completed in a two-stage procedure.

Grants will be awarded on the basis of this ranking, subject to the availability of budget.

Under an IHI JU two-stage evaluation procedure, at the end of stage 1, for each topic only the highest ranked proposal will be retained for stage 2 and invited to prepare a full proposal together with the pre-identified industry consortium and the contributing partners.

Under a single-stage evaluation procedure, the IHI JU ranked list consists of:

- a main list (proposals proposed for funding);
- normally also a reserve list (in case proposals are withdrawn, excluded or extra funding becomes available);
- a list of proposals that cannot be funded because of insufficient budget.

In addition, IHI JU will make a list of proposals that did not pass the thresholds or have been found to be ineligible (e.g. out of scope).

If your proposal has been successfully evaluated:

- at the end of the stage 1 of a two-stage evaluation, you will be informed that your short proposal has been successfully evaluated and will be invited to submit your full proposal together with the pre-identified industry consortium and contributing partners;
- at the end of a single-stage evaluation or stage 2 of a two-stage evaluation, we will **invite you to the grant agreement preparation** via a grant preparation invitation letter sent through the electronic exchange system within 5 months of the call submission deadline.

If your proposal is second or third-ranked in stage 1 under a two-stage evaluation process, or put on a reserve list, we will inform the coordinator and let them know of any subsequent change.

Under the stage 2 preparation process, the applicant consortia of the second and third-ranked short proposals (stage 1) for a given topic may be invited by the IHI JU, in priority order, for preliminary discussions with the industry consortium **if the preliminary discussions with the highest ranked proposal and the industry consortium fail**. The IHI JU may explore this possibility if the first ranked applicant consortium and the industry consortium jointly notify the IHI JU that the preparation of a stage 2 proposal is not feasible. This notification must be sent without delay and not later than 30 days from the invitation to submit the stage 2 proposal. It also must be accompanied by a joint report clearly stating the reasons why a stage 2 proposal is considered not feasible in order for the IHI JU to take the decision whether or not to invite the next ranked consortium. In the absence of a joint notification within the deadline, it is deemed that the first ranked applicant

consortium and the industry consortium are going to submit the stage 2 proposal. Accordingly, the second and third-ranked short proposals will be formally rejected.

If your proposal has not been retained for funding or invited to the following stage, we will inform the coordinator (via a proposal rejection letter sent through the electronic exchange system), together with the reasons why and how to appeal. The means of redress for such rejections are described in the next section 'Complaints'.

If the proposal is retained for funding, but one organisation may not participate (e.g. because it is found to have insufficient operational capacity or to be ineligible), we will inform that organisation and the coordinator via an 'applicant rejection letter' sent through the electronic exchange system.

5.3.5 Grant agreement preparation

After the evaluation, the proposals proposed for funding will receive from IHI JU the 'evaluation summary report' and the successful consortia will be requested to help prepare a grant agreement. The agreement must be signed at the latest 3 months after starting grant preparation.

Please note that the grant preparation invitation is not a formal commitment that we will fund your project. The final decision on the project will only be taken at a later stage — this depends on the finalisation of grant preparation and further checks which we still need to make (i.e. financial capacity, non-exclusion, etc).

The grant agreement will set out the framework for the grant and its terms and conditions, particularly concerning deliverables, reporting and payments.

The grant agreement must not differ from the proposal. This is without prejudice to corrections needed:

- changes to meet legal and financial requirements;
- requirements resulting from ethics review or security scrutiny;
- due to the removal of participant (if agreed by IHI);
- correction of clerical errors and obvious inconsistencies;
- eligibility and viability checks;
- anti-fraud measures and risk-based controls are carried out;
- shortcomings identified by the experts in the 'evaluation summary report' may be corrected, provided that this does not delay the preparation of the grant agreement beyond the applicable deadlines.

The members of the consortium are also obliged to sign a consortium agreement between themselves. In principle the consortium agreement must be concluded before the signature of the IHI JU GA. This may be challenging especially for large consortia. Consequently, the applicants are advised to give appropriate consideration to this as early as feasible. For more information, see Article 7 of the HE MGA, which clarifies that *'the beneficiaries must have internal arrangements regarding their operation and coordination, to ensure that the action is implemented properly. These arrangements must be set out in a written consortium agreement between the beneficiaries, covering for instance: - the internal organisation of the consortium - the management of access to the Portal - different distribution keys for the payments and financial responsibilities in case of recoveries (if any) - additional rules on rights and obligations related to background and results (see Article 16) - settlement of internal disputes - liability, indemnification and confidentiality arrangements between the beneficiaries. The internal arrangements must not contain any provision contrary to'* the Grant Agreement. To simplify the preparation of this document, applicants may utilise a template consortium agreement, a number of which are available online including the DESCA model consortium agreement which is available at this link: <https://www.desca-agreement.eu/desca-model-consortium-agreement/> and the template prepared by the IHI private members specifically for use in IHI projects which is in preparation.

5.3.6 Financial and operational capacity and exclusion

5.3.6.1 Financial capacity assessment (FCA)

Applicants must have **stable and sufficient resources** to successfully implement the projects and contribute their share. Organisations participating in several projects must have sufficient capacity to implement all these projects¹².

The financial capacity check will be done on the basis of the documents uploaded in the [Funding & Tender Opportunities Portal](#) during the grant preparation stage (e.g. profit and loss account and balance sheet, business plan, audit report produced by an approved external auditor, certifying the accounts for the last closed financial year, etc.). The analysis will be based on neutral financial indicators, but will also take into account other aspects, such as dependency on EU funding and deficit and revenue in previous years.

The check will normally be done for the coordinator if the requested grant amount is equal to or greater than EUR 500 000, except for:

- public bodies (entities established as a public body under national law, including local, regional or national authorities) or international organisations; and
- cases where the individual requested grant amount is not more than EUR 60 000 (low value grant).

If needed, it may also be done for other applicants, including affiliated entities. If the financial capacity is structurally guaranteed by another legal entity, the financial capacity of that legal entity will be verified.

If the granting authority considers that the financial capacity is not satisfactory, they may require:

- further information;
- an enhanced financial responsibility regime, i.e. joint and several responsibility of affiliated entities; and
- prefinancing paid in instalments; or
- propose no prefinancing;
- request that the applicant concerned is replaced or, if needed, reject the entire proposal.

If the FCA must be checked, the entity will be contacted by the Central Validation Service via its PIC account in the participant register in the Funding and Tender Portal.

Supporting documents requested to perform FCA:

- balance sheet and profit and loss account or business plan for new established entities;
- external audit report (or signed self-declaration) if requested EU contribution exceeds EUR 750 000;
- explanatory notes and/or annexes that form part of the above financial statements (if available);
- any other type of document to be requested in case of missing information.

¹² The Financial Capacity Assessment (FCA) is a necessary step of grant agreement preparation, and its legal basis are Articles 196 and 198.3 of EU Financial Regulation (REGULATION (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union) and Article 27 of the Horizon Europe regulation (Regulation EU 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination).

Once completed, the assessment is valid for 18 months from the closing date of the assessed documents.

i For more information, see [Rules on Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#).

5.3.6.2 Operational capacity

Applicants must have the **know-how, qualifications, and resources** to successfully implement their tasks in the project and contribute their share (including, when appropriate, sufficient experience in EU/transnational projects of comparable size).

This assessment of operational capacity will be carried out during the evaluation of the award criterion 'quality and efficiency of the implementation'. It will be based on the competence and experience of the applicants and their project teams, including their operational resources (human, technical and other) or, exceptionally, the measures proposed to obtain the necessary competence and experience by the time the tasks are implemented.

If the evaluation of this award criterion leads to a score above the applicable threshold, then the applicants are considered to have sufficient operational capacity.

For this assessment, applicants will be required to provide the following information in the application form (Part B):

- general profiles (qualifications and experience) of the staff responsible for managing and implementing the project;
- description of the consortium participants; and
- list of EU-funded actions/projects in the last 4 years.

Additional supporting documents may be requested if they are needed to confirm the operational capacity of any applicant.

Public bodies, Member State organisations and international organisations are exempted from the operational capacity check.

5.3.6.3 Exclusion

Applicants that are subject to **EU administrative sanctions** (i.e. exclusion)¹³ or are in one of the following **exclusion situations**¹⁴ that bar them from receiving EU grants can NOT participate:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts);
- they are in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts);
- they are guilty of grave professional misconduct (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant);
- they are guilty of fraud, corruption, having links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons

¹³ See Article 136 EU Financial Regulation [2018/1046](#).

¹⁴ See Articles 136 and 141 EU Financial Regulation [2018/1046](#).

having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant);

- they have shown significant deficiencies in complying with their main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant);
- they are guilty of irregularities within the meaning of Article 1(2) of Regulation No [2988/95](#) (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant); or
- they have created under a different jurisdiction an entity with the intent to circumvent fiscal, social or other legal obligations in the country of origin or created another entity with this purpose (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant).

Applicants will also be refused if it turns out that¹⁵:

- during the award procedure, they misrepresented information required as a condition for participating or failed to supply that information; or
- they were previously involved in the preparation of the call and this entails a distortion of competition that cannot be remedied otherwise (conflict of interest).

¹⁵ See Article 141 EU Financial Regulation [2018/1046](#).

5.3.7 Complaints

If the applicants consider that a proposal rejection was based on a flaw in the selection procedure, the coordinator can submit a complaint following the deadlines and procedures set out in the evaluation result letter.

The means of redress are the following:

- admissibility/eligibility or evaluation review (redress review) — within 30 days of receiving the rejection letter;
- action for annulment under Article 263 TFEU — within 2 months of receiving the rejection letter.

Please do not take more than one formal action at a time. If you would like to use more than one means of redress, start with the administrative review procedure first. Wait for the reply to your first complaint, and then take further action against that decision if you continue to disagree. We will count the deadlines for further action always as from when you receive the reply to the previous complaint.

Please note that notifications which have not been opened within 10 days after sending are considered to have been accessed and that deadlines will be counted from opening/access in the system (see [Portal Terms and Conditions](#)).

5.3.7.1 Evaluation review procedure

Redress requests must be related to the evaluation process or admissibility/eligibility check.

An internal committee may be convened by IHI JU to examine the redress requests that have been submitted within the deadline mentioned above through the means described in the rejection letter. Requests that do not meet the above-mentioned conditions, or do not deal with the admissibility, eligibility or evaluation of a specific proposal, will not be admitted. Applicants who, before the deadline, submit redress requests via other means than those set out in the rejection letter will be requested to resubmit using the dedicated means.

Your complaint must demonstrate a procedural irregularity, factual error, manifest error of assessment or misuse of powers. Mere repetitions of your application or mere disagreement with the result of the evaluation or the scientific assessment done by the experts will not be considered.

Depending on the nature of the complaint, the committee may review the profile and expertise of the independent experts, their individual comments, and the evaluation summary report. However, the committee will not call into question the scientific judgement of the independent experts.

Your review request will not automatically trigger a re-evaluation of your application. A re-evaluation will only be carried out if your request shows that the selection procedure was flawed by a breach which affects the final decision on whether to fund your project.

If the complaint is justified, IHI JU will arrange for a re-evaluation and inform the coordinator.

If the complaint is not justified, IHI JU will inform the coordinator, together with the reasons why.

Should your request lead to a re-evaluation, it will be done on the application as initially submitted; no additional information is admissible. The re-evaluation will be partial (limited to the criterion affected by the error) or full (when the entire procedure was flawed), depending on the case. The score following re-evaluation will be regarded as definitive. Please be aware that this may result in the score being lower than the original score.

Only one request for review per proposal will be considered.

All requests for review will be treated as confidential.

6 Ethics and integrity

In addition to the scientific evaluation, proposals above threshold and considered for funding (in single-stage calls and stage 2 of two-stage calls) will undergo an ethics review carried out by independent ethics experts. Projects involving ethics issues will have to undergo an ethics review to authorise funding and may be made subject to specific ethics requirements that will become part of the grant agreement.

The ethics review procedure focusses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of the research methods, and the applicants' awareness of the ethical aspects and social impact of their planned research.

The ethics review covers issues as: human rights and protection of human beings, animal protection and welfare, data protection and privacy, health and safety, environmental protection, and artificial intelligence. It may also cover issues of research integrity, including fabrication, falsification, and plagiarism in proposing, performing, or reviewing research or in reporting research results.

For all activities funded by the EU, the ethical dimension is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. There is a clear need to make a thorough ethical evaluation from the conceptual stage of the proposal not only to respect the legal framework but also to enhance the quality of the research. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. This includes the adherence to the highest standards of research integrity as described in the European Code of Conduct for Research Integrity.

The process to assess and address the ethical dimension of activities funded under Horizon Europe is called the ethics appraisal procedure.

For more information read the **Ethics Appraisal Procedure** https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

6.1 Ethics appraisal procedure

The ethics appraisal procedure concerns all activities funded under Horizon Europe and includes the ethics review procedure, conducted before the start of the project, as well as ethics checks, reviews and audits conducted during the project.

When preparing a proposal, the consortium must conduct an ethics self-assessment, starting with the completion of an **ethics issues table**. You can read further practicalities in the following guide on how to complete your ethics self-assessment: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

6.2 Ethics review procedure

All proposals above threshold and considered for funding will undergo an ethics review carried out by independent ethics experts. The review starts with the ethics screening which can include, in the cases where there is no ethics issue identified in the proposal, a pre-screening to confirm or not the absence of ethics issues (this check can be conducted by qualified staff). If appropriate, a further analysis called the **ethics assessment** is conducted. The ethics assessment can lead to **ethics requirements** that become **contractual obligations**.

The ethics review covers issues as:

- human rights and protection of human beings;
- animal protection and welfare;
- data protection and privacy;
- health and safety;
- environmental protection;
- artificial intelligence.

It may also cover issues of research integrity, including, fabrication, falsification and plagiarism in proposing, performing, or reviewing research or in reporting research results; this includes misrepresenting credentials and improprieties of authorship.

6.3 Ethics screening

The ethics screening is carried out during the scientific evaluation or soon after.

The ethics experts are asked to flag the proposals that have serious or complex issues (on the basis of the guidelines on serious and complex ethics issues) that will be the subject of a more in-depth analysis (ethics assessment).

Proposals involving the use of human embryonic stems cells (hESCs) or human embryos (hE) automatically proceed to the second step, the ethics assessment. Further to the ethics screening, the proposals that will be funded and are not flagged as serious or complex must handle the ethics issues in the proposed activities in line with national and European legislation and practice and the 'how to complete your ethics self-assessment' guide.

The ethics summary report will list the main ethics issues identified in your proposal. Ethics screening will not issue ethics requirements but can lead to the obligation to nominate an external independent ethics advisor or board to assist the project in adhering to the relevant ethical and legal standards.

6.4 Ethics assessment

For the proposals flagged as serious or complex and for all the proposals involving the use of hESCs or hE, the ethics screening is followed by an ethics assessment prior to the signature of the grant agreement.

The ethics assessment is an in-depth analysis of the ethical issues of the proposals, taking into account the analysis made during the ethics screening.

The ethics assessment can lead to ethics requirements that are inserted as obligations in the grant agreement. If the proposal undergoes an ethics assessment, you will receive an ethics summary report with an ethics opinion on your proposal. The possible outcomes of the ethics assessment are:

- ethics clearance;
- conditional ethics clearance;
- request for additional information (intermediate outcome);
- no ethics clearance;
- ethics requirements and ethics work package;
- ethics checks, reviews and audits.

6.5 Summary of the ethics appraisal steps

Activity	Who?	When?	How?
Ethics self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics screening	Ethics experts (and/or qualified staff if a prescreening is conducted)	Evaluation phase	Review of application material
Ethics assessment (for proposals involving hESC/hE or flagged as serious or complex)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics check/review/audit	Project officer and/or ethics officer and/or ethics experts	Implementation phase	Review of project deliverables/interview with applicants/on-site visit

7 Security

Activities carried out under the programme must comply with the applicable security rules and, in particular, rules on the protection of classified information against unauthorised disclosure, including compliance with any relevant Union and national law. Where appropriate, the actions carried out under the Horizon Europe Programme must comply with Commission Decision (EU, Euratom) 2015/444, and its implementing rules. The Horizon Europe Model Grant Agreement includes specific security related obligations (Article 13 and Annex 5). The Horizon Europe Programme Security Instruction (PSI) has to be followed in case a proposal selected for funding will lead to a project that involves classified information.

Security issues will be checked systematically in all proposals above threshold and considered for funding (in single-stage and at the second stage of two-stage calls), based on the **security self-assessment** provided by the applicants at the submission phase. The focus of the check is on:

- whether the proposal uses or generates EU classified information;
- potential of misuse of results (that could be channelled into crime or terrorism);
- whether activities involve information or materials subject to national security restrictions.

The security pre-screening is carried out during the scientific evaluation or soon after, in the following cases:

- if the proposal has been submitted under a call or topic not flagged as security sensitive and the applicant has replied positively to at least one of the questions in the security issues table in the Part A of the proposal;
- if the proposal has been submitted under a call or topic not flagged as security sensitive and the applicant has replied negatively to all the questions in the security issues table, but the granting authority has, nevertheless, detected security issues.

8 Points to remember

- **Registration** — Before submitting the application, all beneficiaries and affiliated entities must be registered in the [participant register](#). The participant identification code (PIC) (one per participant) is mandatory for the application form. Associated partners can register later on (at the latest during the grant preparation stage). For validation, beneficiaries and affiliated entities will be requested to upload the necessary documents showing their legal status and origin during the grant preparation stage.
- **Consult** the topic page on the Portal regularly. IHI JU will use it to publish updates and additional information on the call (call updates).
- **Do not wait until the last moment to submit** — Complete the application sufficiently in advance of the deadline to avoid any last-minute **technical problems**. Problems due to last-minute submissions (*e.g. congestion, etc.*) will be entirely at applicants' own risk. Call deadlines can NOT be extended at the request of applicants.
- **Consortium roles** — When setting up the consortium, applicants should think of organisations that can help them reach objectives and solve problems. The roles should be attributed according to the degree of participation of each participant in the project. The main participants should participate as beneficiaries (including private members and/or contributing partners) or affiliated entities; other entities can participate as associated partners, subcontractors, or third parties giving in-kind contributions. Associated partners and third parties giving in-kind contributions should bear their own costs (they will not become formal recipients of EU funding). Subcontracting should normally constitute a limited part and must be performed by third parties (not by another beneficiary). The consortium agreement allows the grant to be customised to the needs of the consortium. It is also important that the consortium considers on how best to reflect the public-private partnership nature of IHI JU in the allocation of the consortium roles, for example via dual leadership of the work packages, including the appointment of a scientific leader.
- The consortium should ensure that the 45 % contribution is secured collectively by the private members and any contributing partners, in compliance with the rules on IKOP and IKAA, otherwise the proposal will be declared ineligible and therefore will not be evaluated.
- While building the budget table (see also examples in the relevant sections of this guide), pay special attention to IHI specific columns (IKOP/FC/Non-EU/IKAA). These amounts will be assessed and also define the eligibility of your proposal.
- The proposal should respect the page limit set out in the application form. Excess pages will be automatically made illegible and will not be taken into consideration by the evaluators.
- If you plan to be the consortium coordinator, ensure that you are financially viable. Otherwise, if your proposal is selected, your organisation should be replaced during the grant preparation phase, and this may delay the signature of the grant.
- Complete accurately the researchers table (Proposal Part A) and ensure a gender balance. This might impact the proposal ranking in case of equal scores. For more information see [Horizon Europe Work Programme General Annexes Part F — Procedure](#).
- Ensure that all information is explicitly described to allow the expert-evaluators to assess your proposal against the evaluation sub-criteria. Carefully read the topic text, get familiar with the evaluation subcriteria, and provide (explicit) answers to these sub-criteria in your proposal... Follow the proposal structure / template, paying special attention on **how to complete your ethics self-assessment**.
- **Right to object to transfer of ownership and exclusive licensing of results.**

According to Annex 5 of the Horizon Europe Model Grant Agreement, the IHI JU has a right to object to transfers of ownership or exclusive licensing of results generated within the framework of the action. The Call conditions will clarify where the IHI JU can exercise or not the right to object in the specific call topic. Where this right is applicable, beneficiaries that intend to transfer ownership or grant an exclusive licence

must therefore formally notify the IHI JU, before the intended transfer or licensing takes place and provide details of the planned transfer/licensing. This notification should be made by the project Coordinator via the Funding & Tenders Portal, using the submission template and uploading any relevant related documents.

- A Beneficiary that intends to transfer or exclusively licence results to a specifically identified third party, may request that the IHI JU formally waive the right to object with respect to those project results and that specific third party. The waiver request must be submitted following grant signature but it can be submitted prior to signature of the specific beneficiary's accession form, identifying the specific results concerned (expected, if not yet produced), the details of the transfer/licence, and the specific third party/ies to whom the results are to be transferred/the exclusive license is to be issued. Additionally, the request must include reasons supporting the request and a clear reference to the appropriate measures in place to safeguard EU interests, sufficient enough to allow the IHI to assess the request and make an informed decision. The waiver request must be submitted by the project Coordinator using the Funding & Tenders Portal.

Upon receipt of the request, the IHI JU will provide a written reply within 60 days of either receiving the initial request or receiving any additional information requested by the IHI JU in response to the initial request.

Results must be specifically identified by referencing either a line item in the 'Key Expected Results' list in the specific action's Description of Action or a line item in the specific action's 'Work Package Deliverables' list. The project's Results Ownership List comprised in the Final Report must also include and identify all results covered by the waiver (both anticipated and unanticipated results).

- **Affordability, availability and accessibility of results**

Article 125.3 of the Regulation establishing IHI requires that participants to indirect actions ensure that products and services they develop based or partly based on the results of clinical studies undertaken as part of an indirect action are affordable, available and accessible to the public at fair and reasonable conditions (the "3A"). In line with this provision, some specific exploitation obligations applying to Call 1, topics 2 and 3, can be found in the work programme, underspecific call conditions.

Additionally, the examples described below are provided to allow compliance of project activities with such provisions, with reference to Call 1, topic 2 and 3.

Activities that would not fall under the scope of Article 125.3: clinical studies that serve the purpose of establishing and validating an infrastructure or capability or methodology; phase 0 and 1 clinical trials; re-use of existing data, generated outside of projects.

Additionally, non-project assets (products or services) are not impacted by Article 125(3) if they indirectly rely on IHI project results from previous 3A IHI designated projects. Non-project assets are considered those assets which were not investigated (in whole or in part) under a 3A designated IHI project and which are developed by the beneficiary outside or after such project, and where there is an indirect reliance on results of such project (without the intention to commercialize such results themselves). Examples are the reliance on a placebo arm results of a 3A designated IHI action for the development of a non-project asset, or the reliance on a patient stratification biomarker result identified in a clinical study in an action, for identification of suitable patients for further clinical development of the non-project asset.

Project results coming out of 3A designated IHI projects that are subsequently made available to the research community by means of a scientific publication, through open access or equivalent terms, will be also exempted from further obligations on 3A under Article 125.3.

Examples where 125.3 would apply: clinical studies testing an investigational asset of any nature (drug, device including IVD, combination product or a related service) for product/service development of such investigational asset.

Examples where 125.3 would not apply: small pilot or exploratory studies; clinical studies involving an already marketed asset; projects that are setting up clinical trial infrastructures or services such as placebo-controlled basket trials, application of micro sampling capabilities for decentralized trials; projects that

utilize data from prospective and/or retrospective clinical trials carried out independently of the selected project(s).