

Joint Industry Webinar

How to prepare a project proposal – rules and operational guidance under the Innovative Health Initiative

Date: 28 April 14.00 – 17.00 CEST

Location: GoToWebinar

Register here: <https://attendee.gotowebinar.com/register/1795442436894851853>

Introduction

The first calls for project proposals under the Innovative Health Initiative (IHI) are expected to be launched in June. As companies start building their consortia and get prepared to submit project proposals (on single-stage topics) or to confirm their commitment (two-stage topics), many questions arise: how to create a budget? What are the conditions and constraints for funding? What is an acceptable industry contribution? What is the difference between In-Kind contributions to Projects and In-Kind contributions to Additional Activities?

The objective of this workshop is to provide an overview of the established guidance and rules and provide hands-on insights into the best way to create a successful project proposal. In addition, any gaps in the current knowledge and open questions are captured to channel into the development of further guidance.

The target audience are research managers, researchers, financial and legal experts in the industry associations' member companies who are directly involved in the drafting of proposals. Information will be targeted both for experts with existing experience in EU funding programmes (Horizon 2020, Innovative Medicines Initiative, ECSEL JU etc.) and newcomers.

If you already have any questions in advance, please contact Annika Eberstein (eberstein@cocir.org).

Draft agenda

14.00 – 14.05 Welcome & introduction

14.05 – 14.30 Brief overview of general rules and conditions under Horizon Europe and IHI

Council Regulation, (Annotated) Model Grant Agreement, guidance on rules for participation, difference between single-stage and two-stage calls, etc.

14.30 – 15.30 Industry contribution: IKOP, IKAA, contributions from outside the EU – what is it, how is it planned, how is it valued?

15.30 – 16.30 Building a project budget: financial and funding rules

16.30 – 16.55 Building a consortium: what other legal conditions do I need to consider?

IPR, governance, Model Consortium Agreement etc.

16.55 – 17.00 Conclusions

Joint IHI Industry Webinar

How to prepare a project proposal

Rules and operational guidance under the Innovative Health Initiative

28 April 2022, 14:00-17:00



ANTITRUST GUIDELINES

When competitors discuss and/or coordinate policy issues, there is a risk that antitrust rules are infringed. Adherence with the following guidelines ensure compliance with EU competition law.

**DO NOT DISCUSS ANY OF THE
FOLLOWING
AND IF SOMEBODY ELSE DOES, SPEAK UP**

- Company prices and pricing strategies
- Terms of sales
- Production or distribution costs
- Company figures or plans on supply, production, inventory, sales, marketing and promotion
- Information on individual suppliers or customers
- Information on company plans concerning technology or investments
- **ANY OTHER ISSUE YOU BELIEVE MAY BE INAPPROPRIATE FOR DISCUSSION**

TOPICS WHICH MAY BE DISCUSSED INCLUDE:

- Non-confidential, technical issues relevant to the industry, e.g. standards, environmental concerns, matters related to corporate social responsibility, health and safety matters, regulatory policy developments
- Publicly available information on market trends (not a particular company's promotional plans)
- General promotional opportunities
- Industry public relations advocacy activities

House-keeping rules

- The webinar is **restricted to members** of COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe.
- The webinar will be **recorded**
- Webinar participants are **muted during presentations**
- **Any questions?**
 - Please feel free to submit your question in the Q&A part
 - Raise your hand for any oral question 🖐
 - Please state your name and company affiliation

1. Welcome and introduction

14:00-14:05

Patrick Boisseau (MedTech Europe), Nicolas Creff (EFPIA), Annika Eberstein (COCIR), Gaëlle Lanckmans (IHI)



Context

Context:

1st IHI Call launch in June, companies start building their consortia and get prepared to:

- submit project proposals (on single-stage topics)
- or to confirm their commitment (two-stage topics)

Many questions arise, in particular on financial aspects:

- how to create a budget?
- what are the conditions and constraints for funding?
- what is an acceptable industry contribution?
- what is the difference between In-Kind contributions to Projects (IKOP) and In-Kind contributions to Additional Activities (IKAA)?
- what is the legal framework? which legal and IP aspects should be taken into account?

Objectives of the workshop

Objectives:

- Provide an overview of the established guidance and rules on IHI
- Provide hands-on insights into the best way to create a successful project proposal (on operational aspects, scientific content aside)
- Capture any gaps in the current knowledge and open questions, for the development of further guidance.

Caveat: today's webinar is based on **information available as of today**.

Some points will be mentioned as indicative or to be clarified: they will require further updates until call launch in June.

Agenda

Time	Item	Speaker
14.00 - 14.05	1. Welcome & introduction	Patrick Boisseau (MedTech Europe), Nicolas Creff (EFPIA), Annika Eberstein (COCIR), Gaëlle Lanckmans (IHI)
14.05 - 14.30	2. Brief overview of general rules and conditions under Horizon Europe and IHI	Nicolas Creff (EFPIA), Annika Eberstein (COCIR)
14.30 - 15.45	3. Industry contribution: IKOP, IKAA, contributions from outside the EU – what is it, how is it planned, how is it valued, how is it reported and certified?	Gaëlle Lanckmans (IHI)
15.45 - 16.30	4. Building a project budget: financial and funding rules	Annika Eberstein (COCIR)
16.30 - 16.55	5. Building a consortium: what other legal conditions do I need to consider?	Christophe Verbruggen (Janssen)
16.55 - 17.00	Conclusion	Patrick Boisseau (MedTech Europe), Nicolas Creff (EFPIA), Annika Eberstein (COCIR), Gaëlle Lanckmans (IHI)

2. Brief overview of general rules and conditions under Horizon Europe and IHI

14:05-14:30

Nicolas Creff (EFPIA), Annika Eberstein (COCIR)



FROM IMI TO IHI

IHI PARTNERS

WHAT IS IHI?

IHI IS EUROPE'S NEW PARTNERSHIP FOR HEALTH

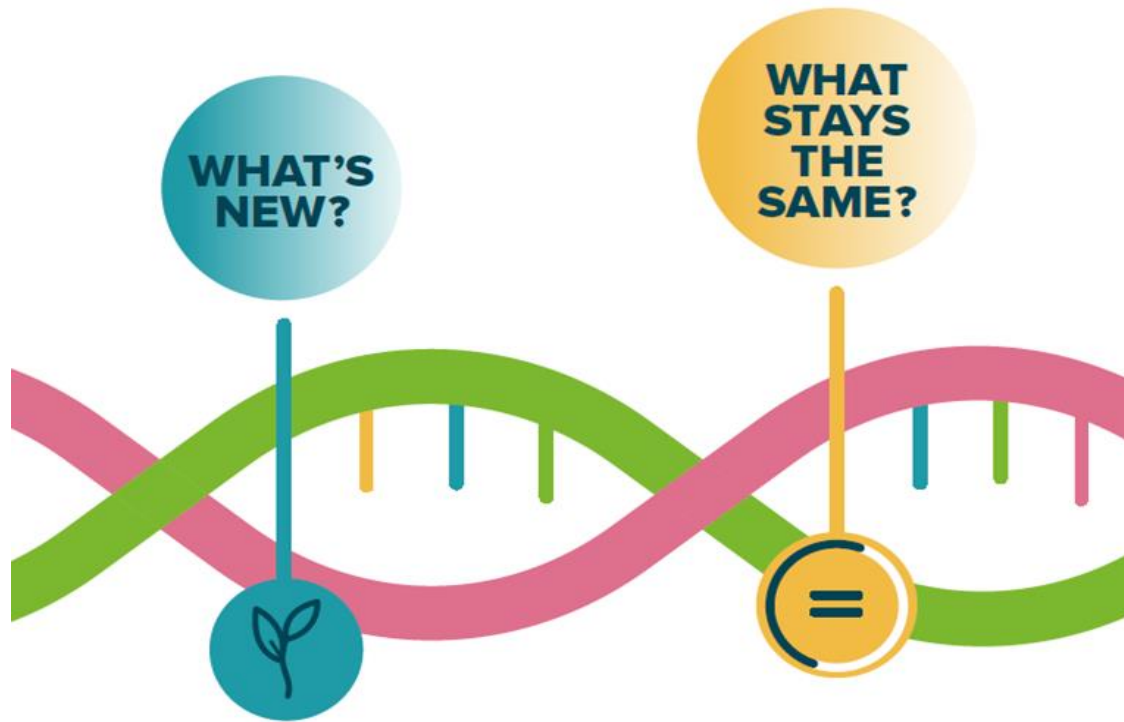
IHI is a **collaboration** between the EU and the biopharmaceutical, biotechnology, digital health and medical technology sectors, as well as academics, patients, regulators and other healthcare professionals.

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

The industry members that make up the new partnership are:

COCIR
EFPIA
EuropaBio
MedTech Europe
Vaccines Europe

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



- The way we're governed will change.
 - The scope of the partnership is broader than IMI as it will cover the **entire continuum of care**.
 - There will be new, specific objectives that align with the EU's latest health policy strategies.
- **Funding comes equally** from the public and industry partners.
 - Calls for proposals will be **open and competitive**.
 - Projects started under IMI will be managed by IHI.

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

IHI Trade associations at a glance

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

IHI JU Budget

IHI will work to reach its objectives with the following resources:

- up to EUR **1.2 billion** provided by the European Union (Horizon Europe Health Cluster),
- at least EUR **1.0 billion** provided by the member industry associations,
- up to EUR **200 million** from Contributing Partners.



How call topics are generated

Council Regulation (EU) 2021/2085

Strategic Research and Innovation Agenda (SRIA)

Ideas for call topics

SIP review

Annual Work Programme (AWP). Includes the annual scientific priorities & call topics

**Consultation with
advisory bodies (SIP &
SRG)**

AWP adopted by IHI Governing Board



IHI Calls 1 & 2

- **Draft topic texts** published on the IHI website page “Future opportunities” to give applicants the opportunity to start familiarising with the potential topic content and start building consortia to prepare strong proposals
www.ih.europa.eu/apply-funding/future-opportunities
- **Call 1 (single stage) & Call 2 (two-stage) – *Indicative* timelines:**
 - Launch in mid-June
 - Submission deadline in September
 - Project start in March 2023 (single stage) and July 2023 (two-stage)
- [Brokerage event](#) (14 June) and webinars organised up to Call launch

2 types of calls

Single-stage (e.g. Call 1)

- Broad topic, not specific to one single product/technology/solution
- **Private Members apply simultaneously with Public Members in mixed consortia**
- Due to its nature of openness and competitive character, **Private Members can receive funding**
- **Pharma companies will abstain from requesting funding**
- Industry is building consortia alongside with public partners (like in HE regular calls)
- Budget includes **at least 45% in-kind contribution** (e.g. 10 million total budget: up to 5.5 mln costs funded by IHI, at least 4.5 in-kind provided by members of founding associations. Industry associations' policy actually requires 50% in-kind, meaning the breakdown would actually be 5 mln funding vs 5 mln industry contribution).

2-stage (e.g. Call 2)

- Targeted topics and budget are determined by Private Members
- The industry consortium is built first, and then the public consortium is built separately (that's why we call it 2 stages). **Only the public consortium applies in the first stage** (i.e. September deadline for Call 2)
- Anyone interested can subscribe to these calls, in line with available funding
- Winning consortium is coupled to Private Members' consortium to prepare second stage full proposal
- Due to its nature of company-detailed topics, **Private Members are not eligible for funding**
- In fact, no funding will be made available for any company with annual turnover > 500M

Call 1 draft topics: single-stage

- An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities.”
- Next generation imaging and image-guided diagnosis and therapy for cancer
- Personalised oncology: Innovative people-centred, multi-modal therapies against cancer
- Access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need

Call 2 draft topics: two-stage

- Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring
- Setting a harmonised methodology to promote uptake of Early Feasibility Studies for clinical and innovation excellence in the European Union

Who can participate?



Any legal entity or international organisation regardless of its place of establishment



At least 3 independent legal entities established in a different Member State or Associated Country



IHI specific eligibility criterion **NOT** applicable: stage one of two-stage calls:

NEW

Costs related to contributions provided by participants* shall amount to at least 45% of the total project cost.

NEW

IMPORTANT!

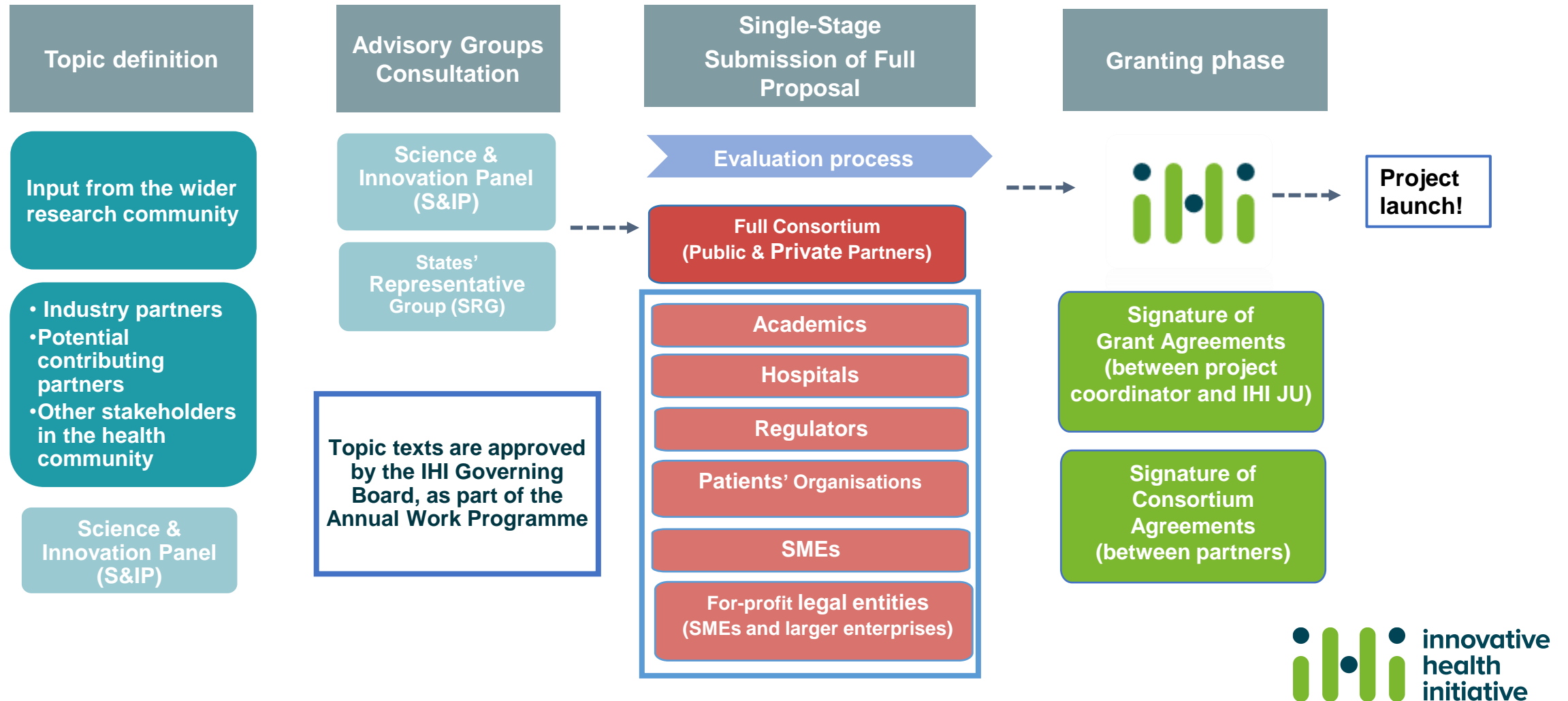
1 legal entity should be established in a Member State

IKOP, IKAA or FC



**Must be either members of the industry associations or contributing partners*

How does IHI work? single-stage process



Call 1 – single stage – Indicative timelines

April 2022

• Publication of draft topics

mid-June 2022

• Launch of the Call

end-September 2022

• Call Submission Deadline - Full Proposals (FP)

October 2022

• Scientific evaluation

end-November 2022

• Information to the applicants - evaluation outcome

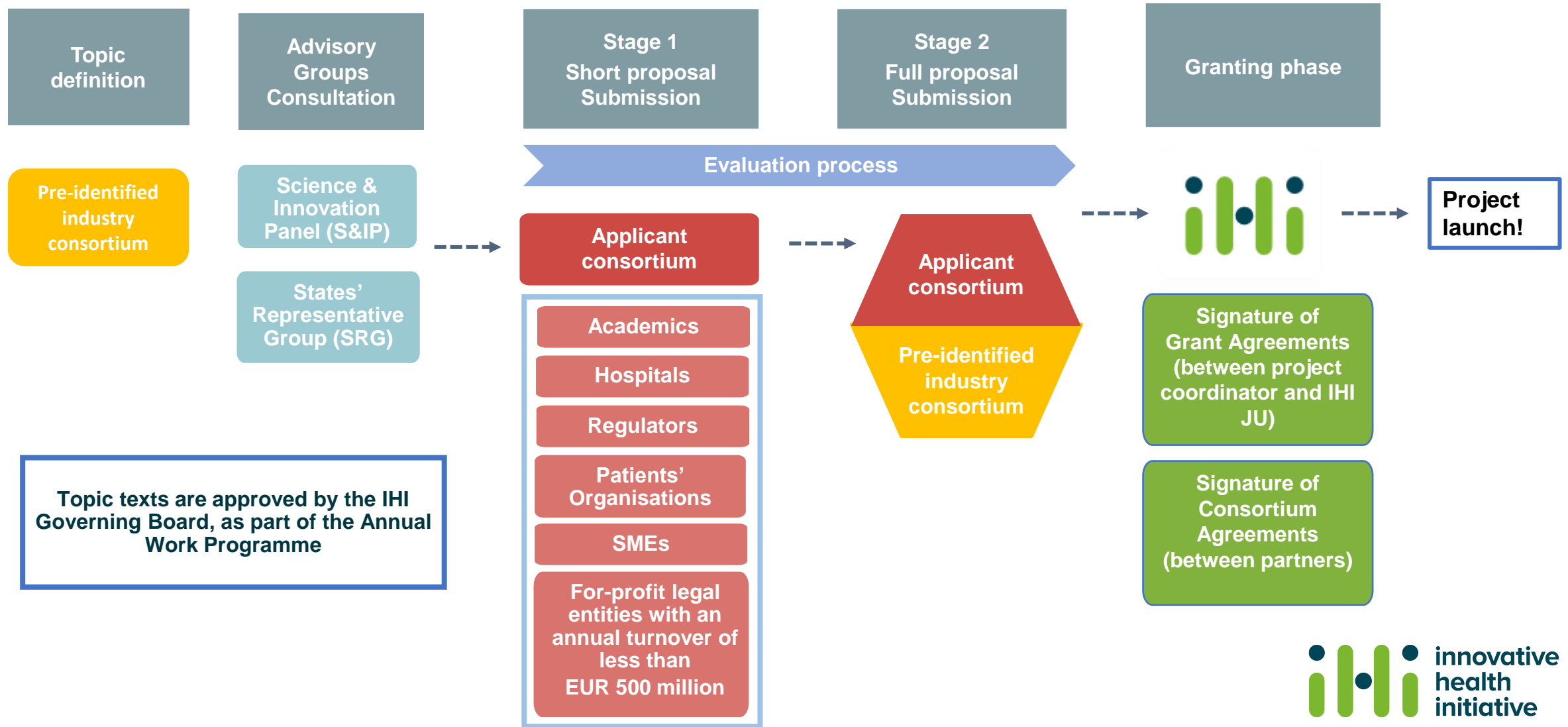
March 2023

• Grant Agreement Preparation (GAP) and GA signature

Eligibility rules: funding for single-stage Calls



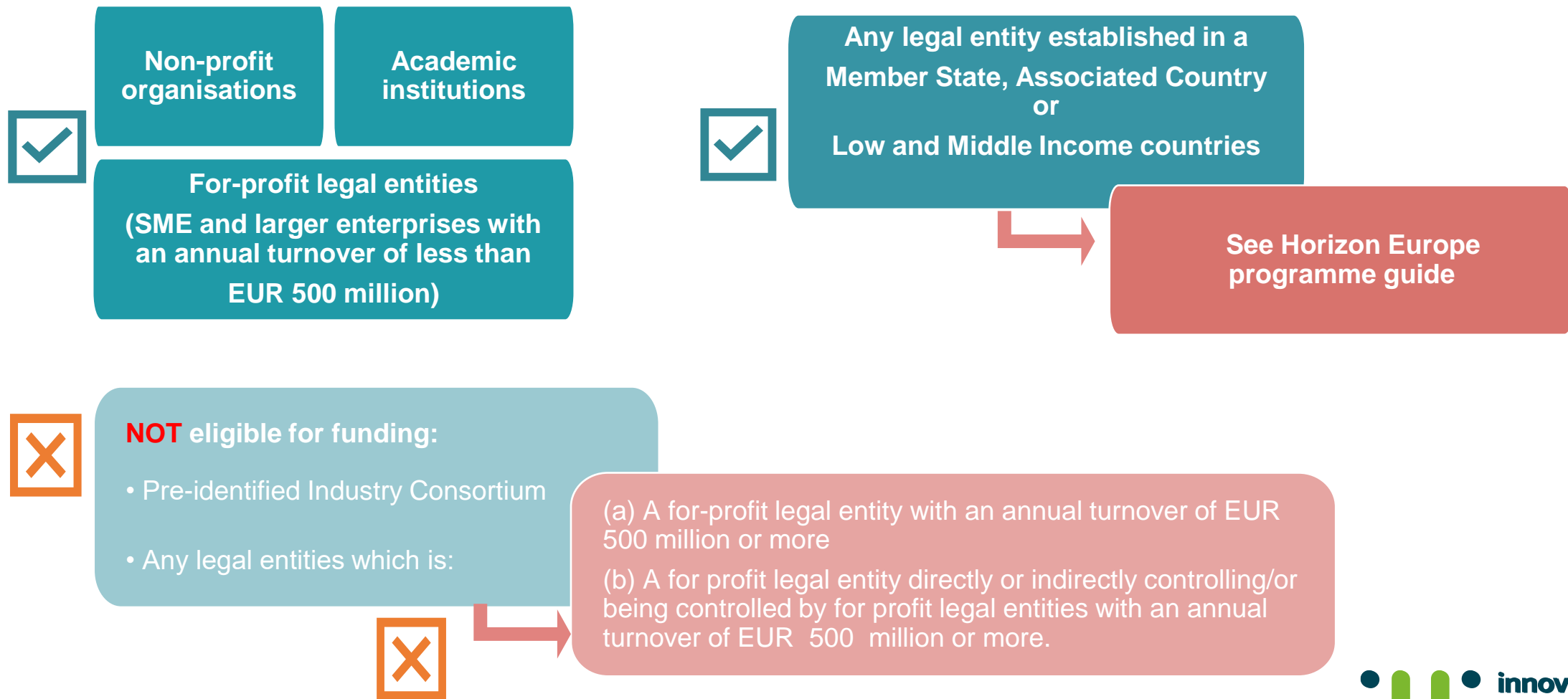
How does IHI work? two-stage process



Call 2 - two-stage – Indicative timelines



Eligibility rules: funding for two-stage Calls



SMEs affiliated to one of our associations: can choose to be either on (i) industry side (no funding) or (ii) public side (funding but no guaranteed seat in consortium)

Brokerage event



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[Home](#) > [News and events](#) > [Events](#) > IHI Kick-off and brokerage event

IHI Kick-off and brokerage event

The first calls for proposals will be launched in June 2022! Interested in IHI's strategic research priorities? Do you know how to write a good IHI project proposal? Are you looking for partners to build consortia? Join our brokerage event and find the answers you need.



HYBRID

14 June 2022

08:30 - 17:00

Europe/Brussels

Save to calendar



<https://www.ihi.europa.eu/news-events/events/ihi-kick-and-brokerage-event>

Proposal submission and template

- **Proposals have to be submitted via the [EU Funding and Tenders](#) portal for the relevant IHI Calls.**
- **“Part B” - Based on Horizon Europe model. Two distinct templates:**
 - **Full proposal:**
 - for single-stage calls submissions (Call 1)
 - for 2nd stage of two-stage calls (i.e. for full public-private consortia in Call 2)
 - **Short proposal:** for first stage of two-stage calls (for ‘public’ consortia in Call 2, i.e. including only participants receiving funding)

Proposal template: *indicative* content

Section	Short proposal	Full proposal
1. Excellence		
1.1 Objectives and ambition	Yes – e.g. 3 pages	Yes – e.g. 4 pages
1.2 Methodology	Yes – e.g. 8 pages	Yes – e.g. 16 pages
2. Impact		
2.1 Project's pathway towards impact	Yes – e.g. 4 pages	Yes – e.g. 5 pages
2.2 Measures to maximise impact	No	Yes – e.g. 5 pages
2.3 Summary	No	
3. Quality and efficiency of the implementation	Yes	
3.1 Workplan and resources	Outline – e.g. 3 pages	Yes – e.g. 17 pages incl. table
3.2 Capacity of participants and consortium as a whole	Yes – e.g. 3 pages	Yes – e.g. 3 pages
<u>TOTAL page limit</u>	20 pages	50 pages
+ Annexes and tables	No	Yes

Full proposal tables

Table 3.1a: List of work packages (*also in Short proposal*)

Table 3.1b: Work package description

Table 3.1c: List of Deliverables

Table 3.1d: List of milestones

Table 3.1e: Critical risks for implementation

Table 3.1f: Summary of staff effort

Table 3.1g: 'Subcontracting costs' items

Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

Table 3.1i: 'Other costs categories' items (e.g. internally invoiced goods and services)

Table 3.1j: 'In-kind contributions' provided by third parties

Table 3.1k: Financial contributions

Table 3.1l: Non-EU in-kind contributions to operational activities

Table 3.1m: In-kind contributions to additional activities (IKAA)

Full proposal annexes

- **CONSORTIUM SELF-DECLARATION REGARDING THE IHI JU ELIGIBILITY CONDITION:**
Costs related to contributions (IKOP, IKAA and FC) provided by participants in the proposed action shall amount to at least 45% of the total eligible costs of the action and related IKAA.
- **PARTICIPANT TYPE:** participant type, sector, industry type
- **IKAA:** Annex describing the project related additional activities
- **CLINICAL TRIALS:** Annex with information on clinical trials
- **FINANCIAL SUPPORT TO THIRD PARTIES:** Annex with information on financial support to third parties.
- **CALLS FLAGGED AS SECURITY SENSITIVE:** Annex with information on security aspects.
- **ETHICS:** ethics self-assessment should be included in proposal part A. However, in calls where several serious ethics issues are expected, the character limited in this section of proposal part A may not be sufficient for participants to give all necessary information. In those cases, participants may include additional information in an annex to proposal part B.

Key message

- **Single-stage** - open process:

- Now: form consortia to submit proposals in September, please read topic texts carefully
- 14 June: use the Brokerage event for networking
- You may already reach out to public & private participants based on the published draft topics www.ih.europa.eu/apply-funding/future-opportunities

- **Two-stage:**

- public consortia only submit proposals in September,
- public-private consortia to then write full proposals from November-December onwards
- Companies cannot interact with participants applying for funding

3. Industry contribution: IKOP, IKAA, contributions from outside the EU

What is it, how is it planned, how is it valued, how is it reported?

14:30-15:45

Gaëlle Lanckmans (IHI)





Industry contributions

Guidance for IKOP, FC, IKAA, non-EU

Industry contributions

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

Eligible costs incurred in implementing an IHI project

- **FC** - Financial contribution

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

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

Costs for implementing additional activities

Private
members



Contributing
Partners



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



IKOP

In-Kind contribution for OPerational activities

General rule

Companies providing IKOP are subject to the same rights and obligations as any other beneficiary signing the GA

- Same cost eligibility criteria
- Same costs types allowed
- Same rules for project reporting

...

HE Cost Eligibility criteria (Art 6 MGA)

Costs must be:

- **Actual** (real, not estimated or budgeted)
- Incurred during the project lifetime (start date – end date)
- **Connected** to the action as described in DoA and **necessary** for its implementation (Annex 1)
- Foreseen in the estimated **budget** (Annex 2)
- **Reasonable**, justified and comply with the principle of sound financial management

...

HE Cost Eligibility criteria (Art 6 MGA)

...

- Identifiable and **verifiable** (auditable)
- Recorded in the **accounts** of the beneficiary
- In line with **usual** cost accounting **practices** of the beneficiary
- In line with the **accounting standards** of the country where the beneficiary is established
- they must comply with the applicable **national law** on taxes, labour and social security

Types of project costs

- Personnel costs
- Subcontracting costs
- Purchase costs: Travel and subsistence, Equipment, Other goods, works and services
- Other cost categories
 - Financial support to third parties,
 - Internally invoiced goods and services,
 - Transnational access to research infrastructure unit costs,
 - Virtual access to research infrastructure unit costs.
- Indirect costs: flat-rate of 25% of the eligible direct costs (excl. subcontracting costs)

Personnel costs

Cost of employee (most common case)

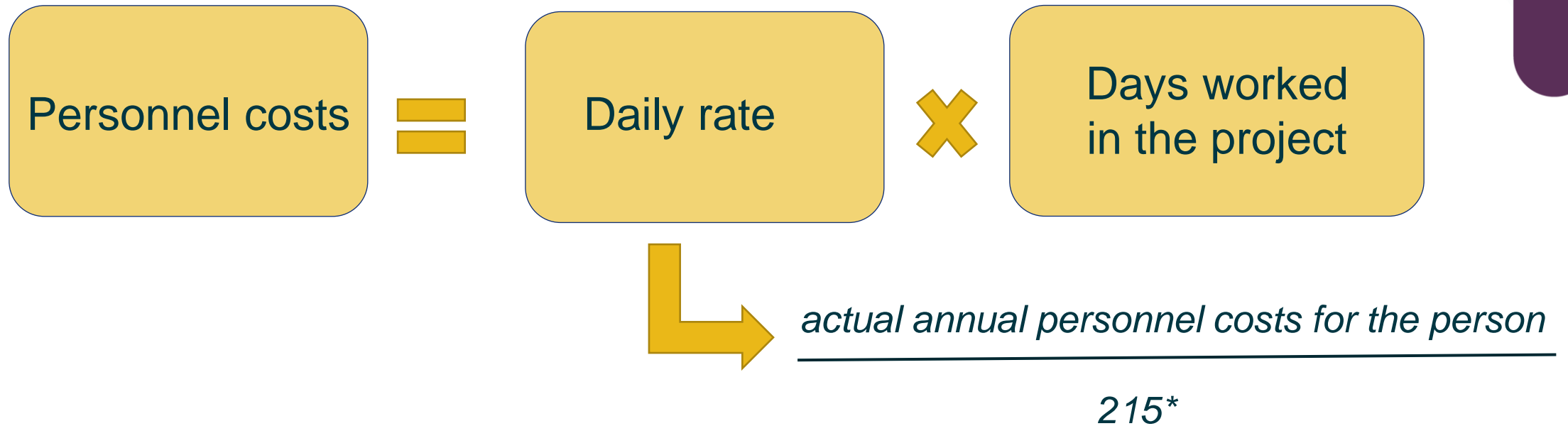
2 options:

- Use of actual costs
 - Use of average personnel costs (unit cost according to usual cost accounting practices)
-
- No distinction at proposal stage: Total estimated Personnel costs to be specified
 - Distinction (actual/unit cost) made at Grant Agreement Preparation (GAP) stage

Personnel costs

Cost of employee (most common case)

Option 1: Actual costs



Personnel costs

Cost of employee (most common case)

Option 2: Unit cost according to usual cost accounting practices

- The general eligibility conditions must be fulfilled (art 6)
- The daily rate must be calculated
 - according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria
 - using the actual personnel costs recorded in the beneficiary's accounts
 - excluding any ineligible costs or costs already included in other budget categories (so, it should exclude indirect costs!)

Personnel costs

Keeping records

- Time worked on the project must be documented
 - Either use Time-sheets (paper or computer-based) or sign a monthly declaration ([template](#))
 - In both cases: dated and signed at least monthly by the person working on the project and his/her supervisor

If Unit cost: keep records that show that the daily rate does not include indirect costs or any other direct cost already foreseen in other cost categories (e.g. travel costs)

Subcontracting costs

- Third party carrying part of the work on action tasks for the Beneficiary
- Contractual link between subcontractor and Beneficiary
- Only a limited part of the action can be subcontracted
- Selection of subcontractor: follow your usual practice, ensure the best value for money (or lowest price if appropriate) and no conflict of interest
- Subcontracting between beneficiaries or to affiliated entities is not allowed

Purchase costs

- Travel, accommodation and subsistence
- Equipment (depreciation cost – part used for the project)
- Other goods, works or services, if necessary to implement the action - normally limited in scope (If a contract covers the implementation of action tasks, this will be considered as a case of subcontracting - see Article 6.2.B)

Indirect costs

- Fixed flat rate calculated automatically as 25% of the eligible direct costs (except subcontracting costs and other specific cost categories, if any)
- Also applies to companies providing IKOP (\neq IMI2)
- No indirect costs should be included in the calculation of Personnel costs (no double counting)

Non-EU IKOP

- Consisting of eligible costs incurred in third countries OUTSIDE the EU or HE-Horizon Europe associated countries
- EU: 27 countries
- Third Countries Associated (AC) to Horizon Europe: (as of 15.04.2022)
 - 12 HE associated countries: Armenia, Bosnia and Herzegovina, Georgia, Iceland, Israel, Kosovo, Moldova, Montenegro, North Macedonia, Norway, Serbia, Turkey
 - Ongoing agreements: Albania, Faroe Islands, Morocco, Tunisia, Ukraine, United Kingdom
 - Switzerland and UK:
 - currently not covered by an arrangement
 - If not AC at the time of the GA signature → IKOP is Non-EU

Non-EU IKOP

- Criteria: where the underlying activities are carried out. Does not take into account where the company is established.
- Limit of **20%** Non-EU IKOP at IHI JU **Programme level**
- **First IHI Call: limit at Project level – see with Industry**
- Only IKOP can be Non-EU
- FC is always considered EU
- IKAA can only be EU

Affiliated entities (Art 8 MGA)

- Entities that have a legal link (already prior to the project) with the main entity
- Do not sign the GA but are part of the consortium and are treated like beneficiaries – have the same obligations: have their own financial statement, must provide their own CCS/CFS, must contribute to the technical report, must submit deliverables, etc)
- Beneficiary's obligations under the GA also apply to its affiliated entity(ies)
- To add affiliated entity(ies) in a project: an amendment of the GA is needed

Financial Contributions (FC)

Financial contributions (FC)

- Cash contributions made to Beneficiary of the same consortium to fund eligible costs incurred by that Beneficiary in implementing the project
- To cover costs that are not already reimbursed by the IHI JU
- Based on a legal agreement between the two parties (in DoA – Annex 1 of GA or separate legal agreement)
- Explained in Proposal (FC provider, FC recipient, activity to perform with the FC received) and set in Budget table
- Such financial contribution must also be reported by the Beneficiary receiving it as receipt in the final period of the project



IKAA

In-Kind contribution for additional activities

IKAA Definition

Cumulative criteria to fulfil IKAA conditions:

- Contribute to IHI JU's objectives and tasks;
- be set out in the IKAA Plan annexed the IHI JU WP (or when necessary in a plan included to relevant project proposals);
- not be funded by the IHI JU or any other Union funding programme;
- be carried out in the Union or in countries associated with HE (i.e. cannot be non-EU);
- can be of two types:
 - Programme specific: contribute to the uptake of results from IHI JU, IMI2 JU, IMI JU projects or that have a significant added value for the Union.
 - Project specific: contribute towards the achievement of objectives of IHI JU funded projects, or the dissemination, sustainability or exploitation of IHI JU project results

Only Industry members. Not for Contributing Partners

Threshold= Max 40% Industry members in-kind contributions (IKOP + IKAA) for the whole IHI Programme

IKAA vs IKOP

- IKOP: eligible costs in implementing project tasks/activities as described in the DoA
- IKAA: costs for additional activities that are not project tasks (i.e. not IKOP)
- It is up to the consortium to identify IKOP and IKAA for their respective project

IKAA Plan and eligibility timeframe

- Programme level AA
 - IKAA Plan is Annual: AA and their annual estimated value for year N have to be set out in the IKAA Plan annexed to the annual IHI Work Programme
 - So, in case AA run several years, it should be mentioned in several consecutive IKAA Plan (for year N, for year N+1,...)
 - Costs should be incurred during the year foreseen for the related AA as specified in the IKAA Plan
 - IKAA Plan to be provided by Industry members by end of year N-1 (exception for 2022)
- Project level AA
 - IKAA Plan should be provided in project proposal (fully proposal for 2-stage calls)
 - IKAA Plan is Pluriannual: AA and their total estimated value (not annual) are approved at projects selection (award decision)
 - Costs may be incurred between the date of submission of the (full) proposal and up to 2 years after project end date*

IKAA Plan

- Approved by the IHI Governing Board, following consultation of advisory bodies (SRG and SIP)
- Two IKAA Plan Proposal templates (xls): Programme and Project level
- Contains both publishable and confidential information
 - Confidential info (yellow): only disclosed to IHI GB, IHI Office, project evaluators
Company legal name, affiliation type, confidential AA description
 - Public info (blue): IHI Work Programme (WP) and Annual Activity Report (AAR)
AA Category, AA type, publishable AA description, link to IHI objectives...(see next slide)

IKAA Plan Proposal - Programme level

Company legal name	Participant Identification code (PIC)	Industry Affiliation	Category of AA	Envisaged type of AA (Select from "List of AA Types" tab)	<u>Publishable</u> Description of the Additional Activities	<u>Confidential</u> Description of the Additional Activities	Total duration of the AA	Link to partnership's objectives / KPIs	Link to partnership's project/ topic (if applicable) (Insert [Project name(s)] if the AA contributes to the uptake of results from IHI JU/IMI2 JU/IMI1 JU project(s))	Estimated Union added-value or impact* [Free text]	Estimated annual value (Insert [amount] in EUR)	Estimated TOTAL value (Insert [amount] in EUR)
		COCIR/EFPIA/EuropaBio/Med Tech Europe/VaccinesEurope										
Total Estimated IKAA											Total	Total

*may be shared by the IHI GB with the SRG and the SIP if it is necessary to provide their opinion on the concerned AA

IKAA Plan in Project (full) Proposal

Participant number in Project	Company legal name	Category of Additiona Activities [please select]	Type of Additional Activities	<u>Confidential</u> Description of the Additional Activities	<u>Publishable</u> Description of the Additional Activities	Estimated period for the AA* (before/during/after project implementation)	Link to IHI Project How the AA contributes towards the achievement of objectives of the IHI JU funded project, or the dissemination, sustainability or exploitation of the IHI JU project results.	Estimated TOTAL value (Insert [amount] in EUR)
confidential	confidential	public	public	confidential	public	confidential	public	<i>public</i>

*may be shared by the IHI GB with the SRG and the SIP if it is necessary to provide their opinion on the concerned AA

AA categories and AA types

AA Categories (fixed)	AA Types (can be adjusted)
1. Support to additional R&I	<ul style="list-style-type: none"> Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe Low-TRL research activities, feeding into Partnership projects (Horizon Europe projects and Horizon 2020 projects under a predecessor partnership) Support to industry-academia cooperation
2. Scale-up of technologies	<ul style="list-style-type: none"> Pre-commercial trials and field tests Validation of the technology in a lab or in the 'real' operational environment Scale-up and uptake of results from Partnership projects into product / Proof of Concept Bridging between projects with real-field implementation instruments or initiatives
3. Demonstrators	<ul style="list-style-type: none"> Carry out demonstrations of a prototype in an operational environment, with the view to local, regional and Union-wide deployment
4. Creating new business opportunities	<ul style="list-style-type: none"> Invest in start-ups, spin-offs on solutions developed within the projects Start incubators/accelerators Matchmaking between different start-ups, SMEs, participating companies, stakeholders Investments in procurement of innovative solutions
5. Training and skills development	<ul style="list-style-type: none"> Joint training programmes Contributing to the identification of gaps and needs in skills development and training
6. Contribution to the development of new standards, regulations and policies	<ul style="list-style-type: none"> Contributions to groups that develop new standards/standardisation efforts Contribution to groups that develop input to public policy-making in the area of the new product/innovation (e.g. governmental ministries)
7. Supporting ecosystem development	<ul style="list-style-type: none"> Industrial partner engages with a regional technology cluster / innovation hub (supports capacity building and knowledge sharing) Industry partners provide mentoring/ coaching for SMEs Investments in synergies with other European Partnerships and with other initiatives at international, EU, national, regional level (including missions) Activities to develop the ecosystem at EU/national/regional or international level that will enable or accelerate the development of the solutions from the Partnership Activities to support open science, open innovation and data sharing
8. Communication, dissemination, awareness raising, citizen engagement	<ul style="list-style-type: none"> Investment in societal uptake and citizen engagement Contribution (generation/collaboration) to publications Organisation of conferences and webinars on specific topics, networking events Knowledge building and repository Activities to ensure a stronger engagement at local level with regions, cities, citizens and other local stakeholders
9. Other	

Build now your IKAA Plan for year 2022

- September 2022: Amendment of Work Programme 2022 foreseen → should include IKAA Plan 2022 for Programme-specific AA
- Information in the Plan should not be too detailed (avoid long description), just sufficient to allow assessment of IKAA criteria (slide 'IKAA Definition')
- Important to identify ALL additional activities (AA) for 2022
 - Only costs for AA foreseen in the Plan for 2022 can be accepted by IHI
 - Adding new AA not yet foreseen in the Plan requires a WP amendment (which is not foreseen to happen any more in 2022)

Deviations from the IKAA Plan

- IKAA Plan to be amended when major deviations:
 - New AA not yet foreseen in the IKAA Plan
 - Significant modification in the scope/purpose of foreseen AA in the Plan, leading de facto to a new AA
 - Increase of the total estimated value of the AA by more than 25% and increase of at least EUR 50,000
 - AA cancelled leading to significant decrease of the estimated budget of at least EUR 50,000

IKAA Cost valuation

- Costs are determined in compliance with the usual cost accounting practices of the entity
- In principle not subject to HE's eligibility rules unless the entity so requires and justifies
- IKAA can consist of any types of costs as far as it is necessary for the implementation of an approved AA (e.g. personnel costs, subcontracting costs, financial contributions, other direct costs, etc...)
- IHI GB can approve **simplifying methods** such as lump-sums or unit costs if deemed necessary for simplification, cost effectiveness and protection of confidential commercial data
 - Private members to identify potential activities and send Proposal to IHI GB including:
 - Justification to demonstrate the 3 above criteria are fulfilled
 - Clear cost calculation method

IKOP vs IKAA

	IKAA		IKOP
	Project specific IKAA	Programme-specific IKAA	
Scope	Costs in implementing additional activities that are <u>not</u> project tasks		Eligible costs in implementing <u>project tasks</u> (as specified in Annex 1-DoA of the Grant Agreement)
Eligibility Timeframe	Costs incurred from (full) proposal submission date and up to 2 years after project end date.	Costs incurred during IHI JU Programme implementation. Costs must be incurred during the year foreseen in the annual IKAA Plan annexed to the IHI JU WP of the concerned year.	Costs incurred during project implementation (from project start date to project end date)
Contributors	Only private members		Both private members and contributing partners
EU/ non-EU	<u>Only EU</u> : additional activities carried out in the Union or in associated countries to HE		EU and non-EU: project activities carried out in the Union, associated countries to HE or in third countries

IKOP vs IKAA

	IKAA		IKOP
	Project specific IKAA	Programme-specific IKAA	
Affiliated entity(ies)	One Reporting and one Certification for both the main Legal entity and its affiliated entity(ies)		<u>Separate</u> Reporting and separate Certification for main Beneficiaries and for its affiliated entity(ies)
Reporting deadline and content	Reporting due each year by 31 May of year N+1 For the costs incurred during the last calendar year (1 January - 31 December of year N)		Reporting due 60 days after the end of each reporting period For the costs incurred between the start date and the end date of each reporting period
Reporting tool	Activities and costs reported in a separate tool (to be developed by EC) Reporting template – under discussion at EC		Activities and costs reported in the project Periodic Report, via the Funding and tenders Portal.
Audit Certification	All IKAA should be certified to count for the matching. No minimum threshold. Certification template – under discussion at EC		If <u>no funding requested</u> : Certificate on the statements of contributions (CCS) required at the end of the project if IKOP+FC ≥ EUR 430 000 (per beneficiary or affiliated entity). <u>If requesting funding</u> : still to be clarified by EC

Budget Table (Proposal)

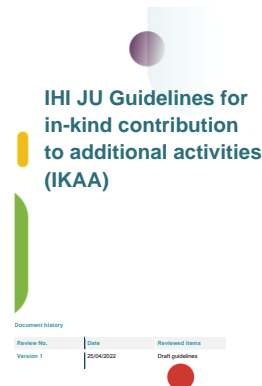
No	Participant name	Country	Estimated expenditure						Estimated income								
			Estimated eligible costs						Requested EU contribution			Revenues	Other sources of financing		Total estimated income		
									EU contribution to eligible costs			Income generated by the action	Financial contributions	Own resources			
			A. Personnel costs/€ (a1)	B. Subcontracting costs/€ (b)	C. Purchase costs			D. Other cost categories (dx) [specific cost categories]	E. Indirect costs/€ (e) = 25% of [(a1) + (c1) + (c2) + (c3) + (d7)]	Total eligible costs (h) = (a1) + (b) + (c1) + (c2) + (c3) + (d) + (e)	Funding rate (U)				Maximum EU contribution to eligible costs (i) = (U) * (h)	Requested EU contribution to eligible costs/€ (Requested grant amount) (m) (n)	(o)
			C.1 Travel and subsistence/€ (c1)	C.2 Equipment/€ (c2)	C.3 Other goods, works and services /€ (c3)												
1	Participant 1	NL															
2	Participant 2	LB															
	Affiliated Entity	LB															
3	Participant 3	DE															
	Associated Partner	AR															
Total																	

IHI specificities column to add:

- FC
- IKOP
- Non-EU IKOP
- IKAA

Reference documents

- [Model Grant Agreement](#) (MGA) for Horizon Europe, including Annex 5 applicable to JUs
- [Draft AGA/](#) annotated version (annotations not available for Annex 5)
- IKAA guidelines





Thank you for your attention

ihi.europa.eu



4. Building a project budget: financial and funding rules

15:45 – 16:30

Annika Eberstein (COCIR)



Disclaimer

This presentation is designed to facilitate the budgeting process and the necessary considerations in order to successfully launch projects. Ultimately, the scope and ambition of the proposed submissions will determine their success.

General principles

General principles of funding

- **Proposals** require a **balanced contribution (50/50) between the European Union and the Private Members**
 - ‘Private Members’ are members of the involved associations, i.e. EFPIA, EuropaBio, Vaccines Europe, COCIR and MedTech Europe
- **Contributions** to the partnership can only be made **by Private Members** and can consist of:
 - **IKOP**: In-Kind contributions On Projects, where **IKOP = Eligible costs – Reimbursed costs**
 - **IKA**: In-Kind contributions on Additional Activities
 - **Maximum 20% of overall contribution from non-EU**, where non-EU is only through IKOP
 - Financial contributions to administrative costs and monetary contributions to projects
- **Funding principles:**
 - **Two-stage:**
 - large companies (> 500 million annual turnover) cannot receive funding
 - SMEs affiliated to one of our associations: can choose to be either on (i) industry side (no funding) or (ii) public side (funding but no guaranteed seat in consortium)
 - **Single-stage: in principle all participants can request funding.**
 - EFPIA decided its members would not request funding, any exception would require prior approval by EFPIA (RIS group) prior to proposal submission.
 - Other sectors would request partial funding while preserving the 50/50 balance: details in next slides

Budget considerations

By default, industry associations agreed that **submitted proposals should be in line with in-kind ratios applicable at programme level** i.e.:

- IHI funding should be matched by in-kind contributions (50/50)
- IKAA could be up to 40% of total in-kind, IKOP should be at least 60%
- Non-EU could be up to 20% of IKOP

Flexibility can be considered but needs to be first checked between associations in advance.

In case of deviations, associations and their members will be asked to provide mitigations at programme level.

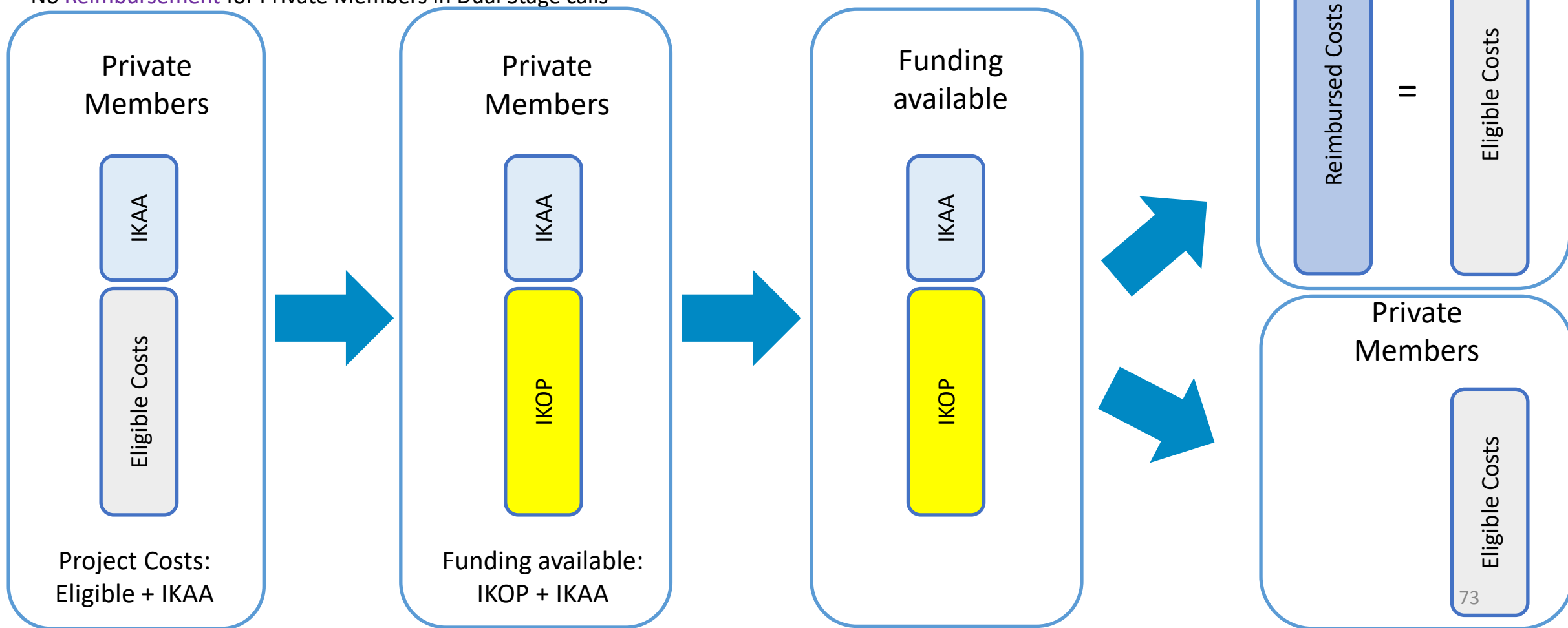
General principles of the proposal examples

- **In the following examples, funding rates are set as follows:**
 - Private Members
 - At 50% of eligible costs i.e. only for single stage calls, for EU participations, and for non-pharma companies
 - Non-Members
 - Non-profit (Univ., RTOs, ...) at 100% of eligible costs; Large companies at 50% of eligible costs (for single-stage only), and SMEs at 100% of eligible costs
- $IKOP = \text{Eligible costs} - \text{received funding}$
- IKAA is not eligible for funding

Proposals always need a 50/50 match of Private Member contributions (IKOP+IKAA) and EU contributions (funding)

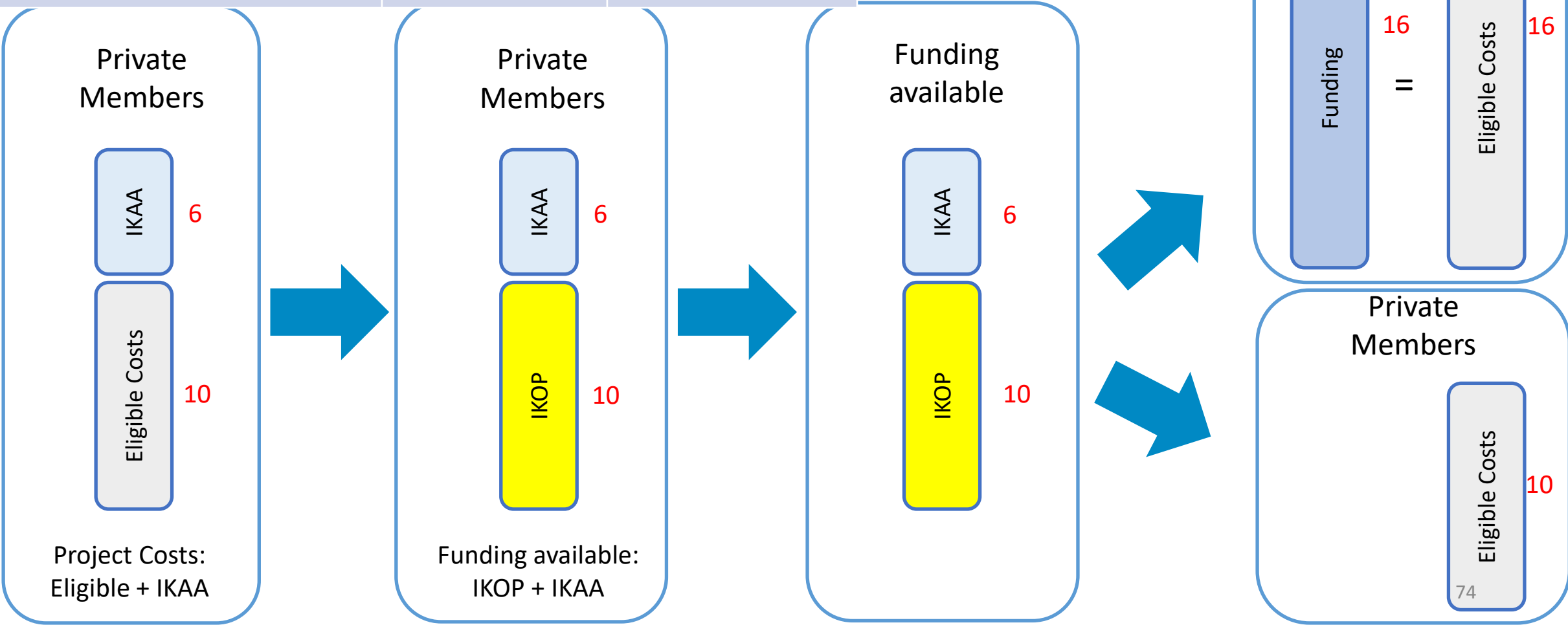
Schematic Example with Ground Rules for IHI

- Only Private Members can make contributions (IKOP + IKAA)
- Contribution = funding available
- IKOP = Eligible Costs – Reimbursed Costs
- $IKAA \leq 0.4 \times (IKAA + IKOP)$
- No Reimbursement for Private Members in Dual Stage calls



	Private Members	Non-Members
Project Costs: Eligible + IKAA	16 M	16 M
Reimbursed Costs	0 M	16 M
Contribution: IKOP + IKAA	16 M	0 M

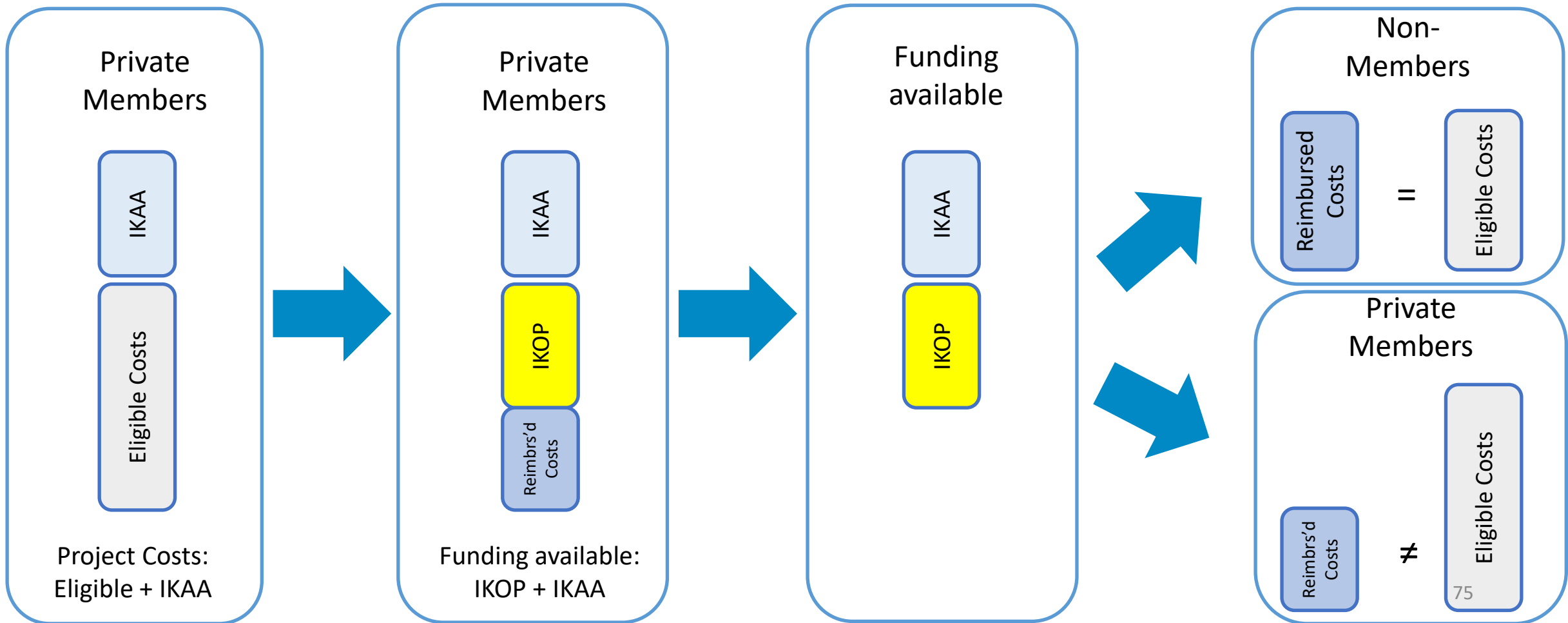
**EXAMPLE: Dual Stage call
Now with Example Figures**



Schematic Example with Ground Rules for IHI

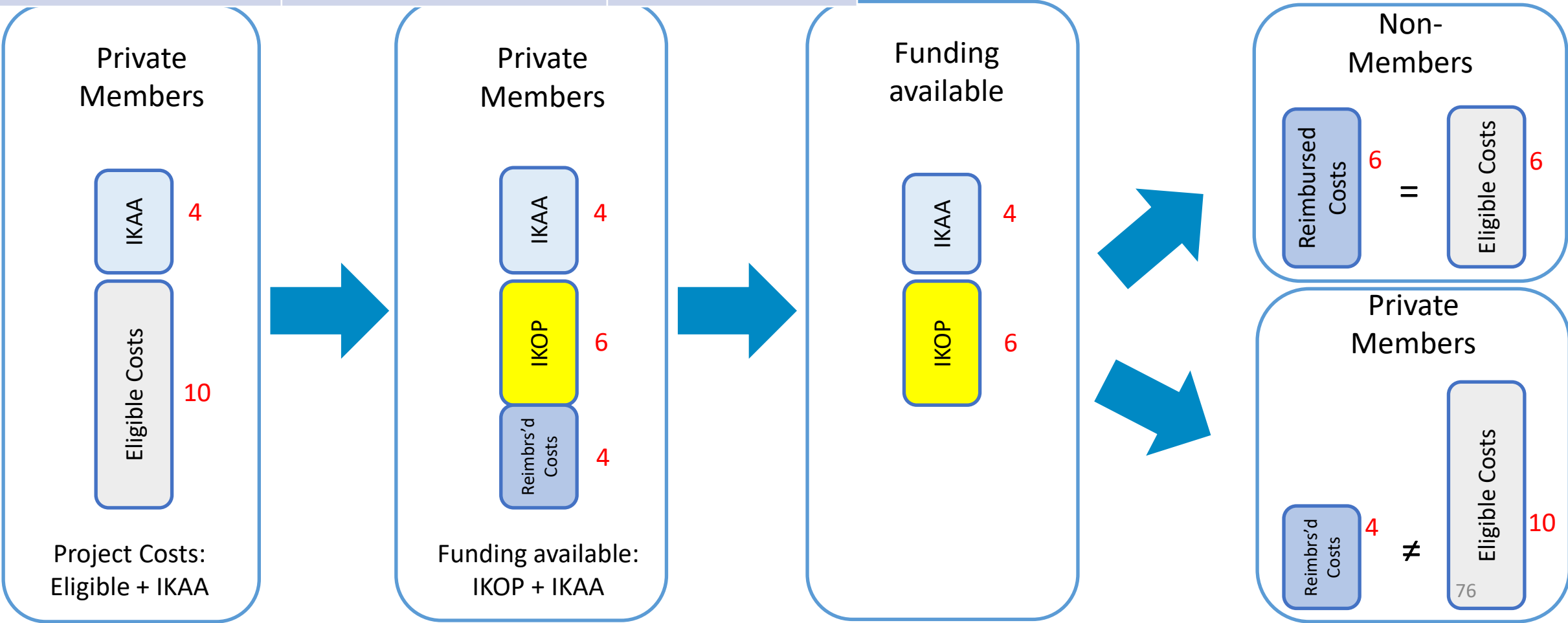
- Only Private Members can make contributions (IKOP + IKAA)
- Contribution = funding available
- $IKOP = \text{Eligible Costs} - \text{Funding}$
- $IKAA \leq 0.4 \times (IKAA + IKOP)$
- Funding for Private Members in Single Stage calls

EXAMPLE: Single Stage call



	Private Members	Non-Members
Costs (Eligible + IKAA)	14 M	6 M
Reimbursed Costs	4 M	6 M
Contribution	10 M	0 M

**EXAMPLE: Single Stage call
Now with Example Figures**



Examples

Examples

Five example projects are shown for demonstration purposes.

- Example A: **Single stage call** with **high academic** participation
- Example B: **Dual stage** call with high IKAA
- Example C: **Single stage** call with Private Member participation from non-EU

- *In annex to be provided after webinar*
 - *Example D: **Single stage** call with **moderate academic** participation*
 - *Example E: **Dual stage** call with low IKAA*

Example A

Single stage call, with high academic participation

EU funds available for targeted topic:	10,833,333
Matching needed by Private Members contributions:	10,833,333

Example – A (single stage call, high academic participation)

Step 1: Calculation of Private Member Contribution

- Private members contribution (IKOP+IKAA) should equal total amount of EU funding available to consortium;
- IKAA brings extra value to the consortium, but these costs are not reimbursable to private members. The added value of the contribution can be matched to non-private members for their costs to be reimbursed.

Private Member	Industry Association	Private Member Eligible Costs	Reimbursed Costs	IKOP	IKAA	Contribution (IKOP+IKAA) = EC funding available
A	COCIR	6,000,000	3,000,000	3,000,000	2,000,000	5,000,000
B	EFPIA	2,000,000	0	2,000,000	1,333,333	3,333,333
C	MTE	1,500,000	750,000	750,000	500,000	1,250,000
D	MTE	1,500,000	750,000	750,000	500,000	1,250,000
TOTALS		11,000,000	4,500,000	6,500,000	4,333,333	10,833,333

Example – A (single stage call, high academic participation)

Step 2: Calculation of Private Members Requested Reimbursement

- Once the requested reimbursement by private members is estimated, the remaining funding available for non-Members can be calculated
- The higher the IKAA (not eligible for reimbursement to private members) towards overall Contribution, the higher the funding available for non-private members

Private Member	Industry Association	Contribution (IKOP+IKAA)	Reimbursement Requested	Funding Remaining for non-Members (Contribution – Reimbursement)	Example: Specific cooperation links with non-members
A	COCIR	5,000,000	3,000,000	2,000,000	Non-Profit X Non-Profit Y Non-Profit Z SME
B	EFPIA	3,333,333	0	3,333,333	
C	MTE	1,250,000	750,000	500,000	
D	MTE	1,250,000	750,000	500,000	
TOTALS		10,833,333	4,500,000	6,333,333	

Example – A (single stage call, high academic participation)

Step 3: (Double) Check eligibility and composition of consortium

- **Eligibility**

- Reimbursed costs \leq Contribution (In this example: Reimbursed Costs Contribution = 10.83M, Contribution = 10.83M)
- $IKAA \leq 0.4 \times (IKAA + IKOP)$

- **Consortium composition**

- Based on funding that remains available, bring on board non-private members
- Make sure the requested funding by non-private members remains within the limits available to the consortium

Example – A (single stage call, high academic participation)

Summary

Consortium Partner	Industry Association	Eligible Costs	Reimbursed Costs	IKOP	IKA	Contribution (IKOP+IKA)	Total Costs (Elig. + IKA)
Private A	COCIR	6,000,000	3,000,000	3,000,000	2,000,000	5,000,000	8,000,000
Private B	EFPIA	2,000,000	0	2,000,000	1,333,333	3,333,333	3,333,333
Private C	MTE	1,500,000	750,000	750,000	500,000	1,250,000	2,000,000
Private D	MTE	1,500,000	750,000	750,000	500,000	1,250,000	2,000,000
Non-Profit X	n/a	1,333,333	1,333,333	0	0	0	1,333,333
Non-Profit Y	n/a	3,000,000	3,000,000	0	0	0	3,000,000
Non-Profit Z	n/a	1,000,000	1,000,000	0	0	0	1,000,000
SME	n/a	1,000,000	1,000,000	0	0	0	1,000,000
TOTALS		17,333,333	10,833,333	6,500,000	4,333,333	10,833,333	21,666,666

Example B

Dual stage call, with high In-Kind on Additional Activities IKAA

EU funds available for targeted topic:	8,333,333
Matching needed by Private Members contributions:	8,333,333

Example – B (dual stage call, high IKAA)

Step 1: Calculation of Private Member Contribution

- Private members contribution (IKOP+IKAA) should equal total amount of EU funding available to consortium
- IKAA brings extra value to the consortium, but these costs are not reimbursable to private members. The added value of the contribution can be matched to non-private members for their costs to be reimbursed.

Private Member	Industry Association	Eligible Costs	Funding	IKOP	IKAA	Contribution (IKOP+IKAA)
A	EFPIA	3,000,000	0	3,000,000	2,000,000	5,000,000
B	COCIR	1,000,000	0	1,000,000	666,666	1,666,666
C	MTE	500,000	0	500,000	333,333	833,333
D	MTE	500,000	0	500,000	333,333	833,333
TOTALS		5,000,000	0	5,000,000	3,333,333	8,333,333

Example – B (dual stage call, high IKAA)

Step 2: Calculation of Private Members Requested Reimbursement

- All the contribution from private members is dedicated to the funding of non-private members because there is no reimbursement of private members

Private Member	Industry Association	Contribution (IKOP+IKAA)	Requested Funding	Remaining Funding
A	EFPIA	5,000,000	0	5,000,000
B	COCIR	1,666,666	0	1,666,666
C	MTE	833,333	0	833,333
D	MTE	833,333	0	833,333
TOTALS		8,333,333	0	8,333,333

Example – B (dual stage call, high IKAA)

STEP 3: (Double) Check eligibility and composition of consortium

- **Eligibility:**

- Requested funding \leq contribution
- $IKAA \leq 0.4x (IKAA + IKOP)$

Consortium composition:

- Based on funding made available, call is launched to bring on board non-members
- Make sure the requested funding by non-members remains within the limits available to the consortium

Example – B (dual stage call, high IKAA)

Step 4 Calculation of Non-Private Member Re-imbursement

Non-Member	Eligible Costs	Requested Funding	Contribution (IKOP+IKAA)
Non-Profit X	2,000,000	2,000,000	0
Non-Profit Y	2,500,000	2,500,000	0
Non-Profit Z	3,000,000	3,000,000	0
SME	833,333	833,333	0
TOTALS	8,333,333	8,333,333	0

Example – B (dual stage call, high IKAA)

Summary

Consortium Partner	Industry Association	Eligible Costs	Funding	IKOP	IKAA	Contribution (IKOP+IKAA)	Total Costs (Elig. + IKAA)
Private A	EFPIA	3,000,000	0	3,000,000	2,000,000	5,000,000	5,000,000
Private B	COCIR	1,000,000	0	1,000,000	666,666	1,666,666	1,666,666
Private C	MTE	500,000	0	500,000	333,333	833,333	833,333
Private D	MTE	500,000	0	500,000	333,333	833,333	833,333
Non-Profit X	n/a	2,000,000	2,000,000	0	0	0	2,000,000
Non-Profit Y	n/a	2,500,000	2,500,000	0	0	0	2,500,000
Non-Profit Z	n/a	3,000,000	3,000,000	0	0	0	3,000,000
SME	n/a	833,333	833,333	0	0	0	833,333
TOTALS		13,333,333	8,333,333	5,000,000	3,333,333	8,333,333	16,666,666

Example C

Single stage call, with participation from members with activities in non-EU countries

EU funds available for targeted topic:	10,000,000
Matching needed by Private Members contributions:	10,000,000

Example – C (single stage call, with participation from non-EU)

Step 1: Calculation of Private Member Contribution

- Private members contribution (IKOP+IKAA) should equal total amount of EU funding available to consortium
- IKAA brings extra value to the consortium, but these costs are not reimbursable to private members. The added value of the contribution can be matched to non-private members for their costs to be reimbursed.

Private Member	Industry Association	Eligible Costs	Funding	IKOP	IKAA	Contribution (IKOP+IKAA)
A	COCIR	6,000,000	3,000,000	3,000,000	1,000,000	4,000,000
B	EFPIA	2,500,000	0	2,500,000	500,000	3,000,000
A' (USA)	COCIR	1,000,000	0	1,000,000	0	1,000,000
C	MTE	3,500,000	1,750,000	1,750,000	250,000	2,000,000
TOTALS		12,000,000	4,750,000	8,250,000	1,750,000	10,000,000

Example – C (single stage call, with participation from non-EU)

Step 2: Calculation of Private Members Requested Reimbursement

- Once the requested reimbursement by private members is estimated, except for non-eu activities, the remaining funding available for non-members can be calculated
- The higher the IKAA (not eligible for reimbursement to private members) towards overall Contribution the higher the funding available for non-private members

Private Member	Industry Association	Contribution (IKOP+IKAA)	Requested Funding	Remaining Funding	Links with non-members
A	COCIR	4,000,000	3,000,000	1,000,000	Non-Profit X Non-Profit Y Non-Profit Z SME
B	EFPIA	3,000,000	0	3,000,000	
A'(USA)	COCIR	1,000,000	0	1,000,000	
C	MTE	2,000,000	1,750,000	250,000	
TOTALS		10,000,000	4,750,000	5,250,000	

Example – C (single stage call, with participation from non-EU)

STEP 3: (Double) Check eligibility and composition of consortium

- **Eligibility:**

- Requested funding \leq contribution
- $IKAA \leq 0.4 \times (IKAA + IKOP) \rightarrow IKAA = 0.175 \times (IKAA + IKOP)$
- % IKOP Contribution from non-EU $\leq 20\%$ (at 12% in this example)

Consortium composition:

- Based on funding that remains available, bring on board non-members
- Make sure the requested funding by non-members remains within the limits available to the consortium

Example – C (single stage call, with participation from non-EU)

Summary

Consortium Partner	Industry Association	Eligible Costs	Funding	IKOP	IKAA	Contribution (IKOP+IKAA)	Project Costs (Elig. + IKAA)
Private A	COCIR	6,000,000	3,000,000	3,000,000	1,000,000	4,000,000	7,000,000
Private B	EFPIA	2,500,000	0	2,500,000	500,000	3,000,000	3,000,000
Private A' (USA)	COCIR	1,000,000	0	1,000,000	0	1,000,000	1,000,000
Private C	MTE	3,500,000	1,750,000	1,750,000	250,000	2,000,000	3,750,000
Non-Profit X	n/a	1,250,000	1,250,000	0	0	0	1,250,000
Non-Profit Y	n/a	3,000,000	3,000,000	0	0	0	3,000,000
Non-Profit Z	n/a	250,000	250,000	0	0	0	250,000
SME	n/a	750,000	750,000	0	0	0	750,000
TOTALS		18,250,000	10,000,000	8,250,000	1,750,000	10,000,000	20,000,000

Conclusions

Additional remarks

- For single- or dual stage calls, the higher IKAA declared by members, the higher the funding available for non-members (but consider the ceiling of 40% of total contributions!)
- Other solutions to reach the 50/50 matching of industry to EU contributions on project level can be achieved e.g. through:
 - Lowering funding rates for Private Members to generate more IKOP; hence less IKAA needed and/or more funding is available to others
 - Lowering funding rates for non-members, thereby consuming less funding to be compensated by contributions from Private Member (unlikely but theoretically possible)
- Choice for low or high IKAA will depend on various factors, besides funding rates and financial contributions:
 - Partners (non-members) needed to fulfill project scope
 - Types of activities to serve as contributions
 - Timing of activities (e.g. IKAA allowed up to two years after project end)
 - ...

Questions

- Submitted prior to the webinar:
 - For IKAA activities where affiliated entities contribute – the reading of guidance document suggests that such contributions can be reported through the main legal entity (like in IMI2), but can it then also be assumed that these affiliates DO NOT REQUIRE to be registered in the portal with a PIC/LEAR/LSIGN/FSIGN etc? Currently we assume this is indeed not the case, but might be good to also confirm this.
 - In IMI2 project development efforts up to the call launch were eligible for reporting (under the SGG umbrella). The team seeks clarification whether such hours are no longer eligible now.
 - Personnel costs: what about bonuses paid in March...?

5. Building a consortium: what other legal conditions do I need to consider?

16:30-16:55

Christophe Verbruggen (Janssen Pharmaceutical' Companies of J&J)

...



Objectives

- Inform members on the **general legal framework** with which the projects are to be carried out in compliance with.
- **Inform members on the agreements required** to enter into a IHI project.
- Basic overview of **IPR rules** and typical **project governance setup**

IHI - general legal framework

➤ **Horizon Europe Regulation (HER) nr 2021/695**

- Establishing Horizon Europe
- Rules for Participation & Dissemination
<http://data.europa.eu/eli/reg/2021/695/oj>

➤ **Single Basic Act (SBA) nr 2021/2085**

- Establishing all joint undertakings under HE, including IHI
- Additional Rules on In-Kind Contributions, non-EU participation,...
<http://data.europa.eu/eli/reg/2021/2085/oj>

➤ **Industry association's commitments & arrangements**

- Joint commitment from the individual associations (Dec 2021)
- Inter-association agreement (arranging responsibilities and each' share in anticipated in-kind)
- Intra-association arrangements in some associations (e.g. EFPIA, on consequences of withdrawal from an ongoing project)

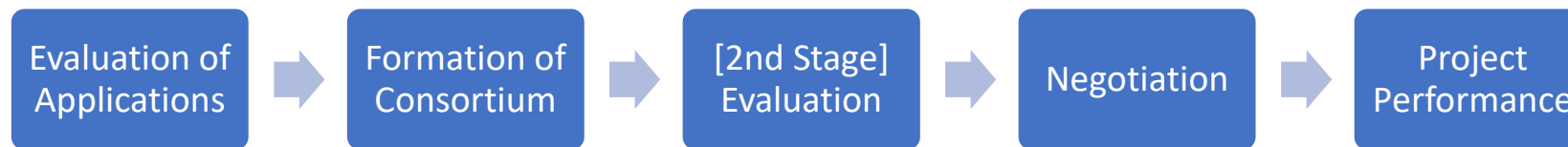
IHI - contractual framework

- **[One-way CDA]**

- [(with JU) to receive 2-staged proposals]
- Prepared by JU
- JU Template

- *** Consortium Arrangement**

- * Grant Agreement (GA)
 - * With JU
 - * Mainly financial
- * Consortium Agreement (CA)
 - * Governance, IP and Access Rights



- *** Multi-Party CDA**

- * Supported by "Coordinator" (1-staged) "Project Leader" (2-staged)
- * Industry Template
- * To allow confidential negotiation

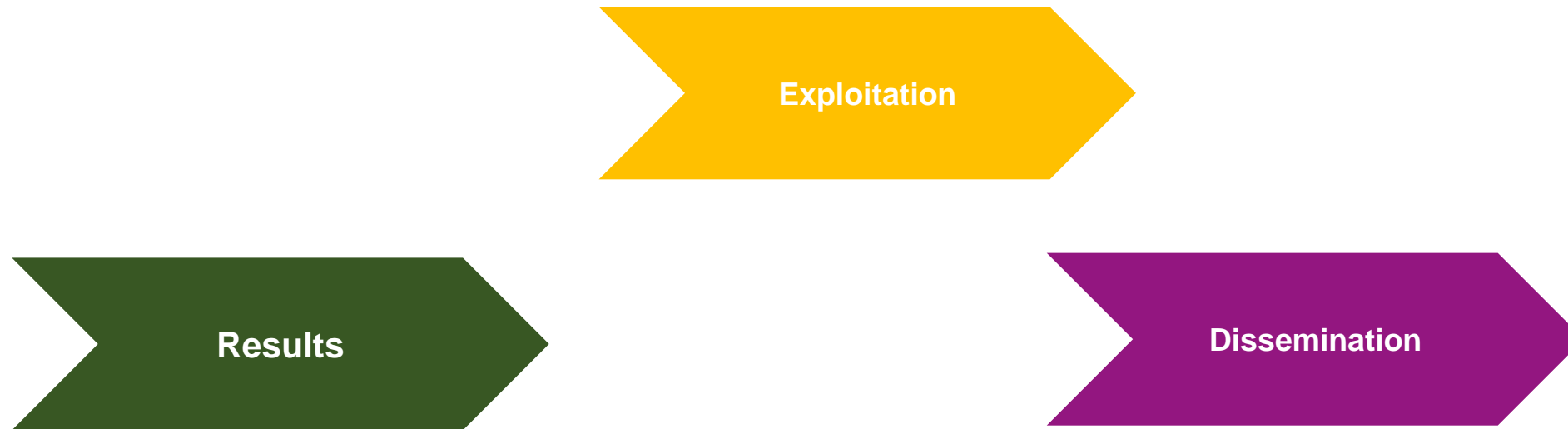
- *** Amendments**

- * To GA
- * To CA

- *** Supporting Agreements** e.g. DTA, Consultants...etc)

- *** Results Ownership List**

Results – Exploitation – Dissemination (3 main principles)



*Outcomes of
'Additional Activities'
are not 'Results'*

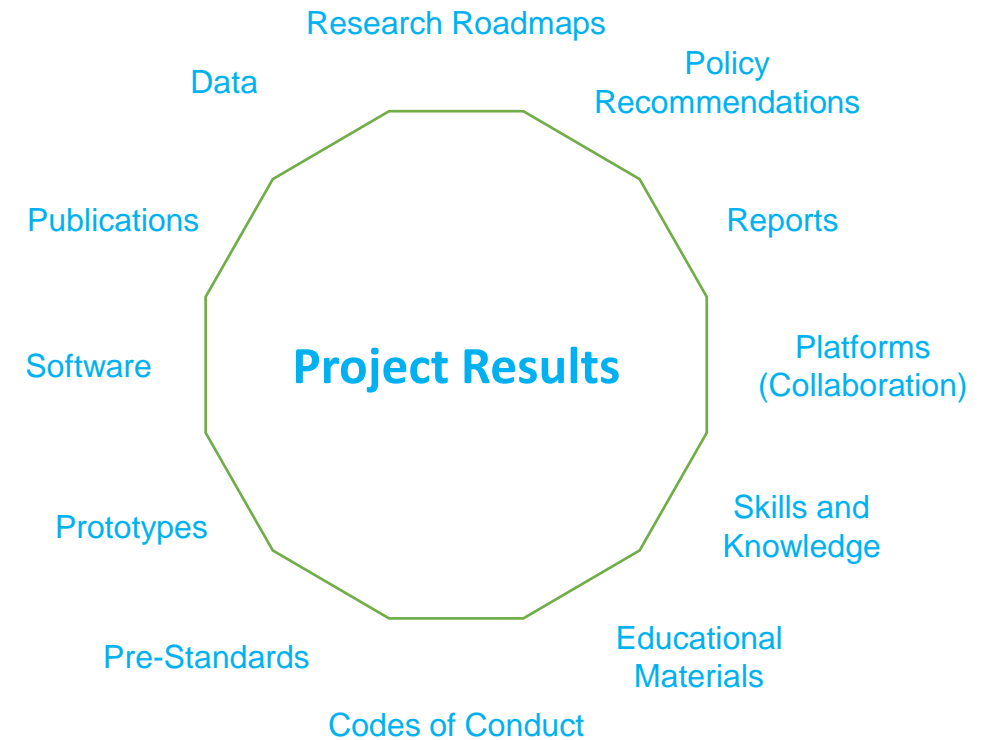
Results

'Results' means any tangible or intangible effect/output 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...

= more broadly defined then before

Research Communities

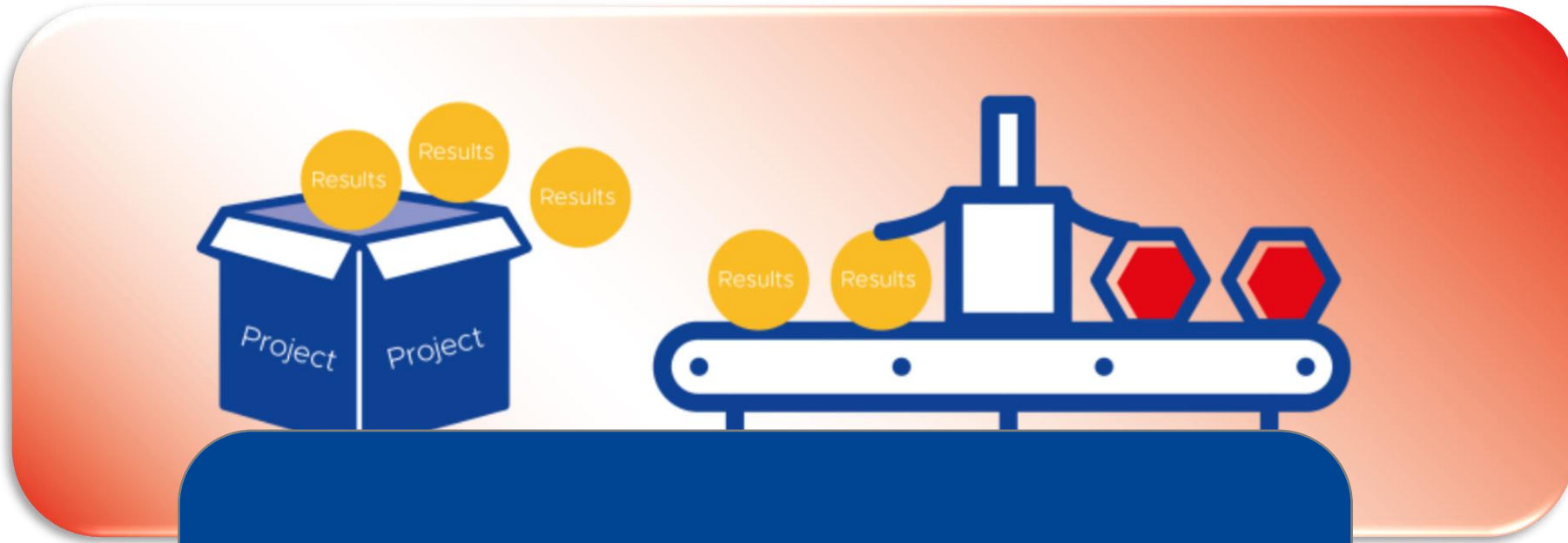
MS, EU Policymakers



Industry, Innovators

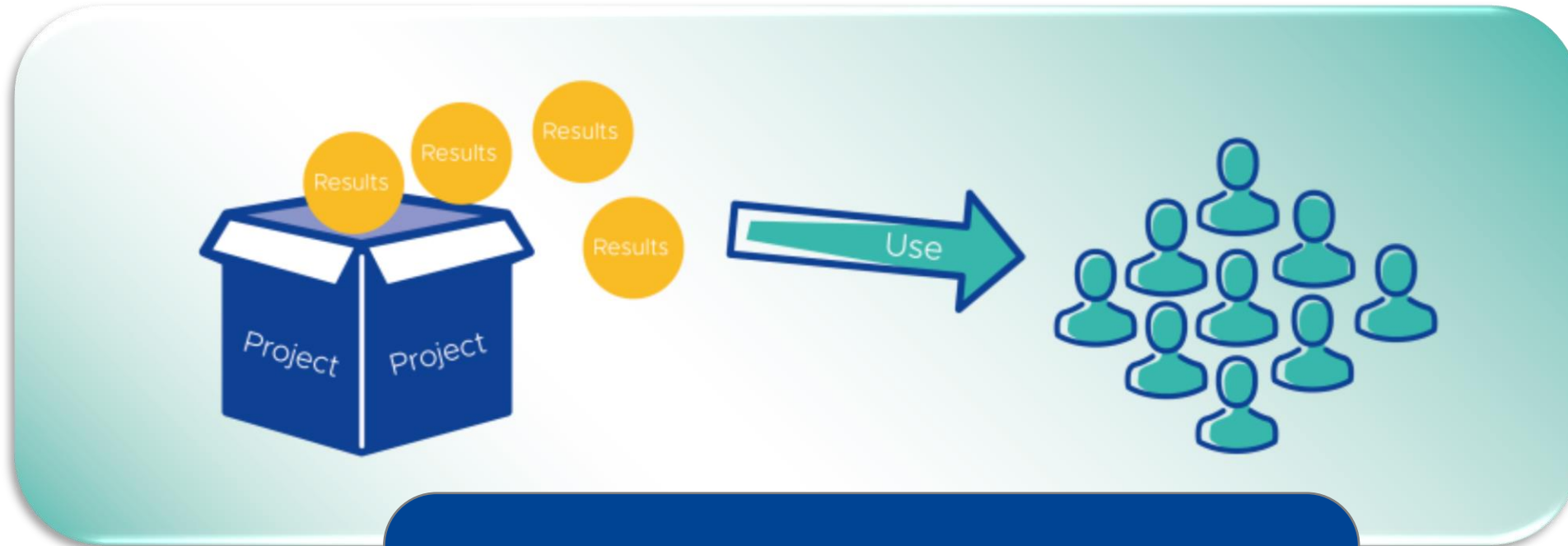
Civic Society, Citizens

Exploitation



The (further) **use of results** (i) in further research and innovation activities, (ii) in commercial exploitation, or (iii) in standardisation activities.

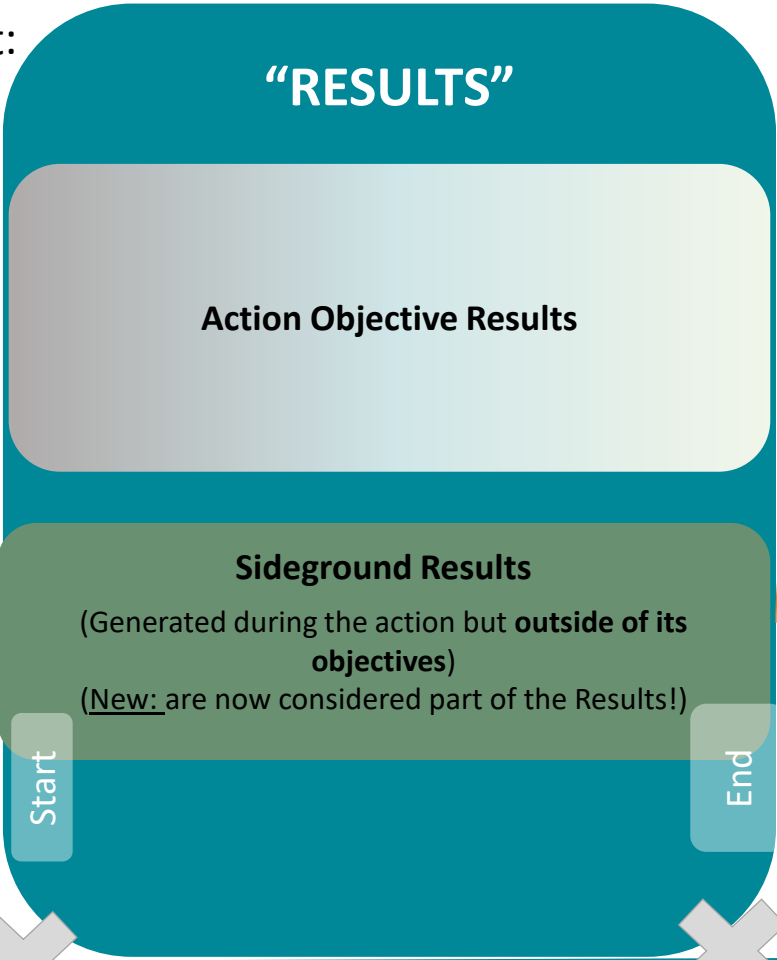
Dissemination



The **public disclosure of the results** by appropriate means (e.g. sci publication)

IPR: Background - Results - Additional Activities

Activities inside the project:



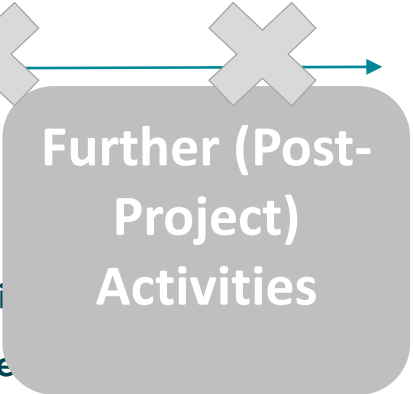
Post-project period
(4 yrs)

Obligation to “exploit”
the Results

IKAA period
(2 yrs)

Timeline

Activities outside the project:



The agreements



Grant Agreement

- Fixed template model ("MGA")
- Issued by IHI office
- Addresses the financials of the grant, grant term and reporting & controls
- Addresses scientific content & scientific deliverables
- Addresses project objectives
- Certain optional clauses (+/- 30) and Special Annex 5 clauses
 - Applicable ones to be identified by IHI JU
 - Annotated grant agreement provides interpretative guidance on each clause of the grant agreement
- Coordinator and Project Lead to be identified
 - Coordinator : either public participant or leading company, appointed in GA
 - Project "Lead": supports the negotiation of agreements until coordinator is formally appointed

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

Annotated Grant Agreement (“AGA”)

- Issued by European Commission (> 300 pages)
- Information on how every clause of the GA needs to be interpreted
- Content to be understood as guiding principles (In case of real disputes, the ECJ has final say)

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf

Grant Agreement structure

General Terms & Conditions (Art 1—45)

Project Data Sheet

Annex 1 : Description of the Action (“DoA”)

- defines project objectives (!)
- defines potential additional exploitation obligations
- defines sustainability plan, data management plan, expected key results list

Annex 2, 3, 4 : Financial breakdowns & grant amounts per partner, reporting forms

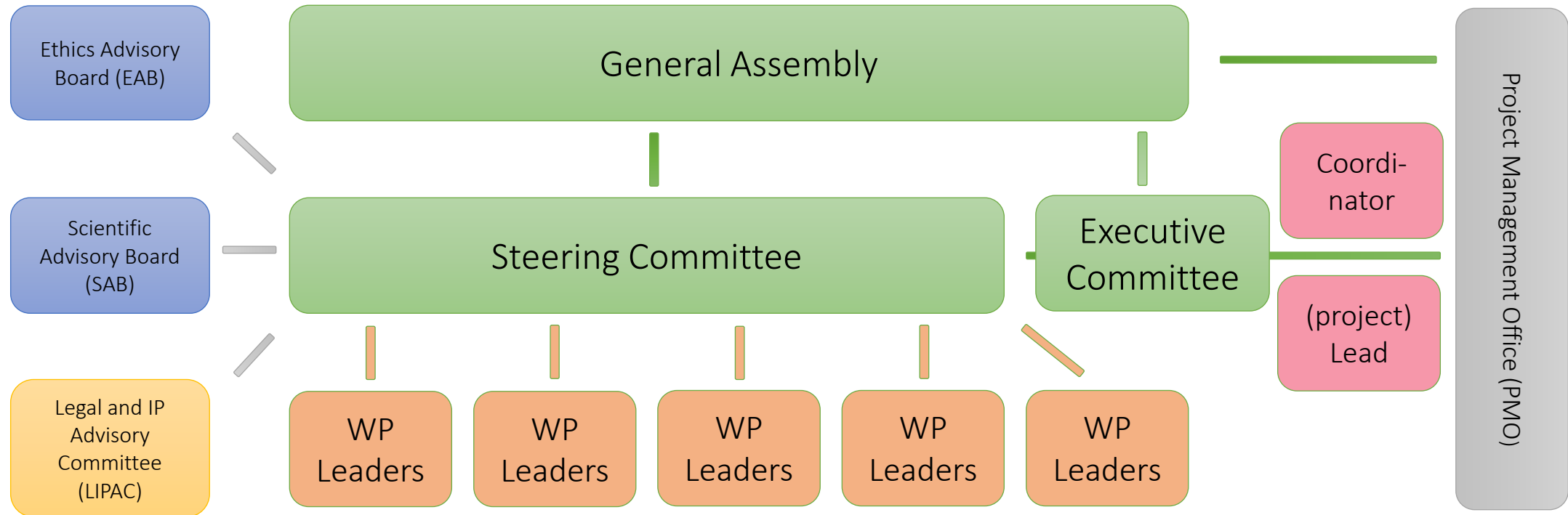
Annex 5 : Special Terms (IP)

→ Only the Project Data Sheet, the Annex 1 DoA, and Annex 2 contain modifiable content and hence require careful review

Consortium Agreement (“CA”)

- Based on a template developed by the Industry Associations
- Agreement between consortium members (IHI JU does not sign)
- Addresses mainly IPR ownership & access rights, as well as governance and disputes
- Council Regulation + GA provides for the terminology to be used
 - Only limited "room for maneuver"
 - Changes can be made based on project nature
 - Consortium Agreement needs to be compliant with Grant Agreement + Regulation

IHI - Project Governance structure



Access rights under the GA and CA

Grant of only minimum Access Rights (maybe too minimal for Industry)

	Access to background	Access to results
Project implementation	Royalty-free (unless differently agreed before the signing of the GA)	Royalty-free
Exploitation of results	On fair and reasonable conditions	On fair and reasonable conditions

Additional Access Rights should be negotiated for (through the consortium agreement)

Research Use of results	On fair and reasonable conditions or Royalty-Free	On fair and reasonable conditions or Royalty-Free
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Consequences of legal framework

- Consortium Agreement (CA) more complex
 - "more" matters "up for negotiation" (e.g. research use license on results)
- Discussion with IHI will be needed on applicability of certain optional clauses
- Administration of 'additional activities' - IKAA

CONCLUSION

16:55-17:00



Key message

- **Single-stage** - open process:
 - Now: form consortia to submit proposals in September, please read topic texts carefully
 - 14 June: use the [Brokerage event](#) for networking
 - You may already reach out to public & private participants based on the published draft topics www.ih.europa.eu/apply-funding/future-opportunities
- **Two-stage:**
 - public consortia only submit proposals in September,
 - public-private consortia to then write full proposals from November-December onwards
 - Companies cannot interact with participants applying for funding
- **List of questions and answers will be provided after the meeting (by mid-May)**
- **Any additional question? Please reach out to us**

More information



- Strategic Research and Innovation Agenda:
ihi.europa.eu/about-ihi/research-and-innovation-agenda
- Future opportunities (incl. Calls 1-2 draft texts):
ihi.europa.eu/apply-funding/future-opportunities
- Horizon Europe General Model Grant Agreement
(incl. Annex 5 - Specific rules for JU Actions)
ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf
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