

IHI 2026 Work Programme

In accordance with Article 25 of the Council Regulation (EU) 2021/2085 and with Articles 6 and 33 of the Financial Rules of the IHI JU.

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1. Chronology and list of reviews

Version	10/12/2025	Items
Version 1 – Work Programme 2026	DD.MM.YYYY	n/a

2 List of acronyms, definitions and abbreviations

ACRONYM	MEANING
ABAC	Accrual Based Accounting System
AD (HR)	Administrator
AER	Average Error Rate
AI	Artificial Intelligence
AST	Assistant
BOA	Back-Office Arrangements
CA (BUDGET)	Commitment Appropriation
BMR	Biennial Monitoring Report
CA (HR)	Contractual Agent
CAAR	Consolidated Annual Activity Report
CAS	Common Audit Service (European Commission)
CEPI	Coalition for Epidemic Preparedness Innovations
CERT-EU	Computer Emergency Response Team for the EU institutions, bodies and agencies
CHIPS JU	Chips Joint Undertaking, the former Key Digital Technologies Joint Undertaking (KDT JU). See https://www.kdt-ju.europa.eu/
COCIR	European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See https://www.cocir.org/
COUNCIL REGULATION (EU) 2021/2085	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. See https://eur-lex.europa.eu/eli/reg/2021/2085
COVID-19	Coronavirus disease
DG CNECT	Directorate-General for Communications Networks, Content and Technology (European Commission)
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission)
DG HR	Directorate-General for Human Resources and Security (European Commission)
DG RTD	Directorate-General for Research and Innovation (European Commission)
DG SANTE	Directorate-General for Health and Food Safety (European Commission)
DMO	Document Management Officer
DPO	Data Protection Officer

ACRONYM	MEANING
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines & HealthCare
EFPIA	European Federation of Pharmaceutical Industries and Associations. See https://www.efpia.eu/
EFTA	The European Free Trade Association. See https://www.efta.int/about-efta/european-free-trade-association
EHDEN	European Health Data & Evidence Network
EHDS	European Health Data Space
EHDS2	European Health Data Space 2
EHRS	Electronic Health Records
EIFU	electronic Instructions For Use
EMA	European Medicines Agency
ENISA	European Union Agency for Cybersecurity
EPPO	European Public Prosecutor's Office
ESR	Evaluation Summary Report
EU	European Union
EUAN	EU Agencies Network
EUDAMED	European Database for Medical Devices
EUDPR	Data Protection Regulation for EU institutions, bodies, offices and agencies
EUIBA	European Institutions, Bodies and Agencies
EUR	Euro
EUREGHA	European Regional and Local Health Authorities
EUROPABIO	European association representing corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 2 600 biotech companies, 2 300 out of them are SMEs. See https://www.europabio.org/
EXAM	External Authorisations Manager (for SUMMA)
FAIR	Findable, Accessible, Interoperable, and Reusable
FC	Financial contributions
FDA	Food and Drug Administration
FG	Function Group
FP	Full Proposal
FTE	Full-Time Equivalent
FWC	Framework Contract

ACRONYM	MEANING
GA	Grant agreement
GAP	Grant agreement preparation
GB	IHI JU Governing Board
GDPR	General Data Protection Regulation
GH EDCTP3	European and Developing Countries Clinical Trials Partnership Programme 3
GMP	Good Manufacturing Practice
HCPS	Healthcare Professionals
HDABS	Health Data Access Bodies
HDHS	Health Data Holders
HDUS	Health Data Users
HERA	European Health Emergency Preparedness and Response Authority
HORIZON EUROPE	Horizon Europe is 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 .
HR	Human Resources
HTA	Health Technology Assessment (bodies)
IAAS	Infrastructure as a Service
IAS	Internal Audit Service of the European Commission
ICT	Information and Communications Technology
IEC	International Electrotechnical Commission
IHI JU	Innovative Health Initiative Joint Undertaking
IHINET	intranet of the Programme Office
IICB	Interinstitutional Cybersecurity Board
IKAA	In-kind contributions to additional activities
IKOP	In-kind contributions to operational activities
IMI1 JU	Innovative Medicines Initiative Joint Undertaking
IMI2 JU	Innovative Medicines Initiative 2 Joint Undertaking
IP	Intellectual Property
IPR-AWARE	Intellectual Property Awareness
ISO	International Organisation for Standardisation
ISPE	International Society for Pharmaceutical Engineering
IT	Information Technology
IVD	<i>in vitro</i> diagnostics
IVDR	<i>In vitro</i> Diagnostic Regulation
IVDS	<i>in vitro</i> diagnostic medical devices

ACRONYM	MEANING
JUS	Joint Undertakings
KPI	Key performance indicator
LLM	Large Language Model
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
MEDTECH EUROPE	European trade association for the medical technology industry including diagnostics, medical devices and digital health. See https://www.medtecheurope.org/
MEP	Member of the European Parliament
ML	Machine Learning
NAMS	New Approach Methodologies
NCA	National competent authorities
NCDS	Non-communicable diseases
NGOS	Non-governmental organisations
NON-EU IKOP	Eligible costs incurred by private members, their constituent or affiliated entities, and contributing partners for implementing project activities carried out in third countries outside of the EU Member States and countries associated to Horizon Europe.
OECD	Organisation for Economic Co-operation and Development
OLAF	European anti-fraud office
OMCL	Official Medicines Control Laboratory
PA	Payment appropriation
PDECA	Plan for the Dissemination, Exploitation, and Communication Activities
PMO	Office for the Administration and Payment of Individual Entitlements (European Commission)
PPP	Public-private partnership
PREMS	Patient reported experience measures
PROMS	Patient reported outcome measures
PSCI	Pharmaceutical Supply Chain Initiative (PSCI)
PV	Pharmacovigilance
R&D	Research and development
RAE	Risk assessment exercise
RDP	Regulatory Data Protection
RIA	Research and innovation actions
R&I	Research & Innovation
RWD	Real World Data
RWE	Real World Evidence

ACRONYM	MEANING
SAAS	Software-as-a-service
SDG	Sustainable Development Goals
SEDIA	Single electronic data interchange area (SEDIA), the funding & tender opportunities portal of the European Commission. See here https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home
SIP	IHI JU Science and Innovation Panel
SLA	Service Level Agreement
SMES	Small and medium-sized enterprises
SO	Specific Objective
SOC	Security Operations Center
SOFIA	IHI JU grant management IT system
SOP	Standard operating procedure
SPOC	Single point of contact
SRG	IHI JU States' Representatives Group
SRIA	Strategic research and innovation agenda
TA	Temporary agent
THCS	Transforming health and care systems
TTG	Time to grant
UK	United Kingdom
WHO	World Health Organization

3 Introduction

3.1. Mission statement of IHI JU

The Innovative Health Initiative Joint Undertaking (IHI JU) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

IHI JU pioneers an integrated approach to health research, recognising the innovation potential that can arise from bringing various sectors together to work on cutting edge health research projects as well as the significant innovation potential towards unmet public health needs offered by technology developments in digital health, mobile devices, artificial intelligence and real world data.

IHI JU projects translate health research and innovation into real benefits for patients and society, to ensure that Europe remains at the forefront of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI JU paves the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

Due to the global nature of today's health challenges and threats, IHI JU is open to participation from academic, industrial, and regulatory actors from Europe and beyond, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve much-needed societal impact, in particular improved health outcomes for EU citizens.

3.2. Background and link with the Strategic Research and Innovation Agenda (SRIA)

Europe has a rising burden of disease, notably non-communicable diseases, and this is linked to its ageing population. Most countries struggle with long-term expenditure, efficacy of health care delivery and workforce planning in healthcare, and this problem grows as the age pyramid changes. This challenges the long-term sustainability of EU healthcare systems, which are under increasing fiscal and organisational pressures.

The COVID-19 health crisis exacerbated the challenges faced by European healthcare systems in combatting and managing (infectious) diseases in a coordinated manner. Simultaneously, it also showed, by the delivery of several COVID-19 vaccines in record time, the critical importance of collaborative R&I to respond rapidly to emerging health threats, as well as the strategic value of public-private partnerships.

The post-covid period has brought further challenges to European healthcare systems that have to deal with the progressive ageing of the EU population and the consequent increase in chronic diseases, growing healthcare worker shortages, underinvestment in health systems and external shocks such as climate change and inflation driven by the Russian invasion of Ukraine. In this complex scenario, boosting European collaborative research and innovation and in particular public-private partnerships is more relevant than ever, as highlighted in the Draghi report¹.

IHI JU, as one of the key public-private partnerships, is uniquely placed to enhance the healthcare ecosystem so that it can efficiently respond to public health needs in Europe. At the same time, IHI helps to boost European competitiveness by providing a strong base to support the launch, growth, and retention of companies in Europe, and to attract competitive companies to Europe by fostering projects that strengthen collaborations between industry sectors, academia, and public authorities.

The fact that the EU is still relatively weak in translating research results into tangible health solutions that are taken up by healthcare systems in the EU can also be partially attributed to the insufficient early consideration of the needs of society and/or patients and end-users. To remedy this, these actors must be involved in all stages of research, from project design through to implementation, to develop meaningful innovations.

These factors shape the context within which IHI JU must lay the foundations for the development of safer and more effective healthcare products or solutions that respond to unmet public health needs. The outputs of IHI projects should enable the translation of scientific knowledge into clinical practice and workflows and the resulting products or solutions should be taken up by healthcare systems and/or foster other important health tech developments.

IHI JU aims to enable the cross-sectoral integration of technologies, know-how, products, services, and workflows for people-centred health care which can contribute to strengthening and building on the European Health Data Space (EHDS), improving clinical trials, and enhancing the use of artificial intelligence in healthcare, which are all important elements highlighted in the Draghi report.

By addressing these underlying drivers of competitiveness, the projects funded through IHI JU lay the foundations for the development of safer and more effective healthcare products or solutions that respond to unmet public health needs and that can be taken up by healthcare systems. The goal is a more targeted intervention strategy leading to personalised treatments and improved individual and population health outcomes, via cost-effective and affordable health solutions.

The research supported by IHI JU should remain at pre-competitive level and does not aim to deliver products or services directly to healthcare systems or the market.

This partnership reflects the importance of the full spectrum of health technologies, as well as the need for progress in the convergence of health technology areas and a significantly more prominent role for digital technologies and data analytics in health research than when IMI2 JU was established. IHI JU thus pursues its actions responding to the recommendation of the IMI2 JU interim evaluation to “enable the active engagement of other industry sectors with the pharmaceutical industry”². A key element linking all these industry sectors is the need to use and share data involving innovative digital tools to perform people-centred translational R&I for the benefit of the European people and health systems.

¹ https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en?filename=The%20future%20of%20European%20competitiveness%20_%20A%20competitiveness%20strategy%20for%20Europe.pdf

² European Commission (2017), The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union

The SRIA³ defines the overall scope of activities of IHI JU, in line with its founding legislation⁴, to enable the achievement of its general objectives by 2030:

- contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations;
- foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contributions to 'Europe's Beating Cancer Plan';
- drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

3.3. Strategy for the implementation of the programme

The strategy will enable continued implementation of the SRIA priorities including areas that are still not, or not sufficiently, covered. This will be achieved through the launch of open and competitive calls for proposals including a new applicant-driven call based on the learnings of the first call of this type (launched in 2025). The objective of the call will be to identify additional opportunities for innovative solutions that address the priorities of the IHI SRIA and contribute to the achievement of key strategic objectives at European level, such as those of the European Life Science Strategy⁵.

The work of the Science and Innovation Panel will be central to the development of call topics and the implementation of the scientific priorities. In addition, an essential element of implementing the priorities is to engage and mobilise industrial partners from all the sectors covered by the programme, as well as all relevant stakeholders such as patients, health care authorities, health care professionals and providers to mention but a few. Efforts will also be committed to establishing synergies with other parts of Horizon Europe, such as missions, partnerships or specific programmes, as well as establishing links with international organisations.

Across all the activities planned, a key element is assertive communications that target audiences with an emphasis on the openness, transparency, relevance, and coherence of IHI JU activities with its defined objectives and those of Horizon Europe. This is particularly important to promote the new applicant-driven approach and attract high quality applications to IHI JU calls for proposals. A key goal of this outreach strategy will be to engage with and mobilise new players and newcomers.

³ https://www.ihj.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.427.01.0017.01.ENG

⁵ https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en?filename=com_2025_525_final.pdf

An important element of the Programme Office work will be to continue to support and monitor the projects established under IIMI2 JU. This is important for two reasons; firstly, the monitoring and acceptance of costs associated with these projects will ensure the continued sound financial management of the programme. Secondly, it is very important to continue to disseminate and promote the results of these projects using all available communication instruments (e.g. publications, presentations, social media...). Meetings, workshops and webinars will be organised to mobilise the established projects and disseminate their results to demonstrate the impact of the work supported by IHI JU and its impact on patients and wider society.

4 Work Programme 2026

Executive summary and message from the Executive Director

2026 is the fifth full year of IHI JU implementation. The Programme Office will continue to commit funds to build new multi-sectorial public-private projects that take advantage of the ongoing technology convergence in the health sector and drive partnerships between European healthcare systems.

The healthcare sector and the health industries are critical for European competitiveness and preparedness. IHI JU as a public-private partnership plays a key role in the European health research ecosystem by systematically addressing drivers of competitiveness and research efficiency⁶, for instance by addressing regulatory innovation for medicines and medical devices⁷, developing networks and methodologies to shorten timelines and boost capacity for clinical trials⁸, and enhancing novel technology utilisation – such as artificial intelligence and digital health – to improve health care delivery or develop large, transnational data collections for public and industrial research⁹. IHI JU continues to seek novel ways to address unmet public health needs and to address the underlying drivers of European competitiveness in health research, e.g. regulatory science, clinical trials, greening of healthcare and sustainable manufacturing¹⁰, as well as advances in digitalisation, AI and the use of 'big' data. By doing so, we aim to accelerate the pace of innovation, address bottlenecks for healthcare systems and professionals, and allow access to the results for a large portion of the EU population, especially patients and carers.

We will also focus on optimising the dissemination and exploitation of results coming from projects launched under IHI JU and the large legacy of IMI projects that IHI JU is managing. The outcomes from this portfolio demonstrate how public-private partnerships can address important problems in difficult research areas and also transform the European health research landscape in areas such as clinical trials, artificial intelligence in healthcare, and real-world data.

We will implement all of this, attentively adhering to the principles of sound financial management and the operational practices which have ensured a clean opinion from the European Court of Auditors in previous years.

⁶ https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en?filename=The%20future%20of%20European%20competitiveness%20%20A%20competitiveness%20strategy%20for%20Europe.pdf

⁷ See e.g. [ADAPT-SMART](#), [HEU-EFS](#), [Regulatory Sandbox](#), [AI in Pharmacovigilance](#)

⁸ See e.g. <https://www.ihj.europa.eu/news-events/events/imi-impact-clinical-trials>

⁹ See e.g. <https://www.ihj.europa.eu/news-events/newsroom/500-million-records-patients-27-countries-being-harmonised-and-readied-real>

¹⁰ See e.g. <https://www.ihj.europa.eu/news-events/newsroom/going-green-meet-projects-boosting-environmental-performance-health-sector>

We will continue to proactively communicate about opportunities for funding from IHI JU, ensuring the widest possible involvement across Europe from all stakeholders and sectors including SMEs. A particular focus will be on dissemination of the opportunities provided by the applicant-driven single-stage call for proposals, that was piloted in early 2025.

IHI JU will drive interactions and collaborations and seek synergies with those organisations and programmes with like-minded or convergent agendas. The contacts already established in this regard with the other European partnerships in health set up under Horizon Europe (such as GH EDCTP3 JU), the Cancer Mission, HERA and EIT Health, will be further developed.

Operational activities of IHI JU for 2026

4.1.1 Objectives, indicators and risks

Key objectives

The key objectives for IHI JU operations in 2026 are identified by the Governing Board in the Work Programme and by the management team at operational level.

The key operational objectives for 2026 are as follows:

- a) drive the implementation of IHI Strategic Research and Innovation Agenda through the launch of open and competitive calls for proposals, ensuring the active engagement of industry sectors covering the pharmaceutical, the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area, and involving health care stakeholders such as SMEs, academia, health care authorities, health care professionals and providers, and patient organisations;
- b) Manage the projects and outcomes from the Innovative Medicines Initiative 2 Joint Undertaking to maximise impact;
- c) Ensure sound budget implementation through the effective and efficient management of the programme including calls for proposals, grant award processes and close monitoring of projects;
- d) Proactively promote the IHI Programme to attract high quality applications to IHI JU's calls for proposals and engage with new potential partners, including synergies with relevant programmes at union, national, and regional level;
- e) Improve and broaden access to project outcomes by embedding dissemination and exploitation activities in all stages of the project lifecycle and seeking new ways to support the deployment and uptake of innovative solutions to deliver real benefits for patients and for society, while supporting development in the health sector at the regional, national and European level;
- f) Demonstrate the EU added value of IHI JU through assertive communication to target audiences with an emphasis on the openness, transparency, relevance, and coherence of IHI JU activities with its defined objectives and those of Horizon Europe, with particular emphasis on the contribution of IHI JU to the health and well-being of European citizens and communities, as well as the competitiveness of the European health sector.

Indicators

IHI JU is built around the idea that cross-stakeholder and cross-sectorial collaboration will enable significant advancements and breakthrough innovations in the field of healthcare, including the pharmaceutical industry but also new sectors such as biopharmaceutical, medical technologies, and biotechnologies.

Therefore, the multi-stakeholder involvement and the cross-sector alliance are fundamental aspects that will be monitored as indicators of good programme performance.

Another important aspect of IHI JU that will be tracked over its lifecycle is the ability of the projects to interact with regulators and potentially improve clinical guidelines.

Additionally, the ability of the projects to generate tools to use in clinical practice/R&D to understand health determinants and the ability to share this knowledge through publications will be observed throughout the programme. In line with the challenges of today's scientific landscape, the performance of IHI JU will also be evaluated by looking at the examples of projects that will be able to generate people-centred integrated healthcare solutions, and to produce innovations enabling the integration and management of health care data as well as the use of artificial intelligence applied to healthcare.

Ultimately, IHI JU will have to demonstrate the ability to translate knowledge into innovation, to address public health needs and to help contribute to a globally competitive EU healthcare industry through the innovations deriving from its funded projects.

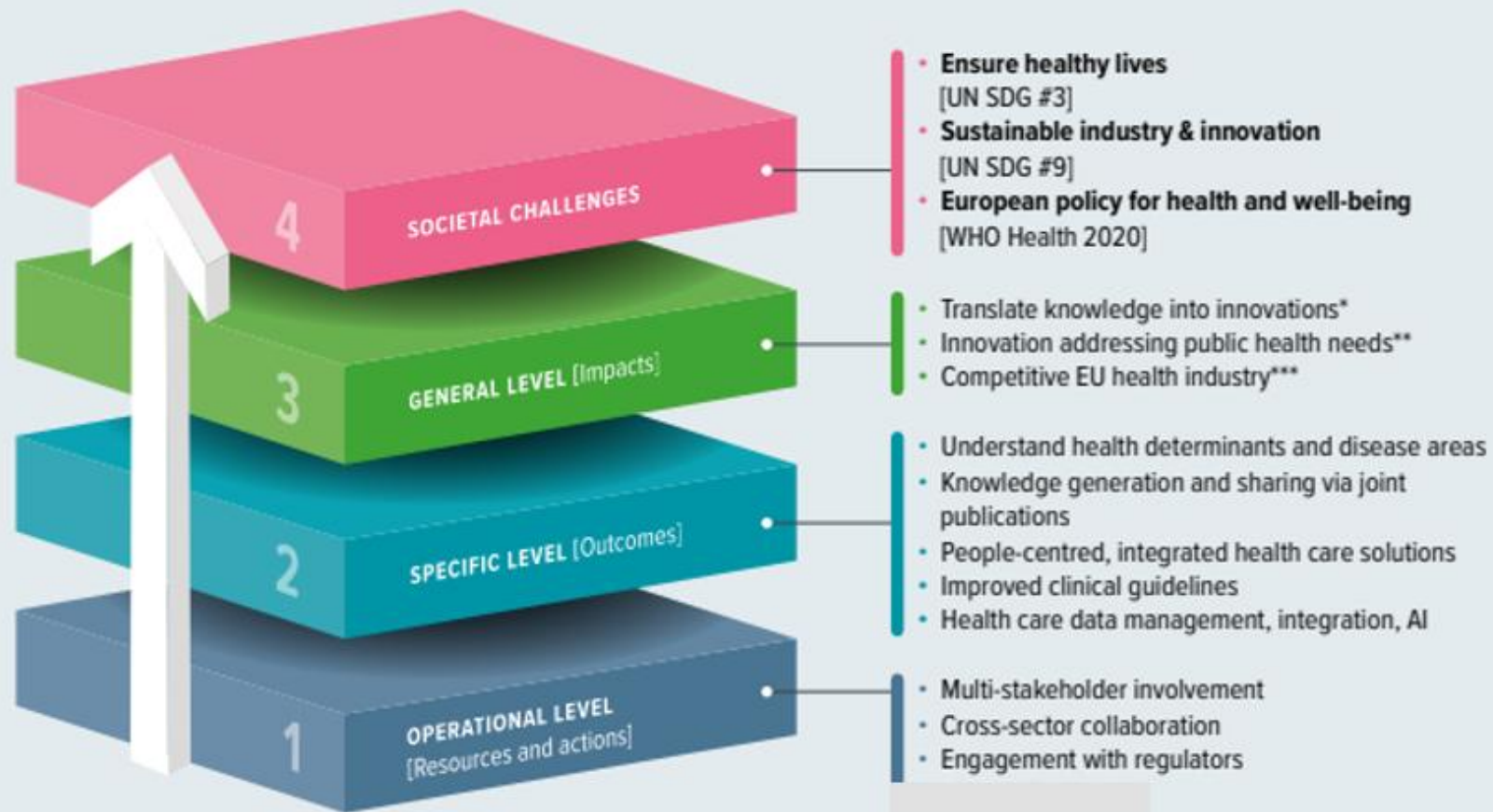
These aspects of IHI JU's nature have been translated into a monitoring framework that consists of a matrix of key performance indicators stratified in 3 levels (in line with the template provided by the EC DG-RTD):

- Operational objectives, also called “**resources and actions**”
- Specific objectives, also called “**outcomes**”
- General objectives, otherwise called “**impacts**”

This type of structure essentially illustrates how the resources (operational objectives) contribute to the outcomes (specific objectives) and to the impacts (general objectives) to ultimately help reach the higher level ultimate goals: -

- UN Strategic Development Goal #3 (good health and well-being)
<https://www.un.org/sustainabledevelopment/health/>
- UN Strategic Development Goal #9 (industry, innovation, and infrastructure)
<https://www.un.org/sustainabledevelopment/infrastructure-industrialization/>
- [The WHO Europe 2020 Health Priorities](#)

IHI vision: contribute to societal challenges through ...



* IHI General Objective 1:
Contribute toward the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations

** IHI General Objective 2:
Foster the development of safe, effective, people-centric and cost-effective innovations that respond to strategic unmet public health needs

***IHI General Objective 3:
Drive cross-sectoral health innovation for a globally competitive European health industry

The IHI JU specific key performance indicators (KPIs) are linked to the IHI JU vision and have been developed ensuring that there is clear alignment between the overall objectives of IHI JU and the measures used to monitor progress throughout the life of the programme. The KPIs have been elaborated¹¹ and guided by the so-called RACER Principles¹².

KPI name	Unit of measurement	Baseline ¹³	Target ¹⁴ 2023	Target 2025	Target 2027	Ambition >2027	Status
Resources (input), processes and activities							
1.1. Involvement of multiple health care stakeholders	Share of projects involving more than two types of health care stakeholders [research higher or secondary education organisations (private or public), small & medium enterprise (SME), large company (for-profit legal entity), non-governmental organisations (NGOs), healthcare professional organisation/healthcare provider, patient / citizen organisation, regulators or regulatory body, notified body, health technology assessment body (HTA), healthcare payer, charity and foundation, public authority] as project participants or advisors	50%	55%	60%	65%	70%	
1.2. Cross-sectoriality of the partnership	Share of projects bringing together private members and/or contributing partners (or their affiliated or constituent entities) from two or more technology sectors ¹⁵	25%	70%	80%	85%	90%	
1.3. Engagement of regulators	Number of projects interacting with regulators ¹⁶ to contribute to new or improved guidelines or methodologies	13	0	5	10	20	

¹¹ See the KPIs adopted by the IHI Governing Board on the IHI JU website here: http://www.ihj.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_2022.pdf.

¹² The RACER principles are 1- Relevant, i.e. closely linked to the objectives to be reached. They should not be overambitious and should measure the right thing (e.g. a target indicator for healthcare could be to reduce waiting times but without jeopardising the quality of care provided); 2- Accepted (e.g. by staff, stakeholders). The role and responsibilities for the indicator need to be well defined (e.g. if the indicator is the handling time for a grant application and the administrative process is partly controlled by Member States and partly by the EU then both sides would assume only partial responsibility). 3-Credible for non-experts, unambiguous and easy to interpret. Indicators should be as simple and robust as possible. If necessary, composite indicators might need to be used instead – such as country ratings, well-being indicators, but also ratings of financial institutions and instruments. These often consist of aggregated data using predetermined fixed weight values. As they may be difficult to interpret, they should be used to assess broad context only. 4 - Easy to monitor (e.g. data collection should be possible at low cost). 5 - Robust against manipulation (e.g. administrative burden: If the target is to reduce administrative burdens to businesses, the burdens might not be reduced, but just shifted from businesses to public administration).

Source: page 250 of “*Better Regulation Guidelines*” EU Commission: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

¹³ Baselines are derived (where possible) from the Innovative Medicines Initiative (IMI2) as the predecessor to IHI.

¹⁴ Reporting methodology: cumulatively reporting from the beginning of IHI until 31/12/2030.

¹⁵ The IHI JU private members COCIR, EFPIA, EuropaBio and MedTech Europe have members from several technology sectors. Contributing partners might also cover further technology sectors.

¹⁶ In this document, the term ‘regulators’ refers to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawal/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of notified bodies may still be relevant for the design and implementation of the activities of the proposed initiative.

KPI Name	Unit of measurement	Baseline	Target 2023	Target 2025	Target 2027	Ambition >2027	Status
Outcomes							
2.1. Cross-stakeholder collaboration	Share of multi-stakeholders' publications identified through bibliometric data analysis [research / higher or secondary education organisations (private or public), small & medium enterprise (SME), large company (for-profit legal entity), non-governmental organisations (NGOs), healthcare professional organisation / healthcare provider, patient / citizen organisation, regulators or regulatory body, notified body, health technology assessment body (HTA), healthcare payer, charity and foundation, public authority]	65%	65%	66%	67%	70%	
2.2. Public-private collaboration	Share of publications across public and private stakeholders identified through bibliometric data analysis (academic, pharmaceutical, biopharmaceutical, medical technologies, biotechnologies)	65%	65%	66%	67%	70%	
2.3. Project outputs for use in clinical practice and health research development and innovation (R&D&I)	Number of: <ul style="list-style-type: none"> new tools for studying new potential drug targets such as new pharmacological tools, therapeutic modalities, and patient-derived assays available to the scientific community; new tools to test diagnostically and/or therapeutically relevant hypotheses in pre-clinical models and/or clinically in uncharted areas of disease biology; new tools for prediction, prevention, interception, surveillance, diagnosis, treatment, and management options to prepare for major epidemic outbreaks; new biomarkers of disease (relevant for diagnosis, efficacy, safety, or prevention) identified and experimentally validated; new taxonomies of disease or new stratifications to define patient sub-populations. 	100	0	50	120	150	

KPI Name	Unit of measurement	Baseline	Target 2023	Target 2025	Target 2027	Ambition >2027	Status
Outcomes							
2.4. Integrated health care solutions considering end-users' needs	Number of project outputs that combine people-centred integrated solutions (pre-competitive tools, methods, solutions as well as products/services or combined products)	No baseline available	0	3	7	10	
2.5. Methodologies for value assessment of integrated solutions	Number of methodologies for the assessment of the added value of combinations of products/services or combined products (including development of patient reported outcomes / experience measures and statistical methods/tools), submitted to health care authorities and organisations ¹⁷	No baseline available	0	2	3	5	
2.6. New or improved clinical guidelines	Number of projects contributing to the development of new or improved clinical guidelines	13	0	5	10	20	
2.7. Management of health data	Number of common standards, protocols and frameworks developed by the projects to enable better access to data, sharing and analysis of health-related data	No baseline available	0	3	7	10	
2.8. Demonstration of data integration	Number of pilots developed by the projects demonstrating integration of data provided by the private and public sectors	No baseline available	0	5	10	20	
2.9. Demonstration of AI in health care	Number of pilots developed by the projects demonstrating feasibility of use of artificial intelligence in health care	No baseline available	0	1	2	3	

¹⁷ Health care authorities and organisations to which it is referred here are HTA bodies, and regulatory authorities, payers and public authorities

- HTA agencies/bodies: http://www.adhophta.eu/toolkit/assets/tools/AdHopHTA_toolkit_tool24_document.pdf; <https://www.eunetha.eu/about-eunetha/eunethanetwork/>
- National and regional public procurement organisations
- National payer and reimbursement organisations (incl. health insurance companies)
- National healthcare authorities: examples are: Dutch NZA; <http://www.euregha.net/> (membership list of regional and local health authorities); <https://eurohealthnet.eu/list-of-members/> (first part of the membership, not the research members)

KPI Name	Unit of measurement	Baseline	Target 2023	Target 2025	Target 2027	Ambition >2027	Status
Impacts							
3.1. Creation of sustainable resources and infrastructures that facilitate the translation of knowledge into innovations	Number of established new research networks, new clinical networks, further public-private collaborations on health R&D&I, research infrastructures, biobanks, collaborative platforms etc. (that outlive the project and are accessible to broader scientific community)	10	0	4	7	15	
3.2. Development of preventive or therapeutic strategies in different therapeutic areas to address unmet public health needs	Share of projects that aim to develop new or improved existing methodologies also across disciplines addressing public health needs ¹⁸ included in the list of the WHO Europe Health 2020 priority areas ¹⁹	No baseline available	90%	90%	90%	90%	

¹⁸ Definition in article 125(1) of the Council Regulation (EU) 2021/2085: "For the purpose of this Regulation, an unmet public health need shall be defined as a need currently not addressed by the health care systems for availability or accessibility reasons, for example where there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people access to healthcare is limited because of cost, distance to health facilities or waiting times".

¹⁹ https://www.euro.who.int/_data/assets/pdf_file/0011/199532/Health2020-Long.pdf <https://www.who.int/europe/publications/i/item/WHO-EURO-2021-1919-41670-56993>

KPI Name	Unit of measurement	Baseline	Target 2023	Target 2025	Target 2027	Ambition >2027	Status
Impacts							
3.3. Cross-sector activities established by the partnership that will help contribute to a globally competitive EU healthcare industry	Number of activities in which cross-sector collaboration drives health innovation, such as: <ul style="list-style-type: none"> Spin-off companies, entities or activities created based on outputs of the project (e.g., new commercial or non-profit entities) Collaboration agreements between large companies²⁰ & SMEs²¹ established for purposes that go beyond the scope of the project during and/or after project lifetime. Other activities where the joint contribution of different partners has generated cross-sectoral health innovation. <p>Examples of collaborative activities across health industry sectors that contributed to the transition to a green and digital economy (as outlined in the new Industrial Strategy for Europe²²)</p>	No baseline available	0	5	10	20	

²⁰ For-profit legal entities with an annual turnover of EUR 500 million or more (Article 123(5) of Council Regulation (EU) 2021/2085)

²¹ Small and medium-sized enterprises (SMEs) are defined in the “EU recommendation 2003/361” (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361&from=EN>) as of page 4 and in the European Commission “User guide to SME definition” (https://ec.europa.eu/regional_policy/sources/conferences/state-aid/sme/smedefinitionguide_en.pdf) especially in page 13

²² “European industrial strategy 2019-2024” (https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en) and “Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe’s recovery” (https://ec.europa.eu/info/sites/default/files/communication-industrial-strategy-update-2020_en.pdf)

Risks

Risk management is a proactive process for identifying and assessing any event that could prevent IHI JU from achieving its objectives and for determining how the corresponding risks should be mitigated.

Therefore, risk management is an integral element of the strategic planning and monitoring cycle.

Following the risk assessment exercise carried out by the Programme Office, none of the risks identified and assessed by the IHI management are considered to present a critical residual risk level, taking into account the mitigating actions implemented and/or planned.

In order to mitigate the risks identified, the Programme Office continuously monitors and reviews them, considering the corresponding mitigating measures identified and taking further actions where necessary to ensure the mitigation remains effective. Relevant IHI JU financial needs and the budget for 2026 have also been appropriately estimated. The staff is regularly informed on the objectives, activities and new planning.

4.1.2 Scientific priorities, challenges and expected impacts

The scope of the scientific priorities for 2026 will contribute to the achievement of the general and specific objectives of IHI JU as defined in the Council Regulation (EU) 2021/2085. They will do this by tackling challenges and making progress towards the outcomes and expected impacts as described in one or more of the five SRIA²³ scope areas/specific objectives. IHI JU is the ideal mechanism to pioneer the integration of technologies and interventions to optimise research, health products and services, as well as healthcare delivery, to ultimately move from siloed healthcare interventions to holistic disease management and patient care.

The scientific priorities reflect IHI JU's objectives, which focus on the pre-competitive area, thereby creating a safe space for efficient collaboration between companies active in different health technologies. The objectives of IHI JU as such are not aimed at delivering products or services directly to healthcare systems or the market, instead IHI JU acts as an enabler and catalyser for turning health research and innovations into real benefits for patients and society and makes Europe's health industries globally competitive.

In 2026 the scientific priorities will continue to focus on cross-sectoral approaches, methods, and tools to facilitate the creation of new products and services to prevent, intercept, diagnose, treat, and manage diseases and foster recovery more efficiently in various disease areas, focusing on unmet public health needs as defined in the Council Regulation (EU) 2021/2085²⁴. In addition, and importantly, the scientific priorities will also cover initiatives which, while not focused specifically on disease areas, have significant potential to generate results that could have a transformational impact on innovation processes in healthcare, including industrial processes.

To achieve these ambitious objectives, IHI JU will continue to grow its pipeline of ideas from a range of sources and stakeholders in the health community, as well as from industry partners, the European Commission, and potential contributing partners including strategic philanthropic organisations/foundations.

²³ https://www.ihj.europa.eu/sites/default/files/flmng/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

²⁴ an unmet public health need shall be defined as a need currently not addressed by the healthcare systems for availability or accessibility reasons, for example where there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people's access to health care is limited because of cost, distance to health facilities or waiting times.

To exploit the full potential of IHI JU, the industry sectors will continue the joint Think Big reflection process to explore the opportunities of systemic and prospective cross-sector integration, and the boundaries of the common pre-competitive space. This reflection process involves research, medical and digital thought leaders from pharmaceutical and medical technology companies and will continue to identify areas where public-private cross-sector collaboration can create a step change in disease prevention, precision medicine, and management of chronic diseases as well as benefiting the healthcare ecosystem at system level. The "Think Big" themes focus on opening new avenues for R&D, addressing patient and societal needs, supporting healthcare systems and ensuring the future resilience and competitiveness of the healthcare industries in Europe.

Insights gathered from the [2024 IHI JU Regulatory Science Summit](#)²⁵ that focussed on rare diseases, paediatrics, real-world data / real-world evidence (RWD/RWE), artificial intelligence (AI) and regulatory sandboxes, as well as those from the 2024 IHI JU workshop on real-world data, digital health and artificial intelligence²⁶ will also continue to be taken into account to progress topic ideas that could contribute to regulatory science going forward.

In addition, IHI JU will continue to collect ideas from the wider health and research community for potential IHI topics via the IHI JU dedicated portal²⁷.

All ideas will be reviewed by the Science and Innovation Panel (SIP), which notably comprises experts from the scientific community and various stakeholder groups. The SIP will determine how well they fit IHI JU's mission and its objectives as described in the SRIA, and if they are suitable starting points for future topics of calls for proposals to be launched in 2026 (and beyond).

The activities funded by IHI JU will be designed taking into consideration synergies with other health-oriented initiatives. These include synergising with existing and future partnerships of Cluster 1 of Horizon Europe, as well as complementing the actions of the EU4Health²⁸ programme and HERA²⁹ and upstream of the EIT Health and the European partnership on transforming health and care systems (THCS)³⁰, wherever relevant. It is also expected that IHI JU activities will contribute to the Union priorities for health research and innovation, such as the Pharmaceutical and Industrial Strategies for Europe³¹, the European Life Science Strategy³², Europe's Beating Cancer Plan³³, the European Green Deal³⁴ and other legislative acts such as the Regulation on the European Health Data Space (EHDS)³⁵, the EU Artificial Intelligence Act³⁶, the Data Act³⁷, and the upcoming EU Biotech Act.

²⁵ https://www.ihj.europa.eu/sites/default/files/uploads/Documents/ProjectResources/RegulatoryScienceSummit_Feb2024_Report.pdf

²⁶ https://www.ihj.europa.eu/sites/default/files/flmngnr/Data%20%26%20Digital%20Report%20PDF_2.pdf

²⁷ <https://www.ihj.europa.eu/shape-our-future-research/propose-ideas>

²⁸ https://hadea.ec.europa.eu/programmes/eu4health/about_en

²⁹ https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

³⁰ <https://www.thcspartnership.eu/>

³¹ https://ec.europa.eu/health/system/files/2021-02/pharma-strategy_report_en_0.pdf and https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en

³² https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en?filename=com_2025_525_final.pdf

³³ https://ec.europa.eu/health/system/files/2022-02/eu_cancer-plan_en_0.pdf

³⁴ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

³⁵ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

³⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

³⁷ <https://digital-strategy.ec.europa.eu/en/policies/data-act>

Participants in activities funded by IHI JU will have to ensure that the 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. For this, the general conditions relating to the IHI JU calls included in this work programme will specify additional exploitation obligations applicable to specific indirect actions.³⁸

Activities funded by IHI JU will cover the whole health innovation chain. Activities will be funded via the launch of calls for proposals and selection of projects (actions) that contribute to the SRIA. Due to their highly interlinked nature, it is expected that most of the activities will address more than one of the SRIA areas (corresponding to the IHI JU Specific Objectives (SOs)), albeit with a focus on one of them.

Importantly, to create further opportunities for new cross-sectoral collaborations in line with IHI JU's general and specific objectives and enhance openness and co-creation/co-ideation also in research areas of the SRIA that are not already well covered, in 2026 IHI JU will launch an applicant-driven call **"To boost innovation for a competitive European health ecosystem"**. The call will be designed based on the lessons learned from the novel applicant-driven approach to public-private partnerships piloted in 2025. The call will contain five topics, each focusing on one of the five IHI JU Specific Objectives, and aims to be attractive to innovative proposals and to a range of new stakeholders including smaller players and private members that might not be already involved in IHI activities.

As deemed relevant, the IHI JU office may organise webinars/workshops to support the implementation of the 2026 scientific priorities.

Impacts achieved in 2026 will be monitored using the predefined key performance indicators, as well as via bibliographic analysis to capture projects' scientific outputs in terms of publications and collaborations.

4.1.3 Calls for proposals

a. General presentation of the 2026 calls for proposals

During 2026, IHI JU is planning to launch single-stage and two-stage open and competitive calls for proposals. The details of the two-stage call will be published with the amended version of this Work Programme which is planned over the course of 2026.

The topic ideas and indicative budgets are drawn up from a range of sources, including industry partners, potential contributing partners and other stakeholders in the health community and in consultation with the SIP and the SRG. The Programme Office leads the drafting of the topic texts and the Work Programme. The latter may be amended as needed.

For IHI JU call 12:

The submission deadline for full proposals (FPs) will be 21/04/2026.

Scientific evaluation of the single-stage call will take place in May-June 2026. Grant Agreement Preparation (GAP) will be completed within 3 (three) months from the notification to applicants of the evaluation results of the full proposal, and maximum eight months from the final date of submission of the FPs, in line with the applicable time to grant (TTG).

³⁸ In accordance with Article 125(3) of the Council Regulation (EU) 2021/2085

b. Conditions of the calls and call management rules

For call management, IHI JU will utilise the EC IT infrastructure available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA).

The General Annexes to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme, including the “Restrictions for the protection of European communication networks” under General Annex B. In accordance with Article 5(2)(a) and Article 125(4) of Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in this Work Programme.

To maximise the efficiency of the calls management, IHI JU will continuously explore and implement simplifications and improve its processes while maintaining the highest standards of the evaluation process, in line with the applicable Horizon Europe rules.

All proposals must conform to the conditions set out in 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, and in Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

GENERAL CONDITIONS RELATING TO THE IHI JU CALLS

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The conditions are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the grant agreements</i>	The conditions are described in General Annex G.

Any specificity for IHI JU is highlighted in the below sections:

STANDARD ADMISSIBILITY CONDITIONS, PAGE LIMITS AND SUPPORTING DOCUMENTS

General Annex A ('Admissibility') to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

In addition, page limits will apply to proposals as follows:

- for a single-stage call, the limit for RIA full proposals is 50 pages;
- at the first stage of a two-stage call, the limit for RIA short proposals is 20 pages;
- at the second stage of a two-stage call, the limit for RIA full proposals is 50 pages.

STANDARD ELIGIBILITY CONDITIONS

General Annex B to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme unless otherwise provided in this Work Programme.

Per the above and by way of derogation from General Annex B of the Horizon Europe Work Programme 2025 the following shall apply:

According to Article 119 of the Council Regulation (EU) 2021/2085, for indirect actions selected under calls for proposals covered by this Work Programme:

- applicant consortia must 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 which are members of IHI JU, their constituent or affiliated entities, and contributing partners;
- While the constituent or affiliated entities of the members other than the union of IHI JU can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA;
- further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided;
- the eligibility condition above and the self-declaration requirement do not apply to the first stage of a two-stage application;
- at project level, the maximum amount of non-EU IKOP is set to:
 - Twenty percent (20%) for IHI JU Call 12.

This is justified as a means to ensure the achievement of project objectives based on Article 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openness to non-EU IKOP in these calls³⁹.

³⁹ It has to be noted that, pursuant to Article 119(4) of Council Regulation (EU) 2021/2085, at the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners. Furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

ENTITIES ELIGIBLE FOR FUNDING

In relation to the single-stage calls for proposals covered by this Work Programme, the relevant provisions of the General Annex B to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis*.

By way of derogation, in relation to the two-stage calls for proposals covered by this Work Programme, the following provisions shall apply:

- Legal entities identified in the topic text of the call for proposals shall not be eligible for funding from IHI JU. Nevertheless:
- These entities will be entitled to provide contributions as IHI JU members other than Union or contributing partners or as constituent or affiliated entities of either.
- Legal entities participating in indirect actions selected under this type of calls for proposals shall not be eligible for funding where:
 - a) they are for-profit legal entities with an annual turnover of EUR 500 million or more;
 - b) they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);
 - c) they are directly or indirectly controlling a legal entity referred to in point (a).

In line with Article 5(2)(a) (additional conditions in duly justified cases) and Article 119(3) (private contributions to amount of at least 45% of an indirect action's eligible costs and costs of its related additional activities) of the Council Regulation (EU) 2021/2085, under two-stage submission procedures, the following additional condition applies:

- The applicants which are IHI JU members other than the Union, or their constituent entities and affiliated entities, and contributing partners and that are pre-identified in the topics – under the section 'Industry consortium' – of a call for proposals shall not apply at the first stage of the call. The applicant consortium selected at the first stage shall, in preparation for the proposal submission at the second stage, merge with the pre-identified industry consortium.
- In addition, in line with Articles 11 and 119(1) and (3) of the Council Regulation (EU) 2021/2085, legal entities providing in-kind contributions as constituent entities or affiliated entities of IHI JU private members or as contributing partners that are:
 - Not eligible for funding in two-stage calls for proposals; or
 - Not established in a country generally eligible for funding in accordance with Part B of the General Annexes to the Horizon Europe Work Programme 2025,

may exceptionally sign the grant agreement.

This is subject to the following conditions:

- Their participation is considered essential for implementing the action by the granting authority; and
- They participate without requesting any funding.

The essentiality of non-EU legal entities for implementing the action shall be ascertained by the granting authority.

Where specified in the call topics conditions, with reference to the Trade and Cooperation Agreement between the EU and the UK including its Protocol I, establishing the UK's association to the Horizon Europe Programme, more particularly to article 2(2) of that Protocol; and Regulation (EU) 2085/2021, more particularly article 174.14, and Commission Delegated Regulation (EU) 2019/887, specifically article 6.5 ('Principle of Annuality'):

- legal entities established in the UK shall not be eligible to receive funding.

Where specified in the call topic's conditions, with reference to the agreement between the European Union and Canada on the participation of Canada in Union programmes, more particularly to articles 6 and 19; and Regulation (EU) 2085/2021, more particularly article 174.14; and Commission Delegated Regulation (EU) 2019/887, specifically article 6.5 ('Principle of Annuality'):

- legal entities established in Canada shall not be eligible to receive funding.

Where specified in the call topic's conditions, with reference to the agreement between the European Union and the Republic of Korea on the participation of the Republic of Korea in Union programmes, more particularly to articles 6 and 17; and Regulation (EU) 2085/2021, more particularly article 174.14; and Commission Delegated Regulation (EU) 2019/887, specifically article 6.5 ('Principle of Annuality'):

- legal entities established in the Republic of Korea shall not be eligible to receive funding.

Where specified in the call topic's conditions, with reference to the agreement between the European Union and the European Atomic Energy Community and the Swiss Confederation on the participation of the Swiss Confederation in Union Programmes, more particularly to articles 7 and 18; and Regulation (EU) 2085/2021, more particularly article 174.14; and Commission Delegated Regulation (EU) 2019/887, specifically article 6.5 ('Principle of Annuality'):

- legal entities established in Switzerland shall not be eligible to receive funding.

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

With reference to Article 23 of the Council Regulation (EU) 2021/2085, the eligibility of participants in a proposal submitted to a call for proposals for any of the topics in this Work Programme will take into account any application of Article 22(5) of the Horizon Europe Regulation as well as Union legislation and guidance relevant for its application triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

General Annex B ('Eligibility') to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

EVALUATION RULES

General Annex D ('Award Criteria') to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme with the following additions:

- the relevant calls for proposals launched under this Work Programme shall specify whether the call for proposals is a single-stage or two-stage call, and;
- the predefined submission deadline.

Award criteria and scores

Experts will evaluate the proposals on the basis of criteria of 'Excellence', 'Impact' and 'Quality and efficiency of the implementation' according to the type of action, as follows:

	Excellence	Impact	Quality and efficiency of the implementation
	Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:
First stage evaluation of two-stage procedure	<ul style="list-style-type: none"> a) Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art. b) Soundness of the overall methodology. 	<ul style="list-style-type: none"> c) Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project. 	<ul style="list-style-type: none"> d) Quality and effectiveness of the outline of the work plan. e) Capacity of each participant, and extent to which the consortium as a whole brings together the necessary expertise.
Single-stage and second stage of two-stage procedure	<ul style="list-style-type: none"> • Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art. • Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate. 	<ul style="list-style-type: none"> • Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project. • Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities. 	<ul style="list-style-type: none"> • Quality and effectiveness of the work plan, assessment of risks (including risk of falling below 45% contribution threshold), appropriateness of the effort assigned to work packages, and the resources overall. • Capacity and role of each participant, and extent to which the consortium as a whole establishes a public-private collaboration and brings together the necessary expertise. If relevant, capacity and role of the contributing partner(s) to the consortium. • Clearly defined and effective integration of in-kind and financial contributions of IHI JU private members, their constituent or affiliated entities to enable a successful public-private partnership. If relevant, clearly defined and effective integration of in-kind and financial contribution of contributing partner(s).

For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of proposals under both single-stage and two-stage submission procedures:

- the threshold for individual criteria will be 3;
- the overall threshold, applying to the sum of the three individual scores, will be 10;
- proposals that pass individual thresholds and the overall threshold will be considered for funding, within the limits of the available budget. Proposals that do not pass these thresholds will be rejected.

Under the single-stage evaluation procedure, evaluated proposals will be ranked in one single list. With the exception of those provisions herein for establishing priority order for proposals with the same score within the same budget envelope, General Annex F ('Procedure') to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis*.

For proposals with the same score within a single budget envelope (with the exception of the first stage of two-stage submissions) the method to establish the **priority order** is as follows:

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 those scores are equal, priority will be based on scores for 'Impact'.
- Proposals that include the highest number of IHI JU private members and constituent and affiliated entities of the IHI JU private members.
- Proposals that provide the highest percentage of contributions (IKOP, IKA and financial contributions) from the IHI JU private members and contributing partners and the constituent and affiliated entities of both, of the proposal's eligible costs and costs for the related additional activities.
- If necessary, the gender balance among the researchers named in the researchers table in the proposal will be used as a factor for prioritisation.
- 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, 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 IHI JU 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) to 6) will then be applied to the remaining equally ranked proposals in the group.

The highest ranked proposals, within the framework of the available budget, will be invited to prepare a Grant Agreement.

Under the two-stage evaluation procedure, and on the basis of the outcome of the first stage evaluation, the applicant consortium of the highest ranked short proposal (first stage) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (second stage).

If the first-ranked consortium and industry consortium decide that the preparation of a joint full proposal is not feasible, they must formally notify IHI JU within 30 days from the invitation to submit the second-stage proposal. This notification must be accompanied by a joint report clearly stating the reasons why a second stage proposal is considered not feasible. In the absence of a joint notification by the deadline, it is deemed that the first ranked applicant consortium and the industry consortium are going to submit the joint second stage proposal. Accordingly, the second and third-ranked short proposals will be formally rejected.

If the preliminary discussions with the higher ranked proposal and the industry consortium fail, the applicant consortia of the second and third-ranked short proposals (first-stage) for each topic may be invited by IHI JU, in priority order, for preliminary discussions with the industry consortium. The decision to invite lower-ranked consortia to enter into discussions with the industry consortium will take into account the content of the report from the joint report from the first-ranked consortium and industry consortium.

Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first-stage evaluation are communicated to the applicants⁴⁰.

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

1. clarify the proposals and help the panel establish their final assessment and scores, and/or;
2. improve the experts' understanding of the information presented.

In cases clearly identified in the relevant call for proposals where a given topic is composed of two or more sub-topics, one short proposal per sub-topic will be invited.

The IHI JU evaluation procedure is confidential.

The members of the applicant consortia shall avoid taking any actions that could jeopardise confidentiality.

Following each evaluation stage, applicants will receive an ESR (evaluation summary report) regarding their proposal.

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT PREPARATION

Information on the outcome of the evaluation (single-stage, or first stage of a two-stage):

- Single-stage: Maximum 5 months from the submission deadline at the single-stage.
- Two-stage: Maximum 5 months from the submission deadline at the first stage.

Information on the outcome of the evaluation (second stage of a two-stage):

- Maximum 5 months from the submission deadline at the second stage.

Indicative date for the signing of grant agreement:

- Single-stage: Maximum 8 months from the submission deadline.
- Two-stage: Maximum 8 months from the submission deadline at the second stage.

General Annex G ('Legal and Financial setup of the Grant Agreements') to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

BUDGET FLEXIBILITY

General Annex F to the Horizon Europe Work Programme 2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme.

⁴⁰ Failure to observe this restriction may result in IHI JU rejecting either the breaching participant or the full proposal per Article 141 point 1, letter (c) of the 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, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision.

SUBMISSION TOOL

Proposals in response to a topic of an IHI JU call for proposals must be submitted online, before the call deadline, by the coordinator via the Submission Service section of the relevant topic page available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA). No other means of submission will be accepted.

PROPOSALS INCLUDING CLINICAL STUDIES⁴¹

Under the single-stage submission procedures and for the second stage of the two-stage submission procedures: applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system⁴².

SPECIFIC CONDITIONS ON AVAILABILITY, ACCESSIBILITY AND AFFORDABILITY (3A)⁴³

When the specific topic condition so requires, the following conditions shall apply:

- The participants must, during the lifetime of the project and for a period of four years after the project ends, 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 broadly⁴⁴ available and accessible, at fair and reasonable conditions.
- In particular, and always to the extent permitted by applicable competition law:
 - At the proposal stage⁴⁵, and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.⁴⁶
 - At the project interim review stage, if relevant⁴⁷, the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.
 - At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.⁴⁸

⁴¹ Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, 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).

⁴² Template for providing essential information in proposals involving clinical studies - https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

⁴³ Article 125(3) of the Council Regulation (EU) 2021/2085.

⁴⁴ This covers EU Member States and countries that are associated to Horizon Europe at the time of call opening.

⁴⁵ For those 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage. Omission/inadequate treatment of 3A would be identified as a shortcoming. The content however, once considered adequate, will not be utilised for positive scoring and will not contribute towards any evaluation criteria.

⁴⁶ Suggested components would be 1) Identification of planned clinical studies that might generate results for which the provisions are relevant; 2) Confirmation that the consortium members are aware of the provisions and will consider them accordingly. 3) Tentatively identifying markets/areas where the product/service could be made affordable, accessible, available. These points could be checked at the evaluation stage.

⁴⁷ This interim point allows a realistic appraisal of the 3A possibilities during the project lifetime, particularly as to the viability of specific expected 3A results.

⁴⁸ Per the Model Grant Agreement ('MGA') Article 16, the beneficiaries must complete the Results Ownership List ('ROL') which identifies each result generated in the project and the owner thereof. The ROL should inform on the relevant results for which owners implement the 3A strategy in the PDECA for the four years following the project.

- Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (totalling four years from project end), a confidential report⁴⁹ must be submitted to IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

JU RIGHT TO OBJECT TO TRANSFER/EXCLUSIVE LICENSING

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2025 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

c. Country-specific eligibility rules

Following the Horizon Europe Programme Guide, participation in IHI JU indirect actions will be open but eligibility for funding will be however limited to legal entities established in an EU Member State, Associated Country or Low- and Middle-Income Countries (please consult the list in the Horizon Europe Programme Guide⁵⁰).

4.1.4 Calls for tenders and other actions

In 2026, the Programme Office will not launch operational call for tenders.

⁴⁹ Cognisant of IP sensitivities, confidential info, and commercial realities, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:
 - a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
 - b) Broad description of expected downstream actions (including product and service applications);
 - c) broad assessment of expected impact of the above downstream actions towards ensuring affordability, availability, and accessibility.
2. **A Confidential Annex** in which:

The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:

 - a) The planned measures to be taken into effect the 3A obligations;
 - b) That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
 - c) That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

⁵⁰ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

4.1.5 Follow-up activities linked to past calls: monitoring, evaluation and impact assessment

There are 31 IMI2 running projects in 2026, of which 23 will end between 01.01.2026 and 31.12.2026, as indicated in the below table:

In addition to the expected 31 reports for IMI2 programme, there are 4 final reports coming from IMI2 projects that ended in 2025. Therefore, the Programme Office expects to receive 35 periodic reports in 2026, 27 of which will be final reports.

Since the start of IHI JU, 11 calls have been launched by the Programme Office, resulting in 56 projects, with several calls in the Grant Agreement Preparation phase. It is expected that 43 period reports will be submitted by the ongoing IHI projects in 2026.

IMI/IHI calls		Total	Ongoing at 01.01.2026	Of which	
		Projects		Total reports	Project ending in 2026
IHI call 1		5	5	5	0
IHI call 2		2	2	2	0
IHI call 3		9	9	9	0
IHI call 4		6	6	6	0
IHI call 5		7	7	7	0
IHI call 6		2	2	2	0
IHI call 7		8	8	8	0
IHI call 8		4	4	4	0
IHI call 9 ^(a)		13	13		0
IHI call 10 ^(b)					
IHI call 11 ^(b)					
Total IHI		56	56	43	0

(a) some projects still in negotiation phase and not yet signed

(b) Numbers of projects/reports will be further defined after the conclusion of the respective IHI JU calls

In total, the Programme Office expects to receive 78 reports in 2026 (43 for IHI and 35 for IMI2)

Monitoring and analysis of project results

78 project periodic and final reports will be submitted in 2026. These reports will be used to track progress against their stated objectives and deliverables as laid out in the relevant description of the action.

This reporting will also enable an assessment of project achievements and the impact of results. In addition to the usual ex-ante controls, a combination of internal management information systems, external databases, independent evaluations and, if necessary, commissioned studies and surveys will be used to measure the progress and identify significant achievements of IMI and IHI projects.

In 2026, the analysis of the IMI and IHI project scientific outputs in terms of publications and collaboration among IMI and IHI researchers will be continued. Where feasible, monitoring and analysis approaches will be refined in line with observations from the European Court of Auditors (ECA) to ensure the highest possible standards.

Impact assessment of the IMI and IHI projects

The Programme Office remains focused on assessing the performance of the IMI2 programme and has strengthened the monitoring of the IHI programme, building on the lessons learnt from the first IHI projects.

In 2025, the Programme Office continued its systematic monitoring of critical IHI key performance indicators (KPIs) through the SOFIA platform, ensuring that comprehensive and consolidated results were available to feed into the CAAR 2025. This monitoring effort provided a transparent and evidence-based assessment of IHI's progress, and supports informed decision-making.

In 2026 the Programme Office expects to contribute to the impact assessment of IHI within the framework of the Biennial Monitoring Report 2026 (BMR 2026). This report is led by a group of independent experts appointed by the European Commission. It evaluates the performance and impact of the European partnership established under Horizon Europe looking at the strategic objectives and outcomes of various health research partnerships in Europe. It emphasises the importance of collaborative efforts in addressing health challenges and fostering innovation and will inform the upcoming final evaluation of IHI JU.

4.1.6 Cooperation, synergies and cross-cutting themes and activities

The Council Regulation (EU) 2021/2085⁵¹ states that IHI JU should seek and build close collaborations and synergies with other relevant initiatives at Union, national and regional level, in particular with other European partnerships, to achieve greater scientific, socioeconomic and environmental impact and ensure uptake of results. The SRIA lists the European partnerships of potential relevance, notably the partnerships in Cluster 1 of Horizon Europe and EIT Health⁵², wherever relevant. It is also expected that IHI JU activities will contribute to and/or complement the actions of the EU4Health⁵³ programme, HERA⁵⁴, the Digital Europe programme⁵⁵ that will deploy digital capacities and infrastructure related to the health area, and the European Green Deal⁵⁶ by contributing to the development of a greener and more sustainable healthcare sector, and the implementation of the [EU's Life Sciences Strategy](#)⁵⁷, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS)⁵⁸, and the EU Artificial Intelligence Act⁵⁹, where relevant.

Therefore, in 2026 it is planned that IHI JU will continue to explore possible synergies with other Union, national or regional health-oriented programmes, to involve representatives of other European partnerships and initiatives during the process of idea generation and topic drafting where relevant, and to identify the areas in which complementary or joint activities would address the challenges more effectively and efficiently. In particular, IHI JU will liaise with the partnerships created in Cluster 1 of Horizon Europe (notably GH EDCTP3 JU, THCS and ERA4Health), the Innovative SMEs partnership, Chips JU, EIT Health and the Marie Skłodowska-Curie Staff Exchanges action⁶⁰. IHI JU will continue exploring how to best complement the actions of the EU4Health programme, HERA, Coalition for Epidemic Preparedness Innovations (CEPI)⁶¹, the EHDS Regulation and the EU's Life Science Strategy, wherever relevant.

⁵¹ In particular Article 5(2) of the Council Regulation (EU) 2021/2085

⁵² <https://eithealth.eu/>

⁵³ https://hadea.ec.europa.eu/programmes/eu4health/about_en

⁵⁴ https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

⁵⁵ https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en

⁵⁶ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

⁵⁷ https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en

⁵⁸ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

⁵⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

⁶⁰ <https://marie-skłodowska-curie-actions.ec.europa.eu/actions/staff-exchanges>

⁶¹ <https://cepi.net/>

It is also expected that IHI JU activities will complement those of the Digital Europe programme⁶² that will deploy digital capacities and infrastructure related to the health area. Finally, IHI JU will engage more specifically with regional stakeholders, such as EUREGHA⁶³ the reference network for European Regional and Local Health Authorities, and RSCN⁶⁴ representing all accredited active and healthy ageing reference site regions.

IHI JU will seek the advice of the GB in order to identify the most relevant programmes and initiatives. The SIP will support IHI JU in advising on the creation of synergies. The SRG will support IHI JU by reporting on the status of national or regional policy, programmes and activities of relevance.

In addition to attempting to establish collaborations and synergies, IHI JU will continue to engage with its key stakeholders such as patients, regulators and SMEs as part of its cross-cutting activities.

Patients

The IHI JU's goal is to translate health research and innovation into tangible benefits for patients and society by enabling the faster development of people-centred, safe, effective, cost-effective and affordable health solutions that respond to unmet health needs. To achieve this, it is essential to involve all stakeholders including patients in the co-design, co-development and co-implementation of those innovative solutions. IHI JU's aim is to champion a patient-centric approach and especially encourage all funded projects to work in partnership with patients wherever possible.

Patients play an important role when designing and implementing the SRIA, alongside researchers from the public and private sectors including the European life science industry, academia, and regulators. Therefore, IHI JU will continue to strive to embed the patient perspective at all levels, from agenda setting for research in medical innovation and proposal evaluation processes, to project planning, and implementation. Therefore, the systematic involvement of patients in IHI JU's projects and activities will be further supported, facilitated, and strengthened.

Specifically, IHI JU plans to:

1. ensure that patient input is considered at the idea generation and topic writing stage;
2. to explore how best to engage and utilise the IHI Patient Pool;
3. to explore the possibility to organise educational webinars/workshops on patient engagement; communicate on patient engagement needs and opportunities at call launch, facilitating patient engagement in consortia;
4. to identify the most effective channels for communicating information on calls, IHI events, and the most impactful project results to patients and other relevant organisations; and to share best practices of patient engagement in IHI JU projects and ;
5. continue to produce materials for the promotion of patient engagement in IHI JU.

⁶² https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en

⁶³ <https://www.euregha.net/>

⁶⁴ <https://www.rscn.eu/>

Small and medium-sized enterprises

Small and medium-sized enterprises (SMEs) are important IHI JU stakeholders as they can help bring the latest health innovations to the market, leading to tangible benefits for patients and society.

An objective of IHI JU is to enhance the research and innovation capabilities and performance of SMEs by promoting their involvement in IHI JU funded projects. To facilitate this objective relevant call topics will be explored with IHI members and IHI JU will emphasise the importance of SME involvement during info days, consortium-building brokerage meetings, topic webinars and other relevant events. IHI JU will seek to engage with SMEs particularly through their industry members and seek to provide additional information on its rules and procedures to ensure funded SMEs fully benefit from their participation in the programme.

Regulatory and health technology assessment bodies

The regulatory environment is key to ensuring that safe and effective health innovations are developed to address public health needs. To ensure that the science generated by IMI/IHI projects is translated into healthcare solutions, IHI JU will continue engaging with all relevant regulatory authorities.

Notably in addition to continued successful collaboration with the European Medicines Agency (EMA), IHI JU will pursue its efforts to engage more broadly with the national competent authorities (NCA), the Medical Device Coordination Group (MDCG) and, when relevant, with notified bodies for potential input and expertise notified bodies, to reflect the cross-sectoral nature of the partnership.

The regulators' perspective will be embedded in the scientific priorities and calls for proposals, most notably through the representation of regulators in the SIP, input received during IHI JU Regulatory Science Summit as well as consideration of the list of regulatory science research needs established by EMA⁶⁵. In particular, following the [IHI JU Regulatory Science Summit](#) held in 2024⁶⁶ that focused on the five following areas, rare diseases, paediatrics, real-world data / real-world evidence (RWD/RWE), artificial intelligence (AI) and regulatory sandboxes, IHI JU will continue considering the key takeaways from the discussions and see how best to progress them as potential topics that will deliver impactful results for all stakeholders and contribute to regulatory science going forward.

IHI JU will continue to raise the awareness of applicants and project consortia about relevant regulatory aspects and to provide support to consortia to encourage early interactions with regulators whenever relevant to ensure greater impact of projects by translating research outcomes into regulatory practice. This will be done primarily through guidance, including updating as needed the guide [for applicants and project consortia on regulatory considerations for IMI and IHI projects](#) and information sessions.

Using feedback and advice from the members of the SIP and the SRG, IHI JU will lead efforts to further reach out to regulators to promote the programme and encourage their participation in the programme, notably by taking part in IHI projects and fostering cooperation wherever possible.

IHI JU will also strengthen engagement with other international agencies and will seek to enhance collaboration with health technology assessment (HTA) bodies. For instance, in addition to having the HTA's perspective embedded in the scientific priorities and calls for proposals, most notably through the representation of HTA bodies in the SIP, IHI JU will encourage consortia to engage with HTA bodies when relevant in order to better understand the evidence requirements for reimbursement decision-making.

⁶⁵ https://www.ema.europa.eu/en/documents/other/regulatory-science-research-needs_en.pdf

⁶⁶ https://www.ihj.europa.eu/sites/default/files/uploads/Documents/ProjectResources/RegulatoryScienceSummit_Feb2024_Report.pdf

Support to operations of IHI JU in 2026

4.1.7 Communication, dissemination and exploitation

Dissemination and information about project results

Although the responsibility for maximising the impact of their own research and innovation lies primarily with the project consortia, promoting the successes of projects is a core element of both the IHI JU communications and dissemination strategies.

The Programme Office identifies results and successes in a variety of ways, including through formal routes (project periodic reports, interim reviews) and informal routes (direct contacts with project participants, monitoring of project websites and social media, etc.). IHI JU will continue to support and supplement the dissemination of projects' public deliverables via a variety of channels.

In addition, IHI JU will continue to explore how to make better use of EU-specific dissemination tools and channels for the promotion of IMI and IHI projects and their results by actively participating in both the European Commission's Horizon Dissemination and Exploitation Group and the Horizon Feedback 2 Policy Group, and by intensively promoting the Horizon Europe dissemination and exploitation services (the Innovation Radar, the Horizon Results Platform, the Booster and the Horizon Standardisation Booster) among both IHI staff and IMI/IHI projects.

The IHI JU will continue to organise open meetings under the heading "In conversation with..." for those finished projects to showcase their achievements to a general audience. On EU policy relevant topics the Programme Office will organise cross-project meetings or impact meetings on thematic areas to facilitate the identification of significant impacts and learnings from the projects and ensure that this information is disseminated via the channels previously described.

Lastly, IHI JU will continue to fulfil its role/obligation to look after the policy conformity, effectiveness and efficiency of dissemination and exploitation at the level of each project in the portfolio.

Communication

Unfolding IHI's communication strategy

One of the communications team's main objectives will be to report on how both the IHI and IMI ongoing projects will or have met the challenges they were set up to address by: writing news articles, organising impact-focused events, and acting as a sounding board for the communications activities of the projects themselves, building a continuum between the JU's communication and dissemination activities.

The communications team will join forces with the operations team in supporting the call for proposals cycle from ideation to project award, targeting our current stakeholders and broadening our reach to the new sectors that have been brought on board. Targeted thematic workshops, IHI JU info days, brokerage events and call specific webinars as well as external events will remain crucial instruments to address this objective. Particular efforts will go towards refining and promoting the newly developed brokerage platform.

The communication team's third strategic objective will be to consolidate the IHI brand and raise stakeholders' awareness regarding the partnership's research focus, structures and processes, in close collaboration with IHI partners and governance structures. Communication efforts will concentrate on the features and goals that set IHI apart from other funding programmes, as presented in IHI's SRIA and IHI's communication policy.

In order to amplify the reach of new calls for proposals, project success stories and results, IHI JU will keep working in close collaboration with the communication units of the founding partners and our governance bodies, with special emphasis on the SRG.

At the same time, the communications team will remain alert to issues that could damage IHI JU's reputation and respond accordingly by providing timely feedback on stakeholders' views and reactions.

Communication channels

IHI JU will continue to develop content for the following channels with the aim of providing all interested stakeholders with access to relevant and specific information on the work of IHI JU and its projects:

- Events, conferences and brokerage tool;
- website;
- newsletter; social media (LinkedIn, Bluesky, Mastodon);
- videos;
- multipliers (e.g. European Commission & industry partners, SIP, SRG, National Contact Points, relevant scientific associations, patient organisations, healthcare professional associations, etc.);
- media (general and specialist, mainly in Europe but also elsewhere);
- direct mailings;
- publications;
- direct contacts with opinion leaders.

4.1.8 Procurement and contracts

In order to reach its objectives and adequately support its operations and infrastructures, IHI JU will allocate part of its administrative budget to procure the necessary services and supplies.⁶⁷

In 2026, IHI JU will explore different solutions for the acquisition of subscription-based services and cloud-based applications, especially in the field of digital communications. In addition, to guarantee full compliance with IT security measures to ensure the protection and integrity of data, IHI JU may launch a call for tenders for support on Artificial Intelligence, cybersecurity and provision of audit services in the field of information technology (IT). IHI JU may also need to launch procurement procedures linked to specific studies during 2026.

To make tender and contract management as effective and efficient as possible, IHI JU resorts extensively to multi-annual framework contracts and EU inter-institutional tenders. IHI JU will continue the implementation of the public procurement corporate e-procurement tool to simplify, harmonise, modernise and digitise the procurement processes.

Most essential framework contracts are already in place and will be renewed beyond 2026. Synergies with other JUs are created by launching inter-JU joint procurements under the back-office arrangements for corporate, communication, IT and HR related services. The joint procurements are planned on an annual basis and monitored by the Steering Committee set up for the governance of BOA procurement.

⁶⁷ In compliance with the Financial Regulation and Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

4.1.9 Other support operations

a. Relevant functions and administrative synergies within back office arrangements⁶⁸

The JUs have a well-established experience of close collaboration in several areas, including HR, IT, procurement, data protection etc. A lot of information and sharing of best practices is taking place on a regular basis among the peer groups. For example, the Executive Directors, Heads of Administration, HR officers, legal and data protection officers etc. meet regularly to discuss and share experiences. As several JUs are also located in the same premises, the collaboration is concretely serving the business needs – for instance in joint business continuity planning, managing the joint office building and sharing common infrastructure and meeting rooms.

In alignment with the Council Regulation (EU) 2021/2085, a number of areas will be implemented within the back-office arrangements (BOA). In 2026 the implementation under the service level agreements will continue for the accounting services, procurement, HR and ICT. The JUs located in the same office building are also formalising the facility management and logistics under BOA. In 2026 the JUs will work together to further expand the formalised collaboration e.g. in areas like audit and anti-fraud, legal and communication support. This will further enhance the already close collaboration of JUs in order to gain additional cost efficiencies.

b. IT operations

IHI JU is a co-leader of the BOA for ICT services, based on a Service Level Agreement (SLA), in line with the provisions of the Single Basic Act for establishing the Joint Undertakings.

Cybersecurity regulation

The adoption of the “Regulation 2023/2841 laying down measures for a high common level of cybersecurity at the institutions, bodies, offices and agencies of the Union” enforces the establishment of an internal cybersecurity risk management, governance and control framework that ensure effective and prudent management of the cybersecurity risks. The first comprehensive cybersecurity plan will be finalised and submitted to the IICB by 8 January 2026, after which the implementation phase will begin to ensure timely execution of the plan’s objectives, action points and measures.

IHI will continue to coordinate the implementation of the regulation as a leader of the ICT BOA service group 5 “Security and compliance management”, following the official Guidelines from Inter-Institutional Cybersecurity Board and recommendations from CERT-EU and ENISA. Close collaboration and regular use of CERT-EU services like Security Operations Center (SOC), incident response, cybersecurity exercises, penetration tests, security assessments, raising end-user awareness will contribute to strengthening the resilience and security of our systems and operations in 2026.

Stable, secure, and agile IT infrastructure and office automation, more and more focused on the modern (anywhere, anytime) way of working

The Programme Office will continue with the adoption of software-as-a-service (SaaS) solutions from the market and the European Commission.

⁶⁸ Article 13 of the Council Regulation (EU) 2021/2085

Microsoft 365 is the main office automation and core IT infrastructure tool. IHI JU will continue with the evaluation of the existing legacy “on-premise” (IaaS) components with the aim to gradually retire most of them. Migrating to cloud services will simplify the management of the IT infrastructure, lower the cost of hosting and maintenance, and improve overall user satisfaction.

As part of the internal Artificial Intelligence working group, IT will contribute to the implementation of the appropriate AI tool(s) to enhance organisational efficiency and decision-making, focusing on automation of routine tasks, intelligent data analysis, and secure integration within existing systems, while ensuring legal compliance and cybersecurity standards.

Business operations information systems

The main business operations (management of the evaluation of proposals and grants) will continue to be based on the EC eGrants tools. The IT team will monitor satisfactory functioning for all end-users, in close liaison with the European Commission services, including Single Point of Contact (SPOC) functions.

SOFIA, the IHI JU grant management IT system, will be maintained as a complementary tool for business needs that are missing in eGrants like annual reporting of in-kind contributions (IMI 2), overview of project outputs linked to KPIs, WHO priorities addressed by projects, participants’ affiliations and stakeholder types etc.

The IT team contribute to the onboarding new European Commission applications and continue to support the existing ones. In the capacity of External Authorisations Manager (ExAM), we will contribute to the successful migration from ABAC to SUMMA by managing the operational security set-up in conformity with the internal Security Policy and procedures and manage the responsibilities and delegations to the users.

IHI JU will continue with further development of the IHI data warehouse and Qlik sense analytical platform focusing on the integration of IHI JU data and data quality.

Other common JU action points

In the BOA ICT context, IHI JU will contribute to the common work programme for IT with the upgrade of the common meeting rooms in the White Atrium building.

c. Record management, data protection and access to documents

Document management at IHI JU is governed by several regulations. On the one hand, several regulations define the necessary registration and retention, while on the other hand the data protection regulation and the information security policy define access restrictions and deposition of documents.

Therefore IHI JU will continue its efforts undertaken in the wake of the entry into effect of the *vademecum* on record management adopted in 2021⁶⁹, establishing the records management policy for IHI JU based on the European Commission decision C(2020)4482⁷⁰.

IHI JU will continue to take the necessary steps to ensure that all records, data, information, IT systems, transmission (handling) and storage are secure and suitable for both electronic and paper media, are used by IHI JU and fulfil the requirements set in applicable regulations and decisions.

To keep awareness among staff at a high level, IHI JU will continue with procedural guidance and trainings on these matters.

⁶⁹ By Executive Director Decision 19/2021 Ares(2021)5474488

⁷⁰ Commission Decision on records management and archives C(2020)4482.

Record management

Record management covers all information (both electronic and physical) necessary to ensure evidence of IHI JU's activities ensuring an appropriate level of accountability, transparency, and retention of IHI JU's legacy. Effective record management helps to meet IHI JU's transparency obligations, in particular by facilitating public access to documents and implementing the principle of accountability of public actions.

Data protection

For IHI JU, the data protection rules are laid down in Regulation (EU) 2018/1725 on the protection of natural persons regarding the processing of personal data by the Union institutions ('EUDPR')⁷¹.

IHI JU, in compliance with EUDPR, is liaising with the relevant services of the European Data Protection Supervisor and contributing to the activities of the inter-institutional data protection networks and working groups to raise awareness among the staff and stakeholders. Internally, the IHI JU data protection will continue to develop new data protection policies covering horizontal services and encompassing such areas as internal control, procurement, IT, HR, and governance.

Work will continue in maintaining and developing the JU's Record of Processing Activities as mandated by EUDPR, scrutiny and creation of privacy statements in support of the records, and curating the Personal Data Breach Register. The IHI Data Protection Team will also provide further data protection training sessions to cover core topics and keep the IHI staff informed and trained on the data protection legal framework.

Further, the IHI Data Protection Team will continue to advise, where appropriate, on the General Data Protection Regulation ("GDPR") which, in contrast to the EUDPR, applies to the JU's members (other than the Union as well as non-EU organisations and businesses) and governs IHI projects.

Access to information

IHI JU will continue to address requests for access to documents according to Regulation (EC) No 1049/2001, in a spirit of openness and transparency, in order to bring its activities and outputs closer to the public and to retain a high level of public confidence in IHI JU by giving the opportunity to the public to monitor its work.

d. Accounting

The IHI Accounting Officer appointed in 2022 will continue to provide accounting services under BOA accounting. The performance of the accounting services will be monitored carefully in order to ensure business continuity and sound implementation of accounting tasks.

In November 2024 IHI JU was informed by DG BUDG that IHI JU will be migrated to the new European Commission's next generation-corporate financial system, SUMMA, from January 2026. The Programme Office will monitor closely the implementation of the new system in 2026.

⁷¹ OJ L 295, 21.11.2018, p. 39–98

e. Feedback to policy

IHI JU, as a Horizon Europe European partnership, is a key element of the policy approach of Horizon Europe.

The SRIA of IHI JU has been designed to deliver on Union priorities targeted by Horizon Europe and ensure a clear impact for the Union and its people, which can be achieved more effectively in partnership rather than by the Union alone. More specifically, IHI JU's projects contribute to EU policies, most notably Horizon Europe (of which IHI JU is a part), as well as Europe's Beating Cancer Plan, the new Industrial Strategy for Europe, the Pharmaceutical Strategy for Europe and the European Health Data Space. In addition, IHI JU aims to contribute to the United Nations Sustainable Development Goal (SDG) 3 on ensuring healthy lives and promoting well-being for all at all ages.

IHI JU, as a public-private partnership, will continue to lead on innovation and explore how to further contribute to a more circular and resilient economy, support the EU green and digital transitions and development of high-value technologies in the EU, as outlined in the Political Guidelines for the next European Commission 2024-2029⁷². More recently, the Strategy for European Life Science⁷³, and the Competitiveness Council conclusions and roadmap for a strategy on life sciences and biotechnology elaborated on the key challenges identified in the Letta report⁷⁴ on the future of the single market and the Draghi report⁷⁵ on the future of European competitiveness. The documents set out a number of recommendations for developing the European health innovation landscape, pinpointing the critical role of Europe in providing an attractive environment for clinical trials, developing capacity and speed for multi-country clinical trials, operationalising new and innovative approaches to health data, digital health and artificial intelligence, and strengthening Europe's position for advanced cell and biological therapies to ensure that Europe stays at the forefront of innovation and European patients benefit from access to the latest treatments.

Importantly, IHI JU will encourage the exploitation of research and innovation results and actively disseminate and exploit results, in particular for leveraging private investments and for policy development.

4.1.10 Human resources

a. HR management

In 2026, the total number of IHI JU staff will be 53 (comprising 39 temporary agents and 14 contract agents).

The Programme Office will start its fourth year of activity, which should lead to a decrease in staff turnover in comparison to the previous transition years. Nevertheless, the overall reduction in the number of human resources combined with the necessity to manage:

- a large and complex legacy from IMI2 JU projects and;
- new IHI projects;

⁷² https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf

⁷³ COM(2025) 525 final, Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030

⁷⁴ <https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf>

⁷⁵ https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en?filename=The%20future%20of%20European%20competitiveness%20_%20A%20competitiveness%20strategy%20for%20Europe.pdf

will result in a significant impact on the management of the Programme Office's human resources and will lead to an increased pressure on staff. Therefore, the workload will be closely monitored and the management team of IHI JU will need to continue exploring various measures to ensure business continuity, achieve synergies and efficiency and minimise potential impacts on the well-being of staff.

Selection and recruitment

In 2026 the HR priorities will remain:

- the successful and timely management of the selection procedures to guarantee that the best talents, with the necessary set of competences and skills are recruited; and
- the efficient on-boarding of statutory staff, trainees and interims. To this end, the HR team will set up measures to attract the best candidates and will ensure alignment throughout the organisation, establishing a strong link between HR processes and business results and connecting the Programme Office's overall strategic goals with staff performance management.

IHI JU will also foster its traineeship programme to provide young university graduates with the opportunity to gain hands-on professional experience in scientific fields related to IHI JU and to develop and strengthen their skills and competences.

Gender balance and equality will remain important elements in IHI JU's selection and recruitment procedures (today the ratio is 32% male and 68% female with an equal distribution in the IHI JU management team).

To guarantee business continuity, some interims might also be recruited to cope with peaks of work and absences during the year. Finally, further development and improvement of recruitment practices and employer branding may be envisaged.

Career development

To ensure that IHI JU existing talents are retained, the HR team will further explore internal mobility opportunities, staff engagement actions, career coaching, and other career development activities (e.g. job shadowing, staff exchanges, learning opportunities, etc.). Particular attention will continue to be given to the performance management cycle (appraisal and reclassification exercises). To optimise the daily management of the HR activities, and to streamline these two exercises, in 2026, the HR team will continue organising tailor-made training courses for managers and staff and optimise the e-appraisal tool to facilitate the procedure and follow up of the different steps and phases.

The HR team will keep overseeing duties and responsibilities assigned to staff in order to fulfil IHI JU's objectives and tasks.

Learning & Development

To help the development and the personal and professional growth of IHI JU staff and to keep staff knowledge up-to-date, the HR team will further develop the learning and development framework, paying particular attention to the training needs of the staff and the Programme Office.

The HR team will also continue advising management on means and actions to enhance operational efficiency and effectiveness. Tailor-made training courses and coaching programmes for managers will be organised to keep them abreast with managerial skills and techniques, and to support them in their day-to-day management of staff and operational activities; particular attention will be given to performance management.

The Programme Office is committed to preserving a physically and psychologically healthy work environment where work is meaningful, and people are surrounded by the right environment to succeed. To this end, the Programme Office will:

- keep paying particular attention to the wellbeing of its staff, by developing tailor-made wellbeing activities to increase wellness in the workplace (e.g. wellbeing lunchtime sessions, workshops, mental health, first aid training, etc);
- develop teambuilding activities to strengthen collaboration among staff members, to enhance the team spirit and culture; and
- remain vigilant and reiterate its strong commitment to a zero tolerance towards psychological and sexual harassment and a disrespectful work environment.

Legal matters

IHI JU will continue working closely with the relevant European Commission services and the Standing Working Party (group following the Staff Regulations and its General Implementing Provisions) to ensure the adoption of the implementing rules and to strengthen its legal framework, also adopting internal guidelines. In 2026, IHI JU will expect to adopt the model decision on the prevention of and fight against psychological and sexual harassment. Until then, the previous model decision on prevention of harassment will still apply.

In addition to the above, the human resources team will deal with core functions such as: day-to-day management of administrative workflows and processes, salary, compensation and benefits, performance management, career development, reclassification, learning and development, safety and wellbeing at work; employees' motivation and communication.

b. Strategy for achieving efficiency gains and synergies

According to Council Regulation (EU) 2021/2085, Joint Undertakings shall achieve synergies via the establishment of back-office arrangements (BOA) operating in some identified areas. Article 13 identifies Human Resources Support among the areas where common BOAs can be set up. In that context, IHI JU is acting as back-up JU whereas CBE JU is the lead JU for the BOA HR. **Scope of the BOA HR Support**

Established in 2024, the BOA HR will build on the achievements of its first two years and – in 2026 - will continue to focus on the following key areas of HR support, while further developing new projects and activities:

Recruitment

Alignment and harmonisation of the JUs' recruitment processes: following its finalisation in 2025, the common selection process guidelines—designed in accordance with best practices and the applicable legal framework—will be implemented across all JUs, ensuring a consistent and transparent approach whenever a selection procedure is launched.

Organisation of joint selection procedures: to increase efficiency gains, the JUs will strive to organise joint selection procedures for common profiles with same grades. This practice, already in place, will be strengthened in 2026.

Establishment and sharing of reserve lists/ job profiles library: where appropriate, the JUs will continue sharing their reserve lists to shorten their recruitment processes and time-to-recruit.

Inter-JU Competency framework : the BOA HR will continue to work on the common inter-JU competency framework and harmonisation of job profiles, reinforcing consistency and clarity across all roles and supporting more effective HR management in JU's.

HR Legal Framework

The JUs share a common legal framework in the HR domain, therefore additional synergies can be achieved by enhancing the existing collaboration in this area. The focus in 2026 will be on:

- **Staff wellbeing and conflict prevention:** expanded in 2025 with four additional members further to a new call for expression of interest, the JUs will continue to offer to the JU's staff a common network of Confidential Counsellors. Information campaigns and joint actions will be launched to promote staff well-being, raise awareness about psychological and sexual harassment, and implement preventive measures aimed at mitigating workplace conflicts. In this context the JUs will also increase the visibility of mediation services to JU's staff.
- **Collaboration with the EU agencies network (EUAN) and the EC:** the JUs will continue to attend EUAN meetings, including possible ad-hoc participation of the HR Officers to different working groups. The JUs will continue strengthening their collaboration with DGHR/PMO about common HR matters. Notably, building on the recent reinforcement of the collaboration with DG HR, the latter and DG HR will explore the feasibility of working on new synergies such as the possibility for JUs to join the Standing Working Party, access the newly developed modules of the HRT platform of DG HR and a more agile sharing of reserve lists among EU bodies, including executive agencies.
- **BOA HR network:** the JUs HR Officers will continue their strong collaboration. A new multi-annual work plan which will include inter-JU new projects and activities will be developed and adopted by the BOA HR Steering Committee.

After two years of existence, the BOA HR will take stock of its experience and will reflect on the modalities of its governance.

HR Digitalisation

In 2026, the JUs will continue to move towards a digitalisation of HR processes. The BOA HR will continue to share good practices in the use of HR IT systems. and will continue to actively take part in the HR Transformation programme led by the EC.

c. Staff Establishment Plan

Function group and grade	2024				2025				2026	
	Authorised budget		Actually filled as of 31/12/2024		Authorised budget		Actually filled as of 31/12/2025		Authorised budget	
	Perma nent posts	Tempo rary posts	Perma nent posts	Tempo rary posts	Perman ent posts	Tempo rary posts	Perman ent posts	Tempor ary posts	Perman ent posts	Tempora ry posts
AD 16										
AD 15										
AD 14		1		1		1				1
AD 13										
AD 12		2		1		2				2
AD 11		2		2		2				2
AD 10		1		2		1				1
AD 9		6		4		6				6
AD 8		6		2		6				6
AD 7		4		4		4				4
AD 6		10		7		10				10
AD 5		3		10		3				3
TOTAL AD		35		33		35				35
AST 11										
AST10										
AST 9										
AST 8		1		1		1				1
AST 7										
AST 6										
AST 5										
AST 4		3		2		3				3
AST 3										
AST 2										

Function group and grade	2024				2025				2026	
	Authorised budget		Actually filled as of 31/12/2024		Authorised budget		Actually filled as of 31/12/2025		Authorised budget	
	Perma nent posts	Tempo rary posts	Perma nent posts	Tempo rary posts	Perman ent posts	Tempo rary posts	Perman ent posts	Tempor ary posts	Perman ent posts	Tempora ry posts
AST 1										
TOTAL AST		4		3		4				4
AST/SC 6										
AST/SC 5										
AST/SC 4										
AST/SC 3										
AST/SC 2										
AST/SC 1										
TOTAL AST/SC										
TOTAL AD+AST+ AST/SC										
GRAND TOTAL	39		34		39				39	

Contract Agents	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025	FTE corresponding to the authorised budget 2026
Function Group IV	5	4	4	5		5
Function Group III	10	8	8	9		9
Function Group II						
Function Group I						
TOTAL	15	12	12	14		14

Seconded National Experts	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025	FTE corresponding to the authorised budget 2026
TOTAL	0	0	0	0	0	0

Recruitment forecasts 2026 following retirement/mobility or new requested posts						
Job title in the JU	Type of contract (Official, CA, TA)		TA/Official		CA	
			Function group/grade of recruitment internal (Brackets) and external (single grade) foreseen for publication		Recruitment Function Group (I, II, III and IV)	
	Due to foreseen retirement/mobility	New post requested due to additional tasks	Internal (brackets)	External (brackets)		
	0	0				

Governance activities in 2026

Planned activities

- Support the Governing Board (GB), the Science and Innovation Panel (SIP), the States' Representatives Group (SRG) and provide all the necessary information for the performance of their respective tasks.
- Align planning activities (strategy, Work Programme and related budget) and the associated monitoring and reporting activities.
- Improve process efficiency, responsibilities and accountability.
- Enhance communication and transparency.

4.1.11 Governing Board

The GB gathers representatives of IHI JU members. It is the main decision-making body, and as such it has the responsibility of ensuring that the IHI JU achieves its objectives as well as overseeing the operations of the IHI JU and the implementation of its activities.

Three meetings are planned for 2026. The chairperson may be invited to attend the SRG meetings as an observer.

4.1.12 States' Representatives Group

The SRG acts as an advisory body. It must be consulted and, in particular, it must review information and provide opinions on the following matters: Work Programme (and subsequent amendment(s)), the Consolidated Annual Activity Report, the progress of IHI JU and the achievement of its targets.

The SRG will report to the GB on a range of matters, in particular by means of an annual report describing the status of relevant national or regional research and innovation programmes and initiatives, and identifying potential areas of cooperation.

Two meetings of the SRG are planned for 2026 and workshops on specific matters of relevance for the SRG may be considered where appropriate. The chairperson and the vice-chairperson will participate in the GB meetings as observers and in the SIP meetings as permanent panellists.

4.1.13 Science and Innovation Panel

The SIP is the scientific advisory body. It provides the GB with science-based advice on a range of matters, notably by means of reports to the GB, in particular on the annual scientific priorities, ideas submitted by the wider scientific community, the proposed call topics, the planning of additional activities and synergies with other Horizon Europe activities, including other European partnerships as well as other EU and national programmes.

The permanent panellists include representatives of the European Commission, industry partners and the SRG as well as representatives from the scientific community and the wider healthcare community appointed by the GB following an open selection process (the call for expressions of interest was launched in January 2022).

The permanent panellists from the European Commission, industry partners and SRG may invite *ad-hoc* panellists with key scientific or technical expertise to discuss specific subjects with the SIP.

Two meetings are planned for 2026. The chairperson may be invited to participate in the GB meetings as an observer whenever issues falling within the scope of the SIP tasks are discussed. The SIP chairperson is invited in the SRG meetings as an observer to report on SIP activities.

A second joint meeting between the SRG and the SIP might be planned for 2026 to strengthen the interactions between the members of the two advisory bodies.

Strategy and plans for the organisational management and the internal control system in 2026

4.1.14 Internal Control Framework

The priority objective of 2026 will be to maintain an effective internal control system so that reasonable assurance can be drawn that:

1. resources assigned to the activities are used according to the principles of sound financial management;
2. risk of errors in operations is minimised; and
3. the control procedures put in place give the necessary assurance concerning the legality and regularity of the underlying transactions.

This is achieved by IHI JU via a combination of systems, procedures, and supervision, notably including ex-ante and ex-post controls of transactions and monitoring of financial performance.

The implementation of recommendations from audits by the European Court of Auditors and the Commission's Internal Audit Service also play a key role in this area.

Due consideration will be given to:

- a) optimising and updating internal procedures and processes in order to ensure efficiency, effectiveness and better synergies;
- b) a risk management process is integrated into the annual planning cycle by performing a risk assessment exercise and following up with risk mitigation action plans;
- c) incorporating – to a broad extent – the horizontal guidelines and controls to ensure compliance, a harmonised approach across the implementation of the programme, fair and equal treatment towards beneficiaries, and to gather reasonable assurance.

4.1.15 Ex-ante and ex-post controls

Ex-ante controls

Ex-ante controls are rigorously implemented by IHI JU for each transaction (commitments and payments). They are tailored to the different forms of costs and combine trust-based baseline checks and risk-based targeted controls. Together, ex-ante and ex-post controls (see the following section) provide the Authorising Officer with the necessary elements of assurance on the research and innovation budget. IHI JU is implementing the control strategies for the H2020 and Horizon Europe programmes (including ex-ante and ex-post controls and anti-fraud) in 2026.

Specific attention will be paid to:

1. raising beneficiaries' awareness of the financial and administrative aspects of the H2020 and Horizon Europe rules and how to avoid errors in cost reporting;
2. validation of financial and technical reports;
3. ex-ante controls for interim and final payments;
4. following up recovery orders where needed.

Ex-post controls

For IMI2 JU projects running under the H2020 Framework Programme

Ex-post controls of grants are aligned with the harmonised strategy adopted for the entire H2020 Programme. 2025 was the last year of the H2020 audit campaign. In 2026, the Commission Common Audit Service (CAS) will finalise the ongoing H2020 ex-post audits in accordance with the common H2020 audit strategy. The Programme Office contributes to the implementation of the H2020 audit strategy in close cooperation with the CAS and ensures that its ex-post audit strategy is complied with, including its audit coverage ratio. The last risk-based ex-post audits were launched in 2025 according to the Programme Office risk-based audit strategy and will be finalised in 2026. The harmonised legal framework will enable the Programme Office to draw an additional element of assurance from the extension of systematic errors identified in ex-post audits to unaudited financial statements of common audited beneficiaries across H2020.

For IHI JU projects running under the Horizon Europe Framework Programme

Article 31 "Ex-post audits" of the Council Regulation (EU) 2021/2085 stipulates that audits of expenditure on indirect actions shall be carried out in accordance with Article 53 "Audits" of the Horizon Europe Regulation (Regulation (EU) 2021/695 of the European Parliament and of the Council), in particular in line with the audit strategy referred to in Article 53(2) of that Regulation (EU) 2021/695. The Programme Office will contribute to the implementation of the Horizon Europe Control strategy as adopted by the HE Executive Committee on 12 September 2023⁷⁶ in close cooperation with CAS. The Programme Office will continue implementing the common implementation approach of the HE Control strategy and will sample a second batch of risk-based audits. The harmonised legal framework will enable the Programme Office to draw an additional element of assurance from the extension of systematic errors identified in ex-post audits to unaudited financial statements of common audited beneficiaries across Horizon Europe.

⁷⁶ Ref. Ares(2023)4508864

4.1.16 Audits

Internal and external audits

IHI JU audit arrangements are set up in accordance with Articles 28 and 54 of the IHI JU Financial Rules and Article 32 of the SBA.

The audits provide reasonable assurance about the state of effectiveness of risk management, control and governance processes and serve as a building block for the Executive Director's (Authorising Officer's) annual Declaration of Assurance.

In 2026 the European Commission Internal Audit Service (IAS) in the function of IHI JU's internal auditor will finalise the implementation of the Strategic Internal Audit Plan (2023-2025)⁷⁷. The ongoing IAS audit on the set up of the Back Office Arrangements in JUs is expected to be finalised in 2026.

In 2026, the Programme Office will focus on:

- coordinating and supporting IAS's audit work and ensuring an adequate level of assurance from the internal audit;
- closing two audit recommendations originating from the audit on IHI JU Call topic development and stakeholder relations;
- preparing and implementing new action plans where relevant.

External audits are carried out by the European Court of Auditors (ECA). In accordance with the new approach to auditing joint undertakings for the Statement of Assurance starting from the audit of the accounts for the 2025 financial year, the ECA will audit IHI JU and will provide:

- an opinion based on reasonable assurance regarding the reliability of the accounts and the legality and regularity of revenue;
- an opinion based on limited assurance regarding the legality and regularity of payments.

Moreover, ECA will provide an overall opinion based on reasonable assurance regarding the legality and regularity of payments for all JUs together.

In accordance with the IHI JU Financial Rules, IHI JU's 2025 annual accounts will be audited in 2026 by the Baker Tilly audit company that IHI JU contracted. The ECA will draw up its annual audit opinion on the basis of their work.

In view of the overall corporate objective of receiving an unqualified ('clean') ECA audit opinion and positive Statement of Assurance, the key activities will focus on:

- liaising and supporting ECA auditors throughout the full audit cycle of financial years 2025 and 2026;
- implementing actions to address ECA observations from previous audits, and coordinating preliminary findings and action plans for new recommendations

⁷⁷ Ares(2023)638585 of 27/01/2023

4.1.17 Anti-fraud

The IHI JU continues implementing anti-fraud prevention, detection and correction measures aligned with the Commission Anti-Fraud Strategy (CAFS 2019 and 2023 update), the Common Anti-Fraud Strategy for the Research family (RAFS 2023 update) and the common action plan.

In addition to the common approach for the research sector, IHI JU is implementing a specific JU-level anti-fraud strategy and action plan. The 2026 objective is to update the IHI JU Anti-Fraud Strategy and prepare a new action plan.

IHI JU actively participates in the Fraud and Irregularities in Research (FAIR) Committee and contributes to other anti-fraud activities related forums (e.g. EUAN working groups on anti-fraud, transparency and ethics) and trainings.

IHI JU will pursue effective collaboration with the services of the European Anti-Fraud Office (OLAF) and establish cooperation with the European Public Prosecutor's Office (EPPO).

5 Budget 2026⁷⁸

IHI JU is jointly funded by the contributions of its members. The administrative costs are covered by financial contributions divided equally between the EU and the industry partners (EFPIA, COCIR, MedTech Europe and EuropaBio). The operational costs are covered by the financial contributions of the EU and the in-kind contributions of the industry.

The following elements are incorporated into the 2026 budget:

- The initial operational commitment appropriations planned for 2026 in the Single Basic Act was up to EUR 200,000,000. In 2026, the EU contribution has been reduced by EUR 8,000,000 following the review of financial programming in the frame of the mid-term revision of the Horizon Europe. An additional reduction of EUR 6,145,000 should be implemented in 2026 following a reallocation of appropriations inside Horizon Europe to contribute to the AI Gigafactories initiative.
- Carry overs from previous years:
 - EUR 543,687 from 2024 unused commitment administrative appropriations carried over to 2026 administrative (EUR 125,000 EC and EUR 125,000 Industry) and operational (EUR 293,687 EC) budget.
 - EUR 53,584,920 from 2023 and 2024 de-committed appropriations, carried over to operational budget.
 - EUR 10,153,555 from 2024 unused payment appropriations, carried over to administrative (EUR 125,000 and EUR 125,000 Industry) and operational (EUR 9,903,555) budget.
- The actual EFTA rates used for 2026 budget are 2.60% for Horizon Europe and 2.19% for H2020, compared with the planned ones 2.75% for Horizon Europe and 2.33% for H2020.

⁷⁸ Subject to approval of the European Union Budget (DB) for 2026 by the Budgetary Authority (comprised of the Council of the European Union and the European Parliament) as proposed by the European Commission.

- Effective 1st of January 2026, the new financial system SUMMA will replace ABAC. Please note the updated budgetary terminology:
 - VOBU is the new term for C1 (fresh credits).
 - REACT replaces C2 (reactivation of carry overs).
 - IAR is the updated term for C4 (recoveries from beneficiaries).
 - Commitment items is the updated term for budget lines.

Operational budget

- Total commitment appropriations of EUR 239,453,210 consist of fresh credits (EUR 185,574,603) and carry overs (EUR 53,878,607).
- Total payment appropriations of EUR 189,645,469 consist of fresh credits (EUR 179,741,914) and carry overs (EUR 9,903,555).
- The total budget of **call 12** is **EUR 163,100,000**. Outline the call 12 budget on the budget line 3112 fresh credits (EUR 110,000,000), 3212 carry overs UK-based entities non eligible (EUR 43,300,000) and 3312 carry overs CH-based entities non eligible (9,800,000).
- The budget for **call 13** is **EUR 75,000,000**, outlined on the specific budget line 3113 fresh credits⁷⁹.⁸⁰
- The total budget for evaluation experts will be EUR 778,607, outlined on the specific budget line 3900 carry overs .

⁷⁹ The topic text will be added in the 2026 amended Work Programme.

⁸⁰ The total budget of call 12 will remain unchanged, but the allocation per fund sources (fresh credits VOBU, carry overs REACT) will be adapted. The adaptation reflects the requirements resulting from the EU-UK and EU-CH association agreements (for which related carry overs cannot be used to support UK/CH-based entities that are part of selected proposals) and to maximise the use of carry overs fund sources REACT, which need to be used first.

Table 1. Carry overs breakdown

Carry overs to operational budget	Commitment Appropriation (CA)	Payment Appropriation (PA)
Unused 2023 fresh credits (UK entities non-eligible)	2,788,832	
De-committed appropriations stemming from calls 4 and 5 launched in 2023 (UK entities non-eligible)	40,596,843	
Unused 2024 fresh credits (UK entities eligible, CH entities non-eligible)	126,715	
De-committed appropriations stemming from calls 6 and 7 launched in 2024 (UK entities eligible, CH entities non-eligible)	9,534,490	
Unused administrative costs 2024 EC 50% (UK entities eligible, CH entities non-eligible)	293,687	
Unused 2024 operational payment appropriations		9,903,555
De-committed appropriations from evaluation experts from 2023 (EUR 362,310) and 2024 (EUR 175,730)	538,040	
Unused 2024 administrative payment appropriations		125,000
Total	53,878,607	10,028,555
Carry overs to administrative budget	Commitment Appropriation (CA)	Payment Appropriation (PA)
Unused administrative costs 2024 EC 50%	125,000	
EC total carry overs	54,003,607	10,028,555
Unused administrative costs 2024 Industry 50%	125,000	125,000
Total carry overs	54,128,607	10,153,555

Administrative budget

The amount of administrative budget is divided equally (50%-50%) between the EC and industry partners (JU founding members other than the Union): EFPIA, EuropaBio, COCIR and MedTech.

The founding members other than the Union have agreed how to share their contribution to the administrative costs of IHI JU, which shall be covered by:

- a lump sum annual financial contribution of EUR 15,000 from EuropaBio;
 - a financial contribution from EFPIA covering 50% of the relevant amount minus the contribution from EuropaBio, and financial contribution from MedTech and COCIR each covering 25% of the relevant amount.
- The initial administrative contribution out of Horizon Europe budget planned in the Single Basic Act was EUR 4,590,000 (EUR 2,295,000 EC and EUR 2,295,000 industry). Due to difference between the actual and planned EFTA rate for the 2026 budget, there is a total difference of - EUR 6,700 in commitment appropriations (- EUR 3,350 EC and - EUR 3,350 industry).
 - The frontloaded administrative contribution out of H2020 budget is EUR 5,610,000 (EUR 2,805,000 EC and EUR 2,805,000 industry).
 - Total commitment appropriations of EUR 10,443,300 consist of fresh credits (EUR 10,193,300) and carry overs (EUR 250,000).
 - Total payment appropriations of EUR 10,435,624 consist of fresh credits (EUR 10,185,624) and carry overs (EUR 250,000).

- The EUR 250,000 carry over is split equally between the European Commission (EC) and industry partners (EUR 125,000 each), maintaining the initial budget's allocation rates. Industry partners include EFPIA, EuropaBio, COCIR, and MedTech.

Table 2. Industry contributions per programme

Industry contribution per programme	Initial	Carry overs	Total contribution	%
	EUR	EUR	EUR	
IHI JU	2,291,650	56,205	2,347,855	45%
IMI2	2,805,000	68,795	2,873,795	55%
Total	5,096,650	125,000	5,221,650	100%

Regarding industry carry overs, contributions per Members:

- IMI2:
 - EFPIA EUR 68,795
- IHI JU: EUR 56,205 is distributed based on initial budget ratios:
 - EFPIA: EUR 27,540 (49%)
 - Europa Bio: EUR 563 (1%)
 - COCIR: EUR 14,051 (25%)
 - MedTech: EUR 14,051 (25%)

2026 IHI JU BUDGET REVENUE

Table 3. Statement of revenue per founding member

IHI JU - STATEMENT OF REVENUE (EUR)				
	Heading Revenue	Budget 2026		Comments
Chapter/Item		Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution			
1000	European Commission contribution (including EFTA contribution) for current year for IMI2	2,805,000	53,831,251	Commitment appropriations include EUR 2,805,000 for administrative costs. Payment appropriations include EUR 2,801,162 for administrative costs and EUR 51,030,089 for operational costs.
1002	European Commission contribution (including EFTA contribution) for current year for IHI	187,866,253	131,003,475	Commitment appropriations include EUR 2,291,650 for administrative costs and EUR 185,574,603 for operational costs. Payment appropriations include EUR 2,291,650 for administrative costs and EUR 128,711,825 for operational costs.
1001	European Commission - appropriations carried over from previous years	54,003,607	10,028,555	Carry overs from previous years (2023, 2024)
10	European Commission contribution - total	244,674,860	194,863,281	
20	JU members other than the Union contribution			
2000	EFPIA contribution for current year for IMI2	2,805,000	2,801,162	EFPIA contribution to IHI administrative costs
2002	EFPIA contribution for current year for IHI	1,130,825	1,130,825	EFPIA contribution to IHI administrative costs
2001	EFPIA - appropriations carried over from previous years	96,336	96,336	
	EFPIA contribution - total	4,032,161	4,028,323	
2010	EuropaBio contribution for current year	15,000	15,000	EuropaBio contribution to IHI administrative costs
2011	EuropaBio - appropriations carried over from previous years	562	562	
	EuropaBio contribution - total	15,562	15,562	
2020	COCIR contribution for current year	572,913	572,913	COCIR contribution to IHI administrative costs
2021	COCIR - appropriations carried over from previous years	14,051	14,051	
	COCIR contribution - total	586,964	586,964	
2030	MedTech Europe contribution for current year	572,913	572,913	MedTech contribution to IHI administrative costs
2031	MedTech Europe - appropriations carried over from previous years	14,051	14,051	
	MedTech Europe contribution - total	586,964	586,964	
20	JU members other than the Union contribution - total	5,221,650	5,217,812	
IAR	External assigned revenue*	p.m.	p.m.	
	Total revenue	249,896,510	200,081,093	

*pro memoria (p.m.) External assigned revenue, primarily from beneficiary recoveries, totalled EUR 7,746,059 in 2024, largely related to operational activities.

Table 4. Statement of revenue financial years 2025-2026

STATEMENT OF REVENUE EUR								
Title Chapter Heading	Financial year 2025				Financial year 2026			
	Commitment Appropriations	%	Payment Appropriations	%	Commitment Appropriations	%	Payment Appropriations	%
EU contribution (excluding EFTA and third countries contribution)	212,586,908	63%	174,157,359	85%	185,910,510	75%	180,361,310	90%
of which (fresh VOBU) Administrative (Title 1&2)	1,908,441		1,908,441		2,233,577		2,233,577	
of which frontloaded commitments (Title 1&2)	2,964,000		2,877,670		2,805,000		2,741,132	
of which Operational (Title 3)	207,714,467		169,371,248		180,871,932		175,386,602	
Of which related to additional entrusted tasks								
EFTA and third countries contribution	5,764,630	2%	4,491,804	2%	4,760,743	2%	4,473,416	2%
of which Administrative EFTA(Title 1&2)	52,482		119,532		58,073		118,104	
Of which administrative third countries excluding EFTA (Title 1&2)								
of which Operational EFTA (Title 3)	5,712,148		4,372,272		4,702,670		4,355,312	
Of which operational third countries excluding EFTA (Title 3)								
Financial Members other than the Union contribution	5,134,267	2%	5,114,987	3%	5,221,650	2%	5,217,812	3%
of which Administrative (Title 1&2)	4,924,923		4,905,643		5,096,650		5,092,812	
carry overs	209,344		209,344		125,000		125,000	
of which Operational (Title 3)								
Financial Contributing partners contribution								
Interest generated								
Unused appropriations from previous years	112,882,379	34%	20,220,024	10%	53,465,567	21%	10,028,555	5%
Of which administrative	963,400		209,344	0	418,687		125,000	
Of which operational	111,918,979		20,010,680	0	53,584,920		9,903,555	
External assigned revenue*	p.m.		p.m.		p.m.		p.m.	
TOTAL REVENUE	336,368,184	100%	203,984,174	100%	249,896,510	100%	200,081,093	100%

*pro memoriam (p.m.) External assigned revenue, primarily from beneficiary recoveries, totalled EUR 7,746,059 in 2024, largely related to operational activities.

EFTA % used for 2026 is 2.60% for HE and 2.19% for H2020.

EFTA % used for 2025 is 2.75% for HE and 2.33% for H2020.

2026 IHI JU BUDGET EXPENDITURE

Operational commitment appropriations will be used by calls to be launched under the Horizon Europe programme. The total operational budget is set to decrease by 27% compared to 2025. Fresh credits will be reduced by 13% due to the financial programming review which is part of the mid-term revision of Horizon Europe and the redeployment of the budget to contribute to the AI Gigafactories initiative. Carry overs from previous years will decrease by 53% due to effective spending measures implemented last year.

- The budget for **call 12** budget will be **EUR 163,100,000** outlined on the specific budget line 3112 fresh credits (EUR 110,000,000), 3212 carry overs UK-based entities non eligible (EUR 43,300,000) and 3312 carry overs CH-based entities non eligible (EUR 9,800,000).
- The budget for **call 13** will be **EUR 75,000,000**⁸¹ outlined on the specific budget line 3113 fresh credits⁸².
- The total budget for evaluation experts will be EUR 778,607, outlined on the specific budget line 3900 carry overs .
- The payment appropriations will be used for making intermediate and final payments for the FP7 and H2020-related projects as well as pre-financing for projects under the Horizon Europe programme.

The **administrative** budget for 2026 is set to increase by 2% compared to 2025.

Here is a breakdown of the changes:

- Salaries and related costs (Title 1): The budget for this area is increasing to account for salary adjustments and inflation. External staff will increase by 12% in line with operational needs.
- Starting in 2026, IHI will combine all salaries and related costs into a single budget line (1100) to improve efficiency.
- Infrastructure costs (Title 2): Covering expenses like rent, IT, and meetings, this part of the budget will see a 3% decrease.
- IT and Services: There will be a specific increase in costs for IT and service contracts. This is driven by new investments in cybersecurity and the implementation of the new financial system, SUMMA.
- There will be cost reductions related to meetings by holding them online and rental savings.

⁸¹ The topic text will be added in the 2026 amended Work Plan

⁸² The total budget of Call 12 will remain unchanged, but the allocation per fund sources (fresh credits VOB, carry overs REACT) will be adapted. The adaptation reflects the requirements resulting from the EU-UK and EU-CH association agreements (for which related carry overs cannot be used to support UK/CH-based entities that are part of selected proposals) and to maximise the use of carry overs fund sources REACT, which need to be used first.

Table 5. Statement of expenditure per chapters

IHI JU STATEMENT OF EXPENDITURE (EUR)				
Title Chapter	Heading	Budget 2026		Comments
		Commitment Appropriations (CA)	Payment Appropriations (PA)	
1	Staff expenditure	EUR	EUR	
11	Staff in active employment	6,588,000	6,588,000	Salaries and allowances of current staff (TAs and CAs), , promotion and indexation
12	Expenditure relating to staff recruitment	5,000	5,000	Miscellaneous expenditure on staff recruitment: publication of vacancy calls, medical visits to take up duties, services provided by the European Personnel Selection Office (EPSO)
13	Missions and duty travels	135,000	135,000	Missions expenditure
14	Socio-medical infrastructure	322,000	322,000	Other staff costs: EU school, medical check-up, trainings
15	External Services	375,000	375,000	Interim staff expenses
17	Receptions, events and representation	10,000	10,000	Representation expenses
Total Title 1 (Staff expenditure)		7,435,000	7,435,000	
Title Chapter	Heading	Commitment Appropriations (CA)	Payment Appropriations (PA)	Comments
2	Infrastructure expenditure	EUR	EUR	
20	Rental of buildings and associated costs	620,000	620,000	Building related expenditure: rent, works, charges, maintenance, repairs, security and surveillance
21	Information, communication technology and data processing	1,228,300	1,220,624	IT purchases, software licences, software development
22	Office equipment (movable property and associated costs)	5,000	5,000	Purchases and rental of office equipment, maintenance and repair
23	Current administrative expenditure	124,000	124,000	Office supply, newspaper subscriptions, translation services, bank charges and miscellaneous office expenditure
24	Telecommunication and postal expenses	49,000	49,000	Data communication such as telephone, video and audio conferences and postal services
25	Expenditure on formal meetings	92,000	92,000	Official meetings such as States Representative Group, Science and Innovation Panel, Governing Board and working groups created by the Governing Board
26	Administrative expenditure in connection with operational activities	270,000	270,000	Expenditure in connection with research activities and objectives of IHI (workshops, meetings and events targeting IHI projects)
27	External communication, information and publicity	300,000	300,000	External communication and events such as Info Days, stakeholder forums
28	Service contracts	320,000	320,000	Studies, audits, accounting services
Total Title 2 (Infrastructure expenditure)		3,008,300	3,000,624	
TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)		10,443,300	10,435,624	

Title 3	Heading	Commitment Appropriations (CA)	Payment Appropriations (PA)	Comments
3	Operational expenditure	EUR	EUR	
30	Implementing the research agenda of IMI1 and IMI2 JU		51,030,089	Payment appropriations - payments FP7, H2020.
31 VOB	Implementing the research agenda of IHI JU	185,574,603	128,011,825	Commitment appropriations - Calls Horizon Europe. Payment appropriations - payments Horizon Europe.
39_VOB	Evaluation experts		700,000	Costs linked to evaluations, experts contracts.
	Total fresh credits VOB	185,574,603	179,741,914	
30 REACT	IMI2 JU carry overs from previous years		8,781,714	Appropriations carried over from previous years
31 REACT	IHI JU carry overs, UK & CH-based entities eligible	-	630,736	Appropriations carried over from previous years
32 REACT	IHI JU carry overs, UK & CH-based entities non eligible	43,300,000	462,435	Appropriations carried over (CA from 2023)
33 REACT	IHI JU carry overs, UK-based entities eligible, CH entities non-eligible	9,800,000		Appropriations carried over (CA from 2024)
39_REACT	Evaluation experts	778,607	28,670	Costs linked to evaluations, experts contracts.
	Total carry overs REACT	53,878,607	9,903,555	
Total Title 3 (Operational expenditure)		239,453,210	189,645,469	
IAR	External assigned revenue*	p.m.	p.m.	
TOTAL EXPENDITURE		249,896,510	200,081,093	

- *pro memoriam (p.m.) External assigned revenue, primarily from beneficiary recoveries, totalled EUR 7,746,059 in 2024, largely related to operational activities.

Table 6. Statement of expenditure financial years 2025-2026

Chapter	STATEMENT OF EXPENDITURE								
	Title Chapter Heading	Financial year 2025				Financial year 2026			
		Commitment Appropriations	% Ratio	Payment Appropriations	% Ratio	Commitment Appropriations	% Ratio	Payment Appropriations	% Ratio
			Year 2025/year 2024		Year 2025/year 2024		Year 2026/year 2025		Year 2026/year 2025
1	Title 1 - Staff expenditure	7,156,000	3%	7,156,000	3%	7,435,000	4%	7,435,000	4%
11	Staff in active employment (salaries & allowances)	6,337,000	0%	6,337,000	0%	6,588,000	4%	6,588,000	4%
	- Of which establishment plan posts	5,227,000	0%	5,227,000	0%	5,440,000	4%	5,440,000	4%
	- Of which external personnel	1,110,000	0%	1,110,000	0%	1,148,000	3%	1,148,000	3%
12	Expenditure relating to staff recruitment	13,000	0%	13,000	0%	5,000	-62%	5,000	-62%
13	Missions and duty travels	134,000	-7%	134,000	-7%	135,000	1%	135,000	1%
14	Socio-medical infrastructure	202,000	11%	202,000	11%	242,000	20%	242,000	20%
14	Training	115,000	0%	115,000	0%	80,000	-30%	80,000	-30%
15	External services	335,000	0%	335,000	0%	375,000	12%	375,000	12%
17	Receptions, events and representation	20,000	0%	20,000	0%	10,000	-50%	10,000	-50%
2	Title 2 - Infrastructure expenditure	3,112,533	0%	3,073,973	0%	3,008,300	-3%	3,000,624	-2%
20	Rental of buildings and associated costs	690,000	0%	690,000	0%	620,000	-10%	620,000	-10%
21	Information, communication technology and data processing	1,216,533	2%	1,177,973	-2%	1,228,300	1%	1,220,624	4%
22	Office equipment (movable property and associated costs)	5,000	0%	5,000	0%	5,000	0%	5,000	0%
23	Current administrative expenditure	124,000	0%	124,000	0%	124,000	0%	124,000	0%
24	Telecommunication and postal expenses	47,000	0%	47,000	0%	49,000	4%	49,000	4%
25	Expenditure on formal meetings	122,000	22%	122,000	22%	92,000	-25%	92,000	-25%
26	Administrative expenditure in connection with operational activities	300,000	-3%	300,000	-3%	270,000	-10%	270,000	-10%
27	External communication, information and publicity	300,000	0%	300,000	0%	300,000	0%	300,000	0%
28	Service contracts	308,000	-9%	308,000	-9%	320,000	4%	320,000	4%
3	TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)	10,268,533	2%	10,229,973	2%	10,443,300	2%	10,435,624	2%
3	Title 3 - Operational expenditure	326,099,651	-13%	193,754,200	-10%	239,453,210	-27%	189,645,469	-2%
	<i>Of which fresh credits</i>	213,426,615		173,743,520		185,574,603	-13%	179,741,914	3%
	<i>Of which carry overs from previous years</i>	112,673,036		20,010,680		53,878,607	-53%	9,903,555	-51%
	TOTAL OPERATIONAL (Title 3)	326,099,651	-13%	193,754,200	-10%	239,453,210	-27%	189,645,469	-2%
	External assigned revenue*	p.m.		p.m.		p.m.		p.m.	
	TOTAL EXPENDITURE	336,368,184	-12%	203,984,173	-10%	249,896,510	-26%	200,081,093	-2%

*pro memoriam (p.m.) External assigned revenue, primarily from beneficiary recoveries, totalled EUR 7,746,059 in 2024, largely related to operational activities.

EFTA % used for 2026 is 2.60% for HE and 2.19% for H2020.

EFTA % used for 2025 is 2.75% for HE and 2.33% for H2020.

Table 7. Overview of the budget per commitment items

Commitment items Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1	Staff expenditure	EUR	EUR
1100	Staff in active employment and costs linked to employees	6,588,000	6,588,000
11	Staff in active employment	6,588,000	6,588,000
1200	Miscellaneous expenditure on staff recruitment	5,000	5,000
12	Staff recruitments - miscellaneous expenditure	5,000	5,000
1300	Mission expenses	135,000	135,000
13	Missions and duty travels	135,000	135,000
1401	EU school costs	195,000	195,000
1410	Other trainings	50,000	50,000
1420	Supplementary aid for the disabled	2,000	2,000
1430	Medical service	25,000	25,000
1440	Trainings covered by the EC service level agreement	30,000	30,000
1490	Other interventions	20,000	20,000
14	Socio-medical structure	322,000	322,000
1500	External staff expenditure	375,000	375,000
	<i>initial</i>	<i>125,000</i>	<i>125,000</i>
	<i>carry overs 2024</i>	<i>250,000</i>	<i>250,000</i>
15	External staff services	375,000	375,000
1700	Representation expenses	10,000	10,000
17	Representation	10,000	10,000
Total Title 1 (Staff expenditure)		7,435,000	7,435,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2	Infrastructure expenditure	EUR	EUR
2000	Rentals office building	440,000	440,000
2001	Guarantees		
2002	Contributions		
2010	Insurance		
2020	Charges (water, gas, electricity, works)	165,000	165,000
2030	Cleaning and maintenance		
2040	Furnishing of premises	10,000	10,000
2050	Security and surveillance	5,000	5,000
2090	Other expenditure on buildings		
20	Rental of buildings and associated costs	620,000	620,000
2101	Hardware, infrastructure and related services	460,000	460,000
2102	Software development, licenses and related services	768,300	760,624
2103	Other expenses maintenance and repair		
21	ICT expenditure	1,228,300	1,220,624
2200	Purchase office equipment		
2201	Rentals office equipment		
2202	Maintenance utilisation and repair	5,000	5,000
2203	Other office equipment		
22	Office equipment (movable property and associated costs)	5,000	5,000
2300	Stationery and office supply	50,000	50,000
2320	Bank charges		
2321	Exchange rate losses		
2329	Other financial charges		
2330	Legal expenses	15,000	15,000
2350	Other operating expenditure	3,000	3,000
2351	Petty expenses		
2360	Library stocks purchase of books and subscriptions	51,000	51,000
2370	Translation, interpretation	5,000	5,000
23	Current administrative expenditure	124,000	124,000
2400	Correspondence and communication expenses	49,000	49,000
24	Postage and telecommunication expenses	49,000	49,000
2500	Formal meetings	92,000	92,000
25	Formal meetings expenditure	92,000	92,000
2600	Administrative costs in connection with operational activities		
2601	Events targeting projects		
2602	Workshops	270,000	270,000
2603	Knowledge management		
26	Administrative costs in connection with operational activities	270,000	270,000
2700	External communication	60,000	60,000
2701	Events external communication	200,000	200,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2	Infrastructure expenditure	EUR	EUR
2702	Material	40,000	40,000
27	Communication activities	300,000	300,000
2800	Ex-post audits		0
2801	Studies, consultancy	125,000	125,000
2802	Audits services	25,000	25,000
2803	Accounting services	170,000	170,000
28	External services	320,000	320,000
Total Title 2 (Infrastructure expenditure)		3,008,300	3,000,624
Total administrative expenditure Title 1 +Title 2		10,443,300	10,435,624
Commitment items Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3	Operational expenditure	EUR	EUR
3020	Implementing the research agenda of IMI2 JU		51,030,089
3100	Horizon Europe	574,603	128,011,825
3112	IHI JU Call 12 UK&CA&CH-based entities eligible	110,000,000	
3113	IHI JU Call 13 UK&CA&CH-based entities eligible	75,000,000	
3900	Evaluations experts		700,000
30 - VOB	Implementing the research agenda of IMI2 JU	185,574,603	179,741,914
Commitment items Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3020 - REACT	Implementing the research agenda of IMI2 JU appropriations carried over from previous years		8,781,714
3100 - REACT	Horizon Europe appropriations carried over from previous years, UK&CH-based entities eligible		630,736
3212 - REACT	IHI JU Call 12 UK&CA&CH-based entities non eligible	43,300,000	462,435
3312 - REACT	IHI JU Call12 UK-based entities eligible, CH entities non-eligible	9,800,000	
3900 - REACT	Evaluations experts	778,607	28,670
31_32_39 - REACT	Implementing the research agenda of IHI JU	53,878,607	9,903,555
Total Title 3 (Operational expenditure) VOB + REACT		239,453,210	189,645,469
IAR	External assigned revenue*	p.m.	p.m.
Total expenditure		249,896,510	200,081,093

*pro memoriam (p.m.) External assigned revenue, primarily from beneficiary recoveries, totalled EUR 7,746,059 in 2024, largely related to operational activities.

Annex 1 - IKAA Plan for 2026

The IKAA Plan contains additional activities expected to be carried out by IHI JU private members, their constituent or affiliated entities. It is composed of two types of additional activities:

- project-specific additional activities that contribute towards the achievement of objectives of the IHI JU funded projects, or the dissemination, sustainability, or exploitation of IHI JU project results;
- programme-specific additional activities that contribute to the uptake of results from funded projects (by IHI JU or its preceding initiatives, i.e. IMI1 JU or IMI2 JU) or have a significant added value for the Union.

The IKAA Plan, including additional activities expected to be carried out in 2026, is composed of the following elements:

- Project-specific additional activities approved by the GB⁸³ related to grants signed of call 1, 2 and 3 – amounting respectively to EUR 15,023,959 for call 1, EUR 994,750 for call 2, and EUR 5,556,800 for call 3 (the amounts of EUR 15,023,559 for call 1, EUR 1,083,250 for call 2 and EUR 5,589,966 for call 3 were approved by the GB and are now modified to EUR 15,023,959, EUR 994,750 and EUR 5,556,800 respectively following corrections by private members);
- Project-specific additional activities approved by the GB⁸⁴ related to grants signed of call 4, 5 and 7 – amounting respectively to EUR 8,833,053 for call 4, EUR 8,791,145 for call 5 and EUR 24,083,673 for call 7 (the amount of EUR 24,191,673 for call 7 was approved by the GB and it is now reduced to EUR 24,083,673 following the termination of one private member in an IHI project);
- Project-specific additional activities related to grants signed of call 6 – amounting to EUR 1,870,000 – that are reflected in the IKAA Plan available [here](#).
- Project-specific additional activities related to projects selected under the IHI JU call 8 and call 9 amounting respectively to EUR 15.255.358 for call 8 and to EUR 44.963.657 for call 9⁸⁵. The concerned additional activities will be formally included in the IKAA Plan after the respective grant agreements are signed.
- Potential project-specific additional activities for 2026 related to projects that will be selected under call 10 and call 11 (launched in 2025) as well as under call 12 (launched in 2026) may be planned from (full) proposals submission stage⁸⁶. However, the exact nature of these additional activities and their amounts planned may be known only when the GB approves the list of projects selected for funding.
- There will be no project-specific additional activities for 2026 related to projects to be selected under the IHI JU call 13 as the full proposal submission stage is expected in 2027.
- Programme-specific additional activities that started in a prior year and were already approved by the GB⁸⁷ amounting to EUR 38,119,325;
- Programme-specific additional activities that started in a prior year and were already approved by the GB but for which the initial estimated total value is increased by EUR 48,000 due to extended duration of activities;

⁸³ See adopted [IKAA Plan](#) in [WP 2024](#).

⁸⁴ See adopted [IKAA Plan](#) in [WP 2025](#).

⁸⁵ IHI-GB-DEC-2025-19 Decision approving the list of proposals selected for funding and reserve list pursuant to the evaluation of the IHI Call 9 for proposals.

⁸⁶ “Costs associated with project-specific additional activities must be incurred between the date of submission of the proposal and up to two years after the end date of the indirect action” as per Article 120 of the of the Council Regulation (EU) 2021/2085.

⁸⁷ See adopted [IKAA Plan](#) in [WP 2025](#).

- Programme-specific additional activities that will start in 2026 amounting to EUR 283,861, identified in the table below.

The IKAA Plan (project and programme levels) amounts to EUR 163,823,582 and is available [here](#).

Overall it contains:

- EUR 125,372,396 of project-specific IKAA (including EUR 65,153,380 of IKAA in signed grants and EUR 60,219,015 of IKAA in selected proposals)
- EUR 38,451,186 of programme-specific IKAA.

It may be subject to modification following a separate GB decision in 2026 as needed. The updated IKAA Plan will be available on the IHI JU website [here](#).

OVERVIEW ESTIMATED IKAA FOR YEAR 2026⁸⁸						
Title of the additional activities	Description of the additional activities	Category of additional activities	Type of additional activities	Linked to project	Linked to programme	Estimated total value (in EUR)
C4C stichting membership	Cash funding to C4C Stichting in the form of a membership	Creating new business opportunities	Invest in start-ups, spin-offs on solutions developed within the projects	No	Yes	150,000
Post-Term Agreement to the MACUSTAR project	The purpose of this Post-Term Agreement is to facilitate the completion of the Post-Term Activities and to agree on certain practical details and the financial impact of these Post-Term Activities.	Support to additional R&I	Support to public-private partnership cooperation	No	Yes	73,861
C4C stichting membership	Cash funding to C4C Stichting in the form of a membership	Creating new business opportunities	Invest in start-ups, spin-offs on solutions developed within the projects	No	Yes	60,000
TOTAL PLANNED IKAA starting in 2026						283,861

⁸⁸ This table includes only new programme-specific additional activities expected to be carried out by IHI JU private members, their constituent and affiliated entities in 2026. Therefore, it neither includes project-specific additional activities nor programme-specific additional activities that started in a prior year and were already approved by the GB. The IKAA Plan (project and programme levels) is available [here](#).

Annex 2 - IHI call 12

Boosting innovation for a competitive European health ecosystem

Introduction to the Call and general elements to be considered for all topics.

This call aims to fund pre-competitive⁸⁹ Research and Innovation Actions (RIA)⁹⁰ that contribute to addressing the IHI JU's Specific Objectives, as defined in IHI JU's legal basis⁹¹ and described in more detail in the IHI JU [Strategic Research and Innovation Agenda](#) (SRIA).

The call contains five topics, each focusing on one of the five IHI JU Specific Objectives (SOs):

- **Topic 1 (SO1):** contribute towards a better understanding of the determinants of health and priority disease areas;
- **Topic 2 (SO2):** integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users;
- **Topic 3 (SO3):** demonstrate the feasibility of people-centred, integrated healthcare solutions;
- **Topic 4 (SO4):** exploit the full potential of digitalisation and data exchange in healthcare;
- **Topic 5 (SO5):** enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

The scope of each of the topics is broad in order to harness new science and technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently, and that could ultimately be integrated/implemented into the healthcare ecosystem for the benefit of patients and society.

In line with the first IHI JU general objective '*to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations*', actions to be funded under this call are expected to perform activities at scale that drive novel, concrete and transformational outcomes.

⁸⁹ In the context of IHI, pre-competitive refers to collaborative research among potential competitors addressing common challenges, building knowledge and developing foundational technologies or standards that benefit all the actors in that research space, rather than individual companies.

⁹⁰ Research and innovation actions (RIA) — Activities that aim primarily to establish new knowledge or to explore the feasibility of a new or improved technology, product, process, service or solution. This may include basic and applied research, technology development and integration, testing, demonstration and validation of a small-scale prototype in a laboratory or simulated environment (see General Annex B ('Eligibility') to the Horizon Europe Work Programme 2025)

⁹¹ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

Furthermore, actions to be funded under this call should address unmet public health needs in line with the second IHI JU general objective of delivering safe, effective health innovations that cover the entire spectrum of care – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need.

Unmet public health needs are needs that are currently not addressed by the healthcare systems for various reasons; for example, if no health technologies⁹² are known to tackle a disease effectively, or because of a general overload on health care systems that challenges the capacity to deliver the right care at the right time.

In this context applicants should consider at least one of the below points:

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;
- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

Most activities are expected to be cross-sectoral, reflecting the integrative nature of IHI as a public-private partnership, and to consider the different innovation cycles of the pharmaceutical and medical technology industries. In particular, the call welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development, deployment and user uptake of novel treatments and healthcare solutions.

Proposals that aim to demonstrate the feasibility and/or scalability of integrating novel solutions into global, national, or regional healthcare systems and/or of innovations are welcomed. However, the research supported by this call for proposals should remain at the pre-competitive level and should translate into solutions that can be applied by all players in the ecosystem.

Proposals submitted under the topics of this call may cover activities over the whole health innovation chain including, but not limited to:

- discovery of new molecules, mechanisms of action, processes, technologies;
- development and testing of these discoveries;
- development of methodologies for assessment of safety, health outcomes or health-economic evaluation;
- standardisation activities;
- contribution to regulatory science;
- pilots/proofs of feasibility including *in-silico* trials.

As proposals can only be submitted under one topic, applicants must carefully consider which IHI JU Specific Objective is the most relevant to the primary focus of their proposal and submit it only under the corresponding topic. Applicants must clearly justify the alignment of the objectives of their proposed work with the IHI JU Specific Objective selected. Considering the complementarity of the IHI JU Specific Objectives, proposals may also cover aspects related to other Specific Objective(s). If so, applicants should also highlight this in their proposal.

⁹² Health technology means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in health care.

Applicants are therefore encouraged to read the IHI JU SRIA⁹³ carefully for full information on the IHI JU Specific Objectives. Furthermore, applicants should carry out a landscape analysis of the relevant existing initiatives/projects to avoid unnecessary overlap and duplication of efforts.

⁹³ https://www.ihj.europa.eu/sites/default/files/1/mnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Topic 1: Boosting innovation for a better understanding of the determinants of health

NOTE: Applicants must also read the section ‘Introduction to the Call and general elements to be considered for all topics’ carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they add novel contributions to a better understanding of the determinants of health and priority disease areas, in line with the IHI JU’s Specific Objective 1 as set out in the [IHI JU Strategic Research and Innovation Agenda](#) (SRIA).

Actions (projects) to be funded under this topic must deliver outcomes that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods and technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 1 ‘**contribute towards a better understanding of the determinants of health and priority disease areas**’, as defined in IHI JU’s legal basis⁹⁴ and described in more detail in the IHI JU SRIA⁹⁵.

⁹⁴ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

⁹⁵ https://www.ihj.europa.eu/sites/default/files/flmngnr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
 - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
 - the high economic impact of the disease for patients and society;
 - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics);
- b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or in industrial processes;
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposals, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective⁹⁶. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in-vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services, such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation⁹⁷ in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

⁹⁶ 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

⁹⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 1 as set out in the IHI JU SRIA, i.e.:

- patients benefit from preventive treatment or early disease intervention before onset of symptoms;
- prevention and early diagnosis of disease combined with better understanding of the mechanisms involved, leading to the development of more cost-effective strategies;
- patients benefit from improved healthcare through regular monitoring of critical parameters using validated tools;
- development of new vaccine strategies targeted to specific sub-populations;
- increased preparedness of EU healthcare systems for disease outbreaks.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the EU's Life Sciences Strategy⁹⁸ and its specific aims such as:
 - i) reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions;
 - ii) promoting a holistic approach to the life sciences (e.g. One Health approach among others).

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the [European Green Deal](#), [Europe's Beating Cancer Plan](#), the [EU Mission on Cancer](#), the [Apply AI Strategy](#), the [European Virtual Human Twins Initiative](#), the [1+ Million Genomes Initiative](#), the [preparedness and response to health emergencies](#), the upcoming EU Biotech Act, the [Regulation on the European Health Data Space \(EHDS\)](#), and the [EU Artificial Intelligence Act](#), where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

⁹⁸ https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 30 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension, as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members⁹⁹ and the contributing partners. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the proposed project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

⁹⁹ The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry)

Topic 2: Boosting innovation through better integration of fragmented health R&I efforts

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the integration of fragmented health R&I efforts to enable development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users in line with the IHI JU's Specific Objective 2 as set out in the [IHI JU Strategic Research and Innovation Agenda](#) (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 2 '*integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users*' as defined in IHI JU's legal basis¹⁰⁰ and described in more detail in the IHI JU SRIA¹⁰¹:

¹⁰⁰ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

¹⁰¹ https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
 - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
 - the high economic impact of the disease for patients and society;
 - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or industrial processes.
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

Proposals may address specific target populations, underserved communities or areas with limited resources, and/or support challenging unmet needs and diagnostic or treatment gaps.

In their proposal, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective¹⁰². In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, scale-up, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation¹⁰³ in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

¹⁰² 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

¹⁰³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 2, as set out in the IHI JU SRIA, i.e.:

- breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative, people-centred, integrated healthcare solutions that can seamlessly be introduced in healthcare systems;
- fostering development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation;
- better and faster integration of future products, services and tools along the healthcare pathway (including health promotion and disease prevention), responding to patients' specific needs and leading to improved health outcomes and patient well-being;
- patients and industry benefit from innovative manufacturing processes such as 3D printing, on-demand small-scale good manufacturing practice (GMP) synthesis, on-site portable production systems etc.;
- green transition enabled across all aspects of healthcare, both in the delivery of healthcare to patients, and in the technologies and products that emerge from a competitive European industry.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the [EU's Life Sciences Strategy](#) and its specific aims such as:
 - i) reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions; biotechnology innovation; bringing together fragmented efforts into dynamic and connected R&I ecosystems;
 - ii) driving industrial innovation and sustainability (e.g. improving processes to green European industrial health industry, novel tools such as new approach methodologies (NAMs), or others).

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the [European Green Deal](#), [Europe's Beating Cancer Plan](#), the [EU Mission on Cancer](#), the upcoming Cardiovascular Plan, the [Apply AI Strategy](#), the [European Virtual Human Twins Initiative](#), the [1+ Million Genomes Initiative](#), the [preparedness and response to health emergencies](#), the upcoming EU Biotech Act, the [Regulation on the European Health Data Space \(EHDS\)](#), and the [EU Artificial Intelligence Act](#), where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 60 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 15 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members¹⁰⁴ and/or the contributing partners (if any). IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the proposed project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

¹⁰⁴ The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry)

Topic 3: Boosting innovation for people-centred integrated healthcare solutions

NOTE: Applicants must also read the section ‘Introduction to the Call and general elements to be considered for all topics’ carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the feasibility of people-centred, integrated healthcare solutions in line with the IHI JU’s Specific Objective 3 as set out in the [IHI JU Strategic Research and Innovation Agenda \(SRIA\)](#).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to diseases management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases, and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the IHI JU’s Specific Objective 3 ‘*demonstrate the feasibility of people-centred, integrated healthcare solutions*’, as defined in IHI JU’s legal basis¹⁰⁵ and described in more detail in the IHI JU SRIA¹⁰⁶.

¹⁰⁵ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

¹⁰⁶ https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
 - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
 - the high economic impact of the disease for patients and society;
 - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) have people-centric, rather than product- and pathology-centric, approaches – the focus being on the patient and citizen journey through health care, with the help of most suitable health technologies and social innovations and taking account of demographic trends;
- c) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- d) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

In their proposal, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective¹⁰⁷. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation¹⁰⁸ in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

¹⁰⁷ 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

¹⁰⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 3, as set out in the IHI JU SRIA, i.e.:

- raised awareness among citizens and patients on their own role in managing their health;
- improved patient adherence to prevention programmes and medical interventions;
- people, including vulnerable populations (e.g. elderly and children as well as their carers and/or representatives), are better able to make informed decisions with their healthcare professionals about prevention, treatment interventions and disease management;
- increased frequency and quality of cooperation between patients, citizens and industrial stakeholders in the development of healthcare solutions, in particular integrated care solutions;
- patients benefit from prevention and treatment that is better adapted to their needs through improved diagnostic and monitoring;
- integrated healthcare solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and citizens, supporting an inclusive approach;
- successful implementation of digital solutions supporting people-centred care;
- facilitated introduction of innovative solutions for improved home care of patients;

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the [EU's Life Sciences Strategy](#) and its specific aims such as reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions; better means to engage with citizens to work closer with end-users to ensure adequate solutions for their specific needs and to beat disinformation and build trust.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the [European Green Deal](#), [Europe's Beating Cancer Plan](#), the [EU Mission on Cancer](#), the [Apply AI Strategy](#), the [European Virtual Human Twins Initiative](#), the [1+ Million Genomes Initiative](#), the [preparedness and response to health emergencies](#), the upcoming EU Biotech Act, the [Regulation on the European Health Data Space \(EHDS\)](#), and the [EU Artificial Intelligence Act](#), where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 20 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin, e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members¹⁰⁹ and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

¹⁰⁹ The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry)

Topic 4: Boosting innovation through exploitation of digitalisation and data exchange in healthcare

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the digitalisation and data exchange in healthcare in line with the IHI JU's Specific Objective 4 as set out in the [IHI JU Strategic Research and Innovation Agenda](#) (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 4 '*exploit the full potential of digitalisation and data exchange in healthcare*', as defined in IHI JU's legal basis¹¹⁰ and described in more detail in the IHI JU SRIA¹¹¹.

¹¹⁰ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

¹¹¹ https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
 - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
 - the high economic impact of the disease for patients and society;
 - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposal, applicants are expected to perform at scale activities that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective¹¹². In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA), through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation¹¹³ in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

¹¹² 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

¹¹³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 4, as reflected in the IHI JU SRIA, i.e.:

- wider availability of interoperable, quality data, respecting FAIR (findable, accessible, interoperable, reusable) principles, facilitating research and the development of integrated products and services;
- improved insight into the real-life behaviour and challenges of patients with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies;
- advanced analytics / artificial intelligence supporting health R&I, resulting in:
 - i) clinical decision support for increased accuracy of diagnosis and efficacy of treatment;
 - ii) shorter times to market;
 - iii) wider availability of personalised health interventions to end-users;
 - iv) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the [EU's Life Sciences Strategy](#) and its specific aims such as unlocking the power of new knowledge, data and AI for breakthrough innovation.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the [European Green Deal](#), [Europe's Beating Cancer Plan](#), the [EU Mission on Cancer](#), the [Apply AI Strategy](#), the [European Virtual Human Twins Initiative](#), the [1+ Million Genomes Initiative](#), the [preparedness and response to health emergencies](#), the upcoming EU Biotech Act, the [Regulation on the European Health Data Space \(EHDS\)](#), and the [EU Artificial Intelligence Act](#), where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 43,300,000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members¹¹⁴ and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the proposed project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

Legal entities established in the UK

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the UK are not eligible to receive funding.

Legal entities established in Canada

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Canada are not eligible to receive funding.

Legal entities established in the Republic of Korea

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the Republic of Korea are not eligible to receive funding.

¹¹⁴ The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry)

Legal entities established in Switzerland

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Switzerland are not eligible to receive funding.

Topic 5: Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions in line with the IHI JU's specific objective 5 as set out in the [IHI JU Strategic Research and Innovation Agenda](#) (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing challenge(s) and scope of the IHI JU's Specific Objective 5 '*enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions*'; as defined in IHI JU's legal basis¹¹⁵ and described in more detail in the IHI JU SRIA¹¹⁶.

¹¹⁵ Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

¹¹⁶ https://www.ihj.europa.eu/sites/default/files/flmnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
 - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
 - the high economic impact of the disease for patients and society;
 - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) inform innovation-responsive guidance and regulatory science approaches;
- c) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- d) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposal, applicants are expected to perform at scale activities that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective¹¹⁷. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies that are established under the European Health Data Space Regulation¹¹⁸ in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project-generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

¹¹⁷ 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

¹¹⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 5 as reflected in the IHI JU SRIA, i.e.:

- seamless and successful implementation in healthcare settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems and society as a whole;
- patients have improved access to innovations that meet their needs and those of the healthcare systems;
- better informed decision-making at different levels of the healthcare system (authorities, organisations), that will in turn contribute to a better allocation of resources towards cost-effective innovations;
- faster entry to the market of cost-effective innovative solutions developed by industry, which could translate to a positive effect on their R&I investments.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular integrated health solutions, and thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the [EU's Life Sciences Strategy](#) and its specific aims such as:
 - i) reinforcing European R&I e.g. supporting multinational clinical trials and improving the clinical research ecosystem;
 - ii) providing smooth and rapid market access for life science innovations e.g. through promoting innovation-responsive regulation to ensure timely real value delivery of innovations to people;
- c) the improvement of the health technology assessment (HTA) methodology for instance through:
 - i) development and uptake of innovative HTA approaches tailored to meet the demands of HTA organisations, policy makers, and industry, including aspects such as usability, integration into care pathways, and patient experience. This also covers novel methods for assessment of added value of combined technologies;
 - ii) crafting and deploying dissemination and educational programs to ensure unified HTA expertise throughout the EU, covering both medical technology and pharmaceutical innovations;
 - iii) uptake of innovative medical devices and in-vitro diagnostics.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the [European Green Deal](#), [Europe's Beating Cancer Plan](#), the [EU Mission on Cancer](#), the [Apply AI Strategy](#), the [European Virtual Human Twins Initiative](#), the [1+ Million Genomes Initiative](#), [preparedness and response to health emergencies](#), the upcoming EU Biotech Act, the [Regulation on the European Health Data Space \(EHDS\)](#), and the [EU Artificial Intelligence Act](#), where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, tax payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 9,800,000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 4 900 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members¹¹⁹ and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the proposed project's activities and expected outcomes and impacts.

¹¹⁹ The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry)

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

Legal entities established in the Republic of Korea

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the Republic of Korea are not eligible to receive funding.

Legal entities established in Switzerland

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Switzerland are not eligible to receive funding.

<p>HORIZON-JU-IHI-2026-12-SINGLE-STAGE-01</p> <p>Boosting innovation for a better understanding of the determinants of health</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p>HORIZON-JU-IHI-2026-12- SINGLE-STAGE-02</p> <p>Boosting innovation through better integration of fragmented health R&I efforts</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 60 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p>HORIZON-JU-IHI-2026-12- SINGLE-STAGE-03</p> <p>Boosting innovation for people-centred integrated healthcare solutions</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 20 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p>HORIZON-JU-IHI-2026-12- SINGLE-STAGE-04</p> <p>Boosting innovation through exploitation of digitalisation and data exchange in healthcare</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 43,300,000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p>HORIZON-JU-IHI-2026-12- SINGLE-STAGE-05</p> <p>Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 9,800,000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>



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