innovative health initiative

IHI 2025 Amended 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.

COCIR Advancing Healthcare
efpia
EuropaBio The European Association for Bioindustries
MedTech Europe from diagnosis to cure
Vaccines Europe
Co-funded by the European Union

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1. Chronology and list of reviews

Version	Date of the adoption by the GB	Items
Version 1 – Work Programme 2025	11.12.2024	n/a
Version 2 – amended Work Programme 2025	13.06.2025	2. List of acronyms, definitions and abbreviations 3.2 3.2 Background and link with the Strategic Research and Innovation Agenda (SRIA) 4.2.2 Scientific priorities, challenges and expected impacts 4.2.3 Calls for proposals 4.2.5 Follow-up activities linked to past calls: monitoring, evaluation and impact assessment 4.2.6 Cooperation, synergies and cross-cutting themes and activities 4.3.1 Communication, Dissemination and Exploitation 4.3.3 Other support operation – Accounting 4.3.4 Human resources – Staff Establishment Plan 4.4.3 Science and Innovation Panel 4.5.3 Audits 5. Budget 2025 6.1 IKAA Plan for 2025 6.3 IHI JU call 11

2 List of acronyms, definitions and abbreviations

ACRONYM	MEANING
ABAC	Accrual Based Accounting System
ACS	American Chemical Society
AD (HR)	Administrator
AD	Alzheimer's disease
AER	Average Error Rate
AhE	Animal Health Europe
AI	Artificial Intelligence
AMR	Antimicrobial Resistance
ASCs	Ambulatory Surgical Centres
AST	Assistant
BOA	Back-Office Arrangements
CA (Budget)	Commitment Appropriation
BMR	Biennial Monitoring Report
CA (HR)	Contractual Agent
CCI	Confidential Commercial Information
CEPI	Coalition for Epidemic Preparedness Innovations
CERT-EU	Computer Emergency Response Team for the EU institutions, bodies and agencies
CGM	Continuous glucose monitoring
Chips JU	Chips Joint Undertaking, the former Key Digital Technologies Joint Undertaking (KDT JU). See https://www.kdt-ju.europa.eu/
CIOMS	Council for International Organizations of Medical Sciences

ACRONYM	MEANING
CMV	CytoMegaloVirus
CNS	Central nervous system
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
EBV	Epstein Barr Virus
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEG	Electroencephalography
EFPIA	European Federation of Pharmaceutical Industries and Associations. See https://www.efpia.eu/

ACRONYM	MEANING
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
EPITA	European Pancreas and Islet Transplant Association
EPITR	European Pancreas and Islet Transplantation Registry
EPND	European Platform for Neurodegenerative Diseases
EPPO	European Public Prosecutor's Office
ESR	Evaluation Summary Report
EU	European Union
EUDAMED	European Database for Medical Devices
EUIBA	European Institutions, Bodies and Agencies
EUR	Euro
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/
FAERS	FDA Adverse Event Reporting System
FAIR	Findable, Accessible, Interoperable, and Reusable
FC	Financial contributions
FDA	Food and Drug Administration

ACRONYM	MEANING
FG	Function Group
fMRI	Functional magnetic resonance imaging
FP	Full Proposal
FTE	Full-Time Equivalent
FWC	Framework Contract
GA	Grant agreement
GAP	Grant agreement preparation
GB	IHI JU Governing Board
GDI	Genomic Data Infrastructure
GDPR	General Data Protection Regulation
GH EDCTP3	European and Developing Countries Clinical Trials Partnership Programme 3
GMP	Good Manufacturing Practice
GSPR	General Safety and Performance Requirement
HCPs	Healthcare Professionals
HDABs	Health Data Access Bodies
HDHs	Health Data Holders
HDUs	Health Data Users
HERA	European Health Emergency Preparedness and Response Authority
HITL	Human in the Loop
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
HSV	Herpes Simple Viruses
HTA	Health Technology Assessment (bodies)

ACRONYM	MEANING
IaaS	Infrastructure as a Service
IA	Infectious agent
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
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	in-vitro diagnostics
IVDR	*In vitro* Diagnostic Regulation
IVDs	*in vitro* diagnostic medical devices
JUs	Joint Undertakings
KPI	Key performance indicator
LE	Lived experience
LLM	Large Language Model
MDCG	Medical Device Coordination Group

ACRONYM	MEANING
MDD	Major depressive disorder
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/
MEG	Magnetoencephalography
MEP	Member of the European Parliament
ML	Machine Learning
MoA	Mechanism of action
MRI	Magnetic Resonance Imaging
NCA	National competent authorities
NCDs	Non-communicable diseases
NLP	Natural language processing
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
OS	Operating system
PA	Payment appropriation
PARC	Assessment of Risk from Chemicals
PET	Positron emission tomography
PFAS	Per- and Poly-fluoroalkyl substance
PoS	Probability of Success

ACRONYM	MEANING
PPE	Personal protective equipment
PPP	Public-private partnership
PPWD	Packaging and Packaging Waste
PREMs	Patient reported experience measures
PROMs	Patient reported outcome measures
PSCI	Pharmaceutical Supply Chain Initiative (PSCI)
PTFE	Polytetrafluoroethylene
PV	Pharmacovigilance
R&D	Research and development
RAE	Risk assessment exercise
RDP	Regulatory Data Protection
RIA	Research and innovation actions
RM&I	Reward/motivation and impulsivity
RWE	Real World Evidence
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
SMEs	Small and medium-sized enterprises
SO	Specific Objective
SOP	Standard operating procedure
SPOC	Single point of contact
SRG	IHI JU States' Representatives Group
SRIA	Strategic research and innovation agenda

ACRONYM	MEANING
SRSs	Spontaneous reporting systems
SSbD	Safe and sustainable by design
SSCP	Safety and clinical performance
T1D	Type 1 Diabetes
TA	Temporary agent
TFA	Trifluoroacetic acid
THCS	Transforming health and care systems
TIR	Time in Range
TiTR	Time in Tight Range
TSA	Total shoulder arthroplasty
UK	United Kingdom
VZV	Varicella Zoster Virus
WHO	World Health Organization

3 Introduction

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, building on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU) on the need for sectorial convergence in cutting-edge health research projects. IHI JU also builds on the learnings from the health activities in the former ECSEL/KDT JU, now Chips JU, such as enabling electronics components and systems, and the establishment of pilot production lines for smart medical devices and implants involving diverse MedTech actors, which are of high relevance for future activities under IHI JU.

IHI JU projects translate health research and innovation into real benefits for patients and society, to ensure that Europe remains at the cutting edge 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.

As current health challenges and threats are global, IHI JU is open to participation from European and international academic, industrial, and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for EU citizens.

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 in record time of several COVID-19 vaccines, 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 the European healthcare systems that have to deal with the progressive ageing of population and consequent increase of 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 report[1]. IHI JU, as one of the key public-private partnerships, represents a unique recipe to enhance the healthcare ecosystem to efficiently respond to public health needs in Europe, while helping 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 insufficient early consideration of the needs of society and/or patients and end-users. Thus, these actors must be involved in all stages of research, from project design through to implementation, to develop meaningful innovations.

All of the above is also important for IHI JU to achieve its aims of laying the foundations for the development of safer and more effective healthcare products or solutions that respond to unmet public health needs and can be taken up by healthcare systems and foster other important healthtech developments which would enable translation of scientific knowledge into clinical practice and workflows.

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, 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.

The SRIA[3] defines the overall scope of activities of IHI JU, in line with its founding legislation[4], to enable the achievement of its general objectives by 2030:

[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

[3] https://www.ihi.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

- 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 contribution 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.

Strategy for the implementation of the programme

The 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.
In 2025 IHI will pilot an applicant-driven approach to identify additional opportunities for innovative solutions that address the priorities of the IHI SRIA. 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 of 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.

An important element of the Programme Office work will be to continue to support and monitor the projects established under IMI1 and IMI2 programmes. 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 etc 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 Amended Work Programme 2025

Executive summary and message from the Executive Director

2025 is the fourth 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 the European healthcare systems.

The healthcare sector and the health industries are important for European competitiveness. Public-private partnership plays a key role in the European health research ecosystem by systematically addressing drivers of competitiveness and research efficiency[5] such as developing networks and methodologies to shorten timelines and boost capacity for clinical trials[6] , for enhancing novel technology utilisation to improve health care delivery or develop large, transnational data collections for public and industrial research[7]. 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 as well as advances in digitalisation, AI and the use of 'big' data. By doing so, we aim to accelerate the pace of innovation and allow access to the results for a large portion of the EU population, especially patients and their 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 and real-world data.

We will implement all of this, taking care to abide by the principles of sound financial management which have permitted a clean opinion from the European Court of Auditors in prior years.

We will continue to proactively communicate about opportunities for funding for IHI JU ensuring the widest possible involvement across Europe from all sectors including SMEs. A particular focus will be on dissemination of the opportunities provided by the novel, applicant-driven, approach to public-private partnerships piloted in 2025.

IHI JU will drive new partnerships 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.

[5] 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

[6] See e.g. https://www.ihi.europa.eu/news-events/events/imi-impact-clinical-trials

[7] See e.g. https://www.ihi.europa.eu/news-events/newsroom/500-million-records-patients-27-countries-being-harmonised-and-readied-real

Operational activities of IHI JU for 2025

4.1.1 Objectives, indicators and risks

Key objectives

The key objectives for IHI JU operations in 2025 are identified by the Governing Board in the amended Work Programme and by the management team at operational level.

The key operational objectives for 2025 are as follows:

1. 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;

2. manage the projects and outcomes from the Innovative Medicines Initiative 2 Joint Undertaking to maximise impact;

3. 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;

4. 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;

5. 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, training, education and regional development in the health sector;

6. 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

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-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/sustainable-development-goals/
- UN Strategic Development Goal #9 (industry, innovation, and infrastructure) https://www.un.org/sustainabledevelopment/sustainable-development-goals/
- The WHO Europe 2020 Health Priorities

IHI vision: contribute to societal challenges through ...

- **Ensure healthy lives** [UN SDG #3]
- **Sustainable industry & innovation** [UN SDG #9]
- **European policy for health and well-being** [WHO Health 2020]

- Translate knowledge into innovations*
- Innovation addressing public health needs**
- Competitive EU health industry***

- Understand health determinants and disease areas
- Knowledge generation and sharing via joint publications
- People-centred, integrated health care solutions
- Improved clinical guidelines
- Health care data management, integration, AI

- Multi-stakeholder involvement
- Cross-sector collaboration
- Engagement with regulators

* **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 elaborated[8] and guided by the so-called RACER Principles[9].

KPI name	Unit of measurement	Baseline[10]	Target[11] 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[12]	25%	70%	80%	85%	90%	
1.3. Engagement of regulators	Number of projects interacting with regulators[13] to contribute to new or improved guidelines or methodologies	13	0	5	10	20	

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

[9] 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

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

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

[12] 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.

[13] 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: • 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[14]	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	

[14] 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.eunethta.eu/about-eunethta/eunethtanetwork/)
- 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[15] included in the list of the WHO Europe Health 2020 priority areas[16]	No baseline available	90%	90%	90%	90%	

[15] 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".*

[16] 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: • 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 companies[17] & SMEs[18] 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. Examples of collaboration activities across health industry sectors that contributed to the transition to a green and digital economy (as outlined in the new Industrial Strategy for Europe[19])	No baseline available	0	5	10	20	

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

[18] 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

[19] "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 pose a threat to the achievement of the IHI JU objectives and determining how the corresponding risks should be managed. 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 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 control 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 controls remain effective. Relevant IHI JU financial needs and the budget for 2025 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 2025 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 the challenges and making progress towards the outcomes and expected impacts as described in one or more of the five SRIA[20] 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 2025 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) 2021/2085[21]. 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.

[20] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

[21] 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 started in 2023 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 has identified several areas where public-private cross-sector collaboration can create a step change in disease prevention, precision medicine, and management of chronic diseases. 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. In 2025 IHI will launch the next wave of topics generated by these reflections.

Insights gathered from the 2024 IHI JU Regulatory Science Summit[22] that focussed on the areas of rare diseases, paediatrics, real-world data / real-world evidence (RWD/RWE), artificial intelligence (AI) and regulatory sandboxes, and those from the 2024 IHI JU workshop on real-world data, digital health and artificial intelligence[23] will also be taken into account to progress topic ideas that would 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 portal[24].

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 2025 (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 EU4Health[25] programme and HERA[26] and upstream of the EIT Health and the European partnership on transforming health and care systems (THCS)[27], 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 the Industrial Strategies for Europe[28], Europe's Beating Cancer Plan[29], to digital policies such as the European Health Data Space[30] , AI Act[31] and Data Act[32] and to the European Green Deal[33].

[22] https://www.ihi.europa.eu/sites/default/files/uploads/Documents/ProjectResources/RegulatoryScienceSummit_Feb2024_Report.pdf

[23] https://www.ihi.europa.eu/sites/default/files/flmngr/Data%20%26%20Digital%20Report%20PDF_2.pdf

[24] https://www.ihi.europa.eu/shape-our-future-research/propose-ideas

[25] https://hadea.ec.europa.eu/programmes/eu4health/about_en

[26] https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

[27] https://www.thcspartnership.eu/

[28] 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

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

[30] https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

[31] https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

[32] https://digital-strategy.ec.europa.eu/en/policies/data-act

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

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 amended work programme will specify additional exploitation obligations applicable to specific indirect actions.[34]

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 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 2025 IHI JU will launch a pilot applicant-driven Call "**To boost innovation for a competitive European health ecosystem**". 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.

Additionally, in 2025 IHI JU will also address some areas of strategic importance via focussed thematic topics.

For example, IHI JU will launch two topics under SO1. The first topic "**Understanding how infections foster and induce non-communicable diseases**" aims to unravel connections between infectious agents and non-communicable diseases (neurological and cardiometabolic) that could be utilized to develop better diagnostic, preventative, and therapeutic approaches and strategies. The second topic "**Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction**" aims to address the challenge that current diagnosis and patient stratification in health disorders with CNS-driven symptoms are not aligned with underlying biological processes and mechanisms, a key reason for the limited success in developing new and more efficacious treatments. Both topics contribute to the scope of SO1 of identifying new mechanisms of health status and disease development, new mechanisms for therapeutic actions and biomarker identification and validation, via innovative methods of data exploitation. These topics will contribute to several of the outputs of SO1, e.g. an increased understanding of health and disease mechanisms at molecular level, the delivery of novel identified and validated biomarkers for disease interception, diagnosis, progression and treatment monitoring tested in real-world settings and the improved understanding of host-pathogen (including microbiota) interactions.

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

Three topics will be launched in line with the scope of IHI JU SO2 of boosting innovations and outcomes within the context of the European Green Deal, and Europe's sustainability goals. The first topic, **"Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector"**, aims to **i**dentify and map PFAS types and applications in the healthcare sector, propose cross-sector solutions to develop PFAS alternatives and propose sector-specific solutions to reduce and reuse PFAS materials. The second topic **"Digital label: one source of comprehensive information for medical technologies products"** aims to establish a consensus-based digital label concept applicable to all types and classes of medical devices and *in vitro* diagnostics (IVDs), while making use of existing technologies that will be further improved to suit medical technology products specifically. The topic aims to a streamlined and 'green' delivery of information by reducing the carbon footprint of labelling, while improving accessibility of information for users. Both topics will contribute to SO2 outputs aiming to improve the industry's competitive position with sustainable technologies and products that reduce the overall environmental impact of healthcare for the benefit of Europe and its citizens. The third topic "**Leveraging Europe's Expertise to accelerate Cell Therapy for Type 1 Diabetes**" aims to address the critical challenges (e.g. need for renewable cell sources, optimized islet preparations, standardized manufacturing protocols, robust monitoring tools, sustainable reimbursement models, and trained healthcare professionals to manage complex treatments) to move beta-cell replacement therapy towards becoming a functional cure, This topic will contribute to the SO2 outputs as methodologies and standards for the combination of technologies into integrated health care solutions to address pathologies for an individual patient and of delivering innovations in manufacturing. IHI will launch two strategic topics under the scope of SO4.
The topic **"Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)"** addresses the challenge in IHI JU SO4 that while the EU offers a strengthened framework on data protection, uncertainties remain, e.g. on the secondary use of health data, which creates an additional layer of complexity for innovators, among others. The European Health Data Space (EHDS) is a key initiative under the European Strategy for Data and the European Health Union that enables secondary use of health data for various purposes, including research and innovation. The topic aims to identify ways for innovation through the EHDS while safeguarding intellectual property and trade secrets in health data. This topic will contribute to the achievement of the impacts of such an ambitious initiative as the EHDS and to its future translation in practice.

Additionally, the topic "**AI-Powered Signal Detection in Pharmacovigilance**" aims to generate evidence-based and practical guidance, with aligned perspectives of public and private stakeholders, on the use of artificial intelligence (AI) for signal detection and other pharmacovigilance (PV) applications.
This topic will contribute to the output of SO4 of developing and piloting methodologies and tools in cooperation with downstream decision-makers (e.g., regulators) making full use of real-world data from various sources and multiple stakeholders, public and private ones to identify patterns and signals to improve safety of medical products and services.

Under SO5 IHI will launch the topic "**Establishing Ortho and Cardiology Ambulatory Surgical Centres in Europe**" aiming to address some of the challenges that would enable moving the performance of more surgical procedures in facilities outside hospitals easing the demand on overstretched hospitals and reducing hospital acquired infections. This topic will contribute to addressing the SO5 scope of improving implementation of technological innovations in health care systems by providing a better understanding of the factors that would affect their successful introduction. It will also contribute to the SO5 outputs as improved methodologies to assess the added value of health interventions and integrated solutions, to determine their long-term effects on costs and outcomes for patients and health systems, as well as evidence-based strategies to improve the successful implementation of innovative technologies in health care settings.

As relevant the IHI JU office may organise webinars/workshops to support the implementation of the 2025 scientific priorities.

Impacts achieved in 2025 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 2025 calls for proposals

During 2025, IHI JU will launch single-stage and two-stage open and competitive calls for proposals.

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 9:

The submission deadline for full proposals (FPs) will be 29/04/2025.

Scientific evaluation of the single-stage call will take place in Q2 2025. 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).

For IHI JU call 10:

The submission deadline for short proposals (SPs) will be 23/04/2025 and the full proposals (FPs) submission deadline will be 14/10/2025.

Scientific evaluation of the SPs and FPs under the two-stage call will be completed by 2025. 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).

For IHI JU call 11:

The submission deadline for short proposals (SPs) will be 09/10/2025 and the full proposals (FPs) submission deadline will be 29/04/2026.

Scientific evaluation of the SPs and FPs under the two-stage call will be completed by 2026. 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).

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 of the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this amended Work Programme, including the “Restrictions for the protection of European communication networks” under General Annex B. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, 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 amended 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.

GENERAL CONDITIONS RELATING TO THE IHI JU CALLS	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The conditions are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the grant agreements	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 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this amended 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 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme unless otherwise provided in this amended Work Programme.

Per the above and by way of derogation from General Annex B of the Horizon Europe Work Programme 2023-2025:

According to Article 119 of the Council Regulation (EU) 2021/2085, for indirect actions selected under calls for proposals covered by this amended 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 9[35];
    - One hundred percent (100%) for IHI JU Call 10;
    - One hundred percent (100%) for IHI JU Call 11.

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 calls[36].

ENTITIES ELIGIBLE FOR FUNDING

In relation to the single-stage calls for proposals covered by this amended Work Programme, the relevant provisions of the General Annex B to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis*.

By way of derogation, in relation to the two-stage calls for proposals covered by this amended 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.

[35] Even if this threshold of 20% is not intended as an eligibility condition *per se*, proposals recommended for funding that will feature a non-EU IKOP amount higher than the 20% of IKOP, will be requested to remove the exceeding part. If this is the case, this non-EU IKOP reduction exercise will need to comply with eligibility criteria whereby 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.

[36] 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.

- 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 2023 – 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 agreement between the European Union and Canada on the participation of Canda in Union programmes, more particularly to articles 6 and 21; 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.

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 amended Work Programme will take into account any application of Art 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 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

EVALUATION RULES

General Annex D ('Award Criteria') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme with the following additions: The relevant calls for proposals launched under this amended 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 Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**Impact** Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**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:
First stage evaluation of two-stage procedure	• 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 overall methodology.	• 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.	• Quality and effectiveness of the outline of the work plan. • 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	• 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	• 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.	• 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.

	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.		• 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 2023-2025 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:

1) 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.
2) 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'.
3) Proposals that include the highest number of IHI JU private members and constituent and affiliated entities of the IHI JU private members.
4) Proposals that provide the highest percentage of contributions (IKOP, IKAA 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.
5) If necessary, the gender balance among the researchers named in the researchers table in the proposal, will be used as a factor for prioritisation.
6) 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).
7) 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.

8) 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 within 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 applicants[37].

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.

[37] 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.

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 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

BUDGET FLEXIBILITY

General Annex F to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this amended Work Programme.

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 STUDIES[38]

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 system[39].

SPECIFIC CONDITIONS ON AVAILABILITY, ACCESSIBILITY AND AFFORDABILITY (3A)[40]

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 project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly[41] available and accessible, at fair and reasonable conditions.

[38] 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).

[39] 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

[40] Article 125(3) of the Council Regulation (EU) 2021/2085.

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

- In particular, and always to the extent permitted by applicable competition law:

  a) At the proposal stage[42], 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.[43]

  b) At the project interim review stage, if relevant[44], 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.

  c) 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.[45]

  d) 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 report[46] 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 2023-2025 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.

FINANCIAL SUPPORT TO THIRD PARTIES

[42] 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.
[43] 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.
[44] 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.
[45] 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.
[46] Cognisant of IP sensitivities, confidential info, and commercial realties, 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:
   a) 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:
      i. The planned measures to be taken to effect the 3A obligations;
      ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
      iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

Financial support for third parties in IHI projects is allowed for the call(s) covered by this amended Work Programme. The additional conditions contained in General Annex B to the Horizon Europe Work Programme 2023-2025 for Financial Support to Third Parties shall apply *mutatis mutandis.*

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 Guide[47]).

4.1.4 Calls for tenders and other actions

In 2025, the Programme Office will not launch operational call for tenders.

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

IMI/IHI calls	Total	Ongoing at 01.01.2025	Of which	
	Projects		Total reports	Project ending in 2025
IMI1 call 1	15			
IMI1 call 2	8			
IMI1 call 3	7			
IMI1 call 4	7			
IMI1 call 5	1			
IMI1 call 6	2		1	
IMI1 call 7	2			
IMI1 call 8	4			
IMI1 call 9	4			
IMI1 call 10	1			
IMI1 call 11	8			
Total IMI1	**59**	**0**	**1**	**0**

The last IMI1 project Combacte-NET (call 6) ended on 30 November 2024 and its final report was submitted on 31st March 2025, with final assessment during 2025.

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

There are 40 IMI2 running projects in 2025, of which 19 will end throughout the year, as indicated in the below table:

IMI/IHI calls	Total	Ongoing at 01.01.2025	Of which	
	Projects		Total reports	Project ending in 2025
IMI2 call 1	1			
IMI2 call 2	8			
IMI2 call 3	5			
IMI2 call 4	1			
IMI2 call 5	6			
IMI2 call 6	4			
IMI2 call 7	7			
IMI2 call 8	4			
IMI2 call 9	6			
IMI2 call 10	8	2	2	1
IMI2 call 11	3			
IMI2 call 12	7	1	4	1
IMI2 call 13	13	5	5	3
IMI2 call 14	4	3	3	1
IMI2 call 15	7	5	5	2
IMI2 call 16	5	3	3	1
IMI2 call 17	3	3	3	2
IMI2 call 18	6	6	6	4
IMI2 call 19	2	0	0	0
IMI2 call 20	6	6	6	1
IMI2 call 21	8	2	2	2
IMI2 call 22	3	0	0	0
IMI2 call 23	6	6	6	1
Total IMI2	**123**	**42**	**42**	**19**

10 calls were launched since the start of IHI JU

IMI/IHI calls		Total	Ongoing at 01.01.2025	Of which	
		Projects		Total reports	Project ending in 2025
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 [a]		2			
IHI call 7 [b]		8	4	1	0
IHI call 8 [a]		4			
IHI call 9 [c])					
IHI call 10[c]					
Total IHI		43	33	30	0

(a) some projects still in negotiation phase and not yet signed
(b) call 7: four projects started after 01.02.2024
(c) Numbers of projects/reports will be further defined after the conclusion of the respective IHI JU calls
.

In addition to the expected 73 reports for all 3 programmes, there are an additional 12 final reports coming from IMI2 projects that ended in 2024 Therefore the IHI office expects to receive 85 periodic reports in 2025, 24 of which will be final reports.

Monitoring and analysis of project results

85 project periodic and final reports will be submitted in 2025. 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 2025, 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 continuing to assess the performance of the IMI2 programme and has started monitoring the IHI programme, drawing from experience with the initial IHI projects.

In this context, the Programme Office contributed to the evaluations of Horizon 2020 and Horizon Europe[48]. The interim evaluation of IHI JU and the final evaluation of IMI2 JU were launched by the European Commission. The outcome was a report called *"Interim evaluation of the Innovative Health Initiative (IHI) and final evaluation of the Innovative Medicines Initiative (IMI2)"* supported by two case studies: *"From Innovative Medicine Initiative to Innovative Health Initiative – the early experience"* and "*IMI2 and IHI: Driving Innovation in Digital Health*". It was published by the Publications Office of the EU on 2 August 2024. This evaluation assesses both initiatives, focusing on their relevance, effectiveness, efficiency, and EU-added value. It highlights the significant achievements of IMI2, particularly in advancing health research through extensive collaborations and impactful projects. The report also emphasises the promising beginnings of IHI in addressing emerging health challenges and supporting EU health policies. For more details, you can view the report here.

The Programme Office has also contributed to the draft of the "*Performance of European partnerships - Biennial monitoring report 2024 on partnerships in Horizon Europe"*, that was published by the Publications Office of the EU on 19 September 2024. The draft of this report was led by a group of independent experts appointed by the European Commission. It is the second in a series intended to evaluate the performance and impact of European partnerships established under Horizon Europe. The Biennial Monitoring Report (BMR) evaluates 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. Key outcomes include improved research synergies, enhanced patient involvement, and the promotion of sustainable practices in health research. For the details in full, you can access the report here.

In 2025 and in the following years the Programme Office will continue to support the impact assessment initiatives that will be launched by the European Commission. In the future, the Programme Office expects to contribute to the BMR 2026 on partnerships in Horizon Europe and to the final evaluation of IHI JU[49].

[48] Article 171.4 of the Council Regulation (EU) 2021/2085 "The Commission shall carry out an interim and a final evaluation of each Joint Undertaking feeding into the Horizon Europe evaluations, as specified in Article 52 of the Horizon Europe Regulation."

[49] In accordance article 5.2(d) of the Council Regulation (EU) 2021/2085 concerning the requirements of Horizon Europe set out in article 50 of the Horizon Europe Regulation.

4.1.6 Cooperation, synergies and cross-cutting themes and activities

The Council Regulation (EU) 2021/2085[50] 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 Health, wherever relevant. It is also expected that IHI JU activities will contribute to and/or complement the actions of the EU4Health[51] programme, HERA[52], the Digital Europe programme[53] that will deploy digital capacities and infrastructure related to the health area, and the European Green Deal[54] by contributing to the development of a greener and more sustainable healthcare sector.

Therefore, in 2025 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, 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 the partnerships created in Cluster 1 of Horizon Europe (notably GH EDCTP3 JU, THCS and ERA4Health), the Innovation SMEs partnership, Chips JU, EIT Health and the Marie Skłodowska-Curie Staff Exchanges action[55]. IHI JU will continue exploring how to best complement the actions of the EU4Health[56] programme, HERA[57] and Coalition for Epidemic Preparedness Innovations (CEPI)[58], wherever relevant. It is also expected that IHI JU activities will complement those of the Digital Europe programme[59] that will deploy digital capacities and infrastructure related to the health area. Finally, IHI JU will engage more specifically with regional stakeholders, starting with EUREGHA[60] the reference network for European Regional and Local Health Authorities, and RSCN[61] 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.

[50] In particular Article 5(2) of the Council Regulation (EU) 2021/2085

[51] https://hadea.ec.europa.eu/programmes/eu4health/about_en

[52] https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

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

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

[55] https://marie-sklodowska-curie-actions.ec.europa.eu/actions/staff-exchanges

[56] https://hadea.ec.europa.eu/programmes/eu4health/about_en

[57] https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

[58] https://cepi.net/

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

[60] https://www.euregha.net/

[61] https://www.rscn.eu/

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 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 ensure that the IHI Patient Pool is engaged for the evaluation of proposals submitted under IHI calls and the review of ongoing projects, as needed; (3) to explore the possibility to organise educational webinars/workshops on patient engagement; communicate on patient engagement needs and opportunities at call launch; facilitate 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.

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, IHI JU will emphasise the importance of SME involvement during IHI JU info days, consortium-building brokerage meetings, topic webinars and other relevant events.

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 EMA[62]. In particular, following the IHI JU Regulatory Science Summit held in 2024[63] 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 further consider the key takeaways from the discussion and see how best to progress them as potential topics that would deliver impactful results for all stakeholders and contribute to regulatory science going forward.

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

[63] https://www.ihi.europa.eu/sites/default/files/uploads/Documents/ProjectResources/RegulatoryScienceSummit_Feb2024_Report.pdf

IHI JU will continue to raise the awareness of applicants and project consortia about regulatory aspects to be considered 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.

Support to operations of IHI JU in 2025

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 projects and their results by actively participating in both the European Commission's Dissemination and Exploitation Network (D&E Net) and the Feedback 2 Policy Network, and by intensively promoting the Innovation Radar, the Horizon Results Portal, the Horizon Results 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. When necessary, the Programme Office may organise cross-project meetings, or impact meetings in 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.

Planned IHI events 2025

Month	Event	Targeted audience	Strategic Objective
Jan	Info session Call 9 x 3	Potential applicants	Engaging stakeholders in calls for proposals
	Info session Call 10 x 4		
	Everything you need to know about IHI contributing partners - webinar	Potential Contributing Partner	
Feb	In conversation with Beat-DKD & HypoResolve	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
	Stand at the European Congress of Radiology	Potential applicants	Engaging stakeholders in calls for proposals and establishing the brand
Mar	Successful R & I in Europe 2025	Potential applicants	Engaging stakeholders in calls for proposals and establishing the brand
	IHI Alzheimer's disease / neurodegeneration project coordination meeting	Ideas creators and IHI projects	Highlighting project successes and demonstrating IHI's alignment with its purpose
Apr	In conversation with ITCC-P4	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
May	MedTech Forum 2025	Potential applicants	Engaging stakeholders in calls for proposals and establishing the brand
	Impact on Cancer	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
	High-level discussion on Europe's Research Partnerships at the European Parliament	Policy makers	Establishing the brand and raising awareness of IHI's core identity
June	HERA Industry days 2025	Wide range of EU health research stakeholders	Establishing the brand and raising awareness of IHI's core identity
	HLTH Europe 2025	Potential applicants	Engaging stakeholders in calls for proposals and establishing the brand
	Info session Call 11 x 6	Potential applicants	Engaging stakeholders in calls for proposals
July	Deep dive IHI data project	Ideas creators and end users	Demonstrating IHI's alignment with its purpose
Aug	/		
Sep	Spotlight on Cardiovascular (TBC)	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
Oct	In conversation with (TBC)	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
Nov	Brokerage Event	Potential applicants	Engaging stakeholders in calls for proposals and establishing the brand
	In conversation with (TBC)	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
Dec	In conversation with TRIC-TB	End users	Highlighting project successes and demonstrating IHI's alignment with its purpose
	Impact - maximising regulatory impact of IHI/IMI projects (TBC)	IHI projects	Highlighting project successes and demonstrating IHI's alignment with its purpose

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.

In 2025, 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 might launch a call for tenders for the 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 2025.

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 roll-out 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 2025. Synergies with other JUs will be created by launching inter-JU joint procurement under the back-office arrangements for corporate, communication 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.

4.1.9 Other support operations

a. Relevant functions and administrative synergies within back office arrangements[64]

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 2025 the implementation under the service level agreements will be for the accounting services, procurement, HR and ICT. The JUs located in the same office building are also aiming to formalise the facility management under BOA. The experience from the implementation will be used to explore further collaboration within the BOA in additional areas like anti-fraud measures, legal and corporate services. This will further enhance the already close collaboration of JUs in order to gain additional cost-efficiencies.

b. IT operations

The existing common JU governance of IT operations and infrastructure, providing efficiency, economy of scale and gains will be further enhanced to BOA ICT based on a Service Level Agreement. IHI is leading service group 5 “Security and compliance management” and co-leading services 1 “Inter-JU IT Governance” and 2 “Management of shared ICT infrastructure”.

[64] Article 13 of the Council Regulation (EU) 2021/2085

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 most important legal milestones (listed in the table below) are foreseen for 2025.

ACTIVITY	INITIAL MILESTONE DATE	REVIEW FREQUENCY
Initial cybersecurity review	[8 February 2025][65]	N/A
Cybersecurity risk-management, governance, and control framework	8 April 2025	At least every 4 years
Cybersecurity maturity assessment	8 July 2025	At least every 2 years
Cybersecurity risk assessment[66]	[8 July 2025]	At least every 2 years
Cybersecurity risk-management measures	8 September 2025	N/A
Cybersecurity plans	8 January 2026	At least every 2 years

IHI will coordinate the implementation of the regulation in the context of ICT BOA service group 5 "Security and compliance management", following closely the official Guidelines from Inter-Institutional Cybersecurity Board and recommendations from CERT-EU and ENISA.

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.

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 and the legacy applications and platforms based on Liferay 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.

Close collaboration with CERT-EU and regular use of their services like cybersecurity exercises, penetration tests, security assessments, raising end-user awareness including phishing campaigns, knowledge transfer etc. will remain a main pillar of IT security in 2025.

[65] The Regulation does not define a deadline for performing cybersecurity risk assessments. However it was introduced to align with the cybersecurity maturity assessment deadline and to make sure that the definition of risk-management measures will be able to use the findings from the risk assessment as inputs.

[66] Although no specific deadline is defined in the Regulation for the initial cybersecurity review, it needs to be performed prior to the Framework establishment (8 April 2025). Therefore Union entities shall plan their initial review soon enough so that results can feed into the subsequent work and the final deadline for the Framework can be met.

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 contribution (IMI 2), overview of project outputs linked to KPIs, WHO priorities addressed by projects, participants' affiliations and stakeholder types etc.

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.
The IT team will support existing tools and the migration to new European Commission tools.

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 and migrations to new land lines and internet providers.

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 2021[67], establishing the records management policy for IHI JU based on the European Commission decision C(2020)4482[68].

The Record Management Working Group[69] established in 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.

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.

[67] By Executive Director Decision 19/2021 Ares(2021)5474488

[68] Commission Decision on records management and archives C(2020)4482.

[69] The composition of the group: Head of Administration and Finance, Document Management Officer (DMO), Data Protection Officer (DPO), IT Manager with the Internal Control and Risk Manager as an observer (non-statutory).

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')[70].

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. Additionally, the deputising accounting officer arrangements are set for 2024 annual accounts to ensure that the regulatory deadlines for the annual accounts are met. 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 from January 2026. During the course of 2025 the Programme Office will work together with the SUMMA Task Force and DG BUDGET to ensure a smooth transition to the new system.

e. Feedback to policy

European partnerships are 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

[70] OJ L 295, 21.11.2018, p. 39–98

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 2024-2029[71]. More recently, the Letta report[72] on the future of the single market and the Draghi report[73] on the future of European competitiveness identified a range of recommendations for developing the European health research landscape, including articulation of a fifth freedom on access and benefit of scientific results and pinpointing the critical role of e.g. clinical trials, innovative approaches to health data, and advanced cell and biological therapies to ensure that Europe stays at the forefront of research 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 2025, the total number of IHI JU staff will be 54 (comprising 39 temporary agents and 15 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:

i. a large and complex legacy from IMI1 JU and IMI2 JU projects; and

ii. new IHI projects; will result in a significant impact on the management of the Programme Office's human resources.

This will unavoidably lead to an increased pressure on staff. Therefore, the management team of IHI JU will need to continue exploring measures to minimise potential impacts on the well-being of staff and to ensure business continuity.

Selection and recruitment

In 2025, the HR priorities will remain:

(i) 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

(ii) 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).

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

[72] https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf

[73] 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

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 2025, the HR team will continue organising tailor-made training courses for managers and staff and launch a new 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:

(i) 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, etc);

(ii) develop teambuilding activities to strengthen collaboration among staff members, to enhance the team spirit and culture; and

(iii) 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 Regulation and its implementing rules) to ensure the adoption of the implementing rules and to strengthen its legal framework, also adopting internal guidelines. In 2025, 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 respect, IHI JU is acting as back-up JU whereas CBE JU is the lead JU for the BOA HR.

The objective of the BOA HR is to maximise synergies among the JUs, harmonise procedures by valorising best practices, ensure coherent HR support services, achieve efficiencies and economy of scale, and increase the negotiation power of JUs towards contractors and service providers.

The collaboration will also continue with the agency network and the EC HR support services (DG HR and PMO) with participation of the HR function to different working groups.

The JUs that are under the Council Regulation (EU) 2085/2021[74] will contribute to the BOA HR, together with EuroHPC and SESAR 3, and will participate on specific initiatives in line with their internal priorities and according to their own specificities[75].

Scope of the BOA HR

In order to ensure commitment and execution of the BOA HR Annual Work Plan, a Service Level Agreement among the JUs was signed, and enhanced coordination of the Network of JUs' HR officers was developed.

The implementation of the BOA HR started in 2024, and will continue in 2025 on three predefined areas of HR support:

Recruitment

Alignment and harmonisation of the JUs' recruitment processes: in 2024, based on the existing legal framework, the JUs started working on best practices to organise a common selection process, which will be applied across all JUs when launching a selection procedure. This project includes, among others, the creation of common templates, scoring guides, platforms and tools that will provide a consolidated ground for individual and common selection procedures and recruitments.

Organisation of joint selection procedures: to increase efficiency gains, the JUs will organise as far as possible joint selection procedures for common profiles with the same grades. This practice is already in place but will continue in 2025; moreover, they will also start working on the harmonisation of job profiles which facilitate the selection and recruitment procedures.

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

[74] Circular Biobased Europe, Clean Aviation, Clean Hydrogen, Europe's Rail, EDCTP3 Global Health, Smart Networks and services, Chips JU, Innovative Health Initiative.

[75] SESAR JU despite being part of the Council Regulation (EU) 2085/2021, is exempted by the provisions related to the Back-office arrangements.

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 2025 will be on:

- **Inter-JU network of Confidential Counsellors (CCs)**: currently the JUs share a common network of confidential counsellors and regularly organise joint calls for expressions of interest to expand the network. Training, information campaigns and joint actions are also organised to promote the wellbeing of JU staff, raise awareness on psychological and sexual harassment and to prevent interpersonal conflicts. A new inter-JU call for expression of interest will be launched in order to replace the current Confidential Counsellors, whose mandate will end. New training sessions will be provided to the Confidential Counsellors but also to staff members on this matter. In the context of the HR BOA, the JUs will also promote the visibility of mediation services by organizing an information campaign for all JU staff.
- **Collaboration with the EU agencies network (EUAN) and the European Commission**: the JUs will continue attending EUAN meetings including possible ad-hoc participation of the HR Officers to different working groups. The JUs will continue to liaise with DGHR/PMO about common HR matters and seek advice for specific topics.
- **Inter JUs' HR Officers network:** the JUs' HR Officers will continue to meet bi-weekly to share best practices and also provide support to the newly established JU's. For this, a common collaborative platform was be created (Teams) to facilitate the interactions between HR Officers, the exchange of information and documents.

HR Digitalisation

In 2025, the JUs will continue to move towards a digitalisation of HR processes and will work on the harmonisation of their IT systems in the HR area.

The inter-JU HR Officers will continue sharing good practices regarding the use of their IT systems and will continue to actively take part in the HR Transformation programme led by the European Commission, notably by contributing to the projects of the second wave (2024-2025).

The JUs will implement the actions defined in the 2025 BOA HR Annual Work Plan and more specifically the following projects:

(i) Alignment and harmonisation of practices for selection and recruitment procedures;

(ii) Identifying common recruitments for 2025 and sharing reserve lists;

(iii) Developing an inter-JU Competency Framework;

(iv) Continuation of the 2024 actions.

c. Staff Establishment Plan

Function group and grade	2023				2024				2025	
	Authorised budget		Actually filled as of 31/12/2023		Authorised budget		Actually filled as of 31/12/2024		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16										
AD 15										
AD 14		1		0		1		1		1
AD 13										
AD 12		2		1		2		1		2
AD 11		2		2		2		2		2
AD 10		1		2		1		2		1
AD 9		7		4		6		4		6
AD 8		6		3		6		2		6
AD 7		4		3		4		4		4
AD 6		9		5		10		7		10
AD 5		3		11		3		10		3
TOTAL AD		**35**		**31**		**35**		**33**		**35**
AST 11										
AST10										
AST 9										
AST 8		1		1		1		1		1
AST 7										
AST 6										
AST 5										
AST 4		3		2		3		2		3
AST 3										

Function group and grade	2023				2024				2025	
	Authorised budget		Actually filled as of 31/12/2023		Authorised budget		Actually filled as of 31/12/2024		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AST 2										
AST 1										
TOTAL AST		**4**		**3**		**4**		**3**		**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**		**36**		**39**	

Contract Agents	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	FTE corresponding to the authorised budget 2025
Function Group IV	4	3	3	5	4	5
Function Group III	11	7	7	10	8	9
Function Group II						
Function Group I						
TOTAL	**15**	**10**	**10**	**15**	**12**	**14**

Seconded National Experts	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	FTE corresponding to the authorised budget 2025
TOTAL	0	0	0	0	0	0

Recruitment forecasts 2024 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 2025

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 2025. 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 2025 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). Each permanent panellist has been appointed for a period of three (3) years, and his/her term may be renewed by the respective appointing organisations.

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.

In 2025, the respective appointing organisations will decide on whether to renew the mandate of the permanent panellists who have indicated their willingness to continue for an additional period of three (3) years. Where necessary, the respective appointing organisations will appoint new representative(s) for a period of three (3) years. The elections for the new SIP chairperson and vice- chairperson will then take place.

Two meetings are planned for 2025. 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 joint meeting between the SRG and the SIP might be planned for 2025 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 2025

4.1.14 Internal Control Framework

The priority objective of 2025 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:

- optimising and updating internal procedures and processes in order to ensure efficiency, effectiveness and better synergies;
- a risk management process is integrated in the annual planning cycle by performing a risk assessment exercise and following up with risk mitigation action plans;
- 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.

4.1.15Ex-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 2025.

Specific attention will be paid to:

- raising beneficiaries' awareness of the financial and administrative aspects of the H2020 and Horizon Europe rules and how to avoid errors in cost reporting;
- validation of financial and technical reports;
- ex-ante controls for interim and final payments;
- 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. The Commission Common Audit Service (CAS) will continue carrying out the 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. Risk-based ex-post audits will be launched according to the Programme Office risk-based audit strategy. 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 2023[76] in close cooperation with CAS. The Programme Office is testing a common implementation approach of the HE Control strategy and will sample the first 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. 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 2025 the European Commission Internal Audit Service (IAS) in the function of IHI JU's internal auditor will continue implementing the Strategic Internal Audit Plan (2023-2025)[77]. Following the finalisation of the audit on Call topic development and stakeholder relations and the approval of the action plan in early 2025, the Office aims to implement two audit recommendations by the end of 2025. The audit on the BOA is performed throughout 2025 with the expected finalisation in early 2026.

In 2025, the Programme Office will focus on:

- coordinating and supporting IAS's audit work and ensuring an adequate level of assurance from the internal audit;
- preparing and implementing the action plans.

External audits are carried out by the European Court of Auditors (ECA). The ECA will audit and issue opinions on the legality and regularity of the underlying transactions, revenue, and reliability of accounts. In accordance with the IHI JU Financial Rules, IHI JU's 2024 and 2025 annual accounts will be audited by a selected external audit company that IHI JU contracts. The ECA will draw up its annual audit opinion on the basis of their work and issue a special annual report on JUs. 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 2024 and 2025;
- implementing actions addressing ECA observations in 2023 and preliminary findings in 2024.

4.1.17 Anti-fraud

The 2025 objective is to carry on with the implementation of the IHI JU Anti-Fraud Strategy and the action plan, report upon it and initiate an update as envisaged in the Strategy.

IHI JU contributes to the implementation of the updated Common Anti-Fraud Strategy in the research and innovation family and the common action plan adopted in 2024.

IHI JU will continue to actively participate in the FAIR committee and other anti-fraud activities related forums and trainings. IHI JU will pursue close collaboration with the services of the European Anti-Fraud Office (OLAF) and establish cooperation with the European Public Prosecutor's Office (EPPO).

[77] Ares(2023)638585 of 27/01/2023

5 Amended Budget 2025

The budget for the financial year 2025 is revised based on the information available. The following elements are incorporated into the amended 2025 budget:

- Carry overs from previous years:
  - EUR 418,687 from 50% unused 2024 administrative appropriations carried over to 2025 administrative budget, on commitment and payment appropriations.
  - EUR 20,202,000 from 2024 operational appropriations de-committed from 2024 calls 6 and 7.
- **The total budget of call 11 is EUR 57,411,000.** Outline the call 11 budget on the specific budget lines: 3211 C2 of EUR 37,209,000 and 3311 C2 of EUR 20,202,000.
- From 2025, new budget lines (3300 to 3311) will identify pre-2025 carry-overs not eligible for CH and KR--based entities (Switzerland and South Korea).

Operational budget

The total amended operational budget for 2025 is EUR 326,099,651 in commitment appropriations. This includes carry over of EUR 92,471,036 (initial budget and re-allocation to administrative budget) and EUR 20,202,000 (budget amendment 1), from unused 2022, 2023 and 2024 operational commitment appropriations.

It has been outlined the budget for IHI JU call 11 (EUR 57,411,000) on the respective budget lines:

- EUR 37,209,000 (topics 2 to 5) on budget line 3211 C2 (carry overs 2022-2023) IHI JU Call 11 UK&CA-based entities non eligible and
- EUR 20,202,000 (topic 1) on budget line 3311 C2 (carry overs 2024) IHI JU Call 11 CH-based entities non eligible.

Carry overs from 2022-2023 (EUR 11,300,000 for call 6, budget line 3206 C2; EUR 13,542,420 for call 7, budget line 3207 C2) were used to finance two projects without UK-based entities in the 2024 calls 6 and 7. This allowed for the de-commitment of EUR 20,202,000 from the 2024 budget, which can now be carried over to fund UK and CA -based entities.

EUR 490,000 was transferred to evaluation experts (budget line 3900 C2) from the 2022-2023 carry overs bringing the evaluation experts total budget to EUR 1,290,000.

The total operational payment appropriations remain unchanged, of EUR 193,754,200.

Table 1. IHI JU Overview of the operational budget

Title Chapter	Heading	Commitment Appropriations (CA)	Payment Appropriations (PA)	Comments
3	**Operational expenditure**	**EUR**	**EUR**	
30	Implementing the research agenda of IMI1 and IMI2 JU		69,544,660	Payment appropriations for project payments.
31 C1	Implementing the research agenda of IHI JU	213,160,000	103,932,245	Commitment appropriations - calls Horizon Europe. Allocated to call 9 and call 10 with the initial budget. Payment appropriations for project payments.
39_C1	Evaluation experts	266,615	266,615	Costs linked to evaluations, experts contracts.
	Total fresh credits C1	**213,426,615**	**173,743,520**	
30 C2	IMI2 JU carry overs from previous years	-	6,815,621	Payment appropriations carried over for project payments.
31 C2	Implementing the research agenda of IHI JU Horizon Europe - carry overs	11,689,900	161,674	Commitment appropriations carried over from 2024, allocated to call 9 and call 10 with the initial budget. Payment appropriations carried over for project payments.
3200 C2	IHI JU carry overs, UK&CA-based entities non eligible initial budget	17,706,331	12,010,000	Commitment appropriations carried over from 2022-2023, remained unallocated. Payment appropriations carried over for project payments.
3206 - C2	IHI JU Call 6 UK&CA-based entities non eligible	11,300,000		
3207 - C2	IHI JU Call 7 UK&CA-based entities non eligible	13,542,420		
3211 - C2	IHI JU Call 11 UK&CA-based entities non eligible budget amendment 1	37,209,000		
3300 - C2	IHI JU carry overs, CH-based entities non eligible	-	-	New budget line to reflect appropriations to be carried over from financial years before 2025.
3311 - C2	IHI JU Call 11 UK&CA eligible; CH entities non-eligible budget amendment 1	20,202,000		Commitment appropriations carried over from 2024 allocated to call 11.
39_C2	Evaluation experts	1,023,385	1,023,385	Costs linked to evaluations, experts' contracts.
	Total carry overs C2	**112,673,036**	**20,010,680**	
Total Title 3 (Operational expenditure)		**326,099,651**	**193,754,200**	

Table 2. Breakdown of the carry overs

Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
Carry overs stemming from unused budget related to calls 1, 2 and 3 launched in 2022 and evaluation experts.	71,211,094	
Carry overs stemming from unused 2023 operational fresh credits.	8,282,600	
50% carry overs of 2023 unused administrative commitment appropriations (out of it, EUR 209,344 re-allocated to administrative budget)	963,400	
Carry overs stemming from 2023 unused operational payment appropriations.		20,010,680
Carry overs stemming from unused 2024 operational fresh credits.	12,223,285	
Carry overs stemming from de-committed 2024 calls 6 and 7 (operational appropriations).	20,202,000	
Total	**112,882,379**	**20,010,680**

Administrative budget

The total amended administrative budget for 2025 is EUR 10,268,533 in commitment appropriations and EUR 10,229,973 in payment appropriations. This includes carry over of EUR 418,687 from 50% unused 2024 administrative appropriations.

The carry overs are allocated to the following areas:

- EUR 300,000 to staff expenditure, addressing external staff, SUMMA trainings, school allowances and representation.
- EUR 118,687 to IT expenditure, covering increased external cybersecurity services.

The EUR 418,687 carry over is split equally between the European Commission (EC) and industry partners (EUR 209,344 each), maintaining the initial budget's allocation rates. Industry partners include EFPIA, EuropaBio, COCIR, and MedTech.

The carry overs are sourced from existing programmes:

- 40% (EUR 83,353) from IHI JU
- 60% (EUR 125,991) from IMI2

Regarding industry contributions:

- IMI2: EFPIA contributes the entire EUR 125,991.
- IHI JU: The EUR 83,353 is distributed based on initial budget ratios:
  - EFPIA: EUR 40,843 (49%)
  - EuropaBio: EUR 834 (1%)
  - COCIR: EUR 20,838 (25%)
  - MedTech: EUR 20,838 (25%)

The final amended 2025 administrative budget contributions are:

- EC: EUR 5,134,267.
- Industry partners: EUR 5,134,267.

Table 3. Distribution of industry contributions per funding source

Industry contribution to the total administrative amended budget for 2025 (EUR)	**5,134,267**	**%**
IHI JU	2,044,276	40%
IMI2	3,089,991	60%

2025 IHI JU BUDGET REVENUE

Table 4. IHI JU Statement of revenue per founding member

IHI JU - STATEMENT OF REVENUE (EUR)								
	Heading Revenue	**Budget 2025.1**		**Budget 2025 amendment 1**		**Amended budget 2025.1**		***Comments***
Chapter/Line		**Commitment Appropriation (CA)**	**Payment Appropriation (PA)**	**Commitment Appropriation (CA)**	**Payment Appropriation (PA)**	**Commitment Appropriation (CA)**	**Payment Appropriation (PA)**	
10	**European Commission contribution**							
1000	European Commission contribution (including EFTA contribution) for current year for IMI2	2,964,000	72,489,380			2,964,000	72,489,380	Commitment appropriations include EUR 2,964,000 for administrative costs. Payment appropriations include EUR 2,944,720 for administrative costs and EUR 69,544,660 for operational costs.
1002	European Commission contribution (including EFTA contribution) for current year for IHI	215,387,538	106,159,783			215,387,538	106,159,783	Commitment appropriations include EUR 1,960,923 for administrative costs and EUR 213,426,615 for operational costs. Payment appropriations include EUR 1,960,923 for administrative costs and EUR 104,198,860 for operational costs.
1001	European Commission - appropriations carried over from previous years	92,680,379	20,010,680	20,202,000	209,344	112,882,379	20,220,024	Carry overs from financial year 2024.
10	**European Commission contribution - total**	**311,031,917**	**198,659,843**	**20,202,000**	**209,344**	**331,233,917**	**198,869,187**	
20	**JU members other than the Union contribution**							
2000	EFPIA contribution for current year for IMI2	2,964,000	2,944,720			2,964,000	2,944,720	EFPIA contribution to IHI administrative costs
2002	EFPIA contribution for current year for IHI	965,462	965,462			965,462	965,462	EFPIA contribution to IHI

IHI JU - STATEMENT OF REVENUE (EUR)								
								administrative costs
2001	EFPIA - appropriations carried over from previous years			166,834	166,834	166,834	166,834	
	EFPIA contribution - total	**3,929,462**	**3,910,181**	**166,834**	**166,834**	**4,096,295**	**4,077,015**	
2010	EuropaBio contribution for current year	15,000	15,000			15,000	15,000	EuropaBio contribution to IHI administrative costs
2011	EuropaBio - appropriations carried over from previous years			834	834	834	834	
	EuropaBio contribution - total	**15,000**	**15,000**	**834**	**834**	**15,834**	**15,834**	
2020	COCIR contribution for current year	490,231	490,231			490,231	490,231	COCIR contribution to IHI administrative costs
2021	COCIR - appropriations carried over from previous years			20,838	20,838	20,838	20,838	
	COCIR contribution - total	**490,231**	**490,231**	**20,838**	**20,838**	**511,069**	**511,069**	
2030	MedTech Europe contribution for current year	490,231	490,231			490,231	490,231	MedTech contribution to IHI administrative costs
2031	MedTech Europe - appropriations carried over from previous years			20,838	20,838	20,838	20,838	
	MedTech Europe contribution - total	**490,231**	**490,231**	**20,838**	**20,838**	**511,069**	**511,069**	
20	**JU members other than the Union contribution - total**	**4,924,923**	**4,905,643**	**209,344**	**209,344**	**5,134,267**	**5,114,987**	
C4	**External assigned revenue***					**p.m**	**p.m**	
Total revenue		**315,956,840**	**203,565,486**	**20,411,344**	**418,687**	**336,368,184**	**203,984,173**	

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

Table 5. IHI JU Statement of revenue financial years 2024-2025

STATEMENT OF REVENUE (EUR)								
Title Chapter Heading	**Financial year 2024**				**Amended budget financial year 2025**			
	Commitment Appropriations	**In % in total**	**Payment Appropriations**	**In %**	**Commitment Appropriations**	**In %**	**Payment Appropriations**	**In %**
EU contribution (excluding EFTA and third countries contribution)	**178,588,695**	**68%**	**165,433,693**	**84%**	**212,586,908**	**63%**	**174,157,359**	**85%**
of which (fresh C1) Administrative (Title 1&2)	1,635,717		1,635,717		1,908,441		1,908,441	
of which frontloaded commitments (Title 1&2)	3,146,000		3,053,570		2,964,000		2,877,670	
of which Operational (Title 3)	173,806,978		160,744,406		207,714,467		169,371,248	
Of which related to additional entrusted tasks								
EFTA and third countries contribution	**6,251,305**	**2%**	**5,406,307**	**3%**	**5,764,630**	**2%**	**4,491,804**	**2%**
of which Administrative EFTA(Title 1&2)	58,283		150,713		52,482		119,532	
Of which administrative third countries excluding EFTA (Title 1&2)								
of which Operational EFTA (Title 3)	6,193,022		5,255,594		5,712,148		4,372,272	
Of which operational third countries excluding EFTA (Title 3)								
Financial Members other than the Union contribution	**4,840,000**	**2%**	**4,840,000**	**2%**	**5,134,267**	**2%**	**5,114,987**	**3%**
of which Administrative (Title 1&2)	4,840,000		4,840,000		4,924,923		4,905,643	
Of which Administrative Title 1&2 budget amendment 1					209,344		209,344	
of which Operational (Title 3)								
Financial Contributing partners contribution								
Interest generated								
Unused appropriations from previous years	**72,353,086**	**28%**	**22,271,000**		**112,882,379**	**34%**	**20,220, 024**	**10%**
Of which administrative initial budget		-		-	963,400		-	
Of which administrative budget amendment 1							209,344	
Of which operational initial budget		-	22,271,000	0	91,716,979		20,010,680	
Of which operational budget amendment 1	72,353,086				20,202,000			
External assigned revenue*					p.m.		p.m.	
TOTAL REVENUE	**262,033,086**	**100%**	**197,951,000**	**100 %**	**336,368,184**	**100 %**	**203,984,173**	**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 2024 is 3.54% for HE and 3% for H2020.

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

2025 IHI JU BUDGET EXPENDITURE

Table 6. IHI JU Statement of expenditure per chapters

IHI JU STATEMENT OF EXPENDITURE (EUR)				
		Budget 2025		
Title Chapter	**Heading**	**Commitment Appropriations (CA)**	**Payment Appropriations (PA)**	**Comments**
1	**Staff expenditure**	**EUR**	**EUR**	
11	**Staff in active employment**	**6,337,000**	**6,337,000**	Salaries and allowances of current staff (TAs and CAs), SNE, promotion and indexation
	initial budget	*6,290,000*	*6,290,000*	
	budget amendment 1	*47,000*	*47,000*	
12	**Expenditure relating to staff recruitment**	**13,000**	**13,000**	Miscellaneous expenditure on staff recruitment: publication of vacancy calls, medical visits to take up duties, services provided by the European Personnel Selection Office (EPSO)
	initial budget	*5,000*	*5,000*	
	budget amendment 1	*8,000*	*8,000*	
13	**Missions and duty travels**	**134,000**	**134,000**	Missions expenditure
14	**Socio-medical infrastructure**	**317,000**	**317,000**	Other staff costs: EU school, medical check-up, trainings
	initial budget	*282,000*	*282,000*	
	budget amendment 1	*35,000*	*35,000*	
15	**External Services**	**335,000**	**335,000**	Interim staff expenses
	initial budget	125,000	125,000	
	budget amendment 1	210,000	210,000	
17	**Receptions, events and representation**	**20,000**	**20,000**	Representation expenses
	initial budget	*10,000*	*10,000*	
	budget amendment 1	*10,000*	*10,000*	
Total Title 1 (Staff expenditure)		**7,156,000**	**7,156,000**	
Title Chapter	**Heading**	**Commitment Appropriations (CA)**	**Payment Appropriations (PA)**	**Comments**
2	**Infrastructure expenditure**	**EUR**	**EUR**	

IHI JU STATEMENT OF EXPENDITURE (EUR)				
		Budget 2025		
Title Chapter	**Heading**	**Commitment Appropriations (CA)**	**Payment Appropriations (PA)**	**Comments**
20	**Rental of buildings and associated costs**	**690,000**	**690,000**	Building related expenditure: rent, works, charges, maintenance, repairs, security and surveillance
21	**Information, communication technology and data processing**	**1,216,533**	**1,177,973**	IT purchases, software licences, software development
	initial budget	1,107,846	1,069,286	
	budget amendment 1	108,687	108,687	
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**	**47,000**	**47,000**	Data communication such as telephone, video and audio conferences and postal services
25	**Expenditure on formal meetings**	**122,000**	**122,000**	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**	**300,000**	**300,000**	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**	**308,000**	**308,000**	Ex-post audits, studies, audits, accounting services
Total Title 2 (Infrastructure expenditure)		**3,112,533**	**3,073,973**	
TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)		**10,268,533**	**10,229,973**	

Title Chapter	Heading	Commitment Appropriations (CA)	Payment Appropriations (PA)	Comments
3	**Operational expenditure**	**EUR**	**EUR**	
30	Implementing the research agenda of IMI1 and IMI2 JU		69,544,660	Payment appropriations - payments FP7, H2020.
31 C1	Implementing the research agenda of IHI JU	213,160,000	103,932,245	Commitment appropriations - calls Horizon Europe. Payment appropriations - payments Horizon Europe.
39_C1	Evaluation experts	266,615	266,615	Costs linked to evaluations, experts' contracts.
	Total fresh credits C1	**213,426,615**	**173,743,520**	
30 C2	IMI2 JU carry overs from previous years	-	6,815,621	Appropriations carried over from previous years
31 C2	IHI JU carry overs, UK&CA-based entities eligible	11,689,900	161,674	Appropriations carried over from 2024
32 C2	IHI JU carry overs, UK&CA-based entities non eligible	79,757,751	12,010,000	Appropriations carried over from before 2024
33 C2	IHI JU carry overs, CH-based entities non eligible	20,202,000	-	Appropriations carried over from before 2025
39_C2	Evaluation experts	1,023,385	1,023,385	Costs linked to evaluations, experts' contracts.
	Total carry overs C2	**112,673,036**	**20,010,680**	
Total Title 3 (Operational expenditure)		**326,099,651**	**193,754,200**	
C4	**External assigned revenue***	**p.m.**	**p.m.**	
TOTAL EXPENDITURE		**336,368,184**	**203,984,173**	

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

Table 7. IHI JU Statement of expenditure financial years 2024-2025

Chapter	Title Chapter Heading	STATEMENT OF EXPENDITURE (EUR)							
		Financial year 2024				Financial year 2025			
		Commitment Appropriations	% Ratio Year 2024/year 2023	Payment Appropriations	% Ratio Year 2024/year 2023	Commitment Appropriations	% Ratio Year 2025/year 2024	Payment Appropriations	% Ratio Year 2025/year 2024
1	**Title 1 - Staff expenditure**	**6,674,000**	**3%**	**6,674,000**	**3%**	**7,156,000**	**7%**	**7,156,000**	**7%**
11	**Staff in active employment (Salaries & allowances)**	6,128,000	3%	6,128,000	3%	6,337,000	3%	6,337,000	3%
	- Of which establishment plan posts	***5,158,000***	3%	***5,158,000***	3%	***5,227,000***	1%	***5,227,000***	1%
	initial budget					*5,180,000*		*5,180,000*	
	budget amendment 1					*47,000*		*47,000*	
	- Of which external personnel	***970,000***	4%	***970,000***	4%	***1,110,000***	14%	***1,110,000***	14%
12	**Expenditure relating to Staff recruitment**	**5,000**	0%	**5,000**	0%	**13,000**	160%	**13,000**	160%
	initial budget					*5,000*		*5,000*	
	budget amendment 1					*8,000*		*8,000*	
13	**Missions and duty travels**	**144,000**	0%	**144,000**	0%	**134,000**	-7%	**134,000**	-7%
14	**Socio-medical infrastructure**	**182,000**	20%	**182,000**	20%	**202,000**	11%	**202,000**	11%
14	**Training**	**80,000**	0%	**80,000**	0%	**115,000**	44%	**115,000**	44%
	initial budget					*80,000*		*80,000*	
	budget amendment 1					*35,000*		*35,000*	
15	**External Services**	**125,000**	-29%	**125,000**	-29%	**335,000**	168%	**335,000**	168%
	initial budget					*125,000*		*125,000*	

Chapter	Title Chapter Heading	STATEMENT OF EXPENDITURE (EUR)							
		Financial year 2024				Financial year 2025			
		Commitment Appropriations	% Ratio Year 2024/year 2023	Payment Appropriations	% Ratio Year 2024/year 2023	Commitment Appropriations	% Ratio Year 2025/year 2024	Payment Appropriations	% Ratio Year 2025/year 2024
	budget amendment 1					*210,000*		*210,000*	
17	**Receptions, events and representation**	**10,000**	0%	**10,000**	0%	**20,000**	100%	**20,000**	100%
	initial budget					*10,000*		*10,000*	
	budget amendment 1					*10,000*		*10,000*	
2	**Title 2 - Infrastructure expenditure**	**3,006,000**	**0%**	**3,006,000**	**0%**	**3,112,533**	**4%**	**3,073,973**	**2%**
20	**Rental of buildings and associated costs**	**690,000**	-1%	**690,000**	-1%	**690,000**	0%	**690,000**	0%
21	**Information, communication technology and data processing**	**1,090,000**	0%	**1,090,000**	0%	**1,216,533**	12%	**1,177,973**	8%
	initial budget					*1,107,846*		*1,069,286*	
	budget amendment 1					*108,687*		*108,687*	
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**	18%	**47,000**	18%	**47,000**	0%	**47,000**	0%
25	**Expenditure on formal meetings**	**100,000**	25%	**100,000**	25%	**122,000**	22%	**122,000**	22%
26	**Administrative expenditure in connection with operational activities**	**310,000**	24%	**310,000**	24%	**300,000**	-3%	**300,000**	-3%
27	**External communication, information and publicity**	**300,000**	0%	**300,000**	0%	**300,000**	0%	**300,000**	0%

Chapter	Title Chapter Heading	STATEMENT OF EXPENDITURE (EUR)							
		Financial year 2024				Financial year 2025			
		Commitment Appropriations	% Ratio Year 2024/year 2023	Payment Appropriations	% Ratio Year 2024/year 2023	Commitment Appropriations	% Ratio Year 2025/year 2024	Payment Appropriations	% Ratio Year 2025/year 2024
28	**Service contracts**	**340,000**	-20%	**340,000**	-20%	**308,000**	-9%	**308,000**	-9%
3	**TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)**	**9,680,000**	**2%**	**9,680,000**	**2%**	**10,268,533**	**6%**	**10,229,973**	**6%**
3	**Title 3 - Operational expenditure**	**252,353,086**	**23%**	188,271,000	**-10%**	**326,099,651**	**29%**	**193,754,200**	**3%**
	Of which fresh credits	*180,000,000*		*166,000,000*		*213,426,615*		*173,743,520*	
	*Of which carry overs from previous years initial budget***			*22,271,000*		*92,471,036*		*20,010,680*	
	Of which carry overs from previous years budget amendment 1	*72,353,086*				*20,202,000*			
C4	**External assigned revenue***					**p.m.**		**p.m.**	
	TOTAL OPERATIONAL (Title 3)	**252,353,086**	**23%**	**188,271,000**	**-10%**	**326,099,651**	**29%**	**193,754,200**	**3%**
	TOTAL EXPENDITURE	**262,033,086**	**22%**	**197,951,000**	**-10%**	**336,368,184**	**28%**	**203,984,173**	**3%**

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

** EUR 209,344 administrative carry overs re-allocated from operational to administrative budget (50% EC)

EFTA % used for 2024 is 3.54% for HE and 3% for H2020.
EFTA % used for 2025 is 2.75% for HE and 2.33% for H2020.

Comparison between 2025 and 2024 budget in commitment appropriations

In 2025 the staff costs (Title 1) increased by 7%, mainly due to increase in external staff. The missions' expenditures decreased, due to decrease in operational needs. The socio-medical expenditure increased in line with operational needs and prices indexation of external services provided.

Within Title 1, the increase of staff costs of 3% is covered by carry overs stemming from unused 2024 administrative budget.

The infrastructure costs (Title 2), covering costs like rent, IT, communication, and meetings increased by 4%. The increase is covered by carry overs stemming from unused 2024 administrative budget. The increase will address the operational needs as:

- IT costs: increase expected due to cybersecurity investments.
- meetings costs: more in-person meetings will lead to increased costs.

The operational costs (Title 3) foresee operational expenditure relate to Horizon Europe calls and evaluations experts' costs.

Table 8. IHI JU Statement of expenditure 2024-2025

Title Chapter	Heading	Commitment Appropriations (CA)	Commitment Appropriations (CA)	%Var +/-
1	**Staff expenditure**	**2024**	**2025**	**2025 vs 2024**
11	Staff in active employment	6,128,000	6,337,000	3%
12	Expenditure relating to staff recruitment	5,000	13,000	160%
13	Missions and duty travels	144,000	134,000	-7%
14	Socio-medical infrastructure	262,000	317,000	21%
15	External Services	125,000	335,000	168%
17	Receptions, events and representation	10,000	20,000	100%
Total Title 1 (Staff expenditure)		**6,674,000**	**7,156,000**	**7%**
Title Chapter	**Heading**	**Commitment Appropriations (CA)**	**Commitment Appropriations (CA)**	**%Var +/-**
2	**Infrastructure expenditure**	**2024**	**2025**	**2025 vs 2024**
20	Rental of buildings and associated costs	690,000	690,000	0%
21	Information, communication technology and data processing	1,090,000	1,216,533	12%
22	Office equipment (movable property and associated costs)	5,000	5,000	0%
23	Current administrative expenditure	124,000	124,000	0%
24	Telecommunication and postal expenses	47,000	47,000	0%

Title Chapter	Heading	Commitment Appropriations (CA)	Commitment Appropriations (CA)	%Var +/-
25	Expenditure on formal meetings	100,000	122,000	22%
26	Administrative expenditure in connection with operational activities	310,000	300,000	-3%
27	External communication, information and publicity	300,000	300,000	0%
28	Service contracts	340,000	308,000	-9%
Total Title 2 (Infrastructure expenditure)		**3,006,000**	**3,112,533**	**4%**
TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)		**9,680,000**	**10,268,533**	**6%**
Title Chapter	**Heading**	**Commitment Appropriations (CA)**	**Commitment Appropriations (CA)**	**%Var +/-**
3	**Operational expenditure**	**2024**	**2025**	**2025 vs 2024**
30	Implementing the research agenda of IMI1 and IMI2 JU			
31 - C1 fresh credits	Implementing the research agenda of IHI JU	180,000,000	213,426,615	19%
32 - C2 carry overs	Carry overs from previous years	72,353,086	112,673,036	56%
	initial budget		92,471,036	
	budget amendment 1		20,202,000	
C4	**External assigned revenue***		**p.m.**	
Total Title 3 (Operational expenditure)		**252,353,086**	**326,099,651**	**29%**
TOTAL EXPENDITURE		**262,033,086**	**336,368,184**	**28%**

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

Overview of the 2025 budget per budget line

Table 9. IHI JU 2025 budget per budget lines

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1	**Staff expenditure**	**EUR**	**EUR**
1100	Staff in active employment and costs linked to employees	3,926,000	3,926,000
	initial budget	*3,879,000*	*3,879,000*
	budget amendment 1	*47,000*	*47,000*
1101	Family Allowances	310,000	310,000
1102	Transfer and expatriation allowances	480,000	480,000
1110	Contract Agents	1,110,000	1,110,000
1111	Seconded National Experts	-	-
1130	Insurance against sickness	127,000	127,000
1131	Insurance against accidents and occupational diseases	17,000	17,000
1132	Unemployment insurance for temporary staff	50,000	50,000
1133	Pension	30,000	30,000
1140	Birth and death allowances	1,000	1,000
1141	Annual travel costs from the place of employment to the place of origins	60,000	60,000
1144	Fixed local travel allowances		-
1149	Other allowances		-
1172	Cost of organising traineeships within IMI2 JU	10,000	10,000
1175	Translation and typing services		-
1177	Other services rendered	90,000	90,000
1178	Paymaster Office (PMO) fees	70,000	70,000
1180	Sundry recruitment expenses	5,000	5,000
1181	Travelling expenses (including taking up duty)	1,000	1,000
1182	Installation allowance	20,000	20,000
1183	Moving expenses	10,000	10,000
1184	Temporary daily allowance	15,000	15,000
1190	Weightings (correction coefficient)	5,000	5,000
1191	Salaries adaptation		-
11	**Staff in active employment**	**6,337,000**	**6,337,000**
1200	Miscellaneous expenditure on staff recruitment	13,000	13,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
	initial budget	5,000	5,000
	budget amendment 1	8,000	8,000
12	**Staff recruitments - miscellaneous expenditure**	**13,000**	**13,000**
1300	Mission expenses	134,000	134,000
13	**Missions and duty travels**	**134,000**	**134,000**
1401	EU school costs	170,000	170,000
1410	Other trainings	85,000	85,000
	initial budget	*50,000*	*50,000*
	budget amendment 1	*35,000*	*35,000*
1420	Supplementary aid for the disabled	1,000	1,000
1430	Medical service	19,000	19,000
1440	Trainings covered by the EC service level agreement	30,000	30,000
1490	Other interventions	12,000	12,000
14	**Socio-medical structure**	**317,000**	**317,000**
1500	External staff expenditure	335,000	335,000
	initial budget	125,000	125,000
	budget amendment 1	210,000	210,000
15	**External staff services**	**335,000**	**335,000**
1700	Representation expenses	20,000	20,000
	initial budget	10,000	10,000
	budget amendment 1	10,000	10,000
17	**Representation**	**20,000**	**20,000**
Total Title 1 (Staff expenditure)		**7,156,000**	**7,156,000**

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2	**Infrastructure expenditure**	**EUR**	**EUR**
2000	Rentals office building	480,000	480,000
2001	Guarantees		
2002	Contributions		
2010	Insurance		
2020	Charges (water, gas, electricity, works)	180,000	180,000
2030	Cleaning and maintenance		

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2040	Furnishing of premises	10,000	10,000
2050	Security and surveillance	20,000	20,000
2090	Other expenditure on buildings		
20	**Office building and associated costs**	**690,000**	**690,000**
2101	Hardware, infrastructure and related services	450,000	450,000
2102	Software development, licenses and related services	736,533	697,973
	initial budget	*627,846*	*589,286*
	budget amendment 1	*108,687*	*108,687*
2103	Other expenses maintenance and repair	30,000	30,000
21	**Information technology purchases**	**1,216,533**	**1,177,973**
2200	Purchase office equipment	0	0
2201	Rentals office equipment	0	0
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	0	
2321	Exchange rate losses	0	
2329	Other financial charges	0	
2330	Legal expenses	15,000	15,000
2350	Other operating expenditure	3,000	3,000
2351	Petty expenses	0	
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	47,000	47,000
24	**Telecommunication and postal expenses**	**47,000**	**47,000**
2500	Formal meetings	122,000	122,000
25	**Expenditure on formal meetings**	**122,000**	**122,000**
2600	Administrative costs in connection with operational activities	20,000	20,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2601	Events targeting IMI projects	0	0
2602	Workshops	280,000	280,000
2603	Knowledge management	0	0
26	**Administrative costs in connection with operational activities**	**300,000**	**300,000**
2700	External communication	60,000	60,000
2701	Events external communication	200,000	200,000
2702	Material	40,000	40,000
27	**External communication, information and publicity**	**300,000**	**300,000**
2800	Ex-post audits	43,000	43,000
2801	Studies, consultancy	120,000	120,000
2802	Audit services	55,000	55,000
2803	Accounting services	90,000	90,000
28	**Service contracts**	**308,000**	**308,000**
2900	Evaluation Experts meetings	0	0
2901	Evaluation Facilities		
2902	Evaluations Exploring New Scientific Opportunities (ENSO)		
29	**Expert contracts and cost of evaluations**	**-**	**-**
Total Title 2 (Infrastructure expenditure)		**3,112,533**	**3,073,973**
Total administrative expenditure Title 1 +Title 2		**10,268,533**	**10,229,973**
Budget line Chapter	**Description**	**Commitment Appropriations (CA)**	**Payment Appropriations (PA)**
3	**Operational expenditure**	**EUR**	**EUR**
3000	Implementing the research agenda of IMI1 JU	-	-
3020	Implementing the research agenda of IMI2 JU		69,544,660
3100	Implementing the research agenda of IHI JU Horizon Europe		103,932,245
3109	IHI JU Call 9	180,000,000[78]	
3110	IHI JU Call 10	33,160,000	

[78] The total budgets of Call 9, Call 10 and Call 11 will remain unchanged, but the allocation per fund sources (fresh credits C1, carry overs C2) will be adapted. The adaptation reflects the requirements resulting from the EU-UK and EU-CA association agreement (for which carry overs cannot be used to support UK and CA-based entities that are part of selected proposals) and to maximise the use of carry overs fund sources C2, which need to be used first.

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3900	Evaluations experts	266,615	266,615
3999	Recovery Ex-post audit		
C1 current year budget	**Implementing the research agenda of IMI2 JU**	**213,426,615**	**173,743,520**

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3020 - C2	Implementing the research agenda of IMI2 JU appropriations carried over from previous years		6,815,621
3100 - C2	Research agenda of IHI JU Horizon Europe carry overs		161,674
3109 - C2	IHI JU Call 9 UK&CA-based entities eligible	11,000,000	
3110 - C2	IHI JU Call 10 UK&CA-based entities eligible	689,900	
3200 - C2	IHI JU carry overs, UK&CA-based entities non eligible initial budget	17,706,331	12,010,000
3206 - C2	IHI JU Call 6 UK&CA-based entities non eligible	11,300,000	
3207 - C2	IHI JU Call 7 UK&CA-based entities non eligible	13,542,420	
3211 - C2	IHI JU Call 11 UK&CA-based entities non eligible budget amendment 1	37,209,000	
3300 - C2	IHI JU carry overs, CH-based entities non eligible		
3309 - C2	IHI JU Call 9 CH entities non-eligible	-	
3310 - C2	IHI JU Call 10 CH entities non-eligible	-	
3311 - C2	IHI JU Call 11CH entities non-eligible	20,202,000	
3900 - C2	Evaluations experts	1,023,385	1,023,385
C2 carry overs	**Implementing the research agenda of IHI JU**	**112,673,036**	**20,010,680**
Total Title 3 (Operational expenditure) C1 +C2		**326,099,651**	**193,754,200**
C4	**External assigned revenue***	**p.m.**	**p.m.**
Total expenditure		**336,368,184**	**203,984,173**

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

IKAA Plan for 2025

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 2025, is composed of the following elements:

- Project-specific additional activities approved by the GB79 related to grants signed of call 1, 2 and 3 – amounting respectively to EUR 15,023,559 for call 1, EUR 1,083,250 for call 2, and EUR 5,589,966 for call 3;
- Project-specific additional activities related to grants signed of call 4, 5 and 7 – amounting respectively to EUR 8,833,052.7 for call 4, EUR 8,791,146 for call 5 and EUR 24,691,672.5 for call 7 – that are reflected in the IKAA Plan available on the IHI JU website here.

Project-specific additional activities related to projects selected under the IHI JU call 6 amounting to EUR 1,870,000 [80]**.** The concerned additional activities will be formally included in the IKAA Plan after the respective grant agreements are signed, subject to a separate GB decision before publication on the IHI JU website.

Potential project-specific additional activities for 2025 related to projects that will be selected under call 8 (launched in 2024) as well as under calls 9 and 10 (launched in 2025) may be planned from (full) proposals submission stage[81]. 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 2025 related to projects to be selected under the IHI JU call 11 as the full proposal submission stage is expected in 2026.

Programme-specific additional activities that started in a prior year and were already approved by the GB[82] amounting to EUR 30,546,732;

- Programme-specific additional activities that will start in 2025 amounting to EUR 7,572,593, identified in the table below.

The IKAA Plan (project and programme levels) amounts to EUR 103,501,971 and is available here. It may be subject to modification following a separate GB decision in 2025 as needed. The updated IKAA Plan will be available on the IHI JU website here

[79] See adopted IKAA Plan in WP 2024.

[80] IHI-GB-DEC-2024-34 Decision approving the list of proposals selected for funding and reserve list pursuant to the evaluation of the IHI 6th Call stage 2 for proposals.

[81] "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.

[82] See adopted IKAA Plan in WP 2024.

OVERVIEW ESTIMATED IKAA FOR YEAR 2025[83]						
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)**
EFPIA's support to the Rare Disease EU R&I ecosystem	Activities to develop a rare disease ecosystem by supporting robust patient need-led research & addressing bottlenecks hampering ATMP development. This activity supports synergies across Horizon Europe partnerships, namely IHI and ERDERA.	Support to additional R&I	Support to public-private partnership cooperation	No	Yes	400,000
R&I activities linked to the European Rare Diseases Research Alliance (ERDERA)	Activities encompass the FTE dedicated to regulatory support and Technology Accelerator Hub. This work aims at development of a rare disease ecosystem. This activity supports synergies across Horizon Europe partnerships, namely IHI and ERDERA.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	250,000
Development of sustainability strategies to the services offer: financial and training activities support in C4C stitching.	Complement to the project's last year main objective (C4C): the transfer of deliverables (services created) to a new legal entity/non-profit foundation (C4C Stichting) that will ensure sustainability.	Creating new business opportunities	Invest in start-ups, spin-offs on solutions developed within the projects	No	Yes	10,000
IHI and EU SME Community	Promotion and integration of IHI into SME and national communities.	Communication, dissemination, awareness raising, citizen engagement	Knowledge building in the specific area and/or among stakeholders community	No	Yes	30,000
Complementary activities focused on the uptake of results of IMI2 project EHDEN	EHDEN Foundation membership to continue a strong and growing open science community with Data Partners, SMEs, researchers, public & private, and NGOs.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	30,000
R&I activities linked to the European Rare Diseases Research Alliance (ERDERA)	In kind funding for activities to develop a Rare Disease ecosystem by supporting robust patient need-led research & addressing technical bottlenecks hampering ATMP R&D and manufacturing.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	1,000,000
Membership fees provided to support the non-profit EUPATI foundation, which is shaping the evolution of patient involvement across the whole spectrum of the medicines R&D process.	Membership fees provided to support the non-profit EUPATI foundation, which is shaping the evolution of patient involvement across the whole spectrum of the medicines R&D process.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	27,000
Membership of Our Future Health, a public-private research consortium	Founding Industry member of Our Future Health, the UK's largest ever research programme & the	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic	No	Yes	2,000,000

[83] 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 2025. 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.

	world's largest consented cohort study of its kind, recruiting up to 5M participants.		Research and Innovation Agenda but not funded by Horizon Europe			
Industry partner of FinnGen, a public-private research consortium	Industry partner providing funding to FinnGen3 leveraging the rich FinnGen genotype & phenotype resources / discoveries to enhance target prioritisation as well as the development of personalised medicine.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	428,000
The UK Biobank Pharma Proteomics Project	Funding provided to enable the UK Biobank Pharma Proteomics Project to analyse 300,000 human samples to study circulating proteins.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	550,000
Complementary activities focused on the uptake of results of IMI projects EUPATI & EFOEUPATI	Membership fees provided to support the non-profit EUPATI foundation, which is shaping the evolution of patient involvement across the whole spectrum of the medicines R&D process.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	27,000
Consortium member of the UK Biobank Pharma Proteomics Project	Funding provided to enable the UK Biobank Pharma Proteomics Project to analyse 300,000 human samples to study circulating proteins.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	333,488
Industry partner of FinnGen, a public-private research consortium	Industry partner providing funding to FinnGen3 leveraging the rich FinnGen genotype & phenotype resources / discoveries to enhance target prioritisation as well as the development of personalised medicine.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	1,349,000
Exploitation of Transbioline results after project ends	Funding to exploit Transbioline project results and undertake linked post-term activities	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	190,000
Respiratory syncytial virus (RSV) awareness campaign	Complementary activities focused on the uptake of results from IMI PROMISE	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	113,207
Complementary activities focused on the uptake of results of IMI2 project EHDEN	EHDEN Foundation membership to continue a strong and growing open science community with Data Partners, SMEs, researchers, public & private, and NGOs.	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	47,500
Complementary activities focused on the uptake of results of the IMI1 project GetReal and the IMI2 project GetReal Initiative	Supporting the GetReal Institute, a non-profit entity built on the success of two IMI projects (GetReal and The GetReal Initiative) and which facilitates the adoption and implementation of real-world evidence in health care decision-making in Europe	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	24,000
Sustainability IMI2 INNODIA / INNODIA Harvest webpage	Supporting sustainability, accessibility and functionality of the IMI2 INNODIA / INNODIA Harvest webpage	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	38,000
Sustainability IMI2 INNODIA / INNODIA Harvest database	Supporting sustainability, accessibility and functionality of the IMI2 INNODIA / INNODIA Harvest database	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	40,000

Uptake of results IMI2 TransBioLine	Supporting uptake of results and exploitation of IMI2 TransBioLine data	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	13,000
Membership in EHDEN Foundation	The membership aims to contribute to support of a strong and growing open science community with Data Partners, SMEs, researchers, public & private, and NGOs	Support to additional R&I	Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	No	Yes	30,000
Dissemination of data sharing good practice and gools	Communication/dissemination activities for the data sharing playbook and related guidance and good practice.	Support to additional R&I	Support to Public-Private Partnership Cooperation	No	Yes	28,000
Science and technology watch	Science and technology watch and building cross sector understanding and integration	Support to additional R&I	Support to public-private partnership cooperation	No	Yes	240,000
Regulatory Science Impact	Contribution to regulatory science platforms and EMA focus groups which support acceptance of result generated by precompetitive consortia.	Contribution to the development of new standards, regulations and policies	Contribution to groups that develop input to public policy-making in the area of the new product/innovation (e.g. governmental ministries)	No	Yes	150,000
Corporate sponsorship of ELRIG organisation	Corporate sponsorship to support the non-profit ELRIG organisation in delivering leading events that are free-to-attend and curate topical content for the life sciences and drug discovery community.	Communication, dissemination, awareness raising, citizen engagement	Organisation of conferences and webinars on specific topics, networking events	No	Yes	8,400
IMI Impact videos	Production of IMI project impact videos to share knowledge and increase stakeholder engagement in IMI projects and results	Communication, dissemination, awareness raising, citizen engagement	Knowledge building in the specific area and/or among stakeholders community	No	Yes	5,836
Corporate sponsorship of European Laboratory Research & Innovation Group (ELRIG)	Corporate Sponsorship to support the non-profit ELRIG organisation in delivering leading events that are free to attend and curate topical content for the life sciences and drug discovery community	Communication, dissemination, awareness raising, citizen engagement	Organisation of conferences and webinars on specific topics, networking events	No	Yes	18,662
Awareness and Deployment of existing results	Setting-up effective measures for sustainability and deployment and upscaling of results.	Communication, dissemination, awareness raising, citizen engagement	Knowledge building in the specific area and/or among stakeholders community	No	Yes	158,000
Cross-sectorial and stakeholder engagement	Cross-sectorial and stakeholders engagement at european, national and regional level	Communication, dissemination, awareness raising, citizen engagement	Activities to ensure a stronger engagement at local level with regions, cities, citizens and other local stakeholders	No	Yes	33,500
TOTAL PLANNED IKAA starting in 2025						**7,572,593**

IHI call 9

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-competitive[84] Research and Innovation Actions that contribute to addressing the IHI JU's Specific Objectives, as defined in IHI JU's legal basis[85] 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 at scale activities that drive concrete and transformational outcomes.

Furthermore, actions to be funded under this call should address unmet public health needs in line with the second IHI JU general objective "*deliver 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"*.

[84] meaning it will not deliver products or services directly into healthcare systems or the market.

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

Unmet public health needs are needs that are currently not addressed by the healthcare systems for various reasons; for example, if no health technologies[86] 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 and implementation of novel treatments and healthcare solutions.

Proposals that aim to demonstrate the feasibility and/or scalability of integrating 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.

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.

To emphasise the people-driven mission and the inclusive objectives of the call, applicants are strongly encouraged to provide open access to project-generated outputs such as standards, GDPR compliant data sets and other research results.

As proposals can only be submitted under one topic, applicants must carefully consider which 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 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.

[86] 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 SRIA[87] carefully for full information on the Specific Objectives.

NOTE: While under each topic some examples are provided, these are only suggestions and applicants should refer to the text in the SRIA under each Specific Objective for full details on the scope covered by each topic.

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 the project, ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 1 '*contribute towards a better understanding of the determinants of health and priority disease areas*', 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science88.

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 etc. 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 basis[89] and described in more detail in the IHI JU SRIA[90]:

[87] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

[88] In the context of IHI, 'implementation science' refers to the 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, uptake, scale-up, piloting in healthcare).

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

[90] https://www.ihi.europa.eu/sites/default/files/flmngr/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.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[91] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to 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 benefitting 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.

[91] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

b) contribute to strengthening 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.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[92], 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 increasing 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 therefore 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 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 25 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 is necessary to allow a proposal to address these outcomes appropriately. 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 members 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).

[92] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

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.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Activities to deliver new insights into mechanisms of diseases and factors contributing to health status.
- Activities to identify and validate biomarkers as well as to elucidate potential new mechanisms for therapeutic actions, including innovative methods of data exploitation.
- Standardisation activities to facilitate the development of new health technologies, better identify individuals with disease predisposition, predict and monitor disease progression, and assess the efficacy of targeted treatments.
- Use of the opportunity offered by emerging industrial technologies (e.g. innovative imaging methods, robotics or artificial intelligence, smart medical devices) to provide better targets and approaches to develop new and more precise personalised health innovations for prevention, diagnosis and therapy, as well as facilitating good health while aging.

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 the project, ensuring that they contribute to at least one of IHI JU's potential outputs linked to 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 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[93].

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 etc. 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 basis[94] and described in more detail in the IHI JU SRIA[95]:

[93] In the context of IHI, 'implementation science' refers to the 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, uptake, scale-up, piloting in healthcare).

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

[95] https://www.ihi.europa.eu/sites/default/files/flmngr/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.

   When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, including open science and 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.

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[96] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's 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;

[96] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

- 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.

b) contribute to strengthening 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.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[97], 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 increasing 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 therefore 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 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 100 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 15 000 000 is necessary to allow a proposal to address these outcomes appropriately. 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.

[97] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members 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 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.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Break down fragmentation between various disciplines of medicine – including computational and technological areas – to accelerate innovations from early discovery to patient treatment.
- Integrate diverse components (e.g. from focused mission-based research projects, collaborative platforms, databases, AI/ML to diagnostics, medicinal products, medical devices, wearables, digital solutions) in order to foster the development of people-centred, ambitious, large-scale and transformative solutions along the healthcare pathway from beginning to end, including treatment discovery.
- Novel and harmonised approaches to data generation and federation, algorithm optimisation and applicable ML outputs.
- Activities to deliver open-source computational outputs such as machine learning methods for prediction at scale derived from a collaborative, community-driven ecosystem.
- Activities that catalyse data-driven AI/ML-influenced discoveries and therapies e.g. integration of *in vitro*, *in vivo* approaches, small molecules, screening platforms, manufacturing processes (such as mass protein expression), diagnostics and prognostics (for early and adapted treatment, for multimodal disease and/or cross-therapy area applications or for management approaches).
- Activities addressing innovations and outcomes within the context of the European Green Deal, so that advances are part of Europe's sustainability goals, supporting the commercial sustainability transition and reducing the overall environmental impact of healthcare.

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 the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 3 '*demonstrate the feasibility of people-centred, integrated healthcare solutions'*, as reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[98].

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 etc. 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 basis[99] and described in more detail in the IHI JU SRIA[100].

[98] In the context of IHI, 'implementation science' refers to the 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, uptake, scale-up, piloting in healthcare).

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

[100] https://www.ihi.europa.eu/sites/default/files/flmngr/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.

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[101] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's 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 better adapted to their needs through improved diagnostic and monitoring;

[101] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

- 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;
- healthcare solutions assessed according to criteria that matter to patients and citizens (in particular, patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) contributing to achieving people-centred healthcare.

b) contribute to strengthening 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.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[102], 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 increasing 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 suitable for end-users therefore, 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 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 30 000 000.

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

[102] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

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 members 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.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

Activities to foster the development of integrated healthcare solutions, combining different technological areas and taking into account the needs of patients and citizens to, among others:

a) facilitate patient contributions to R&I activities;

b) support shared decision-making with healthcare professionals; and

c) enable self-management of disease and health, *de facto* engaging in social innovation.

In this context, amongst others, the following elements could be relevant for the proposals:

- the development of harmonised patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs),
- the development of methods to elicit people's preferences and digital tools to enable patient involvement.
- accessibility and inclusivity, particularly for patients with limited digital skills or disabilities.
- considerations for how patient feedback will be gathered and applied in the design of the healthcare solutions.
- considerations regarding health economics aspects.

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 the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 4 '*exploit the full potential of digitalisation and data exchange in healthcare*', as reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[103].

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 etc. 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 directly 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 basis[104] and described in more detail in the IHI JU SRIA[105]:

[103] In the context of IHI, 'implementation science' refers to the 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, uptake, scale-up, piloting in healthcare).

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

[105] https://www.ihi.europa.eu/sites/default/files/flmngr/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.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[106] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's 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;

[106] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

- advanced analytics / artificial intelligence supporting health R&I, resulting in a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment; b) shorter times to market; c) wider availability of personalised health interventions to end-users; d) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.

b) contribute to strengthening 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.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[107], 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 increasing 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 suitable for end-users therefore, 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 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 24 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 is necessary to allow a proposal to address these outcomes appropriately. 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.

[107] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members 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 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.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Activities to support the generation, pooling, integration and sharing of high-quality, harmonised, interoperable data (either existing or generated de novo), as well as the use of advanced analytical tools (including artificial intelligence, computational modelling and simulation or digital twin approaches).
- Activities to support the development of better assistance systems for healthcare professionals to facilitate timely decision-making over the course of a disease, thereby improving patient outcomes.

Amongst others, considerations on health economics aspects could be relevant.

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 the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to 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* reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[108].

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 etc. 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 basis[109] and described in more detail in the IHI JU SRIA[110].

[108] In the context of IHI, 'implementation science' refers to the 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, uptake, scale-up, piloting in healthcare).

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

[110] https://www.ihi.europa.eu/sites/default/files/flmngr/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.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[111] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's 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.

[111] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

b) contribute to strengthening 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.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Twins Initiatives, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[112], 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 increasing 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 suitable for end-users, therefore, 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 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 12 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 5 000 000 is necessary to allow a proposal to address these outcomes appropriately. 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 members 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).

[112] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

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.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

Activities to develop methods and tools to assess the added value of emerging and converging health technologies, taking into consideration different stakeholders' value dimensions, to support harmonised approaches for evidence generation.

HORIZON-JU-IHI-2025-09-01 **Boosting innovation for a better understanding of the determinants of health**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000. 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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. 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.
HORIZON-JU-IHI-2025-09-02 **Boosting innovation through better integration of fragmented health R&I efforts**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 100 000 000. 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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. 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.
HORIZON-JU-IHI-2025-09-03 **Boosting innovation for peopled centred integrated healthcare solutions**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000. 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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. 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.

HORIZON-JU-IHI-2025-09-04 **Boosting innovation through exploitation of digitalisation and data exchange in healthcare**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000. 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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. 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.
HORIZON-JU-IHI-2025-09-05 **Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 12 000 000. 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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. 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.

IHI call 10

Topic 1: Digital label: one source of comprehensive information for medical technology products

Expected outcomes

The action under this topic must contribute to all of the following outcomes:

1. A consensus-based digital label concept/framework for medical devices and *in vitro* diagnostic medical devices (IVDs) is available to be used by manufacturers that meets end users' requirements and addresses regulators' demands.
2. Multiple valid and scalable digital label solutions based on a standardised approach are available and they:
    a. all work with the same enabler (label reader) for all medical technology product labels (all medical devices and IVDs, all types, all classes). This topic does not cover pharmaceutical products as such. Combination products that fall under the scope of regulations on medical devices and *in vitro* diagnostic medical devices (MDR/IVDR) are, therefore, regulated as devices and are considered to be part of this topic;
    b. serve as an up-to-date single point of access to all information about the specific device;
    c. are interoperable with other EU legislation (such as digital product passport) and national legislation (e.g. language requirements);
    d. consider accepted international standards for data carriers[113];
    e. are acceptable after verification via user testing.
3. Evidence-based recommendations are available that may inform the European Commission's and the national competent authorities' policy recommendations.
4. Training materials on digital labels are available to the end users (healthcare professionals (HCPs) and patients), regulators (national competent authorities) and notified bodies in the EU Member States.
5. A basis towards future international acceptance is created via:
    - documentation gathered that would be needed to launch a proposal for a new digital label standard or adaptation of an existing standard[114] under the International Organisation for Standardisation / International Electrotechnical Commission (ISO/IEC) – note that development of a standard itself is not planned during the lifetime of the project;
    - awareness raising with other international jurisdictions that consider digital label initiatives.

[113] Note: The term data carrier is synonymous with the ISO 19762 definition of Automatic Identification and Data Capture (AIDC) technologies (e.g., bar codes, smart cards, radio frequency identification, (RFID), etc.

[114] e.g ISO 20417 already offers a segway for digital label. This standard is also foreseen for harmonisation with MDR.

Scope

A digital label is a form of e-labelling provided as an array of elements supporting a medical technology product, which is additional to critical information on the printed label (identification and traceability of the device, warnings and precautions, handling and use information). Access to the digital label is achieved, for example in the form of barcodes, 2D data matrix, QR codes, etc., which provides a scannable link to curated digital landing pages (websites) where the additional information will be displayed.

Under the current Regulations on medical devices and *in vitro* diagnostic medical devices (MDR/IVDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical) both critical information as well as additional information have to be included on the product's printed label.

While many medical technology products are decreasing in physical size, mandatory requirements for additional product compliance information are growing, which leads to various problems. Users might find it difficult to locate the desired information on the label due to the extensive text and small print.
Manufacturers have to update their entire physical label if they change an economic operator.
Such label changes have an impact on the environment, product availability and inventory and they cause inefficiencies and ultimately raise costs. Local requirements for the label regarding device disposal are rising and lead to increased amounts of packaging (and therefore later increased amounts of waste).
In case of new environmental legislation, the physical label needs also to be updated during the device's lifetime.

The overall aim of this topic is to establish a consensus-based digital label concept applicable to all types and classes of medical devices and IVDs, making use of existing technologies that will be further improved to suit medical technology products specifically.

Note that this topic does not cover medicinal products, except combination products that fall under the scope of MDR/IVDR regulations and are, therefore, regulated as devices. Furthermore, this topic does not directly address the electronic provision of IFU (instructions for use) as this is already allowed for certain medical devices and IVDs in the EU. Access to eIFU through the digital label is only an additional benefit to facilitate access to all relevant information in one place (on top of the means of delivery allowed currently by MDR/IVDR). Finally, the scope of this topic does not address post market surveillance aspects.

To fulfil the overall aim, the action funded under this topic must:

- deliver a framework for:
    - mapping of data elements that must be physically present on the label and those that the manufacturer can provide digitally. The framework will consider the requirements of EU Regulations (MDR General Safety and Performance Requirement (GSPR) 23.1, IVDR GSPR 20.1; the Packaging and Packaging Waste (PPWD) Directive; Digital Product passport, waste and packaging, battery, etc.) and is meant to also support future EU legislation (or transposition thereof in Member States).
    - a standardised concept in providing digital content and structure for the medtech manufacturers. taking into account the different device types.
- define and make publicly available key performance indicators (KPIs) (e.g. trends of access and digital content type) or other measures to assess the acceptability and workability of the potential digital label solution(s), provided by manufacturers, and to be tested with end users (HCPs and patients).

- generate evidence on the acceptability and usability of digital label solutions through testing in a variety of use environments that will be defined by the full consortium. This will include user feedback on behaviour changes in a variety of use environments. The action should also make the results of testing, analysis and conclusions public:
    - conducting usability studies will support end-user age demographics and capture metrics on the acceptability/usability of end-user participants' potential disabilities related to interacting with digital technologies.
- engage with all relevant stakeholders (e.g. HCPs, patients, national competent authorities, notified bodies) throughout the project lifetime to get robust input through consultations, surveys, workshops and testing in order to:
    - maximise end user adoption (and understanding) of digital labels;
    - ensure that concerns and demands of end users and regulators are met.
- based on the results of testing and body of evidence gathered, develop recommendations on digital labels to inform relevant stakeholders, regulators, policy makers, and the relevant ISO/IEC bodies for the possible development of ISO/ IEC standards for digital labelling for medical devices and IVDs (or for the update of an existing standard) – note that the standard itself will NOT be developed during the lifetime of the project.
- ensure appropriate knowledge dissemination via:
    - developing training materials;
    - subsequently finetuning training material for deployment to the public at large in all EU national languages: end users (HCPs, patients) / regulators (national competent authorities) / notified bodies in the EU Member States and any other relevant stakeholders;
    - facilitating awareness and communication with other global jurisdictions' digital label initiatives.

Applicants should develop a strategy and plan for generating appropriate evidence as well as for engaging and formally consulting with regulators (e.g. national competent authorities).

Expected impacts

The action to be funded under this topic is expected to achieve the following impacts:

1. Streamlined and 'green' delivery of information
    a. Key information as well as additional information is easily (and more) visible, accessible and identifiable to users (HCPs, patients) and health authorities equipped with a simple smart device (e.g., phone or tablet device);
    b. Significant reduction of carbon footprint and avoidance of over-labelling, hereby contributing to the European Green Deal.

2. Improved accessibility of information for users (HCPs and patients) and regulators. All the information that users might need is available in one place in their language of choice, thus increasing equal access of users to medical technologies.
    a. Targeted information based on user location: in the EU: summary of safety and clinical performance (SSCP), the European database for medical devices (EUDAMED) modules when available[115]; globally: electronic instructions for use (eIFU);
    b. Crucial information from the printed label is additionally visible upon scanning (e.g. expiry date);
    c. Connection to technical support in case of problems;
    d. Reducing risk of use errors;
    e. Real time updates;
    f. Avoidance of cluttered labels.
3. Increased alignment between MDR and other EU and national legislations and streamlined compliance for all. One digital carrier will directly link the user with the up-to-date information required by the Digital Product passport in multiple languages (EU Packaging and Packaging Waste Regulation EU Battery regulation, information on spare parts, etc.), hereby contributing to the European Green Deal.
4. Increased competitiveness in the EU market thanks to improved supply management and streamlined packaging and labelling operations.
5. Driving acceptance through (voluntary) adoption of digital labels by medical device manufacturers and their use by end users, notified bodies, national competent authorities in the European market, supported by the developed training material. Digital label is considered an additional tool to requirements in current legislation (MDR, IVDR).

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

The digital label is an innovative concept offering benefits to all healthcare stakeholders and society at large. Currently, no regulatory basis exists for the medical technology industry anywhere in the world. There is therefore a need to test this concept with users, gather evidence for regulatory decision making and build regulators' as well as users' trust as a basis for a common standard and policy recommendations.

This new approach of providing information on the label digitally will therefore need all stakeholders (industry, health institutions, healthcare professionals, patients, researchers, including researchers in health literacy, regulators (national competent authorities) and notified bodies to work together in a neutral framework to lay the groundwork for a sustainable and user centred healthcare information delivery in the EU and ensure its regulatory acceptance.

An aligned multistakeholder approach to the digital label will ensure the speedy success of this concept.

[115] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L_202401860

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Arthrex (lead)
- bioMérieux
- Johnson & Johnson
- Terumo
- Thermo Fisher Scientific

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary.

Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 3 806 900.
- The indicative in-kind contribution from industry beneficiaries is EUR 6 156 800.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 36 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

- IT infrastructure provision and IT expertise;
- expertise in labelling; regulatory affairs and intelligence; clinical research, marketing and communications, global supply chain management, project management etc.;
- usability engineering.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

This may require mobilising the following expertise and/or resources:

- project management experience in running multi-stakeholder, cross-sectoral projects;
- digital labels for medical devices;
- healthcare, medical device engineering and design, as well as medical device regulation and compliance;
- demonstrated experience in interacting with regulators, citizens and/or patient representatives, health care professionals;
- data standards and interoperability;
- software and digital health;
- legal, patient literacy, health literacy, ethical, social science.

At the second stage, the consortium selected at the first stage and the pre-defined industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not apply.

Topic 2: Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Expected outcomes

The European Health Data Space (EHDS) is a key initiative under the European Strategy for Data and the European Health Union that enables the secondary use of health data for various purposes, including research and innovation. The outcomes of this topic will lead to the identification of pathways for enabling innovation through the EHDS while safeguarding intellectual property, Regulatory Data Protection (RDP)[116], and trade secrets in health data.

This topic must contribute to all of the following outcomes:

- comprehensive frameworks, processes, policies and guidelines are available to support the procedural and operational aspects of the EHDS from an innovation perspective;
- recommendations to inform EHDS governance are available to address the needs of a broad set of stakeholders, including citizens, hospitals, public institutions and the healthcare industry. The right balance must be struck between the need for an EHDS that enables efficient data sharing for the secondary use of health data to promote research and innovation in healthcare, and the need for maintaining a strong Intellectual Property (IP) system[117] while preserving confidential information within health research data;
- recommendations are available for enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs) to address issues around innovation, as well as dealing with IP, RDP, and Trade Secrets, utilising the EHDS and the operationalisation of the EHDS; and
- materials, guidance, recommendations, training and other support tools are available to educate interested parties about innovation and data sharing under the EHDS.

The target groups for all the outcomes are:

- those establishing the EHDS and the EHDS infrastructure, through which health data will be made available for secondary purposes;
- member state agencies involved with the establishment and functioning of HDABs;
- HDHs making IP, RDP and trade secret protected data, which may include sensitive and confidential data, available through the EHDS for secondary use; and
- HDUs intending to access IP, RDP and trade secret protected data for secondary use.

[116] 'RDP': regulatory data protection rights, i.e. Article 10(1) of Directive 2001/83/EC, and Article 14(11) of Regulation (EC) 726/2004

[117] 'IP System': the set of legal and regulatory measures established within the EU for the protection of IP rights, including RDP and Trade Secrets

Scope

The background to this topic arises from the EU regulation for an EHDS. This topic focuses on the secondary use aspects of the regulation establishing the EHDS and recognises that, to be successful, there is a need to consider both the societal benefits of data-driven advancements in healthcare and the legitimate interests of public and private sector innovators for a strong IP system and an efficient means of supporting the secondary use aspect of the EHDS.

The specific challenges/problems addressed by the topic include:

- balancing the societal benefits of data-driven innovation in healthcare against the legitimate interests of public and private sector innovators to safeguard relevant legal and regulatory rights related to their data (e.g., copyright, (*sui generis*) database rights, CCI (Confidential Commercial Information), trade secrets, RDP (Regulatory Data Protection**),** patents, etc.);
- empowering HDHs and HDUs to engage with and use the EHDS for data-driven healthcare innovation by providing them with knowledge and tools, e.g., contractual agreements between HDHs and HDUs for data sharing or other potential legal, organisational or technical measures, to operationalise secondary data sharing and to safeguard intellectual property rights, trade secrets and regulatory data protections;
- developing robust frameworks and guidelines to support the implementation of the EHDS to enable harmonised and efficient sharing of IP-protected data (including in the context of cross-over with data anonymisation considerations) across all member states while safeguarding IP and trade secrets in support of innovation; and
- exploring concerns regarding commercial and competition-sensitive data and the risk of unauthorised disclosures.

The topic objectives are to:

- build trust and confidence in the EHDS: respecting and keeping proprietary information confidential, creating trust and confidence among stakeholders and promoting their active participation in the EHDS to enable responsible and timely data sharing;
- propose implementation practices that will support the efficient inclusion of health data in the EHDS for secondary research purposes and support the procedural and operational aspects of the EHDS;
- support innovators' competitiveness by safeguarding valuable IP and trade secrets data whilst fostering further research and innovation;
- advance data governance and confidentiality practices within the EHDS to ensure appropriate protection of IP and trade secrets;
- ensure data governance throughout the whole product life cycle, from development to post market monitoring and update;
- minimise the administrative burden for HDABs, HDHs and HDUs impacted by the EHDS;
- ensure that relevant legal and regulatory rights of innovators are respected and timely preserved to minimise uncertainty and maximise opportunities for innovation under the EHDS;
- support an EHDS implementation that facilitates data sharing, innovation, and research to advance healthcare for EU citizens, and uses processes that take advantage of existing practices in industry and health authorities and are resource efficient.

Applicants should envisage the following activities as part of their proposal:

With regards to the outcome supporting the procedural and operational aspects of the EHDS:

- conduct research into data strategy, management and governance;
- conduct comparative reviews of existing data exchanges and the need for transparency, interoperability and standardisation of data;
- conduct comparative reviews with work developed in the context of national data spaces;
- through elaborate use cases, explore the procedural and operational aspects of the EHDS from various perspectives, including:
    - assessing data sharing platforms and technologies, such as data security measures like encryption technologies, access control mechanisms, black boxes, federated learning, and their implications on the data sharing and IP system;
    - investigating the sharing of different types of data covered by the EHDS, which include trade secrets and/or data protected by IP or RDP as well as complex data (for example, imaging data), for secondary use. This will help to address different scenarios regarding purpose, time of sharing, and territorial scope, potentially leveraging test environments to evaluate operational and practical aspects of data sharing and data usability under the EHDS.
- identify best practices, guidelines, standards, and tools for intellectual property, trade secret, and opt-in/out management that can be used and advanced within the EHDS frameworks;
- develop proposals for comprehensive frameworks, processes, policies and guidelines balancing the needs of HDHs to safeguard the IP system and minimise the administrative burden while facilitating data sharing and collaboration;
- develop mechanisms and technologies for IPR-aware data manipulation, including reviewing best practices in anonymisation / pseudonymisation techniques and synthetic data generation, with the goal of facilitating the reuse of electronic health data that is subject to IP protection;
- prepare recommendations for technical standards for access controls, data minimisation, secure data storage, anonymisation techniques, handling of evolving data sets, etc., which might benefit innovation related to trade secrets and IP protected data covered by the EHDS.

With regards to the outcome striking the appropriate balance:

- evaluate and comparatively study laws, including trade secret laws and other laws of the EU Strategy for Data and of the EU Member States, to identify common and differentiating features and legal bases in order to propose recommendations for Member State implementation of HDABs and to develop guidance for IP and regulatory data protection covering areas such as dataset descriptions, data sharing policies and agreements, access controls, and governance practices and data use;
- conduct comprehensive research into the interplay between IP, transparency, regulatory data protection, state aid, competition laws, international treaties, the need for openness, and the potential risk for misuse of data under the EHDS;
- conduct research exploring compatibility and gaps of the EHDS versus existing laws around data and data sharing, IP, including protection of confidential information and trade secrets, and related laws, such as privacy, the EU data governance act, the EU data act, the EU AI act and regulatory data protection;

- propose guidelines and frameworks regarding data sharing and data use to support the balance of the societal benefits of data-driven healthcare research and innovation under the EHDS against the legitimate interests of public and private sector innovators for a strong IP system, including, for example, a classification of data into categories depending on IP sensitivity;
- develop guidance on responsible use and mechanisms to hold irresponsible / misusing HDUs accountable and prevent misuse;
- develop clear rules for data ownership and IP ownership determination for all kinds of newly generated data using EHDS;
- propose a harmonisation framework including standard agreements for IP ownership to enable secondary use of data provided via the EHDS for research purposes;
- analyse and provide recommendations on exploitation and publication of results by HDU and impact on HDHs with IP and trade secret protected data.

With regards to the outcome establishing frameworks for dialogues:

- engage public and private innovators in the European Health Data Space 2 (EHDS2) Stakeholder Engagement initiative to shape the definition of responsible secondary use of data for research and innovative purposes under the EHDS, including territorial considerations;
- prepare recommendations to develop a framework for dialogues between innovators and HDABs to address issues around innovation and operationalisation under the EHDS, balancing all the relevant stakeholders' legitimate interests. This engagement should, where possible, leverage and complement the action providing support to stakeholders on secondary use of data within the European Health Data Space[118].

With regards to the outcome educational aspects:

- develop training packages, including educational materials, guidance, recommendations, and other support tools to educate stakeholders about innovation, data sharing and the IP system under the EHDS. Training packages developed as part of this action should, where possible, leverage and complement outputs from the action developing capacity building for secondary uses of health data for the European Health Data Space[119];
- educate stakeholders about using the EHDS for innovative purposes.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with relevant regulators in a timely manner.

Applicants should consider as relevant existing infrastructures/networks/collaborations to ensure synergies and complementarities.

[118] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/31fb9b46-36be-42ba-9b7a-9dea85c4abb7-CN

[119] https://hadea.ec.europa.eu/calls-tenders/capacity-building-secondary-uses-health-data-european-health-data-space_en

Expected impacts

The action contributes to all the general objectives of IHI JU, particularly to specific objective 4 '*exploit the full potential of digitalisation and data exchange in health care'*.

The action under this topic is expected to achieve all of the following impacts:

- Fostering data-driven research and innovation advancing healthcare in the EU;
- A world-leading approach to IP protection of data;
- Improved balance between data utilisation and access control rights;
- Best practices for data sharing, data security and prevention of unauthorised disclosure;
- Recommendations for legal and ethical standards; and
- Increased industry confidence in the EHDS.

The action will also contribute to several European policies/initiatives, which include:

- The European Health Data Space;
- The European Commission's Pharmaceutical Strategy for Europe, specifically the pillar on competitiveness, innovation, and sustainability;
- Related measures under the ongoing revision of the pharmaceutical legislation;
- The Trade Secret Directive;
- The European Strategy for Data, incl. GDPR, Data Act, Data Governance Act, AI Act;
- The Digital Strategy; and
- The Digital Single Market Strategy.

Overall, these expected impacts aim to create a secure, collaborative, and innovative ecosystem within the EHDS, which will increase trust and confidence among stakeholders, optimise data utilisation, enhance protection of intellectual property, and facilitate advancements in healthcare research and innovation.

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

The Intellectual Property ('IP') system exists to support innovation and is a key driver for all healthcare industries operating in EU. Thus, understanding how the EHDS interacts with, and might impact, the IP system will be key to its success and that of the European innovation landscape.

Public and private partners will be Health Data Holders (HDHs) and Health Data Users (HDUs) who may simultaneously be innovators. Thus, combining the strengths and expertise of private and public partners is essential to develop holistic solutions balancing the protection of IP (including trade secrets) with an EHDS that facilitates data sharing and utilisation for research and innovation.

Industry partners bring expertise in secondary use of health data, IP and trade secret management, which can be leveraged to develop effective strategies for protecting innovation whilst also facilitating health data sharing. They also understand the concerns of industry in protecting innovation with IP.

Public partners bring their knowledge of and insights into the healthcare sector, and expertise in health data management as well as technology transfer. Public partners will provide insights into the needs of the healthcare system and societal considerations for sharing health data for secondary use.

The proposed public-private collaboration is essential to develop robust frameworks, policies, and processes addressing the complex challenges posed by the EHDS. A close collaboration is necessary for the implementation of an EHDS that facilitates secondary use of data whilst also respecting the needs of innovators for a strong IP system. The collaboration will enable the EHDS to exploit the full potential of digitalisation and data exchange in health care.

The relevant stakeholders for this topic are those involved with the establishment of the EHDS for secondary use purposes and those who will provide and access data utilising the EHDS, which include, amongst others:

- HDHs and HDUs, including healthcare providers, pharmaceutical companies, and medical technology companies;
- Patient organisations and other Non-Governmental Organisations in the health research space;
- Universities and institutions or other organisations with an interest in health data;
- EU and Member State authorities responsible under the EHDS to handle and protect data of HDHs; and
- EU and Member State authorities who will establish federated data networks, HDABs and secure processing environments under the regulation for the EHDS.

Pre-identified industry consortium and contributing partners

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries (‘constituent or affiliated entities of private members’):

- AbbVie
- Astra Zeneca
- Bayer
- bioMérieux
- Boehringer Ingelheim
- GSK
- Johnson & Johnson (Lead)
- Merck
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Sanofi (Co-lead)
- UCB

In addition, the following contributing partners will participate to the IHI project:

- Brightinsight
- Clarivate

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries, it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to a constituent or affiliated entity of a private member.

Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 6 043 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 5 772 500.
- The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500.

Due to the global nature of the participating industry beneficiaries, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 36 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the pre-identified industry consortium and contributing partner(s) may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The pre-identified industry consortium and contributing partner(s) expect to contribute to the IHI JU project by providing the following expertise and assets:

- Legal, paralegal experts and advisors/consultants specialised in IP & trade secrets protection in the digital and medical environments;
- Governmental affairs and policy experts;
- ISRM (Information Security & Risk Management) experts;
- Data strategy and governance experts;
- Communication expertise for webinars & workshops;
- Data privacy experts;
- Public affairs experts.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partner(s).

This may require mobilising the following expertise and/or resources:

- Academic and/or research organisations involved in innovation and competition with particular expertise in legal and IP;
- ISRM (Information Security & Risk Management) experts;
- Hospital networks/HDHs/HDUs (clinical research units);
- Implementers of large digital healthcare infrastructures for primary and secondary data use (i.e., which make use of the EU policies mentioned in the expected impact section) from across the EU;
- Project management expertise related to qualitative market research and public relations;
- Project management organisations with project management expertise of large multi-stakeholder European public-private partnerships;
- Legal expertise and, in particular, privacy and regulatory data protection expertise;
- Experts from, or with connections to country ministries, involved with implementing and operating Health Data Access Bodies;
- Publicly accessible datasets.

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium and contributing partner(s) will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not apply.

Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

Expected outcomes

Per- and Poly-fluoroalkyl substances (PFAS) are a broad range of materials which have many uses within the scope of healthcare products, including as components of medicines, vaccines, medical devices, and diagnostics. These substances are currently critical to product quality, safety, and efficacy and essential to their manufacture and safe storage. PFAS make up a large group of persistent anthropogenic chemicals which are difficult to degrade and/or dispose of in an environmentally respectful manner.
This IHI topic prioritises phasing-out PFAS of concern *(specified below)* as much as possible by using alternatives that maintain at least the same level of patient safety and product performance.
Additionally, where it is not feasible to replace the use of PFAS, e.g. for technical or toxicological reasons, applicants should investigate how their use can be minimised / adequately controlled with respect to environmental exposure. The current knowledge needed to address these challenges is fragmented and incomplete.

The action under this topic must contribute to all the following outcomes:

- replace PFAS: new environmentally sustainable materials as alternatives to PFAS that maintain patient safety are developed for the benefit of the healthcare industry and the citizens;
- reduce / re-use PFAS: improved usage of PFAS materials and minimised exposure is achieved for the benefit of the environment and therefore citizens and society;
- a mapping of the types and applications of PFAS throughout the supply chain is available for healthcare technologies and products, including collaborating with upstream suppliers;
- a database of alternatives to PFAS is available;
- new disposal processes of PFAS are available for the benefit of the environment and therefore citizens and society.

Scope

To replace PFAS in medical technologies without risking human health, input from supply chain actors, scientists, and engineers is crucial. This includes assessing material availability, feasibility, and testing. Where current technology falls short, understanding PFAS environmental exposure and mitigation must improve. Standardised testing protocols and quantification methodologies are needed to measure exposure accurately. Effective mitigation requires knowledge of exposure routes and environmentally sensitive disposal methods. A scientific, data-driven approach that aligns with the safe and sustainable by design (SSbD[120]) framework is essential for lifecycle exposure management and ensuring alternative materials are safe and effective. Collaboration among scientists, policymakers, regulators, healthcare providers, chemical manufacturers, patient groups and trade associations and waste managers is vital to address technical, legal, and practical considerations. Proper scientific assessment of alternatives is necessary to maintain safety and quality.

[120] https://publications.jrc.ec.europa.eu/repository/handle/JRC128591

The key challenges in the field include:

- obtaining information on PFAS uses in healthcare due to a complex global supply chain and limited data sharing;
- many specific use requirements and potential exposure routes exist due to the ubiquitous nature of PFAS use in the healthcare sector, including in production equipment, consumables, packaging, delivery devices, medical devices, complex machinery and cleaning agents;
- identifying alternatives for high-performing PFAS like polytetrafluoroethylene (PTFE) while ensuring product quality and safety;
- end-of-life management of healthcare products is underdeveloped, with inconsistent approaches to multi-component waste management;
- current wastewater treatment technologies struggle to eliminate complex PFAS;
- consideration of PFAS guidelines and regional policy disparities that may impact the global utility of this study.

The overall aim of this IHI JU topic is to provide world-leading, fully integrated and globally applicable solutions to address PFAS emission and exposure concerns, for example by substitution.

To fulfil the IHI JU's topic aim, the applicant should address the following objectives:

Objective 1: Cross-sector solutions to develop PFAS alternatives

- **Activities:**
  - Establish public-private collaboration to increase knowledge about PFAS applications and alternatives with a focus on prioritised PFAS chemicals listed in Table 1;
  - Document key performance characteristics for PFAS used in healthcare products, manufacture, and testing;
  - Exploit industry, academic and manufacturing collaborations, incorporating skills such as chemical synthesis, material sciences and analytics to develop PFAS alternatives;
  - Test and validate PFAS alternatives generated by this project and, in addition, PFAS alternatives developed through research external to this project against performance characteristics and applications.
- **Outputs:**
  - Reporting system to label PFAS-containing raw materials or medical device components;
  - Technology on optimised materials capable of replacing PFAS in specific applications;
  - Reliable data on alternative materials that could replace PFAS and corresponding design and performance characteristics;
  - Technology for replacing PFAS chemicals in chemical synthesis or excipients in drug manufacturing;
  - Replacements for trifluoroacetic acid (TFA) in chromatography and other analytical methods;
  - Development of PFAS-free process aids (tubing, gaskets, fittings);
  - Searchable database of validated PFAS alternatives.

Objective 2: Understanding PFAS in the medtech sector

- **Activities:**
  - Identify and map PFAS types and applications in the medtech sector and align with those already identified in previous mappings of PFAS in the pharmaceutical industry;
  - Develop a methodology for risk-benefit analysis of PFAS use;
  - Establish public-private collaboration to gain knowledge about PFAS applications, alternatives, risks, and risk management options;
  - Identify suppliers to raise awareness of PFAS alternatives and secure continuous supplies of raw materials and parts;
  - Collect data on PFAS materials used in the supply chain, emissions, and mitigation options.
- **Outputs:**
  - Increased knowledge of PFAS types and applications throughout the medtech and diagnostic process supply chain;
  - Robust evaluation of PFAS alternatives;
  - Enhanced stakeholder information sharing between medtech and the manufacturers of equipment, devices, disposables, PPE manufacturers and other activities identified by this mapping exercise.

Objective 3: Sector-specific solutions to reduce and reuse PFAS materials

- **Activities:**
  - Map and calculate PFAS exposure from different categories of applications;
  - Develop end-of-life management options across the sector in line with the SSbD framework;
  - Evaluate and leverage PFAS removal technologies;
  - Evaluation of sector specific circular economy principles for applications where removal is not yet possible;
  - Evaluate sector-specific solutions to minimise PFAS exposure in partnership with healthcare facilities and waste management companies.
- **Outputs:**
  - End-of-life management guidelines for PFAS components/chemicals, including circularity aspects and waste treatment;
  - PFAS-specific removal, decontamination or environmentally responsible disposal technologies for TFA from wastewaters.

PFAS application	PFAS materials
Films/plastics (primary contact material) for final drug product sterile packaging: • Cap or stopper coatings/liners • Vial stoppers • Syringe stoppers • Seal linings • Blister packs	ETFE (cap or stopper liners) Other coatings (proprietary) e.g., OmniFlex stopper coatings PTFE (coating for vial and syringe stoppers and seal linings)
Films/plastics (primary contact material) in manufacture and containment of drug intermediates (drug substance): • Containers/films/bottles • Single-use processing bags • Single-use bioreactors • Probes/inserts • Sterile liquid filtration membranes • Liquid filtration – virus clearance • Vent and/or gas filtration (of bioreactors/carboys) – filter membranes • Devices • PTFE thread sealing tape in engineering systems • Biopharma drug cryostorage bags and cell culture cryostorage bags • Support filters (e.g., HEPA/HVAC air purification)	PVDF PTFE PTFE bottles FEB bags/bottles
Films/plastics (primary contact material) for final drug product non-sterile packaging – blister packs	PCTFE
• Analytical HPLC methods • Intermediate, raw material or ancillary material used in manufacture or purification of protein-based drugs	Use TFA in the mobile phase PTFE filters PTFE seals
Tubing and tube fittings (manufacturing engineering systems and transfer of drug material intermediates and final product) incl. gaskets and O-rings Hardware systems (lined pipes, TFF cassette seals/components/solvent exchange systems/lined valves/gaskets Pumps and components (diaphragm)	PVDF (tubings and fittings), PTFE, FKM (tubing/O-rings/gaskets), FEP, PFA
Heat and/or chemical resistant components, nonreactive coatings/insulation/lubricants/refrigerants	Additive of ABS Additive in polycarbonates
ETFE: Ethylene tetrafluoroethylene; PTFE: Polytetrafluoroethylene; PVDF: Polyvinylidene fluoride; FEP: Fluorinated ethylene propylene; PCTFE: Polychlorotrifluoroethylene; TFA: Trifluoroacetic acid Table adapted from EFPIA response to the ECHA consultation on the proposal for a universal ban on PFAS, Annex 3: ISPE_Industrial Use of Fluoropolymers & Fluoroelastomers in Pharmaceutical Manufacturing Facilities	

Table 1 – Types of PFAS in use in healthcare industry. The project scope includes exploring alternatives to the PFAS materials listed here. (Table adapted from EFPIA response to the ECHA consultation on the proposal for a universal ban on PFAS, Annex 3: ISPE_Industrial Use of Fluoropolymers & Fluoro-Elastomers in Pharmaceutical Manufacturing Facilities).

In addition to the critical uses in Table 1, the following high-priority PFAS use cases in the healthcare sector are core to this project's scope:

- production equipment and consumables (filters, tubing, seals/gaskets);
- primary and secondary packaging;
- medical devices (with and without patient contact) e.g. catheters, implants, needles, contact lenses; *in vitro* diagnostics (IVD), device handles;
- medical technology processing aids;
- complex machinery (diagnostic, imaging, research equipment);
- healthcare cleaning agents;
- healthcare consumables (surgical drapes, gowns, packaging, tapes, sutures, wound dressings, personal protective equipment (PPE));
- wastewater treatment.

The proposal should aim to collaborate with the following actors and initiatives:

- Industry associations and task forces with PFAS focus, such as EFPIA PFAS task force, Biophorum PFAS response team, Innovative Quality (Pharma) Consortium, American Chemical Society ACS) Green Chemistry Institute Pharmaceutical Roundtable, Pharmaceutical Supply Chain Initiative (PSCI), Animal Health Europe (AhE);
- IMI/IMI2 JU and IHI JU consortia (past and ongoing), including Prioritisation and Risk Evaluation of Medicines in the EnviRonment (PREMIER) and Intelligent Assessment of Pharmaceuticals in the Environment (iPiE) (on waste treatment), and the project resulting from IHI Call 4 topic 5 *Safe & sustainable by design (SSbD) packaging and single use device solutions for healthcare products*;
- Ongoing Horizon 2020 projects and future Horizon Europe calls comprising a PFAS focus;
- The Partnership for the Assessment of Risk from Chemicals (PARC);
- Regulators (to inform, align expectations, assess impact on regulatory pathways and ensure data and results produced will be fit-for-purpose); for the pharmaceutical and medical device industries including the European Medicines Agency (EMA), European Directorate for the Quality of Medicines & HealthCare (EDQM) & Official Medicines Control Laboratory (OMCL) network as well as additional national competent authorities. In the scope of this specific topic, engagement with the European Chemicals Agency (ECHA) should also be included.

Applicants should consider developing and implementing a strategy and plan to support relevant regulatory interactions.

Expected impacts

This IHI JU topic will enable and directly contribute to the EU health priorities, initiatives, and policies. Healthcare products containing PFAS are often essential for the health of citizens in Europe and worldwide. The proposed IHI JU topic would strengthen collaboration between healthcare system stakeholders to reduce emissions of, and exposure to PFAS, evaluate alternatives and therefore, contribute to the EU Chemicals Strategy for Sustainability of the EU Green Deal.

The action under this topic is expected to achieve the following impacts:

1. contribute to IHI JU SRIA objectives, driving cross-sectoral health innovation for a competitive European health industry. Contribute to the objectives of the Industrial Strategy for Europe and Pharmaceutical Strategy for Europe;
2. understanding human health and environmental risks from PFAS in healthcare from a life cycle perspective, i.e. mapping where PFAS is introduced in the healthcare industry and removal, where possible;
3. manage PFAS risks with novel mitigation measures, including safe disposal, reuse, and recycling;
4. develop methodologies and solutions for PFAS replacement that meet regulatory requirements without compromising efficacy, quality, safety, or environmental performance;
5. position the EU as a leader in safe, sustainable PFAS alternatives through industry-academia collaboration; foster medicine supply in the EU, avoid non-EU dependencies, and keep R&D activities in Europe for active substances to address societal and political needs;
6. strengthen stakeholder collaboration to reduce emissions and exposure until alternatives are found;
7. share industry knowledge and best practices to inform future PFAS policy;
8. improve business planning certainty for medical technology manufacturers, ensuring long-term sustainability and patient access.

Possible target groups: medical technology and medicines manufacturers and their supply chains, stakeholders involved in regulatory approval process (i.e., notified bodies, policy makers); waste management companies; hospitals and other healthcare settings and providers.

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

Addressing widespread PFAS use in medical technologies, medicinal products and vaccines requires cross-sector collaboration, involving industry (the pharmaceutical and vaccines development and manufacturing industry, as well as the medical technology development and manufacturing industry (medical devices, *in vitro* diagnostic devices (IVDs), imaging devices, drug-device combination products, etc.), plus academia, healthcare professionals, patients, health authorities, manufacturers, and IHI JU's partners. Mapping, risk assessments, and understanding performance characteristics need expertise from chemistry, environmental science, healthcare, and engineering. Resource sharing through a public-private partnership is essential for funding, research facilities, and data. Engaging diverse stakeholders ensures comprehensive and accepted solutions.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following pharmaceutical and medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Abbott
- Abbvie
- AstraZeneca
- Bayer
- Biotronic
- Boehringer Ingelheim
- BSCI
- Gilead
- GSK
- Johnson & Johnson
- LabCorp
- Edwards Lifesciences
- Eli Lilly
- Ion Beam Applications
- Karl Storz
- Merck KGaA
- Novartis
- Novo Nordisk
- Olympus
- Pfizer
- Roche

- Sanofi
- Servier
- Stryker
- Terumo
- UCB (lead)

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with several proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted in the second stage, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the full consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 24 000 000.
- The indicative in-kind and financial contribution from industry beneficiaries is EUR 23 902 900.

Due to the global nature of the participating industry beneficiaries, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The allocation of the EUR 567 500 financial contribution (FC) from industry beneficiaries will be decided by the full consortium at the second stage when preparing the full proposal.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium will provide the following expertise:

- chemical synthesis and active pharmaceutical ingredient (AP)I/drug product manufacturing;
- medical device manufacturing and assembly, packaging, distribution, medical supply chain management and quality control;
- regulatory affairs topics, occupational safety;
- standardised analytical methods and in process controls;

- use of process aids, their procurement and quality assurance aspects (e.g. qualification);
- management of chemical/biotechnology waste and decontamination of waste water;
- circular economy expertise;
- safe and sustainable by design methodologies;
- activities, results and insights from existing pilots and studies (these may include historical data generated outside of the project timelines that will not constitute part of the in-kind contribution);
- publication support and data dissemination.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

This may require mobilising the following expertise and/or resources:

- academic centres and research organisations:
    - expertise in PFAS analytics, chemical synthesis, material sciences, coatings, and biodegradation;
    - researchers working on PFAS alternatives and optimising existing materials.
- manufacturers:
    - PFAS materials (e.g., films, spare parts, equipment, implants, foils);
    - Medical manufacturing, critical technologies, medicinal products, and vaccines;
    - Drug substance manufacturing/vaccines targeting PFAS excipient replacements/reductions.
- analytical methods experts: replace TFA in chromatography and other technologies;
- standards organisations: develop and update analytical standards/testing methodologies;
- process aids development experts: replace PFAS-containing process aids (tubing, gaskets, fittings) with PFAS-free alternatives;
- circular economy experts: establish PFAS-specific collection and recycling systems;
- “Safe and sustainable by design” experts;
- Healthcare waste management organisations;
- Urban wastewater treatment management organisations;
- Healthcare sector consultants: provide input and test solutions;
- project management:
    - coordinate communication, meetings, and risk management;
    - grant administration, financial management, and reporting;
    - digital/IT development and implementation to support data governance and management;
    - coordinate internal and external networking and stakeholder engagement.

At the second stage, the consortium selected at the first stage and the pre-identified industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not apply.

HORIZON-JU-IHI-2025-10-01 **Digital label: one source of comprehensive information for medical technology products**	The maximum financial contribution from IHI JU is up to EUR 3 806 900. The indicative in-kind contribution from industry partners is EUR 6 156 800. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-10-02 **Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)**	The maximum financial contribution from IHI JU is up to EUR 6 043 000. The indicative in-kind contribution from industry partners is EUR 5 772 500. The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-10-03 **Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector**	The maximum financial contribution from IHI JU is up to EUR 24 000 000. The indicative in-kind and financial contribution from industry partners is EUR 23 902 900. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.

IHI call 11

Topic 1: Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction

Expected outcomes

The action generated by this topic is expected to contribute to all the following outcomes:

1. A sustainable and collaborative large, multimodal data platform that can identify novel transdiagnostic candidate markers and endpoints for the symptom domains of reward/motivation (including anhedonia) and impulsivity (RM&I) [1],[2] in neuropsychiatric, neurodegenerative, and physical health disorders. Relevant disorders include Alzheimer's disease (AD), major depressive disorder (MDD) and obesity (priority areas). Other relevant disorders/diseases include but are not limited to substance use and associated disorders, schizophrenia, bipolar disorder, borderline personality disorder and Parkinson's disease. For a disorder/disease to be relevant, there must be evidence to show that reward/motivation and/or impulsivity are clinically significant symptom domains;
2. Novel transdiagnostic candidate markers and endpoints are identified and progressed towards validation. Learnings are applied in drug discovery to increase probability of success (PoS);
3. A clear roadmap to achieve full validation of candidate markers and endpoints by regulatory and health technology assessment (HTA) bodies. Clinical best-practice guidelines are developed, and recommendations are made to the current diagnostic classifications[121] to expedite the adoption of precision medicine;
4. A greater understanding of the biological foundations of RM&I symptom domains and their role in AD, MDD, obesity and other relevant disorders, enabling the generation of novel therapeutic approaches by industry;
5. Closer alignment between psychiatry, neurology, and physical health disciplines to enable dialogue between healthcare professionals (HCPs) and other medical specialists to optimise outcomes, particularly for individuals with complex healthcare needs and comorbidities.

Scope

Current diagnosis and patient stratification in health disorders with Central Nervous System (CNS)-driven symptoms are based on DSM-5 / ICD-11 codes, which are not aligned with underlying biological processes and mechanisms. Subsequent suboptimal disease classification and patient stratification is a key reason for the low PoS of clinical development and the historical lack of new and more efficacious treatments. This topic aims to address these challenges by adopting a holistic, transdiagnostic approach [3] focused on the common underlying biology of RM&I symptom domains across the relevant disorders listed in the first expected outcome.

The topic seeks to build on an existing federated data platform to consolidate, curate, link and analyse robust, multimodal datasets from relevant patient populations. Thus, activities related to building a new platform or a biorepository from scratch are out of scope. The data platform must enable data/sample discovery, access, and support advanced computational analysis including artificial intelligence (AI)/ machine learning (ML) technologies while ensuring interoperability with other global data platforms to illuminate the biological basis of the RM&I symptom domains and identify related candidate markers and endpoints. The

[121] Diagnostic and Statistical Manual of Mental Disorders (DSM) and International Classification of Diseases (ICD)

hypotheses will be prospectively tested in clinical case studies focusing on but not limited to AD, MDD, and obesity. Post-project, the platform will be available as open access for ongoing research and validation.

The topic also priorities collaboration with relevant stakeholders, including people with lived experience (LE), carers, HCPs, providers, regulators, HTA bodies and payers, to prepare the healthcare system for this transformative shift. People with LE can provide unique insights and expertise that comes as the result of first-hand experience of health challenges. Integrating LE expertise improves research by bringing an understanding beyond academic and clinical knowledge. The perspectives of people with LE across the relevant symptom domains must be represented within the consortium and applied wherever appropriate.

Applicants must outline their approach to inclusive and equitable practices throughout the initiative, possibly through a risk register and appropriate mitigations. Example areas for consideration include data representation, bias mitigation, stakeholder engagement, ethics, and feedback mechanisms.

Objectives of the topic

Applicants are expected to address all four main objectives of the topic in their proposal:

1. Adapt and extend an existing federated data platform that is sustainable, enabling collaborative curation, access and analysis of clinical datasets and samples (as mentioned above). Consolidate existing multimodal datasets and samples from cohorts with relevant disorders[122] into the adapted platform;
2. Collect additional new clinical datasets and samples to address gaps and integrate these into the adapted platform;
3. Test hypotheses for candidate markers and endpoints within a defined context (e.g. patient selection, diagnosis, or treatment monitoring) in a transdiagnostic patient population presenting symptom domains of RM&I, including those with AD, MDD, and obesity;
4. Establish a collaborative platform to bring together people with LE, HCPs, regulators, HTA bodies and payers to achieve consensus on the value of candidate markers and endpoints, how to operationalise them into new diagnostic and treatment frameworks and achieve readiness in the healthcare system.

Activities under objective 1:

The success of this topic hinges on access to a large of amount of high-quality, multimodal data and biological samples collated from applicants and other partners (including industry). The applicants must list the datasets and samples that they will bring and confirm that they will be made accessible to the whole public-private partnership (PPP) from the start of the action.

1.1 Collate existing multimodal, longitudinal and transdiagnostic datasets at an individual level, including relevant parameters outlined under 1.2. These datasets can come from public or private databases, observational studies, clinical trials, real-world evidence (RWE) studies, biobanks, electronic health records, registries, and/or other digital health technologies and platforms. In their short proposal applicants must include a strategy to utilise relevant data from the European Platform for Neurodegenerative Diseases (EPND) catalogue[123] as much as possible as well as other relevant datasets available from previous projects (including pre-clinical data).

[122] Relevant disorders: Alzheimer's disease, major depressive disorder and obesity are priority areas for this topic. Other relevant disorders/diseases include but are not limited to substance use disorders, schizophrenia, bipolar disorder, borderline personality disorder and Parkinson's disease. For a disorder/disease to be relevant, there must be evidence to show that reward/motivation and/or impulsivity are clinically significant symptom domains.
[123] https://discover.epnd.org/catalogue/studies

1.2 Relevant multimodal datasets ideally include as many as possible from the following: neurophysiology data (e.g. electroencephalography (EEG), magnetoencephalography (MEG)), brain imaging data (e.g. functional magnetic resonance imaging (fMRI), MRI), qualitative subjective assessments, behavioural data, real-world data, medical claims and billing data, routine clinical data (from medical and psychological assessments including data on metabolic status), physiological/activity monitoring data (polysomnography, actigraphy, digital data from wearables, etc.), speech/language data, patient reported outcome data (e.g. questionnaires), molecular biodata (e.g. "-omics"), and potentially data gained via therapeutic protocols (drugs, neuromodulation (deep brain stimulation, transcranial magnetic stimulation, transcranial functional ultrasound, etc.)). Biological samples (e.g. blood, urine, stools, cerebrospinal fluid) from biobanks should be leveraged. Datasets should be from individuals with relevant disorders as well as healthy controls.

1.3 Propose a strategy to integrate and connect the datasets from different sources.

1.4 Outline an approach to inclusive and equitable practices, including data representation, including but not limited to gender, ethnicity, and age (e.g. paediatric and adolescent populations).

1.5 Adapt and extend a federated data platform by building on existing infrastructures proven effective in PPPs, including the AD Workbench[124] and the EPND hub[125] (made available via the pre-identified industry consortium). The adapted platform should leverage available resources (including standard operating procedures) from EPND [4]. The adapted platform must be scalable and adaptable to curate high-quality, multimodal, retrospective, prospective and longitudinal data as mentioned under 1.1 and 1.2. It must enable data/sample discovery, access, and support AI analysis, while ensuring interoperability with other global data platforms.

1.6 Ensure high data quality by verifying the robustness of methodologies before integration into the adapted platform. This could be achieved by establishing a Data Quality Assessment Committee.

1.7 Implement fair and transparent governance for data- and sample-sharing including model interpretability, data provenance, and traceability of AI decision-making processes. Applicants must explain how they will develop a consensus on data sharing principles, complying with legal and ethical standards (e.g. General Data Protection Regulation (GDPR) and intellectual property rights (IPR)) and ensuring robust protection of data volunteers' rights. For example, leveraging the Data Sharing Playbook[126] and setting up a Data Access Review Committee.

1.8 Review the collated dataset to identify key gaps and develop a strategy to guide new data collection under Objective 2.

1.9 Identify potential algorithms for activities under 3.3 in Objective 3.

1.10 Ensure platform sustainability by creating a strong value proposition and user ecosystem beyond the consortium, with a clear strategy for a long-term, AI-powered platform accessible to the broader research community, including the healthcare industry. Relevant activities need to be in place from the start of the action.

[124] https://www.alzheimersdata.org/ad-workbench
[125] https://epnd.org/news-and-resources
[126] Data Sharing Playbook: https://www.ihi.europa.eu/sites/default/files/uploads/Documents/ProjectResources/IMI_IHI_DataSharingPlayBook_2024.pdf

Activities under objective 2

2.1 Collect new prospective multimodal and ideally longitudinal data from transdiagnostic cohorts, focussing on individuals affected by RM&I abnormalities in the relevant disorders, and ideally also collect biological samples. The datasets should close data gaps identified under 1.8 and be integrated into the adapted platform, meeting the same criteria described in objective 1.

2.2 Continue to recognise and fill data gaps to expand and maintain the adapted data platform, keeping it current with technological and scientific advancements. Whenever appropriate, utilise AI/ML, such as synthetic data generation, image analysis, natural language processing etc., to enhance the dataset.

2.3 Continue identification of potential algorithms for activities under 3.3 in Objective 3.

Activities under objective 3

3.1 The short proposal should propose an initial pilot clinical case study designed to test a scientifically robust and data-supported hypothesis on candidate markers and/or endpoints in RM&I symptom domains during the project's initial year. It must include transdiagnostic populations from AD, MDD, and obesity. The case study must include as a minimum neurophysiological data (e.g. EEG or MEG) and brain imaging data (e.g. MRI, fMRI) from each subject. In addition, datasets should include as many parameters as possible from the list described in 1.2. The precise scope of the initial clinical case study will be developed by the full consortium during the preparation of the full proposal. (Additional case studies are described under 3.4).

3.2 In the first 6 months, prepare a systematic literature review (white paper) of the available potential markers in RM&I symptom domains in relevant disorders to support hypothesis generation and subsequent testing. This should be kept up to date throughout the action.

3.3 Apply suitable statistical methods, advanced computational analytics (including, whenever appropriate, AI/ML as part of the statistical/analytical toolbox), modelling, and simulation across the multimodal data in the adapted platform to cluster biologically similar subjects across disorders/diseases, stratified independently of their conventional diagnostic classification. This should enable to identify and confirm clinically significant, quantitative candidate markers for RM&I symptom domains in relevant disorders, incorporating hypothesis-driven and data-driven approaches. It should also establish the foundation for a new transdiagnostic framework based on phenotypes/biotypes to enable detection of factors for susceptibility, risk stratification, diagnostic precision, disease monitoring, treatment response prediction, and overall patient outcomes. In addition, it should elucidate the biological underpinnings of the relationship between psychiatric and physical health (e.g. for obesity, understanding the interplay between metabolic disturbances, mental health and eating behaviours).

3.4 Test putative transdiagnostic markers and endpoint hypotheses derived from 3.2 and 3.3 through additional non-sequential pilot clinical case studies, incorporating insights from stakeholder consultations as mentioned in objective 4. These case studies must test the same transdiagnostic marker/endpoints in separate pre-defined patient populations in two or more of the relevant disorders to strengthen the transdiagnostic approach. As a preference, the three priority disorders should be included in at least one study each as a lead indication. For instance, one study with AD, one with MDD and one with obesity as the lead indication, each including at least one additional relevant disorder. Each study must include neurophysiological and brain imaging data and include as many other parameters as possible from the list outlined under 1.2. Studies must be powered sufficiently to allow analyses both within and across the included disorders. All results must be integrated into the adapted platform. The studies should enhance the platform's ability to accelerate hypothesis testing of new candidate markers and endpoints within a defined context of use (e.g. patient selection, diagnosis, or treatment monitoring) in representative patient populations. These studies must not involve the development of new *in vitro* diagnostic tools or digital sensors. The resulting evidence from pilot case studies (including the initial pilot clinical study under 3.1) should:

- be verifiable and applicable for patient stratification and/or monitoring in future clinical trials;
- demonstrate clinical utility to foster new patient pathways and clinical guidelines;
- contribute to bridging the gap between health care needs and capacity.

Activities under objective 4

4.1 Create an efficient collaborative platform to support seamless communication and collaboration among key stakeholders in the field of the relevant disorders. This includes innovators, researchers, clinicians, people with LE, carers, patient advocates, HCPs, regulators, scientific societies, HTA bodies, payers, and policy makers to collectively define and implement a new framework for the diagnosis and treatment of these disorders.

4.2 Form advisory/working groups comprising different stakeholders to support activities under objectives 1, 2 and 3, and co-create solutions. Ensure active and meaningful participation of people with LE, carers, and advocacy organisations throughout the activities and governance.

4.3 Engage with regulators (via experts with relevant expertise), e.g. EMA and/or national competent authorities, proactively initiating early consultations as appropriate. This should set the basis for continuation towards full validation of markers and endpoints beyond the action. Applicants are expected to consider the potential regulatory impact of the results and as relevant, develop a regulatory strategy and interaction plan early on to define a strategic approach to evidence collection and analysis where feasible (including case studies under objective 3) for generating appropriate evidence, as well as engaging with regulators in a timely manner (e.g. national competent authorities, EMA Innovation Task Force, qualification advice). Similarly, appropriately engage with HTA bodies and payers on the value of new transdiagnostic framework, candidate markers and endpoints when used to support claims of effectiveness of new therapies, paving the way for future reimbursement.

4.4 Craft evidence-based clinical guidelines through consultations with stakeholders, including people with LE, regulators, HTA bodies, payers, and medical organisations. Achieve consensus on best practices for implementing the new transdiagnostic framework. Develop recommendations and provide proposals for updates to the classification of disorders[127].

[127] Relevant disorders: Alzheimer's disease, major depressive disorder and obesity are priority areas for this topic. Other relevant disorders/diseases include but are not limited to substance use disorders, schizophrenia, bipolar disorder, borderline personality disorder and Parkinson's disease. For a disorder/disease to be relevant, there must be evidence to show that reward/motivation and/or impulsivity are clinically significant symptom domains.

4.5 Design and implement a comprehensive training programme for HCPs to adopt the new transdiagnostic framework. Create educational materials and implement trainings for people with LE, families and carers in multiple languages, ensuring readiness across the healthcare system for the paradigm shift in healthcare delivery throughout Europe and helping to reduce stigma.

Applicants are expected to leverage and build on the learnings and outputs from previous and ongoing relevant PPPs[128] and other relevant global, European and national initiatives. They should consider synergies with the future European Genomic Data Infrastructure (GDI)[129], part of the European 1+Million Genomes Initiative[130], the future European Partnership for Brain Health[131] and other relevant upcoming projects[132].

Expected impacts

The action under this topic is expected to achieve the following impacts:

Data platform for precision medicine: A comprehensive, sustainable data-driven health platform linking behaviours and symptoms to quantitative biological markers. This will deliver much-needed refinements to existing diagnostic frameworks and treatment paradigms, providing a clear step towards personalised healthcare for CNS-driven symptoms. This platform could be a model for other disease areas where there is need for more biology-driven precision medicine.

Advancing mechanistic understanding: Clarification of the biological basis of CNS transdiagnostic symptoms expediting the identification of novel and more effective precision therapies across the relevant disorders, boosting the competitiveness of European industry and beyond. Advanced mechanistic understanding will also galvanise innovation in diagnostics.

Patient outcomes and stigma: A significant improvement in care quality (more integrated and personalised care) and in health outcomes for people within the RM&I driven relevant disorders. This includes healthcare innovations arising from improved understanding of the relationship between psychiatric and physical health and their underlying biology with far-reaching implications for patient health beyond psychiatry and neurology. This will also lead to reduction of stigma and provide opportunities for early intervention.

Efficiency in the healthcare system: Precision treatments reduce avoidable waste in healthcare resources, leading to overall cost reduction, higher productivity, and a positive economic impact on the European health care budget. Overall, a transformative shift towards a more integrated and personalised approach to healthcare will benefit patients across Europe and beyond.

The action will also support the EU political priority to boost European competitiveness and contribute to a number of European policies/initiatives, which include the European Health Data Space Regulation (EHDS)[133], the EU Artificial Intelligence Act[134] and the European Commission's Communication on a comprehensive approach on mental health[135] and the Healthier Together- EU Non-Communicable Diseases initiative[136].

[128] EPND, PRISM/ PRISM2, RADAR-CNS, RADAR-AD, MOBILISE-D, IDEA-FAST, EU-PEARL, SOFIA, READI, AIMS-2-TRIALS, EHDEN, PROMINENT, PREDICTOM, AD-RIDDLE, among others.
[129] Synergies with the future European Genomic Data Infrastructure (GDI) are encouraged. https://gdi.onemilliongenomes.eu/
[130] https://gdi.onemilliongenomes.eu/ ; https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
[131] https://www.brainhealth-partnership.eu/about/
[132] IHI Call 11 T1: Understanding how infections foster and induce non-communicable diseases as well as relevant projects funded under IHI Call 9.
[133] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327
[134] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689
[135] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/comprehensive-approach-mental-health_en
[136] https://health.ec.europa.eu/non-communicable-diseases/healthier-together-eu-non-communicable-diseases-initiative_en

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

The development of a scalable, sustainable, public-private federated data and biobanking infrastructure, as well as the collation of multimodal, transdiagnostic data, is crucial to address the current marker/endpoint challenges in neuropsychiatric, neurodegenerative, and physical health disorders including AD, MDD and obesity. Acquisition and harmonisation at this scale is beyond the capacity of a single organisation. The Innovative Health Initiative (IHI) provides an ideal model for creating such an initiative, integrating all relevant stakeholder groups in a focussed and collaborative framework. This public-private consortium will collate resources, share knowledge, and coordinate efforts to transform the diagnosis, treatment, categorisation and understanding of disorders driven by the RM&I symptom domains.

Pre-identified industry consortium and contributing partner

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- AbbVie
- Boehringer Ingelheim (Lead)
- Gates Ventures LLC (Co-lead)
- iFAB
- Novo Nordisk
- Roche

In addition, the following contributing partners will participate in the IHI JU action:

- Wellcome Trust

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 20 202 000.
- The indicative in-kind and financial contribution from industry beneficiaries is EUR 13 987 940.
- The indicative in-kind and financial contribution from IHI JU contributing partners is EUR 6 642 533.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The EUR 2 600 000 financial contribution (FC) from industry beneficiaries and EUR 5 940 550 from the contributing partner is further described under the section *Contribution of the pre-identified industry consortium and contributing partners.*

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partner

The pre-identified industry consortium and contributing partner expect to contribute to the IHI JU action by providing the following expertise and assets:

- the AD Workbench[137], which has already been leveraged in EPND, will be made available as well as facilitation of access to EPND hub infrastructure including the EPND catalogue.[138]
- expertise and capabilities for data management, biostatistics and data science, development of processes for data and sample collection, quality assurance/control, and data analyses; contributions to implementation of data analysis algorithms and large language models (LLM) and other AI methodologies;
- contributions to systematic literature reviews;
- activities to make available multimodal datasets and (if possible) samples collected from historical clinical trials and activities to collect data in prospective clinical trials (e.g. placebo and potentially comparator data from Phase I/II/III trials in relevant disorders);
- clinical trial, translational, digital health, and medical expertise and guidance related to clinical protocol design, clinical operations, clinical and real-world data collection and analysis;
- expertise in legal, ethics, compliance, and representativeness in research/study design;
- expertise in regulatory strategy, policy and decision making, HTA assessment and reimbursement, involvement of LE expertise; support for integration of their requirements;
- contribution to the elaboration of educational and training programmes for HCPs, people with LE and carers.

Furthermore, the industry consortium will provide both the project leader and legal support during the project and help with data and knowledge management and communication/dissemination of results. It will also provide contributions to joint meetings and steering committees, networking, exploitation and sustainability.

Full details regarding the FC of EUR 2 600 000 from industry partners and of EUR 5 940 550 from the contributing partner will be provided in the full proposal. A part of the FC from industry beneficiaries will be allocated to activities related to the pilot clinical case studies.

[137] https://www.alzheimersdata.org/ad-workbench
[138] https://discover.epnd.org/catalogue/studies

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partner.

This may require mobilising the following expertise and/or resources:

- project management expertise and capabilities in running multi-stakeholder cross-sector projects;
- data platform expertise and capabilities to leverage the AD Workbench to establish an extended version of the EPND platform, including data privacy, ethics, and legal expertise, development of principles and processes for data and sample collection, ensuring equitable and inclusive data practices, quality assurance/control, and an approach for the platform's sustainability;
- data capture / data management and analysis expertise and capabilities to import, curate and integrate existing and prospective datasets and ideally samples from public and private sources into the data platform; expertise and capabilities in data science, to develop and apply advanced AI supported analytics, modelling and simulation, and bias mitigation, and conduct multimodal analyses at scale to develop hypotheses of new candidate markers and endpoints;
- proven expertise and capabilities in the conduct of transdiagnostic pilot clinical case studies: i) expertise in RM&I symptom domains, translational, digital and clinical science, development and validation of new markers/endpoints; ii) systematic literature reviews of potential transdiagnostic markers and endpoints and hypotheses generation; iii) design and conduct of all pilot studies including regulatory and ethics approvals, setting up sites, recruitment in AD, MDD and obesity, collection and storage of data and samples, and measurement of all parameters described above. The outline of the first pilot clinical case study must be included in the short proposal (to be finalised by the full consortium during the preparation of the full proposal; study protocols of additional pilot clinical studies will be finalised by the full consortium during the proposed action);
- involvement of LE and patient advocacy groups/organisations as consortium members;
- resources to engage with people with LE, carers, HCPs to prepare training programmes and educational materials;
- expertise and capabilities in interacting with regulatory authorities, HTA bodies, payers, policy makers, medical societies, organisations of people with LE, and patient advocacy groups.
- regional health care centres with a centre of excellence in the relevant disorders.

At the second stage, the selected public consortium, the predefined industry consortium and contributing partners will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall plan and the work packages, based on the selected short proposal.

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' do not apply.

UK based legal entities' eligibility to receive funding

Legal entities established in the United Kingdom are eligible to receive funding in this topic.

Canadian legal entities' eligibility to receive funding

Legal entities established in Canada are eligible to receive funding in this topic.

References

[1] Nusslock R, and Alloy L B (2017) Reward Processing and Mood-Related Symptoms: An RDoC and Translational Neuroscience Perspective. J Affect Disord. 4;216:3–16. doi: https://www.sciencedirect.com/science/article/abs/pii/S0165032716310011?via%3Dihub

[2] Mata F, Treadway T, Kwok A, et al. (2017) Reduced Willingness to Expend Effort for Reward in Obesity: Link to Adherence to a 3-Month Weight Loss Intervention. Obesity 25 (10): 676-1681: https://onlinelibrary.wiley.com/doi/full/10.1002/oby.21948

[3] Towards a consensus roadmap for a new diagnostic framework for mental disorders, European Neuropsychopharmacology, 2025, 90: 16-27, https://doi.org/10.1016/j.euroneuro.2024.08.515

[4] The European Platform for Neurodegenerative Diseases (EPND) https://doi.org/10.1002/alz.079164

Topic 2: Understanding how infections foster and induce non-communicable diseases

Expected outcomes

The action under this topic must contribute to all of the following outcomes:

1. **Accelerated access to interventions:**

   A better understanding of the potential causal links between infections and non-communicable diseases and their accompanying biomarkers could:

   - more precisely define a person's level of risk for long term health complications
   - lead to the development of better diagnostic approaches such as early detection and monitoring strategies that will make preventive medicine more effective for the benefit of patients.

2. **Development of vaccine strategies:**

   A better understanding of the potential causal links between infections and chronic diseases could lead to the generation of vaccine strategies with the capacity to prevent the development of one or more chronic diseases over the course of a person's life, significantly reducing the long-term burden of disease.

3. **Early intervention strategies:**

   A clear understanding of the mechanisms of action used by infections to cause chronic diseases could more precisely define which cellular processes, metabolic pathways, enzymatic activities, and gene expression changes should be the focus of early intervention strategies. These strategies could halt or potentially reverse the progression of chronic diseases and would aim to replace many current treatments that only manage symptoms.

4. **Improved quality of life:**

   A better understanding of the potential causal links between infections and chronic diseases, as well as the biomarkers and mechanisms of action involved, could more precisely define development strategies for prophylactic vaccines, early diagnosis, and early intervention therapeutics that could significantly improve the quality of life of individuals by preventing health decline and avoiding escalating healthcare costs.

5. **Adoption of innovative approaches:**

   The establishment of a more systematic collaborative approach to mining existing research cohorts and biobanks to determine potentially causal links between infections and chronic diseases by combining multi-omics, artificial intelligence, and pre-clinical model verification to potentially accelerate the development of prophylactic vaccine, early diagnostic and early intervention strategies.

Scope

Infectious agent (IA) and non-communicable disease (NCD) interplay has driven effective prevention strategies. However, a growing field of research suggests that there are many unexplored connections between IAs and NCDs that could be utilised to develop better diagnostic, preventative, and therapeutic approaches to burdensome diseases. A cohort analysis identified 96 distinct NCDs correlated to IAs [1]. Other cohort analyses identified neurodegenerative diseases, defined as the progressive loss of neurons resulting in loss of motor function or cognition, with links to viral infection [2], including Alzheimer's disease, amyotrophic lateral sclerosis, dementia, vascular dementia, Parkinson's disease and multiple sclerosis. IA links to cardio-metabolic NCDs such as HSV (Herpes simplex viruses) and coronary artery disease [3], CMV (cytomegalovirus), EBV (Epstein-Barr virus), VZV (varicella-zoster virus), influenza and parvovirus B19 have been shown to induce cardiomyopathies [4], and *H. pylori* infections may drive myocardial infarction [5].

While cancer, autoimmune, neurological, and cardiometabolic NCDs all have significant links to IAs, the scope of this topic is focused on neurodegenerative and cardiometabolic diseases, which carry significant disease burdens, potentially caused by direct, immune-mediated, or microbiota-gut-brain-axis damage/dysregulation, and lack early intervention strategies. Via the action funded under this topic, Europe's research community could potentially find more infection-based approaches for diagnosing, preventing, and treating NCDs.

The action funded under this topic aims to identify potential causal links and biomarkers leading to mechanism of action (MoA) studies. The literature [6][7][8] demonstrates research cohorts' utility in exploring the interplay between IAs and NCDs, increasing the likelihood of success. For instance, causative links were determined for oncolytic viruses, EBV [9] and human papillomavirus (HPV) [10], using Hill's causation criteria. The action funded under this topic should:

- develop methodologies to demonstrate non-carcinogenic IA to NCD causal relationships;
- consolidate data in one repository of IA/NCD causal relationships, biomarkers, and MoAs.

Applicants are expected to define a strategy to assess non-carcinogenic infection-associated NCD causative links and related biomarkers, incorporating a modelling perspective alongside AI-assisted data mining, appropriate statistical methodologies, and prioritisation approaches for the exploration of mechanisms of action (MoA). Applicants should also detail their methodological approach and data collection procedures, providing preliminary data to show potential for success and strategies for mitigating main methodological risks and limitations.

- As part of the first objective of proposed activities, applicants should work toward generating robust evidence toward proof of causality rather than only strengthening the known associations of IAs and NCDs. Applicants should take advantage of the available research cohorts, biobanks, and exposome data, including microbiota-gut-brain-axis samples from large general population studies, neurodegenerative disease cohorts, or cardiovascular disease cohorts. Association strength, consistency, and specificity should be indicated by similarity of measurement across different cohorts. Insurance data could be used to analyse temporality where infection occurs prior to medically attended disease. Cohorts from patients that have received transplants or immunosuppressive treatments with longitudinal data could demonstrate temporality and biological gradient effects from opportunistic infections, the strength of the immune response to IAs to demonstrate elements of causality driven by immune-mediated damage. Selection of research cohorts should prioritise data sets with populations from diverse ethnicities, socio-economic statuses, and balanced for gender. Applicants should develop/use pre-clinical models for causal link plausibility verification. Applicants are expected to follow and comply with all relevant ethical and data privacy standards for research. Applicants are also expected to conduct their consortium work with full transparency, clearly communicating data provenance, model interpretability, traceability, and limitations, especially when using AI modelling and decision-making.

- The second objective is identifying novel biomarkers, ideally to classify associated IAs, to better stratify individuals (children, adults, the elderly) who are at risk of developing NCDs post infection. This could be done using immune or metabolic markers, host and microbiome metabolomics, sequencing, etc. This pillar can utilise the same cohorts, biobanks, and exposome data used for pillar 1 if sufficient, but should supplement with additional cohorts where needed. To ensure outcomes within the 5-year timeframe of the project, the launch of new prospective cohorts is out of scope but limited recruitment to fill specific data gaps in existing cohorts could be considered.
- The third objective is to define the MoA that IAs use to drive NCD development. MoA identification would require tissue samples from pillars 1 & 2, as well as pre-clinical or *in silico* experimentation according to the targeted conditions or diseases.

No product development is expected from this action in the proposed timeline.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with regulators in a timely manner. Additionally, applicants should anticipate engaging regional healthcare systems and authorities to prepare for clinical implementation and outcome acceptance when necessary.

Applicants should include in their proposal a strategy to ensure sustainability of the outputs of the project beyond the funding period.

The funded project should explore synergies with the funded project from IHI Call 11 Topic 'Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction' (once the funded projects are awarded) to increase impact. Applicants are also expected to consider synergies with other relevant global, European and national initiatives including projects generated from Cluster Health topic "Relationship between infections and non-communicable diseases (HORIZON-HLTH-2023-DISEASE-03-07).

Expected impacts

The action under this topic is expected to achieve the following impacts:

- accelerate the EU's access to more cost-effective interventions for the most burdensome diseases;
- decrease the risk of developing serious diseases later in life by defining specific prevention strategies;
- contribute to halting the progression of chronic diseases by using biomarkers in early interventions;
- improve the quality of life for healthy individuals and patients by preventing further health decline, avoiding escalating care costs, and properly stratifying individuals and patients earlier in the diagnostic pathway;
- accelerate the adoption of innovative approaches to diagnostic, preventative, and therapeutic strategies, strengthening the EU positioning as an innovator in healthcare.

The action will also support the EU political priority to boost European competitiveness and contribute to a number of European policies/initiatives, which include the European Commission's European Health Data Space Regulation (EHDS)[139] and the EU Artificial Intelligence Act[140].

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

[140] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

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

Elucidating the potentially complex relationships between infectious agents and non-communicable diseases can take decades using traditional research structures. In order to accelerate the understanding of how infectious agents drive non-communicable diseases, a multi-disciplinary approach is necessary to bring together multi-omics data, AI modelling, and existing cohort resources. This will shorten the timelines required to design appropriate studies and analyse longitudinal samples, making translational outcomes for the work feasible in the timeframe of a project. As many of these disease areas do not traditionally overlap with infectious disease research, the understanding of the interplay between infection and chronic disease also requires a dedicated partnership between academic researchers with expertise in microbiology, multi-omics approaches and NCDs and private companies currently pursuing preventative and therapeutic options for the selected disease areas. This new collaborative partnership could be an extremely fruitful way to develop preventative and therapeutic interventions over the long-term.

The greatest advantage of the IHI model is that it increases the access of all players in the ecosystem to existing research cohorts, biobanks, and exposome datasets, including the microbiome. Such datasets, whether privately held by industry players or largely publicly available, may need to be compared directly to effectively extract biomarkers, pathways activated and novel pathogen information. Additionally, biomarker identification in at-risk populations may lead to the development of diagnostic strategies for early intervention. The unravelling of the MoAs will inform on the right clinical endpoint diagnostics in time for clinical development of new prophylactic/therapeutic strategies.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries (‘constituent or affiliated entities of private members’):

- Gates Ventures LLC
- Sanofi (Lead)

In addition, the following philanthropic organisation will participate in the IHI JU action:

- Novo Nordisk Foundation

In the spirit of partnership, and to reflect on how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 7 127000.
- The indicative in-kind and financial contributions from industry beneficiaries is EUR 8 167 000.
- The indicative in-kind and financial contributions from the philanthropic organisation is EUR 1 020 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The allocation of the EUR 1 000 000 financial contribution (FC) from industry beneficiaries will be decided by the full consortium at the second stage when preparing the full proposal.

The allocation of the EUR 1 000 000 financial contribution (FC) from the philanthropic organisation will be decided by the full consortium at the second stage when preparing the full proposal.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

1) Expertise and Assets:

- **Expertise and access to cohorts and patients' data in Disease Areas of Interest**:
  - Neurodegenerative diseases (e.g., Parkinson's disease, Alzheimer's disease); especially access to the European Platform for Neurodegenerative Diseases (EPND) data hub
  - Cardiometabolic/cardiovascular diseases.
- **Pillars of Interest**:
  - Infectious agent target discovery expertise and methodology;
  - Tools and methodology for biomarker identification (infectious agents & health conditions);
  - Mechanisms of action.
- **Resources**:
  - Data and cohort access;
  - Biomarker identification (multi-omics);
  - Immune profiling;
  - Microbiome expertise;
  - *In silico* modelling, preclinical investigations *in vitro* and *in vivo*;
  - Federated analyses;

- Internal expertise, wet lab work;
- Advanced multi-omics including immuno-proteomics, spatial proteomics, plasma proteomics, bioinformatics;
- Expertise in analytics;
- Initiatives focusing on the better use of health data and cohorts;
- Knowledge transfer and early detection initiatives;
- Artificial intelligence and machine learnings.

2) General Contributions:

- **Data and cohort Access**: Access to large cohorts and biobanks for data mining and biomarker identification;
- **Biomarker identification**: Expertise in multi-omics, immune profiling, and advanced proteomics, including artificial intelligence/bioinformatics;
- **Therapeutic expertise**: Small molecule drug discovery, vaccines, and therapeutic interventions;
- **Knowledge transfer**: Initiatives focusing on health data usage, early detection, and disease associations.

These contributions aim to leverage existing resources and expertise to advance the project's goals in understanding and addressing the interplay between infectious agents and NCDs.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on all the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partner(s).

This may require mobilising the following expertise and/or resources:

Academic institutions can provide complementary expertise in neurodegenerative and cardiometabolic/cardiovascular diseases, as well as access to innovative assets and methodologies such as the following list of suggested, non-exhaustive capabilities:

Expertise:

1. **Infectious diseases:**
   - Microbiology expertise in virology, bacteriology or parasitology;
   - Preclinical model of infection to determine causality, pathogenesis and mechanisms of action;
   - Omics expertise: sequencing, spatial transcriptomics, proteomics to identify the infectious agents;
   - Immunology to study serostatus, immune profiling, cytokines and single cell ribonucleic acid (RNA) sequencing to understand the pathogenesis and mechanisms of action.
2. **Neurodegenerative diseases, cardiometabolic/cardiovascular**:
   - Cellular and molecular biology to understand molecular mechanisms;
   - Expertise in neuroscience, cardiometabolism to understand pathogenesis, especially the microbiota-gut-brain axis for neurodegenerative diseases;
   - Innovative preclinical models including organ-on-chip and/or organoid to understand mechanisms and pathogenesis;
   - Multi-omics expertise such as sequencing, epigenetics, transcriptomics, proteomics, lipidomics, metabolomics to identify biomarkers and expertise to understand pathogenesis and mechanisms of action.

3. **Bioinformatics and biostatistics**:
    - Expertise in data analysis, integration and modelling;
    - Original data mining techniques;
    - Statistical methodologies for data interpretation.
4. **Biomarker discovery**:
    - Expertise in identifying and validating biomarkers;
    - Expertise in designing, monitoring and diagnostics assay.

Assets:

1. **Large patient cohorts**:
    - Access to cohorts, databases, and patients;
    - Access to samples, databases, and cohorts available from relevant public-private European partnership platforms in neurodegenerative and cardiometabolic diseases.
2. **Enhanced Consortium Capabilities**:
    - Improved understanding and addressing of neurodegenerative and cardiometabolic/cardiovascular diseases;
    - Access to digital twins for understanding how infections could increase risk for NCDs post infection.

At the second stage, the consortium selected at the first stage and the predefined industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not 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 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 Canda are not eligible to receive funding.

References

[1] Lape, Michael et al. “After the Infection: A Survey of Pathogens and Non-communicable Human Disease.” medRxiv : the preprint server for health sciences 2023.09.14.23295428. 30 Dec. 2024, doi:10.1101/2023.09.14.23295428. Preprint.

[2] Levine, Kristin S et al. “Virus exposure and neurodegenerative disease risk across national biobanks.” Neuron vol. 111.7 (2023): 1086-1093.e2. doi:10.1016/j.neuron.2022.12.029.

[3] Roivainen, M et al. “Infections, inflammation, and the risk of coronary heart disease.” Circulation vol. 101,3 (2000): 252-7. doi:10.1161/01.cir.101.3.252.

[4] Martens, Colton R, and Federica Accornero. “Viruses in the Heart: Direct and Indirect Routes to Myocarditis and Heart Failure.” Viruses vol. 13,10 1924. 24 Sep. 2021, doi:10.3390/v13101924.

[5] Zito, Francesco, et al. “Helicobacter pylori infection and the risk of myocardial infarction: Role of fibrinogen and its genetic control.” Thrombosis and Haemostasis, vol. 82, no. 07, 1999, pp. 14–18, https://doi.org/10.1055/s-0037-1614622.

[6] Lape, Michael et al. “After the Infection: A Survey of Pathogens and Non-communicable Human Disease.” medRxiv : the preprint server for health sciences 2023.09.14.23295428. 30 Dec. 2024, doi:10.1101/2023.09.14.23295428. Preprint.

[7] Levine, Kristin S et al. “Virus exposure and neurodegenerative disease risk across national biobanks.” Neuron vol. 111.7 (2023): 1086-1093.e2. doi:10.1016/j.neuron.2022.12.029.

[8] Miklossy, Judith. “Alzheimer's disease - a neurospirochetosis. Analysis of the evidence following Koch's and Hill's criteria.” Journal of neuroinflammation vol. 8 90. 4 Aug. 2011, doi:10.1186/1742-2094-8-90.

[9] Sugden, Bill. “Epstein-Barr virus: the path from association to causality for a ubiquitous human pathogen.” PLoS biology vol. 12,9 e1001939. 2 Sep. 2014, doi:10.1371/journal.pbio.1001939.

[10] Bosch, F X et al. “The causal relation between human papillomavirus and cervical cancer.” Journal of clinical pathology vol. 55,4 (2002): 244-65. doi:10.1136/jcp.55.4.244.

Topic 3: AI-Powered Signal Detection in Pharmacovigilance

Expected outcomes

Industry, regulators, researchers and other stakeholders have access to evidence-based and practical guidance, with aligned perspectives of public and private stakeholders, on the use of artificial intelligence (AI) for signal detection and other pharmacovigilance (PV) applications to ensure patient safety.

Patients and citizens will benefit from earlier and more accurate signal detection, which will lead to earlier risk communication and more effective measures to manage the risks.

More specifically the action under this topic must contribute to all of the following outcomes (which can be applied to various therapeutic areas irrespective of the size and composition of the safety database and to products under development as well as those in post-marketing setup):

- AI-powered algorithms and methods for faster and more accurate signal detection;
- a comprehensive list of data sources where AI methods could be used for improved signal detection, including a set of recommendations, along with principles to be followed to support a suitable common data model for simultaneous analyses of a wide range of different data sources (including clinical trials and post-marketing surveillance data) for the same purpose;
- AI-powered algorithms and methods for highly accurate risk prediction to help identify potential risks in the future before they escalate into significant public health issues and enable proactive measures to mitigate risks;
- recommendations, including practical considerations for implementing AI-powered signal detection and risk prediction systems in real-world scenarios, to enable effective and trusted use of AI;
- tools and templates for practical implementation of AI – power signal detection and risk predictions by the public and private stakeholders;
- training and user guides and other education materials on the implementation of the recommendations and the use of AI.

Central to the delivery of these outcomes are transparency, trustworthiness, and adherence to the ethical and legal principles of the use of patient-level data and any proprietary information.

Scope

Spontaneous reporting systems (SRSs) have been essential for signal detection in pharmacovigilance but suffer from low accuracy and delays, impacting patient safety. More recently, electronic health records (EHRs) have also been used for signal detection[141], but the performance needs to be improved [1]. A safety signal is information on a new or known adverse event that may be caused by a medicine and requires further investigation[142]. Signal detection is the identification of potential exposure-outcome relationships that warrant further consideration.

AI offers a promising solution by improving the efficiency, accuracy, and timeliness of signal detection using diverse and untapped data sources to allow for enhanced and timely benefit-risk profile evaluation. Recent regulatory developments include the FDA's January 2025 guidance on AI for decision-making (FDA Guidance AI), which provides recommendations for using AI in regulatory decision-making about drug safety and effectiveness. Additionally, the EMA's September 2024 reflection paper (EMA- Reflection paper on AI) discusses AI's role throughout the lifecycle of medicinal products, from drug discovery to post-authorisation.

Advances in digital technology and computer science, such as generative AI, machine learning, and predictive analytics, have the potential to enable faster and more accurate analysis of both traditional and emerging data sources, which will improve patient safety, provision of healthcare, and public health. There are different PV areas where AI could potentially be applied, including individual case safety report (ICSR) management, periodic reports, signal detection, and risk management. The scope of this topic focuses on the use of AI for signal detection and risk prediction. It also covers opportunities that may not be 'signal detection' per se but rather augmentations/support beyond signal detection for instance with the expanded use of data and AI-powered methods, including characterisation of cases that can provide context for interpreting an exposure-outcome relationship.

The use of AI for ICSR management and processing as well as periodic reports are out of the scope of this topic.

To fulfill this aim, the action funded under this topic should:

1. Evaluate, select, optimise and test AI algorithms using disparate data sources for signal detection. This implies:
    - carrying out a review of existing literature, including results from previous initiatives. and practical applications. This will help to understand the strengths and limitations of different approaches and identify a collection of systems, AI methods, and tools that have been tested on various data sources;
    - selecting the most effective algorithms for signal detection based on this review;
    - pilot testing the algorithms to evaluate their performance using a series of use cases against different business scenarios from different stakeholders' perspectives. Performance metrics include accuracy, reliability/repeatability, and trustworthiness. The criteria of the use case studies will be developed at an early stage of the project when promising algorithms and tools have been identified;
    - optimising AI algorithms to perform signal detection at the level of a medical concept or syndrome, with emphasis on transparency requirements, including model interpretability, data provenance, and traceability of AI decision-making processes.

[141] Signal Identification Methods in the Sentinel System

[142] Signal management | European Medicines Agency (EMA)

2. Evaluate diverse data sources to be considered within a cohesive pharmacovigilance network for the purpose of signal detection. This implies:
    - identifying data sources and reference datasets needed to pilot test the algorithms. This will include EHRs (medical records, claims, registries) as one of the main data sources in this project and other data sources such as spontaneous reporting systems (EudraVigilance, FDA Adverse Events Reporting System FAERS and WHO Vigibase), social media and genomics;
    - evaluating these data sources addressing their overall quality, how fit they are for purpose, current limitations and future opportunities, such as electronic health records, social media platforms, and others. This includes evaluating them individually or simultaneously to ensure a holistic view of drug safety, enhancing the analysis and monitoring of adverse drug reactions for a more thorough understanding of drug safety;
    - developing a set of recommendations that could be utilised for simultaneous analyses of different data sources, along with the principles to be followed to support a common data model for evaluating different data sources for the same purpose.
3. Evaluate and develop predictive models to identify risks in the future (risk prediction).
    - based on the results from signal detection, develop predictive models using different data sources that may help identify potential risks in the future before they escalate into significant public health issues. These models would use historical data and advanced analytics to forecast potential risks, potentially enabling proactive measures to mitigate risks.
4. Develop a recommendations document for implementing AI-powered signal detection and risk prediction systems in real-world scenarios
    - using the results from the pilot tests, design a recommendations document which will serve as a reference for implementing AI-powered signal detection and risk prediction systems in real-world scenarios. The recommendations will include a set of principles and practical considerations to enable effective, explainable, and trusted use of AI and will include ethical, legal, and governance considerations for the sharing and use of real-world data and AI-algorithms;
    - engage with the European Medicines Agency (EMA) to seek endorsement of the recommendations document via the “Qualification Procedure”.
5. Develop recommendations for human-in-the-loop (HITL) and human-on-the-loop (HOTL) AI in pharmacovigilance signal detection for optimal performance and oversight.
6. Develop templates and tools for practical implementation, including integration into existing PV systems of AI – power signal detection and risk prediction models by different stakeholders.
7. Develop training plans and education materials to disseminate the recommendations widely to the stakeholder community and develop a strategy for uptake.

For all these activities, applicants are expected to adhere to ethical and legal principles. For instance for trustworthy AI, human oversight and verifications will follow regulatory frameworks such as the Assessment List for Trustworthy Artificial Intelligence (ALTAI).

Applicants are expected to develop a regulatory strategy and interaction plan for evidence generation to support the regulatory qualification of the methodology as relevant and engage with regulators in a timely manner (e.g. national competent authorities, EMA Innovation Task Force, qualification advice).

Applicants are also expected to foster proactive and early involvement of regional healthcare systems and health authorities in all stages of the discussion and decision-making processes.

Expected impacts

The action under this topic is expected to achieve the following impacts:

- enhanced drug safety by improving the speed and accuracy of identifying adverse drug reactions (signal detection);
- proactive risk management by improving risk assessment and prediction, scalability in monitoring, and fostering collaboration among stakeholders;
- improved patient safety through an earlier and more effective risk management plan, risk communication, and risk mitigation;
- faster and more informed decision-making through AI-driven insights;
- increased efficiency through rapid processing of vast amounts of data at a much faster rate compared to traditional methods;
- streamlined processing by automating routine pharmacovigilance tasks, thereby reducing the manual workload for healthcare professionals, and the operational costs associated with these activities;
- support for future policies and the shaping of regulations through evidence generated on the use of AI in signal detection and pharmacovigilance to improve patient safety;
- increased consistency in approaches used by industry, academia and regulators.

The action will also support the EU political priority to boost European competitiveness and contribute to a number of European policies/initiatives, which include European policies and regulations on AI for signal detection, the Regulation on the European Health Data Space (EHDS)[143] through recommendations of data space for pharmacovigilance activities, the EU Artificial Intelligence Act[144] and the European Health Emergency Preparedness and Response Authority (HERA) through earlier risk communication and mitigation.

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

The successful integration of diverse data sources and the development of advanced AI algorithms necessitate a collaborative effort. This multi-disciplinary collaboration brings together expertise from various fields, including data science, pharmacovigilance, regulatory affairs, and clinical research. It is crucial to unite public and private sectors, along with different biopharma industries, to address these challenges effectively. The Innovative Health Initiative Joint Undertaking (IHI JU) plays a crucial role in facilitating this collaboration by providing a platform where experts from different disciplines can work together towards common goals.

Regulatory science and oversight are at the heart of pharmacovigilance and therefore the active involvement of regulators in this collaborative partnership is needed to foster shared confidence in AI tools, regardless of who is using them.

A public-private partnership is the ideal framework to bring all stakeholders, which includes patients, academics, industry, regulators to align on overarching principles to minimise risks.

[143] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847

[144] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

Large-scale projects often require significant resources and infrastructure that individual organisations might find challenging to provide on their own. By bringing together public and private sectors, the IHI setting addresses this challenge by offering the necessary support, including funding, technological infrastructure, and access to a network of experts. This support enables the successful execution of ambitious projects that have the potential to make a substantial impact on the field.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- AbbVie
- Amgen
- Astellas
- AstraZeneca
- Biogen
- Bristol Myers Squibb
- GSK
- Johnson & Johnson
- Merck KGaA
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi (Lead)
- Takeda
- UCB

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 8 906 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 11 418 645.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

- AI and machine learning specialists:
  - data scientists to develop and implement AI, machine learning, and other AI-powered models for signal detection;
  - natural language processing (NLP) experts for processing and analysing unstructured data from various sources like medical literature and social media.
- Pharmacovigilance experts:
  - pharmacologists to understand drug safety and adverse event reporting;
  - regulatory experts to ensure compliance with regulatory standards and guidelines.
- Ethics and data protection specialists
- Healthcare data analysts, real-world data/real-world evidence experts:
  - epidemiologists for analyses of trends and patterns in adverse event data and for validation of signals;
  - biostatisticians for statistical analysis and validation of signals.
- IT and data management professionals:
  - database administrators: to manage large datasets and ensure data integrity;
  - software engineers: to develop and maintain the infrastructure for AI applications.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and, where available, building on existing structures.

This may require mobilising the following expertise:

- pharmacovigilance, epidemiology, biostatistics;
- data science, AI;
- risk modelling, risk assessment and risk management;
- data privacy and protection, ethics;
- experience in engaging with patients;
- regulatory and compliance Framework Standard Operating Procedures (SOPs): expertise for AI model validation and monitoring;
- project management experience for large multi-stakeholder European public-private partnerships.

Furthermore, the applicant consortium is expected to provide the below resources:

Technological infrastructure:

- high-performance computing for processing large volumes of data;
- data storage solutions to securely store and manage data from various sources.

Access in a GDPR-compliant (General Data Protection Regulation) manner to data sources:

- electronic Health Records (EHRs): comprehensive patient data for analysis;
- spontaneous reporting systems: voluntary reports of adverse drug reactions;
- medical literature;
- other emerging data sources arising from new advancements in digital technology and computer science (such as social media, laboratory outputs, radiology data, genomics): to be used for exploratory purposes and additional insights as well as other datasources currently in use, including chemometric, biologic;
- all project members need to have access in a GDPR-compliant manner to these data sources;
- data must comply with GDPR and informed patient consent regulations.

The applicant consortium is expected to enable effective collaboration with regulatory authorities, national competent authorities, and may consider, for instance, engaging them as consortium partners, or in an advisory capacity.

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium will form the full consortium. Considering the role of the European Medicines Agency (EMA) in coordinating the European Union (EU) pharmacovigilance system and operating services and processes to support pharmacovigilance in the EU, EMA is prepared to join the applicant consortium selected at the first stage along with the pre-identified industry consortium (the full consortium). EMA’s provisions include substantial and unique data access and expertise, as well as sharing experience from ongoing activities with national competent authorities exploring AI use cases in pharmacovigilance.

The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not 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 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 Canda are not eligible to receive funding.

References

[1] Taylor LG, Kürzinger ML, Hermans R, Enshaeifar S, Dwan B, Chhikara P, Li X, Thummisetti S, Colas S, Duverne M, Juhaeri J. Considerations for practical use of tree-based scan statistics for signal detection using electronic healthcare data: a case study with insulin glargine. Expert Opin Drug Saf. 2024 Aug 23:1-11. doi: 10.1080/14740338.2024.2393274. Epub ahead of print. PMID: 39162331.

Topic 4: Leveraging Europe's expertise to accelerate cell therapy for type 1 diabetes

Expected outcomes

The action under this topic must contribute to all of the following outcomes:

1) Researchers, industry, and healthcare providers will benefit from a standardised framework for impurity thresholds and manufacturing best practices, ensuring regulatory alignment, facilitating clinical translation, and supporting the scalable production of safe and effective beta-cell therapies for type 1 diabetes (T1D).
2) Regulatory authorities, academic researchers, healthcare professionals (HCP) and industry partners will have access to validated immune-modulating strategies that enhance graft survival and promote immune tolerance, alongside advanced models and biomarkers for assessing engraftment success, metabolic function, and immune responses.
3) Pharmaceutical companies, regulatory bodies, and payers will benefit from established, scalable and cost-effective manufacturing processes for beta-cell therapy, ensuring the production of high-quality, reproducible products that meet regulatory standards and support market approval and reimbursement.
4) Academic researchers, regulatory bodies, and healthcare providers will have improved preclinical models and clearly defined clinical criteria for different patient demographics, ensuring that beta-cell therapies are accessible, safe, and effective across diverse populations.
5) Healthcare providers, industry, and information and communication technology (ICT) companies will utilise AI-driven predictive models and real-time monitoring technologies to enhance the assessment of transplant success, immune responses, and metabolic function, enabling personalised treatment plans, optimised immunosuppression regimens, and reduced therapy failure.
6) Healthcare providers and regulatory bodies will adopt patient-centred clinical endpoints as key indicators of treatment success, accurately reflecting quality of life and disease burden in T1D.
7) Health technology assessment (HTA) bodies, people living with diabetes, payers, and policymakers will benefit from cost-effectiveness assessments, pilot reimbursement programmes, and policy recommendations that enable the establishment of a reimbursement framework, thus paving the way for the adoption of beta-cell therapies for T1D.
8) Healthcare providers, researchers, and policymakers will benefit from training programmes for endocrinologists, diabetologists, and transplant surgeons, enhancing expertise in cell therapy, immunosuppression, and post-transplant care. Collaboration with professional societies will drive the development of clinical pathways, ensuring the generation of appropriate evidence for integrating cell-based therapies into standard diabetes care.
9) Academia, industry, regulatory agencies, patient organisations, people living with diabetes and policymakers will collaborate through fully operational European innovation hubs, facilitating knowledge sharing, driving research advancements, and harmonising regulatory practices to accelerate the adoption and implementation of beta-cell therapies across Europe.
10) People living with diabetes will benefit from all these outcomes, as they will lead to improved treatment options, enhanced long-term health outcomes, better access to innovative therapies, and an overall improved quality of life.

It is expected that certain existing assets will be used as background in this action. Such background assets may include, but are not limited to, cell manufacturing technologies, gene editing platforms, scaffold materials, encapsulation systems, and delivery and release technologies, among others. The exact nature of the background to be brought into the project will depend on the proposals presented by the public consortia. Therefore, beneficiaries intending to participate in this action need to be comfortable with the principle that ownership of specific deliverables / project results which would be considered direct improvements to a beneficiary's background asset, will need to be transferred back to the beneficiary who contributed the background asset to the project. Provision for and conditions relating to such transfers should be specified in the project's consortium agreement.

Scope

Challenges and Background

T1D is an autoimmune disease that destroys insulin-producing pancreatic beta-cells, leading to lifelong insulin dependence. Despite advances in technology, achieving stable blood glucose levels remains challenging, which increases the risk of severe complications, and this in turn impacts negatively on daily life, work productivity, and mental health, and contributes to stress, anxiety, and depression.

Beta-cell replacement therapy offers a promising path towards a functional cure, but critical challenges must be addressed, including the need for renewable cell sources, optimised islet preparations, standardised manufacturing protocols, robust monitoring tools, sustainable reimbursement models, and trained healthcare professionals to manage complex treatments. These challenges align with key priorities from the Draghi Report[145], emphasising harmonised regulatory pathways, early engagement with HTA bodies, standardised manufacturing processes, and patient-centred clinical endpoints. Without urgent action, the full potential of beta-cell therapies will remain unrealised.

Key Objectives:

1) Establishing standardised criteria and analytical methods:

This objective aims at developing standardised criteria and analytical methodologies to detect, quantify, and characterise unintended bystander cells and impurities in stem cell-derived or beta-cell therapies for T1D. This work is intended to support the field at large by generating reference materials, optimising detection technologies, and defining regulatory-compliant thresholds that can inform future research and development—not to advance a specific product. The focus is on creating translatable, broadly applicable tools and standards that ensure safety, consistency, and quality. Engagement with the European Medicines Agency (EMA) is encouraged to facilitate the regulatory relevance and potential adoption of these methodologies in preclinical and clinical research settings.

2) Enhancing graft survival and immune tolerance:

This objective aims at developing immune-modulating strategies that support the long-term survival of beta-cell grafts and promote immune tolerance. This work is intended to generate insights, tools, and models that advance scientific understanding and inform future therapeutic approaches. Activities will include retrospective analyses of human cadaveric islet transplantation cohorts from different European countries and healthcare systems to support biomarker discovery and predictive modelling. Key biomarkers – such as continuous glucose monitoring (CGM) metrics, C-peptide levels, HbA1c, inflammatory cytokines, immune cell subsets, beta-cell-specific autoantibodies, and gene expression profiles – will be explored to identify indicators of graft survival, immune tolerance, and beta-cell function.

[145] Mario Draghi, 'The Future of European Competitiveness', European Commission, September 9, 2024

In addition, a prospective study may be designed to identify novel biomarkers related to glycaemic variability, immune regulation, insulin independence, beta-cell regeneration, and inflammatory pathways. These efforts are aimed at supporting the development of robust monitoring tools and decision-making frameworks, not at advancing a therapeutic candidate toward clinical use.

3) Advancing manufacturing and quality control:

The objective is to establish robust cryopreservation techniques that preserve the viability and functionality of beta-cells post-thaw, with an emphasis on the identification and validation of biomarkers to guide and assess these processes. Building on this, the applicants should aim to develop and optimise scalable, cost-effective manufacturing methodologies and quality control frameworks that support the production of consistent, high-quality beta-cell therapy materials in a research and innovation context. The goal is to generate foundational knowledge, technical standards, and reference systems, not to develop specific commercial products. Additionally, the consortium should work toward establishing standardised criteria for the production and quality control of excipient raw materials used in beta-cell therapy delivery systems, to ensure their stability, safety, and suitability for future clinical applications.

4) Streamlining preclinical and clinical development:

This objective aims at enhancing preclinical models for allogeneic cell therapies, ensuring standardised approaches and consistent methodologies in transplantation science and surgery. The focus is on harmonised regulatory approval, defining patient demographics for broader accessibility, and tailoring treatment requirements for personalised care. Establishing definitions for insulin independence, investigating and working toward the regulatory acceptance of clinically meaningful endpoints, such as ‘Time in Range (TIR)’ and ‘Time in Tight Range (TiTR)’, and optimising clinical trial design for allogeneic therapies are essential components of the future project.

5) Implementing advanced monitoring and artificial intelligence (AI)-driven predictive tools:

Leveraging real-time monitoring technologies like continuous glucose monitoring (CGM) and biosensors to assess transplant success and metabolic function, this objective aims to integrate advanced techniques from various fields, including oncology. Specifically, immune monitoring strategies used in oncology, such as immune checkpoint inhibitors and tumour biomarker profiling, will be explored to enhance the understanding of immune responses in beta-cell transplantation. AI-powered predictive models will personalise treatment plans and optimise immunosuppression regimens.
Additionally, non-invasive imaging techniques, such as magnetic resonance imaging (MRI) and positron emission tomography (PET), will track graft survival and immune responses, ensuring better monitoring and management of beta-cell therapies. The action should also reinforce transparency requirements, including model interoperability, data provenance, and traceability of AI decision-making processes.

6) Defining clinically meaningful and patient-centred endpoints using real-world evidence:

This objective aims at leveraging real-world data to define clinically meaningful endpoints that capture quality of life and disease burden in T1D. This includes identifying surrogate endpoints to enable clinical trials that demonstrate long-term benefits without requiring extended study durations. Additionally, generating data on the advantages of achieving normoglycemia in individuals already within target glucose ranges will help refine treatment goals and support regulatory decision-making. A small pilot study must be conducted to test these endpoints and gather initial data on their feasibility and impact.

7) Exploring reimbursement models for beta-cell therapies:

This objective aims at developing initial cost-effectiveness models that highlight the potential financial and healthcare benefits of beta-cell therapies, focusing on key aspects like reduced complications and improved quality of life. Early-stage collaboration with health technology assessment (HTA) bodies, payers, and policymakers must be sought to help build a foundation for understanding the value of these therapies, laying the groundwork for future integration into healthcare systems across Europe.

8) Integration of cell therapy into diabetes care and collaborative networks:

Beta-cell therapies should be integrated into standard diabetes care through specialised training for healthcare providers and the creation of a network of multidisciplinary centres across Europe. Clinical guidelines should be put in place to ensure a smooth transition from current treatments. Additionally, a network of European innovation hubs must be established to foster collaboration, knowledge exchange, and harmonised regulatory approaches, accelerating the development and clinical application of beta-cell therapies. It will also be crucial to collaborate with professional societies to define a clear clinical pathway, ensuring alignment with best practices and optimising patient outcomes across the region.

Additional key considerations:

Applicants are expected to consider a sustainability plan for the maintenance, update, and validation of the project's results beyond the project's duration to ensure long-term impact and continual improvements.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g. national competent authorities, EMA Innovation Task Force, qualification advice).

Applicants are expected to ensure transparent and open dissemination of outcomes, including models and tools, to enable their integration and reuse throughout the wider ecosystem.

Applicants should give adequate consideration in the ethical standards and data privacy frameworks applicable to the use of personal health data and biobanks.

The action funded under this topic is also expected to explore synergies with complementary initiatives to advance research and innovation in Europe, such as NHPIG[146], which is developing the first T1D autoimmune pig model, the Vanguard-project[147], the Islet-project[148], JOIN4ATMP[149], and relevant Horizon 2020/Europe projects. Furthermore, the project should explore synergies with the European Pancreas and Islet Transplantation Registry (EPITR)[150], an initiative led by the European Pancreas and Islet Transplant Association (EPITA) to establish a pan-European registry collecting data on individuals who have received pancreas or islet transplants. By leveraging their insights and networks, the project aims to strengthen the impact of beta-cell therapy development, ensuring that these collaborations contribute to a more comprehensive and effective approach to tackling T1D through cell-based therapies.

[146] https://www.nhpig.eu/

[147] https://vanguard-project.eu/

[148] https://isletproject.eu/

[149] https://www.join4atmp.eu/

[150] https://esot.org/epita/epita-epitr/

Expected impacts

The action under this topic is expected to achieve the following impacts:

- to support the widespread adoption of beta-cell therapy, ensuring long-term efficacy, accessibility, and integration into healthcare systems;
- to accelerate the development of stem cell-based therapies through advancements in manufacturing, preclinical models, regulatory alignment, and predictive tools;
- to strengthen Europe's position as a leader in beta-cell therapy by fostering innovation hubs and clinical networks;
- scientific and regulatory progress will advance regenerative medicine for other metabolic and autoimmune disorders beyond T1D;
- patients, healthcare providers, regulators, policymakers, and industry stakeholders will all benefit from improved treatments, clearer guidelines, and increased investment;
- boosting European industrial competitiveness by driving innovation in cell-based therapies, fostering cross-sector collaboration, and enhancing Europe's global leadership in regenerative medicine.

These impacts are expected to advance IHI JU's objectives of improving healthcare quality, accessibility, and sustainability while contributing to European health policies and initiatives.

The action under this topic is expected to contribute to the following EU policies/initiatives:

- The European Health Union: addressing the chronic disease (diabetes) burden; accelerating groundbreaking therapies while drawing on the potential of digital and AI solutions; contributing to modern and innovative health policies (by working on models, tools and pathways enabling the adoption of innovative/breakthrough therapies by European healthcare systems);
- The Pharmaceutical Strategy for Europe: Advancing innovative cell therapies and improving patient access to cutting-edge treatments;
- The EU political priority to boost European competitiveness: establishing Europe as a hub for cutting-edge scientific and research innovation; contributing to the announced EU Biotech Act as a forward-looking framework to leverage the potential that biotechnologies can bring to our economy;
- UN Sustainable Development Goals (SDG 3: Good Health & Well-being): reducing the impact of non-communicable diseases (NCDs) like type 1 diabetes;
- The action will also contribute to a number of European policies/initiatives, which include the European Commission's European Health Data Space Regulation (EHDS)[151] and the EU Artificial Intelligence Act[152].

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

[152] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

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

The outcomes outlined can only be achieved through a cross-sectoral, multidisciplinary public-private partnership (PPP) like the IHI JU action, given the complexity of the challenges involved. The development of innovative immune-modulating strategies, scalable manufacturing processes, and advanced preclinical models requires collaboration across multiple sectors, including pharmaceuticals, academia, medical devices, health ICT, clinical societies and patient organisations. Europe's strong academic expertise in islet transplantation is critical for advancing beta-cell therapies, and academic institutions can provide the foundational research necessary to drive progress in this field. Collaboration with pharmaceutical companies, healthcare practitioners, and regulators ensures that beta-cell therapies are scientifically sound, clinically effective, and aligned with patient needs.

In addition to academic and industry expertise, patient organisations, payers, and HTA bodies play a pivotal role in making these therapies accessible and sustainable. Patient organisations provide valuable insights into real-world patient needs, helping shape therapies that focus on improving quality of life. Payers and HTA bodies ensure that beta-cell therapies are financially viable and can be integrated into healthcare systems across Europe. Their involvement helps secure reimbursement and fosters the widespread adoption of these therapies.

This public-private collaboration facilitates the efficient use of resources, combining scientific research, innovation, clinical expertise, regulatory guidance, and patient input. It enables the creation of therapies that are scalable, cost-effective, and accessible to diverse patient populations. By leveraging Europe's collective expertise, this model accelerates the development and integration of beta-cell therapies, making them a sustainable and viable solution for patients with type 1 diabetes across Europe.

Pre-identified industry consortium and contributing partners

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of IHI JU private members'):

- Eli Lilly
- Novo Nordisk

In addition, the following contributing partners will participate in the IHI JU action:

- Breakthrough T1D (Lead)
- Fundación DiabetesCERO
- Fondazione Italiana Diabete

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 8 825 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 2 300 000.
- The indicative in-kind and financial contribution from IHI JU contributing partners is EUR 7 340 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The allocation of the EUR 6 550 000 financial contribution (FC) from IHI JU contributing partner(s) will be decided by the full consortium at the second stage when preparing the full proposal.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The pre-identified industry consortium and contributing partners expect to contribute to the IHI JU project by providing the following expertise and assets:

- provision of training materials for healthcare professionals on cell therapy;
- regulatory, R&D, and clinical expertise;
- specialised knowledge in clinical protocol design and the development and regulatory alignment of clinically meaningful endpoints;
- expertise in defining clinically meaningful endpoints;
- engagement with payers, policymakers, and regulatory agencies to support value-based healthcare adoption;
- dissemination and communication efforts, including the open sharing of all relevant learnings, tools, and materials to maximise their accessibility and uptake across the healthcare ecosystem.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partners.

This may require mobilising the following expertise and/or resources:

1) **Scientific expertise**
    - *Beta-cell biology & immune modulation*: Deep knowledge of immune tolerance, beta-cell biology, and strategies to prevent graft rejection and enhance long-term cell survival;
    - *Stem cell technology*: Proficiency in generating and assessing stem cell-derived beta cells in preclinical and clinical settings;
    - *Gene editing and advanced therapies*: Expertise in gene-editing technologies (e.g., CRISPR) to improve cell compatibility and function, alongside immune-modulating therapies.
2) **Manufacturing and quality control expertise**
    - *Cell therapy production*: Experience in scalable cell therapy manufacturing, cryopreservation, and adherence to Good Manufacturing Practices (GMP);
    - *Process development*: Capability to design cost-effective, reproducible manufacturing systems with batch consistency.
3) **Regulatory expertise**
    - *Regulatory affairs*: Strong background in regulatory engagement with bodies like the EMA to facilitate beta-cell therapy approval;
    - *Clinical trial design*: Expertise in preclinical and clinical trial development, particularly for different age groups.
4) **Preclinical and clinical development resources**
    - *Preclinical models*: Access to predictive models that accurately simulate human T1D for assessing safety and efficacy;
    - *Clinical trial networks*: Established networks to support the transition from research to human trials, including patient recruitment;
    - *Retrospective and prospective data analyses*: The applicants are expected to bring data from both retrospective and prospective analyses, including clinical, biomarker, and health outcomes data from cadaveric islet transplantation cohorts. This data should include samples from islet transplants that have successfully provided full insulin independence, as well as those that have not, to support the development of models and biomarkers to assess engraftment success, metabolic function, and immune responses;
    - *Access to islet transplantation datasets*: Availability of and experience working with comprehensive datasets from islet transplantation registries, including long-term clinical outcomes, graft function, metabolic control, and immune response data. These datasets will be instrumental in developing predictive models and biomarkers for therapy success.

5) **Advanced monitoring technologies**

- *Monitoring systems development*: Ability to create real-time tracking tools such as continuous glucose monitoring (CGM) and biosensors;
- *AI and machine Learning*: Expertise in predictive models for personalised treatment and immunosuppression optimisation;
- *Imaging technologies*: Access to non-invasive imaging (e.g., MRI, PET) for monitoring graft health and immune responses.

6) **Patient-centred research**

- *Patient engagement*: Integration of patient perspectives and real-world data to define meaningful clinical endpoints;
- *Post-transplant care*: Development of protocols to minimise immunosuppression side effects and ensure long-term therapy sustainability.

7) **Economic and policy expertise**

- *Health economics*: Ability to assess cost-effectiveness and long-term viability of beta-cell therapies;
- *Health technology assessment (HTA)*: Experience engaging with HTA bodies to secure reimbursement pathways.

8) **Multidisciplinary collaboration**

- *Healthcare training*: Development of training programmes for clinicians in cell therapy management;
- *Collaborative networks*: Existing partnerships with academic institutions, industry, regulators, and patient organisations.

9) **Engagement with regional healthcare systems and health authorities**

- Early and active involvement of regional healthcare systems and health authorities in discussions to ensure alignment with local healthcare priorities, regulatory requirements, and reimbursement pathways. This will facilitate smoother integration of innovations into healthcare practice and enhance the broader societal impact of the project.

10) **Infrastructure for knowledge sharing**

- *Knowledge exchange platforms*: Capacity to organise workshops, webinars, and conferences for knowledge dissemination;
- *European networks*: Ability to participate in or establish innovation hubs dedicated to beta-cell therapy.

11) **Technological capabilities**

- *Advanced technologies*: Access to gene editing platforms, real-time monitoring systems, and imaging tools;
- *Data sharing infrastructure*: Capability for secure, multi-institutional data collaboration.

12) **Patient advocacy and public engagement**

- *Engagement with patient groups*: Active collaboration with advocacy organisations to improve access, awareness, and policy influence.

These combined resources and expertise are essential for applicants to effectively contribute to achieving the objectives of advancing beta-cell therapies for T1D, ensuring successful clinical translation and adoption across Europe. Applicants must also document that these resources are shareable with the full public-private partnership from the beginning of the action to ensure broad impact across the European research and healthcare landscape.

At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not 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 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 Canda are not eligible to receive funding.

Topic 5: Establishing ortho and cardiology ambulatory surgical centres in Europe

Expected outcomes

With advances in clinical and surgical techniques, medical technology, pain management as well as pre- and post-surgical care, more procedures that have been traditionally performed in hospital settings can now be performed in facilities outside hospitals with no overnight stays required, easing the demand on overstretched hospitals and reducing hospital acquired infections. These facilities are referred to as ambulatory surgical centres (ASCs).

The actions under this topic contribute to all the following outcomes:

1. Consensus-based understanding on the hurdles, needs and requirements to establish ASCs within a European healthcare setting with a regional/national expert committee driving the community involved and acting as reference opinion leaders;

2. Comprehensive framework and 'know how' for establishing ASC facilities with details on infrastructure, medical technology, protocols and healthcare resources required for establishing new facilities;

3. Training schemes and programmes including care pathways and enhanced recovery protocols for all health care providers (HCPs) involved in ASCs in orthopaedics and cardiology, operating safe scalable models that achieve high quality results;

4. Creation of a clinical database and generation of economical evidence forming a basis towards European acceptance, standardisation and funding allowing establishment of ASC services as an integrated part of healthcare services provided;

5. The availability of an interoperable IT technology solution required to integrate clinical data from multiple stages of the patient journey and the related digital health solutions for patient preparation, post-discharge management and home monitoring.

Target group for the outcomes are:

- hospital managers, healthcare system providers, medical technologies and digital companies seeking solutions in European, national and regional healthcare services, to address capacity and efficiency hurdles in hospitals in the fields of orthopaedics and cardiology;
- HCPs establishing ASCs in orthopaedics and cardiology to further provide and advance healthcare services and efficiency;
- patient groups and carer associations working towards patient access to more convenient locations, shorter waiting times and easier scheduling (relative to hospital inpatient and outpatient procedures). This will improve patient experience, satisfaction and outcomes from pre-procedure to recovery at home;
- HCPs and researchers working on incorporating advanced medical technology in and out of hospital settings for improved patient outcomes and healthcare efficiency;
- reimbursement bodies as well as HTA bodies providing guidelines and innovative payment schemes.

Scope

The EU's ageing population and a rising burden of diseases and disorders, in particular noncommunicable diseases (such as cardiometabolic diseases, cancers, neurodegenerative or musculoskeletal disorders), have resulted in increasing health care costs and limited procedural capacity in operating rooms and cath labs (catheterisation laboratory). Lack of specialists is also an issue. This delays patient access to health care and increases the need for alternative and more cost-effective forms of care [5]. The shift of inpatient surgeries and treatments to ambulatory surgical centres (ASCs) could potentially provide a solution to the hospital capacity problem as well as reducing hospital acquired complications and providing improved access to healthcare services for patients in rural areas. ASCs are healthcare facilities focused on providing same-day surgical care, including diagnostic and preventative procedures for patients who do not require overnight stays. It is believed that ASCs can transform the outpatient experience for patients by providing them with a more convenient alternative to hospital-based outpatient procedures. ASCs can be operated by private or public healthcare services.

Numerous factors influence whether surgical procedures can be carried out within ambulatory surgical centres. The key drivers are changes and further development in clinical practice and medical technology. The action funded under this topic will be focused on ASCs specialised in orthopaedics for knee and hip joint replacement surgery as well as ASCs specialised in cardiology for cardiac ablation procedures and elective rhythmology. All of these procedures are elective and will increase in the next years due to the ageing population, improved diagnostics and extension of medical guidelines. Based on patient selection, these procedures have been proven suitable for ambulatory settings. This is reinforced by the downward trend in length of stay in hospitals for these procedures in recent years. This also reflects developments in medical technology in these procedures over the last years, that have led to more precise, faster, easier, gentler and more patient-specific interventions. Shifting those procedures from hospitals into ASCs can help to relieve inpatient capacities, enabling faster patient access to those surgeries and in the end reducing overall health care costs. It is important to stress that treatment in ASCs requires good patient selection prior to the surgery based on medical classifications – like the American Society of Anaesthesiologists' risk classification for estimating the perioperative risk – and social factors, such as the individual domestic situation of the patient, to make the intervention in ASC successful. Severe and complicated cases will still have to be treated in hospitals.

ASCs offer a lot of benefits to the health care system and can address some problems associated with inpatient treatments in hospitals. Studies show that outpatient procedures are safe and can achieve similar or superior functional outcomes compared to inpatient procedures and, for example, the early mobilisation facilitated by outpatient pathway in hip and knee replacement surgeries contributes to faster recovery timelines [1] [2].

Due to the fact that the costly infrastructure of the hospital is not needed, and patients go home the same day after an outpatient procedure, the shift of procedures into the outpatient setting results in significant cost savings (an outpatient total shoulder arthroplasty (TSA) results in a 40% decrease in charges [3] and unicompartmental knee replacement (UKR) saving up to roughly EUR 18 000 [USD 20 500] per patient [4]). Enhanced healthcare resource utilisation and reduced patient waiting times are additional benefits. Additionally, there are also some patient-related benefits of outpatient procedures. It is proven that patients benefit from recovering in familiar home setting, with various technologies to help monitor their recovery and provide them with access to HCPs. This reduces anxiety [1] and leads to earlier mobility, thus a faster recovery time and a quicker return to daily activities. Overall, this enhances patient satisfaction [1] [2]. On top of that, ASCs decrease the risk of nosocomial infections with the reduced exposure to hospitals environment.

Effective implementation of ASCs faces multiple hurdles including:

1. reimbursement models: lack of reimbursement and funding procedures, limiting financial incentives to move procedures from in-hospital to ASCs;
2. stakeholder acceptance: non-clinical decision-makers are not fully comfortable with ASC as a part of the solution to the capacity and demand problem;
3. evidence: lack/limitation of safety and quality data measuring performance and outcomes;
4. human resource readiness: HCPs are not trained to perform in ASCs and run them efficiently;
5. digital infrastructure: data privacy hurdles, interoperability, digital exclusions;
6. protocols: lack of standardised care models across different therapies. Limited implementation of patient-centred evidence-based approaches for quicker and improved recoveries – enhanced recovery programmes;
7. patient readiness: patient expectations and previous experiences making them unwilling to accept procedures in ASCs;
8. home recovery and care system: lack of integration of ASCs with the broader healthcare systems.

Applicants should envisage the following activities as part of the action funded under this topic:

- Establish a multistakeholder advisory board leading and advocating for change in national and regional healthcare services. The advisory board will quantify the requirements for establishing ASCs in orthopaedics and cardiology including different financial and resource models, training modules, reimbursement pathways, digital health solutions for patient preparation and post-discharge management, registry databases as well as clinical and economical end points required for studies and reimbursement pathways;
- Demonstrate the safety of targeted procedures for patients performed in ASC facilities through the conduct of two medical cohort studies: one in orthopaedic joint replacement and another in cardiology cardiac ablation. These studies will assess the risks, patient medical eligibility complications, and patient outcomes of ASCs in comparison to hospital-based procedures;
- Generate and share protocols and best practices across multiple centres in same country and beyond borders, including a strategy for contextual adaptation for ASC scalability across Europe;
- Create a network of selected ASCs, with successful ASCs leading in sharing best practice, protocols, trainings, and efficiency models;
- Collect real world evidence (RWE) to demonstrate and model the cost-effectiveness of ASCs vs hospital-based procedures. The study should be multicentre and will establish a registry database answering proposed research questions;
- Develop a shared framework for clinical data interoperability, and combine an interoperable IT technology solution to integrate clinical data collected at multiple stages of the patient journey with the related digital health solutions that are used for patient preparation, post-discharge management and home monitoring. Adequate consideration should be given to relevant ethical and privacy aspects.
- Provide a sustainability strategy for the maintenance, update, and validation of the project's results beyond the project duration.

Applicants should consider learnings and synergies with relevant initiatives at national and European level to maximise the potential impact of the future project.

Expected impacts

The action under this topic is expected to achieve the following impacts:

1. Contribute to IHI JU SRIA objectives, driving cross-sectoral health innovation for a competitive European health industry;
2. Infrastructure funding initiatives establishing ASCs in orthopaedics and cardiology;
3. New long term healthcare strategy, planning and funding in HCP recruitment and training as well as digital solutions and medical technology for efficient ASC services;
4. Implementing new payment systems (coding and reimbursement) allowing for patient referral to ASC based on medical and clinical decisions and provider capacity, rather than on payment system;
5. Establishment of a sustainable network of ASCs followed by the creation of national and regional ASCs associations;
6. Regulation and accreditation of ASC facilities;
7. Comprehensive and interoperable digital solutions supporting people-centred care, disclosing entire patient treatment pathways and experiences including points of access for patients;
8. Treatment database/registry as a source of evidence enabling research, decision making, further development and improvement of ASCs.

The action will also support the EU political priority to boost European competitiveness and contribute to a number of European policies/initiatives, which include the European Commission's European Health Data Space Regulation (EHDS)[153] and the EU Artificial Intelligence Act[154].

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

Changing trajectory and practice from in-hospital procedures to ambulatory surgical centres will depend on the involvement of a range of stakeholders: hospital management, healthcare providers, technology developers, academics, health insurance companies, reimbursement agencies, patient organisations as well as medical technology companies. IHI facilitates this collaboration by fostering cross-sector cooperation which is unique and a pivotal requirement for initiatives of complex scale.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Medacta
- Medtronic
- Johnson & Johnson
- Smith & Nephew
- Stryker
- Zimmer Biomet (Lead)

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

[154] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 12 351 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 12 351 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

- Facilitate logistics and communication for advisory board establishment and ASC network;
- Access to the latest medical technologies and equipment, ensuring that ASCs can offer high-quality care;
- Assistance with training medical and administrative staff, ensuring that ASCs have skilled personnel to deliver excellent patient care;
- Facilitate partnerships with other healthcare providers, organisations and established ASCs, which can conduct training, share best practices in enhancing service offerings and patient care
- Research and regulatory expertise and guidance in conducting studies, setting databases and real world evidence generation;
- Health economics modelling;
- Digital solutions for tracking patient pathways to streamline and enhance patient experience;
- Project management.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

The consortium must demonstrate the ability to jointly deliver innovation, evidence generation, and implementation across various healthcare systems in Europe.

This may require mobilising the following expertise and/or resources:

1) Hospitals and healthcare providers - required expertise:
    - Experience in performing orthopaedic and cardiac procedures, including joint replacement and ablation;
    - Involvement in outpatient care models or previous piloting of ASCs;
    - Capacity to lead and contribute to clinical studies comparing inpatient and ASC-based interventions;
    - Insight into patient pathways, clinical protocols, and integration with home recovery services.
2) Academia and research and technology institutions - required expertise:
    - Design and conduct of health services research and clinical studies, including RWE (real world evidence) and health economics;
    - Capability to lead evidence generation on safety, efficacy, and cost-effectiveness of ASCs;
    - Methodological support for patient selection criteria, Patient Reported Outcomes Measures (PROMs) collection, and statistical evaluation.
3) Medical technology companies - required expertise:
    - Developers and providers of surgical devices, diagnostics, and digital tools used in orthopaedics and cardiology;
    - Capacity to adapt or develop technology suited for ASC environments;
    - Expertise in digital health solutions including remote monitoring, electronic health records integration, and telemedicine platforms.
4) Digital health and IT Providers - required expertise:
    - Deployment of interoperable health information systems across care settings;
    - Data security and privacy compliance (e.g. General Data Protection Regulation, 2016 ‘GDPR’) and digital infrastructure support;
    - Tools for patient management, telehealth, and care navigation;
    - Development of ASC registries and clinical databases.
5) Patient organisations - required expertise:
    - Insight into patient expectations, preferences, and concerns regarding surgical care in ASCs;
    - Contribution to communication strategies and patient-centred design of care pathways;
    - Support in recruitment for surveys and qualitative research.
6) Payers and reimbursement bodies - required expertise:
    - Understanding of current reimbursement frameworks and their gaps;
    - Co-development of innovative payment models adapted to ASCs;
    - Guidance on defining clinical and economic endpoints relevant for reimbursement acceptance.

7) Policy and regulatory experts - required expertise:
   - Knowledge of national healthcare policies and regulations affecting outpatient and ASC settings;
   - Development of recommendations for ASC recognition, quality assurance, and standardisation;.
   - Engagement with health technology assessment bodies and regulators to support project sustainability.
8. Professional medical societies and networks - required expertise:
   - Support in standardisation of care protocols and guidelines for ASC procedures;
   - Dissemination of training materials and best practices;
   - Endorsement and outreach to accelerate uptake across member organisations.

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not 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 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 Canda are not eligible to receive funding.

References

[1] Daher, M., Cobvarrubias, O., Boufadel, P., Fares, M. Y., Goltz, D. E., Khan, A. Z., Hornef, J. G., & Abboud, J. A. (2024). Outpatient versus inpatient total shoulder arthroplasty: A meta-analysis of clinical outcomes and adverse events. Journal of Shoulder Surgery. Int Orthop. 2025 Jan;49(1):151-165. doi: 10.1007/s00264-024-06364-5. Epub 2024 Nov 5. PMID: 39499293

[2] Bemelmans, Y. F. L., Keulen, M. H. F., Heymans, M., van Haaren, E. H., Boonen, B., & Schotanus, M. G. M. (2021). Safety and efficacy of outpatient hip and knee arthroplasty: a systematic review with meta-analysis. Arch Orthop Trauma Surg. 2022 Aug;142(8):1775-1791. doi: 10.1007/s00402-021-03811-5. Epub 2021 Feb 15. PMID: 33587170.

[3] Ahmed, A. F., Hantouly, A., Toubasi, A., Alzobi, O., Mahmoud, S., Qaimkhani, S., Ahmed, G.O., & Al Ateeq Al Dosari, M. (2021). The safety of outpatient total shoulder arthroplasty: A systematic review and meta-analysis. Int Orthop. 2021 Mar;45(3):697-710. doi: 10.1007/s00264-021-04940-7. Epub 2021 Jan 23. PMID: 33486581; PMCID: PMC7892728.

[4] French JMR, Woods A, Sayers A, Deere K, Whitehouse MR. Day-case knee and hip replacement. Bone Joint J. 2024 Dec 1;106-B(12):1385-1392. doi: 10.1302/0301-620X.106B12.BJJ-2024-0021.R1. PMID: 39615519.

[5] Messerle R, Hoogestraat F, Wild EM. Which factors influence the decision of hospitals to provide procedures on an outpatient basis? –Mixed-methods evidence from Germany, Health Policy, Volume 150, 2024, 105193

HORIZON-JU-IHI-2025-11-01 **Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction**	The maximum financial contribution from IHI JU is up to EUR 20 202 000. The indicative in-kind contribution from industry partners is EUR 13 987 940. The indicative in-kind contribution from IHI JU contributing partners is EUR 6 642 533. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-11-02 **Understanding how infections foster and induce non-communicable diseases**	The maximum financial contribution from IHI JU is up to EUR 7 127 000. The indicative in-kind contribution from industry partners is EUR 8 167 000. The indicative in-kind contribution and financial from the philanthropic organisation is EUR 1 020 000. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-11-03 **AI-Powered Signal Detection in Pharmacovigilance**	The maximum financial contribution from IHI JU is up to EUR 8 906 000. The indicative in-kind and financial contribution from industry partners is EUR 11 418 645. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-11-04 **Leveraging Europe's Expertise to accelerate Cell Therapy for Type 1 Diabetes**	The maximum financial contribution from IHI JU is up to EUR 8 825 000. The indicative in-kind and financial contribution from industry partners is EUR 2 300 000. The indicative in-kind and financial contribution from IHI JU contributing partners is EUR 7 340 000. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-11-05 **Establishing Ortho and Cardiology Ambulatory Surgical Centres in Europe**	The maximum financial contribution from IHI JU is up to EUR 12 351 000. The indicative in-kind and financial contribution from industry partners is EUR 12 351 000. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.

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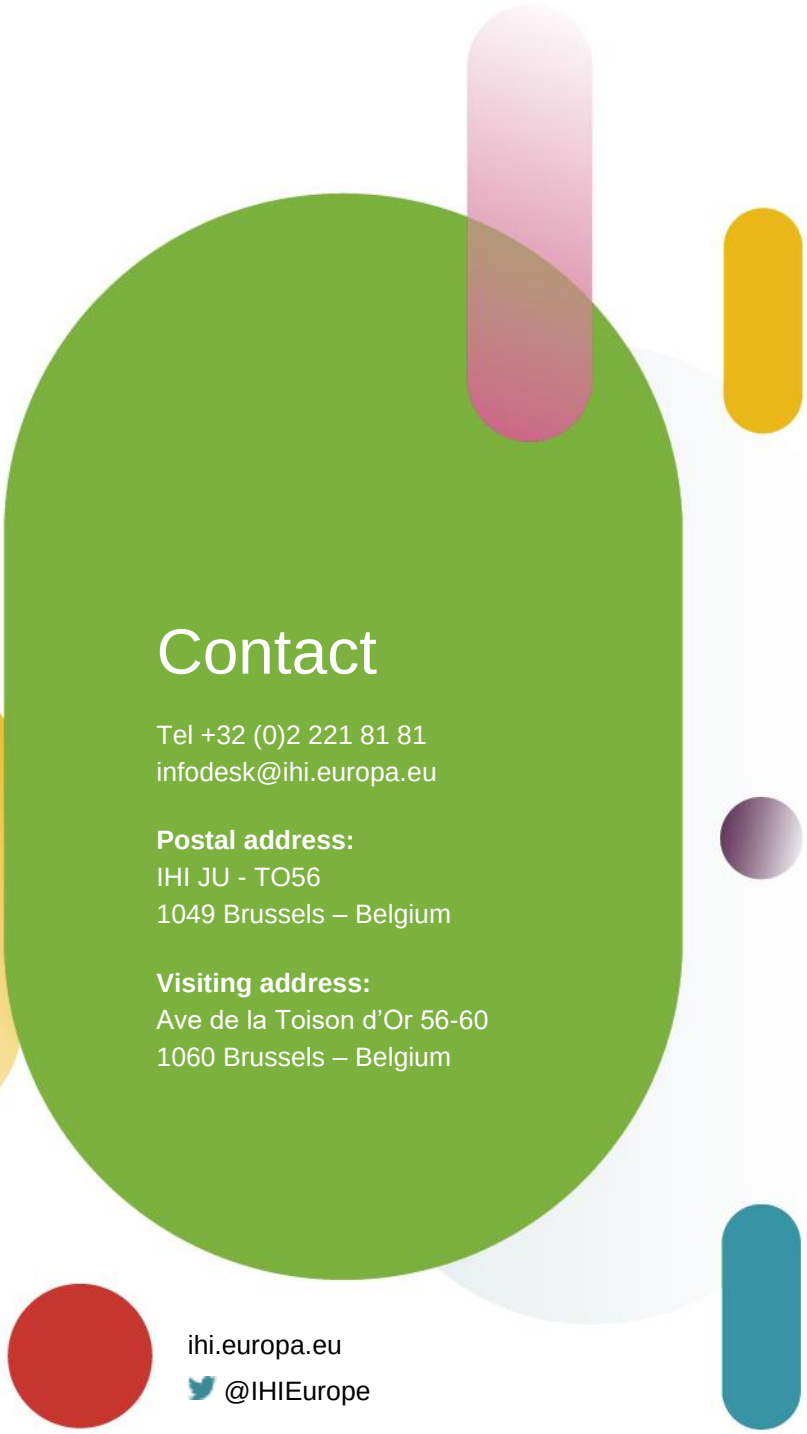

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