

2023 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.

1. Table of Contents

2	List of acronyms, definitions and abbreviations	3
3	Introduction.....	7
3.1	Mission statement of IHI JU.....	7
3.2	Background and link with the Strategic Research and Innovation Agenda (SRIA).....	7
3.3	Strategy for the implementation of the programme	8
4	Work Programme 2023	10
4.1	Executive summary and message from the Executive Director.....	10
4.2	Operational activities of IHI JU for 2023	11
4.2.1	Objectives, indicators and risks	11
4.2.2	Scientific priorities, challenges and expected impacts	19
4.2.3	Calls for proposals	23
4.2.4	Calls for tenders and other actions	23
4.2.5	Follow-up activities linked to past calls: monitoring, evaluation and impact assessment	24
4.2.6	Cooperation, synergies and cross-cutting themes and activities	26
4.3	Support to operations of IHI JU in 2023.....	29
4.3.1	Communication, dissemination and exploitation	29
4.3.2	Procurement and contracts	31
4.3.3	Other support operations	31
4.3.4	Human resources	35
4.4	Governance activities in 2023	40
4.4.1	Governing Board	40
4.4.2	States' Representatives Group	40
4.4.3	Science and Innovation Panel	40
4.5	Strategy and plans for the organisational management and the internal control system in 2023	41
4.5.1	Internal Control Framework	41
4.5.2	Ex-ante and ex-post controls	41
4.5.3	Audits	43
4.5.4	Anti-fraud	44
5	Budget 2023	45
6	Annex.....	56
6.1	IKAA Plan for 2023.....	56

2 List of acronyms, definitions and abbreviations

ACRONYM	MEANING
ABAC	Accrual Based Accounting System
AD (HR)	Administrator
AER	Average error rate
AMR	Antimicrobial resistance
AST	Assistant
BOA	Back-office arrangements
CA (Budget)	Commitment appropriation
CA (HR)	Contractual Agent
CEPI	Coalition for Epidemic Preparedness Innovations
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
DG HR	Directorate-General for Human Resources and Security (European Commission)
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (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
EC	European Commission

ACRONYM	MEANING
ECA	European Court of Auditors
EFPIA	European Federation of Pharmaceutical Industries and Associations. See https://www.efpia.eu/
EFTA	The European Free Trade Association. See https://www.efta.int/about-efta/european-free-trade-association
EMA	European Medicines Agency
ESR	Evaluation Summary Report
EU	European Union
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/
FC	Financial contributions
FG	Function Group
FTE	Full-time equivalent
FP	Full proposal
FWC	Framework contract
GA	Grant Agreement
GAP	Grant Agreement preparation
GB	IHI JU Governing Board
GDPR	General Data Protection Regulation
GH EDCTP3	European and Developing Countries Clinical Trials Partnership Programme 3
HERA	European Health Emergency Preparedness and Response Authority
Horizon Europe	Horizon Europe is the EU's key funding programme for research and innovation. See https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en .

ACRONYM	MEANING
HR	Human resources
HTA	Health technology assessment (bodies)
IAS	Internal Audit Service of the European Commission
ICT	Information and communications technology
IHI JU	Innovative Health Initiative Joint Undertaking
IHInet	The intranet of IHI JU
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
IT	Information technology
JUs	Joint undertakings
KDT JU	Key Digital Technologies Joint Undertaking. See https://www.kdt-ju.europa.eu/
KOL	Key opinion leader
KPI	Key performance indicator
LFS	Legislative Financial Statement of the European Commission's proposal. See https://eur-lex.europa.eu/resource.html?uri=cellar:7efecf4b-75de-11eb-9ac9-01aa75ed71a1.0001.02/DOC_1&format=PDF
MDCG	Medical Device Coordination Group
MedTech Europe	European trade association for the medical technology industry including diagnostics, medical devices and digital health. See https://www.medtecheurope.org/
MEP	Member of the European Parliament
NCA	National competent authorities
Non-EU IKOP	Eligible costs incurred by private members, their constituent or affiliated entities, and contributing partners for implementing project activities carried out

ACRONYM	MEANING
	in third countries outside of the EU Member States and countries associated to Horizon Europe.
OLAF	European Anti-Fraud Office
PA	Payment appropriation
PPP	Public-private partnership
R&D	Research and development
RAE	Risk assessment exercise
RIA	Research and Innovation Actions
SMEs	Small and medium-sized enterprises
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
SOP	Standard operating procedure
SPOC	Single Point of Contact
SRIA	Strategic Research and Innovation Agenda
SRG	IHI JU States' Representatives Group
TA	Temporary Agent
TRL	Technology readiness levels
VaccinesEurope	Specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA). See https://www.vaccineseurope.eu/
WHO	World Health Organisation

3 Introduction

3.1 Mission statement of IHI JU

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

IHI JU aims to pioneer a new, more integrated approach to health research, building on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU). IHI JU also builds on the learnings from the health activities in the former ECSEL JU, now Key Digital Technologies Joint Undertaking (KDT 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 aims to translate health research and innovation into real benefits for patients and society, and 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 will pave 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 should be open to participation by 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 Union citizens.

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

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

The COVID-19 health crisis has exacerbated the challenges faced by European health care 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.

Strengthened collaboration between industry sectors, academia and public authorities will not only offer better opportunities to respond to public health needs in Europe, but also provide a strong base to launch, grow, and keep companies in Europe, and attract competitive companies to Europe.

The EU has leading health care systems and is a strong global actor in health research. However, it is still relatively weak in translating research results into tangible health solutions that are taken up by health care systems in Europe. This can partially be 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.

IHI JU aims to enable the cross-sectoral integration of technologies, know-how, products, services, and workflows for people-centred health care.

IHI JU aims to lay the foundations for the development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be taken up by health care systems. The goal is a more targeted intervention strategy leading to personalised treatments and improved individual 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 health care systems or the market.

This partnership reflects the importance of the full spectrum of health technologies, as well as the progress in 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 will thus respond to the recommendation of the IMI2 JU interim evaluation to “enable the active engagement of other industry sectors with the pharmaceutical industry”¹. A key element for linking all these industry sectors is the necessity 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 SRIA² defines the overall scope of activities of IHI JU, in line with its founding legislation³, to enable the achievement of its general objectives by 2030:

1. 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;
2. 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’;
3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

3.3 Strategy for the implementation of the programme

The key focus of the strategy for 2023 will be to continue to ensure the implementation of the SRIA priorities. This will be achieved through the launch of open and competitive calls for proposals. 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 will be 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.

¹ 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

² https://www.ihj.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf

³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.427.01.0017.01.ENG

Across all of the activities planned a key element will be to adopt an assertive communication strategy 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. This is particularly important to promote the new programme 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 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. 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 Work Programme 2023

4.1 Executive summary and message from the Executive Director

2023 will be the second full year of IHI JU implementation. The Programme Office, having prepared all of the structures for governance and implementation in 2022, will fine tune and solidify processes to optimise the functioning of the governing bodies of IHI JU.

We will commit funds to build new multi sectorial public private projects that take advantage of the ongoing technology convergence in the health sector, advances in digitalisation 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 the large legacy of IMI projects that IHI JU is managing.

We will implement all of this taking care to abide by the principles of sound financial management which has 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 from all sectors, SMEs and the widening countries. Equally assertive, we will communicate on all of the results and impacts coming from projects of IHI JU and the preceding initiatives.

IHI JU will drive new partnerships and seek synergies with those organisations with like-minded or convergent agendas. The initial contacts established in this regard with GH EDCTP3, the Cancer Mission, KDT JU, HERA and EIT Health will be further developed.

4.2 Operational activities of IHI JU for 2023

4.2.1 Objectives, indicators and risks

Key objectives

The key objectives for IHI JU operations in 2023 are identified by the Governing Board in the Work Programme and by the management team at operational level.

The key operational objectives for 2023 are as follows:

1. execute the Strategic Research and Innovation Agenda priorities, enabling the active engagement of industry sectors covering the pharmaceutical, the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area, and a range of other key stakeholders involved in health care (including SMEs, academia, health care authorities, health care professionals and providers, and patient organisations), in particular through the launch of open and competitive calls for proposals;
2. ensure continuity with, and manage the legacy from, the Innovative Medicines Initiative 2 Joint Undertaking;
3. ensure sound budget implementation through the effective and efficient management of calls for proposals, grant award processes, close monitoring of projects and error rate;
4. promote the cross sectorial partnership in health through proactive outreach strategies to attract high quality applications to IHI JU calls for proposals and engage with new players and newcomers;
5. 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;
6. explore synergies with relevant programmes at Union, national, and regional level, in particular with those supporting the deployment and uptake of innovative solutions, training, education and regional development;
7. improve and broaden access to project outcomes by embedding dissemination and exploitation activities in all stages of the project lifecycle.

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 be also 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 health care industry through the novelties and inventions deriving from its funded projects.

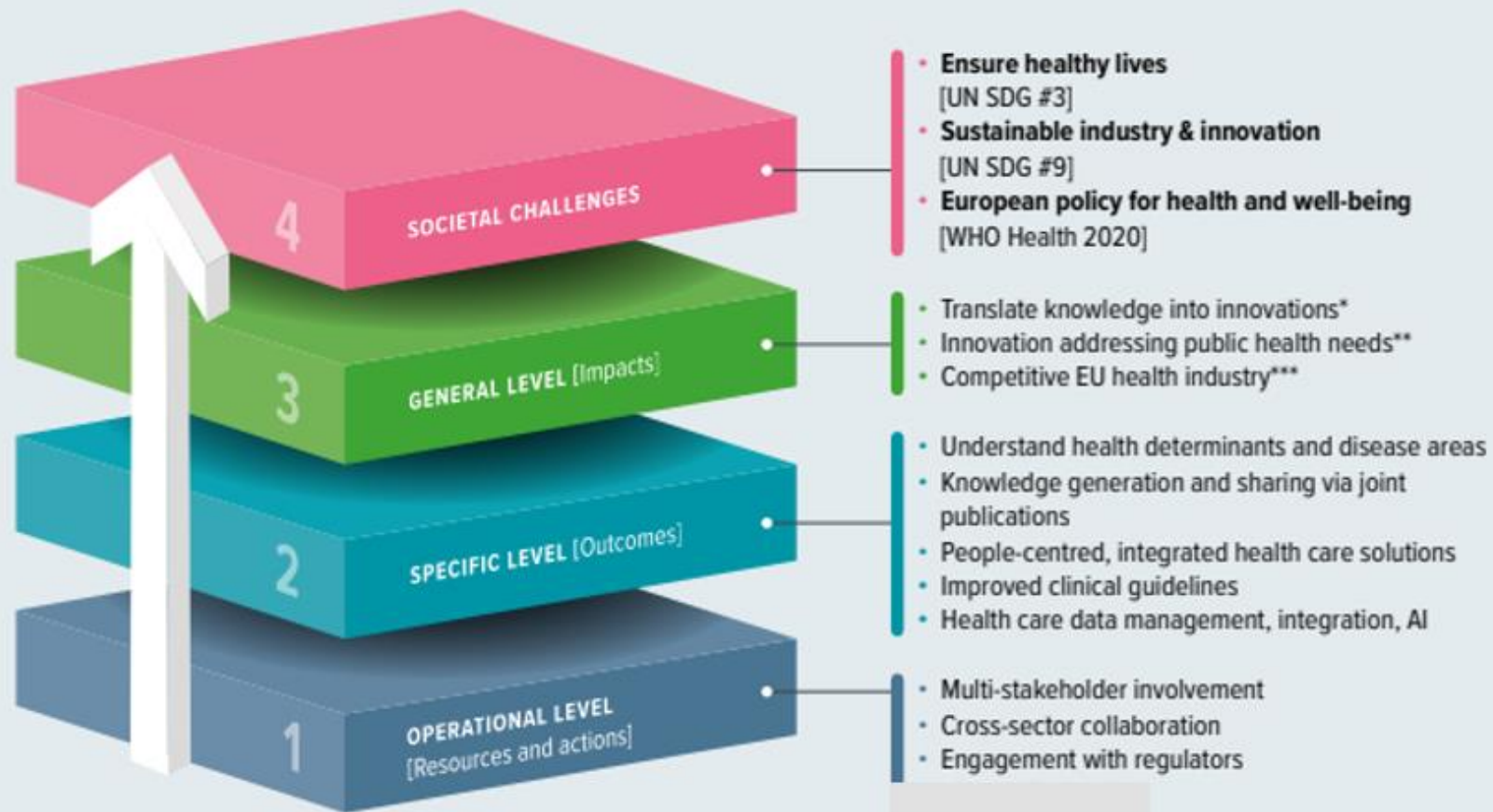
These aspects of IHI JU's nature have been translated into a monitoring framework that consists of a matrix of key performance indicators stratified in 3 levels (in line with the template provided by the EC-RTD):

- 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
https://www.euro.who.int/_data/assets/pdf_file/0011/199532/Health2020-Long.pdf

IHI vision: contribute to societal challenges through ...



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

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

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

The IHI JU specific key performance indicators (KPIs) are linked to the IHI JU vision and have been developed ensuring that there is clear alignment between the overall objectives of IHI JU and the measures used to monitor progress throughout the life of the programme. The KPIs have been elaborated and guided by the so-called RACER Principles⁴.

KPI name	Unit of measurement	Baseline ⁵	Target ⁶ 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), health care 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 ⁷	25%	70%	80%	85%	90%	
1.3. Engagement of regulators	Number of projects interacting with regulators ⁸ to contribute to new or improved guidelines or methodologies	13	0	5	10	20	

⁴ 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 health care 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 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

⁵ Baselines are derived (where possible) from the Innovative Medicines Initiative (IMI2) as the predecessor to IHI.

⁶ Reporting methodology: cumulatively reporting from the beginning of IHI until 31/12/2030.

⁷ 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.

⁸ 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, withdrawing/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), health care 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)	<p>Number of:</p> <ul style="list-style-type: none"> new tools for studying new potential drug targets such as new pharmacological tools, therapeutic modalities, and patient-derived assays available to the scientific community; new tools to test diagnostically and/or therapeutically relevant hypotheses in pre-clinical models and/or clinically in uncharted areas of disease biology; new tools for prediction, prevention, interception, surveillance, diagnosis, treatment, and management options to prepare for major epidemic outbreaks; new biomarkers of disease (relevant for diagnosis, efficacy, safety, or prevention) identified and experimentally validated; new taxonomies of disease or new stratifications to define patient sub-populations. 	100	0	50	120	150	

KPI Name	Unit of measurement	Baseline	Target 2023	Target 2025	Target 2027	Ambition >2027	Status
Outcomes							
2.4. Integrated health care solutions considering end-users' needs	Number of project outputs that combine people-centred integrated solutions (pre-competitive tools, methods, solutions as well as products/services or combined products)	No baseline available	0	3	7	10	
2.5. Methodologies for value assessment of integrated solutions	Number of methodologies for the assessment of the added value of combinations of products/services or combined products (including development of patient reported outcomes / experience measures and statistical methods/tools), submitted to health care authorities and organisations ⁹	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	

⁹ 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 ¹⁰ included in the list of the WHO Europe Health 2020 priority areas ¹¹	No baseline available	90%	90%	90%	90%	

¹⁰ 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 health care is limited because of cost, distance to health facilities or waiting times”.

¹¹ 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 health care industry	<p>Number of activities in which cross-sector collaboration drives health innovation, such as:</p> <ul style="list-style-type: none"> Spin-off companies, entities or activities created based on outputs of the project (e.g., new commercial or non-profit entities) Collaboration agreements between large companies¹² & SMEs¹³ established for purposes that go beyond the scope of the project during and/or after project lifetime. Other activities where the joint contribution of different partners has generated cross-sectoral health innovation. <p>Examples of 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 Europe¹⁴)</p>	No baseline available	0	5	10	20	

¹² For-profit legal entities with an annual turnover of EUR 500 million or more (Article 123(5) of Council Regulation (EU) 2021/2085)

¹³ 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

¹⁴ “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, risks management is an integral element of the strategic planning and monitoring cycle.

Following the risk assessment exercise carried out by the Programme Office in view of this work programme, the following areas prone to critical risks might affect the achievement of the objectives planned by IHI JU in 2023. Most of these risks relate to the external environment (outside IHI JU), and to planning, processes and systems:

- The expected high degree of coverage/exposure on how IHI JU is implementing the new governance structure and generation process for ideas and call topics.
- The remaining uncertainties about the operational implementation of the new key concepts and modalities (such as the monitoring of in-kind contribution to additional activities, the management of contributions at the minimum threshold of 45 % of an indirect action's eligible costs and costs of its related additional activities throughout the project cycle), combined with the need of manual interventions in the programme management platform built and maintained by external parties.

In order to control the risks identified, the Programme Office ensures their monitoring and continuous reviewing, 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 2023 have also been appropriately estimated. The staff is regularly informed on the objectives, activities and new planning.

4.2.2 Scientific priorities, challenges and expected impacts

The scope of the scientific priorities 2023 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 SRIA¹⁵ 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 are not aimed at delivering products or services directly to healthcare systems or the market as such.

In 2023 the scientific priorities will 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

¹⁵ https://www.ihj.europa.eu/sites/default/files/flmng/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Council Regulation (EU) 2021/2085¹⁶. In addition and importantly, the scientific priorities will also cover initiatives which, while not focused specifically on disease areas, have a significant potential to generate results that could have a transformational impact on innovation processes in healthcare.

To achieve these ambitious objectives, IHI JU will continue to build a 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.

The level of cross-sector integration to be achieved by IHI JU is uncharted territory. Thus to make sure to exploit the full potential of IHI JU, R&D, digital and medical executives from pharmaceutical and medtech companies will explore areas of common interest, the boundaries of the common pre-competitive space, and areas that would benefit most from cross-sectorial collaboration at scale to deliver significant benefit and meet important unmet public health needs. The resulting “Big Themes” will further inform the ideation process.

In addition, by 2023 IHI JU will have received the first ideas from the wider health and research community for potential IHI topics via the IHI JU dedicated portal¹⁷ and more will continue to be submitted.

All ideas will be reviewed by the SIP, which comprises experts from the scientific community, various stakeholder groups, and industry sectors. 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 2023 (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 EU4Health¹⁸ programme and HERA¹⁹ and upstream of the upcoming European partnership on transforming health and care systems²⁰, 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 Europe²¹, Europe's Beating Cancer Plan²², to digital policies such as the European Health Data Space²³ and Data Act²⁴ and to the European Green Deal²⁵.

Participants in activities funded by IHI JU will have to ensure that the products and services they develop based or partly based on the results of clinical studies undertaken as part of an indirect action are affordable, available and accessible to the public at fair and reasonable conditions. For this, the general conditions relating to the IHI JU calls included in this work programme will specify additional exploitation obligations applicable to specific indirect actions.²⁶

¹⁶ 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's access to health care is limited because of cost, distance to health facilities or waiting times.

¹⁷ <https://www.ihj.europa.eu/shape-our-future-research/propose-ideas>

¹⁸ https://hadea.ec.europa.eu/programmes/eu4health/about_en

¹⁹ https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

²⁰ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-care-10-01>

²¹ 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

²² https://ec.europa.eu/health/system/files/2022-02/eu_cancer-plan_en_0.pdf

²³ https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

²⁴ <https://digital-strategy.ec.europa.eu/en/policies/data-act>

²⁵ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

²⁶ In accordance with Article 125(3) of the Council Regulation (EU) 2021/2085

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 scope areas of the SRIA. Due to their highly interlinked nature, it is expected that most of the activities in the scope of the priorities will address more than one of the areas (corresponding to the IHI JU specific objectives), albeit with a main focus on one of them.

Specific Objective 1 (SO1) addresses the challenge of unravelling causal factors of disease that are still poorly understood, such as the interplay between genetic and environmental factors, for example the impact of climate change on health. By elucidating the mechanisms of diseases and factors contributing to health status, better targets and approaches can be developed for new and more precise personalised health innovations in prevention, diagnosis, and therapy, as well as for facilitating good health while aging. To contribute to this objective in 2023, attention will be paid for example to the important aspect of disease prevention both for communicable and non-communicable diseases.

An other area of priority might be on infectious diseases, antimicrobial resistance (AMR), and pandemic preparedness & system resilience, while making sure synergies and/or gaps are appropriately addressed versus existing and newly developed EU initiatives (such as HERA).

Specific Objective 2 (SO2) addresses one or more of the barriers for the development of new types of products or services in the health domain that integrate diverse components (such as diagnostics, medicinal products, medical devices, wearables, treatment monitoring, digital solutions), also including the challenge of enabling the green transition across all aspects of healthcare. To fully exploit the potential of various technologies and approaches, existing silos must be broken down across discovery science and translational research as well as between different academic research disciplines and industry sectors. New and harmonised approaches to data generation must be pursued and it would be important to exploit the significant potential of digital R&D for transformative breakthroughs in healthcare. Regulatory challenges related to products that combine different technologies and services must be addressed by offering a neutral platform for all interested stakeholders to exchange experiences and views on issues such as the harmonisation of approaches to evidence generation across sectors. The expected impact for both patients and healthcare would be the enabling of faster development of people-centred, safe, effective, cost-effective, and affordable health solutions along the health care pathway with a reduced environmental footprint, and fostering hospital efficiencies and decreased staff burden. An example to contribute to the achievement of the impacts of this objective, would be an initiative on “Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare”.

A priority of IHI JU in 2023 will be to launch initiatives to foster innovative robust solutions that improve the translation from animal to human in the evaluation of new health technologies, and have the potential to enhance the development new, efficient, and safe health technologies, while at the same time contributing to the aims of Directive 2010/63/EU²⁷ on the protection of animals used for scientific purposes and the principle of the 3Rs (replace, reduce and refine the use of animals). This priority will contribute to SO2 by improving the sustainability and quality of biomedical research and development (R&D) in areas of unmet medical need.

Importantly, an impactful initiative will be launched to deliver improved tools for the development and early-stage evaluation of new health technologies building on recent improved biological knowledge, technological advances, computer simulations and innovative methods (such as organoids, complex 3D cell models and microphysiological systems among others) that are relevant to human health and biology and provide the opportunity to minimise/replace the need for animal experiments.

²⁷ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF>

A special focus of Directive 2010/63/EU is on the need to replace the use of non-human primates in research. In this context IHI JU will for example launch an initiative on “Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment” as meaningful contribution to the demonstration of the latest *in vivo* models as alternative to non-human primates in the later-stage evaluation of medical technologies, medical devices, and pharmaceuticals, while exploiting the latest *in vivo* technologies to boost animal welfare and improving understanding of the impact of animal welfare on scientific outcomes.

The European Green Deal aims to make the European Union climate neutral by 2050. To fulfil this ambitious plan, contributions will be needed from across the spectrum of the healthcare sector, from healthcare systems delivering care to patients, to the full healthcare value chain producing medical products and services, extending to early stage innovation across multiple technologies. Stakeholders from across the healthcare ecosystem must be engaged, including regulatory, standards, policy and technology leaders.

IHI will include as a priority area for 2023 a meaningful contribution to the development of a greener and more sustainable healthcare sector by, for example, targeting the development and use of more sustainable chemicals, products or processes across the value chain to adhere to the Chemicals Strategy for Sustainability²⁸ reducing greenhouse gas emissions and waste produced by healthcare systems.

Outputs from this priority area will ensure that the quality, safety and efficacy of medical products and services and the performance of healthcare systems are safeguarded while significantly improving their environmental footprint and sustainability. Activities from this priority area will contribute to the achievement of SO2 by supporting commercial sustainability transition and reducing the overall environmental impact of healthcare.

The great majority of activities in scope of the scientific priorities of 2023 are expected to contribute to Specific Objective 3 (SO3), which addresses the patient-centricity of innovations and the challenge of effectively engaging with all relevant health care actors (patients and civil society, health care professionals, health care providers, regulators, health technology assessment bodies and payers) for the design and development of new and/or integrated health solutions. As stated in the IHI JU SRIA: “*Patients and end-users need to be involved in all stages of research, from project design through to implementation, to develop meaningful innovations*”.

In addition, in 2023, to contribute to SO3, one or more topics could be launched to address the way clinical studies, including clinical trials for medicinal products, clinical investigations for medical devices, and performance studies for *in vitro* diagnostics, are conducted in Europe, notably to facilitate and increase patient recruitment and retention, with a particular focus on under-represented and underserved patient populations. As expected impacts, through increased access and inclusiveness of diverse patient populations in clinical studies, more patients would benefit from improved innovative health technologies that meet the specific needs and profiles of all patient populations; patients’ trust in the evidence will be enhanced; and health equity advanced. It will also contribute to the ACT EU (Accelerate Clinical Trials in EU)²⁹ objectives to proactively deliver inclusive patient-oriented medicines development and delivery across populations.

Specific Objective 4 (SO4) addresses the issue that currently, data in many countries are hard to gather and demonstrate limited interoperability. Even when available, data and databases may exhibit variable quality, lack of standardisation and poor interconnectivity. Europe also still lacks a sufficiently skilled workforce to handle, analyse and interpret the data. The Union offers a strengthened framework on data protection, but uncertainties remain, like on the secondary use of health data, which creates an additional layer of

²⁸ https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

²⁹ <https://www.ema.europa.eu/en/news/accelerating-clinical-trials-eu-act-eu-better-clinical-trials-address-patients-needs>

complexity. Furthermore, security, explainability for users, and ethical considerations should be ensured when developing new data analytics tools, including the use of artificial intelligence. It is expected that most of the activities generated from the 2023 priorities will contribute to the achievement of the impacts of this objective, e.g. by contributing to the European Health Data Space that was put forward as the legislative proposal from the Commission³⁰.

Impacts achieved in 2022 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.

4.2.3 Calls for proposals

IHI JU will implement the 2023 Scientific Priorities by bringing forward calls for proposals. This Work Programme will be amended accordingly.

4.2.4 Calls for tenders and other actions

n/a

³⁰ https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

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

IMI calls	Total	Ongoing at 01.01.2023	Of which	
	Projects		Total reports	Project ending in 2023
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	1	1
IMI1 call 7	2			
IMI1 call 8	4			
IMI1 call 9	4			
IMI1 call 10	1			
IMI1 call 11	8	1	1	1
Total	59	2	2	2
IMI1				
IMI2 call 1	1	1	1	1
IMI2 call 2	8	0	0	0
IMI2 call 3	5	0	0	0
IMI2 call 4	1	0	0	0
IMI2 call 5	6	1	1	1
IMI2 call 6	4	1	1	1
IMI2 call 7	7	3	3	2
IMI2 call 8	4	3	3	3
IMI2 call 9	6	3	3	3
IMI2 call 10	8	6	6	4
IMI2 call 11	3	0	0	0
IMI2 call 12	7	6	6	4

IMI calls	Total	Ongoing at 01.01.2023	Of which	
	Projects		Total reports	Project ending in 2023
IMI2 call 13	13	9	9	2
IMI2 call 14	4	3	3	0
IMI2 call 15	7	7	6	1
IMI2 call 16	5	4	5	2
IMI2 call 17	3	3	3	0
IMI2 call 18	6	6	6	0
IMI2 call 19	2	2	2	1
IMI2 call 20	6	6	6	0
IMI2 call 21	8	4	4	1
IMI2 call 22	3	3	3	1
IMI2 call 23	6	6	6	0
Total	123	77	77	27
IMI2				
IHI call 1	-	-	-	-
IHI call 2	-	-	-	-
IHI call 3	-	-	-	-
Total	-	-	-	-
IHI *				
Totals IMI+ IMI2 +IHI	182	79	79	29

* Numbers on projects/reports will be further defined after the conclusion of the respective IHI JU calls

Monitoring and analysis of project results

79 project periodic reports will be submitted in 2023 (see column in the table above – ‘Project periodic report due in 2022 – Total reports’). 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 allow 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 projects.

In 2023, the analysis of the IMI project scientific outputs in terms of publications and collaboration among IMI 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 projects

An important part of evaluating the performance of IMI2 JU consists in assessing the impact of the IMI projects. As set out in the Strategic Research Agenda for IMI2 JU, the Programme Office remains focused on the needs of patients and society, and on delivering tools and resources to speed up the development of urgently-needed treatments.

In 2021 and 2022, the Programme Office ideated and initiated a small-scale impact assessment pilot involving a limited set of IMI2 finished projects in the field of nervous system disorders, experimenting a new methodology. The new methodology includes the leadership of the impact assessment by an independent expert as well as the engagement of the key project stakeholders through web-assisted interviews. The Programme Office will assess the feasibility, time and resources required to expand this approach to a larger pool of projects in the same or in different therapeutic fields.

4.2.6 Cooperation, synergies and cross-cutting themes and activities

The Council Regulation (EU) 2021/2085 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. Therefore, in 2023 it is planned that IHI JU will continue to explore possible synergies with other health-oriented initiatives, with the Cancer Mission, the partnerships created in Cluster 1 of Horizon Europe (notably GH EDCTP3 JU) and EIT Health, complementing the actions of the EU4Health³¹ programme, HERA³² and Coalition for Epidemic Preparedness Innovations (CEPI)³³, wherever relevant. It is also expected that IHI JU activities will complement those of the Digital Europe programme³⁴ that will deploy digital capacities and infrastructure related to the health area.

IHI JU will seek the advice of the GB, SIP and SRG in order to identify the most relevant programmes and initiatives.

In addition to attempting to establish institutional collaborations, IHI JU will continue to engage with its key stakeholders such as patients, regulators and SMEs.

³¹ https://hadea.ec.europa.eu/programmes/eu4health/about_en

³² https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

³³ <https://cepi.net/>

³⁴ https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en

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, implementation and close out. 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: launch a new call for expressions of interest and update the IHI patient pool to reflect all the health areas covered by the IHI JU objectives; ensure that patient input is considered at the idea generation and topic writing stage; communicate on patient engagement needs and opportunities at call launch; facilitate patient engagement in consortia; identify the most effective channels of communicating information on calls to patients and other relevant organisations; share best practices of patient engagement in IHI JU projects; continue to produce materials for the promotion of patient involvement 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 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 projects is translated into people-centred 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) and the Medical Device Coordination Group (MDCG) to reflect the cross-sectoral nature of the partnership.

IHI JU will seek to increase the awareness of applicants and projects' consortia about regulatory needs to be considered when relevant. It will also continue to provide support to consortia through guidance and information sessions to encourage early interactions with regulators whenever relevant to ensure greater impact of projects by translating research outcomes into regulatory practice.

The regulators' perspective will be embedded in the scientific priorities and calls for proposals, most notably through the representation of regulators in the SIP, as well as consideration of the list of regulatory science research needs established by EMA³⁵.

³⁵ https://www.ema.europa.eu/en/documents/other/regulatory-science-research-needs_en.pdf

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, encourage their participation in the programme notably by taking part in IHI projects and foster 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 have 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.

4.3 Support to operations of IHI JU in 2023

4.3.1 Communication, dissemination and exploitation

Dissemination and information about projects 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 the European Commission's Dissemination and Exploitation Network (D&E Net) and intensively promoting the Innovation Radar, the Horizon Results Portal and the Horizon Results Booster among both IHI staff and IMI/IHI projects.

In 2023, IHI JU expects to receive approximately 29 final project reports. The exact number remains to be determined as the COVID-19 pandemic continues to affect the activities of projects and this may result in further no cost extension requests.

For most of the projects ending late 2022 and in 2023, close-out meetings will be organised around the time of submission of the final report. IHI JU will prepare specific communication materials for each project based on information provided in the final report and close out meeting. When necessary, the Programme Office may organise cross-project meetings, or 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 policy conformity, effectiveness and efficiency of the dissemination and exploitation at the level of each project in the portfolio.

Communication

Unfolding IHI's new communication strategy

The 2023 IHI JU communication work plan will be the first plan developed under the new IHI communication policy.

In 2023 the first IHI JU projects will hit the ground running while a large number of ongoing IMI projects will yield new results. One of the communications team's main objectives will be to report on how both newly launched and ongoing projects will or have met the challenges they were set to address by: writing news articles, organising impact-focused events, and acting as 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 opening 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 a crucial instrument to address this objective.

Since IHI JU will still be a very young programme in 2023, the communication team's third strategic objective will be to establish the IHI JU brand and raise stakeholders' awareness regarding the partnership's new research focus, new structures and new processes, in close collaboration with IHI partners and governance structures.

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;
- website;
- newsletter;
- social media (LinkedIn, Twitter);
- 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.

4.3.2 Procurement and contracts

In order to reach its objectives and adequately support its operations and infrastructures, IHI JU will allocate funds to procure the necessary services and supplies.

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. In 2023, IHI JU intends to implement one such framework contract by concluding a specific contract for infrastructure as a service (IaaS) and IT development and support of SOFIA, the intranet, collaborative platforms and other IHI JU specific applications.

In 2023 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 2023. Additionally, IHI will create synergies with other JUs by launching inter-JU joint procurement in e.g. ICT services and event logistics.

4.3.3 Other support operations

a. Relevant functions and administrative synergies within back office arrangements³⁶

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 best practices sharing is taking place on a regular basis among the peers. E.g., the Executive Directors, Heads of Administration, HR officers, legal officers etc. meet regularly to discuss and share experiences. As several JUs are also located in the same premises, the collaboration is concrete serving the business needs e.g., in joint business continuity planning, managing the joint office building and sharing common infrastructure and meeting rooms. In 2023 IHI JU will also continue to provide office space for EDCTP3 JU's use. This will bring important cost-benefits to the Programme Office and is enabled by the new hybrid working mode implemented in accordance with the EC guidelines.

In alignment with the Council Regulation (EU) 2021/2085 a number of areas will be implemented within the back office arrangements (BOA). In 2022 the BOA implementation were launched by the JUs in accounting, ICT, procurement and HR services. In 2023 the experience from the implementation from the first set of service areas will be used to expand the collaboration within the BOA into 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 IHI JU information technologies (IT) team's strategic objective is to deliver value to the organisation and to be a key enabler of new organisational initiatives with the goal of supporting and shaping the present and future of the Programme Office.

IHI JU is part of common governance of IT operations and infrastructure, together with five JUs located in the same premises. This provides efficiency, economy of scale and gains in the operation of the organisation.

³⁶ Article 13 of the Council Regulation (EU) 2021/2085

Another very important key success factor is cooperation, shared services and knowledge sharing within ICTAC (Information and Communication Technologies Advisory Committee, part of the European Union Agencies Network) and with EC services.

To achieve the afore-mentioned goals, the IT team will focus its 2023 activities on the following areas:

1. 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 adoption of software-as-a-service (SaaS) solutions both from the market and the European Commission.

Microsoft 365 (SaaS) will eventually become the main office automation and core IT infrastructure tool. After careful evaluation, most of the obsolete infrastructure-as-a-service (IaaS) components will be retired.

2. 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 the 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:

- main tool for the ongoing IMI1 projects
- complementary tool for information missing in eGrants IMI2 and IHI JU specificities - e.g. annual reporting of in-kind contributions, overview of project outputs for JU-specific KPIs (including completely new module for IHI JU) etc.

The Programme Office will also continue the further development of the IHI JU data warehouse and Qlik sense analytical platform with a particular focus 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.

3. Collaboration, communication and administration management information systems

The IHI net (intranet) and collaborative platforms, providing support to the governance bodies, will continue their evolution on M365 SharePoint technology. They have already proved their effectiveness as the main internal communication tool supporting business activities.

4. IT Procurement and transition to the FWCs

In 2023 the main IT operations will be onboarded to new FWCs as follows:

- IT managed services: current inter-JUs FWC awarded to RealDolmen in 2018 will expire in 2022. The services will be handed over to the winner of the open call for tenders, which should have been concluded in 2022.
- Infrastructure as a service (IaaS): after the expiration of the European Food Safety Authority (EFSA) FWC "Broker model for the provision of cloud services" in 2023, IHI JU we will move the remaining part of IaaS from the Cancom data centre to the EC DIGIT CLOUD II FWC provider.

- IT development and support of SOFIA, intranet, collaborative platforms and other IHI JU specific applications, currently carried out by Intrasoft via DIGIT-XM FWC (expiring in March 2023) will be procured via a new FWC as well.

5. *New Regulation on Information Security*

The adoption of the new Regulation on Information Security, expected in late 2022, will enforce the establishment of an internal cybersecurity risk management, governance and control framework that ensures an effective and prudent management of all cybersecurity risks.

IHI JU will evaluate the requirements in the final text of the regulation and will find the most effective way to create this framework.

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 (ED DEC No19/2021³⁷), establishing a new records management policy for IHI JU based on the European Commission decision C(2020)4482³⁸.

The Record Management Working Group³⁹ 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 records, necessary to ensure evidence of IHI JU's activities ensuring an appropriate level of accountability, transparency, and retention of IHI JU's legacy. Effective record management helps to meet IHI JU's transparency obligations, in particular by facilitating public access to documents and implementing the principle of accountability of public actions.

Data protection

The data protection rules are enshrined in the General Data Protection Regulation ("GDPR") for public organisations and businesses. 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.

³⁷ ED Decision 19/2021 Ares(2021)5474488

³⁸ Commission Decision on records management and archives C(2020)4482.

³⁹ 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).

IHI JU 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.

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 keep a high-level of public confidence in IHI JU by giving the opportunity to the public to monitor its work.

d. Accounting

2023 will be the first year with the new accounting services and new Accounting Officer within the back office arrangements. The performance of the new accounting services will be monitored carefully in order to ensure business continuity and sound implementation of accounting tasks.

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 aim to 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.

The SRIA identifies the other candidate European partnerships of potential relevance, notably with the Mission Cancer, the partnerships in Cluster 1 of Horizon Europe and EIT Health, complementing the actions of the EU4Health⁴⁰ programme and HERA⁴¹ wherever relevant. It is also expected that IHI JU activities will contribute to and complement those of the Digital Europe programme⁴² that will deploy digital capacities and infrastructure related to the health area, and the European Green Deal⁴³ by contributing to the development of a greener and more sustainable healthcare sector.

IHI JU will begin to seek opportunities to synergise 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.

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.

Lastly, 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.

⁴⁰ https://hadea.ec.europa.eu/programmes/eu4health/about_en

⁴¹ https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera/overview_en

⁴² https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en

⁴³ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

4.3.4 Human resources

a. HR management

In 2023, the total number of IHI JU staff will be 54 (of which 39 temporary agents and 15 contract agents). Due to the reduction in the staff numbers in the Staff Establishment Plan (SEP), in 2023 IHI will no longer employ Seconded National Experts (SNE). In September 2022, Dr Hugh Lavery, IHI Head of Scientific Operations was appointed by the IHI Governing Board as IHI Executive Director *ad interim*, while the selection procedure of the new Executive Director has been ongoing.

In 2023, the Programme Office will start its second 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 and IMI2 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 well-being of its staff and to ensure business continuity.

1. Selection and recruitment

In 2023, 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 will be 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, connecting the Programme Office overall strategic goals with staff performance management. The new e-selection tool SYSTAL implemented in 2022 will be fully operational in 2023 and will contribute to the achievement of the above-mentioned objectives. Gender balance and equality will remain important elements in IHI JU selection and recruitment procedures (today the ratio is 33% male and 66% female with an equal distribution in the IHI JU management team). 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. 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.

2. 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 2023, the HR team will aim to implement the SYSPER II module Evaluation and Promotion, as well as organise tailor-made training courses for managers and staff.

The human resources team will keep overseeing duties and responsibilities assigned to staff in order to achieve the fulfilment of IHI JU's objectives and tasks.

3. 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 human resources team will further develop the learning and development framework, paying particular attention to the training needs of its 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 support and keep them abreast in their day-to-day management of staff and operational activities, and particular attention will be given to performance management.

The Programme Office is committed to preserve a physically and psychologically healthy work environment where work is meaningful, and people have the conditions to contribute to their best. To this end, the Programme Office will:

- (i) keep paying particular attention to the well-being of its staff, by developing tailor-made well-being activities to increase wellness in the workplace (e.g. well-being lunchtime sessions, workshops, etc);
- (ii) develop teambuilding activities to strengthen collaboration among staff members, to enhance the team spirit and culture, and to help staff get acquainted with the hybrid working;
- (iii) remain vigilant and reiterate its strong commitment to a zero tolerance towards psychological and sexual harassment and disrespectful work environments.

4. Legal matters

IHI JU will continue working closely with DG HR 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. The COVID-19 outbreak showed that new ways of working are possible and revision of some existing rules will be needed to adapt to the “new norm”.

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

Under the IHI JU 2023 Staff Establishment Plan there is a decrease of 3.6% of the human resources, from a total of 56 staff members in 2021 to 54 staff members in 2023. In addition, no new resources were provided to IHI JU while setting up the new programme requiring to manage three complex programmes in parallel (IMI1, IMI2 and IHI). Thus, in 2023 the Programme Office will have to pay even more attention to the efficiency and cost-effective management of its resources due to the limited allocation of human resources.

In 2023, the JUs will continue sharing the human resources IT tools (e.g. the e-recruitment tool SYSTAL, SYSPER, etc) and, where necessary, common calls for tender, selection procedures, training courses for JU staff and managers as well as a common approach to the implementing rules of the EU staff regulations. The JUs also share an inter-JU network of confidential counsellors; this network will be reinforced in 2022 with the publication of a new call and appointment of additional confidential counsellors. Their assignment will start in 2023.

c. Staff Establishment Plan

Function group and grade	2021				2022		2023	
	Authorised budget		Actually filled as of 31/12		Authorised budget		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16								
AD 15								
AD 14		1		1		1		1
AD 13								
AD 12		2		1		2		2
AD 11		2		2		2		2
AD 10		1		2		1		1
AD 9		7		5		7		7
AD 8		6		4		6		6
AD 7		2		4		3		4
AD 6		11		6		10		9
AD 5		1		6		2		3
TOTAL AD		33		31		34		35
AST 11								
AST10								
AST 9								
AST 8		1		1		1		1
AST 7								
AST 6								
AST 5								
AST 4		4		3		4		3

Function group and grade	2021				2022		2023	
	Authorised budget		Actually filled as of 31/12		Authorised budget		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AST 3				1				
AST 2		1						
AST 1								
TOTAL AST		6		5		5		4
AST/SC 6								
AST/SC 5								
AST/SC 4								
AST/SC 3								
AST/SC 2								
AST/SC 1								
TOTAL AST/SC								
TOTAL AD+AS T+ AST/SC								
GRAND TOTAL	39		36		39		39	

Contract Agents	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023
Function Group IV	3	3	3	4	4
Function Group III	11	9	9	11	11
Function Group II	1	1	1		
Function Group I					
TOTAL	15	12	12	15	15

Seconded National Experts	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023
TOTAL	2	1	2	1	0

Recruitment forecasts 2023 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			

4.4 Governance activities in 2023

Planned activities

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

4.4.1 Governing Board

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

Two meetings are planned for 2023. The chairperson may be invited to attend the SRG meetings as an observer.

4.4.2 States' Representatives Group

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

The SRG shall report to the GB, in particular on the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation.

Two meetings of the SRG are planned for 2023. The chairperson and the vice-chairperson shall participate in the GB meetings as observers and in the SIP meetings as permanent panellists.

4.4.3 Science and Innovation Panel

The SIP is the scientific advisory body. It provides the GB with science-based advice on a range of matters, in particular on the annual scientific priorities, the draft 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 for a period of three (3) years following an open selection process (call for expressions of interest launched in January 2022).

Two meetings are planned for 2023. 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.

4.5 Strategy and plans for the organisational management and the internal control system in 2023

4.5.1 Internal Control Framework

The priority objective of 2023 will be to implement and 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 the 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;
- risk management process integrated in the annual planning cycle by performing risk assessment exercise and following up risk mitigation action plans;
- incorporating to a broad extent the horizontal guidance on controls to ensure compliance and a harmonised approach across the implementation of the programme and fair and equal treatment towards beneficiaries, and to gather reasonable assurance.

4.5.2 Ex-ante and ex-post controls

Ex-ante controls

Ex-ante controls are rigorously implemented by IHI JU for each transaction (commitments and payments). Standard ex-ante control measures are in place for FP7, Horizon 2020 and for Horizon Europe programmes. 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 following section) provide the Authorising Officers with the necessary elements of assurance on the research and innovation budget under their responsibility. To that purpose, IHI JU will continue to work in 2023 with all R&I family services and the European Court of Auditors to conclude and start implementing the control strategy for the Horizon Europe programme (including ex-ante and ex-post controls and anti-fraud).

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 IMI1 projects running under the Seventh Framework Programme

The Programme Office will carry on with the implementation of its ex-post audit strategy as a means to ensure the legality and regularity of operational expenditure. This strategy complements ex-ante controls embedded in IHI JU's management processes and includes the rejection of any costs found to be in breach with the requirements of IMI JU Grant Agreement. Representative ex-post audits of participants will be launched on new cost claims accepted by the Programme Office since the last audited period to reach the audit coverage ratio set in its ex-post audit strategy. If necessary, risk based ex-post audits will be launched according to the Programme Office risk-based audit strategy. Rejection of systematic errors identified in ex-post audits will continue to be extended to unaudited financial statements ('Form C') of the audited participants.

Ex-post audits of accepted declarations of in-kind contributions by EFPIA companies will not be carried out in 2023 as the work plan on ex-post audits of EFPIA companies under IMI JU has reached its end in 2021 and the majority of the EFPIA companies' in-kind contributions have been covered by ex-post audits. Controls of in-kind contributions by EFPIA companies will also be based on the review of audit certificates provided by independent auditors for the final reporting period. Risk-based ex-post audits of accepted declarations of in-kind contributions may nevertheless be initiated should a specific need arise.

For IMI2 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 carry 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. If necessary, 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.

In line with Article 4.4 of the applicable Regulation (Council Regulation (EU) No 557/2014), controls of in-kind contributions by EFPIA companies will be based on the review of audit certificates provided annually by independent auditors and their validation by the Authorising Officer. In case of remaining uncertainties, ex-post audits of accepted declarations of in-kind contributions may be performed.

For IHI 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 contributes to the implementation of the Horizon Europe audit strategy in close cooperation with the Commission Common Audit Service and ensures that its ex-post audit strategy is complied with, including its audit coverage ratio. In line with Article 53(2) of Regulation 2021/695, the representative ex-post audits shall be complemented by risk based ex-post audits 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 Horizon Europe.

In line with Article 11.2 of the Council Regulation (EU) 2021/2085, controls of in-kind contributions to additional activities by members other than the Union will be based on the review of audit certificates provided annually by independent auditors and their validation by the Authorising Officer.

4.5.3 Audits

Internal and external audits

IHI JU audit arrangements are set up in accordance with Article 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 annual Declaration of Assurance of the Executive Director.

The Audit Manager will coordinate audits carried out by IHI JU's internal and external auditors, will follow up and assess the implementation of the Internal Audit Service (IAS) of the European Commission and the European Court of Auditors (ECA) recommendations with the objective to confirm their effective implementation.

Internal audits are carried out by the IAS in liaison with the Audit Manager.

In 2023 IAS will commence implementation of the Strategic Internal Audit Plan (2023-2025) and launch an audit engagement on one of the selected topics.

In 2023, the focus will be put on:

- coordinating and supporting IAS's audit work and ensuring an adequate level of assurance from internal audit.

External audits are carried out by the 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 2022/2023 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 joint undertakings. 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 audits of 2022 and 2023 accounts and following up on preliminary findings and recommendations;
- liaising with an independent external auditor and coordinating with the ECA throughout the audits of the accounts for the financial years 2022 and 2023.

4.5.4 Anti-fraud

The objective of 2023 will be to carry on with the implementation of the IHI JU anti-fraud strategy

IHI JU implements the common Research Anti-Fraud Strategy. In March 2019, CIC adopted the revised Research Family Anti-Fraud Strategy (RAFS 2019) and the associated action plan (replacing RAFS 2015 and its action plan). The implementation of the action plan, which deals with the fraud risks related to the implementation of the research and innovation programmes concerning grant management, is monitored through regular meetings of the Fraud and Irregularity Committee (FAIR), in which IHI JU takes part.

IHI JU will continue to apply harmonised preventive measures for fraud detection, e.g. via the enhanced monitoring tool available as a feature in Sygma-Compass workflow.

The IHI JU anti-fraud strategy also covers areas that are not related to grant management, i.e. fraud risks related to procurement, expert management, internal misconduct, etc.

IHI JU will continue to collaborate closely with the services of the European Anti-Fraud Office (OLAF) and will actively participate in the OLAF-chaired meetings/trainings.

5 Budget 2023

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

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

- a lump sum annual financial contribution of EUR 15,000 from EuropaBio;
- a financial contribution from EFPIA covering 50% of the relevant amount minus the contribution from EuropaBio, and financial contribution from MedTech and COCIR covering each one 25% of the relevant amount.

STATEMENT OF REVENUE								
Title Chapter Heading	Financial year 2022				Financial year 2023			
	Commitment Appropriations	In % in total	Payment Appropriations	In %	Estimate Commitment Appropriations	In %	Estimate Payment Appropriations	In %
EU contribution (excluding EFTA and third countries contribution)	254,617,631	96%	151,445,971	90%	204,709,974	95%	208,811,442	95%
of which (fresh C1) Administrative (Title 1&2)	905,631		1,349,663		1,384,974		1,384,974	
of which frontloaded commitments (Title 1&2)	3,712,000		3,712,000		3,325,000		3,325,000	
of which Operational (Title 3)	250,000,000		146,384,308		200,000,000		204,101,468	
Of which related to additional entrusted tasks								
EFTA and third countries contribution	3,727,369	1%	3,649,029	2%	5,820,026	3%	5,938,558	3%
of which Administrative EFTA(Title 1&2)	22,369		33,337		40,026		40,026	
Of which administrative third countries excluding EFTA (Title 1&2)								
of which Operational EFTA (Title 3)	3,705,000		3,615,692		5,780,000		5,898,532	
Of which operational third countries excluding EFTA (Title 3)								
Financial Members other than the Union contribution	4,640,000	2%	4,640,000	3%	4,750,000	2%	4,750,000	2%
of which Administrative (Title 1&2)	4,640,000		4,640,000		4,750,000		4,750,000	
of which Operational (Title 3)								

STATEMENT OF REVENUE

Title Chapter Heading	Financial year 2022				Financial year 2023			
	Commitment Appropriations	In % in total	Payment Appropriations	In %	Estimate Commitment Appropriations	In %	Estimate Payment Appropriations	In %
Financial Contributing partners contribution								
Interest generated								
Unused appropriations from previous years								
Of which administrative	537,963	0	100,000	0				
Of which operational	1,800,760	0	7,950,873	0				
TOTAL ESTIMATE REVENUE	265,323,723	100 %	167,785,873	100 %	215,280,000	100%	219,500,000	100%

EFTA (2022 is 2.47%,
2023 is 2.89%)

2022 budget in line with the Second amended Work Programme 2022 adopted on 08 December 2022

Commitment appropriations financial year 2023: Calls under Horizon Europe

Payment appropriations financial year 2023: FP7, H2020 and Horizon Europe related projects

The 2023 operational payment appropriations forecasting have been revised to EUR 165,000,000 (EFTA contribution included) and this will be communicated during the hearings in order to ask for the reduction of the PA via Global Transfer exercise during 2023.

Budget revenue per founding member 2023

The table below shows the contributions to IHI JU budget for 2023 per founding member.

IHI JU - STATEMENT OF REVENUE				
	Heading Revenue	Budget 2023		Comments
Chapter/Line		Commitment Appropriation (CA)	Payment Appropriation (CA)	
10	European Commission contribution			
1000	European Commission contribution (including EFTA contribution) for current year for IMI2	3,325,000	3,325,000	Commitment appropriations include EUR 3,325,000 for administrative costs. Payment appropriations include EUR 3,325,000 for administrative costs.
1002	European Commission contribution (including EFTA contribution) for current year for IHI	207,205,000	211,425,000	Commitment appropriations include EUR 1,425,000 for administrative costs and EUR 205,780,000 for operational costs. Payment appropriations include EUR 1,425,000 for administrative costs and EUR 210,000,000 for operational costs.
1001	European Commission - appropriations carried over from previous years			
10	European Commission contribution - total	210,530,000	214,750,000	
20	JU members other than the Union contribution			
2000	EFPIA contribution for current year for IMI2	3,325,000	3,325,000	EFPIA contribution to IHI administrative costs
2002	EFPIA contribution for current year for IHI	697,500	697,500	EFPIA contribution to IHI administrative costs
2001	EFPIA - appropriations carried over from previous years			
	EFPIA contribution - total	4,022,500	4,022,500	
2010	EuropaBio contribution for current year	15,000	15,000	EuropaBio contribution to IHI administrative costs
2011	EuropaBio - appropriations carried over from previous years			
	EuropaBio contribution - total	15,000	15,000	
2020	COCIR contribution for current year	356,250	356,250	COCIR contribution to IHI administrative costs
2021	COCIR - appropriations carried over from previous years			
	COCIR contribution - total	356,250	356,250	
2030	MedTech Europe contribution for current year	356,250	356,250	MedTech contribution to IHI administrative costs
2031	MedTech Europe - appropriations carried over from previous years			
	MedTech Europe contribution - total	356,250	356,250	
20	JU members other than the Union contribution - total	4,750,000	4,750,000	
	Total revenue	215,280,000	219,500,000	

Regarding *the administrative budget*, the total amount for 2023 is EUR 9,500,000 in commitment appropriations.

The amount is divided equally (50%-50%) between the EC and industry partners (JU founding members other than the Union): EFPIA, EuropaBio, COCIR and MedTech. As such, the total EC contribution to the administrative budget is EUR 4,750,000. The total Industry contribution to the administrative budget is EUR 4,750,000. EU and industry contributions are stemming from IMI2 JU and IHI JU budgets.

EFPIA's contribution to the IMI2 budget for 2023 is EUR 3,325,000. The industry contribution to the IHI JU budget for 2023 is EUR 1,425,000.

The table below shows how the industry contribution is divided between the IMI2 and IHI programmes.

Industry contribution to the total administrative budget for 2023 (EUR)	4,750,000	%
IHI JU	1,425,000	30%
IMI2	3,325,000	70%

Budget expenditure 2023

The budget for the financial year 2023 is based on the currently available information.

Operational commitment appropriations will be consumed by calls to be launched by IHI JU in 2023, under Horizon Europe. The payment appropriations will be consumed as intermediate and final payments for the FP7 and H2020 projects as well as pre-financing for Horizon Europe projects.

The overall budget of administrative expenditure will slightly increase by 2% in 2023 compared to 2022, mainly due to increases in IT costs and the number of meetings related to project reviews and workshops. It is worth mentioning that the budget for missions and meetings was low in 2022, being planned in the context of COVID-19, hence the higher increase in 2023. The budget has been reallocated between chapters, in line with the operational needs of different areas.

STATEMENT OF EXPENDITURE								
Title Chapter Heading	Financial year 2022				Financial year 2023			
	Commitment Appropriations	% Ratio	Payment Appropriations	% Ratio	Estimate Commitment Appropriations	% Ratio	Estimate Payment Appropriations	% Ratio
		Year 2022/ year 2021		Year 2022/ year 2021		Year 2023/ year 2022		Year 2023/ year 2022
Title 1 - Staff expenditure	6,464,000	7%	6,464,000	6%	6,488,000	0%	6,488,000	0%
Salaries & allowances	6,032,000	3%	6,032,000	3%	5,922,000	-2%	5,922,000	-2%
- Of which establishment plan posts	5,014,000	3%	5,014,000	3%	4,992,000	0%	4,992,000	0%
- Of which external personnel	1,018,000	1%	1,018,000	2%	930,000	-9%	930,000	-9%
Expenditure relating to Staff recruitment	5,000	-50%	5,000	-50%	5,000	0%	5,000	0%
Mission expenses	80,000	60%	80,000	60%	144,000	80%	144,000	80%
Socio-medical infrastructure	132,000	5%	132,000	5%	152,000	15%	152,000	15%
Training	80,000	0%	80,000	0%	80,000	0%	80,000	0%
External Services	125,000	0%	125,000	0%	175,000	40%	175,000	40%
Receptions, events and representation	10,000	0%	10,000	0%	10,000	0%	10,000	0%
Social welfare								
Other Staff related expenditure								
Title 2 - Infrastructure and operating expenditure	2,816,000	-8%	3,371,000	-2%	3,012,000	7%	3,012,000	-11%
Rental of buildings and associated costs	660,000	2%	702,000	2%	698,000	6%	698,000	-1%
Information, communication technology and data processing	1,009,000	-6%	1,089,000	-6%	1,090,000	8%	1,090,000	0%
Movable property and associated costs	5,000	0%	5,000	0%	5,000	0%	5,000	0%
Current administrative expenditure	124,000	-2%	149,000	-2%	124,000	0%	124,000	-17%
Postage / Telecommunications	38,000	0%	38,000	0%	40,000	5%	40,000	5%
Meeting expenses	70,000	150%	87,000	150%	80,000	14%	80,000	-8%

STATEMENT OF EXPENDITURE								
Title Chapter Heading	Financial year 2022				Financial year 2023			
	Commitment Appropriations	% Ratio	Payment Appropriations	% Ratio	Estimate Commitment Appropriations	% Ratio	Estimate Payment Appropriations	% Ratio
		Year 2022/ year 2021		Year 2022/ year 2021		Year 2023/ year 2022		Year 2023/ year 2022
Running costs in connection with operational activities	200,000	43%	225,000	43%	250,000	25%	250,000	11%
Information and publishing	300,000	-18%	300,000	-18%	300,000	0%	300,000	0%
Studies	410,000	-2%	776,000	-2%	425,000	4%	425,000	-45%
Other infrastructure and operating expenditure								
TOTAL ADMINISTRATIVE EXPENDITURE (Title 1+ Title 2)	9,280,000	2%	9,835,000	3%	9,500,000	2%	9,500,000	-3%
Title 3 - Operational expenditure	256,043,723		157,950,873	-21%	205,780,000	-20%	210,000,000	33%
TOTAL OPERATIONAL (Title 3) *	256,043,723		157,950,873	-21%	205,780,000	-20%	210,000,000	33%
ESTIMATE TOTAL EXPENDITURE	265,323,723		167,785,873	-20%	215,280,000	-19%	219,500,000	31%

*no operational CA in 2021, first year of the new programme Horizon Europe

Overview of the budget per budget line

An overview of the 2023 Budget per budget line is set out in the table below.

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1100	Staff in active employment and costs linked to employees	3,620,000	3,620,000
1101	Family Allowances	370,000	370,000
1102	Transfer and expatriation allowances	500,000	500,000
1110	Contract Agents	930,000	930,000
1111	Seconded National Experts	-	-
1130	Insurance against sickness	122,000	122,000
1131	Insurance against accidents and occupational diseases	15,000	15,000
1132	Unemployment insurance for temporary staff	48,000	48,000
1133	Pension		
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	110,000	110,000
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	30,000	30,000
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	5,922,000	5,922,000
1200	Miscellaneous expenditure on staff recruitment	5,000	5,000
12	Staff recruitments - miscellaneous expenditure	5,000	5,000
1300	Mission expenses	144,000	144,000
13	Missions and duty travels	144,000	144,000
1401	EU school costs	120,000	120,000
1410	Other trainings	50,000	50,000
1430	Medical service	20,000	20,000
1440	Trainings covered by the EC service level agreement	30,000	30,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1490	Other interventions	12,000	12,000
14	Socio-medical structure	232,000	232,000
1500	External staff expenditure	175,000	175,000
15	External staff services	175,000	175,000
1700	Representation expenses	10,000	10,000
17	Representation	10,000	10,000
Total Title 1 (Staff expenditure)		6,488,000	6,488,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2000	Rental of office building	480,000	480,000
2001	Guarantees		
2002	Contributions		
2010	Insurance		
2020	Charges (water, gas, electricity, works)	208,000	208,000
2030	Cleaning and maintenance		
2040	Furnishing of premises	10,000	10,000
2050	Security and surveillance		
2090	Other expenditure on buildings		
20	Office building and associated costs	698,000	698,000
2101	Hardware, infrastructure and related services	325,000	325,000
2102	Software development, licenses and related services	765,000	765,000
2103	Other expenses maintenance and repair		
21	Information technology purchases	1,090,000	1,090,000
2200	Purchase office equipment	0	0
2201	Rentals office equipment	0	0
2202	Maintenance utilisation and repair	5,000	5,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
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	40,000	40,000
24	Telecommunication and postal expenses	40,000	40,000
2500	Formal meetings	80,000	80,000
25	Expenditure on formal meetings	80,000	80,000
2600	Administrative costs in connection with operational activities	30,000	30,000
2601	Events targeting IMI projects	0	0
2602	Workshops	220,000	220,000
2603	Knowledge management	0	0
26	Administrative costs in connection with operational activities	250,000	250,000
2700	External communication	60,000	60,000
2701	Events external communication	200,000	200,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2702	Material	40,000	40,000
27	External communication, information and publicity	300,000	300,000
2800	Ex-post audits	200,000	200,000
2801	Studies, consultancy	100,000	100,000
2802	Audit services	55,000	55,000
2803	Accounting services	70,000	70,000
28	Service contracts	425,000	425,000
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)		3,012,000	3,012,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3000	Implementing the research agenda of IMI1 JU		14,000,000
3001	IMI1 JU Call 1		
3002	IMI1 JU Call 2		
3003	IMI1 JU Call 3		
3004	IMI1 JU Call 4		
3005	IMI1 JU Call 5		
3006	IMI1 JU Call 6		
3007	IMI1 JU Call 7		
3008	IMI1 JU Call 8		
3009	IMI1 JU Call 9		
3010	IMI1 JU Call 10		
3011	IMI1 JU Call 11		
3012	Exploring New Scientific Opportunities (ENSO) 2012		
3013	Exploring New Scientific Opportunities (ENSO) 2013		
3020	Implementing the research agenda of IMI2 JU		120,000,000
3021	IMI2 JU Call 1		
3022	IMI2 JU Call 2		
3023	IMI2 JU Call 3		
3024	IMI2 JU Call 4		

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3025	IMI2 JU Call 5		
3026	IMI2 JU Call 6		
3027	IMI2 JU Call 7		
3028	IMI2 JU Call 8		
3029	IMI2 JU Call 9		
3030	IMI2 JU Call 10		
3031	IMI2 JU Call 11		
3032	IMI2 JU Call 12		
3033	IMI2 JU Call 13		
3034	IMI2 JU Call 14		
3035	IMI2 JU Call 15		
3036	IMI2 JU Call 16		
3037	IMI2 JU Call 17		
3038	IMI2 JU Call 18		
3039	IMI2 JU Call 19		
3040	IMI2 JU Call 20		
3041	IMI2 JU Call 21		
3042	IMI2 JU Call 22		
3043	IMI2 JU Call 23		
3100	Horizon Europe *	205,180,000	75,400,000
3101	IHI JU Call 1		
3102	IHI JU Call 2		
3103	IHI JU Call 3		
3104	IHI JU Call 4		
3900	Evaluations experts	600,000	600,000
3999	Recovery Ex-post audit		
30	Implementing the research agenda of IMI2 JU	205,780,000	210,000,000
Total Title 3 (Operational expenditure)		205,780,000	210,000,000
Total expenditure		215,280,000	219,500,000

*No indicative budget per Calls available, more detailed budget per Calls will follow in the subsequent budget amendments.

6 Annex

6.1 IKAA Plan for 2023

The IKAA Plan shall be composed of two types of additional activities:

- Project-specific additional activities 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 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.

Potential project-specific additional activities for 2023 related to projects to be selected under the IHI JU calls that would be launched in 2023 may be planned from full proposals submission stage⁴⁴. However, the exact nature of these activities and their amounts planned will be known only when the GB will approve the list of projects selected for funding. Therefore, the IKAA Plan 2023 including the project-specific additional activities will be subject to a separate GB decision before publication on the IHI JU website.

Potential programme-specific additional activities expected to be carried out by IHI JU private members in 2023 are identified in the IKAA Plan below.

⁴⁴ “Costs associated to 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.

IKAA Plan⁴⁵

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Support to additional R&I				
Support to public-private partnership cooperation	Facilitating data sharing in precompetitive projects: User-friendly online IMI/IHI Data Sharing Playbook to facilitate data sharing including solutions, good practice, workflows, and document templates, etc. (consultancy support, time, workshops)	General objective c	IMI2 projects with data-sharing dimension, including but not limited to ND4BB projects	10,000
Support to public-private partnership cooperation	Science and technology watch and building cross sector understanding and integration to increase the impact of projects and enable deployment of results: desk research, workshops	Task d	n.a	10,000

⁴⁵ The IKAA Plan 2023 includes only potential programme-specific additional activities expected to be carried out by IHI JU private members in 2023. It does not include project-specific additional activities.

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	<p>Complementary research activities focused on the uptake of results from the IMI CARE project:</p> <p>One of the goals of the CARE project is the development of therapeutics to address the current and/or future coronavirus outbreaks. To identify potential antiviral drugs, more than 800,000 compounds in various assays were screened. These screening efforts resulted in numerous hits and hit series that are being evaluated under the umbrella of the CARE project.</p> <p>One chemical series is further being developed internally. These additional activities complement the other activities, e.g. the development of mAbs, performed under the IMI CARE project to accelerate the development of a potential COVID-19 treatment, contributing to the world's response to the current COVID-19 outbreak, and ensure we are better prepared for further coronavirus outbreaks in the future.</p>	General objectives a and b	CARE	2,707,150

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	<p>Complementary activities focused on the uptake of results from the IMI EBOVAC Programme:</p> <p>In support of the Janssen Ebola vaccine licenses (Ervebo and Mveabea licenses) Janssen is continuing the research and development efforts. These activities add on to the work performed on the IMI Ebovac1-2-3 projects to ensure the future manufacturing of Ebola vaccine supplies can be maintained. This also includes EMA post marketing commitments, lifecycle management activities, and process development optimizations</p>	General objectives a and b	EBOVAC3	967,748
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	<p>Complementary research activities focused on the uptake of results from the IMI ESCULAB project:</p> <p>The IMI ESCULAB envisages the screening of a shared compound collection on a set of novel targets owned by the various consortium members. Each consortium member screens a number of unique targets during the project and (if successful) identifies a number of active hit compounds / lead series of compounds, suitable for further development. Such further development activities are no longer part of the project, and occur outside or after the project.</p>	General objectives a and b	ESCULAB	440,000

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
	Further chemistry investigation into the lead series, synthesizing additional compound analogues to improve the activity, SAR and profile of the compound, to come to an Optimized Lead or even NME candidate, and the biological and in-vitro ADME-TOX evaluation of these additional or improved compound analogues, including secondary and tertiary in-vitro or in-vivo activity evaluation on the disease target.			
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	Research and innovation activities supportive of PPP projects in EU. Optimization of clinical trial design and recruitment. Developing and implementing strategies to maximize patient engagement and incorporation of patient preferences in trial design and data sharing.	General objective a	Trials@Home, FACILITATE, EHDEN, H2O, SISAQOL and other projects	458,000

OVERVIEW ESTIMATED IKAA FOR YEAR 2023

Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	Uptake of results of IMI2 project RESCEU: Support to the sustainability of the biobank of the IMI2 RESCEU project (Respiratory syncytial virus consortium in Europe)	Specific objectives a and b	RESCEU	18,333
Creating new business opportunities				
Matchmaking between different start-ups, SMEs, participating companies, stakeholders	Sustainability and deployment of project assets: Activities to guide project teams in sustaining their project assets by enabling resource effective (re)use of project outcomes, on a consortium level or within the company (e.g. continued database access, FAIRIFICATION of data, further EFPIA-wide sustainability arrangements, bridging between existing knowledge networks in the field of asset deployment, ...)	General objective a, specific objectives b and d	Entire IMI2 portfolio and upcoming IHI portfolio	610,918

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Supporting ecosystem development				
Activities to develop the ecosystem at EU/national/regional or international level that will enable or accelerate the development of the solutions from the partnership	Europe-wide industrial engagement with stakeholders in rare diseases and ATMPs, with a focus on regulatory frameworks and active participation of SMEs within the project objectives linked to accelerated development of ATMPs.	General objectives a and c Task a	n.a	30,000
Communication, dissemination, awareness raising, citizen engagement				
Knowledge building in the specific area and/or among stakeholders community	Analysis of IMI projects regulatory science impact , including mapping of IMI projects against EMA regulatory science research needs.	Task d	Relevant IMI projects need to be mapped	30,000
Organisation of conferences and webinars on specific topics, networking events	Workshop with stakeholders to explore facilitate deployment and upscaling of results such as digital technologies and dissemination activities to put the IMI Scaling Up Field Manual into practice.	Task c	n.a	5,000

OVERVIEW ESTIMATED IKAA FOR YEAR 2023				
Additional Activities type	Description of the Additional Activities	Link to JU objectives/tasks [1]	Link to JU project/ topic (if applicable)	Estimated value for year 2023 (in EUR)
Investment in societal uptake and citizen engagement	Mapping and analysis of impact projects related to modernisation and patient centricity of clinical trials and to optimisation of health outcomes + communication/dissemination activities.	Task e	IMI clinical trials projects	160,000
TOTAL ALL PLANNED IKAA				5,447,149

[1] IHI JU's objectives and tasks are defined in Articles 115 and 116 of the Council Regulation (EU) 2021/2085



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