innovative health initiative

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2022
Second Amended Work Programme

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

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

Table of Contents

1 Chronology and list of reviews

Version	Date of the adoption by the GB	Items
Version 1 – Annual Work Plan 2022, as part of the list of decisions adopted by the Governing Board of the Innovative Medicines Initiative 2 Joint Undertaking that shall continue to apply for the Innovative Health Initiative Joint Undertaking	16.12.2022	**n/a**
Version 2 – amended IHI JU Work Programme 2022	17.06.2022	**all sections**
Version 3 – Second amended IHI JU Work Programme 2022	08.12.2022	• **2 List of acronyms, definitions and abbreviations** • **4.2 Operational activities of IHI JU for 2022** • **4.3 Support to Operations of IHI JU in 2022** • **5 Amended Budget** • **6.1 IKAA Plan for 2022** • **6.4 IHI call 3**

2 List of acronyms, definitions and abbreviations

ACRONYM	MEANING
ABAC	Accrual Based Accounting System
AD (HR)	Administrator
AER	Average error rate
AI	Artificial intelligence
AMR	Antimicrobial resistance
AST	Assistant
ATMPs	Advanced therapy medicinal products
BOA	Back-office arrangements
CA (Budget)	Commitment appropriation
CA (HR)	Contractual Agent
CDSS	Clinical decision support system
COCIR	European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See https://www.cocir.org/
Council Regulation (EU) 2021/2085	Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014. See https://eur-lex.europa.eu/eli/reg/2021/2085
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)
DHT	Digital health technologies
DMO	Document Management Officer

ACRONYM	MEANING
DNA	Deoxyribonucleic acid
DPO	Data Protection Officer
EC	European Commission
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 here: https://www.efta.int/about-efta/european-free-trade-association
EHRs	Electronic health records
EMA	European Medicines Agency
ERNs	European Reference Networks
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/
FAIR	Findable, accessible, interoperable, reusable
FC	Financial contributions
FG	Function group
FTE	Full-time equivalent
FP	Full proposal
FWC	Framework contract
GA	Grant Agreement
GAP	Grant Agreement preparation

ACRONYM	MEANING
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.
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
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
IVD	in-vitro diagnostic
JUs	Joint Undertakings
KDT JU	Key Digital Technologies Joint Undertaking. See https://www.kdt-ju.europa.eu/
KPI	Key performance indicator
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

ACRONYM	MEANING
mRNA	Messenger ribonucleic acid
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 in third countries outside of the EU Member States and countries associated to Horizon Europe.
NPs	Nanoparticles
OLAF	European Anti-Fraud Office
PA	Payment appropriation
PPP	Public-private partnership
PPI	Patient preference information
PREMs	Patient-reported experience measures
PROMs	Patient-reported outcome measures
rAAV	Recombinant adeno-associated virus
R&D	Research and development
R&I	Research and innovation
RAE	Risk assessment exercise
RIA	Research and Innovation Action
SMEs	Small and medium-sized enterprises
SEDIA	Single Electronic Data Interchange Area (SEDIA), the funding & tender opportunities portal of the European Commission. See https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home
SIP	IHI JU Science and Innovation Panel
SOP	Standard operating procedure
SRIA	Strategic Research and Innovation Agenda
SRG	IHI JU States' Representatives Group

ACRONYM	MEANING
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 and builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 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 combating 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 provides 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.

IHI JU builds on lessons learned from the IMI2 JU, with a broadened scope and with new partners and stakeholders. 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 establishing 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 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 SRIA[2] defines the overall scope of activities of IHI JU, in line with its founding legislation[3], 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.

[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.ihi.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

3.3 Strategy for the implementation of the programme

The key focus of the strategy for 2022 will be to finalise the setting up of the new governance structure, to organise the constitutive meetings of the SRG and the SIP, and to ensure the implementation of the SRIA priorities. The latter will be achieved through the launch of the first open and competitive calls for proposals. The work of the SIP will be central to the development of the scientific priorities and topics for the 2022 calls for proposal. 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 identifying synergies with other parts of Horizon Europe, such as missions, partnerships or specific programmes, as well as establishing links with international organisations.

Across all of the activities planned, a key element 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's work will be to continue to support the projects established under IMI1 JU and IMI2 JU. This is important for two reasons. Firstly, coupled with the launch of new calls for proposals, 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 (as the legal successor of IMI2 JU) and its impact on patients and wider society.

4 Amended Work Programme 2022

4.1 Executive summary and message from the Executive Director

2022 will be the first full year of IHI JU implementation. The Programme Office will prepare all of the structures for governance and implementation (work which started at the end of 2021) and fine tune and solidify processes to optimise the functioning of the governing bodies of IHI JU. This will allow implementation of the SRIA and will result in the launch of the first calls for proposals.

We will commit these funds to build new multi sectorial public private partnerships that take advantage of the ongoing technology convergence in the health sector, advances in digitalisation and the use of 'big' data, accelerating the pace of innovation and allowing 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 a large legacy of IMI projects that IHI JU is managing.

We will be implementing 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 proactively communicate about opportunities for funding for IHI JU, ensuring the widest possible involvement from all sectors, SMEs and EU 13 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 overlapping agendas. The initial contacts will be established in this regard with GH EDCTP3 JU, the Cancer Mission, KDT JU and HERA.

4.2 Operational activities of IHI JU for 2022

4.2.1 Objectives, Indicators and Risks

Key objectives

The key objectives for IHI JU operations in 2022 are identified by the GB in the IHI JU amended Work Programme and by the management at operational level.

Key operational objectives for 2022 as follows:

1. establish the IHI JU governance structure and the necessary operational and administrative processes and standards, in accordance with the 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 [4];
2. execute the Strategic Research and Innovation Agenda priorities, enabling the active engagement of industry sectors covering the pharmaceutical, biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area, and a range of other key other 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;
3. ensure continuity with and manage the legacy from IMI2 JU;
4. ensure sound budget implementation;
5. develop and deploy an assertive communication strategy to promote IHI JU, its objectives and new rules for participation, and to target audiences (with particular emphasis on new players and newcomers), with the aim of attracting high quality applications to IHI JU´s first calls for proposals;
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.

[4] OJ L 427, 30.11.2021, p. 17–119 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV) : https://eur-lex.europa.eu/eli/reg/2021/2085

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 alliances 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 along the programme. In line with the challenges of today's scientific landscape, the performance of IHI JU will be also evaluated by looking at 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 application of artificial intelligence 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 ...

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

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

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

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

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

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

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

The IHI JU specific key performance indicators (KPIs) are linked to the IHI JU vision and have been developed ensuring that there is clear alignment between the overall objectives of IHI JU and the measures used to monitor progress throughout the life of the programme. The KPIs have been elaborated and guided by the so-called RACER principles[5].

KPI name	Unit of measurement	Baseline[6]	Target[7] 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[8]	25%	70%	80%	85%	90%	
1.3. Engagement of regulators	Number of projects interacting with regulators[9] to contribute to new or improved guidelines or methodologies	13	0	5	10	20	

[5] 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

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

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

[8] 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.

[9] 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-stakeholder 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)	Number of: • new tools for studying new potential drug targets such as new pharmacological tools, therapeutic modalities, and patient-derived assays available to the scientific community; • new tools to test diagnostically and/or therapeutically relevant hypotheses in pre-clinical models and/or clinically in uncharted areas of disease biology; • new tools for prediction, prevention, interception, surveillance, diagnosis, treatment, and management options to prepare for major epidemic outbreaks; • new biomarkers of disease (relevant for diagnosis, efficacy, safety, or prevention) identified and experimentally validated; • new taxonomies of disease or new stratifications to define patient sub-populations.	100	0	50	120	150	

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

[10] 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[11] included in the list of the WHO Europe Health 2020 priority areas[12]	No baseline available	90%	90%	90%	90%	

[11] 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".*

[12] https://www.euro.who.int/__data/assets/pdf_file/0011/199532/Health2020-Long.pdf

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	Number of activities in which cross-sector collaboration drives health innovation, such as: • Spin-off companies, entities or activities created based on outputs of the project (e.g., new commercial or non-profit entities) • Collaboration agreements between large companies[13] & SMEs[14] established for purposes that go beyond the scope of the project during and/or after project lifetime. • Other activities where the joint contribution of different partners has generated cross-sectoral health innovation. Examples of collaboration activities across health industry sectors that contributed to the transition to a green and digital economy (as outlined in the new Industrial Strategy for Europe[15])	No baseline available	0	5	10	20	

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

[14] 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

[15] "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 that aims to identify and assess any event that could pose a threat to the achievement of IHI JU objectives and to determine how the risks should be managed. Therefore, risk management is an integral element of the strategic planning and monitoring cycle.

Following the risk assessment exercise carried out by the Programme Office 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 2022. Most of these risks relate to the external environment (outside IHI JU), operational processes and human resources:

- The establishment of the IHI JU governance structure and the necessary operational and administrative processes and standards, in accordance with the Council Regulation (EU) 2021/2085.
- The termination of the service Llvel agreement concluded with the EC providing the JUs with accounting expertise and services and the EC proposal to integrate the position of accounting officer as part of the back office arrangements between the JUs set up under Horizon Europe.
- The building and maintenance of the IHI JU programme management platform by external parties.
- The complexity of research activities in healthcare and the uncertainties around key concepts from programme start.

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 2022 have also been appropriately estimated. Moreover, 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 2022 will contribute to the achievement of the general and specific objectives of IHI JU as defined in Council Regulation (EU) 2021/2085[16], by tackling the challenges and progressing to achieve the expected impacts in one or more of the five SRIA[17] scope areas/specific objectives. Due to their highly interlinked nature, it is expected that most of the activities in the scope of the priorities will address several of the areas simultaneously.

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 Council Regulation (EU) 2021/2085[18]. A systems approach to health care (prevention, rehabilitation, not only care for acute /chronic conditions), and the design of a healthy environment, should be fostered. The scope of the scientific priorities may also cover activities which, while not focused on individual disease areas, have the potential to generate results of transformational nature on innovation processes in healthcare.

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 with healthcare systems or onto the market as such.

During 2022, IHI JU will start to build a pipeline of ideas from a range of sources and stakeholders in the health community, including industry partners, the European Commission and potential contributing partners.

By the second half of 2022 the IHI JU dedicated portal[19] for receiving ideas from the wider health and research community for potential IHI topics will have become operational, enabling the reception of the first ideas.

The newly initiated Science and Innovation Panel (SIP), which comprises experts from the scientific community, various stakeholder groups, and sectors, will review the ideas and determine how well they fit IHI JU's objectives and the SRIA and if they are suitable starting points for future topics of calls for proposals to be launched later on in 2022 (and beyond).

The activities funded by IHI JU will be designed taking in consideration synergies with other health-oriented initiatives, initially with partnerships to be created in Cluster 1 of Horizon Europe, complementing the actions of the EU4Health[20] programme and HERA[21] and upstream of the upcoming European partnership on transforming health and care systems[22], wherever relevant. It is also expected that IHI JU activities will

[16] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.427.01.0017.01.ENG

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

[18] 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.

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

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

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

[22] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-care-10-01

contribute to the Union priorities for health research and innovation, such as the Pharmaceutical Strategy[23] , Europe's Beating Cancer Plan[24], and digital policies including the European Health Data Space[25].

Participants in activities funded by IHI JU will have to ensure that the products and services that 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 purpose, the general conditions relating to the IHI JU calls included in this amended work programme specify additional exploitation obligations applicable to specific indirect actions.[26]

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. 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 the achievement of the impacts of this objective, for example IHI JU will launch the topics "**Cardiovascular diseases - improved prediction, prevention, diagnosis, and monitoring**", "**Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need**", and "**Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences**".

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). 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. 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 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. SO2 is central to the mission of IHI JU, therefore it is expected that a significant number of topics of IHI JU will contribute to its impacts. In 2022 for example IHI JU will launch the topics "**An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities**", "**Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiencies** ", and "**Strengthening the European ecosystem for Advanced Therapy Medicinal Products (ATMPs) for rare diseases**".

All activities in scope of the scientific priorities of 2022 are expected to contribute to Specific Objective 3 (SO3), which addresses 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 one topic will be launched in 2022 directly contributing to SO3 impacts: "**Patient generated evidence to improve outcomes, support decision making, and accelerate innovation** ".

[23] https://ec.europa.eu/health/system/files/2021-02/pharma-strategy_report_en_0.pdf

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

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

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

Specific Objective 4 (SO4) addresses the challenge 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 complexity. Furthermore, security, explainability for users, and ethical considerations should be ensured when developing new data analytics tools, including the use of artificial intelligence. In this context, IHI JU will specifically launch the topic **"Access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet public health need".** In addition, it is expected that most of the other activities funded in 2022 will contribute to the achievement of the impacts of this objective.

Specific Objective 5 (SO5) addresses the methodological challenges in assessing the added value of health interventions based on emerging and converging technologies, which can only be partially addressed with current available tools and methods. This is partly because technology categories converge in ways that alter the delivery of health care. In addition, a more integrated and people-centred approach would require assessment of contributions from individual technologies into the combined effect of the various health interventions delivered throughout the health care continuum. Methodological challenges include, among others, the development and consistent use of outcomes measures relevant to patients. In addition, implementation of technological innovations in health care systems should ensure that innovation responds to people and health care system needs. To contribute to the achievement of the impacts of this objective, for example IHI JU will launch the topic " **Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union**".

IHI JU's activities will play an important role in supporting the development of innovations to prevent, faster diagnose and treat cancer and thus significantly contribute to the Europe's Beating Cancer Plan and the Cancer Mission[27]. In this context, for example IHI JU will launch the topic "**Next generation imaging and image-guided diagnosis and therapy for cancer"** (which will contribute to the achievement of the impacts of the Specific Objectives 2 to 5) and the topic " **Personalised oncology: Innovative people centred, multi-modal therapies against cancer**" (which will contribute to the achievement of the impacts of the Specific Objectives 2 and 3).

Impacts achieved in 2022 will be monitored using the predefined key performance indicators, as well as via bibliographic analysis to capture project scientific outputs in terms of publications and collaboration.

[27] https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/cancer_en

4.2.3 Calls for proposals

4.2.3.1 General presentation of the 2022 calls for proposals

2022 will comprise the launch of three competitive calls for proposals (two single-stage calls and one two-stage call) implementing the 2022 scientific priorities.

The topic ideas and indicative budget will be defined from a range of sources, including industry partners, potential contributing partners, and other stakeholders in the health community and in consultation with the SIP and the SRG. The Programme Office will lead the drafting of the topic texts and the work pogramme will be updated accordingly.

The launch date for the first two calls for proposals was on 28 June 2022. The IHI JU call 1 is a single-stage call, while the IHI JU call 2 is a two-stage call.

One more single-stage call for proposals, namely Call 3, will be launched on 13 December 2022.

Timelines for the completion of the evaluation process and for the preparation of grant agreements will be kept as lean as possible but sufficient enough to ensure a high quality process with the aim of completing the signature of the Grant Agreements within the time to grant (TTG) timelines of the Horizon Europe framework, i.e. a maximum of eight months from the final date of submission of the FPs.

All the above reported timelines and deadlines will be reflected in the text of the relevant calls for proposals.

For IHI JU call 1:

In the single-stage submission evaluation procedure of call 1, the submission deadline was on 20 September 2022.

The scientific evaluation of the single-stage call took place in October 2022 and the applicants notified with the outcome by November 2022.

Grant Agreement Preparation (GAP) will be completed within 3 months from the notification to applicants invited to GAP (February or March 2023 depending on the notification date).

For IHI JU call 2:

In the two-stage submission evaluation procedure of call 2, the submission deadline for stage 1 was on 20 September 2022 and the one for stage 2 will be on 28 February 2023. The scientific evaluation of the 1st stage short proposals finished in October 2022 and the applicants notified of the outcome by December 2022.

Scientific evaluation of the full proposals (FPs) under the two-stage call will be completed by March 2023. GAP will be completed within 3 months from the notification to applicants, of the evaluation results of the full proposal, and maximum eight months from the final date of submission of the FPs, in line with the applicable time to grant (TTG).

For IHI JU call 3:

In the single-stage submission evaluation procedure of call 3, the submission deadline will be on 15 March 2023.

The scientific evaluation of the single-stage call will take place in March/April 2023 and the applicants will be notified of the outcome by June 2023.

Grant Agreement Preparation (GAP) will be completed within 4 months from the notification to applicants invited to GAP (end of September 2023).

4.2.3.2 Conditions of the calls for proposals and call management rules

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

The General Annexes of the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* to the calls for proposals covered by this amended Work Programme. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in this amended Work Programme.

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

All proposals must conform to the conditions set out in Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination.

The General Annexes of the Horizon Europe Work Programme 2021 – 2022 shall apply to the calls for proposals covered by this second amended Work Programme. Any specificity for IHI JU is highlighted in the sections below.

GENERAL CONDITIONS RELATING TO THE IHI JU CALLS

Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.

STANDARD ADMISSIBILITY CONDITIONS, PAGES LIMITS AND SUPPORTING DOCUMENTS

Part A ('Admissibility') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

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

- for a single-stage call, the limit for RIA full proposals is 50 pages;
- at stage 1 of a two-stage call, the limit for RIA short proposals is 20 pages;
- at stage 2 of a two-stage call, the limit for RIA full proposals is 50 pages.

STANDARD ELIGIBILITY CONDITIONS

Part B of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the call for proposals covered by this amended Work Programme unless otherwise provided in this amended Work Programme.

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

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

- While private members can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA.
- Further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided.
- The above eligibility condition and self-declaration requirement will not apply to the first stage of a two-stage application.
- At the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners.
- At project level, the maximum amount of non-EU IKOP is set to one hundred percent (100%). This is justified as a means to ensure the achievement of project objectives based on Article 119(4) and 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openess to non-EU IKOP in these calls.
- Furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

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

- Two-stage call: The applicants which are IHI JU members other than the Union, or their constituent entities and affiliated entities, and contributing partners and that are pre-identified in the topics – under the section 'Industry consortium' – of a Call for proposals shall not apply at the stage 1 of the call. The applicant consortium selected at stage 1 shall, in preparation for the proposal submission at stage 2, merge with the pre-identified industry consortium.

ENTITIES ELIGIBLE FOR FUNDING

In relation to the single-stage calls for proposals covered by this amended Work Programme the relevant provisions of the Part B of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis*.

By way of derogation, in line with Article 5(2)(a) and Article 119(3) of the Council Regulation (EU) 2021/2085, in relation to the two-stage calls for proposals covered by this second amended Work Programme the following provisions shall apply:

- Legal entities identified in the topic text of the call for proposals shall not be eligible for funding from IHI JU. Nevertheless, these entities will be entitled to provide contributions as IHI JU members other than the Union, or contributing partners.

- Legal entities participating in indirect actions selected under this type of calls for proposals shall not be eligible for funding where:

  (a) they are for-profit legal entities with an annual turnover of EUR 500 million or more;

  (b) they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);

  (c) they are directly or indirectly controlling a legal entity referred to in point (a).

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

With reference to Article 23 of the Council Regulation (EU) 2021/2085, eligibility of participants in a proposal submitted to a call for proposals for any of the topics in this amended work programme will take into account any application of Art 22(5) of the Horizon Europe Regulation triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

Part B ('Eligibility') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

TECHNOLOGY READINESS LEVELS (TRL)[28]

TRL definitions included in Part B ('Eligibility') of the General Annexes to Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

EVALUATION RULES

Part D ('Award Criteria') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme with the following additions: The relevant calls for proposals launched under this amended Work Programme shall specify whether the call for proposals is a single-stage or two-stage call, and the predefined submission deadline.

Award criteria and scores:

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

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

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

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

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. The best ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

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

[28] The TRL is not utilised for IHI call 1, call 2 and call 3 , however, it is anticipated to be used in future IHI calls

Under the stage 2 preparation process, the applicant consortia of the second and third-ranked short proposals (stage 1) for each topic may be invited by the IHI JU, in priority order, for preliminary discussions with the industry consortium if the preliminary discussions with the higher ranked proposal and the industry consortium fail. IHI JU may explore this possibility if the first ranked applicant consortium and the industry consortium jointly notify IHI JU that the preparation of a joint full proposal is not feasible. If this is the case, the first ranked consortium and the industry consortium shall notify IHI JU without delay, not later than within 30 days from the invitation to submit the stage 2 proposal. This notification must be accompanied by a joint report clearly stating the reasons why a stage 2 proposal is considered not feasible in order for IHI JU to take the decision whether to invite the lower ranked consortium. In the absence of a joint notification within the deadline, it is deemed that the first ranked applicant consortium and the industry consortium are going to submit the joint stage 2 proposal. Accordingly, the second and third-ranked short proposals will be formally rejected. Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first stage evaluation are communicated to the applicants.

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

1. clarify the proposals and help the panel establish their final assessment and scores, and/or

2. improve the experts' understanding of the information presented

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

The IHI JU evaluation procedure is confidential.

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

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

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT PREPARATION

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

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

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

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

Indicative date for the signing of grant agreement:

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

Part G ('Legal and Financial setup of the Grant Agreements') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

BUDGET FLEXIBILITY

Part F of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* to the calls for proposals covered by this amended Work Programme.

SUBMISSION TOOL

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

PROPOSALS INCLUDING CLINICAL STUDIES[29]

Under the single-stage submission procedure of call 1 and for stage 2 of the two-stage submission procedures of call 2: Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system[30].

Under the single-stage submission procedure of call 3: Applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system[31].

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

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

- The participants must, during the liftetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly[32] available and accessible, at fair and reasonable conditions.
- In particular, and always to the extent permitted by applicable competition law:
    a) At the proposal stage[33], and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.[34]

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

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

[31] same as footnote 30

[32] This covers EU Member States and Countries that are Associated to Horizon Europe at the time of call opening.

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

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

b) At the project interim review stage, if relevant[35], the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.

c) At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.[36]

d) Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (in total 4 years from project end), a confidential report[37] must be submitted to IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

JU RIGHT TO OBJECT TO TRANSFER/EXCLUSIVE LICENSING

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2021-2022 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

4.2.3.3 Country specific eligibility rules

Following the Horizon Europe Programme Guide, participation in IHI JU indirect actions will be open but eligibility for funding will be however limited to legal entities established in an EU Member State, Associated Country or Low and Middle Income Countries (please consult the list in the Horizon Europe Programme Guide[38]).

Given the invasion of Ukraine by Russia and the involvement of Belarus, legal entities established in Russia, Belarus or in any occupied territory of Ukraine are not eligible to participate in any capacity. Exceptions may be granted on a case-by-case basis for justified reasons, such as for humanitarian purposes, civil society support or people-to-people contacts.

[35] As discussed, this interim point allows a realistic appraisal of the 3A possibilities during the proejct lifetime, particularly as to the viability of specific expected 3A results.

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

[37] Cognizant of IP sensitivities, confidential info, and commercial realties, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:

a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
b) Broad description of expected downstream actions (including product and service applications);
c) broad assessment of expected impact of the above downstream actions towards ensuring Affordability, Availability, and Accessibility.

2. **A Confidential Annex** in which:

a) The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:
   i. The planned measures to be taken to effect the 3A obligations;
   ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
   iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

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

4.2.4 Calls for tenders and other actions

On Q4, IHI will launch an open call for tenders for the conclusion of a multiannual framework contract to acquire periodic reports on various outputs of projects funded by IMI and IHI. The estimated total budget would be EUR 800,000.

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

IMI calls	Total Projects	Ongoing at 01.01.2022	Of which Total reports	Project ending in 2022
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	
IMI1 call 7	2			
IMI1 call 8	4			
IMI1 call 9	4	1	1	
IMI1 call 10	1	1	1	1
IMI1 call 11	8	2	2	1
Total IMI1	**59**	**5**	**5**	**2**
IMI2 call 1	1	1	1	0
IMI2 call 2	8	0	0	0
IMI2 call 3	5	3	3	3
IMI2 call 4	1	0	0	0
IMI2 call 5	6	4	4	3
IMI2 call 6	4	3	3	2
IMI2 call 7	7	5	5	2
IMI2 call 8	4	4	4	1
IMI2 call 9	6	4	4	1
IMI2 call 10	8	7	7	1
IMI2 call 11	3	0	0	0
IMI2 call 12	7	7	7	1
IMI2 call 13	13	13	13	4
IMI2 call 14	4	4	4	1
IMI2 call 15	7	7	7	1
IMI2 call 16	5	5	5	0

IMI calls	Total Projects	Ongoing at 01.01.2022	Of which Total reports	Project ending in 2022
IMI2 call 17	3	3	3	0
IMI2 call 18	6	6	6	0
IMI2 call 19	2	2	2	0
IMI2 call 20	6	6	6	0
IMI2 call 21	8	8	8	
IMI2 call 22	3	3	3	0
IMI2 call 23	6	6	6	**0**
Total IMI2	123	101	101	24
IHI call 1	-	-	-	-
IHI call 2	-	-	-	-
IHI call 3	-	-	-	-
Total IHI *	-	-	-	-
Totals IMI+ IMI2 +IHI	182	106	106	26

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

Monitoring and analysis of projects' results

106 project periodic reports will be submitted in 2022 (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 2022, 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 finished IMI2 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 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 different therapeutic fields.

4.2.6 Cooperation, synergies and cross-cutting themes and activities

Council Regulation (EU) 2021/2085 states that IHI JU will 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 ensuring uptake of results. Therefore, in 2022 it is planned that the IHI JU will begin to explore possible synergies with other health-oriented initiatives, initially with partnerships to be created in Cluster 1 of Horizon Europe (such as GH EDCTP3 JU), complementing the actions of the EU4Health[39] programme and HERA[40] wherever relevant. It is also expected that IHI JU activities will contribute to and complement those of the Digital Europe programme[41] 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.

Patients

IHI JU's goal is to translate health research and innovation into tangible benefits for patients and society by enabling 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 the projects that it funds 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, to project planning, implementation evaluation processes and content. Therefore, the systematic involvement of patients in IHI JU's projects and activities will be further supported, facilitated, and strengthened.

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

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

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

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

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 engage with all relevant regulatory authorities. Building on the IMI2 JU's successful collaboration with the European Medicines Agency (EMA), IHI JU will 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 awareness of applicants and projects' consortia about regulatory needs to be considered when relevant. It will also continue to encourage and support consortia to interact early 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 EMA[42].

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 develop novel synergies wherever possible.

IHI JU will also strengthen engagement with other international agencies, and 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.

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

4.3 Support to Operations of IHI JU in 2022

4.3.1 Communication, dissemination and exploitation

Dissemination and information about project results

Although the responsibility for maximising the impact of their own research and innovation lies primarily with the project consortia, promoting the successes of projects is a core element of the IIHI JU communications, dissemination and exploitaition 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 and exploitation tools and channels for the promotion of IMI projects and their results, including project deployment and upscaling, 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 IMI staff and IMI projects.

In 2022, IHI JU expects to receive 33 final project reports. However, some projects may request an extension of their duration which results to the postponing of the final report to 2023.

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 upon information provided in the respective 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

A twofold objective: focus on IMI project results and promote the IHI JU programme

In 2022 a significant number of ongoing IMI projects will be yielding results. The 2022 IHI JU communication work plan will focus on how both newly launched and ongoing projects will meet and have met the challenges they were set 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.

Since IHI JU will still be a very young programme in 2022, the communication team's second strategic objective will be to promote the IHI JU brand, and to support 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. IHI JU info days, brokerage events and targeted webinars, as well as external events will remain a crucial instrument to address this objective.

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 communication 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 its work of IHI and 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. Most essential framework contracts are already in place and will be renewed beyond 2022. IHI JU will also seek the possibilities to further advance with the eProcurement.

Furthermore, IHI JU will launch a low value negotiated procedure with an estimated value of EUR 25,000 for the conclusion of a service contract with a consultant to help with the design of the IHI JU communications strategy.

Finally, as a consequence of the migration to a more efficient and hybrid way of working and the synergies created by GH EDCTP3 JU, the Programme Office will significantly reduce the space occupied at its premises. This will result in a rearrangement of the office space. IHI JU may conclude supply contracts through negotiated procedures for the acquisition of furniture which would facilitate hot desking.

4.3.3 Other support operations

4.3.3.1 Relevant functions and administrative synergies within back office arrangements[43]

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 practice sharing takes place on a regular basis among the peers. For example, 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 concretely serves business needs e.g. in joint business continuity planning, managing office spaces and organising joint procurements of the common infrastructure. A specific viability assessment will be carried out in 2022 and its results will be put into practice in alignment with the Council Regulation (EU) 2021/2085.

The back office arrangements (BOA) (establishement of those arrangements under the form of service level agreements between EU Joint Undertakings as originally foreseen by 30/11/2022) for the prioritised service areas for 2022 (accounting, IT, contract management and legal support for procurement and HR) will be put in place or be at least in a state of advanced planning by the set deadline, 30 November 2022. The areas selected seem viable, do not risk the core business and aim to bring added value. The Executive Directors decided to consider the additional areas mentioned in the regulation for possible inclusion in a back office arrangement as from 2023, when the four initial BOA areas are fully implemented and the performance of the BOAs could be assessed. In several of these additional areas the JUs already collaborate across a range of activities. For example, for the area of logistics several JUs have been located in the same building since 2010 and the contract and building management is coordinated by one JU for the benefit of all the JUs. These JUs share also the common meeting rooms and management of these meeting rooms including the IT equipment. Under the future BOA in this area these activities will be formalised.

In the area of communication, the JUs have organised their work in different ways and therefore further reflection and discussion is required to see how communication activities can be incorporated into a BOA. IHI JU has a well-established and efficient communications team to carry out relevant tasks e.g., engaging with European institutions, dissemination, organising events, writing and editing work. For events management IHI JU is using a FWC from the EC and therefore benefiting the procurement organised by the EC.

In the area of anti-fraud, IHI JU is organising a dedicated anti-fraud training for its staff in 2022 in collaboration with OLAF. This training is open for all the other JUs' staff to attend. Options for further viable collaboration in the anti-fraud area will be considered by the Executive Directors in 2023.

As a result, the close collaboration among the JUs will be even more enhanced and additional synergies will be implemented to gain further cost efficiencies.

In 2022 IHI JU will drive further synergies with GH EDCTP3 JU by providing part of the IHI Programme Office's space for GH EDCTP3 JU's use. This will bring cost benefits to IHI JU and is enabled by the new hybrid working mode following the EC guidelines.

In 2022 IHI JU also is running a selection procedure together with KDT JU resulting in a joint reserve list for the position of the Accounting and Finance Correspondent.

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

4.3.3.2 IT operations

IHI JU's information technologies (IT) strategic objective is to deliver value to the business and to be a key enabler of new business 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 Joint Undertakings that are also located in the same premises. This provides efficiency, economy of scale and gains in the operation of the organisation.

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 and in continuity with the successful work in the past years, the IT team will focus its 2022 activities on the following areas:

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

We will continue monitoring and maintenance of the common Infrastructure-as-a-Service (IaaS) infrastructure and end-user office-automation support covering incidents, service requests and improvements.

Jointly with other JUs, and following common DPIA, we will further implement and extend use of Microsoft 365 Software-as-a-Service (SaaS) which eventually became the main office automation and IT infrastructure tool. The Programme Office will continue following general IT trends in adopting SaaS solutions both from the market and EU institutions and agencies (mainly European Commission).

4.3.3.2.2 Business operations' information systems

IHI JU's business operations will continue to be based mainly on the eGrants for the management of evaluations and grants. The IT team will monitor satisfactory functioning for all end-users, in close liaison with the European Commission services, including SPOC functions.

SOFIA will be maintained as the main tool for managing ongoing IMI1 projects and as a complementary tool for missing IMI2 specific requirements in eGrants (e.g. EFPIA and Associated Partners' annual reporting of in-kind contributions, Overview of Project Outputs). Together with the science operations team and IHI JU representatives in the key user group, we will start a gap analysis on IHI JU functionalities in eGrants and their potential implementation in SOFIA.

The Programme Office will also continue further development of the data warehouse and Qlik sense analytical platform and mashups with particular focus on integration of new IHI JU data, data quality and reliability.

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

4.3.3.2.3 Collaboration, communication and administration management information systems

The IHI JU Intranet will continue its evolution and will be completely re-built on M365 SharePoint technology. It has already proved its effectiveness as main internal communication tool, enabling collaboration, and supporting business activities. The core parts of new intranet are service pages by teams/area of activities with the main purpose of informing other colleagues.

New private sites, providing support to the governance bodies (GB, SRG, SIP and 'collecting ideas' tool) will be created in SharePoint online as well. We will initiate a separate project (incl. study and proof of concept) for migrating of archived files from the old IMI document management system (DORA) and shared drive to SharePoint.

4.3.3.3 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 No19/2021[44]), establishing a new records management policy for IHI JU based on the European Commission decision C(2020)4482[45].

The Record Management Working Group[46] 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 high awareness among staff, 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.
An effective record management helps to meet the 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 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.

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.

[44] ED Decision 19/2021 Ares(2021)5474488

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

[46] 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).

4.3.3.4 Accounting

Following the termination of the accounting services unilaterally by DG BUDG, IHI JU will need to reorganise the accounting officer services in 2022. This will be done together with the other JUs as part of the back office arrangements. Before the termination as of 1 December 2022, a proper handover will need to be carried out by DG BUDG to ensure the JU's business continuity and sound implementation of accounting tasks. The decision on the new Accounting Officer will be taken during 2022 by the GB.

4.3.3.5 Feedback to policy

European partnerships are a key element of the policy approach of Horizon Europe.
The SRIA 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 contributes 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 partnerships to be created in Cluster 1 of Horizon Europe, complementing the actions of the EU4Health[47] programme and HERA[48] wherever relevant. It is also expected that IHI JU activities will complement those of the Digital Europe programme[49] that will deploy digital capacities and infrastructure related to the health area.
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 in discussions during the drafting of their work programmes, 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 exploitation of research and innovation results and actively disseminate and exploit results, in particular for leveraging private investments and for policy development.

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

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

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

4.3.4 Human resources

4.3.4.1 HR management

In 2022 the total number of IHI JU staff is 55. In detail, 39 temporary agents (TA), 15 contract agents (CA), and 1 Seconded National Expert (SNE).

2022 will be a transitional and complex year for the Programme Office. The Programme Office will have to manage a large and complex legacy from IMI1 and IMI2 projects while leading the transition and setting up the new programme. This will have a significant impact on the management of the Programme Office human resources and on the staff turnover, thus the Human Resources team (HR), in cooperation with the IHI JU Management Team (MT), will explore measures to minimise potential impacts and to ensure business continuity.

In the light of the above, the 2022 objective for IHIhHumanrResources (HR) will be to ensure an efficient management of staff and an optimal working environment where staff members are engaged and satisfied with the working conditions and career development opportunities at IHI JU. To this end, the HR team will make sure to recruit, develop, assess, motivate and retain highly qualified staff with a view to ensure effective and efficient operation of the IHI JU and equal opportunities. This objective will be implemented through the following four main areas of operation:

4.3.4.1.1 Selection and recruitment

In 2022, one of 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.

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, 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.

To enhance IHI JU selection procedures a new selection and recruitment tool called SYSTAL will be implemented and fully operational in 2022.

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

4.3.4.1.2 Career development

To ensure that existing IHI JU 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). The HR team will make sure to establish a strong link between HR processes and business results, connecting the Programme Office overall strategic goals with staff performance management.

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.

4.3.4.1.3 Learning & development

To help the development and the personal and professional growth of IHI JU staff, the HR team will (i) further develop the learning and development framework paying particular attention to the training needs of its staff and the organisation, and (ii) organise training activities to keep staff knowledge up-to-date. In view of the new programme, particular attention will be given to retraining current IHI JU staff and to equipping them with the necessary set of competences and skills.

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 preserving a physically and psychologically healthy work environment where work is meaningful, and people have conditions to contribute 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 team-building 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 environment.

4.3.4.1.4 Legal matters

IHI JU will continue working closely with DG HR and the Standing Working Party (group following the Staff Regulations 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 2022 new implementing rules will need to be adopted by IHI JU (e.g. decision on working time and hybrid working; model decision on administrative inquiries and disciplinary proceedings; etc).

4.3.4.1.5 Strategy for achieving efficiency gains and synergies

Under the IHI JU 2022 Staff Establishment Plan, there will be a decrease in the human resources (1 less SNE), thus IHI JU will need to pay particular attention to the efficiency and cost-effective management of its resources.

This will be achieved by (i) reshuffling internal resources, to this end IHI JU will keep holding regular resources planning meetings to re-allocate staff on needs based to fill in internal gaps, support those areas of the business in more need, (ii) strengthening the collaboration with other joint undertakings through back office arrangements and mechanisms of pooling expertise for specific time-bound tasks.

In 2022, the JUs will continue sharing the human-resource 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 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.

4.3.4.2 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
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+AST+ 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 2022 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)	
Assistant to the ED	TA	0	AST 1- AST 4	AST 4	
Internal control	TA	0			FGIV
Executive Director	TA	0		AD 14	

4.4 Governance activities in 2022

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 2022. 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 programme 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 2022. 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 2022. 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 2022

4.5.1 Internal control framework

The IHI JU action plan 2022 for the implementation of the internal control framework is driven by three factors, which are considered crucial in order to ensure that the structure and resources in IHI JU continue to meet evolving organisational objectives and needs:

1. The impact of the transition to the new entity and the challenges and developments resulting from the implementation of the new Regulation 2021/2085. Even though the operational structure is continuing in 2022 and its financial framework largely remain the same, the whole governance structure will be changed in accordance with the Regulation 2021/2085.
2. The results of the risk assessment exercise against the objectives of the work programme 2022, the conclusion of the self-assessment of the effectiveness of the internal control system in 2021, and the implementation of the recommendations from the IAS audit Report (IAS.A2-2020-IMI JU-001).
3. The re-assessment of the JU internal control framework in view of the revision of the internal control indicators.

In addition, the unpredictability of the Covid-19 pandemic shall continue to be considered as a variable. Although the operational impact of the pandemic is under control, the evolution of the pandemic has to be monitored carefully in order to ensure business continuity.

In this context, the following operational objectives (presented in order of priority) have been identified for 2022:

- Objective 1: Set up and implement the organisational structure reflecting the new JU under Horizon Europe by adjusting internal control framework to the new governance arrangements and new objectives.
- Objective 2: Maintaining the robustness of the internal control framework and implement the revision of the indicators on control effectiveness considering the needs identified by the management.
- Objective 3: Monitoring the effectiveness of the internal control environment against IT security, communication policy and staff physical safety.

All these activities will be conducted in a timely manner and will be monitored through a defined set of KPIs, such as time to pay (TTP), budget implementation rate, staff trainings, etc. Best practice and the highest quality standards will also be ensured through the revision of the IHI JU Manual of Financial operations and other Standard Operating Procedures.

4.5.2 Ex-ante and ex-post controls

Ex-ante controls

The main objective of the Programme Office will be to ensure that on-going activities are conducted in a timely and efficient manner according to the principle of sound financial management. They will be monitored through the defined set of KPIs, in particular time to pay and the budget and work programme execution.

Best practice and highest quality standards will be ensured through the implementation of a set of standard operating procedures and checklists.

Specific attention will be paid to:

- validation of financial and technical reports;
- ex-ante controls for interim and final payments executing recovery orders where needed;
- raising the awareness of beneficiaries on financial and administrative aspects of H2020 rules and how to avoid errors in cost reporting;
- ensuring the implementation of recommendations resulting from internal and external audits or other review.

Ex-post controls

<u>For IMI1 projects running under the Seventh Framework Programme</u>

For projects running under IMI1 JU (which was set up 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 IMI's management processes and includes the rejection of any costs found to be in breach with the requirements of IMI1 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 2022 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.

<u>For IMI2 projects running under the H2020 Framework Programme</u>

As regards IMI2 JU, 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 the H2020 programme.

In line with the IMI2 JU Regulation, controls of in-kind contributions by EFPIA companies will be based essentially 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 asses 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 IHI JU Audit Manager.

In 2022, the IAS will commence risk assessment to establish the strategic internal audit plan for IHI JU and launch an audit engagement on one of the selected topics.

In 2022, the focus will be put on:

- finalising the implementation of the action plan from previous audit;.
- coordinating and supporting IAS audit work on risk assessment;
- ensuring 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 2021 annual accounts are audited by a selected external audit company that IHI JU contracts. The contract with Baker Tilly ends in July 2022 and therefore the reopening of the competition for the audit of accounts (financial years 2022 and 2023) will be launched.

ECA will draw up its annual audit opinion on the basis of the work done by the external financial auditor and issue a special annual report on the 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 audit of the 2021 and 2022 accounts and following up on preliminary findings and recommendations;
- liaising with an independent external auditor and coordinating with ECA throughout the audit of accounts for financial year 2021 and 2022.

4.5.4 Anti-fraud

In 2022, the Programme Office will continue to ensure the highest commitment against the risk of fraud through a new anti-fraud strategy (AFS) implementing effective anti-fraud measures integrated in all JU activities.

Prevention activities, raising awareness of JU staff and stakeholders and cooperation with the European Commission Research services will be the priorities for the year.

5 Amended Budget 2022

The budget for the financial year 2022 has been revised based on information available. The following elements have been reflected in the 2022 budget amendment 2:

- Carry over of 50% of unused administrative commitment appropriations from 2021, of EUR 537 963, to operational commitment appropriations.
- Carry over of payment appropriations related to administrative commitments carried forward to 2022 (50% EC-50% industry) of EUR 100 000.

Regarding the administrative expenditure, the total amount for 2022 remained unchanged, at the level of EUR 9 280 000 in commitment appropriations. The amount is divided equally (50%-50%) between EC and industry partners (JU founding members other than the Union): EFPIA, EuropaBio,COCIR and MedTech. As such, the total EC contribution to administrative budget is EUR 4 640 000. The total industry contribution to the administrative budget is EUR 4 640 000. EU and industry contributions are stemming from IMI2 JU and IHI JU budgets.

The industry contribution to IHI JU budget for 2022 is EUR 1 383 000. This amount consists of EUR 455 000 (carry over from 2021) and EUR 928 000 (as per legislative financial statement 2022).

The table below shows the percentages of industry contributions per funding source.

Industry contribution to the total administrative budget for 2022 - EUR	**4,640,000**	**%**
IHI JU	1,383,000	30%
IMI2	3,257,000	70%

An overview of the total 2022 budget per revenue chapters is set out below.

IHI JU - STATEMENT OF REVENUE (EUR)

	Heading Revenue	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter/		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	**European Commission contribution**									
1000	European Commission contribution (including EFTA contribution) for current year out of IMI2 budget	4,640,000	171,640,000	-928,000	-17,928,000			3,712,000	153,712,000	Commitment appropriations include EUR 3,712,000 for administrative costs. Payment appropriations include EUR 3,712,000 for administrative costs and EUR 150,000,000 for operational costs (EUR 12m FP7, EUR 138m H2020).
1002	European Commission contribution (including EFTA contribution) for current year out of IHI JU budget			254,633,000	1,383,000			254,633,000	1,383,000	Commitment appropriations include EUR 928,000 for administrative costs and EUR 253,705,000 for operational costs. Payment appropriations include EUR 1,383,000 (928,000 + 455,000) for administrative costs.

	Heading Revenue	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter/		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
1001	European Commission - appropriations carried over from previous years			1,800,760	7,950,873	537,963	50,000	2,338,723	8,000,873	Commitment appropriations include EC appropriations carried over to operational costs of EUR 2,338,723. Payment appropriations include EC appropriations carried over to administrative costs of EUR 50,000 and to operational costs of EUR 7,950,873.
10	**European Commission contribution - total**	**4,640,000**	**171,640,000**	**255,505,760**	**-8,594,127**	**537,963**	**50,000**	**260,683,723**	**163,095,873**	
20	**JU members other than the Union contribution**									
2000	EFPIA contribution for current year out of IMI2 budget	4,640,000	4,640,000	- 1,383,000	- 1,383,000			3,257,000	3,257,000	EFPIA contribution to IHI administrative costs

	Heading Revenue	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter/		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
2002	EFPIA contribution for current year out of IHI budget			661,500	661,500			661,500	661,500	EFPIA contribution to IHI administrative costs
2001	EFPIA - appropriations carried over from previous years						42,175	-	42,175	Payment appropriations include EFPIA appropriations carried over to administrative costs of EUR 42,175.
	EFPIA contribution - total	**4,640,000**	**4,640,000**	**- 721,500**	**- 721,500**	**-**	**42,175**	**3,918,500**	**3,960,675**	
2010	EuropaBio contribution for IHI current year			30,000	30,000			30,000	30,000	EuropaBio contribution to IHI administrative costs
2011	EuropaBio - appropriations carried over from previous years						325	-	325	Payment appropriations include EuropaBio appropriations carried over to administrative costs of EUR 325.
	EuropaBio contribution - total	**-**	**-**	**30,000**	**30,000**	**-**	**325**	**30,000**	**30,325**	

	Heading Revenue	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter/		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
2020	COCIR contribution for IHI current year			345,750	345,750			345,750	345,750	COCIR contribution to IHI administrative costs
2021	COCIR - appropriations carried over from previous years						3,750	-	3,750	Payment appropriations include COCIR appropriations carried over to administrative costs of EUR 3,750.
	COCIR contribution - total	**-**	**-**	**345,750**	**345,750**	**-**	**3,750**	**345,750**	**349,500**	
2030	MedTech Europe contribution for IHI current year			345,750	345,750			345,750	345,750	MedTech contribution to IHI administrative costs
2031	MedTech Europe - appropriations carried over from previous years						3,750	-	3,750	Payment appropriations include MedTech appropriations carried over to administrative costs of EUR 3,750.
	MedTech Europe	**-**	**-**	**345,750**	**345,750**	**-**	**3,750**	**345,750**	**349,500**	

	Heading Revenue	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter/		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
	contribution - total									
20	**JU members other than the Union contribution - total**	**4,640,000**	**4,640,000**	**-**	**-**	**-**	**50,000**	**4,640,000**	**4,690,000**	
Total revenue		**9,280,000**	**176,280,000**	**255,505,760**	**-8,594,127**	**537,963**	**100,000**	**265,323,723**	**167,785,873**	

An overview of the total 2022 budget per expenditure chapters is set out below.

STATEMENT OF EXPENDITURE

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
1	**Staff expenditure**									
11	Staff in active employment	6,032,000	6,032,000					6,032,000	6,032,000	Salaries and allowances of current staff (TAs and CAs), SNE, promotion and indexation
12	Staff recruitments - miscellaneous expenditure	5,000	5,000					5,000	5,000	Miscellaneous expenditure on staff recruitment: publication of vacancy calls, medical visits to take up duties, services provided by the European Personnel Selection Office (EPSO)
13	Missions and duty travels	80,000	80,000					80,000	80,000	Missions expenditure

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
14	Socio-medical structure	212,000	212,000					212,000	212,000	Other staff costs: EU school, medical check-up, trainings
15	External staff services	125,000	125,000					125,000	125,000	Interim staff expenses
17	Representation	10,000	10,000					10,000	10,000	Representation expenses
Total Title 1 (Staff expenditure)		**6,464,000**	**6,464,000**	**0**	**0**			**6,464,000**	**6,464,000**	
	Heading Title 2	**Budget 2022.1**		**Budget 2022 Amendment 1**		**Budget 2022 Amendment 2**		**Amended Budget 2022.2**		**Comments**
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
2	**Infrastructure expenditure**									
20	Office building and associated costs	660,000	660,000		42,000			660,000	702,000	Building related expenditure: rent, works, charges, maintenance, repairs, security and surveillance

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
21	Information technology purchases	1,009,000	1,009,000		20,000		60,000	1,009,000	1,089,000	IT purchases, software licences, software development
22	Office equipment (movable property and associated costs)	5,000	5,000					5,000	5,000	Purchases and rental of office equipment, maintenance and repair
23	Current administrative expenditure	124,000	124,000		25,000			124,000	149,000	Office supply, newspaper subscriptions, translation services, bank charges and miscellaneous office expenditure
24	Telecommunication and postal expenses	38,000	38,000					38,000	38,000	Data communication such as telephone, video & audio conferences and postal services

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
25	Expenditure on formal meetings	70,000	70,000		17,000			70,000	87,000	Official meetings such as States Representative Group, Science and Innovation Panel, Governing Board and working groups created by the Governing Board
26	Administrative expenditure in connection with operational activities	200,000	200,000				25,000	200,000	225,000	Administrative expenditure in connection with research activities and objectives of IHI (workshops, meetings and events targeting IHI projects)
27	External communication, information and publicity	300,000	300,000					300,000	300,000	External communication and events such as Info Days, stakeholder forums

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
28	Service contracts	410,000	410,000		351,000		15,000	410,000	776,000	Ex-post audits, studies, audits, accounting services
29	Expert contracts and cost of evaluations	-	-					0	0	Costs linked to evaluations, expert contracts
Total Title 2 (Infrastructure expenditure)		**2,816,000**	**2,816,000**	**0**	**455,000**	**0**	**100,000**	**2,816,000**	**3,371,000**	
Total Title 1 + 2 (administrative expenditure)		**9,280,000**	**9,280,000**	**0**	**455,000**	**0**	**100,000**	**9,280,000**	**9,835,000**	
	Heading Title 3	**Budget 2022.1**		**Budget 2022 Amendment 1**		**Budget 2022 Amendment 2**		**Amended Budget 2022.2**		**Comments**
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
3	**Operational expenditure**									
30	Implementing the research agenda of IHI JU		166,400,000	253,105,000	-17,000,000			253,105,000	149,400,000	Commitments calls HE Payments FP7, H2020

	Heading Title 1	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
39	Evaluations experts		600,000	600,000	-			600,000	600,000	Costs linked to evaluations experts contracts
30	Appropriations carried over from 2021			1,800,760	7,950,873	537,963		2,338,723	7,950,873	
Total Title 3 (Operational expenditure)		**0**	**167,000,000**	**255,505,760**	**-9,049,127**	**537,963**	**-**	**256,043,723**	**157,950,873**	
Total expenditure		**9,280,000**	**176,280,000**	**255,505,760**	**-8,594,127**	**537,963**	**100,000**	**265,323,723**	**167,785,873**	

Operational budget

The operational budget for the financial year 2022 is based on the currently available information.

Operational commitment appropriations will be consumed by calls to be launched on IHI JU in 2022 and evaluation experts costs, under Horizon Europe program. The payment appropriations will be consumed as intermediate and final payments for the FP7 and H2020 projects. With 2022 budget amendment 2, the unused administrative commitment appropriations from 2021 are carried over to operational commitment appropriations in 2022.

A table overview of the operational budget for 2022 is set out below.

Operational budget financial year 2022

	Heading Title 3	Budget 2022.1		Budget 2022 Amendment 1		Budget 2022 Amendment 2		Amended Budget 2022.2		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
3	**Operational expenditure**									
30	EU contribution to operational costs (fresh credits, including EFTA contribution) - Implementing the research agenda of IHI JU		166,400,000	253,105,000	-17,000,000			253,105,000	149,400,000	Commitments calls HE Payments FP7, H2020
39	EU contribution to operational costs (fresh credits, including EFTA contribution) - Evaluations experts		600,000	600,000	-			600,000	600,000	Costs linked to evaluations experts contracts
30	Appropriations carried over from 2021			1,800,760	7,950,873	537,963		2,338,723	7,950,873	
	Total Title 3 (Operational expenditure)	**-**	**167,000,000**	**255,505,760**	**-9,049,127**	**537,963**	**0**	**256,043,723**	**157,950,873**	

A breakdown of the appropriations carried over to operational budget is set out below.

Description	Commitment Appropriation (CA)	Payment Appropriation (PA)
Budget amendment 1: unused operational commitment and payment appropriations 2021 to be carried over to 2022 on H2020 budget lines	1,593,405	7,950,873
Budget amendment 1: unused operational commitment 2021 to be carried over to 2022 on FP7 budget lines, stemming from recoveries from beneficiaries	207,355	
Budget amendment 2: 50% of unused administrative commitment appropriations carried over from 2021	537,963	
TOTAL	**2,338,723**	**7,950,873**

Administrative budget

The administrative budget for the financial year 2022 is based on the currently available information. The 2022 budget amendment 2 reflects the carry over of payment appropriations related to administrative commitments carried forward to 2022 (50% EC-50% Industry), of EUR 100,000.

Regarding the commitment appropriations, the total administrative budget for 2022 remained unchanged, at the level of EUR 9,280,000.

For commitment appropriations, a comparison table of the financial years 2021 and 2022 budget is set out below.

	Heading	Financial year 2021	Financial year 2022	Evolution	Comments
Title and Chapter		Budget EUR	Budget EUR		
1	**Staff expenditure**				
11	Staff in active employment	5,651,000	6,032,000	7%	it includes 2% promotions and indexations as well as prices indexation of services provided by PMO and OIB
12	Staff recruitments - miscellaneous expenditure	10,000	5,000	-50%	no increase in number of staff
13	Missions and duty travels	60,000	80,000	33%	increased due to expected higher number of missions during 2022. 2021 was budgeted in the context of COVID-19.
14	Socio-medical structure	192,000	212,000	10%	increase of EU school, transport and trainings due to prices indexation
15	External staff services	125,000	125,000	0%	
17	Representation	10,000	10,000	0%	
Total Title 1 (Staff expenditure)		**6,048,000**	**6,464,000**	**7%**	

	Heading	Financial year 2021	Financial year 2022	Evolution	Comments
Title and Chapter		Budget EUR	Budget EUR		
2	**Infrastructure expenditure**				
20	Office building and associated costs	650,000	660,000	2%	increased due to price indexation
21	Information technology purchases	1,079,000	1,009,000	-6%	reallocation to meetings
22	Office equipment (movable property and associated costs)	5,000	5,000	0%	
23	Current administrative expenditure	127,000	124,000	-2%	reallocation to meetings
24	Telecommunication and postal expenses	38,000	38,000	0%	
25	Expenditure on formal meetings	28,000	70,000	150%	increased due to expected higher number of meetings during 2022. 2021 was budgeted in the context of COVID-19.
26	Administrative expenditure in connection with operational activities	140,000	200,000	43%	increased due to expected higher number of meetings during 2022. 2021 was budgeted in the context of COVID-19.
27	External communication, information and publicity	366,000	300,000	-18%	reallocation to meetings
28	Service contracts	419,000	410,000	-2%	reallocation from studies to meetings
29	Expert contracts and cost of evaluations	200,000	0	-100%	transferred to Title 3, as the expenses are related to calls launched, their number of topics and complexity
Total Title 2 (Infrastructure expenditure)		**3,052,000**	**2,816,000**	**-8%**	
Total Title 1+2 (Administrative expenditure)		**9,100,000**	**9,280,000**	**2%**	

Overview of the budget per budget lines

An overview of the 2022 Budget per budget lines is set out in the table below.

Budget line Chapter	Description	C1 - Commitment Appropriations (CA)	C1 - Payment Appropriations (PA)
1100	Staff in active employment and costs linked to employees	3,662,000	3,662,000
1101	Family Allowances	370,000	370,000
1102	Transfer and expatriation allowances	510,000	510,000
1110	Contract Agents	953,000	953,000
1111	Seconded National Experts	65,000	65,000
1130	Insurance against sickness	120,000	120,000
1131	Insurance against accidents and occupational diseases	15,000	15,000
1132	Unemployment insurance for temporary staff	48,000	48,000
1133	Pension	-	0
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	-	0
1149	Other allowances	-	0
1172	Cost of organising traineeships within IMI2 JU	10,000	10,000
1175	Translation and typing services	-	0
1177	Other services rendered	90,000	90,000
1178	Paymaster Office (PMO) fees	65,000	65,000
1180	Sundry recruitment expenses	5,000	5000
1181	Travelling expenses (including taking up duty)	1,000	1000
1182	Installation allowance	30,000	30,000
1183	Moving expenses	7,000	7000
1184	Temporary daily allowance	15,000	15,000
1190	Weightings (correction coefficient)	5,000	5,000
1191	Salaries adaptation	-	0
11	**Staff in active employment**	**6,032,000**	**6,032,000**
1200	Miscellaneous expenditure on staff recruitment	5,000	5,000
12	**Staff recruitments - miscellaneous expenditure**	**5,000**	**5,000**
1300	Mission expenses	80,000	80,000
13	**Missions and duty travels**	**80,000**	**80,000**
1401	EU school costs	100,000	100,000
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	C1 - Commitment Appropriations (CA)	C1 - Payment Appropriations (PA)
1490	Other interventions	12,000	12000
14	**Socio-medical structure**	**212,000**	**212,000**
1500	External staff expenditure	125,000	125,000
15	**External staff services**	**125,000**	**125,000**
1700	Representation expenses	10,000	10,000
17	**Representation**	**10,000**	**10,000**
C1 - Total Title 1 (Staff expenditure)		**6,464,000**	**6,464,000**

Budget line Chapter	Description	C1- Commitment Appropriations (CA)	C1 -Payment Appropriations (PA)
2000	Rentals office building	450,000	450,000
2001	Guarantees		
2002	Contributions		
2010	Insurance		
2020	Charges (water, gas, electricity, works)	200,000	242,000
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**	**660,000**	**702,000**
2101	Hardware, infrastructure and related services	325,000	325,000
2102	Software development, licenses and related services	684,000	704,000
2103	Other expenses maintenance and repair		
21	**Information technology purchases**	**1,009,000**	**1,029,000**
2200	Purchase office equipment	0	0
2201	Rentals office equipment	0	0
2202	Maintenance utilisation and repair	5,000	5,000
2203	Other office equipment		
22	**Office equipment (movable property and associated costs)**	**5,000**	**5,000**
2300	Stationery and office supply	50,000	60,000
2320	Bank charges		
2321	Exchange rate losses		
2329	Other financial charges		
2330	Legal expenses	15,000	30,000
2350	Other operating expenditure	3,000	3,000
2351	Petty expenses		

Budget line Chapter	Description	C1 - Commitment Appropriations (CA)	C1 - Payment Appropriations (PA)
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**	**149,000**
2400	Correspondence and communication expenses	38,000	38,000
24	**Telecommunication and postal expenses**	**38,000**	**38,000**
2500	Formal meetings	70,000	87,000
25	**Expenditure on formal meetings**	**70,000**	**87,000**
2600	Administrative costs in connection with operational activities	30,000	30,000
2601	Events targeting IMI projects	0	0
2602	Workshops	170,000	170,000
2603	Knowledge Management	0	0
26	**Administrative costs in connection with operational activities**	**200,000**	**200,000**
2700	External communication	60,000	60,000
2701	Events external communication	200,000	200,000
2702	Material	40,000	40,000
27	**External communication, information and publicity**	**300,000**	**300,000**
2800	Ex-post Audits	200,000	226,000
2801	Studies, consultancy	90,000	405,000
2802	Audit services	50,000	60,000
2803	Accounting services	70,000	70,000
28	**Service contracts**	**410,000**	**761,000**
2900	Evaluation Experts meetings		
2901	Evaluation Facilities		
2902	Evaluations Exploring New Scientific Opportunities (ENSO)		
29	**Expert contracts and cost of evaluations**	**0**	**0**
C1 - Total Title 2 (Infrastructure expenditure)		**2,816,000**	**3,271,000**

Budget line	Description	C2 - Commitment Appropriations (CA)	C2 - Payment Appropriations (PA)
2102	Software development, licenses and related services		60,000
2602	Workshops		25,000
2800	Ex-post Audits		15,000
C2 - Total Title 2 (Infrastructure expenditure)	**Title 2 Infrastructure and operating expenditure – Total**		**100,000**
C1, C2	**Total Title 1 and 2**	**9,280,000**	**9,835,000**

Budget line Chapter	Description	C1 Commitment Appropriations (CA)	C1 -Payment Appropriations (PA)
3000	Implementing the research agenda of IMI1 JU		12,000,000
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		137,400,000
3021	IMI2 JU call 1		
3022	IMI2 JU call 2		
3023	IMI2 JU call 3		
3024	IMI2 JU call 4		
3025	IMI2 JU call 5		
3026	IMI2 JU Call 6		
3027	IMI2 JU call 7		
3028	IMI2 JU call 8		

Budget line Chapter	Description	C1 Commitment Appropriations (CA)	C1 -Payment Appropriations (PA)
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	Implementing the research agenda of IHI JU		
3101	IHI JU call 1	95,000,000	
3102	IHI JU call 2	21,929,000	
3103	IHI JU call 3	136,176,000	
3900	Evaluations experts	600,000	600,000
3999	Recovery Ex-post audit		
30-C1	**Implementing the research agenda of IHI JU**	**253,705,000**	**150,000,000**

		C2 - Commitment Appropriations (CA)	C2 - Payment Appropriations (PA)
3000	Implementing the research agenda of IMI1 JU	207,355	
3020	Implementing the research agenda of IMI2 JU		7,950,873
3100	Implementing the research agenda of IHI JU	307,368	
3103	IHI JU call 3	1,824,000	
30-C2	**Implementing the research agenda of IHI JU**	**2,338,723**	**7,950,873**
Total Title 3 (Operational expenditure)		**256,043,723**	**157,950,873**
Total expenditure		**265,323,723**	**167,785,873**

6 Annexes

6.1 IKAA Plan for 2022

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 2022 related to projects to be selected under the IHI JU call 1 may be planned from the proposals submission date [50] (20 September 2022). 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 2022 including the project-specific additional activities will be subject to a separate GB decision before publication on the IHI JU website.

There will be no project-specific additional activities for 2022 related to projects to be selected under the IHI JU call 2 and 3 as the proposals submission stages are expected in 2023.

Potential programme-specific additional activities expected to be carried out by IHI JU private members in 2022 are identified in the IKAA Plan below.

[50] "Costs associated to project-specific additional activities may 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 Plan[51]

OVERVIEW ESTIMATED IKAA FOR YEAR 2022				
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 2022 (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)	Specific objective d	IMI2 projects with data-sharing dimension, including but not limited to ND4BB projects	90,000
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
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda, but not funded by Horizon Europe	**Complementary research activities focused on the uptake of results from the IMI CARE project:** 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.	General objectives a and b	CARE	760,379

[51] The IKAA Plan 2022 includes only potential programme-specific additional activities expected to be carried out by IHI JU private members in 2022. It does not include project-specific additional activities.

OVERVIEW ESTIMATED IKAA FOR YEAR 2022				
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 2022 (in EUR)**
	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.			
Complementary research and innovation activities with a clear link to the Strategic Research and Innovation Agenda but not funded by Horizon Europe	**Complementary activities focused on the uptake of results from the IMI Ebovac Programme:** 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.	General objectives a and b	EBOVAC3	1,249,897
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	636,145

OVERVIEW ESTIMATED IKAA FOR YEAR 2022				
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 2022 (in EUR)**
Communication, dissemination, awareness raising, citizen engagement				
Knowledge building in the specific area and/or among stakeholders community	**Analysis of IMI projects regulatory science impact**, incl. mapping of IMI projects against EMA regulatory science research needs.	Task d	Relevant IMI projects need to be mapped	10,000
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
TOTAL ALL PLANNED IKAA				2,761,421

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

6.2 IHI JU call 1

Topic 1: An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities

Expected impacts to be achieved by this topic

The following impacts are expected:

- Enhanced cross-sectoral collaboration between healthcare industries, academia, and all relevant actors of the healthcare ecosystem (including patients and their organisations, carers, regulators, healthcare professionals/ providers), enabling exchange of resources beyond data (such as analytical tools, material for training and professional development of personnel).
- Earlier and more precise diagnosis, more clinically effective interventions, better patient adherence, and reduced hospitalisation (reduction in re-admission/period of hospitalisation).
- A patient stratification able to better predict clinical outcomes to support the development of more patient-adapted interventions / therapeutics including that of potential emerging disease modifying therapies.
- Better patient clinical outcomes and improved patient experience for patients with neurodegenerative diseases.
- More cost-effective and better prepared care pathway management for patients with neurodegenerative diseases.
- Contribute to the 'European Health Data Space[52]' by promoting better exchange of, and access to, different types of health data and data generated by health technologies (through FAIR principles: findable, accessible, interoperable, and re-usable) for the benefit of European citizens, health researchers and health policy makers.

Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must contribute to all of the following outcomes:

- A (sustainable) re-usable, interoperable, easily adaptable, and scalable digital platform, capable of translating a heterogeneous and fragmented set of complex measurable and analysable health data elements into a clinical-decision-support system that can guide patients to better health and quality of life. Initially designed for patients with neurodegenerative diseases and comorbidities (for example using a "sandbox" approach), the platform's easy adaptability ensures its re-use in other health areas for the benefit of healthcare professionals, patients, families, and carers, thereby promoting its wider use.

[52] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711

- A sustainable framework for collaboration across specialities and all relevant stakeholders to foster social innovation to decrease the burden on patients, families, and carers and to develop models to incentivise/maintain collaboration and ensure feasibility of future implementation, including consideration for data management options and functionalities relevant for patients and/or family members.

- Effective and agreed standards and guidelines that support both data collection and all operational features of the digital platform, enabling health technology developers to create efficient clinical decision support systems for a more patient-centric and optimised delivery of healthcare interventions. Healthcare professionals/providers use these solutions leading to improvements in the healthcare pathways.

- Enhanced, and more reliable tools and methods (for example analytical tools and algorithms) able to provide (near) real time feedback on health interventions, including on the usability, efficacy/effectiveness, and long-term safety of health technologies. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions that, additionally, can aid the development of predictive simulation tools and models.

- Enhanced clinical interpretation of those multi-modal, multi-parametric (including socio-economic) data, which influence variations in the status of the patient with neurodegenerative disease and the required levels of care. This will benefit patients, who will receive more person-centric treatment and care. Meanwhile it will help healthcare providers to optimise the allocation of resources and predict how patients' needs will change due to their co-morbid condition or other precipitating medical factors.

Scope

Neurodegenerative disorders represent a high societal burden impacting patients, their families, and public healthcare systems. Patients with a neurodegenerative disorder frequently display at least one comorbidity, which together with the observed polypharmacy creates a highly complex system that needs better understanding to optimise current care pathways. Recent developments give grounds for cautious optimism that a disease-modifying therapy is on the horizon. However, the high disease prevalence, and the complex evaluation process when such a therapy becomes available, will create challenges for already over-burdened healthcare systems. This will increase the demand for and importance of diagnostic and digital solutions that can drive the related clinical pathways and optimise and personalise care delivery.

The primary objective of this topic is to develop a decision-support system to enhance medical decisions with targeted clinical knowledge, patient information, and other health information for a more holistic (better integrating diagnosis, treatment and care and breaking silos across specialities) approach to managing and treating patients with a neurodegenerative disease and a comorbid condition, addressing the needs of today, while creating preparedness for a future paradigm-shift in treatment.

In their proposal, applicants should formulate how to best achieve all the outcomes/outputs of this topic, also describing the expected actual improvement in care and treatment outcomes and reflecting on aspects of implementation into routine care and sustainability, that are barriers to developing and distributing/delivering innovations. This should be preceded by a key stakeholder mapping to grasp the relevant players within this ecosystem and build and leverage as much as possible upon already available resources and learnings.

Proposals should address a patient population with a neurodegenerative disease where there is evidence of the importance of comorbidities in their healthcare pathways and on patient quality of life. The choice of the comorbidity should consider the burden for patients, carers and families, and the availability of medical technology-generated data. Cancer is out of scope.

Applicants should develop a (sustainable) re-usable, interoperable, and scalable digital platform, to safely and efficiently collect, curate, store, share, access, integrate and analyse multimodal longitudinal, dynamic health data generated within and outside the healthcare setting.

This will require breaking existing data silos across different medical specialities to allow the dynamic flow of information on the concomitant conditions and their interplay to improve the selection of the best possible care pathways, and patient adherence.

Data may include medical/laboratory data, automatically collected data, omics data, medical device data, treatment modality/intervention-type data, real-world evidence, including medical condition and lifestyle-related data collected via e-health solutions, smart devices, wearables, medical grade sensors and other patient self-reported data. Data on contextual information, for example on the socioeconomic environment as well as professional and informal caregivers (like availability, roles, interprofessional cooperation, interaction with the patient/client), the setting and organisation of care, staffing, and payment models, should be considered to enrich the dataset informing decision, as well as data from patient registries. Current European activities on digital health and care should be considered when relevant[53]. The patient perspective and notably their quality of life, will need to be sufficiently considered including via patient-reported experiences and outcomes measurements (PREMs; PROMs). The perspective of families and carers should be also included.

Applicants should consider leveraging relevant large datasets that are already available at national and / or European level.

Ensuring data quality will be of paramount importance. In addition, applicants should ensure trustworthy and safe sharing of patient data through 'privacy and security by design'. They should also give ample consideration for the control of data reuse by patients and healthcare professionals, for example by the implementation of 'FAIR' data principles and a suitable data governance structure.

The platform should build on suitable existing platforms or elements thereof (for example specialised research infrastructures, including those developed by IMI projects) with proven efficiency and interoperability, complying with European privacy and security requirements and enabling integrated workflows of data management, curation, and analysis to amplify the intrinsic value of the datasets. Its design should allow for future expansion as well as continuous updates in a secure environment, plus potential integration with other platforms and easy adaptation for use in other health areas.

Advanced analytical and workflow tools (including artificial intelligence (AI)-based) and, where relevant, predictive simulations should be proposed which enable improved analysis of the integrated patient data in combination with clinical insights and expertise to optimise best practice guidelines, support better clinical decision-making and assessment of outcomes for optimised care pathways, bespoke to the patient and the healthcare system.

Applicants should also consider how the proposed solutions could be part of integrated community-based health and social services that optimise independence, quality of life and the wellbeing of the individual, including when relevant behavioural changes, while decreasing the burden on families and carers.

Applicants providing data as part of their applications should include in the proposals evidence that all legal, ethical, and intellectual property permissions are in place to ensure the availability of the data to the consortium.

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

[53] https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

A cross-sectorial and multidisciplinary public-private partnership is needed to deliver the outcomes and impacts of this topic, fostering a trusted collaborative environment where the end-users integrate from day one with the innovation developers to ensure projects generate useful and usable outputs that will be sustained for longer term impact. Collaboration established between different healthcare industries can ensure inclusion of know-how and resources across different technological areas (for example, imaging, diagnostic, digital technologies, pharma), thereby fostering better crosstalk and integration of multi-modal data and the delivery of meaningful converging technology-based innovations to improve healthcare. Contributions from industry partners should be integrated collaboratively with relevant interdisciplinary academic competences, including from the social sciences (for example health economics, ethics, nursing sciences, health sciences/public health, psychology), and with resources like data registries and cohorts. Importantly, the future users of the proposed solutions (for example patients, their families and carers, regulators, healthcare professionals/ providers) should also be included in the partnership from the start to ensure proper consideration of their needs and preferences to foster future implementation in the healthcare ecosystem.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 15 000 000.

IHI estimates that an IHI financial contribution of around EUR 5 000 000 to 7 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[54] under "Specific conditions on availability, accessibility and affordability" do not apply.

[54] See section 4.2.3.2 of this amended Work Programme

Topic 2: Next generation imaging and image-guided diagnosis and therapy for cancer

Expected impacts to be achieved by this topic

- Patients benefit from improved diagnostic and therapeutic procedures and innovations better adapted to their individual health condition, while meeting the needs of the healthcare system.
- Contributing to the development of high-quality tools, high-quality data, advanced patient imaging and image-guided technologies and processes for improved early diagnosis, prognosis, staging, intervention planning, therapy and management of cancer and long term follow up.
- Including next-generation imaging technologies and image-guided solutions as part of combined cancer therapies (e.g., theranostics, chemotherapy, targeted therapy including immunotherapy, radiotherapy and/or surgery) through seamless integration of tools, data and algorithms into the care pathways.
- Enabling the development of improved artificial intelligence (AI) and machine learning (ML) validation and evaluation methodologies for imaging and image guided diagnosis and image-guided therapy for cancer.
- Better informed decision-making at different levels of the healthcare system that will in turn contribute to a better allocation of resources towards cost-effective innovations.
- Contributing to the objectives of Europe's Beating Cancer Plan and to the Horizon Europe Mission on Cancer and the initiatives in the Digital Europe Programmes.

Expected outcomes

The proposals are expected to focus on image-based cancer diagnosis, prognosis, treatment planning and therapy. Project results must contribute to all of these expected outputs and outcomes:

- Expanded use of cancer patient imaging data sources, with improved data quality, annotation and computability, contributing to solutions that automatically link images to clinical data to improve diagnostic, staging, predictive and therapeutic tools for clinicians, including image-guided tools.
- Robust evaluation and validation frameworks for AI/ML-based algorithms applied to cancer patient images, to improve image-guided diagnosis, prediction of therapy outcome, planning and therapy of cancer patients.
- Healthcare professionals across Europe get access to advanced, easy-to-use solutions for minimally invasive interventions, guided by medical imaging for monitoring disease progression or treatment response, in combination with biomarkers and other relevant data.
- Improved image-driven planning and predictive tools that enable healthcare providers to facilitate diagnosis, treatment, and follow-up to improve patient outcomes.
- Novel, continuously self-learning, trustworthy, explainable AI/ML-enabled image guided diagnosis, therapy planning, and interventional systems used in clinics/hospitals and possible related benchmarks.
- Demonstrated added-value for end-users such as patients and carers, healthcare professionals, national health systems, and healthcare providers in using next generation imaging and image-guided diagnosis and therapy solutions for cancer.

- Enable seamless and successful further development of the concepts and solutions developed, leading to integrated products and services delivering proven benefits to patients, carers, healthcare systems and society as a whole.

Scope

The specific challenge to be solved by this call topic is to provide early evidence of improved cancer patient care when using next-generation imaging technologies and image-guided solutions as part of combined cancer therapies. An optimised image-based care path from early diagnosis and screening to treatment and follow-up is essential to improve the outcome of cancer patients and help optimise clinical workflows and cancer patients' journey.

Innovative solutions in cancer diagnosis, therapy planning, interventions and outcomes can be achieved by pooling, linking, and using existing cancer patient imaging and other relevant data for the development of robust AI/ML-based algorithms and enhancing of image-guided tools in clinical settings. A key point underpinning the use of AI and ML in the fight against cancer is access to high quality data. Furthermore, there are limited recognised validation and performance evaluation frameworks for AI/ML-based diagnostic algorithms.

Within the framework of the European Cancer Imaging Initiative[55], and building on the results of other relevant research projects, the proposal should enable secure, General Data Protection Regulation (EU GDPR) compliant and interoperable access to cancer imaging data sources for the purpose of developing and/or enhancing new innovative features of AI/ML-enabled tools used for diagnosis, prognosis, therapy planning, intervention, and follow up. Proposals should also focus on understanding challenges and propose sustainable solutions to close gaps in algorithm validation and algorithm evaluation in the context of developing AI/ML-based tools for cancer diagnosis and outcome prediction.

The proposal should aim to improve AI/ML-enabled imaging and image guided solutions in order to assist and guide clinicians during diagnosis, staging, patient monitoring, therapy planning, intervention and follow-up. Where appropriate, proposals should demonstrate novel ways to interact with the imaging data. The driving principle must be improving and enhancing image-based diagnosis and therapy, e.g. through automated image interpretation and segmentation, quantitative disease assessment, intuitive treatment planning and smart guidance both during treatment itself and in post-treatment monitoring of response to therapy, to enable more efficient patient-centric diagnosis/therapies/interventions and better patient outcomes.

The proposed research and innovation (R&I) activities should result in simplified clinical workflows, for instance through enhanced or complementary robotic-assisted procedures, thus resulting in more precise therapeutic and interventional procedures for patients, reduced workload on staff, a reduction in therapy planning and intervention time, and shorter recovery times/hospital stays.

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

To take advantage of the potential synergistic effects of next-generation imaging technologies and image-guided solutions being part of combined cancer therapies, it is essential that different industry sectors come together, exchange knowledge and experience, and find optimal solutions. Combining expertise from various sectors is critical to the success of this proposal.

This cross-sectorial collaboration is expected to include academia and health care specialists to leverage innovative and novel image-guided concepts in diagnostic and therapeutic applications.

[55] This initiative is part of the Europe's Beating Cancer Plan: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM:2021:44:FIN

This will ensure the clinical relevance of technical and scientific innovations. IHI provides a unique opportunity to break down existing silos to enable faster development of people-centred, safe, effective, cost-effective, and affordable health solutions.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of around EUR 10 000 000 to 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

Indicative duration of the actions

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[56] under "Specific conditions on availability, accessibility and affordability" apply.

[56] See section 4.2.3.2 of this amended Work Programme

Topic 3: Personalised oncology: innovative people centred, multi-modal therapies against cancer

Expected impacts to be achieved by this topic

In addition to contributing to Europe's Beating Cancer Plan, the Mission on Cancer, the EU Industrial and Pharmaceutical Strategy, and implementation of the Sustainable Development Goals of the United Nations, the work supported under this topic will help to achieve several of the expected impacts from IHI specific objective 2: "Integrate fragmented health research & innovation (R&I) efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users."

Specifically, it will do this by doing the following:

- Breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative, people-centred, integrated healthcare solutions that can seamlessly be introduced in healthcare systems.
- Fostering the development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation.
- Better and faster integration of future products, services and tools along the healthcare pathway responding to patients' specific needs and leading to improved health outcomes and patient well-being.

Moreover, the work supported under this topic will also contribute to some expected impacts from IHI Specific Objective 3: "Demonstrate the feasibility of people-centred, integrated health care solutions."

- Patients benefit from treatment and care better adapted to their needs through improved diagnostics, prognosis and monitoring their quality of life while on and beyond treatment.
- Integrated health care solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and healthcare providers through an inclusive approach.
- Successful implementation of digital solutions supporting people-centred care.

Expected outcomes

R&I actions to be supported under this topic shall contribute to all the following outcomes:

Platform, standards and regulatory

- A versatile and dynamically evolving platform for R&I collaboration across sectors, between academia and industry partners with a focus on the early stages of applied clinical research on cancer.
- Cancer healthcare pathway standards to enable personalised treatment and joint registries.
- Demonstration of how the benefits of health technology convergence can be harnessed in line with all relevant regulatory frameworks in Europe.

Improved multi-modal therapy

- Health innovations in cancer therapy through development, testing and validation of multi-modal therapeutic approaches including novel or emerging technical and clinical concepts and potentially supported by in vitro diagnostics.

- Personalised therapeutic options for cancer patients to improve outcomes, including shared information and integration of various specialised clinicians as well as shared decision-making for treatment and care.

- Improved active monitoring and adaptation of therapy through the patient journey, involving early-response biomarkers and evaluation of their predictive power and correlation to clinical outcomes, as well as more involvement of patients in the cancer patient journey.

Scope

Different treatment modalities are available for various cancers, however, the differing biology of cancers as well as the differing efficacy of treatment modalities dictate rather patient-specific approaches. Multi-modal therapies have been shown to be of high value in this respect and there is a strong need to increase the therapeutic arsenal of such multi-modal therapies and to tailor the treatment approach to the individual patient.

The aim of this call topic is biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, *in vitro* diagnostics, co-morbidities, clinical and real-world data.

Proposals should facilitate the development of new health technologies and integrate them with (possibly adapted) current therapy concepts, to create and explore multi-modal therapies personalised to the needs of the individual patient. Applicant consortia should pursue different therapeutic strategies and combine at least two cancer treating modalities[57] (supported by a sound scientific rationale in the application).

The proposed R&I activities should include development of research protocols for multi-modal therapies expected to have a significant potential to create patient benefits. These protocols should be explored via early clinical studies with sufficient sample size and statistical power to assess safety and efficacy and demonstrate feasibility of the chosen multi-modal approach.

Depending on the specific therapies to be studied and combined, the R&I activities should consider the clinical decision-making process aspect among the various disciplines involved. They should also include the evaluation of aspects such as the sequencing, timing and dosing of therapies to maximise treatment effects with minimal toxicity and normal tissue complications. It is expected that the use of prognostic and predictive biomarkers and the combination of diagnostic tools to plan and adapt treatment and evaluate treatment and the follow up of patients will be a key component of the proposed integrated healthcare solutions.

To overcome the barriers to cross-sectoral collaboration, proposals need to consider methodologies and standards for the combination of various technologies into integrated healthcare solutions. Furthermore, proposals should also consider the design and conduct of clinical studies of multi-modal therapies and methods to evaluate their safety and clinical benefits.

[57] Pharmaceutical, nanotechnology, radiology or other therapeutic approaches (e.g. small molecules, hormone-, cell-, or immuno-therapy, drug delivery systems and nanoparticles, radio-ligand therapy, adaptive radiation therapy with guided dose optimisation, altered dose fractionation schemes including hypo-fractionation, ablation and radio-surgical concepts based on photon or charged particle radiation including FLASH (irradiation at ultra-high dose rates, several orders of magnitude higher than conventional dose rates), theranostics and radiopharmaceuticals).

Proposals should include a description of how data will be generated, captured and stored, and how it will be used in line with the FAIR[58] principles and sustained to promote collaboration among stakeholders. Proposals should enable secure, GDPR[59] compliant and interoperable access of the data.

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

Rapid scientific and technical progress in medicinal products, diagnostics, medical devices, and complementary services have created the potential for significant improvements in healthcare. However, the opportunities for developing integrated, interoperable health care solutions can only be fully harnessed if barriers to cross-sectoral collaboration and to collaboration with patients, carers and healthcare professionals are overcome.

To realise the potential synergistic effects of biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, *in vitro* diagnostics, co-morbidities, clinical and real-world data, it will be necessary for different industry sectors to come together and exchange knowledge and experience, and to find optimal combinations of the various solutions they can provide. Moreover, this cross-sectorial collaboration must be extended to academia and healthcare providers to leverage innovative clinical concepts that they can offer, and to ensure the clinical relevance of technical and scientific innovations. IHI provides a unique opportunity to break down existing silos to enable faster development of people-centred, safe, effective, cost-effective and affordable health solutions.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of around EUR 10 000 000 to 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

Indicative duration of the actions

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[60] under "Specific conditions on availability, accessibility and affordability" apply.

[58] Findable, Accessible, Interoperable, Reusable

[59] General Data Protection Regulation

[60] See section 4.2.3.2 of this amended Work Programme

Topic 4: Access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet public health need

Expected impacts to be achieved by this topic

This topic aims to achieve the following:

- Better and faster integration of future products, services and tools along the healthcare pathway, responding to patients' specific needs and leading to improved health outcomes, patient safety and patient well-being.
- Wider availability of interoperable, large scale, quality data, respecting FAIR principles[61], facilitating research and the development of integrated products and services.
- Advanced analytics/artificial intelligence (AI) supporting health research & innovation, resulting in:
  a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment;
  b) wider availability of personalised health interventions to end-users;
  c) better evidence of the added value of new digital health and AI tools, including reduced risk of bias due to improved methodologies.

Expected outcomes

Proposals under this topic should aim to deliver results that contribute to all of the following expected outcomes for a specified disease area of high unmet public health need:[62]

- Researchers, including industry stakeholders, have long-term access to diverse data at scale, enabled by the linkage and integration of novel and cross-sectoral sources, including industry sources. If possible, some of these data should be able to be used for providing evidence to support regulatory decision-making.
- Researchers, including industry stakeholders, have long-term access to new tools that enable the integration and analysis of these data. If possible, some of these tools should be able to be used for providing evidence to support regulatory decision-making.
- Citizens, including patients, are given user-friendly, interoperable tools to access their own health data from different sources to support disease self-management and empower joint health care professional - patient decision making.
- Health care professionals and healthcare providers[63] have access to integrated data from diverse sources and clinical (and other) decision support systems to deliver better healthcare services to patients and populations in the most suitable and efficient manner.

[61] Wilkinson, M., Dumontier, M., Aalbersberg, I. *et al.* The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* **3,** 160018 (2016). https://doi.org/10.1038/sdata.2016.18

[62] Unmet public health needs are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life…) and/or the number of people affected by it. For example, Alzheimer's disease.

[63] The term 'healthcare providers' refers to organisations that deliver healthcare goods and services. Typical healthcare providers are hospitals, long-term care facilities, providers of ambulatory healthcare, laboratories, nursing care facilities, pharmacies and so on.

Scope

Over the past few years, there has been an explosion in the generation of data that could be harnessed for use in healthcare delivery and research. These data include data generated by digital technologies and patient reported outcome and experience measures, as well as data from clinical trials and routine clinical care. However, accessing, integrating & analysing these data to maximise the value for patient care and research is extremely challenging.

This topic aims to provide a scalable platform for the seamless integration or linkage of these diverse data at scale, and develop tools to allow the data to be used in clinical care, patient self-management and research in disease areas of high unmet public health.

For their proposed activities applicants should **clearly identify a disease area** of high unmet public health need,[64] taking into account comorbidities and/or functional status, and **explain their choice** with empirical evidence where possible**.**

For the selected disease area, the project(s) funded under this topic are expected to:

- **Develop / further develop a scalable, open platform** for the seamless integration or linkage of data at scale from diverse public and private data sources relevant to the disease area selected. These data sources should, as a minimum, include all of the following: clinical trials; registries; patient safety data; routine clinical care; publicly available health insurance data; patient reported outcome and experience measures; and data generated by digital technologies such as sensors, wearables and mHealth apps. Preferably, projects should also integrate data that has not usually been used before for the purpose of medical decision-making.
- Develop / further develop **tools focused on the needs of patients**, leveraging these diverse data sources to support patient self-management and empower joint healthcare professional - patient decision making.
- Develop / further develop **clinical (and other) decision support systems** leveraging these diverse data sources to allow clinicians to deliver better healthcare services to patients in the disease area selected.
- Demonstrate the **added value of the platform** and tools compared to current approaches through a use case (study) applied to the disease area selected.
- Demonstrate the widespread applicability and scalability of the platform & tools using data sources from outside of the project
- Publish sufficient information, including access protocols, on the data that has been used in the project to **facilitate long-term access and re-use**, while ensuring compliance with the General Data Protection Regulation and other relevant European legislation.

Applicants should also aim to deliver the following:

- Public release of a set of minimum technical requirements for the developed platform/tools that includes interoperability, connectivity, data protection, cybersecurity and authentication/identification requirements that need to be met to allow the efficient integration of additional data from new devices/sensors/sources into the decision-support system after the project ends.

[64] Unmet public health needs are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life…) and/or the number of people affected by it. For example, Alzheimer's disease.

- Sustainable, ideally open-source tools that help ensure the quality and FAIRness[65] of data at source (e.g., automated tools to help data entry, semantic coding, and data management in particular in registries and databases maintained by healthcare professionals/providers and research institutions) as well as methodologies, quality standards and metrics to assess data quality.
- Sustainable tools to increase cross-border and cross-sector interoperability of health data from the diverse sources mentioned above. Ideally, these tools use open exchange formats and take into account relevant EU initiatives including the eHealth Digital Services Infrastructure (eHDSI)[66] and the European Electronic Health Record Exchange Format (EEHRxF)[67].
- Sustainability plan/business model to ensure the long-term impact of the project results.

Other considerations:

- Applicants should **build on clearly identified existing tools & platforms** where possible, and ensure that the platform and tools developed can be applied to other disease areas or be relevant for other scientific and clinical communities (i.e. ensuring interoperability with other solutions). If applicants choose to develop a new data platform, a strong justification must be provided.
- Applicants must demonstrate that they have **access to sufficient diverse data**, including from industry sources, to meet the objectives of this topic. The data sources (name & country), types, and size must be described in the proposal alongside convincing evidence that the consortium will have access to these data for the project implementation.
- During their activities, applicants should ensure appropriate **engagement of the end-users** of the developed tools, especially **patients and healthcare professionals**.
- Applicants are expected to explore the integration of the outputs with the **European Health Data Space (EHDS)**[68] when it becomes operational, and explore synergies with other relevant health data initiatives and projects.

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

The data to be integrated in the funded projects are expected to come from diverse public and private sources. To access, understand and integrate these data and to develop platforms and tools for clinical decision-making and patient self-management requires significant cross-sectoral expertise including from patients, carers, health care professionals, healthcare data specialists, legal experts, academic researchers, SMEs, pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together to achieve the objectives of this topic.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU up to EUR 40 000 000.

IHI JU estimates that an IHI JU financial contribution of around EUR 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

[65] FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability.

[66] https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

[67] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[68] https://ec.europa.eu/health/ehealth/dataspace_en

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

Indicative duration of the actions

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[69] under "Specific conditions on availability, accessibility and affordability" do not apply.

[69] See section 4.2.3.2 of this amended Work Programme

IHI-2022-01-01 **An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities**	The maximum financial contribution from IHI JU is up to EUR 15 000 000 Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.
IHI-2022-01-02 **Next generation imaging and image-guided diagnosis and therapy for cancer**	The maximum financial contribution from IHI JU is up to EUR 40 000 000 Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking..
IHI-2022-01-03 **Personalised oncology: innovative people centred, multi-modal therapies against cancer**	The maximum financial contribution from IHI JU is up to EUR 40 000 000 Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.
IHI-2022-01-04 **Access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet public health need**	The maximum financial contribution from IHI JU is up to EUR 40 000 000 Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.

6.3 IHI JU call 2

Topic 1: Cardiovascular diseases - improved prediction, prevention, diagnosis, and monitoring

Expected impacts to be achieved by this topic

Cardiovascular disease (CVD) remains one of the leading causes of death globally and, as such, has a major impact at a personal, societal, and economic scale. Over 60 million people in the EU live with CVDs, at an economic cost of EUR 210 billion annually.

CVD risk assessment is not fully implemented in many clinical practices across Europe[70], and treatment of CVD is commonly practiced as with a “one size fits all” approach, meaning that all patients are treated with a standard medical regimen regardless of risk level. The prevalence of well-established CVD risk factors such as obesity, diabetes, and chronic kidney disease is rising, and combined with an ageing population in Europe, the urgency for a more personalised approach to cardiovascular risk assessment becomes evident.

The generation of a personalised risk-benefit approach, based on data derived from transcriptomic, proteomic and multimodality imaging studies, combined with data from electronic interventions via CE certified wearable devices, such as smartwatches or activity trackers, as well as routine clinical data from medical devices, will contribute to all of the following impacts:

- Accuracy of diagnosis and efficacy of treatment will increase thanks to an individualised sub-phenotype-risk approach which will allow for risk-focused targeted therapy.
- Patients will be empowered and encouraged to take control over their health by accessing an integrated overview, including biometric data derived from wearables, of their health information, which can also be used for a more informed dialogue with their healthcare provider(s).
- Early diagnosis of CVDs, combined with better understanding of the mechanisms involved, will lead to the development of more cost-effective strategies, and the identification of new care pathways.

Expected outcomes

The results of the selected project will provide the basis for better primary and secondary prevention of CVD. The goal is to identify existing comprehensive CVD and heart failure (HF) patient datasets (with contextual parameters e.g., behavioural, socioeconomic, gender, ethnicity) and integrate them with data from diagnostic tools (e.g. wearables, imaging devices, bio samples / biopsies) and routine clinical practice. This will provide the basis for independently validated prediction models for improving the stratification of patients, and reveal insights to achieve earlier intervention. Additionally, the project will leverage developed algorithms to define and validate care pathways that tailor therapy towards individual patient needs and compare it to the “one-size-fits-all” approach.

[70] Rossello X, Dorresteijn JA, Janssen A, Lambrinou E, Scherrenberg M, Bonnefoy-Cudraz E, Cobain M, Piepoli MF, Visseren FL, Dendale P, This Paper Is A Co-Publication Between European Journal Of Preventive Cardiology European Heart Journal Acute Cardiovascular Care And European Journal Of Cardiovascular Nursing. Risk prediction tools in cardiovascular disease prevention: A report from the ESC Prevention of CVD Programme led by the European Association of Preventive Cardiology (EAPC) in collaboration with the Acute Cardiovascular Care Association (ACCA) and the Association of Cardiovascular Nursing and Allied Professions (ACNAP). Eur J Prev Cardiol. 2019 Sep;26(14):1534-1544. doi: 10.1177/2047487319846715. Epub 2019 Jun 24. PMID: 31234648.

This project is expected to achieve all of the following outcomes:

- Identification of relevant data sets, for instance derived from classical diagnostic screening; in-vitro diagnostics; 'multi-omic' platforms (comprising genomic, transcriptomic, proteomic and multimodality imaging data, most preferably with multiple timepoint assessments to ascertain the directionality and dynamics of relevant changes); continuous glucose monitoring (CGM) data, continuous electrocardiogram (ECG) data from wearables. In addition HF and activity data, wearable devices, digital health applications and routine clinical practice.
- Leverage data in currently available federated databases with 'open access' generated during, for example, IMI1/IMI2 projects in compliance with GDPR (General Data Protection Regulation), such as results/data/biomarkers/electronic health records provided by project participants, adding to the knowledge base.
- Demonstration of the utility of biomarker combinations including data from different modalities e.g., wearables, smart (acute or chronic) care setting devices, imaging/screening for the diseases and comorbidities.
- Based on existing biomarker combinations, determination of whether new biomarkers are needed for detecting patients at risk.
- Developed and/or evaluated artificial intelligence (AI) models that, using data from various sources, can identify patient subgroups who require and respond differently to the prevention and/or treatment of atherosclerotic cardiovascular disease (ASCVD) and HF in clinical practice.
- Identification of previously undiagnosed subgroups of ASCVD and HF patients, for instance people with insulin resistance, diabetes, and obesity, into clinically meaningful subgroups.
- Documentation and analysis of patient preferences regarding information, diagnosis and treatment of CVD, as well as requirements and preferences of individuals to share their data.
- Integration of patient data (e.g. via a federated database concept) to enable a holistic overview of specific patient groups to enable more effective and efficient disease management and execution of screening programmes and individual treatment tailoring.
- Inclusion of validated patient reported outcome and experience measure (PROMs and PREMs) data including biophysical, mental and psychosocial parameters with the aim of using it in a clinical setting. This may include, but is not limited to, measures on quality of life, sleep quality, physical activity, emotional stress, satisfaction with treatment, healthcare service experience.
- Leveraging developed algorithms/decision trees to define and validate care pathways that tailor therapy towards individual patient needs and compare them to the "one-size-fits-all" approach.
- Sustainability of relevant results and data repositories.
- Identification of incentives that reward positive health behaviour and motivate consistent and continuous data generation especially when health status has changed.
- Utilisation of the knowledge gained from the project to facilitate and guide better prevention, considering the patient perspective.
- Data collection in the patient population with type 1 diabetes that historically has been excluded from clinical trials. Identifying the highest-risk individuals (in the paediatric, adolescent and adult populations, among others) to aim for more intensive contemporary CVD risk lowering agents (such as glucose, lipid and blood pressure lowering), and other, ideally personalised, cardioprotective adjunct therapies could help reduce the burden of CVD and contribute to improving outcomes in type 1 diabetes.
- Data collection in patient populations with other (genetically defined) predispositions to CVD and HF, that historically have been excluded from clinical trials. Identifying the highest-risk individuals could contribute to improving the outcomes in people with obesity, type 2 diabetes or (genetic) predisposition to CVD/HF.

Scope

The overall aim of the project is to provide tools for the earlier diagnosis of atherosclerosis and heart failure as well as earlier identification of patients at risk. This includes biomarker or predictive algorithms to assess changes in risk and stratify patients according to individual responses to therapeutic intervention. Currently, patient data from various sources such as devices, intake forms, and diagnostic and exploratory tests are not integrated or monitored to give a complete understanding of the patient's disease state. Integration of these data sets, e.g. by a federated database, and its accessibility to healthcare providers and researchers will provide better understanding to help detect, monitor, and treat ASCVD and HF. The selected project should clearly outline their approach for data capture, storage and sharing, for instance data federation, or an open, centralised database architecture. The proposed data management strategy should be sustainable, seek synergies with other relevant projects, and align with the FAIR principles[71]. To fulfil this aim, the selected project should:

1. Increase our understanding of the initial hallmarks of disease, which will allow for a better identification of individuals at risk for ASCVD and HF at a young age, and the creation of a clinical risk profile based on a multi-omic approach (e.g. genetic markers, transcriptomics, proteomics, and in depth multimodality imaging data) in adolescents who have either genetic and/or enrichment of specific endpoint associated risk factors (obesity, chronic kidney disease, type 1 diabetes, type 2 diabetes, genetic preponderance for HF and increased atherosclerosis).
2. Generate and validate a risk model better than currently used risk engines such as SCORE, by evaluating whether and to which extent risk factors identified in large prospective CVD primary prevention cohorts are predictive in a secondary prevention setting. The data from surrogate markers such as imaging, electronic health records (EHR), and predictive markers (plasma based multi- omics), as well as data from wearables, will generate a more refined risk engine.
3. Outline the extent to which social, ethical, and regulatory implications can be considered and quantified in the new risk models and gauge the potential additive value of data generated by wearable devices in current healthcare systems. Outline the extent to which regional and legal issues have an impact, and what models and methodologies can be used to examine this. Moreover, as the risk-benefit of wearable derived data will be ascertained in individuals who are likely to be frontrunners in the adoption (i.e. people with type 1 diabetes and people with a (genetic) risk for premature atherosclerosis and/or HF), the project should include behavioural elements to be analysed to provide suggestions to increase adoption in other populations.
4. Model short- and long-term economic and public health morbidity and mortality benefit/risk assessments of therapeutic intervention in people at risk with the new risk models to prevent or delay onset of CVDs.
5. Develop a decision tool that will allow a physician to select the intervention to best address ASCVD and HF in an individual patient. The tool will provide a risk-benefit profile, helping the physician and the patient in a decision-making process, integrating also patient reported outcome and experience measure (PROMs and PREMs) data.
6. Explore possibilities for novel methods of clinical development and trial execution. Based on learnings about risk prediction and pathophysiological modelling, novel surrogate endpoints may be considered for a risk-based cardiovascular outcome trial approach. The project generated from this topic could provide an exploratory and interactive platform to discuss the validity of novel methods of evidence generation, such as the use of data from wearable devices. The project should pave the way to transform the rather static phase 3 clinical trial approach into a more agile (more inclusive/enriched patient population, faster, cost-effective etc.) and sustainable part of clinical development. Specifically, the project should engage in the Regulatory Science Research Needs initiative, launched by the European Medicines Agency (EMA), assessing the utility of real-world healthcare data to improve the quality of randomised controlled trial simulations (H2.3.3). During the COVID-19 pandemic, the world has experienced a transition to virtual and remote care as more and more patients connect with their health care teams online. This presents an enormous opportunity and benefits for patients. A pathway forward could be to through use of real-world evidence (RWE) data to address sex, ethnicity and race disparities in cardiovascular outcome trials and better promote CV management.

[71] https://www.go-fair.org/fair-principles/

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

The data deemed useful in redefining and reclassifying the CVD risk profile are stored in a multitude of databases of clinical academic institutions (large cohorts of patients with multimodality imaging for example), research institutes (data about genetic risk markers; genome wide variation), large pharmaceutical companies (intervention studies with well documented parameters over time, in conjunction with plasma and genetic biobanks), medical device manufacturers (large numbers of datasets using the specific focus of the company e.g. device treatment data, proteomics data, specific novel biomarker tests), and healthcare wearables (large datasets on biometrics).

Concerted action is needed for sustainable data collection that explores news ways of leveraging existing 'open access' databases (see scope), and the subsequent analysis should be performed by the different stakeholders with a multitude of areas of expertise working in aggregated task forces. The subsequent question on whether and to which extent the data derived can and should be used in clinical care and/or clinical trials should be answered in close collaboration with payers, patients, and regulators.

Additionally, to change behaviours in a clinical practice setting where patients are empowered and encouraged to take control over their health and to secure a patient participatory research approach (e.g. through PROMs and PREMs), supported by interest organisations within the area of public health, a combined effort is needed under a public-private partnership that promotes the interchange of knowledge and experience. "Big cohort data" derived from medical care interactions, complemented by use of patient empowered information from biology, behaviour, social networks, geography, and the macroenvironment, should have the potential to yield real-world / real time answers to questions on the efficacy of treatments. Additionally, through a cross-sectorial collaboration focused on clinical research and public health, we can learn to recognise and appropriately address sex[72], race and cultural biases and disparities in the healthcare delivery process of CVD management, whilst enabling novel ways to deliver people-centred, safe, effective, cost-effective, and affordable health solutions.

Pre-identified industry consortium and contributing partners

The pre-identified industry consortium that will contribute to this cross-sectoral IHI project is composed of the following pharmaceutical and medical technology industry partners:

Novo Nordisk ("Lead"), Becton Dickinson, Evotec, Fresenius, Huawei, Philips, Roche Diagnostics, AstraZeneca, Eli Lilly, Amgen

In addition, the following contributing partner will participate in the IHI project:

- JDRF

In the spirit of partnership, and to reflect how IHI two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industrial beneficiaries, it is envisaged that IHI proposals and projects may allocate a leading role within the consortium to an industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industrial beneficiaries may become the coordinator or the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities with regard to such leadership roles. Until such roles are formalised by execution of the Grant

[72] Sex differences in quality indicator attainment for myocardial infarction: a nationwide cohort study | Heart (bmj.com)

Agreement, one of the proposing industrial leaders shall facilitate as project leader an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from IHI up to EUR 11 179 000.
- The indicative in-kind contribution from industry partners is EUR 8 979 000.
- The indicative in-kind and financial contribution from IHI JU contributing partners is EUR 2 200 000.

The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.

Indicative duration of the action

The indicative duration of the action is 48 months.

This duration is indicative only. At stage 2, the consortium selected at stage 1 and the predefined industry consortium and contributing partner may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The industry consortium and contributing partner expect to contribute to the IHI project by providing the following expertise and assets:

- Data: data from clinical trials, biobank data, real world data, wearables and other smart devices, algorithms, identification of risk, sensor technology, telecommunication, data management/hospital information system, AI, mobile technology
- Expertise: medical expertise, bioinformatics, data science, public health, patient input, clinical and regulatory expertise, early identification from wearables
- Technology: such as wearable devices, mobile technology, telecommunication technology and other smart devices that will enable the recording of new data.

The allocation of the EUR 2 000 000 financial contribution from JDRF will be decided by the full consortium at stage 2 when preparing the full proposal.

Applicant consortium

The stage 1 applicant consortium is expected, in the submitted short proposal, to address scope and deliver on the expected outcomes of the topic, considering the expected contribution from the pre-identified industry consortium and contributing partner.

The applicant consortium is expected to address all the research objectives and make key contributions to the defined deliverables in synergy with the industry consortium. Applicants must ensure that the relevant results and data repositories will be sustainable after the end of the project(s) and made public, in compliance with the guidelines on the European Health Data Space (EHDS)[73]. Potential spin offs from the project should be identified. The focus of this project is not target identification, but rather on leveraging currently available data for risk and outcome prediction tools, and subsequent prescription refinement. These are to be generated by artificial intelligence approaches, as brought in by the various project participants.

[73] https://ec.europa.eu/health/ehealth/dataspace_en

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

- Access to cohorts and databases of cardiovascular disease including data on people with atherosclerosis and heart failure.
- Access to cohorts of young adults and adults who have type 1 diabetes, type 2 diabetes, obesity or genetic preponderance for HF and increased atherosclerosis with early CVD risk markers such as inflammatory and mitochondrial biomarkers, aortic and cardiac structure and function, carotid atherosclerosis and arterial stiffness.
- Access to pre-existing clinical cohorts with as broad and detailed relevant phenotyping as possible and access to biobanked specimens for selected biomarker analysis wherever available (including documented informed consent), ideally including cohorts with, when relevant, different treatment approaches.
- Expertise in development of new biomarkers and genetic factors in type 1 and type 2 diabetes in CVD. Expertise in behavioural psychology models.
- Expertise in AI and software.
- Expertise in devices and digital health.
- Economic benefit-risk modelling should engage multidisciplinary teams of patient representatives, health care economists, and health care payers.
- Engagement with patient representatives and other interest organisations within the area of public health.

At stage 2, the consortium selected at stage 1 and the predefined industry consortium and contributing partners will form the full consortium. The full consortium will develop in partnership the full proposal, including the overall structure of the work plan and the work packages, based upon the selected short proposal at stage 1.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[74] under “Specific conditions on availability, accessibility and affordability” do not apply.

[74] See section 4.2.3.2 of this amended Work Programme

Topic 2: Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union

Expected impacts to be achieved by this topic

By setting up a harmonised EU methodology to promote the uptake of early feasibility studies (EFS)[75], this topic will improve patients' access to health technologies, including digital technologies, support technological innovation, and contribute to a smoother development process for these health technologies. As such it will contribute to all the following IHI scientific, technological and economic expected impacts:

- Improve quality of clinical evidence on health technology innovation generated through earlier clinical experience obtained in the development process from an EFS.
- Facilitate uptake of early feasibility studies in health technology development, including for digital technologies.
- Increase the attractiveness of conducting clinical research and trials for healthcare technologies in the EU, including for SMEs, spin-offs and start-ups.
- Enable faster translation of health technology innovation into practice with increased access to treatment for patients, especially those with medical conditions that have limited or no alternative therapeutic options.
- Better refined patient populations, their carers or patient representatives, and strengthened understanding of disease management and functional impairments, and treatment options.

Expected outcomes

The research and innovation action to be supported under this topic is expected to deliver results including a methodology for EFS in the EU, to facilitate compliance with the relevant legislation applicable in the EU, and a stakeholder network. It will contribute to all of the following expected outcomes:

- Patients and/or their representatives are engaged and contribute from the start of the development process of innovative health technologies.
- EU-wide and national regulators, health technologies assessment (HTA) bodies and notified bodies benefit from novel and robust methodologies, gain early knowledge on innovations, and can better anticipate and plan conformity assessment processes.
- Researchers, healthcare professionals, medical societies, and hospitals:
- contribute to the early generation of quality data;
- strengthen our understanding of disease management and treatment options that could inform future medical guideline development;
- provide input on innovation development;
- take part in the development of "hubs of clinical excellence", thereby attracting investment into existing research and innovation as well as other areas (spin-off technologies).

[75] Early feasibility studies are specified in the Questions & Answers Guidance from the Medical Device Coordination Group of April 2021: https://ec.europa.eu/health/system/files/2021-04/mdcg_2021-6_en_0.pdf

- Health technology developers including those developing medical devices, drug-device combination products, imaging equipment and in-vitro diagnostics as well as SMEs, will have:
    - a controlled opportunity to assess their technologies and develop methods and best practices to support them in designing and conducting EFS when relevant.
    - early insights into the technology concept, patient characteristics and human factors that may impact technological performance, technology safety, future technological modifications or operator technique refinements.
    - a framework that will help to inform the subsequent development phase. In particular it will aid designing higher quality clinical studies while mitigating future patient risk, at the same time facilitating the conduct of future clinical investigations in broader patient populations.
- For SMEs, particularly, having access to a methodology and stakeholder network can facilitate the conduct of early feasibility studies. The availability of high-quality data early in the health technology development process would further support investment and development decisions.

Scope

The incremental development of innovative / breakthrough health technologies takes a long time, during which an innovation will have to successfully go through a process of testing and evidence generation before it can be launched.

- As part of this process, early feasibility studies provide the opportunity to capture relevant additional information for the intended use from the real-world setting that would not be possible in non-clinical studies (i.e. bench testing and animal studies) at a very early stage. EFS can make it possible to optimise design and gain necessary information before running a large clinical investigation.

Even if it is legally possible to undertake EFS in the EU, such studies are not yet widely used. Indeed, most EFS are run today outside of the EU, and primarily in the United States[76].

This means that the EU may be at risk of losing out on an important opportunity to attract clinical research and further investments in innovation development to the region.

- This topic seeks to develop and validate a methodology for EFS that is compliant with EU regulations, including a working methodology, easily accessible online, with information on how to undertake such studies, the process and requirements to follow and fulfil.
- It also aims to bring together the relevant stakeholders that could have an interest in EFS and to facilitate use-cases where technologies would run the newly developed EFS methodological framework in order to test it and recommend any adjustments to be made to the methodology.

The project would entail the following:

- **Research & analysis**, including a review of existing international, EU and national guidelines, standards and best practice experiences. This would also include a survey of potential current gaps, barriers and challenges to undertaking EFS in the EU, taking into account the interplay between the different relevant current and future EU regulations.

[76] US National Library of Medicine, ClinicalTrials.gov. Out of the 300 EFS referenced, only 8 are conducted in Europe as per September 2020.

- **Development of an EU methodology for EFS**
    - The methodological framework would include:
        i. definition and scope, including legal considerations;
        ii. the place of EFS in the development pathway of health technologies and when there is an added value for EFS;
        iii. the type of data required to conduct an EFS (technical data, preclinical data, number of patients, etc.);
        iv. process evaluation, methods and tools, including statistical tools adapted to the analysis of EFS results, and tailored to the needs and specificities of different health technologies, including digital and mobile health technologies;
        v. the contribution of EFS to making more patient-centred devices;
        vi. the contribution of EFS to the development of training plans for healthcare professionals that would in turn improve the use of devices.
    - Recommendations for best practices, addressing also ethical aspects from the outset, and contractual elements.
    - Development of a sustainable, freely-accessible online portal, hosted and maintained by the consortium, which would act as a repository for the methodological framework and the best practices, and which would facilitate interactions between stakeholders with an interest in EFS.
- **Facilitate the creation of a sustainable stakeholder network at national and EU level**
    - The network would promote the conduct of EFS and continue to gather experience from subsequent studies where appropriate and relevant to inform the EU EFS methodology.
    - Target groups include patient organisations and representatives, healthcare professionals, research institutions and hospitals, health technology developers, including SMEs, regulators, and HTA bodies.
- **The selection of dedicated use-cases to inform, refine and validate the framework**
    - The purpose of selected use-case technologies will be to undertake an EFS in the EU, whilst applying the methodology developed by the selected project, in order to test the methodological framework and evaluate the benefits for the conformity assessment process and patient access.
    - Learnings acquired on the use-cases will be used to adapt and finalise the methodological framework, and, where necessary, the blueprints and templates.
    - During the project execution, the consortium will define specific criteria and processes to determine which use-cases can be selected. Indicators of success will be developed and defined within each pilot trial, to compare it to other trials, and used as potential stop criteria.

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

Experience from other regions outside the EU has shown[77] that enabling public-private collaboration and endorsing the need for more standardisation on EFS could support their uptake, thereby supporting patient access to novel technologies[78].

As such, the topic seeks to contribute to a strengthened evidence-generation and cross-sectoral and multi-disciplinary innovation ecosystem by facilitating collaboration and early exchange and facilitating the creation of processes to conduct EFS.

To achieve these objectives, it is essential that different industry sectors come together to exchange knowledge and experience. Moreover, this cross-sectorial collaboration must be extended to academia, healthcare professionals, patients, research organisations, regulators, HTA bodies, and SMEs to ensure a harmonised understanding of the best practices and one comprehensive methodology for EFS.

IHI provides a unique opportunity to enable a unified approach towards promoting the uptake of EFS in order to ultimately strengthen clinical development excellence and the innovation attractiveness of the EU.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI project may be composed of the following pharmaceutical and medical technology industry partners:

Edwards Lifesciences AG ("Lead"), Medtronic, W.L. Gore & Associates, Philips Medical Systems B.V., Syntes, Abbott

In the spirit of partnership, and to reflect how IHI 2-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industrial beneficiaries, it is envisaged that IHI proposals and projects may allocate a leading role within the consortium to an industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industrial beneficiaries may become the coordinator or the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities with regard to such leadership roles. Until such roles are formalised by execution of the Grant Agreement, one of the proposing industrial leaders shall facilitate as project leader an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from IHI up to EUR 10 750 000.
- The indicative in-kind and financial contribution from industry partners is EUR 10 750 000.

The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.

[77] MDIC-EFS-Blueprint-for-EFS-Success-2016.pdf; Holmes, D et al. (2018) The 21st Century Cures Act and Early Feasibility Studies for Cardiovascular Devices: What Have We Learned, Where Do We Need to Go? JACC: Cardiovascular Interventions, 11(21), 2220 – 2225

[78] David R. Holmes, Jr., MD, EFS Symposium: Implementation Strategies for Early Feasibility Studies TVT Chicago IL June 12-15, 2019, EFS-Symposium-TVT-EFS-Symposium-Implementation-Strategies-for-Early-Feasibility-Studies.pdf (mdic.org)

Indicative duration of the action

- The indicative duration of the action is 48 months.
- This duration is indicative only. At stage 2, the consortium selected at stage 1 and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal. Where possible the duration of the project could be shortened in order to expedite the delivery of impacts in terms of clinical development excellence and the attractiveness of the EU for innovation.

Contribution of the pre-identified industry consortium

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

- Legal, ethics & compliance, regulatory, R&D, and clinical expertise:
    - input to survey exercise, i.e. industry perspective on barriers to undertake EFS in EU;
    - dissemination of surveys to stakeholders already engaged in EFS, with potential interviews;
    - contribution to the development of the methodology, including best practices;
    - assessment of regulatory and ethical provisions with which EFS should comply.
- Potentially breakthrough technologies across disease areas to test the EFS methodology and inform any further adaptations.
- Project management, dissemination and communication.

Applicant consortium

The stage 1 applicant consortium is expected, in the submitted short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

Applicant consortia should bring together partners with relevant expertise such as regulators, healthcare professionals, patients and patient representatives, health technology developers, research organisations, academia, biostatisticians, legal experts, ethicists.

For the development of the methodology, input from other relevant stakeholders, in particular HTA bodies would be necessary.

Participation of SMEs is encouraged with the aim of ensuring a wide applicability of the methodology and valorising innovations of SMEs for the benefit of citizens. Moreover, SMEs, particularly those with expertise in legal, regulatory and ethical matters, are encouraged to join the consortium to support the development of relevant criteria for the methodology.

The composition of the consortium should also ensure a broad geographical representation of European countries. Diversity aspects, including sex and gender, should be considered in carrying out the relevant activities.

At stage 2, the consortium selected at stage 1 and the predefined industry consortium will form the full consortium. The full consortium will develop in partnership the full proposal, including the overall structure of the work plan and the work packages, based upon the selected short proposal at stage 1.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[79] under "Specific conditions on availability, accessibility and affordability" do not apply.

IHI-2022-02-01 **Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring**	The maximum financial contribution from IHI JU is up to EUR 11 179 000. The indicative in-kind <and financial> contribution from industry partners is EUR 8 979 000. The indicative in-kind contribution <and financial> from IHI JU contributing partners is EUR 2 200 000. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA) Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
IHI-2022-02-02 **Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union**	The maximum financial contribution from IHI JU is up to EUR 10 750 000. The indicative in-kind <and financial> contribution from industry partners is EUR 10 750 000. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA) Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.

[79] See section 4.2.3.2 of this amended Work Programme

6.4 IHI JU call 3

Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Expected impacts to be achieved by this topic

The following impacts are expected:

- Patients benefit from preventive treatment or early disease intervention before onset of symptoms.
- Prevention and early diagnosis of disease, combined with better understanding of the mechanisms involved, leading to the development of more cost-effective interventions and strategies.
- Increased availability of validated biomarkers for disease interception and diagnosis, tested in real-world settings.
- Advanced analytics/artificial intelligence supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.

Expected outcomes

R&I actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for disease(s) of high unmet public health need selected by the applicants[80]:

- Patients will receive more timely personalised interventions (prevention, early treatment to avoid complications, etc) to reduce morbidity and mortality from major diseases, improving the lives of citizens.
- Healthcare professionals have access to a screening platform and clinically validated biomarkers for identifying people at risk of disease to facilitate the selection of the most appropriate preventative action.
- Researchers have new biomarkers for prediction and prevention to allow for the development of safer and more effective personalised interventions tailored to the individual's characteristics.
- Healthcare systems will benefit from reliable evidence to target effective, preventative therapeutic interventions to those citizens who will benefit most from them.

Scope

As the population of the European Union ages, the rising burden of disease is a major challenge to the sustainability and resilience of healthcare systems. The identification of individuals at risk of developing an illness so that they can receive an appropriate treatment before the disease develops is an important factor to address this problem. However, for many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease and how environmental and genetic factors affect the occurrence of the disease.

[80] **Unmet public health needs** are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life…) and/or the number of people affected by it. For example, Alzheimer's disease.

Projects funded under this topic should address this challenge by developing an open platform for screening individuals with the aim of identifying people at risk of disease. Applicants should clearly identify a disease(s) of unmet public health need, and specify the initial biomarkers to identify people at risk that will be used within the project (e.g. genetic, metabolic, digital and imaging biomarkers, lifestyle/environmental, family inherited disease, and/or combinations of these) and explain their choices with relevant evidence where possible. By the end of the project, the screening platform should be able to be used for population screening and decision-making including selection of the most appropriate intervention(s) and new technology development.
In particular, for the selected disease(s), the project(s) funded under this topic are expected to:

- Set up a comprehensive interdisciplinary collaboration of the clinical research, industrial, public health, and health technologies communities to develop the screening platform and generate the evidence base for general population screening. This platform should be built to operate in an open-source environment allowing interoperability with applications from different providers, and build on clearly identified existing initiatives where relevant, while aiming at facilitating reusability (for example, a modular structure to enable flexibility and customisation to support new developments). The ethics considerations of operating such a platform must be considered and relevant guidelines for digital biomarker design and development should be followed as appropriate.
- Clinically validate and assess the utility of the screening platform and biomarkers[81] to identify people at risk by designing and implementing a large-scale general population cohort screening study in several representative European countries.
- Design and clinically validate innovative assay technologies for disease risk identification, including digital technologies with data capture/analysis.
- Deliver digital tools for more effective and efficient management and execution of screening programmes and improved disease prevention. Artificial intelligence (AI) tools should be robust and explainable where relevant.
- Publish the relevant methods, standard operating procedures (SOPs), algorithms, standards and guidelines to allow the platform to be used more broadly and for diagnostics and therapies to be developed.
- Develop a plan/roadmap based on solid evidence to facilitate the regulatory qualification of the biomarkers identified and used within the project, and seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice).
- Develop and optimise relevant clinical practice guidelines through systematic evidence and outcome review, while addressing factors influencing uptake of these biomarkers in clinical practice.
- Raise awareness of disease prevention and provide training and education to relevant healthcare professionals, patients and family members. These training materials should be made available for use after the project ends.

A key objective is to facilitate changing healthcare practice, so applicants will need to demonstrate that their outputs can be taken up by healthcare systems and take steps to facilitate this.

[81] Biomarkers are biological characteristics, which can be molecular, anatomical, physiological, or biochemical. These characteristics can be measured and evaluated objectively. They act as indicators of a normal or a pathogenic biological process. They allow the assessment of the pharmacological response to a therapeutic intervention. A biomarker shows a specific physical trait or a measurable biologically-produced change in the body that is linked to a disease or a particular health condition. A biomarker may be used to assess or detect a specific disease as early as possible (diagnostic biomarker), the risk of developing a disease (susceptibility/risk biomarker), the evolution of a disease (prognostic biomarker) – but it can also predict response to a given treatment including potential toxicity (predictive biomarker).

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

To develop novel biomarker combinations and implement them in a broadly applicable screening platform requires significant cross-sectoral expertise including from patients, healthcare professionals, biomarker specialists, machine learning experts, academic researchers, SMEs, and the pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together in the collaborative environment provided by an IHI project to achieve the objectives of this topic.

Indicative budget

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

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply[82].

[82] See section 4.2.3.2 of this second amended Work Programme

Topic 2: Patient-generated evidence to improve outcomes, support decision making, and accelerate innovation

Expected impacts to be achieved by this topic

The following impacts are expected:

- Enable the added value of people-centred integrated healthcare solutions[83] to be assessed according to criteria that matter to patients and citizens, using patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs).
- Facilitate the development and implementation of integrated healthcare solutions[1] based on patient input including PROMs, PPI, and PREMs. These solutions should better respond to the needs and preferences of patients and citizens and support an inclusive approach.
- Enable the smart use of patient input and patient-generated evidence to facilitate the faster market entry of patient-centric and cost-effective advanced integrated healthcare solutions[1], and also spur further innovation by improving return on research and innovation investments.
- Use patient input gathered via m-health, e-health and other technologies to gain improved insights into the real-life behaviour of, and challenges faced by, patients of all ages with complex, chronic diseases and co-morbidities.

Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for the use cases selected:

- Decision makers have new methods for the integration of PROMs, PPI, and PREMs and other people-generated information into regulatory and health technology assessment (HTA) evaluation processes for integrated healthcare solutions.
- Patients of all ages have access to novel integrated healthcare solutions[1] that are developed using structured patient input and better respond to their needs and preferences.
- Researchers have new methodological approaches to elicit and integrate patient preferences into the conception, development, and implementation of integrated healthcare solutions[1].
- Researchers have wider access to interoperable, quality patient input and patient-generated data, respecting the FAIR (findable, accessible, interoperable, reusable) principles, facilitating the research and development of integrated healthcare solutions.
- Researchers are provided with new outcomes, outcome measures and the time horizon over which value should be assessed to develop appropriate tools and methods for the collection and analysis of PROMs, PPI, and PREMs.

Scope

[83] Integrated healthcare solutions are innovative solutions integrating various technologies, coupled with complementary tools and services.

The amount of health data generated by citizens themselves is rapidly increasing. Such data includes patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs), as well as other digital health data/digital biomarkers. While the potential for these data to be harnessed to improve individual healthcare is enormous, these data are often fragmented among multiple providers, so that neither the citizen, nor the healthcare ecosystem have a comprehensive overview, and therefore it is very challenging to fully use these data to provide reliable evidence for decision-makers, and to improve health outcomes.

Research and innovation (R&I) actions to be supported under this topic will aim to address this challenge by:

- Developing a framework to integrate patient input and patient-generated data for use in decision making (regulatory, health economic evaluation, reimbursement, healthcare programme design, tailored prescription of therapies, and technology development), benefit-risk evaluation and value assessment of integrated healthcare solutions.[1] Applicants should build on existing frameworks where appropriate and appropriately address ethics considerations.
- Implement several use cases to support and demonstrate the use of the framework, focusing on using patient input and patient-generated evidence to address challenges that are not adequately addressed by other initiatives. These use cases should demonstrate the value of using patient input (PROMs, PPI, PREMs) and patient generated data (digital health data/digital biomarkers) along the healthcare continuum, including showcasing improvements to data interoperability, healthcare workflows and processes, disease prevention, and care, including home-based care. These use cases should also act as examples of best practice for future use of the framework.
- Facilitating multi-stakeholder access to patient inputs and patient-generated health data such that actionable harmonised data can be used for quality decision making.
- Comparing/contrasting the properties of the three types of patient input (PROMs, PPI, PREMs), identify differences and opportunities for integrated/complementary use.
- Developing an approach or approaches to integrating PROMs, PPI, and PREMs data into the design of core outcomes sets, end-to-end patient treatment pathways, clinical decision support systems, and treatment guidelines. The core outcome sets used within the project should be made available more widely where possible.

Applicants are expected to seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice) and consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

As the cost of healthcare continues to rise, integrated healthcare solutions[1] offer possibilities for delivering better patient outcomes more efficiently. However, the infrastructure for developing effective solutions at scale and for evaluating novel ‘high-value’ care products, programmes, and services is fragmented.

While patient input is critical to developing these person-centred integrated care solutions, to date, coordination among different types of product and service providers has been mostly on an as-needed basis. There has been little incentive for these diverse research disciplines and different types of product and service providers to coordinate their efforts to develop systematic approaches to the use of patient-generated data.

Such patient input can be derived from multiple sources, which have different theoretical foundations and are at different levels of methodological maturity. Different types of patient input, although complementary, require different skill sets that are often not found within a single institution. Only a pre-competitive collaboration that brings together patients, healthcare professionals, industry sponsors, researchers,

programme designers, and programme evaluators, can ensure the effective implementation of patient input in the design, evaluation, and implementation of effective innovated integrated care strategies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 14 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" do not apply[84].

[84] See section 4.2.3.2 of this second amended Work Programme.

Topic 3: Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiency

Expected impacts to be achieved by this topic

The following impacts are expected:

- Improve patient outcomes of hospital care and foster faster recovery by overcoming issues of fragmentation through combining innovative interventional approaches.
- Seamless and successful implementation in hospital settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems (including hospital staffing), and society as a whole.
- Advanced analytics/artificial intelligence (AI) supporting health research and innovation, resulting in improved clinical decision support for increased efficacy of treatment.

Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes:

- Patients will be offered improved, evidence-based, innovative hospital treatment combinations that lead to better outcomes.
- Healthcare professionals will have access to improved clinical decision support systems that will recommend personalised treatments using patient-specific datasets collected in the hospital setting.
- Healthcare systems will have better evidence on cost-effective combinations of interventions and how these combinations can increase hospital efficiency.
- Researchers will have improved information on treatment combinations to facilitate the development of improved interventions.

Scope

Patients admitted to hospital to undergo elective or non-elective procedures typically require recovery and rehabilitation to get back to normal life. New treatment approaches such as minimally invasive surgical approaches, locoregional interventions, novel imaging and diagnostic techniques, clinical decision support systems, and robotics have the potential to reduce complications, facilitate faster recovery, and help increase hospital efficiencies. However, due to limitations in interoperability, reliable evidence and suitable guidelines, these innovative approaches, treatment options and clinical decision support systems are not being optimally combined to provide the best patient care.

Projects funded under this topic should address this challenge by showcasing how existing hospital interventions, treatment approaches and technologies can be optimally combined to improve patient outcomes, enhance patient pathways, generate efficiency gains, reduce hospital staffing challenges, help to lower costs, and decrease societal burden.

In particular, projects should:

- Access and integrate clinical data routinely generated using existing technologies during the patient journey (e.g. medical history profile of patients, diagnosis achieved, for example, by medical imaging and *in-vitro* diagnostic (IVD) tests, digital information generated during the hospital procedure, vital signs and anaesthesia management, electronic healthcare record systems (EHRs), and drug prescriptions such as analgesics). The interoperability of these data should be addressed as appropriate. Suitable, secure IT infrastructure to support edge and cloud computing in compliance with the general data protection regulation (GDPR) and other data privacy policies at national and local levels should be utilised.
- Train and clinically validate explainable AI algorithms to support the development of training programmes, procedure planning and intraoperative assistance solutions, including clinical decision support systems.
- Demonstrate, via use cases using these data & algorithms, how combinations of and/or synergies between the above-mentioned tools, technologies, and therapeutic approaches can be harnessed to improve patient care. This should include comparing the combination of innovative interventional approaches and clinical decision support systems (CDSS) versus limited or no systematic combination of these innovative interventional approaches and CDSS.
- Implement tools to confirm successful treatment during or after the procedure and monitor therapy response and disease regression.
- Develop and implement new methodologies to assess and demonstrate the added value of combining innovative interventional approaches and clinical decision support systems to all relevant stakeholders.
- Encourage the uptake of the results of the project through a strong communication and outreach plan, including the publication of a gap assessment in order to guide future research in this field.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects including any projects resulting from Horizon Europe Cluster 1 Health topics, and, where relevant, seek engagement with regulators (e.g. through the EMA Innovation Task Force, scientific advice).

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

To achieve the transformation outlined above, a broad cross-sectoral collaboration is needed including healthcare professionals to give insights on their experience with the current technology utilisation and act as champions for the new developments, academic researchers, health economists, hospital management, public procurers, technology developers and vendors, and patients, who will benefit from the solutions. Integrating data from multiple origins/sources requires the cooperation of data holders, both public and private, in a non-competitive, neutral setting like an IHI project.

Indicative budget

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

IHI estimates that an IHI financial contribution of between EUR 8 000 000 and EUR 10 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" do not apply[85].

[85] See section 4.2.3.2 of this second amended Work Programme.

Topic 4: Strengthening the European translational research ecosystem for advanced therapy medicinal products (ATMPs) for rare diseases

Expected impacts to be achieved by this topic

- Benefits for patients both with rare and ultra-rare diseases and who may gain from effective and safe advanced therapy medicinal products (ATMPs) and other related innovative therapeutic modalities.
- A better and more cost-effective development of ATMPs and other related innovative therapeutic modalities due to improved scientific and technological processes. This is applicable especially to those ATMPs intended both for the treatment of rare diseases and those that are currently underserved by current therapies (the latter often being of genetic origin).
- Europe to become more attractive for developing ATMPs due to the availability of sustained, interconnected networks of technological and scientific centres of excellence. Although their current focus is on translational research, linkages to clinical networks, including the European reference networks (ERNs) on rare diseases will enhance their activities. The same is true for synergies to be developed with the European Joint Programme on Rare Diseases and the future European partnership on rare diseases. This would set out a more efficient and effective pathway for the development of treatment modalities for patients with rare diseases in Europe.
- Benefits for a broader range of disorders beyond the rare disease domain due to a more robust development of ATMPs and other related innovative therapeutic modalities as well as knowledge transfer across actors in ATMP development.

Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must work towards results that contribute to all the following expected outcomes.

- A sustainable network of centres of excellence, that should:
    i. advance the most promising, impactful, translatable, quality-controlled technologies that address the bottlenecks in the development of ATMPs and other related innovative therapeutic modalities such as the use of messenger RNA (mRNA), or nucleic acids and nanoparticle (NPs) delivery for gene editing;
    ii. make these technologies accessible to all actors involved in the development of ATMPs and other related innovative therapeutic modalities, including the research community, academia, clinics, small to medium-sized enterprises (SMEs), healthcare professionals, biotech, medical technology and pharmaceutical companies, and patients;
    iii. share information, processes and methods, and build capacity in science and technology, and regulatory awareness of ATMPs, including the ability to assist industrial and academic developers of ATMPs in their translational research.
- Consensus reached on quality standards (e.g. of analytical methods) and translation process by the ATMP community at large that support the timely and robust development of ATMPs and other related innovative therapeutic modalities.
- Strengthened interactions with regulators to enable a more streamlined and transparent regulatory pathway that will optimise and speed up the development and delivery of ATMPs and other innovative therapeutic modalities for rare diseases for the benefit of patients, carers, healthcare systems and society.

- Improved technologies/processes, analytic tools, methods including non-clinical methods, and assays useful for the development of ATMPs and other related innovative therapeutic modalities, beyond those targeting rare and ultra-rare diseases.

Scope

There are over 7 000 rare diseases resulting in 30 million patients[86] in Europe with a rare disease. Globally more than 300 million patients[87] are affected. In Europe, less than 10 % of rare disease patients receive treatment and only 1 % are managed using an approved treatment. ATMPs such as gene and cell therapies and other related innovative therapeutic modalities, are very promising to treat patients with rare diseases, especially ultra-rare diseases. However, ATMPs rely on complex technologies where the development process is hampered by a lack of standardisation, scalability and reproducibility.

The overall aim of this topic is to optimise and streamline the future development of ATMPs and other related innovative therapeutic modalities for rare diseases by strengthening the ecosystem that facilitates the transition of early pre-clinical proof-of-concept research to clinical development. This topic focuses on the scientific, technological and regulatory barriers that are limiting translational research into rapid and cost-effective development of ATMPs and other related innovative therapeutic modalities for rare diseases.

To fulfil this aim, the proposals should:

1. Establish a network of scientific and technical centres of excellence (new and/or existing laboratories/institutions) complementing each other to enable translational research in ATMPs or other related innovative therapeutic modalities relevant to the future treatment of genetically defined diseases. These scientific and technical centres are expected to provide access and advance translatable, quality-controlled technologies, share data, and build capacity to assist industrial and academic developers of ATMPs. They are also expected to explore the establishment of connections with clinical networks, including the ERNs on rare diseases.

2. Develop tools and methods and define key characteristics of ATMPs, and quality standards that are critical to later stages of development of ATMPs and other related innovative therapeutic modalities, in particular those targeting rare diseases with no approved treatment option. Relevant therapeutic modalities must include appropriate vector systems and innovative modalities such as messenger RNA (mRNA) and nanoparticles (NPs) for therapeutics. Technology areas of interest could include targeted delivery (e.g. methods to target distribution), stability (e.g. methods to increase the stability of RNA), transgene expression, advanced redosing technology approaches/reduced immunogenicity of gene delivery platforms, and other underlying biology relevant to the specific therapeutic modality enabling accelerated translation to clinical development and manufacturing.

3. Develop and support the uptake of standardised analytical assays, methods and technological platforms, other non-clinical methods and design strategies as well as translation processes for:

    i. reducing the timeframe and costs and improving the future development of ATMPs and other related innovative therapeutic modalities and/or;

    ii. optimising manufacturing processes to maintain product quality while ensuring broad accessibility of critical manufacturing materials and demonstrating the economy of scale for ATMPs or other related innovative therapeutic modalities.

[86] https://www.eurordis.org/information-support/what-is-a-rare-disease/
[87] https://www.nature.com/articles/s41431-019-0508-0

4. Demonstrate the translatability, scalability, and robustness of technologies suitable for the development of subsequent ATMPs and other related innovative therapeutic modalities. This may include process development, mRNA and NPs scale-up and stability, vector production, increasing the throughput of the systematic assessment of the biological and mechanistic features and product characterisation, and ensuring broad accessibility of critical manufacturing materials such as cell lines and producer plasmids.

5. Assess the methods and technological platforms developed for their translational and regulatory validity/utility. Define a regulatory pathway to support the fit-for-purpose development of ATMPs, taking into account an evolving regulatory environment and the interplay between all applicable legislation. Ensure early engagement with the regulators so that the methods and data generated support regulatory needs.

6. Validate the performance of the methods and technologies developed and demonstrate their higher performance in comparison to existing methods for addressing the bottlenecks in the development and manufacturing cycles of ATMPs and other related innovative therapeutic modalities. In addition, test the functionality of the centres of excellence and demonstrate their capability and performance to support translational research through use cases.
   To achieve this, the submitted proposals must plan for an open expression of interest / call process to invite third parties, external to the initially established consortium, to submit use cases at least twice during the lifetime of the project. These use cases must:

   - showcase the utility and validity of the methods and technologies developed and verify that they are fit for purpose in the context of the scientific, technological or regulatory challenges; and

   - measure and help adjust the capability and performance of centres and networks of excellence in assisting industrial and academic developers of ATMPs in their translational research.

For the use cases, clinical validation of technological solutions developed would be in the scope of this topic (within the framework of the above objectives). While conducting full randomised controlled trials are out of scope for this topic, other forms of clinical studies are in scope under the use cases, which may include pilot clinical studies, observational studies, real world data studies etc., depending on the needs of proponents of the use cases.

7. Contribute to strengthening the European rare disease ecosystem by engaging all relevant stakeholders, especially patients and patients' representatives for rare diseases, carers, clinicians, and regulators.

8. Define relevant metrics and measure the use of centres of excellence by relevant stakeholders for the development of their assets or novel technological solutions/therapies.

9. Define a plan for sustainability beyond the lifetime of the project, including consideration for potential expansion to additional promising technological areas.

Applicant consortia should take stock of the state-of-the-art methods and technologies delivered by other EU and global initiatives on rare diseases (e.g. the Accelerating Medicines Partnership Bespoke Gene Therapy Consortium, the Innovative Medicines Initiative (IMI) project ARDAT, the European Joint Programme on Rare Diseases and the future European partnership on rare diseases, or other EU-funded consortia). Proposals should plan for synergies and collaborations to ensure complementarity while avoiding duplication.

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

A cross-sectorial and multidisciplinary public-private collaboration driving innovative science and technology solutions is needed to deliver on the outcomes and impacts of this topic, fostering a trusted collaborative environment where the end-users integrate from day one with the innovation developers to ensure projects generate useful and usable outputs that will be sustained for longer term impact. There is a need to remove key technical bottlenecks, facilitate cooperation and sharing information and processes and bring together all relevant stakeholders in order to streamline the translation of early research into development of potential ATMPs. This will enable accessibility to world-leading solutions that would otherwise limit or delay progression through development and towards effective treatment for patients. Therefore, collaboration and synergies between the research institutions, clinics who often conduct the early research and biotech, SMEs, pharmaceutical and medical technology companies is critical to ensure that the approaches can be translated. Bringing on board the unique expertise of patients and advocates in rare diseases in this effort is essential. Early engagement with regulators is fundamental to maximising the impact of these technologies on public health and ensuring they are fit for purpose. Finally, connections with clinicians and rare diseases networks are needed to ensure an integrated development pathway for ATMPs for rare diseases.

Indicative budget

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

IHI estimates that an IHI financial contribution of between EUR 20 000 000 and EUR 30 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply[88].

[88] See section 4.2.3.2 of this amended Work Programme.

Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

Expected impacts to be achieved by this topic

The following impacts are expected:

- Enhanced cross-sectoral collaboration between healthcare industries, academia and all other relevant actors of the healthcare ecosystem. This will be achieved keeping the people with mental disorders in the centre, outreaching to the social and educational system as relevant to foster sustained and patient-centric innovation in digital health technologies (DHT) for mental health care.
- Preparedness of the healthcare system for the implementation and integration of DHT with existing clinical care strategies thereby also decreasing the burden on staff.
- Prevention (primary and secondary, relapses, chronification, long-term health consequences), earlier and more precise diagnosis, more clinically effective interventions and monitoring, better patient adherence, and reduced hospitalisation (reduction in re-admission/period of hospitalisation).
- Demonstration of the added value of DHT for better management and care and improved experience of people with mental disorders and their families/caregivers, paving the way for a broader and sustained application of DHT in healthcare.
- More cost-effective care pathway management for people with mental disorders.
- Contribute to the upcoming 'European Health Data Space' by promoting better exchange of and access to different types of health data and data generated by DHT and other medical health technologies (using standards in data, technologies…).
- Knowledge and learnings on mental disorders' long-term impact on physiology and physical health. This will contribute to the better overall health & well-being of the population, especially for people with mental health disorders.

Expected outcomes

R&I actions (projects) to be supported under this topic must contribute to all of the following outcomes:

- Robust evidence on the feasibility, acceptability, adherence, and personal satisfaction with digital health technologies (DHT) in people with mental disorders. People with mental disorders and their families/caregivers should be included in evidence generation. This includes pathways to maximise motivation and engagement with DHT of all relevant end-users and healthcare actors. This includes patient-centric selection of potential application features, measurement technologies and digital endpoints. Proper attention should be given to the issues of vulnerability, stigma and difficulties related to limited digital/eHealth literacy. Consideration should be given to ethical, cultural, gender and age-specific (e.g. adolescents') needs and preferences to ensure continued use of the DHT.
- A flexible, interoperable, and reusable digital platform that can be used across numerous conditions and scenarios (various mental disorders, comorbidities, long-term health consequences and other disease areas) to collect, analyse and integrate diverse multimodal clinical and patient data, including patient reported outcome measures (PROMs) and patient reported experience measures (PREMs), with an emphasis on those generated by DHT. Variability across countries should be addressed, as digital infrastructures and the availability of digital tools may differ. Mapping of the specific links between digital infrastructures and types of digital health technology (e.g. concepts, data types, standards, technological approaches) should be included. Consideration must be given to ethical, social, and legal aspects and to the FAIR (findable, accessible, interoperable, reusable) principles.

- Effective and agreed guidelines for the development and implementation of DHT in clinical research and as a part of everyday health and care, enabling the development of more patient-centric treatments, optimised health and care interventions and better disease prevention. Evidence from quantitative studies on potential favourable/unfavourable effects of the technologies on care, and on their impact on changing clinical research and clinical trials should be included. Relevant organisational and work processes, policy and regulatory aspects should be addressed to foster the sustained integration of DHT in real world practice.
- Robust knowledge for better understanding of mental disorders, their change over time and how all this relates to clinical outcomes including the remission, relapse, and recurrence of the conditions, long-term health conditions and mortality and/or surrogate outcome measures when relevant. Socioeconomic outcomes and family/caregiver burden should be addressed. Better insights into other aspects like patient adherence to therapy and adverse drug reactions should be gained.
- A robust body of data to enable the development of digital tools that optimise the engagement of people with mental disorders, caregivers and other relevant actors (healthcare professionals, social workers etc.) adapted to the needs of the patient population and age-specific needs, tackling the issues of stigma, vulnerability, lack of treatment seeking and overall poor adherence to treatment (including lifestyle related). Consideration should be given to providing intuitive equipment and user interfaces and easy troubleshooting.
- Enhanced and more reliable tools and methods (e.g. analytical tools and algorithms) able to provide (near) real time feedback on the DHT, including on the usability, efficacy/effectiveness, and long-term safety. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions in collaboration with the people with mental disorders and their families.
- Robust evidence of how DHT may influence the treatment or behaviour of people with mental disorders. The inclusion of schools/social workers/psychologists in evidence generation should be considered where relevant.

Scope

Mental health disorders represent an area of severe unmet public health need. This has been further negatively impacted by the COVID-19 pandemic, with a substantial increase in the number and severity of people affected for example by anxiety and depression[89], which places substantial pressures on already strained mental health care systems. People with mental disorders have a reduced life expectancy compared to the general population, and this is linked to a greater risk of developing a range of chronic physical conditions[90]. The long-standing separation of psychiatry from other branches of medicine and the lack of specific training on this issue further contribute to the poor attention dedicated to management of comorbidities of mental health disorders.

Digital health technologies (DHT) applied via electronic devices such as wearable sensors, implanted equipment, and handheld instruments and smartphones have already shown significant promise for the prevention and disease management of chronic conditions (e.g. cardiovascular disease, diabetes, obesity). DHT, by making it possible to virtually perform medical activities that have traditionally been conducted in person, also have the potential to decrease the pressure on healthcare systems and their personnel. Thus, DHT might have the potential to address some of the challenges in the prevention, prediction, monitoring

[89] https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide

[90] https://annals-general-psychiatry.biomedcentral.com/articles/10.1186/s12991-021-00374-y; https://www.nature.com/articles/s41569-020-00463-7

and personalised management of mental disorders and their long-term health consequences, as well as to tackle some of the organisational issues in providing mental health care[91].

The scope of this topic is to investigate how DHT might positively impact the healthcare pathway for people with mental disorders.

Applicants should demonstrate how DHT may enable:

1. better prevention and prediction of disorder onset or relapse;
2. better disease management;
3. tackling comorbidities;
4. addressing long-term health consequences (such as cardiovascular disease or diabetes).

The choice of the specific mental disorder should be justified based on unmet public health need, its impact on quality of life of people with mental disorders and their families/caregivers as well as the feasibility and preliminary evidence available on the use and value of DHT.

To contribute to breaking the silos between psychiatry and other medical branches and better address the impact of co-morbidities in people with mental disorders, applicants should consider relevant co-morbidity/ies where DHT data, learnings and technologies are already available and can be further developed/applied to mental disorders. Co-morbidities can significantly exacerbate mental health disorders, impacting quality of life and the development of long-term health consequences The choice of comorbidy/ies must therefore be justified accordingly.

Ways of decreasing the burden on caregivers and families should be considered, and applicants should actively engage these actors as well as the people with mental disorders in addressing critical issues and research questions, including about (sustained) engagement with DHT[92]. Consortia should propose ways to foster the future integration of digital and clinical mental healthcare, as well as how DHT might enhance the outcomes of interventions by social and healthcare professionals while decreasing the burden on the healthcare system. Applicants should adequately describe how they plan to measure such burden.

Resources,and learnings from previous initiatives at European and national level (Innovative Medicines Initiative funded[93] among others) should be taken into consideration.

Applicants should aim to deliver robust evidence on how DHT may be:

a. made easy to adopt and use in a sustained way for both people with mental disorders, their families/caregivers and health and care providers;
b. effectively incorporated into clinical research and in clinician workflows.

Early engagement with regulators should be sought to ensure the future acceptance and usability of the results for example through scientific advice, qualification advice or qualification opinion.

Applicants are expected to implement activities to achieve all expected outcomes.

[92] https://www.frontiersin.org/articles/10.3389/fdgth.2021.764079/full

[93] https://www.imi.europa.eu/projects-results/project-factsheets?keywords=digital+technology&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All; https://www.imi.europa.eu/projects-results/project-factsheets?keywords=radar+cns&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

Digital health technologies (DHT) have enormous potential to improve the prevention, prediction, diagnosis and treatment of health disorders, especially in areas of high unmet public health need such as mental disorders. To achieve this, all stakeholders — healthcare professionals and systems, academic researchers, including from the social sciences, technology developers, regulators, reimbursement authorities and, most of all, people with mental disorders, families and caregivers, and citizens need to be involved in the discussions. There is thus the need for an appropriate multi-stakeholder and cross-sectorial, public-private platform delivering learnings and sustainable outcomes of value across the ecosystem to foster the development, evaluation, and best use of DHT. IHI offers an ideal setting to bring the relevant stakeholders together and achieve the requested impacts.

People with mental disorders and their families/caregivers must be active partners in all activities of such an initiative to ensure the results fit their needs for effective adoption and continued use.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 6 000 000 and EUR 8 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

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

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply[94].

[94] See section 4.2.3.2 of this second amended Work Programme.

HORIZON-JU-IHI-2022-03-01 **Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000. Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.
HORIZON-JU-IHI-2022-03-02 **Patient-generated evidence to improve outcomes, support decision making, and accelerate innovation**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000. Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking..
HORIZON-JU-IHI-2022-03-03 **Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiency**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000. Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.
HORIZON-JU-IHI-2022-03-04 **Strengthening the European translational research ecosystem for advanced therapy medicinal products (ATMPs) for rare diseases**	Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 30 000 000. Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.

HORIZON-JU-IHI-2022-03-05 **Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000. Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget

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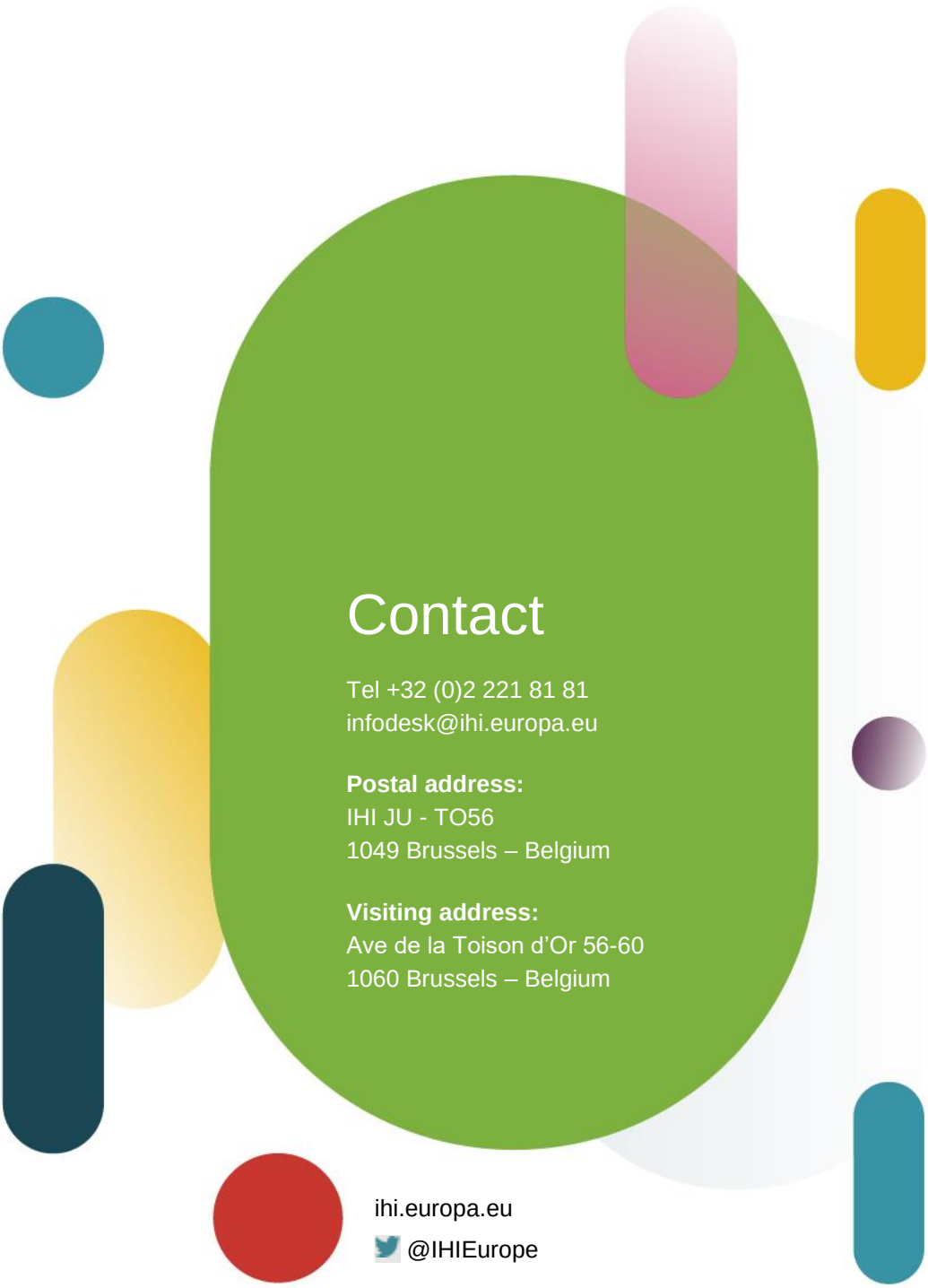

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