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EVALUATION

Interim Evaluation of the Horizon Europe Framework Programme for Research and Innovation (2021 - 2024)

Accompanying the document

Communication from the Commission to the European Parliament and the Council

Horizon Europe: Research and Innovation at the heart of competitiveness

{COM(2025) 189 final}

Annex 18: Evaluation of Innovative Health Initiative (IHI) JU

Annex to the Commission's interim evaluation of Horizon Europe

Contents

1. Effectiveness

1.1 Achievement of the objectives

The Innovative Health Initiative (IHI) Joint Undertaking (JU) was established in November 2021[1] as an institutionalised public-private partnership between the European Union and European life science industries. It follows the Innovative Medicines Initiative 2 (IMI2), in which EFPIA, the European Federation of Pharmaceutical Industry Associations, was the sole private sector partner. IHI constitutes an expansion of the partnership to include a wider set of industry partners who contribute to medical innovation (medical technologies, imaging, diagnostics, biotechnology and companies active in the digital area), complementing pharmaceutical research and development. The new partnership was created in recognition of developments in medical research, healthcare needs and healthcare delivery that require a different and increasingly cross-sectoral approach to research and development[2].

The initiatives' alignment with the objectives of Horizon 2020 and Horizon Europe has been consistent, significantly contributing to Societal Challenge 1 of Horizon 2020 on 'Health, demographic change and well-being' and enhancing Europe's competitiveness in health R&D. They have been integral in addressing public health needs and responding to crises, such as the Ebola and COVID-19 outbreaks, by expediting medical innovation and by promoting cross-sectoral collaborations.

The interim evaluation of IHI and final evaluation of IMI2 provided detailed reporting on the general and specific objectives of IMI2 and IHI[3] and assessed the extent to which IMI2 has achieved its objectives, broken down into specific sets of key performance indicators (KPIs)[4]. Overall, IMI2 has achieved its objectives of boosting pharmaceutical innovation in Europe and speeding up the development of innovative medicines, vaccines and medical technologies, in particular in areas with high unmet needs[5]. It has also demonstrated substantial achievements towards its KPIs, exceeding many of its targets[6]. The most significant achievements include an approved vaccine[7] for Ebola Zaire virus disease[8], an approved new antibiotic drug combination[9], insights into the genetics of Alzheimer's disease[10], the identification of biomarkers associated with

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

[2] Evaluation support study on Horizon Europe's contribution to a Resilient Europe – RTD/2021/SC/021, Final Report Phase 2 – Annexes, Case Study No 1: From Innovative Medicines Initiative to Innovative Health Initiative – the early experience, publication in September 2024. Activities in IMI2 (2014-2020) cover Horizon 2020, with activities in IHI covering Horizon Europe (2021-Present).

[3] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), publication in September 2024, pages 77-78.

[4] Interim evaluation, pages 45-52.

[5] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2).

[6] Interim evaluation, page 68.

[7] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1248

[8] Evaluation study of the European Framework Progammes for Research and Innovation for a Resilient Europe, Case Study 11.

[9] "Game-changing" new drug combination will save many lives (europa.eu)

[10] EPAD | IHI Innovative Health Initiative (europa.eu)

diabetes development[11] and advances on cancer, for instance on using liquid biopsies for less invasive ways of capturing tumour samples[12]. Many projects have made practical contributions to the fight against COVID-19[13].

The programme has made project outputs accessible beyond consortium partners, with 58.3% of projects making resources available to external entities[14]. The programme's scientific productivity and impact are evident in nearly 10 000 publications. Most IMI2 research (64%) was published in high-impact journals and the citation impact of research conducted in IMI2 projects (1.86) was almost twice as high as the world average (1.00) and 75% higher than the EU average (1.16)[15].

Overall, IMI2 has demonstrated a strong track record in achieving its objectives, notably in fostering collaboration, advancing regulatory science, and producing high-impact scientific research that delivers tangible innovations for patients[16]. The initiative's overall performance demonstrates its effectiveness in driving medical innovation and addressing public health challenges in Europe. IMI2 has created a unique environment that fosters collaboration and innovation, bringing together diverse stakeholders to tackle complex health challenges[17].

IMI2 has demonstrated its ability to adapt to emerging health needs, responding to health emergencies and addressing strategic unmet public health needs. In response to the deadly Ebola virus disease outbreak in 2014 in western Africa, IMI2 launched a multi-project Ebola+ programme with a total budget of over EUR 300 million tackling a wide range of challenges in Ebola research, including vaccine development, clinical trials, storage and transport, and diagnostics[18]. In 2020, IMI2 launched a fast-track call for proposal (maximum time to grant: eight months from submission of full proposal) to urgently address the COVID-19 outbreak[19].

The IHI projects launched to date are expected to improve the prevention and diagnosis of cardiovascular diseases, dramatically cut animal use in standard safety studies, lead to a better understanding of mental disorders using digital health technologies and the early diagnosis of chronic liver disease, amongst others. The partnership has also launched calls for public-private, cross-sectorial projects that address key union policy priorities such as regulatory sandboxes (foreseen in pharmaceutical regulation), safeguarding innovation and intellectual property in the European Health Data Space (EHDS), and early feasibility studies to support innovation for

[11] RHAPSODY | IHI Innovative Health Initiative (europa.eu)
[12] CANCER-ID | IHI Innovative Health Initiative (europa.eu)
[13] IHI brochure – Driving the future of healthcare in Europe (2022)
[14] IMI2 KPI 6 captured the share of IMI2 projects whose resources/outputs are made accessible beyond the consortia partners (with or without a fee). These outputs can be major databases, biobanks, in-silico tools (e.g. software, algorithms), training materials and guidance that can be used by those outside the consortium. 67 projects have been reported as having developed such resources, a share of 58.3% of projects, above the 50% target (interim evaluation, page 48).
[15] Interim evaluation of the IHI and its predecessor the IMI2, published in September 2024, page 49. A full bibliometric analysis was undertaken in 2023.
[16] Interim evaluation of the IHI and its predecessor the IMI2, published in September 2024, pages 52, 68.
[17] Interim evaluation, pages 45-52.
[18] Ebola+ | IHI Innovative Health Initiative (europa.eu)
[19] https://www.ihi.europa.eu/sites/default/files/IMI2%20Call%2021%20Coronavirus%20-%20Call%20text_final.pdf

medical devices. It is too early to assess the effectiveness of IHI, but the expanded partnership is on the right track[20].

As IHI continues to evolve, it is essential to build on the successes and lessons learned from IMI2. By doing so, the partnerships can continue to make a significant impact on patient care and quality of life, ultimately improving public health and well-being in the EU.

1.2 Long-term scientific, societal, economic and technological impacts

IMI2 has made a significant contribution to **scientific** advancements. The initiative's model, which promotes collaborative research between public and private stakeholders, has been vital in facilitating these advancements.

IMI2 and IHI aim to foster public-private collaboration in pre-competitive research with the long-term aim of developing innovations beyond the early research phase supported by the JUs. Many of the outputs resulting from this research do not immediately translate into products and services that can be brought to market, but they form the basis of future exploitable outcomes or speed up the research process in general. This shows the need for and relevance of investment in long-term research. Yet, despite the long timelines for developing health innovations and bringing them to market (including regulatory and reimbursement steps), IMI2 has demonstrated substantial impact. This impact is demonstrated through the development of 439 substantial assets (significantly above the target of 50 set for this programme), such as new drug and diagnostic candidates, biomarkers and other research tools. These are significant milestones in the research and innovation process, applicable to many disease areas, such as dementia and diabetes[21].

Advances in cross-cutting topics, such as big data management, patient involvement and paediatrics, have also played a crucial role in improving our understanding of diseases and guiding drug development, ultimately benefiting patients. IMI2's efficacy in achieving its scientific objectives is further evidenced by the completion of 24 regulatory procedures[22], double the target set for the programme. This includes the development of tools and methodologies that have been accepted by regulatory authorities for use in R&D, such as diagnostic panels which can identify SARS-CoV-2 and other respiratory infections and contribute to the improvement of clinical guidelines and practices. This achievement illustrates the significant role the programme plays in regulatory science, speeding up patient access to novel innovations.

IMI2 has also been successful in generating new knowledge about diseases that can be used to inform drug development, with 46 different such disease classifications reported, exceeding the

[20] IHI work programmes 2021-2024

[21] Interim evaluation of the Innovative Health Initiative (IHI) and Final evaluation of the Innovative Medicines Initiative (IMI2), p. 43

[22] The regulatory procedures include four outputs awarded a CE-mark (certifying compliance with EU safety, health and environmental protection requirements), inclusion in six regulatory guidelines, two regulatory letters of support, 10 regulatory qualified opinions and two submissions for qualification opinion. The EHDEN project has established a harmonised data network using a common data model that has now been established as a standard.

target of 30. This has enhanced the personalisation of medical research by enabling the identification of patient sub-populations and informing targeted therapeutic strategies[23].

A significant measure of IMI's scientific productivity is reflected in its publication output. The programme produced almost 10 000 publications between 2010 and 2022, with a majority published in high-impact journals. The citation impact of research conducted in IMI2 projects was twice as high as the world average and 75% higher than the EU average, indicating the scientific relevance and influence of the research conducted under the initiative[24]. IMI2 has facilitated extensive cross-sectoral and international collaborations, with 67% of papers produced by IMI2 projects having co-authors from different sectors, demonstrating the cross-disciplinary nature of the research. Additionally, 65% involved authors from different countries, highlighting the initiative's role in fostering international scientific cooperation.

At **societal** level, IMI2 has made significant strides in addressing unmet public health needs and health emergencies. The initiative's focus on fostering medical innovation in response to these needs has been a key factor in its societal impact, as has its flexibility in responding to health emergencies[25], such as the Ebola outbreak[26] and the COVID-19[27] pandemic.

IMI2 projects have provided new treatment options against multidrug-resistant bacteria, advanced basic science, and established a pan-European network of clinical sites for high-quality clinical studies for new antibiotics. The European Commission approved marketing authorisation for EMBLAVEO® in April 2024[28]. This is a drug combination for use against serious infections caused by multidrug-resistant Gram-negative bacteria. Two of the EMBLAVEO® clinical studies were conducted with the support of COMBACTE-CARE[29], starting in 2015. This illustrates the need for and value of IMI2 'playing the long game on research funding', despite occasional criticism from the research community about the lack of visible impact in the shorter-term.

The initiative has also been successful in creating collaborative networks that would not have been possible without a European partnership. In one IMI2-funded project[30], partners joined forces with US experts in paediatric cancer to reach a much-needed consensus on the best way forward for testing childhood cancer drugs. Another project[31] put in place the infrastructure needed to speed up and facilitate high-quality clinical testing of new treatments for the entire paediatric population via an extensive pan-European network of paediatric clinical trial sites. These networks have facilitated cross-border and cross-sectoral collaboration, bringing together a diverse range of

[23] As an example, the LITMUS project developed a new definition of sub-populations of patients with non-alcoholic fatty liver disease (NAFLD) using histological target conditions. Being able to stratify patients with NAFLD enables non-invasive triage and reduces the need for liver biopsy in clinical practice and clinical trials.

[24] Annual Activity Report 2020: https://www.ihi.europa.eu/sites/default/files/IMI2_GB_DEC_2021_09_Annex%201_AAR2020.pdf.

[25] Evaluation study of the European framework programmes for research and innovation for a resilient Europe - Publications Office.

[26] Impact on: Ebola | IHI Innovative Health Initiative (europa.eu)

[27] IMI2 Call 21: https://www.ihi.europa.eu/sites/default/files/IMI2%20Call%2021%20Coronavirus%20-%20Call%20text_final.pdf.

[28] Health and food safety – Antimicrobial resistance: Commission authorizes a new antibiotic (europa.eu)

[29] IMI-supported treatment against multidrug-resistant bacteria approved by European Commission

[30] https://itccp4.com/

[31] conect4children is a pan-European clinical trial network

organisations to tackle complex global health challenges such as cancer or availability of new paediatric medicines[32].

IMI2 has demonstrated a significant **economic** impact through its ability to mobilise substantial additional contributions from the private sector. The direct leverage factor of IMI2, increased to 1.06, indicates that for every euro contributed by the EU, the initiative succeeded in mobilising an equivalent amount from private partners, surpassing the leverage achieved under its predecessor, IMI1.

IMI2's design, which requires equal contributions from the European Commission and private partners, has been instrumental in attracting considerable investment into health research and innovation. This co-funding model has led to a total project cost of EUR 3.010 billion, with the EU contributing EUR 1.463 billion and private partners, including the EFPIA and Associated Partners, contributing a combined total of over EUR 1.547 billion. Although the participation rate of small and medium-sized enterprises (SMEs) in IMI2 projects was below the 20% target, the programme still managed to attract a significant number of SMEs, and considerably more than IMI1 (see Section 3a).

Moreover, IMI2's focus on fostering collaboration across sectors and countries has led to the establishment of extensive cross-border networks, which will have positive spillover effects for the European economy[33].

In terms of **technological** impact, IMI2 has been instrumental in fostering technological advancements and digital transformation within the health sector. IMI2 has made substantial contributions to the field of digital health, by supporting a broad range of projects that contribute to the study and development of digital health technologies and practical applications. In addition, over two dozen IMI2 projects include a digital health component that contributes to the overall aim of the projects, without necessarily being their key component. Together these constitute a significant investment of IMI2's project funding in the field of digital health[34].

One of the most significant technological impacts of IMI2 has been the development of new tools and processes that are now being used by industry participants. These include animal or non-animal models, standards, biomarkers, standard operating procedures, screening platforms and clinical trial platforms. For example, one IMI2 project set out to shorten the path to rare-disease diagnosis by using newborn genetic screening and digital technologies[35]. Another is developing a collaborative platform that will link up existing European research infrastructures and speed up the discovery of new biomarkers for neurodegenerative diseases[36]. These assets have been instrumental in advancing the pre-competitive space of medical innovation. Moreover, IMI2 has made strides in the regulatory sphere by contributing to new or improved guidelines,

[32] Interim evaluation, page 52. These collaborative networks exist both within sectors (e.g. among academic organisations), between types of organisations (EFPIA companies with academic organisations) and between sectors and organisations based in different countries.
[33] Interim evaluation, page 69.
[34] Evaluation support study on Horizon Europe's contribution to a Resilient Europe – RTD/2021/SC/021, Final Report Phase 2 – Annexes, Case Study No 2: IMI2 and IHI: driving innovation in digital health, publication in September 2024.
[35] Screen4care
[36] European Platform for Neurodegenerative Diseases

methodologies, tools, technologies or solutions accepted by regulatory authorities for use in R&D. The initiative's technological impact extends to the creation of resources and infrastructure, such as research networks, clinical networks, biobanks and collaborative platforms that have become sustainable beyond the formal project lifetime. One IMI2 project[37] aims to create a sustainable, integrated pan-European collaborative paediatric network that will speed up and facilitate the running of high-quality clinical trials in children while ensuring that the voices of young patients and their families are heard.

Moreover, IMI2 and IHI projects generate valuable data, such as to help advance our understanding of Alzheimer's risk, which contributes to increased health data availability in Europe. These resources facilitate the translation of scientific knowledge into practical innovations, ensuring the longevity and accessibility of research outputs beyond the lifespan of individual projects.

The IHI was officially launched in November 2021. By October 2024 the first 16 projects had started, with additional grant agreements in preparation. The specific outputs and impacts will become more apparent as the projects progress and mature beyond this nascent stage. Given the initiative's focus on fostering multi-sectoral collaborations and funding projects aimed at translating health research and innovation into tangible benefits, technological impacts are anticipated.

2. Additionality

IMI and IHI have played crucial roles in mobilising significant public and private funding, stimulating cross-sectoral R&D, and fostering SME involvement within the health sector.

IMI2, the successor to IMI1, showed a considerable rise in contributions, with the direct leverage factor in IMI2 of 1.06 (rise by 6.23 percentage points compared to 0.977 under IMI1).

This means that for every euro contributed by the European Commission, IMI2 succeeded in mobilising an equivalent amount from private and associated partners, reflecting a balanced public-private investment and a strong case for the value of public funding in leveraging additional R&D investment[38]. Crucially, the leverage factor for IMI2 (and IHI) is determined by the design of the partnership which stipulates equal contributions from the two partners; contributions from industry partners and associated partners are matched by the Commission. It underlines the effectiveness of public funding in leveraging extra R&D investment, but the leverage metric does not fully capture the effect of partnership going beyond purely financial terms. The partnerships bring together relevant and competent actors from across Europe and beyond, enhancing research and innovation networks and facilitating collaboration and knowledge-sharing among diverse institutions.

IMI2 and IHI have had a significant economic impact by mobilising substantial financial resources, leading to a significant direct leverage effect. While the leverage effect for IHI is not yet available, these partnerships have underpinned large-scale, cross-sectoral projects that have driven and continue to advance innovation in health research, particularly in digital health, diagnostics and drug and device development.

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[37] conect4children is a pan-European clinical trial network

[38] https://www.ihi.europa.eu/sites/default/files/uploads/documents/reference-documents/EC_factsheet_imi2.pdf

3. Transparency and openness

3.1 Openness to newcomers and SMEs

IHI, and its predecessor IMI2, have demonstrated openness to new participants, expanding beyond the pharmaceutical industry to include a broader range of stakeholders in the life sciences and healthcare sectors. This expansion is reflected in the inclusion of new industry associations as founding members of IHI, which has given representatives from various sectors a voice in its governance structures.

While not explicitly designed to support SMEs, IMI2 saw an increase in SME involvement, reflecting the initiative's role in creating a supportive environment for SMEs, which are vital for innovation and job creation within the EU economy. While the number of SMEs participating in IMI2 projects increased to 256 from 166 under IMI1, the share of SMEs among project participants remained below the target of 20% when counted as participations[39]. Efforts to attract more SMEs have included highlighting tasks suited to SMEs in call topics and providing tailored information and webinars. IHI has seen an increase in the number of SMEs, with new trade association partners like MedTech Europe, EuropaBio and COCIR representing a significant number of SMEs. In line with this, the first IHI projects show strong SME involvement, with SMEs accounting for 22% of participants (69 of the total 315 participants) in the grant agreements signed as of July 2024.

Though still at an early stage, the initial IHI projects (16 signed grant agreements) show valuable progress against some of the IHI-specific KPIs[40]. They demonstrate the ability to involve multiple healthcare stakeholders[41] (100% of projects involve more than two types of healthcare stakeholders as project participants) and generate cross-sectoral collaboration[42] (94% projects bring together private members and/or contributing partners or their affiliated or constituent entities from two or more technology sectors). Moreover, all IHI projects (100%) aim to develop new methodologies or improve existing ones, with some in disciplines addressing public health needs included in the list of the WHO Europe Health 2020 priority areas[43].

However, IMI2 has faced challenges in achieving its target for involving patient organisations and healthcare professional organisations at project level[44]. Members of such groups are involved in around 63.1% of total IMI2 projects, below the 80% target. While progress has been made, these areas highlight the need for continued efforts to increase the societal impact of the initiative. IHI has established a patient pool, which will strengthen the voice of patients and informal caregivers in a range of IHI activities, for example as participants in project meetings or speakers at scientific

[39] Internal evaluations, pages 50, 65, 70.
[40] www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_2022.pdf
[41] Including research higher or secondary education organisations (private or public), SMEs, large companies (for-profit legal entities), non-governmental organisations, healthcare professional organisations/healthcare providers, patient organisations and other associations, regulators or regulatory bodies, notified bodies, health technology assessment bodies, healthcare payers, charities and foundations, public authorities.
[42] Pharmaceutical, biopharmaceutical, medical technologies, biotechnologies, other healthcare sectors.
[43] www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_WHO2020PriorityAreas.pdf
[44] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), publication in September 2024, p. 65.

events, webinars and trainings. The pool was created in 2023 and will run until 2026, with 120 people currently in the pool.

The transition to IHI has also introduced mechanisms to involve a wider set of stakeholders in its official bodies, such as the Science and Innovation Panel (SIP). Under IMI2, the scientific advisory role was taken on by the Scientific Committee, which was smaller and composed of experts from the research community, patient representatives and regulatory bodies only.

In addition, the IHI Ideas Incubator provides an opportunity for a mechanism to provide ideas for potential IHI topics via the IHI website, following the concept of 'co-creation'. When it comes to ideas for potential new call topics, this means that suggestions from the wider health and research community are welcome.

3.2 Mechanisms to ensure openness

IHI has implemented procedures and mechanisms to broaden its partnership base, building on the experience of its predecessor, IMI2. The transition to IHI has led to the incorporation of industries beyond pharmaceuticals into its governance structure[45]. This inclusion of new industry partners[46] has provided a platform for diverse voices in decision-making processes, reflecting a deliberate effort to enhance cross-sectoral collaboration in health research and innovation.

The newly established SIP includes a wider array of stakeholders, such as healthcare professionals and regulatory body representatives, to advise on strategic priorities. In addition, an IHI website has been set up to collect ideas for call topics from a broader set of stakeholders, demonstrating a commitment to openness and inclusivity in setting research agendas.

In January 2025, IHI is planning to launch a pilot for a bottom-up, thematically open call as part of the normal cycle of the single-stage calls. It is expected that this type of call will help to draw in new participants.

3.3 Transparency

IMI demonstrated a commitment to engaging a broad range of stakeholders in identifying research priorities. The governance structure included mechanisms for stakeholder consultation, such as the States' Representatives Group (SRG) and the Scientific Committee, which provided advice on the development of the strategic research agenda (SRA) and call topics. Additionally, IMI2 pioneered online submission of call topic ideas through a dedicated web portal, allowing for wider stakeholder input, but this has only become firmly established under IHI. The setting-up of a patient pool under IMI2, which was later carried over into IHI, further exemplified efforts to involve patients and caregivers in the programme's activities.

[45] For instance, MedTech Europe represents a constituency of several thousand companies, mostly SMEs.

[46] Evaluation support study on Horizon Europe's contribution to a Resilient Europe – RTD/2021/SC/021, Final Report Phase 2 – Annexes, Case Study No 1: From Innovative Medicines Initiative to Innovative Health Initiative – the early experience, published in September 2024. A wider set of industry partners was included in the expansion under IHI: medical technologies, imaging, diagnostics, biotechnology and companies active in the digital area (COCIR, EuropaBio, MedTech Europe – in addition to the original partner EFPIA / Vaccines Europe).

However, the interim evaluation of IMI2[47] suggested that the processes for developing the SRA and annual work programmes could benefit from increased transparency, as some stakeholders perceived that certain applicant consortia had better chances of success.

Action was taken to address these concerns, including efforts to attract a more diverse range of participants, particularly SMEs, and to make call topics less prescriptive. IHI has implemented measures to ensure open and transparent processes for consulting stakeholders on priorities. The development of IHI's strategic research and innovation agenda (SRIA)[48] involved a multi-stage process with contributions from a broad range of stakeholders, including a public consultation phase[49]. Opportunities for stakeholder engagement have been extended with the establishment of the SIP, the possibility for more frequent exchanges between the SRG members, and the establishment of the IHI Ideas Incubator. In addition, IHI has significantly more single-stage calls than IMI2. Single-stage calls are thematically much broader and therefore more open and attractive to a wide range of potential applicants.

4. Efficiency

The table below reports, for the **period 2014-2023**, IMI's and IHI's the total **operational costs** (OC, EU contributions; Validated IKOP; Financial contributions to operational activities by JU partners; Eligible project costs funded by non-JU members to project activities; Contribution from Member States and international organizations to project activities), **certified IKAA** (In-Kind Contributions to Additional Activities) and **running costs** (RC, commitment appropriations EU budget and contributions from sources other than the EU). See also Annex 4.4.1 for a comparison of operational expenditure and administrative expenditure of Joint Undertakings and EIT KICs of the period 2014 -2023.

Table - Operational and administrative expenditures of IMI and IHI JU (2014-2023) (source: CORDA)

The table includes data for Innovative Health Initiative Joint Undertaking and Innovative Medicines Initiative. ***OC****: Operational Costs;* ***IKAA****: Certified IKAA;* ***RC****: Running Costs*

	2014 [EUR]	2015 [EUR]	2016 [EUR]	2017 [EUR]	2018 [EUR]	2019 [EUR]	2020 [EUR]	2021 [EUR]	2022 [EUR]	2023 [EUR]	Total
OC	-	292,373,287	284,463,928	258,331,603	567,112,444	823,881,376	396,571,957	387,739,570	-	352,020,729	3,362,494,895
IKAA	-	-	-	-	-	-	-	-	129,615	-	129,615
RC	8,880,000	8,881,400	9,480,000	9,829,000	10,313,000	11,020,154	11,152,482	9,100,000	9,280,000	9,500,000	97,436,036

KPIs such as time-to-inform (TTI), time-to-grant agreement signature (TTG), and time-to-pay (TTP) have consistently met or exceeded their respective targets[50]. From 2014-2022, TTI was significantly faster than the target of 153 days and the 245-day TTG target was met for every year, except for one grant agreement in 2017. The TTP for pre-financing was significantly below the target of 30 days, while interim payments improved over time and final payments remained below

[47] EC (2017): The Final Evaluation of the Innovative Medicines Initiative2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union, p. 9.

[48] Strategic Research and Innovation Agenda (europa.eu)

[49] Processes for consulting stakeholders and identifying priorities - Research and innovation agenda | IHI Innovative Health Initiative (europa.eu).

[50] Interim evaluation, page 44, Table 8.

the 90-day target[51]. For IHI, 16 grant agreements were signed by October 2024 with an average TTI of 68 days and TTG of 235 days. The 245-day TTG target was thus met in 88% of the cases. This performance underlines IMI2's ability to streamline its processes and manage operations effectively within the constraints of the allocated budget. In practice, though, both IMI2 and IHI manage projects that are twice as much the financial value as it would seem from looking at the EU contribution only, because of private partners' contributions to the operations of the projects (brought in mostly as in-kind and partly as financial contributions)[52]. Taking these total costs into account, this is a significant achievement of the JU regarding high operational efficiency.

IMI2 has made substantial contributions to the scientific community and wider society (see section 1.2), with the potential to drive future breakthroughs in the health and life-sciences, with far-reaching implications for public health. However, accurately quantifying these societal benefits in monetary terms presents a complex challenge. Many of the outputs of IMI2 are in the pre-competitive space, meaning they do not translate directly into marketable products or services, thereby limiting their immediate economic value. Moreover, funding for the development of health innovations typically comes from a variety of public and private sources. IMI2/IHI funding is usually just one source among many, though a crucial one, given its catalytic and cross-sectoral nature.

IHI, still in the early stages of its lifecycle, has yet to undergo a comprehensive assessment of its cost-effectiveness, which can be definitively calculated after the programme has ended[53].

As shown above, IMI2 was successful in generating high-value scientific outputs and in promoting extensive collaboration across various sectors and countries. This success contributed to the European Union's competitiveness in health research and innovation. Turning to IHI, it is too soon to make definitive statements about its cost-effectiveness. However, the interim IHI evaluation[54] highlights the importance of the programme's alignment with Horizon Europe and its contribution to several EU policies, such as Europe's Beating Cancer Plan and the Pharmaceutical Strategy for Europe. As IHI progresses, a comprehensive assessment of cost-effectiveness will become possible, providing a fuller picture of the initiative's value and impact.

5. Coherence and synergies

5.1 Complementarity with relevant regional, national and EU policies/programmes

IMI2 and IHI have demonstrated a significant degree of complementarity with relevant regional, national, and EU policies and programmes. This alignment is evident in its strategic orientation and the execution of its activities, which have been well integrated within the broader framework of Horizon 2020 and are poised to continue under Horizon Europe through the IHI.

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[51] Interim evaluation of the Innovative Health Initiative (IHI) and Final evaluation of the Innovative Medicines Initiative (IMI2), p 41.

[52] For details on leverage factors, see Section 2.

[53] Consolidated Annual Activity Report 2023

[54] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), publication in September 2024.

The 2017 interim evaluation concluded that the objectives of IMI2 were well aligned with the objectives of Horizon 2020[55]: (1) to generate excellent science, (2) to create industrial leadership, and (3) to tackle societal challenges. IMI2 was also well aligned with the aims of Societal Challenges I (SC1) 'Health, demographic change and well-being'.

This final evaluation confirmed that the programme remained well aligned with the objectives of Horizon 2020 and contributed significantly to the aims of Societal Challenges I (SC1) 'Health, demographic change and well-being'. However, it was noted that the policy landscape in which IMI2 and IHI operate has become increasingly complex, making it difficult for individual programmes to navigate this space, increasing the risk of overlaps and redundancies.

IHI is part of Horizon Europe and aligns its strategy with the Health Cluster of Pillar II aimed at responding to global challenges and European industrial competitiveness. As a cross-sectoral institutionalised partnership (based on Article 187 of the Treaty on the Functioning of the EU) within Horizon Europe, it works towards the three objectives of fostering scientific and technological excellence, tackling Commission policy priorities, and boosting Europe's innovativeness and competitiveness. By working on ways to speed up drug, vaccine or device development, IHI also contributes to the strategic autonomy and technological sovereignty of the EU[56].

IHI's alignment with EU policies is further underscored by its direct contributions to initiatives such as Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, and the new Industrial Strategy for Europe. The initiative already played a pivotal role in the development of the European Health Data Space and contributes to the European Green Deal[57], demonstrating its coherence with EU policy priorities. The programme's ability to respond flexibly to health emergencies, such as the Ebola outbreak and the COVID-19 pandemic, also illustrates its complementarity with EU health policy objectives. IMI2's capacity to mobilise substantial investment in medical innovation in response to these challenges showcases the added value of a coordinated European approach to health emergencies.

One of the roles of the IHI States Representatives Group is to identify relevant national and regional programmes. The SRG submitted annual reports for 2022 and 2023[58] and provided input on ideas for IHI projects while taking account of complementarity with existing national and regional policies.

[55] Interim Evaluation 2017, p. 80, also stated in the evaluation in reference 12.
[56] For example, the health data and evidence network created by EHDEN is used by several other IMI2 projects (e.g. OPTIMA, PIONEER, HARMONY). Projects also use the RADAR-base data platform, software and algorithms developed by RADAR-CNS to apply the approach to new disease areas and develop and test digital endpoints that are (prospectively) disease-agnostic as well as technology-agnostic (RADAR-AD, Mobilise-D).
[57] For example, two topics on the environmental impacts of healthcare have been launched and are in line with the goals of the European Green Deal.
[58] States' Representatives Group, IHI Innovative Health Initiative

5.2 Synergies with other parts of the Framework Programme

A dedicated evaluation study assessed the level of coherence between partnerships and other Horizon 2020 activities, looking at the example of IMI2[59]. The findings from the case study (case study 11) and the thematic similarity assessment indicate that despite some apparent similarities, particularly with the Societal Challenge 1 projects, the IMI2 partnership was also consistent with other Horizon 2020 programme parts. Project data shows that IMI2 projects made up less than 1% of all Horizon 2020 projects, while the share of the EU contributions toward IMI2 projects was 2.1% of the total Horizon 2020 EU contributions. IMI2 projects have been over three times larger than the Societal Challenge 1 projects and over ten times larger than the average Horizon 2020 project size.[60]

As concluded in the 2020 report on the bibliometric analysis of ongoing IMI2 projects[61] a high level of scientific excellence was taking place in the IMI2 projects. The field-normalised citation impact of IMI2 papers was 2.05, over twice the world average (1) and much higher than the European average (1.14).

For both partnerships, synergies are created between projects and are encouraged among project participants. This is particularly evident in the field of digital health research, where the are several cases of 'cross-pollination' between IMI2 projects[62]. For example, the health data and evidence network created by EHDEN is used by several other IMI2 projects (e.g. OPTIMA, PIONEER, HARMONY). Projects also use the RADAR-base data platform, software and algorithms developed by RADAR-CNS to apply the approach to new disease areas and develop and test digital endpoints that are (prospectively) disease-agnostic as well as technology-agnostic (RADAR-AD, Mobilise-D).

IHI has set up a task force with the Commission and industry partners to focus on increasing its synergies with other EU programmes, partnerships and Horizon Europe missions and cover all angles and coordinate activities. Some early potential synergies have been identified and a memorandum of understanding has been signed between IHI and EIT Health. Initial contacts have also been established with the EDCPT3 and Key Digital Technologies JUs, as well as the Metrology Partnership and the Health Emergency Preparedness and Response Authority (HERA).

The IHI Office and the Commission are also building links with various regional stakeholders, for example, by linking with the co-funded partnerships on Transforming Health and Care Systems (THCS) and on Personalised Medicine, by establishing contact with the Reference Sites Collaborative Network and by organising regular exchanges with representatives of several European regions.

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[59] Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe, Final Report Phase 1, Evaluation study feeding into the Commission's *ex post* evaluation of Horizon 2020, page 34.
[60] Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe, Final Report Phase 1, Evaluation study feeding into the Commission's *ex post* evaluation of Horizon 2020, page 34.
[61] Bibliometric analysis of ongoing projects 11th Report September 2020.
[62] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), p. 38.

6. EU added value

IMI2 and IHI have provided added value in health and life science research and innovation, exceeding what could be achieved through regional or national collaborative research efforts. Central to this is the creation of extensive, EU-wide, cross-border, cross-sectoral collaborative networks, bringing together a diverse range of stakeholders to tackle complex health challenges. These networks, supported by significant funding, could not have been established at a regional or national level[63].

IMI2 has proven its adaptability by quickly initiating targeted research projects in response to emerging health crises, such as the Ebola outbreak and the COVID-19 pandemic. This ability to address urgent public health needs in real time, leveraging collective expertise and resources, is a key indicator of its added value. The initiative's projects have produced a wealth of widely adopted assets, tools and processes that have reached significant milestones in the innovation process (see section 1.2).

IMI2 and IHI have provided substantial added value by fostering large-scale, cross-sectoral collaborations, responding flexibly to health emergencies, facilitating large-scale, multinational clinical trials and establishing networks, producing widely adopted research outputs and enhancing the international reach and impact of their partnerships. They have achieved a level of integration and collaboration that is unparalleled by individual regional or national programmes.

This has not only accelerated innovation but also ensured that the results are more widely disseminated and adopted across the industry. An example to show the large-scale and outreach would be the IMI2 project UNITE4TB on accelerating clinical trials of tuberculosis drug combinations, ultimately aimed at developing new and highly active treatment regimens for TB, including drug-resistant TB. The total cost of the project is EUR 185 million, including EU funding and support from industry and associated partners. The partners' focus on pre-competitive research encourages the sharing of data and resources, a challenge in more fragmented research landscapes. These initiatives have contributed significantly to the EU's competitiveness in the global health research arena, delivering benefits that extend well beyond the scope of what could be achieved through regional, national, or traditional collaborative research funding mechanisms.

7. Relevance

7.1 Relevance to challenges and needs

The partnership has increased its relevance by expanding to include several more health industry sectors in addition to pharmaceuticals and vaccines[64] (such as medical technologies, imaging, diagnostics, biotechnology and companies active in the digital area). This has enabled the

[63] Interim evaluation, page 69.
[64] Represented by the European Federation for Pharmaceutical Industries and Associations (EFPIA).

development of cross-sectoral innovations with the potential to have a strong impact on patient care and quality of life[65].

While IMI2's objectives cover a wide range of R&D efforts, they are well chosen to address gaps in medical research, drive innovation in response to complex health needs and develop collaboration between a large number of participants that would not have worked together in other ways, including companies that are usually in competition with each other[66].

IHI has built on IMI2's successes and expanded its reach to include more life science sectors, reflecting the evolving demands and opportunities in healthcare. As of June 2024, it was not necessary to update the IHI SRIA, as IHI's objectives are still relevant. IHI has also demonstrated that it can address newly emerging health needs, such as greening of healthcare systems and ensuring their environmental sustainability[67].

This broad approach enhances the initiative's relevance and promotes interdisciplinary collaborations to tackle complex health issues. Both initiatives strongly align with EU health research priorities and have consistently adapted to meet changing healthcare needs. They have significantly contributed to key EU policies with IMI2 projects contributing to building the groundwork for the European Health Data Space, and IHI's objectives being aligned with those of Europe's Beating Cancer Plan and the European Green Deal.

However, the growing complexity of the policy landscape raises challenges around maintaining relevance and avoiding overlap with other health and life science research activities at national and regional levels[68]. Despite these challenges, the initiatives have been successful in fostering a globally competitive European health industry and remain pertinent in driving healthcare innovation. Their objectives clearly recognise the dynamic nature of health research and the need for flexible, strategic responses to public health emergencies and long-term health system needs.

7.2 Flexibility

While IMI2 was focused on priority disease areas (which evolved in response to health emergencies and EU health research policies), IHI gives more space to developing solutions that are disease-agnostic, as well as cross-sectoral, while maintaining a focus on unmet health needs. IMI2's ability to promptly shift focus towards emerging public health crises, such as the Ebola and COVID-19 outbreaks, highlights its capacity to adjust objectives and mobilise resources swiftly.

While IHI objectives demonstrate a continuation from IMI2 objectives, they cover a wider spectrum of health research and innovation, stretching beyond pharmaceutical research and

[65] Evaluation support study on Horizon Europe's contribution to a Resilient Europe – RTD/2021/SC/021, Final Report Phase 2 – Annexes, Case Study No 1: From Innovative Medicines Initiative to Innovative Health Initiative – the early experience, publication in September 2024.
[66] Interim evaluation, page 35.
[67] This has been exemplified by the launching of two topics in IHI call 4 in 2023 covering these areas. These are IHI Call 4, Topic 5: Safe & Sustainable by Design (SSbD) packaging and single use device solutions for healthcare products, EU Funding & Tenders Portal (europa.eu) and IHI Call 4, Topic 6: Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment, EU Funding & Tenders Portal (europa.eu).
[68] Interim evaluation, page 37.

emphasising the need to make better use of digital technologies and integrated health solutions. Patient-centricity and the focus on the determinants of health have also become more prominent in the IHI strategy document, the Strategic Research and Innovation Agenda (SRIA).

The transition into IHI signals a strategic expansion from a largely pharmaceutical-focused model to a broader, cross-sectoral R&D framework. This shift makes it possible to anticipate future interdisciplinary opportunities within the wider life sciences and healthcare sectors.

IHI's inclusion of new industry partners allows for a diverse range of contributions, reflecting its commitment to adaptability. However, the complex policy environment presents a challenge for IHI in maintaining strategic coherence and avoiding overlap with other EU and national programmes in the field of health and life sciences research[69]. As it continues to implement its strategic agenda, IHI's aim to foster synergies with other programmes and improve patient engagement and SME inclusion are indicative of its commitment to evolving in line with stakeholder needs. Monitoring IHI's strategic approach will be key in ensuring its responsiveness and effectiveness within the dynamic R&D ecosystem.

8. Directionality

Both the IMI2's SRA and IHI's SRIA set out a clear vision for the programme and these are supported by relevant and specific objectives. IHI's vision is expressed in its general objectives, which refer to EU scientific leadership in health research, improved population health, and a strong competitive position for the EU's industries. Its specific objectives capitalise on the cross-sectoral nature of the partnership, emphasising joint efforts, integrated solutions, digitalisation and data exchange as pathways for impact in the context of creating new products in the future. The case study in the IMI2/IHI evaluation[70] provides many examples of projects that have made a significant contribution to their respective research fields and developed innovations that promise to have a lasting impact (e.g. digital endpoints for fatigue and sleep disturbances that are on track to gain recognition by the European Medicines Agency; the development of an open-source platform to leverage data from wearables and mobile technologies with the aim of making it available to other researchers, so that they can be used for future commercial and non-commercial purposes).

IMI2 and IHI have contributed to the EU's commitment to addressing global health challenges, such as Ebola, and improving EU competitiveness in health research. IMI2 has surpassed numerous KPIs, produced 439 innovation milestones, including new drug and diagnostic candidates, biomarkers and other tools, and has doubled the target set for regulatory procedures. It has also developed 46 new disease classifications, fostering cross-sectoral collaborations and knowledge-sharing to tackle complex health issues. Despite challenges in patient organisation involvement and SME participation, IMI2 has published nearly 10 000 research papers and established spin-off organisations, strengthening the EU's position as a leader in health research.

IHI is aligned with the Health Cluster under Pillar II of Horizon Europe aimed at responding to global challenges and improving European industrial competitiveness. Although it's too soon to

[69] Interim evaluation, page 37.

[70] Evaluation support study on Horizon Europe's contribution to a Resilient Europe (publication Sep 2024), Case Study 2: IMI2 and IHI: driving innovation in digital health.

assess IHI's full impact, its diverse stakeholder involvement and cross-border collaborations indicate its potential contribution to the European Research Area and beyond.

Both initiatives have demonstrated a clear focus on improving the understanding of diseases, enhancing diagnostic capabilities and addressing unmet public health needs. They have also succeeded in creating a more robust European research ecosystem by promoting international collaboration, improving regulatory processes, and ensuring the sustainability of research outcomes beyond the lifespan of their projects.

9. International positioning

The ability to attract participants from outside the EU is an indicator of a programme's international positioning and visibility. IMI2 projects have addressed many global health challenges (e.g. antimicrobial resistance, tuberculosis, diabetes and Alzheimer's disease) and produced solutions and outputs that will be used beyond the borders of the EU.

IMI2 projects have attracted numerous participants from countries outside the EU, including 74 organisations from Associated Countries (6.5%) and 91 based in Third Countries (7.9%)[71].

Both IMI2 and IHI have enhanced the international positioning and visibility of European research by facilitating the involvement of organisations from outside the EU. The initiatives have attracted global participation and produced research outputs with international outreach. An example is the Ebola vaccine, which has received marketing authorisation following several projects that supported different stages of clinical trials in western.

The wide reach of the programme is also illustrated by the number of publications authored by international teams. Globally, authors from 126 countries have participated in at least one publication resulting from an IMI2 project. There are numerous examples of projects that reach beyond the borders of the EU, in terms of participation as well as impact (IMI2 projects on Ebola, antimicrobial resistance, autism, diabetes, etc.).

Analysis of participation in the first two IHI calls by non-EU organisations shows that the countries involved mirror those prominent under IMI2. The evaluation noted[72] that IMI2 was regarded as a world-first public-private partnership in the field of health research and innovation, while IHI is seen as leading in terms of its cross-sectoral approach to health innovation. However, it was also highlighted that other countries and regions have begun to emulate the approach of IMI2, and that the international prestige of the programme depended on its ability to target resources on the most relevant and most promising topic areas.

During IMI2, associated partners were companies in industries other than the pharmaceutical industry and non-profit organisations, such as foundations or charities that contributed their expertise to the development of call topics and made financial/in-kind contributions[73]. This

[71] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), p. 70.
[72] Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2), p. 59.
[73] Examples of IMI associated partners: Bill and Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations, Autism Speaks, etc. Full list available publicly.

category was created with the goal of opening up activities to a wider range of stakeholders and during IMI2, project participants included a total of 36 associated partners. Given IMI's success as a trailblazer in this respect, the concept of 'contributing partners' was embedded in the legal base of the new scheme for all JUs, including IHI[74].

10. Phasing-out preparedness

According to the Single Basic Act[75] all Joint Undertakings have the legal obligation to adopt a plan for the phasing-out of the partnership from Horizon Europe funding by the end of 2023. The aim of the plan is to ensure a smooth continuation of the JUs' activities in the scenario of no funds available under the next Framework Programme. In this perspective, JUs are asked to perform an in-depth reflection on a phasing out strategy leading to a lesser dependence from the Union contribution.

IHI has prepared a preliminary plan which was adopted by the IHI Governing Board in December 2023. The preliminary plan included administrative and operational adaptations, which should allow the JU to proceed with its activities in case of no Union funding under the next Framework Programme. In detail, the adaptations concern several aspects, such as legal status, staffing, accounting and cashflow, procurement, logistic and IT, follow up of the grant agreement obligations after the end of projects.

The drafting of the updated phasing out plan is currently ongoing and it is planned to be adopted in 2025. It should include concrete reflections on short- and long-term targets, strategic alignment and financial sustainability. The aim is to develop a strategy enabling the JU to obtain the objectives beyond the duration of the Union's participation.

[74] Regulation Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe: CHAPTER 2, Members, contributing partners and contributions.
[75] Council Regulation (EU) 2021/2085 establishing the Joint Undertakings under Horizon Europe.