European Commission

Interim evaluation of the Innovative Health Initiative (IHI) and Final evaluation of the Innovative Medicines Initiative (IMI2)

Evaluation support study on Horizon Europe's contribution to Resilient Europe

Independent Expert Report

Research and Innovation

The information and views set out in this 'Interim evaluation of the Innovative Health Initiative (IHI) and its predecessor the Innovative Medicines Initiative (IMI2)' are those of the authors and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

Interim evaluation of the Innovative Health Initiative (IHI) and Final evaluation of the Innovative Medicines Initiative (IMI2)

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Interim evaluation of the Innovative Health Initiative (IHI)

and

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Evaluation support study on Horizon Europe's contribution to a Resilient Europe – RTD/2021/SC/021

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Key definitions, acronyms, and glossary

AAL	Active and Assisted Living Programme
BMR	Biennial Monitoring Report
CEA	Cost-effectiveness analysis
COCIR	European Trade Association representing the medical radiotherapy, health ICT and electromedical industries
DG	Directorate-General
EC	European Commission
EDCTP Partnership	European and Developing Countries Clinical Trial
EFPIA Associations	European Federation of Pharmaceutical Industries and
EHDS	European Health Data Space
EMA	European Medicines Agency
EU	European Union
HTA	Health Technology Assessment
IHI	Innovative Health Initiative
IKAA	In-kind contributions on additional activities
IKOP	In-kind contributions on operational project costs
IMI	Innovative Medicines Initiative
KPI	Key Performance Indicator
PSIP	Partnership specific impact pathway
R&D	Research and development
SC	Societal Challenge
SDG	Sustainable Development Goal
SIP	Science and Innovation Panel
SME	Small and medium-size enterprise
SRA	Strategic Research Agenda
SRIA	Strategic Research and Innovation Agenda
SRG	States' Representatives Group
UN	United Nations
WHO	World Health Organization

Executive summary

The Innovative Health Initiative (IHI) aims to translate health research, development and innovation into tangible benefits for patients and societies and to ensure that Europe remains at the cutting edge of interdisciplinary, people-centred and sustainable health R&D through funding projects and fostering multi-sectoral collaborations. **IHI is a new partnership between the European Union**, represented by the European Commission (EC), **and five European associations of life science industries**, including the European Federation of Pharmaceutical Industries and Associations (EFPIA), Vaccines Europe, COCIR, MedTech Europe and EuropaBio. It builds on the experience of the Innovative Medicines Initiative (IMI2), which ran from 2014 to 2020 and was comprised of the EC and EFPIA only.

This report presents findings on the interim evaluation of IHI, covering the period from December 2021 to June 2023, and the final evaluation of IMI2. It is organised along five evaluation criteria (relevance, coherence, efficiency, effectiveness, EU-added value) and four partnership-specific criteria (additionality, directionality, international positioning and visibility, and transparency and openness). The methods used for the evaluations included desk research, stakeholder interviews, and two case studies.

The evaluation showed that **IMI2 continues to be relevant** as a programme that aims to foster and accelerate medical innovation in response to unmet public health needs and health emergencies. The expansion of the cross-sectoral partnership under **IHI increases its relevance** in view of evolving healthcare needs and new opportunities to develop innovative solutions in novel research areas. There is coherence with Horizon 2020 and Horizon Europe at programme and participant levels, as objectives of both IMI2 and IHI are well aligned with the aims of their respective framework programmes. **IHI is expected to contribute to several EU policies**, plans and programmes, which will require strategic planning and substantial coordination. At participant level, over 50% of universities and higher education institutions participating in IMI2 projects ranked among the top 1% participants of Horizon 2020, demonstrating the calibre of the academic institutions involved in the programme. In terms of efficiency, the share of administrative costs relative to EC contributions was 4.5%, which is similar to other EC partnerships. During the period of 2014 to 2022, the programme's committed **administrative costs remained significantly below the budget approved** for this purpose. There was some delay in setting up the new partnership relating to the Single Basic Act coming into force later than expected and problems associated with the legal framework that required significant attention at the early stages of IHI. However, stakeholders noted that the IHI governance arrangements work well and that they found the collaboration at governance level **promising and constructive**. In terms of effectiveness, IMI2 performed well against the majority of the key performance indicators (KPIs) set out for it and exceeded many of its targets. More specifically, IMI2 projects produced a large number of assets, tools, processes, as well as taxonomies and stratifications. IMI2 and IHI perform well in relation to their **gender balance** at governing level. However, at project level, only 25% of IMI2 project coordinators were female. The large networks of collaborators, including companies, academic institutions, small and medium-size enterprises (SMEs) across sectors and countries demonstrate the **significant added value** of this public-private European partnership.

In terms of partnership-specific criteria, IMI2 mobilised substantial **additional contributions** from Associated Partners. The direct leverage factor was 1.035; however, the leverage of IMI (and IHI) is determined by the design of the partnership which stipulates equal contributions made by private partners and the EC. Both the objectives of IMI2 and IHI show a clear pathway towards achieving their respective vision, with IMI2 KPIs demonstrating significant achievements. The **international positioning and visibility** of IMI2 is illustrated by the global reach of many of its projects and the large output in publications authored by international teams. However, under IHI the classification of Switzerland as Third Country in combination with new rules applied to entities from Third Countries may provide a disincentive to participate in and contribute to projects for companies and non-profit organisations based in these countries. While companies from non-pharmaceutical companies have already been involved in IMI2, it is expected that the **cross-sectoral nature of the IHI partnership will be able to more fully exploit the opportunities** for cross-sectoral research, development and innovation. Going forward, industry partners and the EC will need to consolidate their priorities, while taking account of inputs from advisory bodies and from the wide set of stakeholders who can submit ideas for call topics through the IHI web portal. IMI2 was open to and supportive of SMEs as project participants, although SME involvement remained below target. As the new partners of IHI include large numbers of SMEs among their constituencies there is the potential to increase SME involvement in projects although this will depend on the contributions that SMEs are able to make to a given project.

Lessons learned from IMI2 include that the programme has been able to tackle complex health and healthcare challenges that individual organisations, disciplines or sectors would not be able to address. The size and ambition of projects also contributed to the growth of the interdisciplinary, cross-country networks, creating a wide range of substantive outputs that contributed to the programme's objectives. RACER principles were useful for steering activities, both in terms of shaping calls for proposals and additional activities. **Suggestions for improvements relating to IHI** include to routinely monitor and review the interaction of governing and advisory bodies, especially relating to their contribution to the process of proposing topic ideas and developing call topics. It is recommended that changes in rules and frameworks consider the nature of public-private partnership more consistently. The administrative burden of implementing new rules should also be monitored. A final recommendation is to develop a strategic approach to create synergies with other initiatives that is efficient, coherent and tailored to individual policies and programmes.

1. Introduction

1.1. Purpose of the evaluation

The purpose of this evaluation is to provide a final assessment of the Innovative Medicines Initiative (IMI2) and an (early) interim assessment of its successor programme, the Innovative Health Initiative (IHI) to the European Commission in compliance with Council Regulation (EU) No 557/2014 and Council Regulation (EU) 2021/2085 of the European Parliament and of the Council. The Decisions stipulate that the European Commission (EC) will carry out a final evaluation of IMI2 no later than two years after the end of the programme and an interim evaluation of IHI. This report presents the findings of the final and interim evaluations carried out by Prognos AG. It is part of a larger evaluation study, the 'Evaluation Study on Resilient Europe', that has been commissioned by the EC to inform the *ex post* evaluation of Horizon 2020 and the interim evaluation of Horizon Europe.

The evaluation is based on the five criteria of the Better Regulation Guidelines and four additional criteria applied to Joint Undertaking/Partnerships. These are set out in Table 12 in the Annex.

1.2. Scope of the evaluation

This report presents the results of the interim evaluation of IHI and the final evaluation of IMI2, its precursor programme. IMI2 covers the period between 2014 and 2021, although a number of IMI2 projects are still running during IHI. It builds on an Interim Evaluation of IMI2 carried out in 2017, reporting on the first 3 years of IMI2 (2014-2016). Altogether 102 projects were still running at the end of the IMI2 programme period, of which 70 are still operational at the time of writing (June 2023).

IHI officially began in November 2021 and will run until 31 December 2027[1]. To date, three calls have been launched and five project grants signed from the first call, with the first projects beginning in April and May 2023. At the time of writing, grant agreements resulting from two more calls are in preparation with an indicative project launch date in the autumn of 2023.

1.3. Methodological approach

The evaluation used a mixed-methods approach, combining documentary review, an analysis of project and administrative data with case study research and interviews.

1 The Single Basic Act notes that the partnerships is financed under MFF 2021-2027. Calls for proposals shall by launched at the latest by 31 December 2027 and only in duly justified cases may calls be launched by 31 December 2028 (Article 3, Single Basic Act).

Documentary review

A wealth of information has been produced by the Programme Office and others over the duration of IMI2 and IHI, including previous evaluations, annual work programmes/plans, annual activity reports and budgetary information. Both IMI2 and IHI provide a substantive amount of information on their programme websites, including detailed information on projects supported, resources for projects and for applicants preparing proposals, and project news and highlights from project results. Documents were purposively selected to address specific evaluation criteria.

Analysis of project and administrative data

A thorough analysis of project and administrative data were conducted by the study team. Data were provided by the Programme Office and covered both IMI2 and IHI. Data included data on projects and proposals received for each programme, key performance indicators (KPIs) as well as other administrative data as relevant. The Programme Office made their dashboard data available to the evaluation team, which allowed for a detailed analysis of the quantitative aspects of all major evaluation questions. Dashboard data were also used for the network analysis which analyses networks established through collaboration in IMI2 projects. In addition, the study team used eCordis data to compare specific outputs to outputs from Horizon 2020 (e.g. the share of small and medium enterprises (SMEs) involved in the programme).

Case studies

Two case studies were conducted to explore specific areas of interest to complement the evaluation questions. Topics were agreed in advance with the relevant EC Officials and the Programme Office to maximise their value. The first case study focuses on the transition from IMI2 to IHI and the early experience of implementing IHI, specifically focusing on the newly established governance arrangements following the inclusion of new partners in the partnership (Case study 1: 'From Innovative Medicines Initiative to Innovative Health Initiative – the early experience'). The second case study examines the contribution of IMI2 to the field of digital health, underlining the importance of emerging digital solutions for pharmaceutical research and development (Case study 2: 'IMI2 and IHI driving innovation in digital health'). The case studies largely draw on documentary analysis and stakeholder interviews. Case studies are stand-alone deliverables, but they are also expected to inform the assessment of the evaluation criteria of the evaluation.

The IMI2 final evaluation also draws on an existing case study that was conducted during phase 1 of the Resilient Europe study. This case study focused on the contribution of selected IMI2 projects to health emergency preparedness ('The Innovative Medicines Initiative – An analysis of the contribution to health emergency preparedness').

Interviews

Interviews were a key method to inform the case studies and evaluations. In total, 20 stakeholder interviews were conducted, of which 4 were with Programme representatives, 6 with programme partners, 2 with members of States' Representative Group (SRG), and 8with project beneficiaries.

Interviews were semi-structured and scheduled for an hour each. A topic guide was used for each interview, adjusted to the thematic focus of the interview (e.g. reflecting the selection of

stakeholders speaking to each case study) and role of the interviewee. The topic guide provided a general structure but also left flexibility to examine specific aspects as they arose during the conversation. Interviews were recorded and a written protocol of the interview was shared with participants.

Interviews were analysed thematically, to contribute to the respective case study. Findings from the case studies, supported by the interviews, were then used to inform the evaluations.

2. Background to the initiative

The Innovative Health Initiative (IHI) is a partnership between the European Union, represented by the European Commission (EC), and five European associations of life science industries. IHI was launched in 2021 and will run until 2027, with all projects due to end before December 2031. It follows the Innovative Medicines Initiative (IMI) that was set up in 2008 as a partnership between the EC and EFPIA, the European Federation of Pharmaceutical Industries and Associations. IMI continued as IMI2 from 2014 to 2021 under the EU's Horizon 2020 Programme.

The IHI Programme was set up as a public-private partnership to bring together different sectors of industry, the EC and other stakeholders to work together to find solutions to complex societal challenges and unmet medical and social need. The idea is to bring together excellence from different sectors to develop solutions through collaboration, to overcome some of the challenges through cross-sectoral, multi-disciplinary and bold research and development.

The transition from IMI2 to IHI – and the change of the name from 'innovative medicines' to 'innovative health' – marked an expansion of the approach from a focus on pharmaceutical research and development (R&D) to promoting cross-sectoral R&D and innovation in the life sciences and healthcare more broadly. This expansion is reflected in the new composition of the IHI Partnership, which now comprises COCIR, MedTech Europe, and EuropaBio as new partners, in addition to EFPIA including Vaccines Europe, along with the EC.

2.1. Intervention logic

The vision of IHI is to translate health research, development and innovation into tangible benefits for patients and societies and to ensure that Europe remains at the cutting edge of interdisciplinary, people-centred and sustainable health R&D through funding projects and fostering multi-sectoral collaborations.

More specifically, general objectives for IHI include: (1) contributing towards an EU-wide health research and innovation ecosystem that facilitates **translation of scientific knowledge into innovations**; (2) fostering the development of safe, effective, people-centred and cost-effective **innovations that respond to strategic unmet public health needs**; and (3) driving cross-sectional health innovations for a **globally competitive European health industry**. The full objectives of IHI are set out in the Council Regulation (EU) 2021/2085, Articles 115 and 116, and can be found in the Annex. The regulation distinguishes between general objectives (also referred to as impacts), to be achieved by 2030, and specific objectives (also referred to as outcomes), in addition to objectives defined for all Joint Undertakings set out in Articles 4 and 5. The Strategic Research and Innovation Agenda of IHI also defines a set of operational objectives, which form the basis of the programme's key performance indicators (KPIs) (see Table 13 in the Annex)[2]. An abbreviated schematic representation of the pathway to impact has been published in the Biennial Monitoring Report on partnerships on Horizon Europe (Figure 21 in the Annex)[3].

Objectives of the predecessor programme IMI2 are also set out in its relevant Council Regulation[4]. The vision of IMI2 also emphasised the importance of supporting the Union's competitiveness and scientific leadership in the field of pharmaceutical R&D. Specific objectives specify the contribution of IMI2 to the overall objectives, identifying concrete opportunities to improve and accelerate the pathway to innovation (e.g. to increase the success rate in clinical trials of priority medicines; develop diagnostic and treatment biomarkers approved by regulators). Compared to IHI, IMI2 objectives and strategic agenda are more strongly focused on pharmaceutical research and specific disease areas for which there is a recognised unmet need (e.g. cancer, immunological, respiratory, neurological and neurodegenerative disease). IMI2 also used a set of Key Performance Indicators (KPIs) to monitor performance against objectives[5]. These KPIs were revised and aligned with the intervention logic model following the Interim Evaluation of IMI2.

While IHI objectives clearly demonstrate a continuation from IMI2 objectives, they cover a wider spectrum of health research and innovation, stretching beyond pharmaceutical research and emphasising the need to make better use of digital technologies and integrated health solutions. Patient-centredness 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), compared with its predecessor.

The intervention logic of IMI2 is summarised in Figure 22 (in the Annex). The model builds on a revised version of the intervention logic diagram published in the interim evaluation 2017, using the schematic representation suggested in the Better Regulation Toolbox[6] Outcomes and impacts represent the objectives stipulated in the Council Regulation. Outputs draw on the (more short-term) KPIs of IMI2.

Achievement against KPIs will be an important consideration when analysing the effectiveness of IMI2. For this purpose, the final evaluation of IMI2 will draw on the existing

2 www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_2022.pdf.

3 EC (2022): Performance of European Partnerships: Biennial Monitoring Report 2022 on partnerships in Horizon Europe, p.230.

4 Council Regulation (EU) No 557/2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking, Article 2.

5 https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf.

6 EC (2021): 'Better regulation' toolbox. p. 401.

reporting of KPI measures published by the Programme Office. No KPI reporting has been published on IHI, which reflects the early stage of the programme[7].

2.2. Baseline

An Interim Evaluation of IMI2 was published in 2017, covering the years 2014 to 2016 of IMI2[8]. A group of experts reviewed the state of the implementation of IMI2 and assessed its performance against five evaluation criteria: effectiveness, efficiency, relevance, coherence, and EU Added Value. The report also included an analysis of the Programme's strengths, weaknesses, opportunities and threats (SWOT-Analysis).

The interim evaluation concluded that IMI2 was well governed and successful in fostering collaborations between competing companies, SMEs and academic institutions and in building trust between these organisations. It also raised a number of points on which the programme could be improved. Stakeholders interviewed for the interim evaluation noted that the processes of developing the Strategic Research Agenda and the annual work programmes lacked transparency and some applicant consortia seemed to have a better chance of succeeding in the competition than others. It also found that the programme could do more to attract partners from other industries, and encouraged further action to increase the participation of regulators in IMI2 projects.

The interim evaluation made several recommendations, addressed to the IMI2 Programme Office, EFPIA and the EC:

- to make a renewed and stronger efforts to attract and integrate industries other than the pharmaceutical industry in the collaborative projects;
- to create a better ecosystem to attract more SMEs, for example, by expanding the scope of projects and by making topics descriptions less prescriptive and more flexible;
- to develop SMART KPIs to assess impacts and socio-economic benefits and increase the accountability of IMI2[9];
- to review the intellectual property policy and make it more flexible to respond to the needs of project participants;
- to improve and broaden access to project outcomes and assure their sustainability.

In response to these recommendations an Action Plan was developed outlining the actions to be taken, deadlines and responsible actors[10].

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7 https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/Reports/IHI_CAAR_2022.pdf.

8 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.

9 While the term ‚SMART' KPIs are used in the Interim Evaluation, these are meant to be 'RACER KPIs', which refer to indicators that are relevant, accepted, credible, easy to monitor, and robust. https://commission.europa.eu/system/files/2023-02/br_toolbox-nov_2021_en.pdf.

10 IMI2 (2017): Action plan in response to the recommendations from the Interim Evaluation of the IMI2 JU. https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/ActionPlan-InterimEvaluation2014-2016.pdf.

3. Implementation state of play

This section presents an overview of the governance arrangements and implementation of IHI and its predecessor programme IMI2 and provides information about the portfolio of activities with regard to project calls, projects funded, proposals received and funding committed. The chapter concludes with an overview of additional activities undertaken by the Programme Office in support of IMI2 and IHI.

3.1. Governance

IHI is a public-private partnership established under the Article 187 of the Treaty on the Functioning of the European Union, as were its predecessor IMI1 and IMI2. Governance arrangements, including structures, processes and standards, are set out in Council Regulations for both IHI and IMI2 (see above). In what follows, the governance structure described applies to IHI, with changes from IMI2 to IHI indicated as they arise.

Governing Board

The Governing Board is the decision-making body of IHI, with overall responsibility for the strategic orientation and supervision of the implementation of activities of the Joint Undertaking. The Board adopted the Strategic Research and Innovation Agenda (SRIA), and is responsible for adopting the annual work programmes, annual budgets and staff establishment plans. It also appoints, provides guidance, and monitors the performance of the Executive Director.

The IHI Governing Board was set up in December 2021. Its role, tasks and procedures are set out in the Council Regulation and its specific Rules & Procedure. It is composed of eight members, four of whom are representatives of the EC (DG RTD, DG Sante, DG Grow and DG Connect) and four represent industry partners (EFPIA including Vaccines Europe, MedTech Europe, EuropaBio, COCIR). Under IMI2, the Governing Board was composed of 10 members, five of whom were from the EC and five representing EFPIA.

Voting rights are equally distributed between the EC on one side and industry partners on the other side. The Governing Board aims to make decisions by consensus, but if this fails decisions are taken by a majority of at least 75% of the votes (with the EC vote being indivisible). The Board usually meets three times per year (March, June and December) and chairmanship alternates annually between the EC and industry partners. The Governing Board Chairperson is invited to attend the meetings of the SRG as an observer. The SIP Chairperson and the SRG Chairperson and Vice-Chairperson are invited to attend Governing Board meetings as observers.

Given the recent establishment of IHI, the IHI Governing Board is now in operation for just over a year. The IHI Office publishes a full list of decisions adopted on its website[11].

11 https://www.ihi.europa.eu/about-ihi/who-we-are/governing-board

The Executive Director and Programme Office

The Executive Director is responsible for the daily operation of IHI in accordance with the decision of the Governing Board and manages the Programme Office.

The Programme Office implements the work programme, launches calls for proposals, coordinates independent evaluation of submitted proposals, and monitors the projects that are being funded during their entire lifecycle. These currently also include projects initiated under IMI2 and a small number of projects initiated under IMI1. The Programme Office also acts as a secretariat for the governance bodies, manages the budget in line with financial rules and implements the communication strategy. In addition, the Programme Office executes a series of monitoring and reporting functions, both vis-à-vis projects participants and the Governing Board and other governing bodies. The Office also implements activities in support of the programme and its objectives (see below).

States' Representatives Group

The States' Representatives Group (SRG) is an advisory body and consists of representatives of EU Member States and countries associated to Horizon Europe. Its role, tasks and procedures are set out in the Council Regulation and its specific Rules and Procedures. Countries can nominate up to two representatives and up to two alternates. The group meets twice a year (three times in the start-up phase in 2022) and acts as the interface between the programme and relevant national and regional stakeholders within their respective country.

The Chairperson and Vice-chairperson of the SRG are observers in meetings of the Governing Board. Furthermore, the SIP Chairperson, EC and industry representatives are invited to attend SRG meetings as observers when needed. The structure and role of the SRG has globally remained the same under IMI2 and IHI. However, the Chairperson and Vice-chairperson of the SRG are now also members of the Science and Innovation Panel (see below).

Science and Innovation Panel

The Science and Innovation Panel (SIP) is an advisory body with the role of providing the Governing Board with science-based advice on a range of topics relevant to IHI, including on the scientific priorities to be addressed in the work programme and the scope of calls for proposals.

Its role, tasks and procedures are set out in the Council Regulation and its specific Rules of Procedure[12]. It is composed of 18 permanent members, including 2 representatives of the EC, 4 representatives of industry partners, 2of the SRG, 4 members of the scientific community and 6 representatives of the wider healthcare community.

Under IMI2, the scientific advisory role was borne by the Scientific Committee, which was smaller and composed of experts from the research community, patient representatives and regulatory bodies only. In IHI the SIP was expanded to involve a wider set of stakeholders

12 https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/SIP/SIP_RulesOfProcedure_20220331.pdf

and formalise the advisory role of healthcare professionals, representatives of regulatory bodies and patients and end-users of healthcare innovations. The SIP Chairperson is invited to SRG and Governing Board meetings as an observer when needed.

3.2. Activities and resources

This section describes the Programme's portfolio of activities and how it evolved during IMI2 and the first year and a half of IHI. It presents an overview of the projects supported, proposals submitted and the type of organisations receiving project support. It also provides information on the contributions to IMI2 and IHI, and the funding provided to project participants. The last section provides an overview of additional activities in support of programme objectives.

Portfolio of activities

The main activity of IHI and its predecessor IMI2 is to launch calls for proposals and select the most promising projects to contribute to the fulfilment of the Programme's objectives. Call topics are derived from the IHI Strategic Research and Innovation Agenda (SRIA) and approved by the Governing Board. IHI topics can be generated from a variety of sources, they are then developed into call text with inputs from partners, the IHI Office, the SRG and the SIP. Under IHI, a mechanism was established to invite a wider group of stakeholders to submit ideas for call topics through a web portal[13].

Under IMI2, topic ideas could be submitted by EFPIA companies, the EC, the IMI Strategic Governing Groups[14], an Associated Partner or by third parties via the IMI Website. The topic text was drafted by companies, supported by the IMI Office and subject to formal consultation of the EC, the IMI SRG and the IMI Scientific Committee[15]. Industry partners played an important role in determining call topics, reflecting the fact that the majority of calls under IMI2 were two-stage calls. Ideas for calls were proposed and discussed by industry experts in the Strategic Governance Groups that also included Commission representation. Certain topic ideas were also put forward by the Commission. From about mid-IMI2 this role was formalised in the 'Think Big Initiative' that brought together EFPIA companies to develop thematic pillars of IMI2. Under IHI, a similar approach has recently been initiated with a larger number of industry partners and companies involved. It is envisaged that the group will begin to develop strategic topics from summer 2023.

Calls and projects initiated

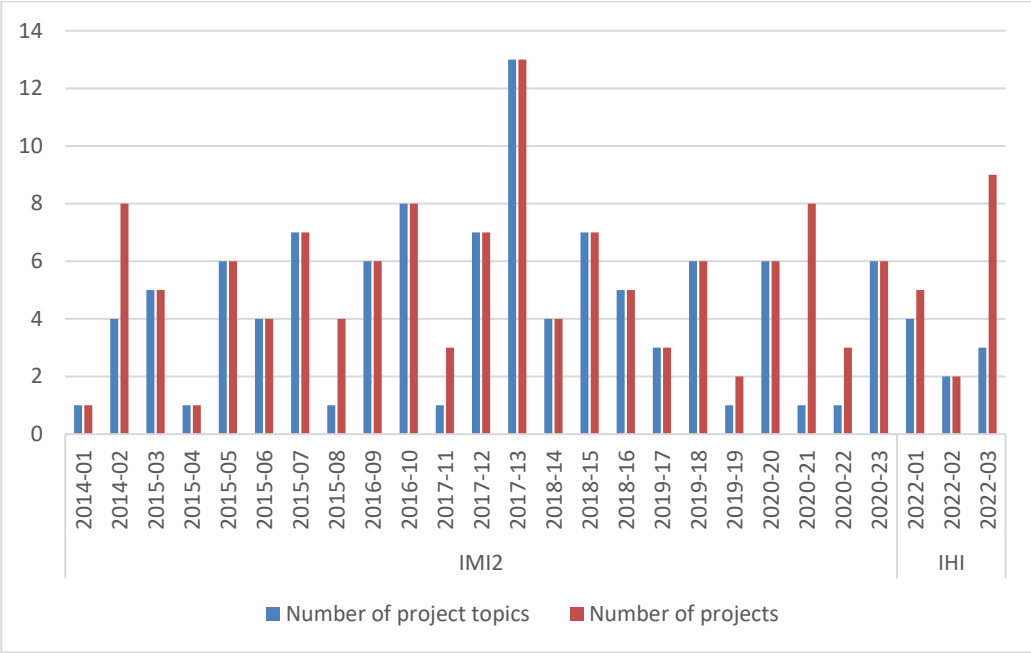
Between 2014 and 2021 IMI2 issued 23 calls for proposals.

13 The web portal was initiated under IMI2 but firmly established under IHI.

14 Under IMI2, Strategic Governing Groups (SGGs) were topic specific groups to work on specific strategic areas, composed of representatives of interested companies, the EC, the IMI Office and the IMI Scientific Committee. The SGGs no longer exist under IHI.

15 The IMI Scientific Committee was replaced by the Science and Innovation Panel under IHI.

Figure 1. Number of call topics and number of funded projects per call



Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Calls can cover one or more topics. During IMI2, for most calls, the number of call topics and the number of projects funded is identical (see Figure 1) due to the two-stage process of most IMI2 calls. However, there are some exceptions where a single-stage process was put in place; for example, Call 2 in 2014 involved four topics concerned with vaccine and diagnostic test development in response to the Ebola outbreak in West Africa (Ebola+ programme), which resulted in 8 projects funded. Similarly, Call 21 in 2020 responded to the global outbreak of the newly emerging Coronavirus by funding eight projects in response to one call topic ('Development of therapeutics and diagnostics combating Coronavirus infections'). In both cases, rapid timelines were used reflecting the nature of these health emergencies.
During IMI2, 123 different projects were launched responding to calls involving 104 call topics[16]. Of these, 21 projects were completed at the end of the programme period in November 2021. Some 53 projects were completed by May 2023.

There are two types of call processes under IMI2 as well as IHI: Single-stage calls require public and private partners to come together in consortia and jointly develop a full application. In two-stage calls, industry partners come together (pre-identified industry consortium) and commit to support a call topic before the call is launched. The successful consortium selected at the first stage (typically composed of public research organisations, universities, small and medium enterprises (SMEs), patient organisations and public bodies) will then be matched with the pre-identified industry consortium, who together will develop the full application at the second stage. Under IMI2, 7 calls were single-stage and 16 were organised in two stages.

16 A full list of call topics can be found in Table 14 the Annex.

Under IHI, the first call was launched in September 2022. As of June 2023, IHI has launched three calls for proposals involving nine call topics. So far, 16 proposals have been selected for funding under IHI. More specifically, grant agreements were signed for five projects of Call 1 and eleven grant agreements are under preparation relating to Calls 2 and 3.

There is an intention to increase the number of single-stage calls under IHI in comparison to IMI2. However, financial rules applying to IHI at programme level stipulate that participants must cover at least 45% of the total project costs. It is possible that this creates a hurdle for consortia applying to single-stage calls as they need to find partners willing to make substantial in-kind contributions, within an application period of 3 months. So far, two IHI calls were single-stage and one was organised in two stages.

Project participants

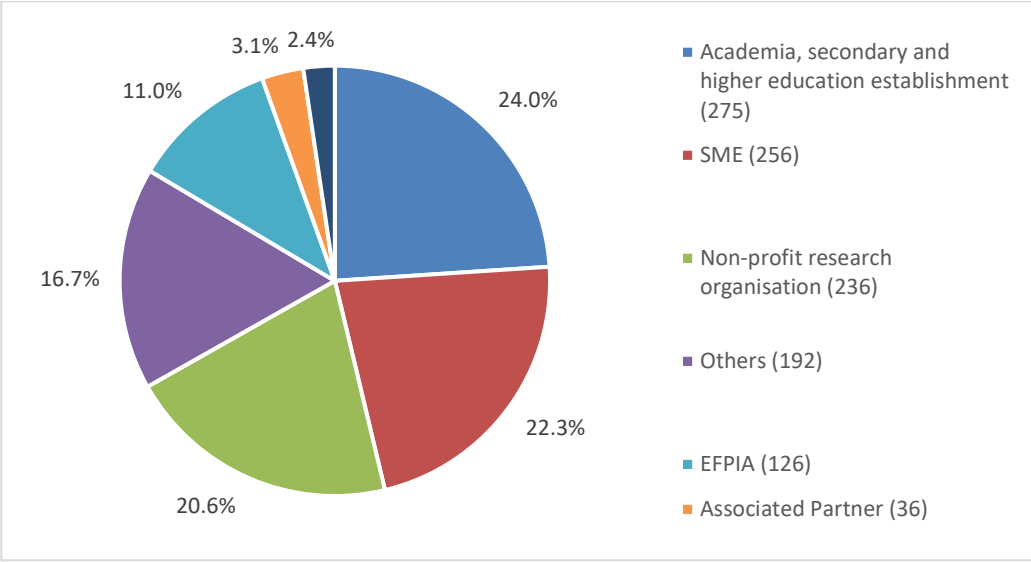
A total of 1 148 organisations participated in the 123 projects funded during IMI2. Of these, 441 organisations participated more than once. Therefore, the number of participations (n = 3 122) is significantly higher than the number of participating organisations.

During IMI2, project participants involved 126 EFPIA companies (i.e. pharmaceutical companies that were members of EFPIA) (11.0% of total participating organisations), 36 Associated Partners (3.1%)[17], 275 were academic, secondary or higher education organisations (24.0 %), 236 non-profit research organisations (20.6 %), 256 SME (22.3 %), 27 patient organisations (2.4 %) and 192 other organisations (16.7%)[18].

17 Under IMI2, Associated Partners could be any legal entity, including charities, and companies that were not members of EFPIA, e.g. in the fields of ICT, imaging, diagnostics or animal health.

18 ‚Others' include public organisations and third sector organisations such as non-profit or non-governmental organisations, and advocacy groups.

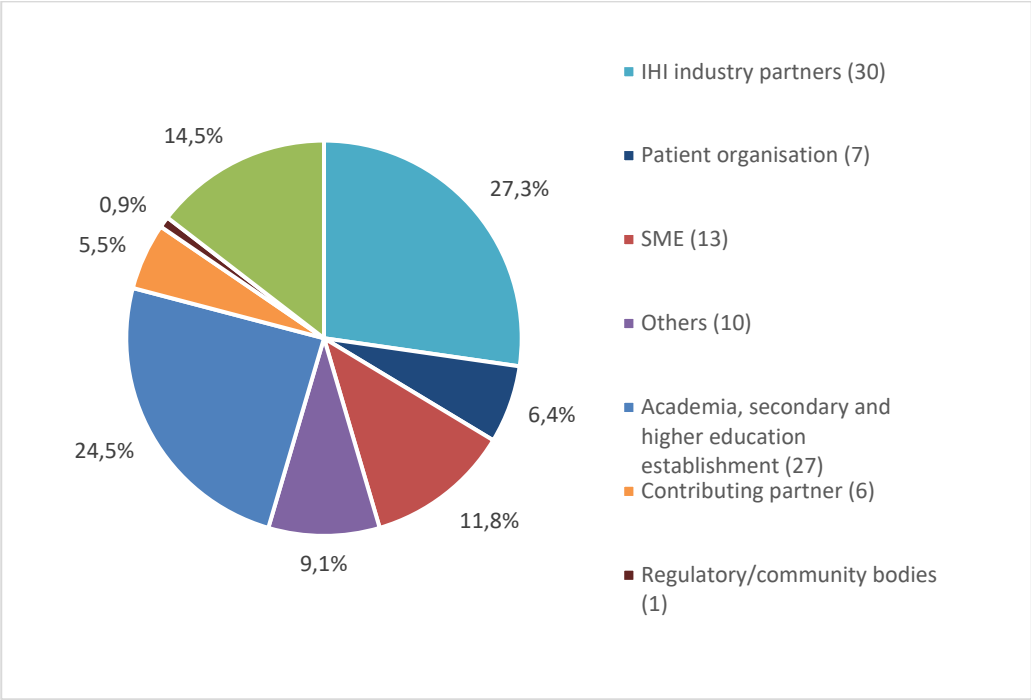
Figure 2. Distribution of IMI2 project participants by type of organisation



Source: IMI2/ IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

In IHI, 110 organisations participate in 5 projects to date and another 200 organisations are expected to participate in the 11 projects under preparation. A distinction between project participants by type of participation is only possible for the first IHI call, as grant agreements are not yet signed for Calls 2 and 3. Of the 110 participants in Call 1, 30 were industrial partners (27.3%), including 14 EFPIA companies, 11 member companies of MedTech, 4 member companies of COCIR, and 1 member of EuropaBio; 27 academic, secondary or higher education organisations (24.5%), 16 non-profit research organisations (14.5%), 13 SMEs (11.8%), 7 patient organisations (6.4%), 6 Contributing Partners (5.5%), 1 regulatory/community body (0.9%) and 10 other organisations (9.1%).

Figure 3. Distribution of IHI project participants by type of organisation in the first Call



Source: IMI2/ IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

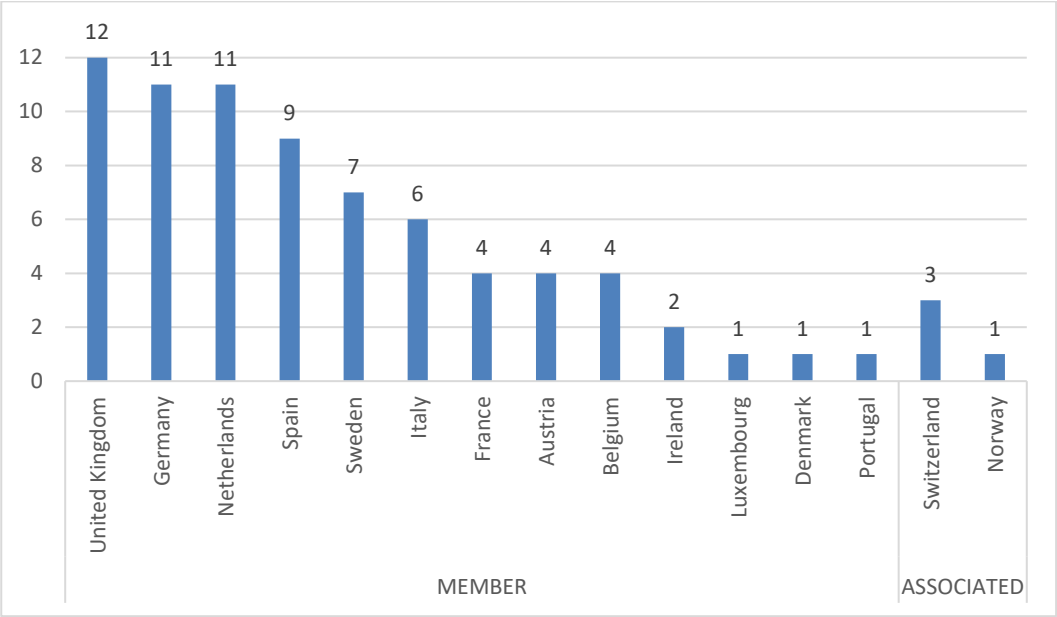
A total of 85.6% of participants in IMI2-funded projects were based in EU-countries[19] (n=983), 6.4% in countries associated with Horizon 2020[20] (n=74) and 7.9% in Third Countries[21] (n=91). Of coordinators of IMI2 projects, 94.8% are based in EU-countries, 5.2% in Associated Countries (Norway and Switzerland). As shown in Figure 4, the three leading countries in which coordinators are based are the United Kingdom, the Netherlands, and Germany. No project coordinator is based in an EU-13 country. Of the academic organisations participating in IMI2 projects, 46% participated only once (n=127), 13% (n=35) participated two times and 41% (n=113) three times or more. The maximum number of participations of a single academic organisation was 38 (University of Oxford in the UK).

19 Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom.

20 Iceland, North Macedonia, Norway, Serbia, Switzerland, Turkey.

21 Australia, Benin, Brazil, Burkina Faso, Canada, China, Congo, Gabon, Israel, Japan, Russian Federation, Senegal, Sierra Leone, Singapore, South Africa, Tanzania, United States.

Figure 4. Distribution of project coordinators by country for IMI2



Source: IMI2/ IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

In IHI, 76.1% of participants are based in EU-countries[22] (n=236), 9% based in countries associated with Horizon Europe[23] (n=28) and 14.8% based in Third Countries[24] (n=46). Coordinators of the 16 IHI projects are based Germany, Netherlands, Spain, Sweden, Belgium, Italy, and Norway.

Project proposals

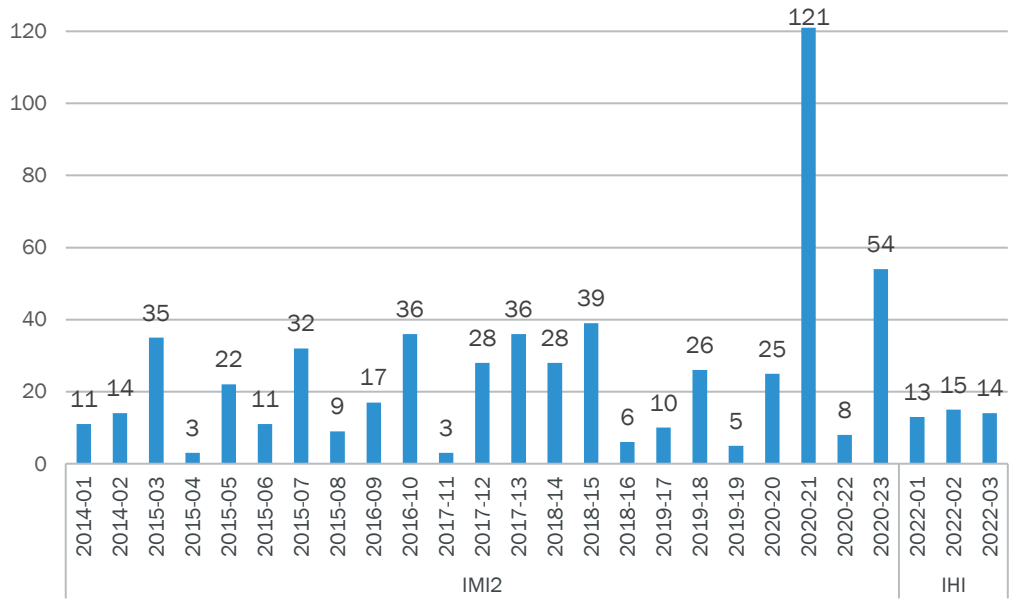
During IMI2, 579 eligible project applications were submitted in total over the programme period. The number of proposals submitted varied by call, partly reflecting the number of call topics, the nature of the call topic, and the type of call process (Figure 5).

22 Austria, Belgium, Croatia, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

23 Norway and the United Kingdom.

24 India, Israel, Switzerland, United States.

Figure 5. Number of proposals by call, IMI2 and IHI



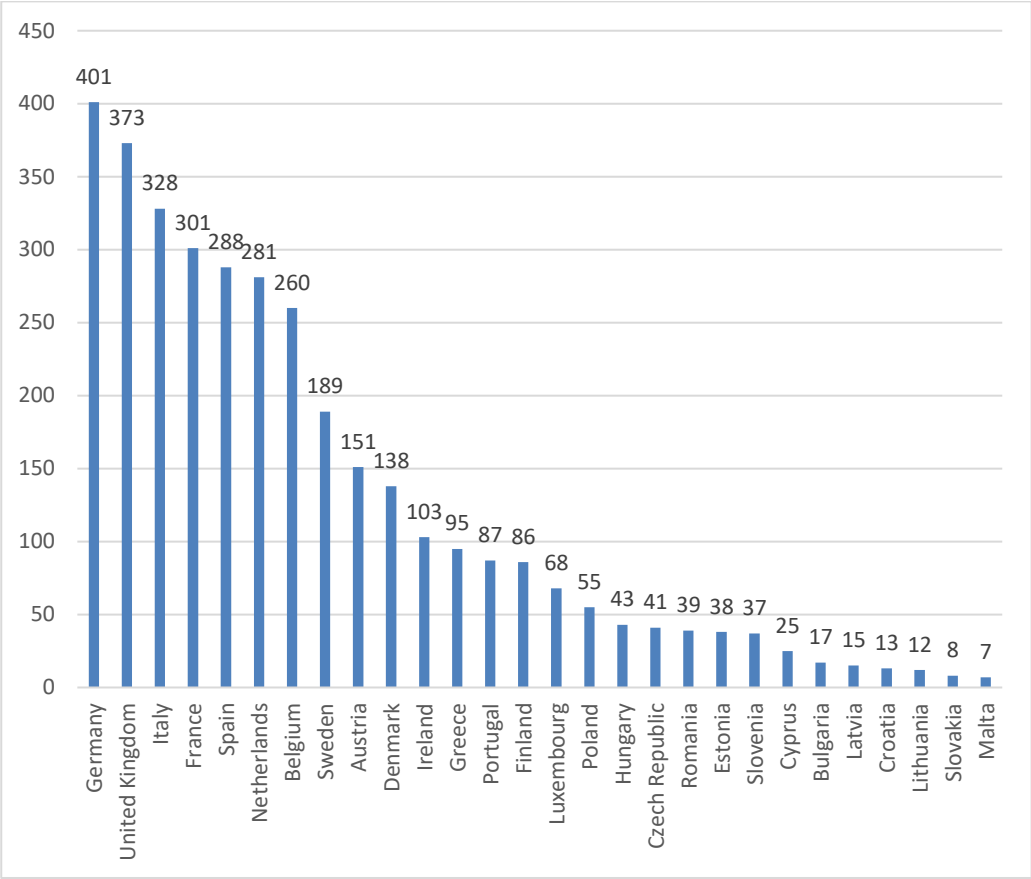
Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Call 21 in 2020 received the highest number of proposals. This call was launched in response to the COVID-19 pandemic ('Development of therapeutics and diagnostics combating Coronavirus infections').

Under IMI2, the average number of proposals submitted to two-stage calls was 26, compared to 24 on average submitted to single-stage calls. This difference becomes more pronounced when comparing median values (median: 27 submitted to two-stage calls and 8 to single-stage calls).

The distribution of participants submitting proposals based in the EU is concentrated in EU-15 countries, showing a similar pattern to the distribution of project participants (Figure 6).

Figure 6. Number of proposals submitted by participants based in EU Member States, IMI2

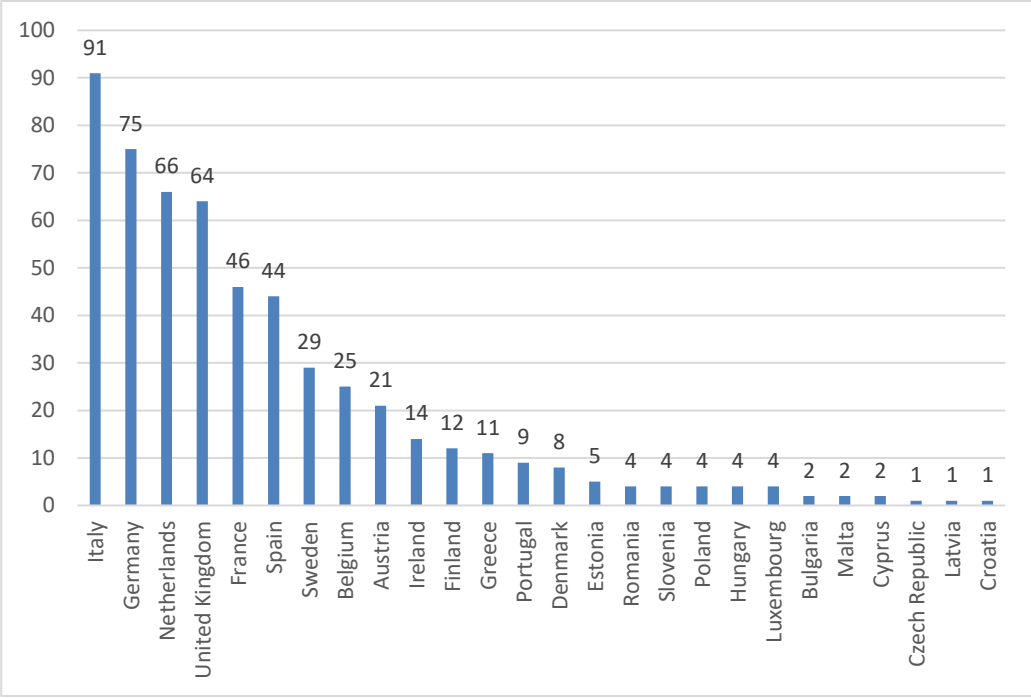


Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023[25].

A similar pattern is shown in the distribution of proposals submitted by project coordinators, with the highest number of proposals led by organisations in Italy, Germany, the Netherlands and the United Kingdom. In total, 546 proposals were led by coordinators based in the EU, 26 were based in Associated Countries, and 7 in Third Countries (Figure 7).

25 Consortium members based in the same country will only be counted as one per proposal.

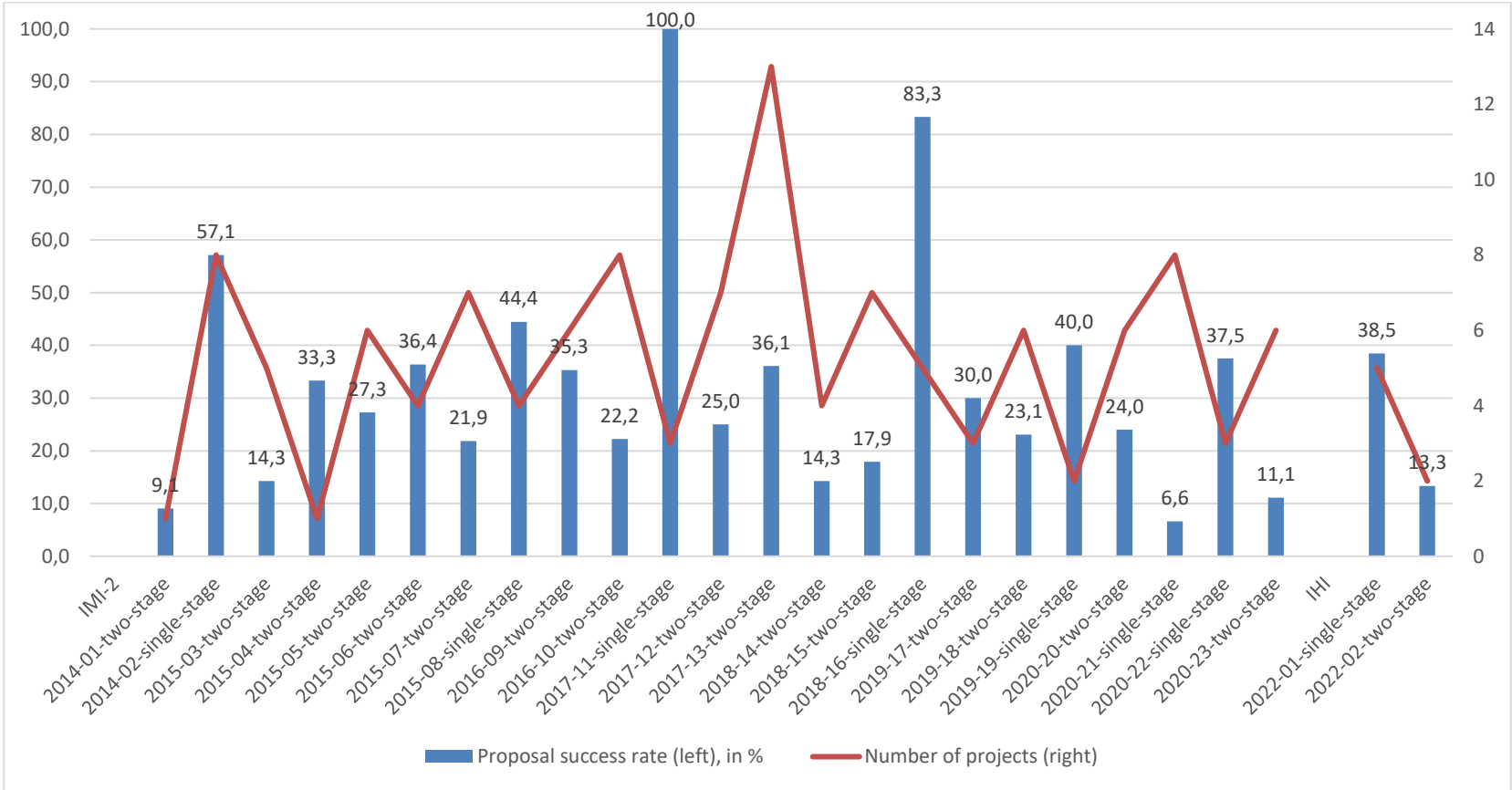
Figure 7. Number of submitted proposals by EU Member State for IMI2 (project coordinators only)



Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

The above also implies that the proposal success rate varies between calls. Single-stage calls tended to have a higher success rate, reflecting the lower number of proposals submitted and that several projects can be selected per topic. An exception is Call 21 that was related to COVID-19 and attracted a very large number of proposals (Figure 8).

Figure 8. Proposal success rate and number of projects funded by call



Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

In-kind and financial contributions to the programme and EC funding

IMI2 was a co-funded partnership between the EC and EFPIA, with both partners required to contribute equally to the costs of the programme. Associated Partners also contribute to the operational costs, counting towards the industry contributions. This balance between private and public funding is assessed at programme level, not at project level.

Over the duration of the programme, total project costs for IMI2 were EUR 3 005 million, of which EUR 1 452 million were committed by the EC, EUR 1 300 million by EFPIA and EUR 203 million by Associated Partners.

Contributions by EFPIA and Associated Partners were mostly made in-kind, with small amounts also made as financial contributions (usually to support specific activities by other consortium members). EFPIA in-kind contributions totalled EUR 1 152 million, those of Associated Partners totalled EUR 170 million. Financial contributions totalled EUR 147.9 million and EUR 32.4 million, respectively. Thirty-three percent (33%) of in-kind contributions from industry partners and Associated Partners were contributed from countries outside the EU (20.31 % EFPIA only), in line with the IMI2 regulation.

Recipients of project funding were project participants (i.e. consortium members) who were not EFPIA members nor Associated Partners. Academic institutions received over half of the project funding (52.8 %), 23.3 % was received by non-profit research organisations, 12.0 % by SMEs, 0.8% by patient organisations and 11.0 % by others[26] (Table 1).

26 ‚Others' include public organisations and third sector organisations such as non-profit or non-governmental organisations, and advocacy groups.

Table 1. Amount and share of project funding received by type of organisation under IMI2 (in EUR)

Organisation type	IMI2	IMI2 in %
Academia, secondary and higher education establishment	766 880 653	52.8%
Non-profit research organisation	338 731 099	23.3%
Others	159 983 430	11.0%
Patient organisation	11 555 227	0.8%
SME	174 939 531	12.0%
Total	**1 452 089 940**	**100 %**

Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Academic institutions and SME also made (small) contributions to the overall project costs, totalling EUR 9.4 million and EUR 280 472 respectively. Table 2 shows the distribution of total contributions by type of partner and country group. The table differentiates between contributions made in-kind and in cash. A full list of contributions can be found in

Table 15 in the Annex.

Table 2. Total contributions by type of partner and country group under IMI2 (in EUR)

Country groups	Associated Partners		EFPIA		Total
	In-kind	Financial	In-kind	Financial	
EU	48 427 915	6 720 415	918 231 558	118 466 476	1 091 846 364
Associated Countries	526 669	955 425	182 084 936	15 267 414	198 834 444
Third Countries	121 443 127	17 739 491 24 739 491	52 001 026	14 195 133	212 378 777
Total	170 397 711	32 415 331	1 152 317 519	147 929 023	1 503 059 585

Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Table 3 shows that the vast majority of project funding was received by organisations in the EU, with academic institutions being the main recipients, followed by non-profit research organisations. A smaller part went to organisations in Associated Countries and in Third Countries. For transparency, the table distinguishes between financial contributions by industry partners and Associated Partners and EC financial contributions.

Table 3. Total project funding received by type of organisation and country group under IMI2 (in EUR)

Country groups	EU	Associated Countries	Third Countries	Total
Financial contributions from industry partners and Associated Partners				
Academia	96 494 198	4 444 850	1 832 314	102 771 362
Non-profit research organisations	43 859 007	1 288 719	56 216	45 203 942
Others	17 660 591	2 682 236	95 000	20 437 827
Patient organisations	721 544	0	0	721 544
SME	11 024 678	185 000	0	11 209 678
Total	169 760 018	8 600 805	1 983 530	180 344 353
EC contributions				
Academia	724 220 865	20 901 160	21 758 628	766 880 653
Non-profit research organisations	323 494 895	7 745 579	7 490 625	338 731 099
Others	113 325 107	34 244 663	12 413 660	159 983 430
Patient organisations	10 667 952	16 250	871 025	11 555 227
SME	160 550 499	11 967 156	2 421 876	174 939 531
Total	1 332 259 318	74 874 808	44 955 814	1 452 089 940
Grand Total	1 502 019 337	83 475 613	46 939 344	1 632 434 294

Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

For IHI, data are available for the first three calls launched in 2022, of which full information is only available for Call 1. Financial information on Call 2 and Call 3 are preliminary and subject to update as they include projects that are still in preparation and grant agreements have not been finalised.

Table 4 shows all contributions to the first three IHI calls, including contributions from the EC and contributions from industry partners and Contributing Partners. These include in-kind operational contributions to projects (IKOP), in-kind contributions for additional activities (IKAA) and financial contributions to other project participants.

Table 4 .Total contributions to IHI by all partners (in EUR)

Call	Total Costs	Requested EC contribution	Total contributions (IKOP + IKAA + Financial contribution)
IHI-2022-01	128 851 049	75 853 845	68 021 162
IHI-2022-02	40 954 081*	21 711 134*	19 746 241*
IHI-2022-03	204 415 632 *	105 221 978*	105 106 218*
Total	**374 220 762***	**202 786 957***	**192 873 621***

Source for IHI-2022-01: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

*Source for IHI-2022-02 and IHI-2022-03: Decision of the Governing Board of the IHI JU (reference IHI-GB-DEC-2023-11 dated 15/05/2023) approving the list of proposals selected for funding and reserve list pursuant to the evaluation of the IHI third Call for proposals. * These figures are indicative only as grant agreements are not yet finalised.*

Table 5 shows the breakdown of total contributions from industry partners and Contributing Partners into IKOP, IKAA and financial contributions. This (preliminary) analysis suggests that about 5% of the total project costs will be allocated to additional activities. These activities aim to aid the dissemination and sustainability of project results beyond the duration of the project and include costs incurred within 4 years of the end of the project.

Table 5. Total contributions to IHI by industry partners and Contributing Partners (in EUR)

Call	IKOP	FC Paid	IKAA
IHI-2022-01	47 897 203	5 100 000	15 023 959
IHI-2022-02	16 619 241*	2 000 000*	1 127 000*
IHI-2022-03	85 397 551*	14 118 701*	5 589 966**
Total	149 913 995*	21 218 701*	21 740 925*

*Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023. Source for IHI-2022-02 and IHI-2022-03: Decision of the Governing Board of the IHI JU (reference IHI-GB-DEC-2023-11 dated 15/05/2023) approving the list of proposals selected for funding and reserve list pursuant to the evaluation of the IHI third Call for proposals. * These figures are indicative only as grant agreements are not yet finalised.*

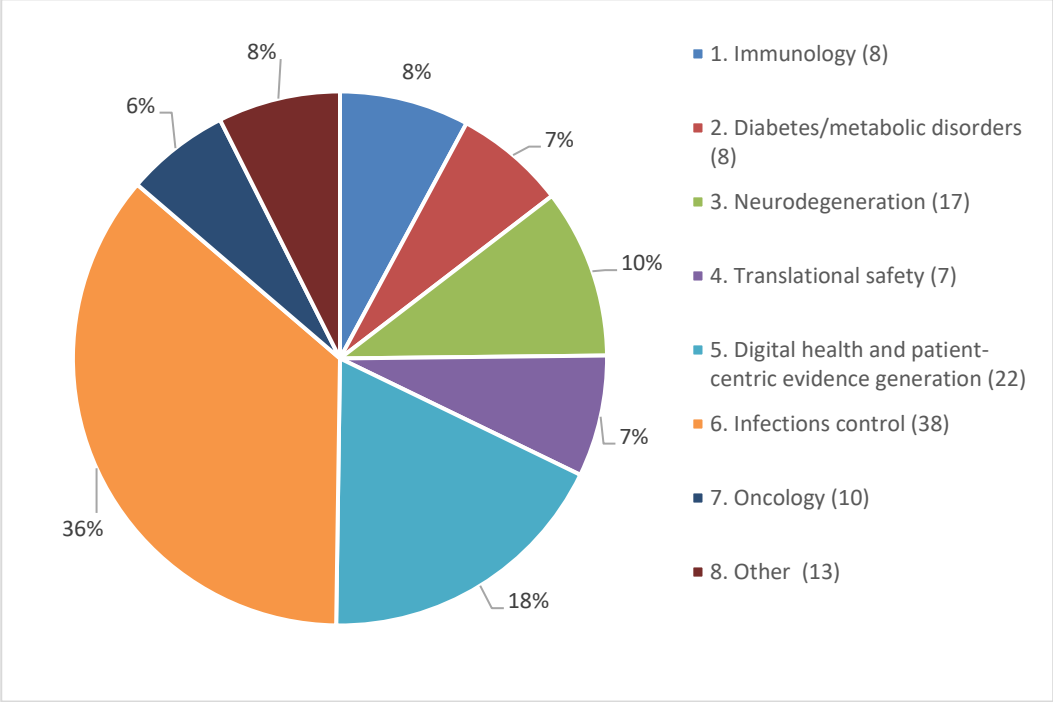
Given the limited amount of data available and its preliminary status, it is not possible to show the distribution of contributions by individual industry partner.

Distribution of funding committed by research area

Under IMI2, the largest share of funding (based on total project costs) was dedicated to research in infections control (36%). These projects often respond to health emergencies, specifically the Ebola outbreak in West Africa in 2014 and the COVID-19 pandemic. They also include projects that focus on addressing antimicrobial resistance.

Some 18% of funding was committed to projects in the field of digital health and patient-centric evidence generation (see Digital Health case study for examples), 10% to projects addressing neurodegeneration and 8% in immunology (Figure 9).

Figure 9. Distribution of total project costs by research area under IMI2



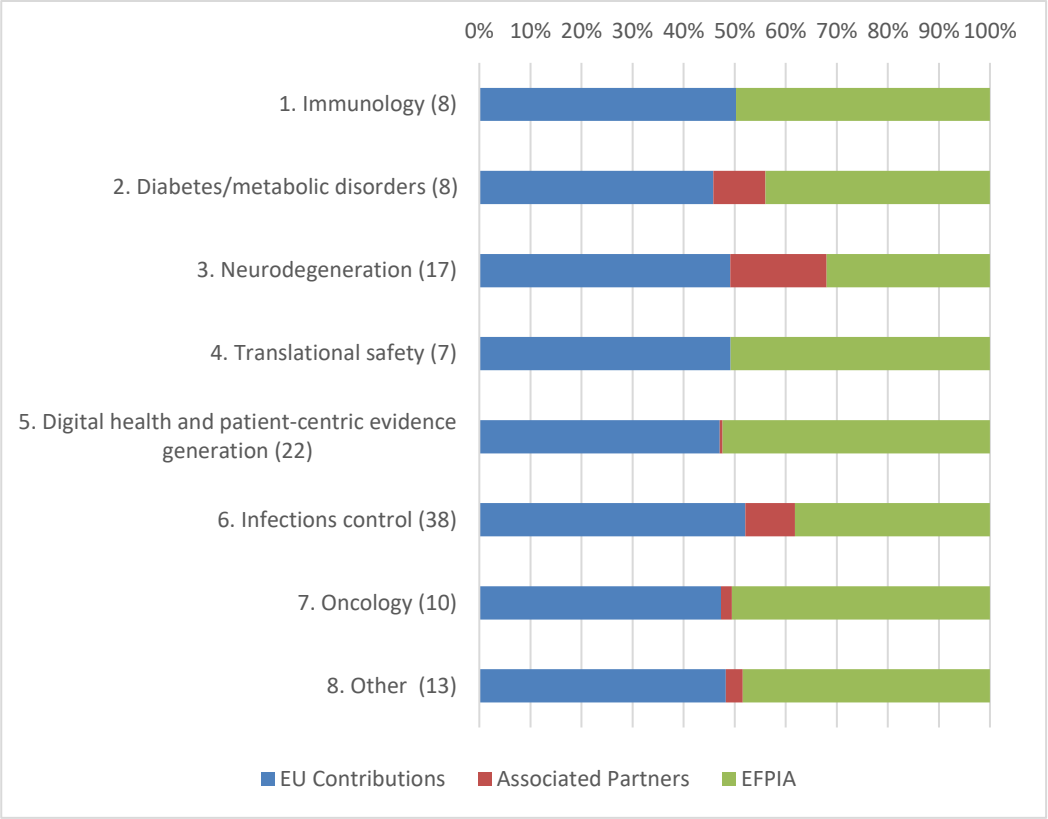
Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023[27].

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[28]. Contributions from these partners are clustered in some research areas, especially in addressing neurodegeneration, infectious control and diabetes and metabolic disorders (Figure 10).

27 ‚Other' includes Advanced therapy medicinal products, manufacturing processes improvement, patient engagement, rare/orphan diseases, transversal project or cross diseases

28 See a full list of IMI Associated Partners in www.imi.europa.eu/get-involved/associated-partners

Figure 10. Distribution of contributions from EU, EFPIA and Associated Partners by research area



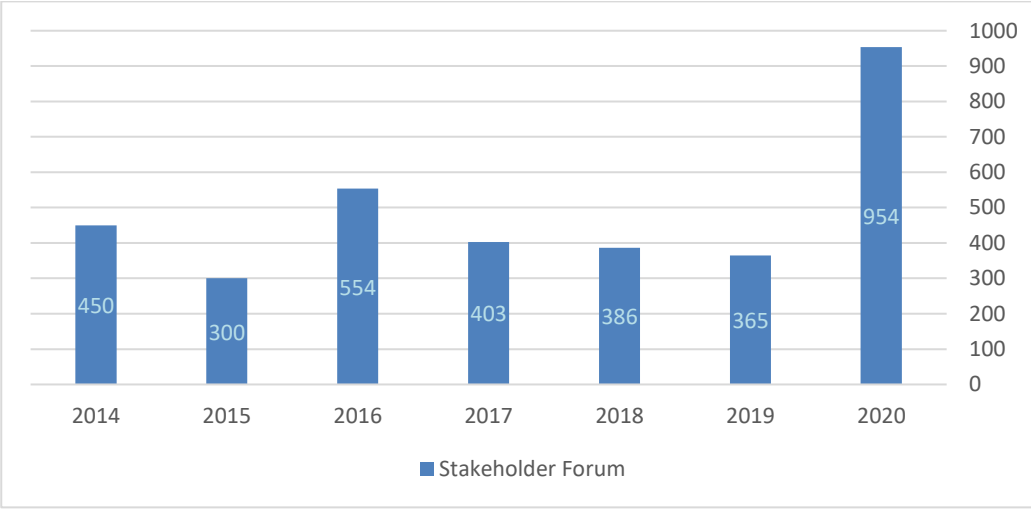
Source: IMI2/IHI Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Other activities

The Programme Office has implemented a portfolio of additional activities in support of the calls for proposals. These activities included engagement with various stakeholder groups and dissemination activities.

During IMI2, the Programme Office organised an annual Stakeholder Forum inviting all stakeholders of IMI2 to exchange experiences and provide feedback to the Programme Office. Council Regulations established the Stakeholder Forum as an official part of IMI's governance structure. The Forum was convened by the Executive Director and was open to all stakeholders in health and medicines R&D, including interest groups from Member States and countries associated with Horizon 2020 and other EU research programmes. Participation in the Stakeholder Forum varied over time with a clear increase in 2020 as the event moved to an online format during the COVID-19 pandemic (Table 6).

Table 6. Number of participants in IMI2 Stakeholder Forum



Source: IMI2 Annual Activity Reports, 2014-2020.

The Programme Office has run a series of webinars for each call for proposals, most importantly to inform future applicants about upcoming calls for proposals and the rules and requirements relating to each call. It has also produced a set of guidance documents to support applicants and project participants in understanding the requirements of the programme (IMI2 and IHI). The Office also organised a series of thematic workshops in preparation for future calls, including on the following topics:

- 'Diagnostics for reducing antimicrobial resistance' in 2017, together with European diagnostic companies and the Wellcome Trust;
- 'Microbiome' in 2017 in collaboration with all IMI2 Strategic Governing Groups and pharmaceutical companies;
- 'Disease interception' in 2018, together with patients and patient organisations, health authorities, healthcare providers, health technology assessment (HTA) bodies, the pharmaceutical and medical technology industry and academia.

In addition, the Office undertook activities to raise awareness among project participants about the opportunities available to interact with regulatory bodies, especially the European Medicines Agency (EMA). In 2017, IMI held a webinar providing an overview of EMA activities in support of EU-funded research projects for medicines innovation, EMA's qualification of novel methodologies, its support for SMEs and its Innovation Task Force. It also covered opportunities for engagement with the FDA[29]. IMI2 also published a guidance document, jointly developed with EFPIA, to raise awareness of regulatory requirements among researchers and summarise the services regulators offer[30]. The Programme Office has held four Regulatory Science Summit events during IMI2, with the next Summit being planned for early 2024.

The Programme Office also has a proactive communication and dissemination strategy in support of programme objectives. A clear example are the Health Spotlights, which showcase how research conducted by IMI projects impacts relevant health challenges. Two elements structure the Health Spotlights: the Impact Series Events (so far focused on diabetes, data, dementia, patient engagement, paediatrics research, SMEs in health data management, early career researchers, clinical trials and Ebola) and the Health Thematic Pages, which act as a focal point for IMI research in these different areas.

The number of press articles peaked in 2020 at 7 233 worldwide, following a decline from 5 077 in 2017 to 3 234 in 2019. The Programme Office also publishes regular news articles and a monthly newsletter that inform stakeholders about the latest programme related developments (such as project outputs, calls, events, publications) as well as news from IMI2/IHI projects. The number of newsletter subscribers increased from 2 398 in 2018 to 4 190 in 2021[31].

The Office also ran a website for IMI2 (https://www imi europa eu), which has been archived, and since December 2021 a new website for IHI (https://www ihi europa eu), which includes all the relevant information from IMI. It operates a LinkedIn, Twitter (now X) and Mastodon account. In 2021, 7 634 accounts followed IMI2 on LinkedIn, 11 827 accounts on Twitter, each increasing in numbers year-on-year.

29 https://www.imi.europa.eu/sites/default/files/events/2017/Regulatory_webinar_Dec2017_web.pdf.

30 IMI (2015): Raising awareness of regulatory requirements. A guidance tool for researchers. https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/RegulatoryRequirementsGuide.pdf.

31 IMI2 Annual Activity Reports and IHI Consolidated Annual Activity Reports.

4. Findings

4.1. Relevance

The 2017 Interim Evaluation concluded that continuing IMI was justified, and objectives had been revised and adjusted to new challenges over time to maintain its relevance, for example, by aligning with the priority medicines identified by the World Health Organization (WHO)[32]. The expert group suggested that the relevance of the programme would be increased by involving a wider group of industry partners in addition to pharmaceutical companies to reflect their role in biomedical innovation and involve a larger spectrum of stakeholders in consultations. They also emphasised that establishing a modus operandi for collaboration among pharmaceutical companies that were typically in competition with each other was the most important achievement of IMI1 and IMI2 at the time (i.e. identifying the pre-competitive space).

IMI2's mission and objectives continue to be relevant as they respond to substantial and often critical unmet public health needs. While the specific objectives cover a wide range of research and development efforts, there is no doubt that they are well chosen to address the gaps in medical research, drive innovation in areas of complex health need 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). The programme also managed to respond flexibly to several health emergencies, generating substantial investment in the development and implementation of an Ebola vaccine and the response to COVID-19.

While IMI2 already involved non-pharmaceutical companies as contributors to projects, industries in the fields of diagnostic imaging, medical technology and IT-based data analysis were not included as founding members of the Programme. This changed with the move from IMI to IHI. The new partnership involves several industry associations that represent sectors in addition to the pharmaceutical industry, including medical devices, biotechnology, vaccines and diagnostics. In contrast to IMI2, these organisations now have a stake in the partnership as founding members and are therefore represented in the governance structure as members of the Governing Board. The Expert Group for the Support of the Strategic Coordination Process for Partnerships used IHI as an example of a partnership whose cross-sectoral approach clearly demonstrates the necessity for EU action to address an existing gap in research and innovation[33].

32 Interim Evaluation (2017), pp. 65-66.

33 EC (2023): Assessing European Partnerships against European policy priorities. Developing and illustrating a methodology for assessing the relevance of European Partnerships as instruments to address current and future European policy priorities. Brussels, DG RTD.

This move to widening the group of private sector partners is also reflected in the new Strategic Innovation and Research Agenda (SRIA). The SRIA is anchored in the objectives set out for IHI in the Single Basic Act. It demonstrates a shift away from a solely medicines development focus to a broader approach to defining priorities, creating space for innovations that apply to more than one disease area or are disease agnostic. Specific objectives give emphasis to the research of the determinants of health, integrated healthcare solutions, digitalisation and data exchange and implementation of innovation in healthcare settings. This arguably constitutes an adjustment to developments that have already informed the selection of IMI2 projects (e.g. projects developing data platforms and demonstrating the feasibility of cross-country or cross-industry data exchange), with the aim to further enhance its impact during IHI.

Stakeholders interviewed confirmed that the programme was still highly relevant and able to drive innovation in novel research areas with the potential of high impact on patient care and quality of life. Many projects yielded impacts in the medium and long term, with some resulting in unforeseen uses added to the preparedness and resilience of the innovation system (as has been demonstrated by the response to COVID-19). It was noted that by widening its focus to cross-sectoral collaboration the programme was still 'ahead of the curve' as a public-private partnership in the field of health research.

Given the early stage of IHI, it is only emerging how the SRIA will be operationalised in practice, with the exception of the calls that have been launched to date. Industry partners are developing and consolidating their positions, including through the 'Think Big' process, but specific pillars have not yet been published. Going forward, it will be crucial how all partners' interests will be balanced and consolidated in priority-setting and call topic definitions. Stakeholders (including representatives of the EC) noted that there is good alignment of partners' interests in terms of public health needs.

Given the early stage of its establishment it is too early to judge the flexibility of IHI. However, the Single Basic Act allows for changes in the SRIA to adjust to changing circumstances and respond to unforeseen health challenges. This provision was missing from IMI2 (but possible during IMI1). However, the programme was able to respond flexibly to a number of emerging challenges. More specifically, IMI2 launched 12 projects in response to the outbreak of Ebola in West Africa and to the COVID-19 pandemic.

4.2. Coherence

4.2.1. Coherence with Horizon Europe and Horizon 2020 and other EU and national policies (programme level)

The 2017 Interim Evaluation concluded that the objectives of IMI2 were well aligned with the objectives of Horizon 2020: (1) to generate excellent science, (2) to create industrial leadership, and (3) to tackle societal challenges[34]. IMI2 was also well aligned with the aims of Societal Challenges I (SC1) 'Health, demographic change and well-being' and specifically addressed the aims of improving preparedness, understanding disease, developing better preventive vaccines, improving diagnosis, using in-silico medicine for improving disease management and prediction, treating disease, transferring knowledge to clinical practice and scalable innovation actions, better use of health data and improving scientific tools and methods to support regulatory needs[35].

This evaluation confirms the assessment of the Interim Evaluation of IMI2. The programme remained well aligned with the objectives of Horizon 2020 and contributes significantly to the aims of Societal Challenges (SC) 1 and 9. However, some stakeholders interviewed also 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 and 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 (Article 185/7) within Horizon Europe it works towards the three objectives of fostering scientific and technological excellence, tackling policy priorities of the EC, and boosting Europe's innovativeness and competitiveness. By working towards these objectives, IHI also contributes to the strategic autonomy and technological sovereignty of the EU[36].

IHI also contributes directly to the implementation of several EU policies, including Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and the new Industrial Strategy for Europe.

Europe's Beating Cancer Plan sets out the EU's strategy for action to reduce cancer prevalence and improve diagnostics, treatment and care for cancer patients. The Plan lists IHI as a key contributor to health innovations in relation to cancer by creating an EU-wide research and innovation system[37]. To date, three projects have been launched under IHI that address unmet need relating to cancer (IDERHA, GUIDE.MRD, IMAGIO).

34 Interim Evaluation 2017, p. 80.

35 EC (2011): Proposal for a Council Decision establishing the Specific Programme Implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011PC0811

36 See IHI's contribution to the Common Indicator survey for the Biennial Monitoring Report (BMR) on Partnerships in Horizon Europe 2024.

37 EC (2021): Europe's Beating Cancer Plan. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342. pp. 6-7.

IHI also aligns with the **Pharmaceutical Strategy for Europe**, specifically through its strategic aims of addressing unmet medical needs, fostering competitiveness and innovativeness of the pharmaceutical and other health industries in Europe, and by contributing to the development of regulatory standards. It is not entirely clear whether and how IHI project results will translate into ensuring access to affordable medicines, a key aim of the Pharmaceutical Strategy; however, the Single Basic Act has enshrined a new commitment to ensuring that products and services resulting from clinical studies undertaken in IHI projects should be 'affordable, available and accessible to the public at fair and reasonable conditions'. Pursuant to this commitment, the designated projects are obliged to report their efforts on ensuring 'affordability, availability and accessibility' of any products or services developed based or partly based on the results of clinical studies within the project to the IHI Office for a duration of four years after project end. This means that selected projects will have to develop specific approaches to ensure affordability, availability, and accessibility, although it will not be possible to apply these criteria to all projects (as they do not generate products or services but work on pre-competitive aspects of research and development).

IHI also supports key aims of the **European Industrial Strategy**, especially the aim to strengthen the innovation ecosystem of which the pharmaceutical and health technology industries are part. It achieves this by bringing together five different industry sectors fostering cross-sectoral collaborations to allow new ways of working, new opportunities to address complex issues in health and to support an enriched research ecosystem in Europe. Some stakeholders noted that lowering the maximum threshold of contributions from industries and Contributing Partners from outside the EU from 30% to 20% at programme level aimed at encouraging industries to conduct R&D in the EU. Other stakeholders voiced their concern about this restriction, as it could potentially undermine the aim of leveraging industry contributions by creating a barrier to participation for some companies.

IHI is also expected to directly contribute to the **European Health Data Space** (EHDS) for which legislation is currently in preparation. Projects launched under IMI2, such as the EHDEN project have already prepared the ground for the EHDS, by developing methods and finding technological solutions for bringing together patient data held by a large number of data owners in different countries. Stakeholders also noted the urgency of IHI contributing to the **European Green Deal**, by encouraging industry partners to invest in green technologies and to increase efforts to reduce the environmental impact of the health sector (e.g. by reducing waste from disposables). There are plans for addressing these challenges in the next IHI call topics that will aim to develop a better understanding of the applicability of green technologies in health systems and existing barriers to implementation.

The Single Basic Act requires IHI to increase its synergies with other EC programmes, partnerships and Horizon Europe missions. The Programme Office has set up an internal task force which includes representatives of several Directorate Generals (DG RTD, DG Connect, DG Sante, DG Grow), as well as industry partners to cover all angles and coordinate activities. These activities are still at an early stage, with potential partners currently being mapped to understand their function within the wider landscape of EU policy implementation. First steps have been undertaken to initiate exchange and identify potential synergies and as a first concrete output a Memorandum of Understanding has been signed between IHI and EIT Health. Initial contacts have also been established with EDCPT2 JU, Key Digital Technologies JU and the Health Emergency Preparedness and Response Authority (HERA)[38]. There is also a role for the SRG to identify relevant national and regional programmes. The SRG is expected to submit an annual report that provides an overview of national and regional policies relevant to IHI and identifies opportunities for collaboration. The IHI Office and the EC are also building links with various regional stakeholders, for example, by linking with the new partnerships on Transforming Health and Care Systems (THCS) and on Personalised Medicine, by establishing contact with the Reference Sites Collaborative Network (RSCN) and by organising regular exchanges with representatives of several European regions. These developments are emergent, and it is too early to judge whether they will be sufficient to create the degree of synergy and related outcomes to which the programme aspires.

4.2.2. Coherence with Horizon Europe and Horizon 2020 (participant level)

To assess the degree of involvement of IMI2 participants in Horizon 2020, we analysed the Horizon 2020 centrality score of 1 099 IMI2 participants[39]. A centrality score refers to the degree of involvement in Horizon 2020, compared to all other Horizon 2020 participants. It is based on the number of participations of each type of organisation and measured in percentiles.

In total, 16.4% of IMI2 participants were among the top 1% of Horizon 2020 participants during the lifetime of Horizon 2020. This rate is particularly high for universities and higher education institutes with 50.4% of them being among the top 1% and 91.1% among the top 10%. This finding underlines the level of excellence of academic research involved in the programme.

Private companies (excluding SMEs) also fair well, with 2.8% among the top 1% of Horizon 2020 participants (i.e. double the average), with 30.9% among the top 10% and 89.9% among the top 50%. The picture is different for SMEs, none of which are among the top 1%, however, 15.5% are among the top 10% and 80.1% among the top 50% participants of Horizon 2020. This finding shows that the programme has attracted project participants, especially among SMEs, that are usually not involved in European research funding programmes.

38 See IHI's contribution to the Common Indicator survey for the BMR 2024.

39 The analysis was conducted by PPMI using CORDA data. The number of participants deviates slightly from the data presented earlier due to incomplete data.

Synergies are also created between projects and are encouraged among project participants. This is particularly evident in the field of digital health research, with the case study providing several examples of 'cross-pollination' between IMI2 projects. 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). Another example is the FAIR project which was set up to test how data generated in IMI projects can be made 'findable, accessible, interoperable and reusable' (FAIR). The aim is to apply these principles and methodologies to at least 20 IMI projects to increase their usability in health research and societal impact[40].

4.3. Efficiency

This section will discuss the efficiency of the implementation of IMI2 and IHI. According to the guidelines received for this evaluation, the efficiency criterion should be based on a cost-effectiveness analysis (CEA). The latter puts the benefits of the intervention in relation to the costs and compares them against best practice or similar interventions[41].

For several reasons this is not a straightforward exercise in this evaluation:

- As shown in the section on Effectiveness (section 4.4), many of the benefits of IMI2 are still emerging. In the case of IHI, with only a few projects just having started, any benefits will be far into the future.
- As shown in section 2.1, the objectives of both IMI2 and of IHI are diverse, combining research-related, societal and economic objectives. This is also reflected in the fact that progress against objectives is measured by a set of 10 KPIs (section 4.4). As pointed out in the EC's Better Regulation Guidelines, 'CEA is less easily applicable to interventions with more than one main objective'[42].
- It is not possible to compare the programme's cost-effectiveness with 'best practice' or a 'similar intervention'. The programme is unique at EU-level and even if there were programmes with similar characteristics at national level, they would be embedded in a different framework and not be useful as a benchmark. The only possible benchmark that could be used is IMI1. But for such a comparison, the IMI2 KPIs would have to be applied to IMI1, which is outside of the scope of this study.

For the above reasons, a CEA lacks the necessary judgement criteria and can therefore not be conducted. Instead, we will assess the efficiency based on the following aspects:

- administrative costs;
- operational efficiency (in terms of time-to-inform, time-to-grant, time-to-pay);
- efficiency of governance mechanisms.

40 The story so FAIR. https://www.imi.europa.eu/news-events/newsroom/story-so-fair.

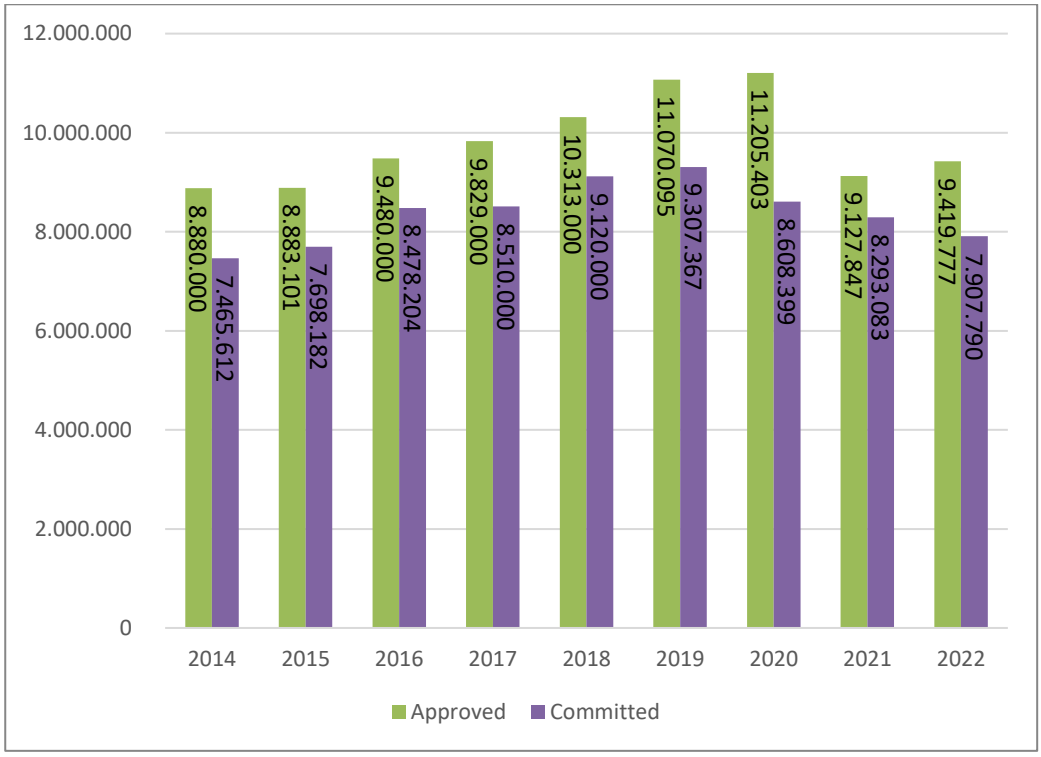
41 European Commission, 2021: Better Regulation Toolbox, pp. 518-519. Available at https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf.

42 Ibid.

4.3.1. Administrative costs

Over the period 2014-2022, a total of EUR 88.2 million had been approved for the administration of the partnership. Of this, EUR 75.4 million were eventually committed. In other words, the partnership was managed with 85.5% of the budget that had initially been approved and set out in the Council Regulation. Figure 11 shows the distribution per year.

Figure 11. Administrative costs (approved and committed), per year



Source: IHI Office.

The difference is particularly pronounced in 2020, when the COVID-19 pandemic interfered with the execution of some of the planned activities (such as meetings and events). From 2021, under Horizon Europe and in line with the Single Basic Act, the planned annual administrative budget was reduced by EUR 2 million per year. Administrative costs are equally split between the EC and industry partners. Of these EUR 75.4 million committed, EUR 45.2 million (60.0%) were committed to personnel costs and EUR 30.2 million (40.0%) to infrastructure. The full breakdown can be found in Table 7.

Table 7. Breakdown of administrative costs IMI2 and IHI for the period of 2014 and 2022

Budget Chapter Description	Budget approved (in EUR)	Committed (in EUR)
Staff in active employment	46 981 009	40 841 954
Miscellaneous expenditure on staff recruitment	174 399	135 654
Missions	1 288 561	875 269
Socio-medical structure	2 836 197	2 676 389
External staff	695 421	558 090
Representation expenses	183 038	115 924
Subtotal - Staff	52 158 626	45 203 281
Rent and related expenditures	6 826 432	6 335 828
IT (hardware and software)	7 338 348	7 095 980
Office equipment	186 630	19 736
Current administrative expenditure	1 207 291	924 813
Postage and telecommunications	514 014	393 870
Meetings	1 080 113	772 348
Expenditure in connection with operational activities	2 783 596	2 158 400
External communication information and publicity	4 678 427	2 776 759
Ex post audit,studies, audit and accounting external services	5 486 102	4 269 659
Expert contracts and meetings	5 948 645	5 437 964
Subtotal - Infrastructure	36 049 598	30 185 356
Total	88 208 224	75 388 636

Source: IHI Office.

The EUR 75.4 million committed for the administration seem reasonable and justified compared to other programmes. While they are higher than for other partnerships such as EDCTP2[43] and AAL2[44], the volume of project funding administered by IMI2/IHI is also significantly higher. Set in relation to the EC contributions of EUR 1.663 million (EUR 1.452 million under IMI2 and 200 million committed to date under IHI), the EUR 75.4 million administration costs represent a share of 4.5%. This ratio is almost equal to that of EDCTP2 (4.4%) and lower than that of AAL2 (5.9%).

43 29.9 million EUR over the period between 2014 and 2020, see: European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Brokevičiūtė, S., Kazlauskaitė, D., et al., Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) second interim evaluation : study in support of the ex-post evaluation of the European Framework Programme for Research and Innovation Horizon 2020, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/741433

44 6.5 million EUR over the period between 2014 and 2020, see: European Commission, Directorate-General for Research and Innovation, Gehrt, D., Ettelt, S., Breuer, A., et al., Active and assisted living research and development programme (AAL2) final evaluation, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2777/068757

4.3.2. Operational efficiency

The programme has also performed well with regard to indicators of operational efficiency (Table 8).

- **Time-to-Inform (TTI)** represents the time needed by the Programme Office to manage the evaluation and selection phase from the Call deadline to informing the participants. TTI has been significantly faster than the target of 153 days throughout IMI2 and IHI.

- **Time-to-Grant (TTG)** represents the maximum 8 months between the call deadline and grant agreement signature. With one exception (in 2017) the programme has managed the process leading up to the grant agreements being signed efficiently within the target of 245 days.

- **Time-to-Pay (TTP)** represents the outcome of the process for the payment of pre-financing to newly signed grant agreements and costs claimed by beneficiaries. TTP has been significantly below target, while interim payments improved over time and final payments remaining below target.

Table 8. Indicators of operational efficiency

	Time-to-inform (TTI)	Time-to-grant agreement signature (TTG)	Time-to-pay (TTP) pre-financing	TTP interim payments	TTP final payments
	Target: 153	Target: 245	Target: 30	Target: 90	Target: 90
2022	72	n/a	n/a	61	72
2021	75	223	10	61	70
2020	67	190	6	64	62
2019	73	210	9	57	65
2018	75	232	9	59	54
2017	81	270	11	66	66
2016	76	232	12	95	62
2015	75	135	13	90	n/a
2014	n/a	123	7	71	n/a

Source: IMI2 Annual Activity Reports, 2014-2020, and IHI Consolidated Annual Activity Reports, 2021-2022.

4.3.3. Efficiency of governance mechanism

With the transition from IMI2 to IHI the governance structure and composition of governance bodies has changed significantly. Stakeholders interviewed judged the partnership as working well and found the collaboration at governance level constructive and promising. New partners stated that they felt their voice is being heard. Going forward, it is important that public and private interests and inputs to discussion are well balanced to aid the programme in achieving its objectives.

It is evident that the interim evaluation is less well timed and therefore less conclusive than intended, reflecting the initial delay in the start of IHI. There have also been challenges associated with the transition to IHI that have required significant attention, notably limitations on industry partners based in Third Countries (of which there are many in the pharmaceutical and medical technology industries) to sign the model grant agreement as beneficiaries (see Case Study 1 'From Innovative Medicines Initiative to Innovative Health Initiative – the early experience''). While a solution has been found, this constitutes a 'work around' as it is not possible to address the source of the issue (which is anchored in the EC's corporate approach). It is yet to be seen how well this solution works in practice and how easy it is to implement.

Stakeholders noted that the newly created Science and Innovation Panel (SIP) is working well and has already made relevant contributions to the IHI work programme and discussions on topic ideas. Stakeholders explained that the role of the States' Representatives Group has remained globally the same as during IMI2. However, it is expected that its role in creating synergies between IHI and national or regional programmes needs to be strengthened. Some stakeholders also felt that the SRG is not sufficiently involved in discussions on call topics, mostly because the body only meets twice a year. However, the possibility of additional online discussions and workshops exists and has already been used.

4.4. Effectiveness

The aim of this section is to assess the extent to which IMI2 has achieved its objectives. It is too early to assess the effectiveness of IHI, given the small number of projects that have been agreed only recently. The section will therefore only comment on the potential of IHI to achieve its objectives. This aspect will also be considered under the criterion of Directionality.

The IMI2 Interim Evaluation reviewed the achievement of several milestones and concluded that there were promising developments but that many of them were not measurable. It noted that the main achievement of IMI2 was that it enabled collaboration between global companies that are normally in competition with each other, with SMEs and academic researchers, and that it had successfully managed to establish new partnerships and build trust between partners at project and programme level[45].

The mission of IMI2 was to promote and accelerate the development of medical innovations to improve health and well-being and to strengthen the competitiveness of medical innovation and research in Europe. These long-term impacts are broken down into a set of specific objectives that set out the ambition for IMI2 but were difficult to measure (see Annex). The Governing Board therefore developed a set of Key Performance Indicators (KPIs) that are measurable and used to assess progress against specific targets. In what follows, each KPI will be assessed in turn, using the information provided in the IHI 2022 Consolidated Activity Report. KPIs are cumulative and cover the entire lifespan of IMI2 from 2014 to 2021. As many IMI2 projects are still running, performance against targets is expected to further improve over time.

45 EC (2017): Interim Evaluation of IMI2. p. 9.

KPI 1: Number of relevant priority areas in the WHO "Priority Medicines for Europe and the World 2013 Update" reflected in the IMI2 Strategic Research Agenda (SRA) and addressed by IMI2 projects

All European Health Priorities set out in the IMI2 SRA cover disease areas defined as priorities for medicines' development by WHO in 2013. While in IMI2 the number of projects in each area varies, there is substantial correspondence between priorities at the level of disease areas. Reporting against KPIs state that 11 out of 12 priority areas were addressed by a total of 80 IMI2 projects. EUR 2.2 billion were committed to these projects[46]. The priority area with no corresponding IMI2 project was osteoarthritis. Stakeholder interviews suggested that the WHO priorities were difficult to operationalise as a KPI given their lack of flexibility in relation to the changing nature of priorities as demonstrated by the need to respond to outbreaks of infectious disease (Ebola, COVID-19) or the increased relevance of digital health topics within the EU health priorities. Therefore, this KPI was not carried forward to IHI.

KPI 2: The number of project-developed assets that completed a significant milestone during the course of an IMI2 project

Assets are programme outputs that are project deliverables created in the pre-competitive space such as new drug and diagnostic candidates, targets and biomarkers and other tools. These deliverables represent significant milestones in the research and innovation process, but do not directly result in products and services that can be brought to market.

In total IMI2 projects have produced 439 assets, which is significantly above the target of 50 set for the programme. Assets include databases of patient data collected during projects that will often be analysed well beyond the duration of the projects. For instance, within the neurodegeneration portfolio, we can find examples such as the RADAR-CNS cohort of patients with multiple sclerosis and the EPAD longitudinal cohort study or patient samples and data such as the neuroimaging datasets from the AMYPAD studies and the ADAPTED biosamples from people with different APOE genotypes[47].

In interviews, project coordinators and industry lead reported efforts to extend access to these data to researchers outside the project consortia. However, this often requires additional resources and a long-term strategy to organise access while ensuring compliance with regulations, for example with respect to data privacy.

KPI 3: New or improved guidelines, methodologies, tools, technologies or solutions accepted by regulatory authorities for use in the context of R&D, specifically for:

- **new tools for preclinical drug development;**
- **biomarkers and tools developed to predict clinical outcomes;**
- **improved protocols to design and process clinical trials;**
- **new biomarkers developed for the efficacy and safety of vaccine candidates.**

To date, the programme reports outputs related to 17 projects that in total have completed 24 regulatory procedures, double the target value aspired to. These include four outputs

46 IHI (2022): Consolidated Annual Activity Report 2022, p. 189.

47 See https://www.frontiersin.org/articles/10.3389/fneur.2022.994301/full.

having received a CE-mark (certifying conformity 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. A case in point is the EHDEN project that has established a harmonised data network using a common data model (OMOP-CDM). This common data model has now been established as a standard and is used in a number of studies executed in compliance with requirements from the EMA. There are more projects that have made submissions for qualification opinion to receive guidance from the EMA on the studies to be performed.

Box 1. Examples of impact on regulatory processes

The **RAPID-COVID** project developed two CE-marked diagnostic panels which can identify not only SARS-CoV-2, but several other respiratory infections such as flu and respiratory syncytial virus (RSV). If used routinely, this device would help doctors to rapidly determine the most appropriate treatment for patients with respiratory symptoms.

The **GetReal Initiative** delivered a range of new tools and resources for incorporating real-life data earlier into drug development and decision-making processes. The project generated ADDIS, a tool to support structured benefit-risk assessment. It was included in EMA's Committee for Medicinal Products for Human Use (CHMP) workplan for 2021 and 2022 as one of the tools to pilot as a supportive tool for structuring benefit-risk assessments.

MOBILISE-D developed a comprehensive system to analyse people's gait based on digital technologies, including sensors worn on the body. The project focuses on conditions which often affect mobility, namely chronic obstructive pulmonary disease (COPD), Parkinson's disease, multiple sclerosis, hip fracture recovery, and congestive heart failure. The results should improve the accuracy of assessment of mobility in clinical trials and help clinicians to monitor patients' mobility. The EMA has issued two letters of support, providing advice on how the new method can be further tested for regulatory approval[48].

PREFER developed a set of systematic methodologies and recommendations to assess, engage and include patient perspectives during the development, approval and post-approval of new therapies. To this end, the project has engaged with EMA and EUnetHTA, the European Network of organisations involved Health Technology Assessment, and received a positive qualification opinion by the EMA's CHMP on its Framework and Points to Consider for Methods Selection[49].

KPI 4: New taxonomies of diseases and new stratifications (such as the definition of patient sub-populations, development, validation and use of new diagnostics) developed

This output relates to new knowledge about diseases generated by a project that can be used to inform drug development. The annual reports of 14 projects have reported 46 different

48 EMA (2020): Letter of support for Mobilise-D digital mobility outcomes as monitoring biomarkers. https://www.ema.europa.eu/en/documents/other/letter-support-mobilise-d-digital-mobility-outcomes-monitoring-biomarkers_en.pdf. EMA (2021): Letter of support for Mobilise_D digital mobility outcomes as monitoring biomarkers. https://www.ema.europa.eu/en/documents/other/letter-support-mobilise-d-digital-mobility-outcomes-monitoring-biomarkers-follow_en.pdf.

49 EMA (2022): Qualification Opinion of IMI Prefer. https://www.ema.europa.eu/documents/regulatory-procedural-guideline/qualification-opinion-imi-prefer_en.pdf.

taxonomies and new stratifications, exceeding the target of 30.As an example, the project LITMUS 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.

KPI 5: Contribution (in-kind or in cash) from non-pharma actors (e.g. non-pharma industries, foundations, charities, professional organisations)

This KPI relates to the financial contributions, made in cash or in-kind, from project participants that were not members of EFPIA (e.g. foundations, charities, professional organisations, industries other than the pharmaceutical industry). These contributions to the overall project budget were matched by the EC contribution to the total project costs. According to the Consolidated Annual Activity Report 2022, EUR 270 million were raised in addition to EFPIA contributions including EUR 203 million from Associated Partners and EUR 67.1 million from EFPIA Partners in Research[50]. The amount raised remained below the target of EUR 300 million.

KPI 6: Share of IMI 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), trainings materials and guidance that can be used by actors outside the consortium. Sixty-seven projects have been reported as having developed such resources, a share of 58.3% of projects, above the target of 50%. EBiSC2 provides an example of how projects outputs are made accessible to the wider research community. The project delivered a self-sustaining biobank, providing well-characterised, quality-controlled pluripotent stem cells. Its expertise was also drawn on by the ADAPTED project to develop stem cell lines on a gene that is a known risk factor for Alzheimer's. A total of four lines of stem cells were generated, included in a biobank, quality controlled and shared internationally. Examples also include a library of chemical compounds, the European Compound Collection, established by the ESCulab project, the open-source RADAR-base data platform developed by RADAR-CNS, and the European federated data network, established by the EHDEN project.

Accessibility beyond the lifetime of the project has been made an obligation for project participants of IHI for some type of project results. Regulation requires project consortia to use their best efforts to ensure that products and services resulting from a clinical study conducted during a project will be "broadly available and accessible, at fair and reasonable conditions' during the lifetime of the project and for a period of four year after the project ends[51].

50 The Partners in Research status was created to allow non-pharmaceutical companies to participate in EFPIA research activities under IMI and IHI. This means that the contributions of Partners in Research are officially included in EFPIA´s contributions. However, the contributions of Partners in Research are tagged to allow the Programme Office to report on KPI 5.

51 See Guide for Applicants, p.7, https://www.ihi.europa.eu/sites/default/files/IHI_Guide_for_Applicants.pdf. Council Regulation (EU) 2021/2085. Article 125 (3).

KPI 7: Co-authorships and cross-sector publications between European researchers on IMI2 projects (sectors include academia, small and mid-sized companies, pharma, regulators, patient organisations, etc.)

Publications are a key measure of scientific productivity and impact. This KPI focuses on publications produced by authors from the different sectors participating in IMI2 projects. According to the Consolidated Annual Activity Report 2022, the number of publications attributed to IMI2 projects at the end of the programme was 2 167, above the target of 1 500.

Bibliometric analysis commissioned by the programme in 2023 shows that the publication output across the duration of IMI1 and IMI2 has been significant, with 9 784 publications for the years 2010 to 2022[52]. Most IMI research (64%) was published in high impact journals. The citation impact of research conducted in IMI projects was twice as high as the world average and 75% higher than the EU average. A total 78.3% of publications were open access. Around 67% of papers produced by IMI projects had co-authors from different sectors, demonstrating the cross-disciplinary nature of the research and the collaborative approach of projects; 65% involved authors from different countries demonstrating international collaboration.

KPI 8: New tools and processes generated by IMI2 projects that have been implemented by the industry participants of IMI projects

This output includes new tools and processes, including animal models, standards, biomarkers, standard operating procedures, screening platforms and clinical trial platforms. 524 such tools and processes have been reported as outputs from IMI2 that are being used by industry partners participating in projects, relating to 56 IMI2 projects. This is substantially above the target of 50.

For example, the network, IT infrastructure, technology platform and assays developed by the INNODIA-HARVEST projects have been used in two drugs trials: IMPACT by Imcyse SA and Iscalimab by Novartis. The project also developed materials to motivate patients and professionals to participate in clinical trials that are used by industry.

52 Clarivate (2023): Bibliometric analysis of ongoing projects. 14th report. March 2023.
https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/Reports/IHI_Bibliometrics_Report_2023_Final.pdf

KPI 9: Share of projects involving patient organisations and healthcare professionals' associations

Patient organisations and healthcare professionals' organisations can be involved in various roles, including as consortium partners, members of advisory boards and members of stakeholder groups associated to projects. At project level, involvement of members of such groups have been reported for 72 projects, constituting about 63.1% of total IMI2 projects. This was below the target of 80%.

Projects that have involved patients and patient organisation often report substantial in-depth engagement activities. In several digital health projects, for example, patients provide important feedback on the feasibility, practicality and convenience of using wearable technology to record data during daily activities (e.g. IDEA-FAST, RADAR-AD, RADAR-CNS, Mobilise-D). Such information is relevant to understand reasons for adherence and non-adherence and can inform strategies to address barriers to the use of such technologies for example in clinical trials. Some projects specifically examined the options for meaningful engagement of patients in clinical studies and developed best practice tools and methodologies (PARADIGM, PREFER However, the relevance of patient engagement at project level depends on the nature of the research and for some projects that address the early phases of research and development patient engagement may not be as meaningful as for other projects (for example, projects that aim to develop a new methodology to produce vaccines (ZAPI under IMI1) or that establish a biobank for induced pluripotent stem cells (EBiSC2 under IMI2)At programme level, IMI2 undertook a number of activities to encourage patient engagement (see also Transparency and Openness). Under IMI, a Patient Pool was piloted. Following the success of the initiative, a new IHI Patient pool was created in 2023[53]. It currently involves 78 patients and 33 caregivers, who are expected to be involved in various aspects of the programme and its projects.

KPI 10: Support to SMEs: share of SMEs participating as formal IMI2 project beneficiaries

While IMI2 was not designed to attract SMEs specifically, IMI2 and IHI have undertaken targeted measures to support SMEs' involvement in the Programme and to increase the share of SMEs among project participants. This involves including specific activities for SMEs when developing topic texts, providing information tailored to SMEs, to webinars on call topics, and organising specific webinars for SMEs (also see Transparency and Openness). However, attracting SMEs to participate in projects has remained a challenge throughout IMI2. The main reason for this is that the programme is designed as a partnership between the EC and established industries that primarily involve large, often multi-national and globally operating companies. This may change under IHI, as the membership of new industries appears to be more heterogenous.

To date, the share of SMEs participating in IMI2 projects has been reported as 16.1% by the end of 2022. This is below the target of 20% set out for this KPI. However, this value is based on participations (i.e. counting each time an organisation participated, as the denominator). The share of SMEs of all participants (i.e. counting every organisation only once irrespective of how often they participated in projects) is 22%. Compared to other research funding programmes in Societal Challenge 1 of Horizon Europe (31%), the participation rate is lower, but it is above the target set as KPI 10[54]. As shown before, IMI2 managed to attract many SMEs that were not previously involved in Horizon 2020.

Box 2. Sustaining project outcomes beyond the lifespan of IMI2 and IHI

IMI2 and IHI aim to foster collaboration between private sector companies and public sector organisations in pre-competitive research. Projects are designed to develop innovations, assets, tools and methods that enable the advancement of research and innovation in Europe. Consequently, many of the outputs resulting from this research do not immediately translate into products and services that can be brought to market. However, the sustainability of these outputs is an increasing concern to IMI2 and IHI.

To help sustain the results beyond the project's lifecycle, under IHI, this aspect has been given a more solid framework both in terms of expectations and requirements communicated towards project participants and in terms of financial resources, that can now be included in the budget calculations as 'additional activities' (in-kind contributions for additional activities, IKAA).

There are already numerous examples of projects that have taken active measures to sustain the novel solutions, assets and approaches developed during IMI2:
The **AIMS-2-TRIALS** project created a clinical trials network to improve the development, testing and implementation of new drugs for people with autism spectrum disorders. The network covers 118 sites in 37 countries, with access to 20 000 new patients per year.

The **Connect for Children (c4c)** project sets up a European clinical trial network for children to improve the development of medicines for children. The project built a network of 19 paediatric national hubs with dedicated national coordinators to oversee activities. The cross-border approach ensure that clinical trials can achieve the patient numbers required for this type of studies. In May 2023 the consortium announced the establishment of a foundation whose task it is to sustain the network.

The **DRAGON** project develops a decision support system that uses artificial intelligence and machine learning to improve the precision of Coronavirus diagnosis and predict patient outcomes. The project established Precision Medicine BioPharmax together with the Paediatric Asthma Alliance and the U-BIOPRED Alliance to secure the results of the project and advance the concept of precision medicine.

RADAR-CNS, RADAR-AD, IDEA-FAST and Mobilise-D, IMI2 projects aimed at developing novel digital endpoints by using wearables to record data during patients' daily activities, have all developed substantive data platforms that will provide a data resource for future researchers in the field. In addition, the projects developed algorithms, approaches to data analytics, software and standards that can aid future users of digital endpoints, including academic researchers, researchers in pharmaceutical and technology companies, as well as end-users in clinical practice and potentially patients themselves.

In conclusion, IMI2 has taken significant steps towards achieving its objectives and demonstrates substantial achievements towards to show for its KPIs.

For IHI, a new set of KPIs has been developed; however, no achievements have been reported yet as the programme only became operational in November 2021 requiring a new set of governance structures and procedures. The IHI KPIs are organised in inputs, outcomes and impacts, which will be helpful for monitoring and measuring progress against objectives. The KPIs are underpinned by (mostly) quantitative targets for the years 2023, 2025, 2027 and beyond. For the purpose of this interim evaluation, it is promising to see a solid set of KPIs in place, but as there are as yet no data, it is not possible to comment on progress towards objectives.

Gender dimension at project and programme level

This section examines the gender balance of IMI2 and IHI at programme and project level

At programme level, the gender balance of IMI2 was generally satisfactory. Half of the Governing Board was female, as was 62% of the SRG, 42% of the Scientific Committee, 55% of experts involved in reviewing proposals and 43% of experts involved in project interim reviews. At project level, only 25% of coordinators of IMI2 projects were female, compared to 52% of the total project workforce[55].

For IHI, the composition of governing bodies has remained well balanced, with 63% of Governing Board members, 50% of the SRG, 63% of members of the SIP and 51% of experts involved in evaluating proposals being female. Women also act in leaderships roles such as chairs of the SRG and the SIP and the rotating chair of the Governing Board[56].

4.5. EU Added Value

The criterion of EU Added Value examines the value of a European partnership compared to national or regional initiatives. The interim evaluation noted that IMI2 projects were successful in creating collaborative networks as an example of EU Added Value[57]. These 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.

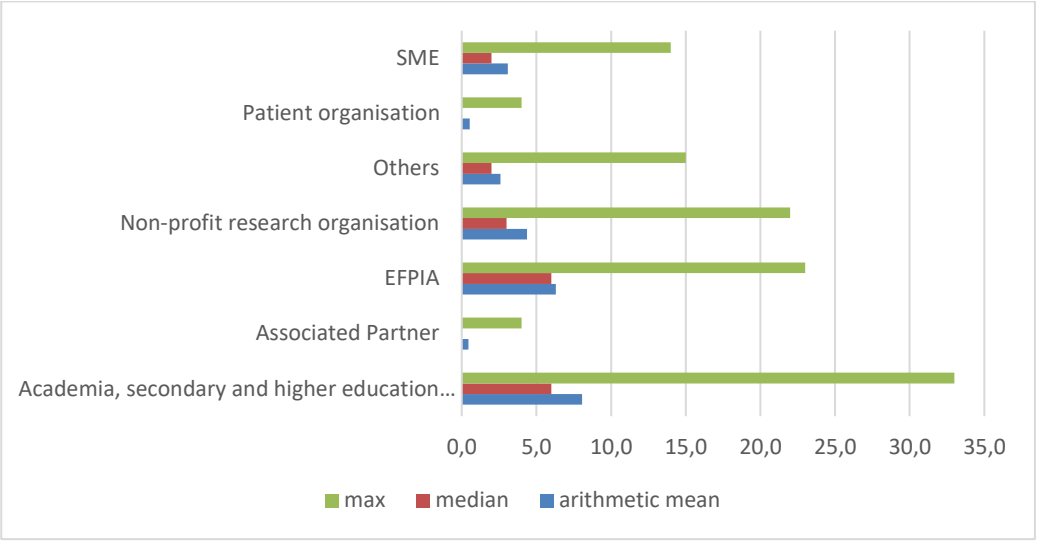
IMI2 projects always need to include participants from at least three countries, so they are always cross-national (the specific perspective of EU Added Value). The size of projects, number and types of project participants, and related budgets, mean that networks through project collaboration were extensive and diverse. The average number of participants working together per project is 25.4 (median: 25), the maximum number is 87 participants. On average, 6.3 EFPIA companies collaborated together per project under IMI2 (median: 6), with 23 EFPIA companies collaborating together at a maximum (Figure 12). Projects also bring together a number of partners from academia, secondary and higher education establishments. On average, 8 academic organisations are involved per project (median: 6), with a maximum of 33. The extent of cross-national and cross-sectoral collaboration is also illustrated by the number of publications authored by multi-national teams (see Effectiveness, KPI 7).

55 Consolidated Annual Activity Report 2021, p.14 and pp.129-130.

56 Consolidated Annual Activity Report 2022, pp-12-13.

57 The financial aspects of added value will be discussed under ‚Additionality'.

Figure 12. Number participants in IMI2 per type of organisation

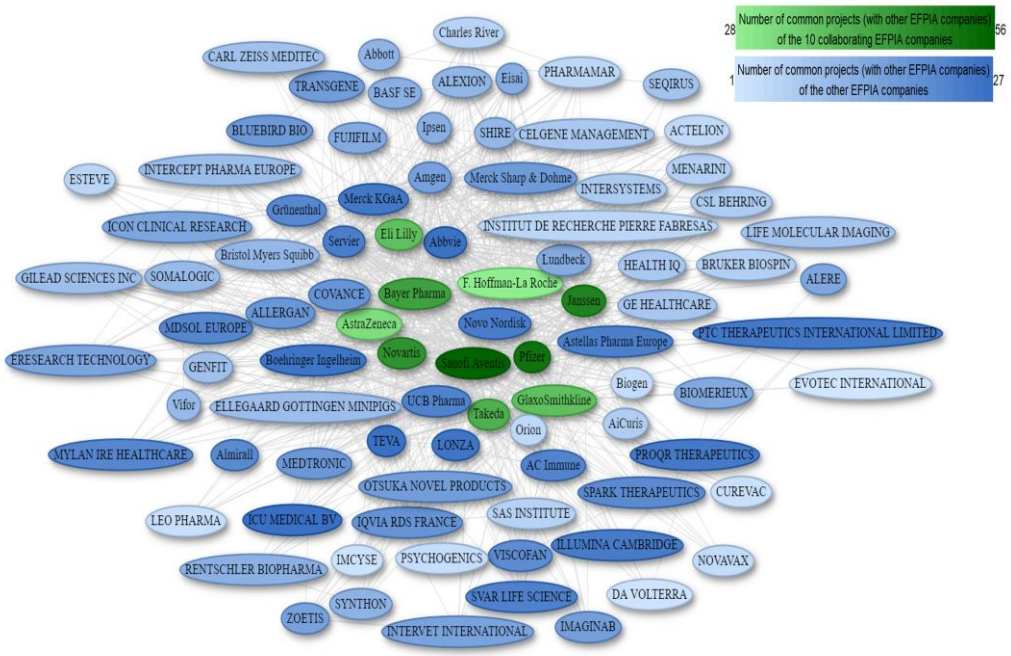


Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

EFPIA companies also established networks among themselves, with some companies collaborating more frequently than others in IMI2 projects. The most frequently participating companies are Sanofi-Aventis (56 collaborations under IMI2), Pfizer (54), Janssen (53), Novartis (49), Bayer Pharma (46), Takeda (39), Eli Lilly (35), GlaxoSmithkline (33) AstraZeneca (31) and F. Hoffmann-La Roche (28).

Figure 13 shows the frequency of collaborations between participating EFPIA companies. The analysis shows the extensive network existing between companies collaborating on IMI2 projects and contributing to IMI2 objectives, by working together in the pre-competitive space. The top 10 collaborating EFPIA companies are highlighted in green, showing their collaboration with all other EFPIA companies, and the collaborations between these companies. The darker the colouring (blue) the more frequent these companies collaborate with other companies.

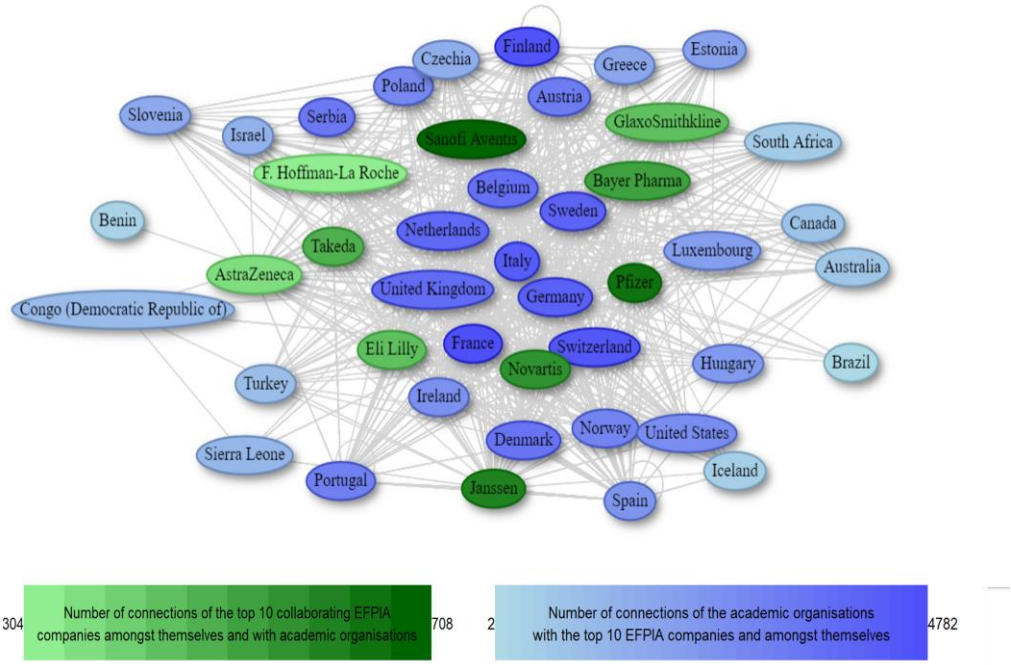
Figure 13. Network of the top 10 collaborating EFPIA companies collaborating with other EFPIA companies



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Networks were also established between pharmaceutical companies and academic organisations based in different countries. To demonstrate the extent of cross-country collaboration, Figure 14 shows the network of the 10 most frequently collaborating EFPIA companies (green) collaborating with academic organisations in different countries (blue). Links between companies and countries show collaborations between a company and (an) academic organisation(s) based in the respective country. Links between countries mean that academic organisations in one country also collaborate with academic organisations in another country. The darker the colouring (blue) the more frequently academic organisations from one country collaborated in IMI2 projects.

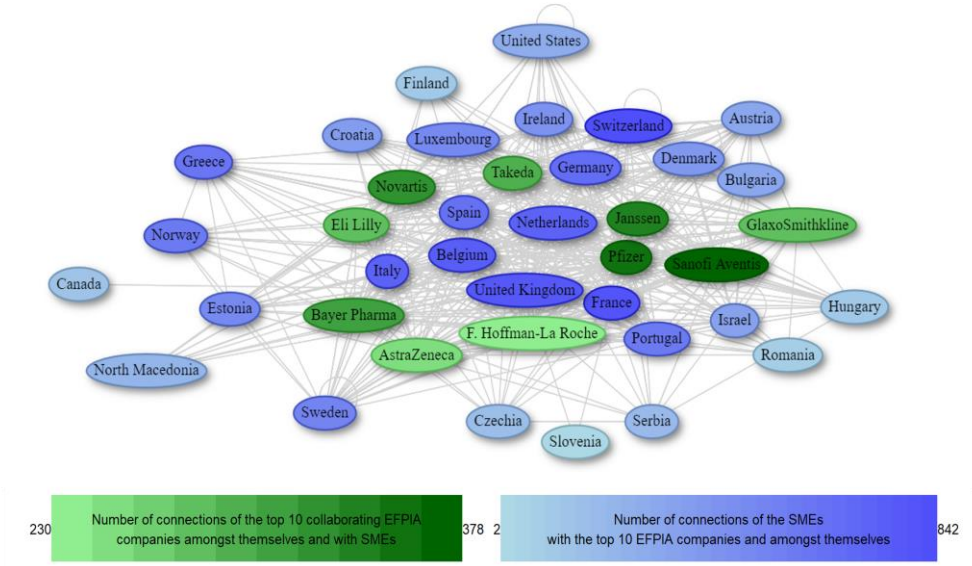
Figure 14. Network of the top 10 collaborating EFPIA companies collaborating with academic organisations from different countries



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Companies also collaborated extensively with SMEs based in different countries. Figure 15 shows the network of the 10 most frequently collaborating EFPIA companies working with SMEs from different countries. Links between EFPIA companies and countries indicate collaboration between the companies and (a) SME(s) based in this country. Links between countries indicate cross-country collaboration between SMEs from different countries. This shows that the IMI2 projects have stimulated extensive collaborations between SMEs and between SMEs and EFPIA companies, across national boundaries.

Figure 15. Network of the top 10 collaborating EFPIA companies collaboration with SMEs based in different countries



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

The strength of the collaborations that have been nurtured by IMI2 is also demonstrated in the number of continuing collaborations after IMI funding has ceased. This is often reflected in the establishment of spin-off not-for-profit organisations and foundations such as the bodies established by EHDEN, GETREAL, INNODIA, EUPATI and others.

It is too early to assess networks for IHI given the small number of projects that have been initiated to date. However, the early data are promising, as can be seen in the chapter 'Implementation state of play'.

4.6. Additionality

Additionality refers to the contributions to research, development and innovation that have been mobilised by the partnership in addition to those made by the EC. The interim evaluation noted that legislation for IMI2 created new incentives for Associated Partners (including companies from industries other than the pharmaceutical industry) to become involved in the programme, by enabling the EC to provide matching funding to their in-kind contributions of up to EUR 213 million[58]. This was not possible under IMI1.

58 Additionality was not a criterion considered in the IMI2 Interim Evaluations although some of its aspects were discussed in the section on EU-added value. EC (2017): IMI2 Interim Evaluation, p.75.

In total, Associated Partners contributed EUR 202.8 million to IMI2, of which EUR 170.4 million were in-kind contributions. EFPIA contributions and contributions from the EC also increased significantly under IMI2, compared with IMI1. However, the budget for EC matching funds has not been fully exhausted (Table 9)[59].

Table 9. Contributions of the EC, EFPIA and Associated Partners to IMI1 and IMI2 projects (in EUR)

	Total Project Costs	Net Total Costs (EU + EFPIA + AP)	EC Contributions	EFPIA total contributions	Associated Partners' total contributions
IMI1	2 088 445 862	1 850 233 755	936 030 588	914 203 167	n/a
IMI2	3 004 857 117	2 955 149 525	1 452 089 940	1 300 246 543	202 813 042

IMI2/ IHI dashboard financial data analysed by Prognos AG. Data as of 06/06/2023.

This evaluation has calculated the direct leverage and leverage factor of IMI1 and IMI2. The calculations follow the guidance on calculating leverage effects provided by the EC[60]. Crucially, the leverage factor of IMI2 (and IHI) is determined by the design of the partnership which stipulates equal contributions made by partners. This means that contributions by industry partners and Associated Partners will be matched by the EC.

Direct leverage refers to the difference between a programme's total eligible project costs and the EC contribution given to the projects. Table 10 shows that the amount of direct leverage under IMI2 has increased significantly compared to IMI1, largely resulting from the increase in net total costs. Financial rules have also changed between IMI1 and IMI2.

Table 10. Direct leverage and direct leverage factor

	Net Total Costs	EC Contributions	Direct leverage	Funding rate	Direct leverage factor
IMI1	1 850 233 755	936 030 588	914 203 167	0.506	0.977
IMI2	2 955 149 525	1 452 089 940	1 503 059 585	0.491	1.035

IMI2/ IHI dashboard financial data analysed by Prognos AG. Data as of 06/06/2023.

The direct leverage factor refers to the ratio of the direct leverage and the EU contribution[61]. The factor has slightly increased between IMI1 and IMI2 by 5.8 percentage points (notably, both are close to factor 1, reflecting the financial arrangements of the partnership set out in the Council Regulation).

59 Council Regulation 557/2014 set a limit to the EU's contribution at 1 638 000 000 (Article 3) to cover administrative and operational costs.

60 Guidance on calculating leverage effects in phase 2 evaluation studies (v.1, 9 June 2023).

61 The direct leverage factor is calculated as 1 divided by the funding rate, minus 1. The funding rate refers to the ratio between the EU contribution given to a project and the project's total eligible costs.

Given the small number of projects launched under IHI to date, and the incomplete financial data currently available, it does not seem sensible to calculate direct leverage of IHI as yet. Direct leverage should be considered in the next evaluation of the IHI.

4.7. 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 of the EU's industries. Its specific objectives capitalise on the cross-sectoral nature of the IHI partnership, emphasising joint efforts, integrated solutions, digitalisation and data exchange as pathways for impact. While these objectives constitute an evolution from IMI2, their focus on cross-sectoral research, development and innovation are significantly more prominent. Its set of KPIs are clearly focused on achieving the objectives set out for IHI.

While IMI2 was focused on priority disease areas (which evolved in response to health emergencies and EU health research policies), IHI gives space to developing solutions that are disease agnostic, as well as cross-sectoral, while keeping a focus on unmet health need. KPIs were also used to monitor and measure progress against objectives for IMI2 and the analysis shows that significant progress has been made towards these KPIs (see Effectiveness). The case study analysis and related interviews also provide many examples of projects that have made significant contributions to their respective field of research and developed innovations that promise to have a lasting impact (e.g. digital endpoints that are en route to recognition by the European medicines regulator, the European Medicines Agency).

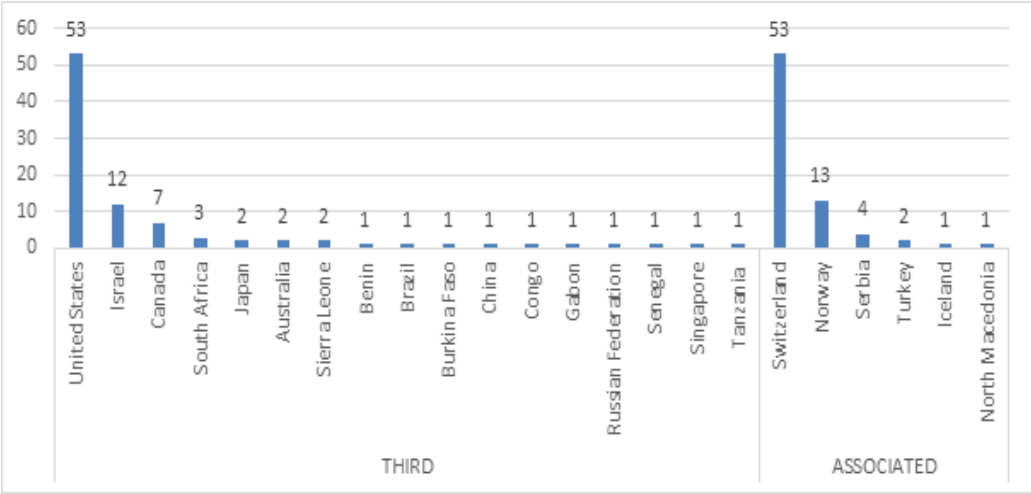
In terms of progress, IHI is still at an early stage following its late start. It is evident that much work has gone into establishing the new structures and procedures. Stakeholders interviewed noted that the new governing bodies are working well, and new and established partners have settled well into the new partnership. Sorting out 'teething problems' such as those arising from the EC Corporate Approach to assigning Associated Partner status to organisations based in Third Countries participating in Horizon Europe have further taken time and required much effort to resolve. While this approach has limited impact on other parts of Horizon Europe, it significantly affects IHI as many companies contributing in-kind contributions in projects (and not requesting any EU funding) are multi-national organisations, many of which have operations outside the EU. There are numerous new requirements in the Single Basic Act that require new approaches and additional efforts, including the implementation of new financial rules by the IHI Programme Office (e.g. monitoring, at project level, the 45% in-kind eligibility criterion, the possibility of in-kind contributions for additional activities, and the reduced threshold for in-kind contributions at programme level), which operates on a reduced administrative budget under IHI.

4.8. International positioning and visibility

The ability to attract participants from outside the EU is an indicator of a programme's international positioning and visibility. In addition, IMI2 projects have addressed many health challenges that are global and produced solutions and outputs that will be used internationally, including beyond the borders of the EU, adding to its international positioning.

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%). Figure 16 shows that a large number of these organisations were based in Switzerland and the United States. A large number of these organisations were pharmaceutical companies, but there were also academic institutions, charities and foundations, and others.

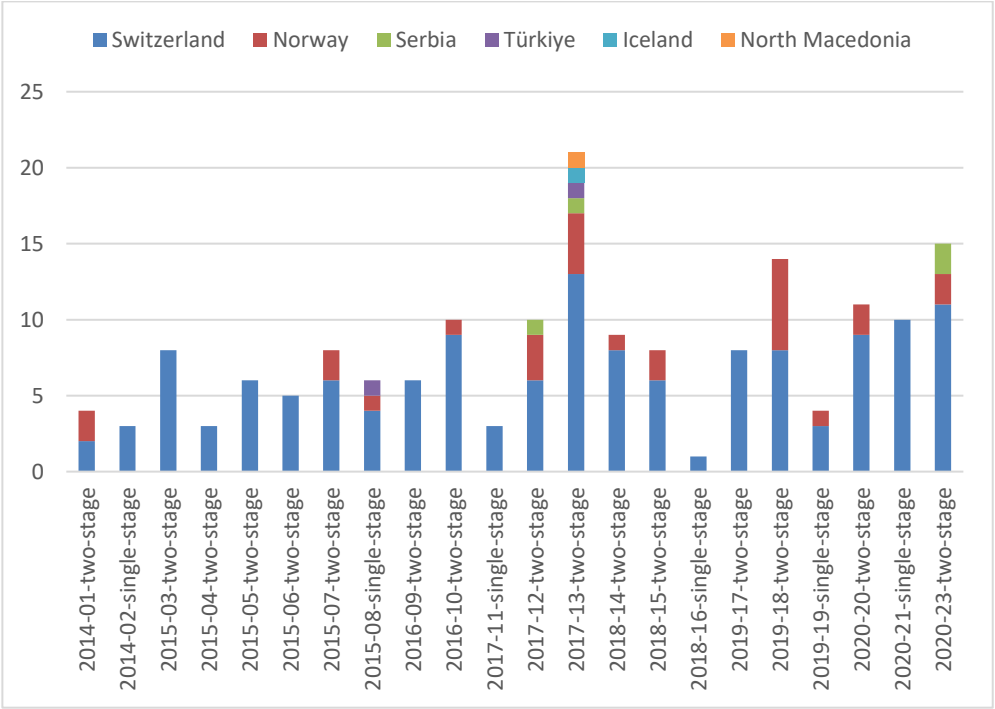
Figure 16. Number of participating organisations from outside the EU under IMI2



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Analysed by call, the breakdown of participants from Associated Countries shows that in 18 out of 22 calls, participation from Associated Countries was limited to organisations from Switzerland and Norway and only 4 calls saw participation from additional Associated Countries (Figure 17). Call 13 was particularly successful in attracting a wider group of participants from Associated Countries. This call included the project ConcepTION that aims to establish a European biobank to inform research into the impact of medication on breastfeeding and during pregnancy and to build a supportive ecosystem to strengthen this type of research.

Figure 17. IMI2 participations of organisations from Associated Countries by call

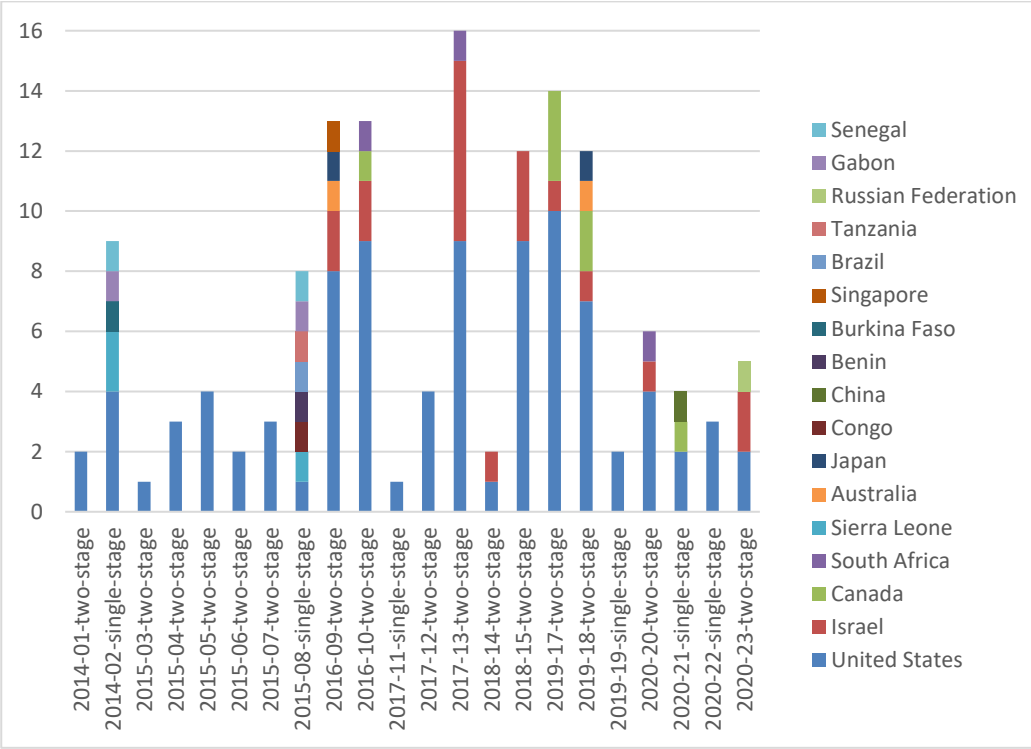


Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023[62]*.*

The breakdown of participations from Third Countries shows a more diverse picture across Calls (Figure 18). There is a wide spread of countries from which organisations participated in projects, although participations from the United States is the most frequent, followed by Israel.

62 Calls that did not result in projects with participants from Associated Countries are not included in this figure (e.g. Call 2020-22).

Figure 18. IMI2 participations for organisations from Third Countries by call



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

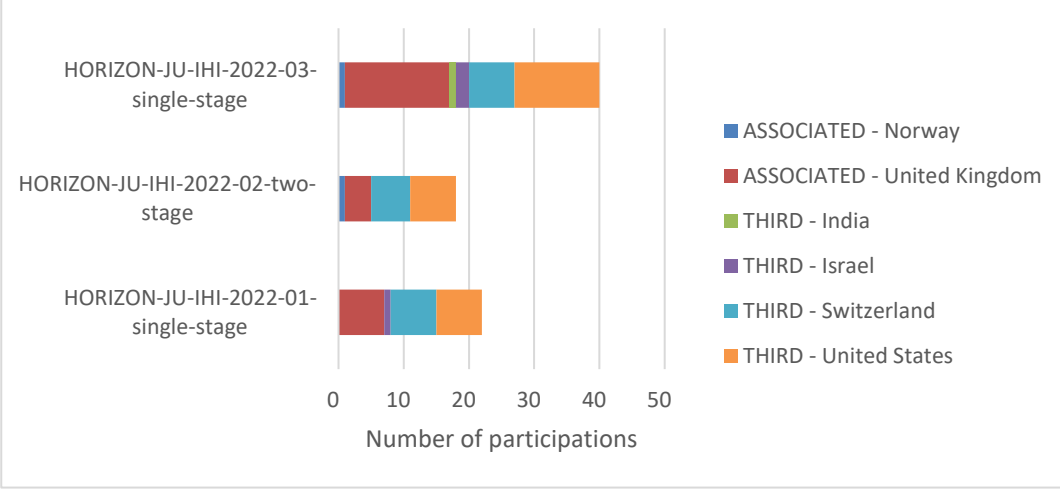
The wide reach of the programme is also illustrated by the number of publications authored by international teams. Globally, authors from 126 countries have participated in at least one publication resulting from an IMI project.

There are numerous examples of projects that reach beyond the borders of the EU, in terms of participation as well as impact. A case in point are the projects supporting several stages of clinical trials of the Ebola vaccine in Western Africa (EBOVAC 1-3, EBODAC) resulting in the vaccine receiving authorisation from regulators. The project AIMS-2-TRIALS built a global clinical trial network to support the development and testing of new medication for people with autism spectrum disorders. Through close collaboration with the National Institutes of Health (NIH) Autism Biomarker Consortium – Clinical Trials, the project has been able to replicate their electroencephalogram (EEG) signal biomarker in an independent cohort of autistic young people. The two consortia submitted their data in parallel to the EMA and the FDA biomarker development programme, facilitating regulatory alignment between the EU and the US. INNODIA has set up a collaboration with the Global Platform for the Prevention of Autoimmune Diabetes (GPPAD) to strengthen synergies between both initiatives. Another example is the project ERA4TB that will create a platform that brings together research to investigate the safety and efficacy of over a dozen drug candidates on a global scale.

Companies based in Third Countries not associated to Horizon Europe are likely to be affected by the new framework regarding the status of their participation in projects, as per the EC Corporate Approach. This foresees that such entities are barred from signing grant agreements as beneficiaries, and should instead join as an Associated Partner. These rules may provide a disincentive for companies based in Third Countries to participate unless an exception is granted by the IHI Executive Director, which will be considered on a case-by-case basis. In addition, there are new financial rules that may hinder participation from organisations making contributions if they are based in Third Countries (e.g. reducing the maximum level of in-kind contribution from those organisations from 30% under IMI2 to 20% under IHI).

Analysing the participations of organisations from Associated and Third Countries in IHI, data are available for the first two calls only. Although it is still early in the implementation of IHI and the small number of participants, the countries outside the EU from which organisations participate are the same as those that were prominent under IMI2 (Figure 19).

Figure 19. IHI participations of organisations from Associated and Third Countries, first two calls



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

Stakeholders interviewed noted the respective novelty of IMI2 and IHI, with one stakeholder suggesting that both programmes were or are 'ahead of the curve'. IMI 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 noted that other countries/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.

4.9. Transparency and openness

4.9.1. Openness towards new participants and mechanisms to involve new members and a broader set of stakeholders

The Interim Evaluation of IMI2 recommended that a 'renewed and stronger effort should be made to attract and integrate other industries than the pharmaceutical industry in collaborative projects'[63]. It also suggested that future initiatives should adapt 'the collaborative and funding model to enable the active engagement of other industry sectors'[64].

This recommendation has been addressed at programme level, with the most significant adaptation of IHI being the expansion of the partnership to include non-pharmaceutical industries that have been shown to be increasingly relevant and are often central to pharmaceutical innovations. Including new partners gives industry representatives from other sectors a voice at the governance level of the programme for the first time. The early experience of IHI suggests that partners use this opportunity to promote cross-sectoral call topics, as demonstrated in the first IHI calls for proposals. In interviews, new partners noted that their voice was being heard at the Governing Board and that they were able to contribute freely to discussions (see Case study 1 'From Innovative Medicines Initiative to Innovative Health Initiative – the early experience'). Established partners such as EFPIA may have more experience in governing the initiative and in collaborating in pre-competitive projects, but new partners were quick to adjust to their new roles. Some stakeholders noted that more could be done to support new partners, for example, by helping them communicate the aims and potential of IHI to their member companies, some of them with a more limited experience of EU partnerships. In this respect, the work of the IHI Office and the experience of EFPIA as an IMI partner were seen as valuable.

While EFPIA was the sole industry partner as a founding member of IMI2, at project level, companies from non-pharmaceutical industries have already been involved in IMI2, including companies in the fields of imaging technology, medical devices, in-vitro diagnostics, digital technology and animal health. This is visible, for example, in the field of digital health and many other projects (Case study 2: 'IMI2 and IHI driving innovation in digital health'). In digital health projects, companies and SMEs can take a variety of roles to support the development of digital endpoints, for example through developing wearable devices used as measuring devices of vital signs and mobility, and of the European health data infrastructure (e.g. EHDEN). It is expected that under IHI the opportunities for cross-sectoral research, development and innovation will be more fully exploited and the early experience from the first calls is encouraging.

While IMI2 and IHI involve the member companies of industry partners by design, joining a project consortium is generally open to any organisation in the field of health research. This is demonstrated by the fact that the programme has attracted many organisations to participate for the first time. Of all participants in IMI2 projects, 707 participated only once (62%), 165 participated in two projects (14%) and 276 participated in more than two projects (24%). These figures are similar to those of project participants under IMI1 (64% participated once, 15% participated twice, and 21% participated more than twice in IMI1 projects).

63 Interim Evaluation of IMI2, p. 82.

64 Interim Evaluation of IMI2, p. 83.

4.9.2. Processes for consulting stakeholders and identifying priorities

Objectives for IMI2 and IHI are set out in the respective Council Regulation and strategic documents. Stakeholders noted that drafting the IHI Strategic Research and Innovation Agenda (SRIA) was a multi-stage process involving many stakeholders, as well as a public consultation. However, the main inputs were given by IHI partners, including the EC, which coordinated positions and input between the different DGs involved in the partnership, and industry partners.

The Governing Board is the main decision-maker and is responsible for setting priorities and approving the work programme. Under IMI2, project priorities were mostly developed by industry partners given that the majority of topics were two-stage ones, with the EC and advisory bodies being formally consulted. Under IHI, industry partners and the EC put forward their topic ideas and need to agree on and consolidate their priorities. The SIP and SRG are routinely consulted when topic ideas are developed into call topics. These processes are described in detail in the chapter 'Implementation State of Play'. Under IHI, the possibility to submit ideas for project calls was broadened to a wider set of stakeholders through the IHI web portal. In interviews, examples of ideas were mentioned that have been taken forward and discussed in the various advisory bodies.

There are also efforts to strengthen the involvement of patients and informal carers at programme and project level. At project level, 27 patient organisations representing different patient groups participated in IMI2 projects. At programme level, a Patient Engagement Strategy Workshop was held in 2016[65]. In addition, the programme has established a Patient Pool to strengthen the involvement of patients in IHI activities. The pool was initially created during IMI2 in 2019, but its role is expected to expand under IHI[66]. A new call for patients was launched under IHI and the pool has been refreshed taking IHI priorities into account. The call was open and individuals could apply to join the pool and contribute their own personal experience and expertise as patients or informal carers. There are many possibilities for members of the Patient Pool to become involved in IHI, for example as participants in project meetings or speakers at scientific events, webinars or trainings.

4.9.3. Accessibility for the enterprise sector and SMEs

The interim evaluation recommended to 'create a better ecosystem to attract more SMEs'[67]. It also suggested to make topic descriptions less prescriptive and to allow more flexibility in order to attract a larger number of SMEs.

Stakeholders noted that including SMEs was not part of the programme design of IMI, which involved an industry partner, whose member organisations are predominantly composed of large, often multi-national companies. While one of the programme's key objectives was focused on strengthening competitiveness of European industries, this aim was not explicitly focused on cultivating SMEs. Under IHI, the national associations affiliated to MedTech Europe and EuropaBio include large numbers of SMEs among their members, so the participation of SMEs in IHI is ensured by design. It has to be noted that the participation of SMEs in project consortia largely depends on the types of challenges tackled in a project and the type of contributions SMEs are able to make to projects responding to these challenges.

65 Patient engagement strategy workshop, 28 April 2016. https://www.imi.europa.eu/news-events/events/patient-engagement-strategy-workshop.

66 IMI pool of patient experts, https://www.imi.europa.eu/get-involved/patients/imi-pool-patient-experts.

67 Interim Evaluation of IMI2, p.82.

Participation is also influenced by the participation rules (such as the time-to-grant) that can be challenging for SMEs.

Reflecting the growing emphasis of EU policies on developing favourable environments for SMEs, IMI2 and now IHI have undertaken a range of activities to strengthen the involvement of SMEs in project consortia. This included, for example:

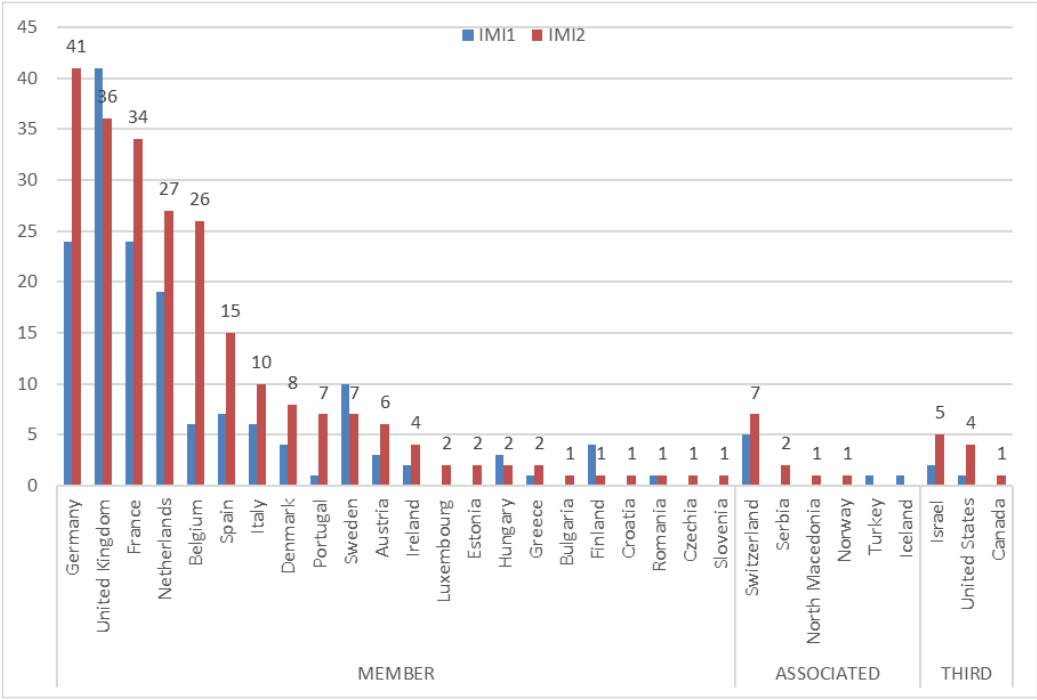
- topic descriptions published in calls highlighted tasks that were particularly suited to SMEs;
- topic seminars held in support of calls and informing prospective applicants highlighted the importance of SMEs as project participants;
- the IMI2 States' Representative Group and Scientific Committee were asked to promote the participation of SMEs towards their respective audiences and communities;
- SMEs can join EFPIA (and now MedTech Europe) as members if they pharmaceutical or technology companies or as Partners in Research if they do not qualify as members, to act as industry contributors.

The number of SMEs participating in IMI projects has increased substantially over time, from 166 under IMI1 to 256 under IMI2 (however, the number of projects initiated also increased). The share of SMEs among IMI2 project participants was 22%, the share of SME participations was 16.1%. This means that the target of 20% has been exceeded if considering participants, but it has not been reached when considering participations. The share of SMEs participating in IMI2 projects is lower than the share of SMEs participating in all projects of Societal Challenge 1 (SC1) of Horizon 2020[68].

As under IMI1, the largest number of SMEs are based in Germany, the United Kingdom and France, with SMEs from the Netherlands and Belgium also performing strongly; however, the number of participating SMEs has also increased in countries in Northern and Southern Europe, as well as in Switzerland and the US (Figure 20).

68 Analysis by PPMI using CORDA data. While this is a standard comparison, the share of SMEs across all projects under SC1 includes substantial variation between the different programmes within SC1.

Figure 20. Number of SMEs participating in project consortia during IMI1 and IMI2, by country



Source: IMI2 Dashboard Data analysed by Prognos AG. Data as of 06/06/2023.

5. Conclusions

In the following section, key findings are summarised for each evaluation criterion.

Relevance

IMI2 continues to be relevant as a programme that aims to foster and accelerate medical innovation in response to unmet public health need and health emergencies. Past experience under IMI2 has demonstrated the flexibility of the partnership to respond to unforeseen health challenges.

Under IHI, the expansion of the partnership to include industries in the fields of diagnostic imaging, medical technology and IT-based data analysis, in addition to the pharmaceutical industry, strengthens its relevance in view of evolving healthcare needs and new opportunities to develop innovative solutions. As a public-private partnership, IHI brings together expertise and experience across sectors, and fosters substantial investment in health research, development and innovation. Stakeholders confirmed that the programme was still highly relevant and able to drive innovation in novel research areas with the potential for high impact on patient care and quality of life.

Coherence

There is coherence with Horizon 2020 and Horizon Europe at programme and at participant levels.

At programme level, IMI remained well aligned with the objectives of Horizon 2020 and contributes significantly to the aims of Societal Challenge 1. However, some stakeholders also noted that the policy landscape in which IMI2, and now IHI, operate, has become increasingly complex.

IHI is part of Horizon Europe and its strategy is aligned with the Health Cluster of Pillar II aimed at responding to global challenges and European industrial competitiveness. The partnership contributes to several EU policies, including Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and its new European Industrial Strategy. It is also expected to directly contribute to the establishment of the European Health Data Space, with some IMI2 projects already contributing to building the groundwork. IHI is also expected to contribute to the European Green Deal. The Single Basic Act requires IHI to increase its synergies with other EC programmes, partnerships and missions. Given the busy landscape of EC and national programmes, potential partners to create synergies with are currently being mapped and a first Memorandum of Understanding has been signed. Plans to strengthen engagement this area of activities is still emergent under IHI.

At participant level, IMI2 scores highly with regard to the involvement of its project participants in other programmes under Horizon 2020 (centrality score), with 16.4% of IMI2 participants being among the top 1% participants of Horizon 2020. The rate is particularly high for universities and higher education institutions (50.4%), but private companies (excluding SMEs) also exceed the average, with 2.8% among the top 1% and 30.9% among the top 10%. There are pertinent examples of synergies between IMI2 projects. Examples are the EHDEN project whose federated health data system has been used by other projects, and the data platform developed by RADAR-CNS that has been used by other projects.

Efficiency

Efficiency has been assessed in terms of the programme's administrative costs, operational efficiency, and efficiency of governance mechanisms.

Administrative costs: Between 2014 and 2022, a total of EUR 88.2 million was approved for the administration of the partnership and EUR 75.4 million were eventually committed. During this period, the share of administrative costs set in relation to the EC contributions was 4.5%, similar to other EC partnerships.

Operational efficiency: The programme has performed well with regard to indicators of operational efficiency, reaching its targets on almost all occasions (i.e. time-to-inform, time-to-grant agreement signature, time-to-pay etc.).

Efficiency of governance mechanism: Stakeholders interviewed considered IHI and its governance arrangements working well and found the collaboration at governance level promising and constructive. However, problems arising at the early stages of IHI relating to the legal framework required significant attention.

Effectiveness

The effectiveness of IMI2 is measured against a set of KPIs that are used to monitor the progress of the programme against its objectives and in view of its contribution to achieving its mission.

Overall IMI2 performed well against the majority of its KPIs and exceeded many of its targets. More specifically, IMI2 projects:

- created 439 different assets that demonstrate achievement of important milestones in the innovation process;
- completed 24 regulatory procedures, double the target aspired to;
- developed 46 new taxonomies and stratifications;
- over 50% of projects made outputs available to others outside their consortia;
- produced almost 10 000 publications attributed to IMI1 and IMI2 projects between 2010 and 2022;
- developed 524 tools and processes that are being used by industry partners.

IMI2 was slightly less successful in reaching its target with regard to involving patient organisations and healthcare professional organisations at project level and involvement of SMEs as project participants, although in both instances substantial progress was made. With regard to patient engagement is has been noted that its relevance depends on the nature of the research and that some projects address early phases of research and development during which patient engagement may not be as meaningful as during later stages of the innovation process.

It can be concluded that IMI2 has made significant progress towards its objectives and has demonstrated substantial achievements towards its KPIs.

It is too early to assess the effectiveness of IHI, given the small number of projects that have been launched only recently.

In terms of gender balance, IMI2 and IHI perform well at governing level. However, at project level, only 25% of IMI2 project coordinators were female (although this is outside the control of the programme).

EU Added Value

The criterion of EU Added Value examines the value of a European partnership compared to national and regional initiatives. The added value of IMI2, and IHI, results from the substantial network of collaborators that have been established across sectors and across countries. These would not have existed in the same way without this European partnership.

IMI2 brought together a large number of organisations and individuals to jointly collaborate in projects. This is evident from the number of participants per project and their distribution across different types of organisations, sectors and countries. EFPIA companies also collaborated with each other intensely, with some companies collaborating in up to 53 different projects. Networks have also been established between companies and other types of organisations, especially academic institutions and SMEs. These are also based in different countries, contributing to the establishment of extensive cross-border networks in Europe and beyond.

It is too early to assess networks for IHI, given the small number of projects that have been initiated to date. However, the early data are promising.

Additionality

Contributions to research, development and innovation mobilised by IMI2 increased substantially compared to IMI1. Associated Partners contributed EUR 203 million under IMI2. Their contribution was strengthened under IMI2 by allowing the EC to provide matching funding.

The direct leverage factor increased from 0.977 under IMI1 to 1.035under IMI2. Crucially, the leverage of IMI (and IHI) is determined by the design of the partnership which stipulates equal contributions made by private partners and the EC.

Directionality

Both the IMI2' SRA and IHI's SRIA set out a clear vision for the programme and these are supported by relevant and specific objectives. The analysis of IMI2 KPIs show that significant progress was made against the programme's objectives.

IHI is still at an early stage following its late start. Much work has gone into establishing the new structures and procedures. However, sorting out 'teething problems' such as those arising from the EC's corporate approach associated with assigning Associated Partner status to organisations based in Third Countries participating in Horizon Europe has taken time and required much effort to resolve. It also resulted in delayed calls and some loss of momentum.

International positioning and visibility

IMI2 projects have attracted numerous participants from countries outside the EU, including pharmaceutical companies, academic institutions, charities and others. These participations are highly variable among calls, reflecting differences in call topics. The wide reach of the programme is also illustrated by its output in publications authored by international teams, with authors from 126 countries having participated in at least one participation. There are numerous examples of projects that reach beyond the borders of the EU.

Under IHI, the classification of Switzerland as a Third Country in combination with new rules applied to Third Countries under the EC Corporate Approach may provide a disincentive for entities such as companies and non-profit organisations based in these countries to participate. Stakeholders noted that both IMI2 and IHI constituted novel approaches and were 'ahead of the curve' when initiated.

Transparency and openness

Addressing recommendations of the interim evaluation, the most significant adaptation of IHI is the expansion of the partnership to include non-pharmaceutical industries. Including new founding members gives industry representatives from other sectors a voice at the governance level. At project level companies from non-pharmaceutical industries have already been involved in IMI2. It is expected that under IHI the opportunities for cross-sectoral research, development and innovation will be more fully exploited and early experience is encouraging. While IMI2 and IHI involve the member companies of industry partners by design, joining a project consortium is generally open to any organisation in the field of health research. This is demonstrated by the fact that the programme has attracted many organisations to participate for the first time.

Under IMI2 and IHI the Governing Board is responsible for setting priorities and approving the work programme. Under IMI2 project priorities were usually proposed by industry partners (as part of a two-stage call process) and agreed with the EC, upon advise from the SRG and the Scientific Committee. Under IHI, industry partners and the EC coordinate and agree the priorities, with the SIP and SRG providing input and advice. The possibility to submit ideas for project calls was broadened to a wider set of stakeholders through the IHI web portal. There are also efforts to strengthen the involvement of patients and informal carers at programme and project level.

IMI2 was not originally designed to focus on cultivating SMEs, although many of its projects include SMEs as participants. Under IHI, new partners such as MedTech Europe and EuropaBio include large numbers of SMEs among their members or their affiliated national associations. However, the participation of SMEs in project consortia largely depends on the types of challenges tackled in a project and the type of contributions SMEs are able to make to projects responding to this challenge. The Programme Office has undertaken a range of activities to strengthen the involvement of SMEs in project consortia. However, while the number of SMEs participating in IMI projects has increased substantially over time, the share of SMEs among participants has remained below its target of 20% (if counted as participations).

6. Lessons learned and suggestions for improvement

This evaluation report presents the findings from the final evaluation of IMI2 and the (early) interim evaluation of IHI. Lessons learned therefore result from the finding relating to IMI2 and those relating to IHI. Suggestions for improvement will relate to IHI only, as IMI2 has been superseded by the new programme (even though many IMI2 projects are still running).

Lessons learned from the implementation of IMI2

Building on the strengths and experiences of IMI1, IMI2 was able to expand in scope and ambition, explore new areas of research, development and innovation, and respond to new health challenges. The programme has resulted in 123 projects bringing together a large number of organisations of high calibre to tackle complex health and healthcare challenges that individual organisations, disciplines or sectors would not be able to address. The **size and ambition of projects**, as well as the volume of funding made available, has also contributed to the growth of the international network and the positioning and visibility of the European programme in Europe and beyond.

Under IMI2, efforts were made to **widen the group of stakeholders** participating in all aspects of the programme. This included creating the role of Associated Partner to allow organisations such as charitable organisations, foundations and companies not associated with EFPIA to join IMI2 as contributors. It also included establishing a 'bottom-up' route for third parties to submit topic ideas and piloting the Patient Pool to include patients and their carers in programme activities.

The programme has achieved the majority of its targets set out in KPIs. IMI2 KPIs were revised following the interim evaluation in 2017 and have shown to be an important tool for steering the programme and monitoring its progress and performance. The experience has shown that KPIs built on **RACER principles are useful for steering activities**, both in terms of shaping calls for proposals and the portfolio of additional activities. It has also shown the difficulty of linking KPIs to priorities set outside of the programme (i.e. by WHO).

While IMI2 was not designed as a tool for promoting SMEs, the number of SMEs increased under IMI2 compared to IMI1. While this increase in part reflects the larger number of projects initiated under IMI2, it **underlines the importance of the efforts** undertaken by the programme to strengthen its accessibility and create a supportive environment for SMEs.

Lessons learned from the early implementation of IHI

The interim evaluation has assessed the first 20 months of the implementation of IHI. During this time, the programme established all necessary governance structures and procedures, and has launched the first three calls for proposal addressing cross-sectoral topics of unmet public health need.

1. The transition from IMI to IHI has shown that it is possible to refresh and expand an institutionalised partnership to strengthen its response to emerging health challenges and to **capitalise on opportunities arising from cross-sectoral research and development** in areas of fast-paced innovation. Establishing new governing bodies and creating new procedures, resulting from the new partnership as well as from new stipulations and rules set out in Council Regulation, has required a substantial amount of work and effort of all parties involved during the early period of implementing IHI.

2. Findings also show that IHI is **open to a wider set of stakeholders** compared to IMI2, addressing a key recommendation of the earlier IMI2 Interim Evaluation. This involves setting up a new partnership with more private partners including trade associations of different sectors of industry, in addition to EFPIA and Vaccines Europe. It also includes creating the Science and Innovation Panel (SIP), which now includes healthcare professionals and representatives of regulatory and health technology assessment (HTA) bodies, in addition to scientific experts and patient representatives. It also institutionalised the mechanism for collecting ideas for call topics through a dedicated web portal on the IHI website and a process of screening and selecting ideas to be taken forward. While stakeholders were generally satisfied with the governance structure and processes, and optimistic about the prospects of the partnership, such structures and processes need to become established and prove themselves in practice. This is particularly relevant when it comes to initiating topic ideas and contributing and advising on the developing of call topics. Active participation and buy-in of all stakeholders are crucial, underlining the importance of continuous engagement and communication with all stakeholders to maintain their satisfaction and commitment.

Recommendation: Interactions between these bodies, and related processes and mechanisms should be routinely monitored and reviewed, especially relating to their contribution to the process of proposing topic ideas and developing call topics.

3. Lessons learned also result from the impact of changes in the **EC corporate rules**, set out in the EU multiannual financial framework, and the approach to harmonising the rules for all partnerships and programmes despite their singular characteristics and requirements. While changes in corporate rules were not targeted at IHI specifically, they particularly affected the programme, as many global pharmaceutical and medical technology companies and Contributing Partners involved are established in Third Countries. The implementation of new rules and requirements also increases the administrative burden associated with the running of IHI, including rules set out in the Single Basic Act that need to be monitored and followed up. There is therefore a need to monitor the adequacy of the financial resources set aside for running the programme and the suitability of the instruments required for its administration.

Recommendation: It is important that the rules and frameworks reflect, and support, the collaborative effort underpinning a public-private partnership to allow all relevant entities to contribute to the programme in full and as intended in a public-private partnership. The administrative burden of running the programme and implementing new rules relative to its administrative resources and instruments should be monitored and reconsidered if necessary.

4. IHI is expected to contribute to a set of diverse EU policies, including the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, the European Industrial Strategy, the European Health Data Space, and the European Green Deal. As an institutionalised partnership with a specific mission, IHI is expected to contribute to the implementation of these policies and plans, and to create synergies with other programmes and initiatives while also avoiding unnecessary overlaps. In addition, it is expected that IHI establishes links with relevant national initiatives and continues to create synergies with various programmes. Given the increasingly busy landscape of EU policies, initiatives, plans and programmes and the growing number of national initiatives this will be a challenge.

Recommendation: Work is underway to map this landscape, however, a strategic approach is needed to create such synergies that are coherent, efficient as well as tailored to individual policies and programmes.

7. Annex

7.1. Definition of key terms

Table 11. Definition of key terms

Term	Definition
Additional activities	Activities that contribute to the objectives of IHI, but are not funded by the partnership as part of a project. Additional activities include activities supporting the dissemination, sustainability or exploitation of project results that go beyond the project duration. Additional activities can take place at project level and at programme level.
Associated countries	Third Countries (i.e. countries that are not member states of the EU) that are associated to Horizon Europe, i.e. they have an agreement with the EC to collaborate within the framework programme.
Associated Partner	The definition of Associated Partner changed between IMI2 and IHI due to changes in the EU model grant agreement and the Horizon Europe regulation. Under IMI2, an Associated Partner could be any legal entity wishing to contribute to an IMI2 project, including charities, and companies that were not members of EFPIA, e.g. in the fields of ICT, imaging, diagnostics or animal health. As contributors to a project their contribution would be matched by the EC. Under IHI, Associated Partner refers to entities that do not request funding or are not eligible for funding. This category was created under Horizon Europe and therefore also relates to IHI, requiring the partnership to adjust its use of the term. Associated Partners contribute to IHI projects, but are legally excluded from signing a grant agreement and therefore their status within the project is different from other project partners.
Beneficiary	A legal entity (other than IHI JU), which is a signatory of a grant agreement (either directly as a coordinator or through an accession form as a project partner).
Contributing Partner	The category of Contributing Partner was created under IHI to enable participation of legal entities who may want to invest in IHI without becoming full members. They are usually not members of the associations that form this partnership. The role of Contributing Partners is similar to Associated Partners under IMI2.
Coordinator	A beneficiary of the consortium responsible for managing the project, submitting reports and deliverables, and acting as a

Term	Definition
	representative on behalf of the project vis-à-vis the grant giving authority.
In-kind contributions on additional activities (IKAA)	Contributions incurred by IHI private members (i.e. partners other than the EC), their constituent or affiliated entities, consisting of costs for implementing additional activities (see definition of additional activities above).
In-kind contributions on operational project costs (IKOP)	Contributions by IHI private members, their constituent or affiliated entities and by Contributing Partners, consisting of eligible costs incurred by them for implementing the action, less the contribution of IHI to those costs.
Partners in Research	The Partners in Research status was created to allow non-pharmaceutical companies to participate in EFPIA research activities under IMI and IHI. Under IHI, MedTech also supports participation of non-member companies as Partners in Research. The contributions of Partners in Research are included in EFPIA´s and MedTech's contributions, respectively.
Science and Innovation Panel (SIP)	An advisory body to IHI with the role of providing science-based advice to the Governing Board. It is composed of 18 permanent members, including members of the scientific community and the wider healthcare community, in addition to representatives of the IHI partners and the SRG. SIP has replaced the Scientific Committee in place under IMI2.
States' Representatives Group (SRG)	An advisory body under IMI2 and IHI, consisting of representatives of EU Member States and countries associated with Horizon Europe (under IHI).
Strategic Governing Groups (SGG)	Under IMI2, Strategic Governing Groups (SGGs) were topic specific groups to work on specific strategic areas, composed of representatives of interested companies, the EC, the IMI Office and the IMI Scientific Committee. The SGGs no longer exist under IHI.

Source: Compiled by the study team.

7.2. Evaluation criteria and guiding questions

Table 12. Evaluation criteria and guiding questions

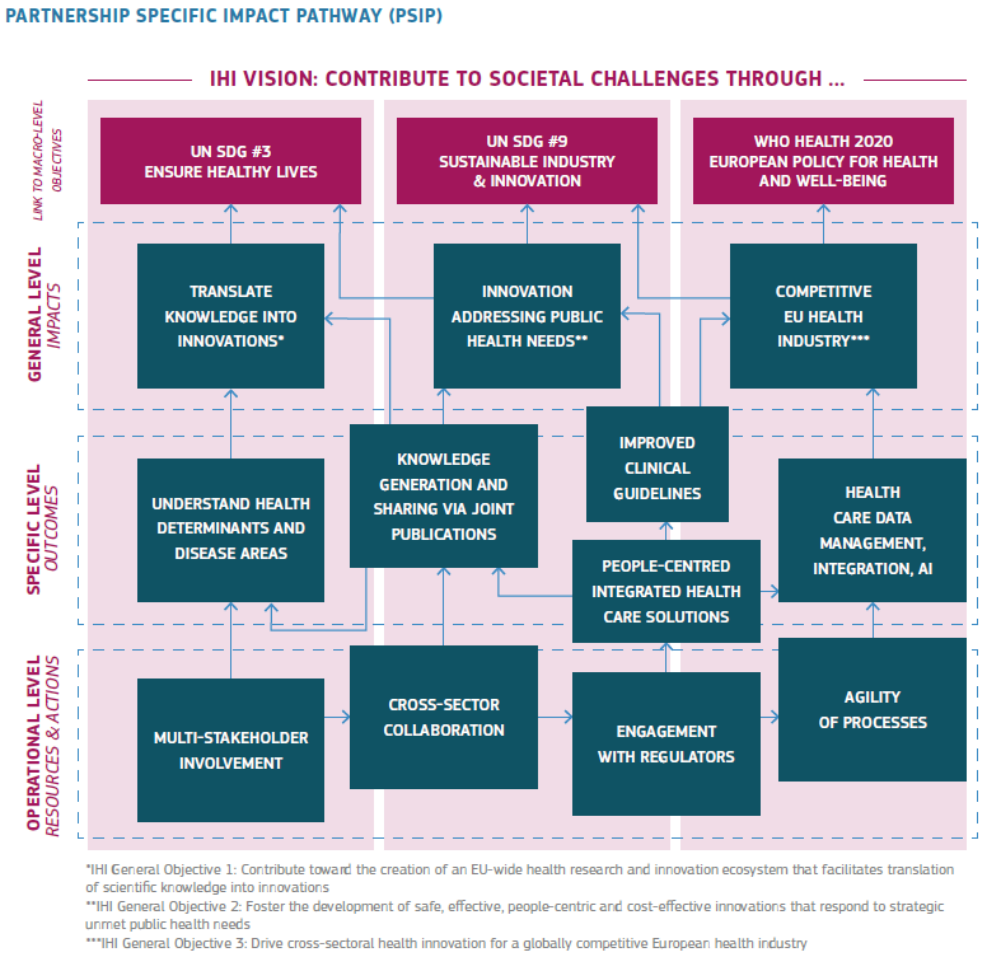
CRITERION	GUIDING QUESTIONS
Evaluation Criteria defined by the Better Regulation Guidelines	
Relevance	To what extent have the objectives of the partnerships been, and are still relevant regarding the challenges and needs addressed in this area by the Framework Programme? How flexible have partnerships in this area proved to be, in updating the Strategic Research Innovation Agendas, or equivalent strategic documents, adjusting objectives, activities and resources to changing market and/or policy needs?
Coherence	What is the level of coherence between this partnership and the other partnerships and the Framework Programme activities in this area? Is this partnership more effective in achieving synergies, compared to other modalities of the programme?
Efficiency	How cost-effective have partnerships been?
Effectiveness	To what extent has this partnership achieved its objectives and contributed to achieving the objectives of the Framework Programme in this area? Has the gender dimension been integrated in R&I content and how?

CRITERION	GUIDING QUESTIONS
EU Added Value	What is the value resulting from partnerships in this area that is additional to the value that could result from interventions carried out at regional or national level?
	Additional partnership-specific criteria
Additionality	How much private and/or public R&I contributions has been mobilised on EU priorities thanks to this partnership? What is the partnership's budget leverage factor, in mobilising additional resources, on top of contribution from partners? How does the partnership facilitate the creation and expansion of R&I networks that bring together relevant and competent actors from across Europe, thus contributing to the realisation of the ERA?
Directionality	What is the progress towards the strategic vision of the partnership? Does the partnership clearly demonstrate progress in the delivery of results for the EU and its citizens, notably global challenges and competitiveness, which cannot be achieved by traditional calls alone?
International positioning	To what extent are partnerships acting as global ambassador for the European R&I system/establishing global relevance/achieving scientific and technological reputation in the international context/serving as hubs for international cooperation, where appropriate? What is the level of international cooperation at partnership and project level and how does this result in visibility for the European Partnership?
Transparency and openness	How open are partnerships to new participants? Are there procedures/mechanisms in place to expand the partnership to involve new members at partnership and project level, as well as gradually engage a broader set of stakeholders across Europe? What is the extent of gender balance in the governance structures of the partnership? Are there open and transparent processes for consulting all relevant stakeholders and constituent entities in the identification of priorities? To what extent are partnerships (notably with industry participation) accessible for SMEs?

Source: Compiled by the study team.

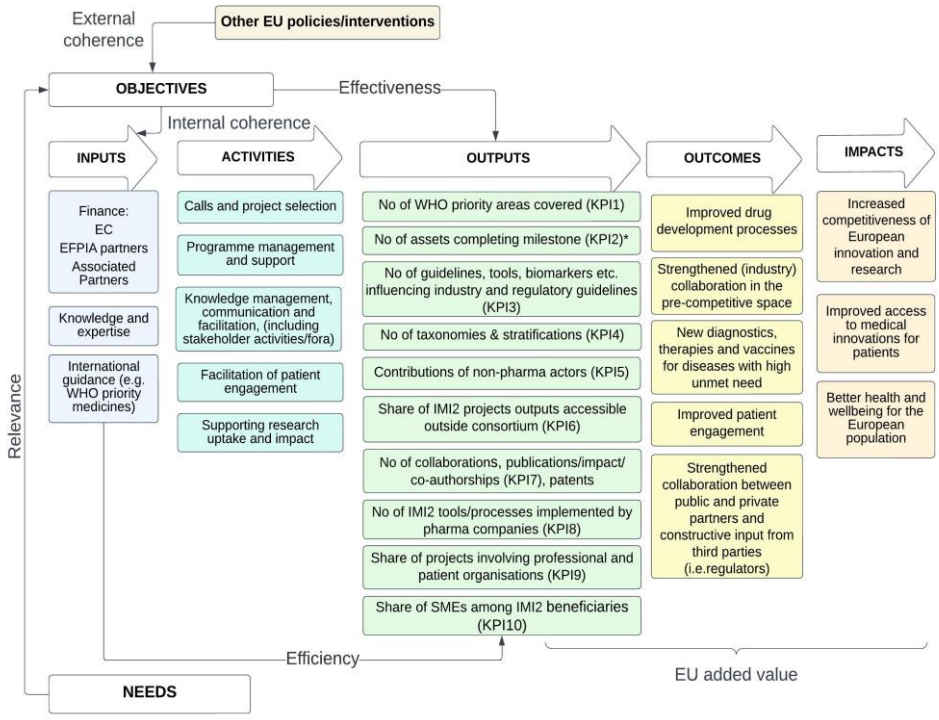
7.3. IHI impact pathway and IMI2 intervention logic model

Figure 21. IHI partnership specific impact pathway



Source: Biennial Monitoring Report 2022, p. 230.

Figure 22. IMI2 Intervention logic model



Source: Own compilation, based on a revision of the intervention logic diagram published in the IMI2 Interim Evaluation 2017, p. 23. Illustration by PPMI.

7.4. Objectives of IHI and IMI2

General and specific objective of IHI

Innovative Health Initiative Joint Undertaking shall reach the following general objectives by 2030:

(a) contribute towards the creation of a **Union-wide health research and innovation ecosystem** that facilitates translation of scientific knowledge into innovations, in particular by launching at least 30 large-scale cross-sectoral projects, focusing on health innovations.

(b) 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 five examples, the feasibility of integrating healthcare products or services, with demonstrated suitability for uptake by healthcare systems. The related projects should address the prevention, diagnosis, treatment or management of diseases affecting the Union population, including contribution to Europe's Beating Cancer Plan.

(c) 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.

More specifically, IHI should:

(a) contribute towards a **better understanding of the determinants of health** and priority disease areas;

(b) **integrate fragmented health research and innovation 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;

(c) demonstrate the feasibility of **people-centred integrated healthcare** solutions;

(d) exploit the full potential of **digitalisation and data exchange** in healthcare;

(e) enable the development of new and improved **methodologies and models for a comprehensive assessment** of the added value of innovative and integrated healthcare solutions

Objectives of IMI2

(a) to support the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges;

(b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to:

(i) increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;

(ii) where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;

(iii) develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;

(iv) develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;

(v) reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;

(vi) improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

7.5. Key Performance Indicators specific to IHI

Key performance indicators (KPIs) have been agreed for IHI. However, data have not yet been reported. KPIs built on IMI2 KPIs but are more comprehensive, clearly structured into inputs, outcomes and impacts and combined with quantified targets for the years 2023,2025, 2027 and beyond. This set of data will be a resource to examine in the future evaluation of IHI.

Table 13. IHI Key Performance Indicators

KPI NAME	UNIT OF MEASUREMENT	BASELINE	TARGET 2023	TARGET 2025	TARGET 2027	TARGET >2027
Resources, processes and activities (inputs)						
1.1. Involvement of multiple healthcare stakeholders	Share of projects involving more than two types of healthcare stakeholders, SME, large company, NGO, healthcare professional organisation etc.	50%	55%	60%	65%	70%
1.2. Cross-sectorality of the partnership	Share of projects bringing together private members and/or Contributing Partners from two or more technology sectors	25%	70%	80%	85%	90%
1.3. Engagement of regulators	Number of projects interacting with regulators to contribute to new or improved guidelines and methodologies	13	0	5	10	20
Outcomes						
2.1. Cross-stakeholders' collaboration	Share of multi-stakeholders' publications identified through bibliometric data analysis	65%	65%	66%	67%	70%
2.2. Public-private collaboration	Share of publications across public and private stakeholders identified through bibliometric data analysis	65%	65%	66%	67%	70%
2.3. Project outputs for use in clinical practice and health research R&D&I	Number of: - new tools for studying new potential drug targets - new tools to test diagnostically and/or therapeutically relevant hypotheses - new tools for prediction, prevention, interception, surveillance, diagnosis, treatment, and management options to prepare for major epidemic outbreaks	100	0	50	120	150

KPI NAME	UNIT OF MEASUREMENT	BASELINE	TARGET 2023	TARGET 2025	TARGET 2027	TARGET >2027
	- new biomarkers of disease identified and experimentally validated - new taxonomies of disease or new stratifications to define patient sub-populations					
2.4. Integrated health and care solutions considering end-users' needs	Number of project outputs that combine people-centred integrated solutions	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, submitted to healthcare authorities and organisations	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 healthcare	Number of pilots developed by the projects demonstrating feasibility of use of artificial intelligence in healthcare	No baseline available	0	1	2	3
Impacts						
3.1. Creation of sustainable resources and infrastructures that	Number of established new research networks, new clinical networks, further public-private	10	0	4	7	15

KPI NAME	UNIT OF MEASUREMENT	BASELINE	TARGET 2023	TARGET 2025	TARGET 2027	TARGET >2027
facilitate translation of the knowledge to innovations	collaborations on health R&D&I, research infrastructures, biobanks, collaborate platforms etc.					
3.2. Development of preventive of 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 including in the list of the WHO Europe Health 2020 priority areas	No baseline available	0	5	10	20
3.3. Cross-sector activities established by the partnership that will help contribute to a globally competitive EU healthcare industry	Number of activities in which cross-sector collaboration derives from health innovation such as: - Spin-off companies, entities or activities created based on outputs of the project - Collaboration agreements between large companies and SMEs established for purposes that go beyond the scope of the project during and/r after project lifetime - Other activities where the joint contribution of different partners has generated cross-sectoral health innovation	No baseline available	0	5	10	20

Source: Consolidated Annual Activity Report 2022[69].

69 An unabbreviated version of this list can be found in the Consolidated Annual Activity Report 2022, pp. 198-201.

7.6. IMI2 Topics of calls for proposals and financial contributions to calls

Table 14. List of IMI2 calls for proposals and call topics

Topic No	Titles of call topics
IMI2-2014-01-01	Translational approaches to disease modifying therapy of Type 1 Diabetes Mellitus (T1DM)
IMI2-2014-02-01	Vaccine development Phase I, II, and III
IMI2-2014-02-02	Manufacturing capability
IMI2-2014-02-04	Deployment and compliance of vaccination regimens
IMI2-2014-02-05	Rapid diagnostic tests
IMI2-2015-03-01	Remote assessment of disease and relapse - CNS
IMI2-2015-03-02	Assessing risk and progression of prediabetes and Type 2 Diabetes to enable disease modification
IMI2-2015-03-03	Linking clinical neuropsychiatry and quantitative neurobiology
IMI2-2015-03-04	The consistency approach to quality control in vaccine manufacture
IMI2-2015-03-05	Pertussis vaccination research
IMI2-2015-04-01	Enabling platform on medicines adaptive pathways to patients
IMI2-2015-05-01	Patient perspective elicitation on benefits and risks of medicinal products, from development through the entire life cycle, to inform the decision-making process by regulators and Health Technology Assessment bodies
IMI2-2015-05-02	Diabetic Kidney Disease Biomarkers (DKD-BM)
IMI2-2015-05-03	Inflammation and AD: modulating microglia function – focusing on TREM2 and CD33
IMI2-2015-05-04	Understanding the role of amyloid imaging biomarkers in the current and future diagnosis and management of patients across the spectrum of cognitive impairment (from pre-dementia to dementia)
IMI2-2015-05-05	Evolving models of patient engagement and access for earlier identification of Alzheimer's disease: Phased expansion study
IMI2-2015-05-06	From ApoE biology to validated Alzheimer's disease targets
IMI2-2015-06-01	Development of Quantitative System Toxicology (QST) approaches to improve the understanding of the safety of new medicines
IMI2-2015-06-02	Establishing impact of RSV infection, resultant disease and public health approach to reducing the consequences
IMI2-2015-06-03	Real World Outcomes Across the AD Spectrum (ROADS) to Better Care
IMI2-2015-06-04	Development of an outcomes-focused data platform to empower policymakers and clinicians to optimise care for patients with haematologic malignancies
IMI2-2015-07-01	Validation of translational imaging methods in drug safety assessment (TRISTAN)
IMI2-2015-07-02	Identification of druggable targets modulating misfolded proteins in Alzheimer's and Parkinson's diseases
IMI2-2015-07-03	Pathological neuron-glia interactions in neuropathic pain
IMI2-2015-07-04	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention
IMI2-2015-07-05	A comprehensive 'Paediatric Preclinical POC Platform' to enable clinical molecule development for children with cancer
IMI2-2015-07-06	Coordination and support actions (CSA) for the Big Data for Better Outcomes Programme

Topic No	Titles of call topics
IMI2-2015-07-07	Increase access and use of high-quality data to improve clinical outcomes in heart failure (HF), atrial fibrillation (AF), and acute coronary syndrome (ACS) patients
IMI2-2015-08-01	Ebola and other filoviral haemorrhagic fevers (Ebola+) programme: future outbreaks
IMI2-2016-09-01	Addressing the clinical burden of Clostridium difficile infection (CDI): Evaluation of the burden, current practices and set-up of a European research platform (part of the IMI New Drugs for Bad Bugs (ND4BB) Programme)
IMI2-2016-09-02	Development of immune tolerance therapies for the treatment of rheumatic diseases
IMI2-2016-09-03	Data quality in preclinical research and development
IMI2-2016-09-04	Next generation of electronic translational safety - NEXGETS
IMI2-2016-09-05	Identification and validation of biomarkers for non-alcoholic steatohepatitis (NASH) and across the spectrum of non-alcoholic fatty liver disease (NAFLD)
IMI2-2016-09-06	Joint influenza vaccine effectiveness studies
IMI2-2016-10-01	Understanding hypoglycaemia: the underlying mechanisms and addressing clinical determinants as well as consequences for people with diabetes by combining databases from clinical trials
IMI2-2016-10-02	How Big Data could support better diagnosis and treatment outcomes for prostate cancer
IMI2-2016-10-03	Improving the care of patients suffering from acute or chronic pain
IMI2-2016-10-04	Creation of a pan-European paediatric clinical trials network
IMI2-2016-10-05	Biomanufacturing 2020: Development of Innovative high throughput analytical tools and methods to characterise cell culiure fluid during development and commercial cell culture processes
IMI2-2016-10-06	Unlocking the Solute Carrier Gene-Family for Effective New Therapies (Unlock SLCs)
IMI2-2016-10-07	Patient perspectives in medicines lifecycle
IMI2-2016-10-08	Personalised medicine approaches in autism spectrum disorders
IMI2-2017-11-01	Exploitation of IMI project results
IMI2-2017-12-01	Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's Disease (RADAR-AD)
IMI2-2017-12-02	FAIRification of IMI and EFPIA data
IMI2-2017-12-03	Development of sensitive and validated clinical endpoints in primary Sjögren's Syndrome (pSS)
IMI2-2017-12-04	European Health Data Network (EHDN)
IMI2-2017-12-05	Analysing the infectious disease burden and the use of vaccines to improve healthy years in ageing populations
IMI2-2017-12-06	Discovery and characterisation of blood-brain barrier targets and transport mechanisms for brain delivery of therapeutics to treat neurodegenerative & metabolic diseases
IMI2-2017-12-07	European Screening Centre: unique library for attractive biology (ESCulab)
IMI2-2017-13-01	Assessment of the uniqueness of diabetic cardiomyopathy relative to other forms of heart failure using unbiased pheno-mapping approaches
IMI2-2017-13-02	Genome-Environment Interactions in Inflammatory Skin Disease
IMI2-2017-13-03	The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
IMI2-2017-13-04	Mitochondrial dysfunction in neurodegeneration

Topic No	Titles of call topics
IMI2-2017-13-05	Support and coordination action for the projects of the neurodegeneration area of the Innovative Medicines Initiative
IMI2-2017-13-06	A sustainable European induced pluripotent stem cell platform
IMI2-2017-13-07	Linking digital assessment of mobility to clinical endpoints to support regulatory acceptance and clinical practice
IMI2-2017-13-08	Human tumour microenvironment immunoprofiling
IMI2-2017-13-09	ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now
IMI2-2017-13-10	Improving the preclinical prediction of adverse effects of pharmaceuticals on the nervous system
IMI2-2017-13-11	Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease
IMI2-2017-13-14	Pilot programme on a clinical compound bank for repurposing: neurodegenerative diseases
IMI2-2017-13-15	Pilot programme on a clinical compound bank for repurposing: rare/orphan diseases
IMI2-2018-14-01	Targeted immune intervention for the management of non-response and relapse
IMI2-2018-14-02	Non-invasive clinical molecular imaging of immune cells
IMI2-2018-14-03	Development of a platform for federated and privacy-preserving machine learning in support of drug discovery
IMI2-2018-14-04	Centre Of Excellence – Remote decentralised clinical trials
IMI2-2018-15-01	Integrated research platforms enabling patient-centric drug development
IMI2-2018-15-02	Blockchain enabled healthcare
IMI2-2018-15-03	Microenvironment imposed signatures in tissue and liquid biopsies in immune-mediated diseases
IMI2-2018-15-04	Emerging translational safety technologies and tools for interrogating human immuno-biology
IMI2-2018-15-06	Digital endpoints in neurodegenerative and immune-mediated diseases
IMI2-2018-15-07	AMR Accelerator programme Pillar A: Capability building network to accelerate and validate scientific discoveries
IMI2-2018-15-08	AMR Accelerator programme Pillar B: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic
IMI2-2018-16-01	Progress new assets (one pre-new molecular entity (preNME) and one first-time-in-human (FTIH) start) for TB that act synergistically with bedaquiline, cytochrome bc or cytochrome bd inhibitors
IMI2-2018-16-02	Progress novel assets (one FTIH start) for non-tubercular mycobacteria (NTM) that may act synergistically with bedaquiline and cytochrome bc drugs
IMI2-2018-16-04	Determination of gepotidacin levels in tonsils and prostatic tissue
IMI2-2018-16-06	Functional Ethionamide boosters: a novel combination for tuberculosis therapy
IMI2-2018-16-07	Intravenous treatments of serious infections (urinary tract infections, intra-abdominal infections & hospital-acquired pneumonia/ventilator associated pneumonia) caused by Gram(-) bacteria (Enterobacteriaceae +/- Pseudomonas and/or Acinetobacter)
IMI2-2019-17-01	Optimising future obesity treatment
IMI2-2019-17-02	Open access chemogenomics library and chemical probes for the druggable genome

Topic No	Titles of call topics
IMI2-2019-17-03	Intelligent prediction and identification of environmental risks posed by human medicinal products
IMI2-2019-18-01	Central repository of digital pathology slides to support the development of artificial intelligence tools
IMI2-2019-18-02	Health Outcomes Observatories – empower patients with tools to measure their outcomes in a standardised manner creating transparency of health outcomes
IMI2-2019-18-03	Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project
IMI2-2019-18-04	Establishing international standards in the analysis of patient reported outcomes and health-related quality of life data in cancer clinical trials
IMI2-2019-18-05	Accelerating research & innovation for advanced therapy medicinal products
IMI2-2019-18-06	Supporting the development of engineered T cells
IMI2-2019-19-01	Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities
IMI2-2020-20-01	Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in psoriatic arthritis
IMI2-2020-20-02	Innovations to accelerate vaccine development vaccine development and manufacture
IMI2-2020-20-03	Academia and industry united innovation and treatment for tuberculosis (UNITE4TB)
IMI2-2020-20-04	Tumour plasticity
IMI2-2020-20-05	Proton versus photon therapy for oesophageal cancer - a trimodality strategy
IMI2-2020-20-06	Handling of protein drug products and stability concerns
IMI2-2020-21-01	Development of therapeutics and diagnostics combating Coronavirus infections
IMI2-2020-22-01	Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities
IMI2-2020-23-01	Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework
IMI2-2020-23-02	Modelling the impact of monoclonal antibodies and vaccines on the reduction of antimicrobial resistance
IMI2-2020-23-03	A platform for accelerating biomarker discovery and validation to support therapeutics development for neurodegenerative diseases
IMI2-2020-23-04	Optimal treatment for patients with solid tumours in Europe through Artificial Intelligence
IMI2-2020-23-05	Shortening the path to rare disease diagnosis by using newborn genetic screening and digital technologies
IMI2-2020-23-06	Behavioural model of factors affecting atient adherence

Source: IMI2/ IHI dashboard data

Table 15. Contributions of the EC, EFPIA and Associated Partners to IMI2 (in EUR)

			EFPIA			Associated Partners		
Calls	Total project costs	EU Contributions	Total contributions	Financial contributions	In-kind contributions	Total contributions	Financial contributions	In-kind contributions
2014-01-two-stage	41 683 298	17 630 000	13 053 356	4 022 625	9 030 731	10 451 361	8 838 814	1 612 547
2014-02-single-stage	230 429 968	114 090 808	109 248 144	12 994 349	96 253 795	0	0	0
2015-03-two-stage	106 898 728	49 060 000	45 321 073	5 565 760	39 755 313	7 000 000	7 000 000	0
2015-04-two-stage	4 064 146	1 130 000	2 187 631	98 000	2 089 631	0	0	0
2015-05-two-stage	99 531 429	47 476 823	46 583 054	7 213 436	39 369 618	1 850 999	1 363 636	487 363
2015-06-two-stage	93 933 788	46 496 375	46 363 314	4 317 250	42 046 064	0	0	0
2015-07-two-stage	99 954 137	46 794 801	51 698 869	10 361 470	41 337 399	0	0	0
2015-08-single-stage	89 191 960	47 461 988	32 318 441	0	32 318 441	1 730 294	0	1 730 294
2016-09-two-stage	125 215 408	53 605 522	64 411 361	14 227 981	50 183 380	0	0	0
2016-10-two-stage	376 151 094	173 874 258	142 623 713	11 063 623	131 560 089	58 599 135	2 673 300	55 925 835
2017-11-single-stage	5 845 711	3 283 993	2 221 857	654 369	1 567 488	0	0	0
2017-12-two-stage	127 886 463	64 051 532	62 939 220	11 888 945	51 050 275	1 033 132	750 000	283 132
2017-13-two-stage	223 571 772	114 152 102	103 600 670	19 880 202	83 720 468	4 554 515	3 925 840	628 675
2018-14-two-stage	165 787 742	82 310 189	82 202 822	4 299 822	77 903 000	0	0	0

			EFPIA			Associated Partners		
Calls	Total project costs	EU Contributions	Total contributions	Financial contributions	In-kind contributions	Total contributions	Financial contributions	In-kind contributions
2018-15-two-stage	375 008 072	165 608 085	143 904 517	886 825	143 017 692	64 920 470	31 550	64 888 920
2018-16-single-stage	61 602 495	35 183 571	26 374 549	1 221 295	25 153 254	0	0	0
2019-17-two-stage	90 202 212	40 786 000	36 250 230	12 719 100	23 531 130	7 646 519	3 000 000	4 646 519
2019-18-two-stage	161 132 526	74 859 537	82 599 074	4 677 000	77 922 074	2 768 000	0	2 768 000
2019-19-single-stage	25 285 704	12 714 680	8 675 044	2 657 200	6 017 844	3 895 980	3 832 191	63 789
2020-20-two-stage	272 778 742	133 008 956	106 365 796	5 615 000	100 750 796	31 635 256	1 000 000	30 635 256
2020-21-single-stage	116 569 621	71 997 972	37 489 596	5 190 770	32 298 826	5 382 915	0	5 382 915
2020-22-single-stage	17 081 441	8 725 281	7 105 193	1 250 000	5 855 193	1 088 466	0	1 088 466
2020-23-two-stage	95 050 661	47 787 469	46 709 019	7 124 000	39 585 019	256 000	0	256 000
Total sum	**3 004 857 117**	**1 452 089 940**	**1 300 246 543**	**147 929 023**	**1 152 317 519**	**202 813 042**	**32 415 331**	**170 397 711**

Source: IMI2/ IHI Dashboard Data, analysed by Prognos. Data as of 06/06/23.

Table 16. Total in-kind contributions and in-kind contributions from outside the EU to IMI2 (in EUR)

		EU and non-EU			Non-EU		
Calls	Total Costs	Total in-kind contributions	EFPIA in-kind contributions	Associated partners' in-kind contributions	Total in-kind contributions	EFPIA in-kind contributions	Associated Partners' in-kind contributions
2014-01-two-stage	41 683 298	23 504 717	13 053 356	10 451 361	5 486 654	4 931 192	555 462
2014-02-single-stage	230 429 968	109 248 144	109 248 144	0	39 654 119	39 654 119	0
2015-03-two-stage	106 898 728	52 321 073	45 321 073	7000 000	15 122 527	15 122 527	0
2015-04-two-stage	4 064 146	2 187 631	2 187 631	0	353 227	353 227	0
2015-05-two-stage	99 531 429	48 434 053	46 583 054	1 850 999	8 483 837	7 996 474	487 363
2015-06-two-stage	93 933 788	46 363 314	46 363 314	0	16 027 657	16 027 657	0
2015-07-two-stage	99 954 137	51 698 869	51 698 869	0	5 833 352	5 833 352	0
2015-08-single-stage	89 191 960	34 048 735	32 318 441	1 730 294	6 952 156	6 721 756	230 400
2016-09-two-stage	125 215 408	64 411 361	64 411 361	0	11 413 500	11 413 500	0
2016-10-two-stage	376 151 094	201 222 848	142 623 713	58 599 135	88 218 891	32 816 878	55 402 013
2017-11-single-stage	5 845 711	2 221 857	2 221 857	0	96 300	96 300	0
2017-12-two-stage	127 886 463	63 972 352	62 939 220	1 033 132	10 737 375	10 678 259	59 116

		EU and non-EU			Non-EU		
2017-13-two-stage	223 571 772	108 155 185	103 600 670	4 554 515	32 224 741	32 132 866	91 875
2018-14-two-stage	165 787 742	82 202 822	82 202 822	0	37 188 091	37 188 091	0
2018-15-two-stage	375 008 072	208 824 987	143 904 517	64 920 470	110 956 935	56 059 146	54 897 789
2018-16-single-stage	61 602 495	26 374 549	26 374 549	0	360 500	360 500	0
2019-17-two-stage	90 202 212	43 896 749	36 250 230	7 646 519	9 204 638	7 343 500	1 861 138
2019-18-two-stage	161 132 526	85 367 074	82 599 074	2 768 000	16 654 267	16 614 267	40 000
2019-19-single-stage	25 285 704	12 571 024	8 675 044	3 895 980	2 562 789	2 499 000	63 789
2020-20-two-stage	272 778 742	138 001 052	106 365 796	31 635 256	18 057 500	15 282 500	2 775 000
2020-21-single-stage	116 569 621	42 872 511	37 489 596	5 382 915	10 198 822	9 836 428	362 394
2020-22-single-stage	17 081 441	8 193 659	7 105 193	1 088 466	2 187 585	1 870 670	316 915
2020-23-two-stage	95 050 661	46 965 019	46 709 019	256 000	9 590 047	9 590 047	0
Total sum	3 004 857 117	1 503 059 585	1 300 246 543	202 813 042	457 565 510	340 422 256	117 143 254

Source: IMI2/ IHI Dashboard Data, analysed by Prognos. Data as of 06/06/23.

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This report presents the interim evaluation of the Innovative Health Initiative (IHI) and the final evaluation of its predecessor, the Innovative Medicines Initiative (IMI2). The evaluation considers the programmes' relevance, coherence, efficiency, effectiveness, EU-added value, as well as their additionality, directionality, international positioning and visibility, and transparency and openness, and presents lessons learned and suggestions for improvement. This study is one of several studies in support of the European Commission's *ex post* evaluation of the European Framework Programme for Research and Innovation Horizon 2020 and the interim evaluation of its successor framework programme Horizon Europe.

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