Draft proposal for a European Partnership under Horizon Europe
European Partnership for Health Innovation
(current working title: Innovative Health Initiative, IHI)
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About this draft

In autumn 2019 the Commission services asked potential partners to further elaborate proposals for the candidate European Partnerships identified during the strategic planning of Horizon Europe. These proposals have been developed by potential partners based on common guidance and template, taking into account the initial concepts developed by the Commission and feedback received from Member States during early consultation. The Commission Services have guided revisions during drafting to facilitate alignment with the overall EU political ambition and compliance with the criteria for Partnerships.

This document is a stable draft of the partnership proposal, released for the purpose of ensuring transparency of information on the current status of preparation (including on the process for developing the Strategic Research and Innovation Agenda). As such, it aims to contribute to further collaboration, synergies and alignment between partnership candidates, as well as more broadly with related R&I stakeholders in the EU, and beyond where relevant.

This informal document does not reflect the final views of the Commission, nor pre-empt the formal decision-making (comitology or legislative procedure) on the establishment of European Partnerships.

In the next steps of preparations, the Commission Services will further assess these proposals against the selection criteria for European Partnerships. The final decision on launching a Partnership will depend on progress in their preparation (incl. compliance with selection criteria) and the formal decisions on European Partnerships (linked with the adoption of Strategic Plan, work programmes, and legislative procedures, depending on the form). Key precondition is the existence of an agreed Strategic Research and Innovation Agenda / Roadmap. The launch of a Partnership is also conditional to partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them.

The remaining issues will be addressed in the context of the development of the Strategic Research and Innovation Agendas/ Roadmaps, and as part of the overall policy (notably in the respective legal frameworks). In particular, it is important that all Partnerships further develop their framework of objectives. All Partnerships need to have a well-developed logical framework with concrete objectives and targets and with a set of Key Performance Indicators to monitor achievement of objectives and the resources that are invested.

Aspects related to implementation, programme design, monitoring and evaluation system will be streamlined and harmonised at a later stage across initiatives to ensure compliance with the implementation criteria, comparability across initiatives and to simplify the overall landscape.

A Strategic Research Agenda (SRA) is under preparation and its earlier version can be found at www.EUhealthPPP.org. A more consolidated and updated version of the SRA will be prepared later in 2020. It is expected that the draft will continue to evolve as more information about the scope of other European programmes and partnerships become available to more precisely delineate the type of activities that should be prioritised in IHI. The SRA will be adopted at the first meeting of the IHI Governing Board.

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DISCLAIMER: This draft working document reflects the status of current discussions between industry associations and the Commission on the content and governance of the Partnership. Several aspects still require further discussion. Therefore, this Proposal has not been formally endorsed either by the Commission or by industry associations.

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1 Summary

The Partnership for Health Innovation aims to enable the integration of cross-sectoral technologies, know-how, products, services and workflows for people-centred health care. Its ambition is to support the delivery of timely and well-informed prevention, diagnosis and treatment. The partnership aims to keep EU citizens in good health, decrease disease burden for patients, care givers and health care professionals. It will contribute to the sustainability of health care systems, competitiveness of health industries and EU technological sovereignty.

2 Context, objectives, expected impacts

2.1 Context and problem definition

Europe has always strived to deliver high standards of health care. At the same time, health is a constant and major concern for many Europeans, as confirmed by Eurobarometer surveys. The EU has an ageing population and a rising burden of diseases, notably non-communicable and infectious diseases. The current health crisis caused by the novel Coronavirus pandemic shows the challenges that European health care systems face in detecting, combatting and managing outbreaks of infectious diseases. It also provides evidence for the critical importance of collaborative R&I to develop new approaches for detection, diagnosis and treatment, and shows the importance of cross-EU and global collaborations to overcome health challenges. Furthermore, health care expenditure in EU countries is steadily increasing and now accounts for nearly 10% of Gross Domestic Product (GDP), most of which is public spending (7%) . This puts into question the sustainability of EU health care systems, which are under increasing fiscal and organisational pressures.

A significant contribution to addressing these challenges could be made by innovative health interventions. However, they are notoriously complex to design and even more so, to implement as they may stretch over the full spectrum of the health care pathway: prevention, diagnosis, treatment to management of diseases and end of life care. In addition, innovation in health is today based on the use of various technologies (medicines, devices, ATMPs, in-vitro diagnostics, digital technologies, nanotechnologies, …), sometimes combining them to obtain the targeted health strategy, thus blurring the frontier between traditional technological categories. To address these complexities, current silos would have to be broken down across discovery science and translational research as well as between different academic research disciplines and industry sectors, in order to develop people-centred, effective, cost-effective and affordable health solutions faster.

An overarching organisational problem driver for developing innovative health interventions is the limited collaboration across several health industry sectors, driven by historically segregated approaches, starting at research level, and encompassing the entire innovation pathway and regulatory steps. If reinforced– in addition to strengthened collaboration between industry sectors and academia – it would not only offer better opportunities to meet the public health needs in Europe but would also provide a strong base to grow, retain and attract…

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2 Technological sovereignty for Europe is reflected in the Commission’s priorities and in the Commission Industrial Strategy: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_416
5 People-centred care refers to an approach to care that consciously adopts individuals’, carers’, families’ and communities’ perspectives as participants in, and beneficiaries of health care systems that are organised around the comprehensives needs of people rather than individual diseases, and respects social preferences. This approach requires that people have the education and support to enable them to make decisions and participate in their own health and care, while also supporting carers. World Health Organization 2016, Framework on integrated, people-centred health services.
competitive companies in Europe that excel in global markets. The European health industry is a highly research-intensive industrial sector that employs more than 1.3 million highly skilled employees (2016 figures) and that generates a very significant EU trade surplus. The industry represents a key asset in terms of generating the scientific progress affecting cross-sectoral solutions. The opportunities are thus significant.

Despite the EU being a strong global actor in health research, it is still relatively weak in translating research results into tangible health products, services and solutions delivered to the market and adopted by the health care systems in Europe. Even when innovation does happen, insufficient early consideration of societal or user needs acts as barrier to acceptance and uptake. Therefore, better innovation requires involvement of patients and other end-users from project design, project specifications to project implementation. In addition, access to products and services by patients and health care professionals may be delayed for reasons such as lack of evidence to demonstrate their added value, affordability issues or lack of preparedness of health care systems.

The slow translation of scientific discoveries into tangible innovations and limited technology convergence lead to dwindling innovation pipelines. This, in addition to insufficient innovative products reaching health care services and patients, poses not only a threat to the competitiveness of EU health research, it puts Europe at risk of becoming dependent on other countries for technological developments and innovative health care solutions. The danger of Europe losing competitiveness hence puts into question Europe’s future sovereignty and preparedness to face issues like emerging pandemics.

Therefore, the following factors were identified as the key problem drivers, from a research and innovation (R&I) point of view:

a) **Incomplete understanding of health and disease**, notably in areas of unmet public health needs, including incomplete understanding of underlying molecular mechanisms hampering the development of precisely targeted prevention policies, timely and accurate diagnostics, and more personalised therapeutic interventions.

b) **Limited collaboration in health R&I across academia and industry**. Such collaboration is key to translate research into innovation. However, it is often inhibited by a range of factors. These include, among others: the compartmentalisation of departments within universities and hospitals; a cultural divide between academic, industry and clinical researchers; limited access to a suitable funding vehicle that would enable such collaboration; concerns about the poor reproducibility of research; maintaining confidentiality; restricted freedom to publish experimental data. Of note, the reporting on results from academic clinical trials is well below that of industry, possibly

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7 Unmet public health needs refers to needs currently not addressed by the health care systems for availability or accessibility reasons, for examples if there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people access to health care is limited because of cost, distance to health facilities or waiting times. Areas of public health importance are those where the burden of disease is high for patients or society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life, ...) and/or the number of people affected by it and where unmet public health needs generate significant costs for society.


due to greater experience and resources of industry to comply with regulatory frameworks.

c) **Limited collaboration in health R&I within and across industry sectors**, including pharmaceuticals, vaccines, diagnostics, medical devices, advanced therapies, imaging, biotech and digital industries. For a long time, various industry sectors worked in relative segregation, as there was no platform to collaborate on integrated solutions where drugs, devices and software are seamlessly combined into personalised and convergent solutions. This is due to competition, very diverse business and R&I investment models in different industry sectors and different development timelines across sectors. Furthermore, there are certain barriers that limit the transformative potential of digitalisation, information and data exchange for health R&I: the lack of data interoperability and accessibility, limited analytical methods and tools, and the need to tackle fundamental considerations concerning ethics, privacy and security beyond the existing guidelines.

d) **Market barriers affecting innovation in health and care** include failure and lack of appropriate business models that encourage companies to invest in R&I, in particular in areas of high, unmet public health needs with high risk (e.g. due to high attrition rates) and potentially low return on investment. The issues around market barriers are exacerbated by the fact that innovations combining different types of technologies do not easily fit into existing regulatory schemes. In addition, demonstrating the added value for patients and society of such highly integrated and cross-sectoral innovations poses new methodological challenges, partly because technologies converge in ways that alter the delivery of health care in ways not anticipated before. At last, lack of consideration of societal and user needs, in particular patients and health care professionals, can hamper acceptance and uptake of health innovations.

**The time to act is now**, for the following reasons:

- The European health care systems are at the verge of becoming unsustainable and the various efforts to solve this problem so far have delivered limited success. The current Partnership may be a game-changer that will translate valuable scientific and technological ideas into potential solutions, and will establish a neutral platform to bring together the ideas of originators (industrial and academic partners) and the needs of end-users (including health authorities and health technology assessment (HTA) bodies, 12

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11 Value in health care is a multidimensional concept as highlighted by the Expert Panel on effective ways in investing in Health (EXPH). Most common elements of existing value frameworks to assess health interventions include: therapeutic benefit, safety, costs, innovation level, health problem (severity of the disease and medical need), organisational aspects, ethical aspects, societal and legal aspects. Those various elements need to be evidence-based informed and combined using an appropriate approach (e.g. cost-effectiveness analysis, multi-criteria decision analysis) so as to inform decision-making on the reimbursement, pricing, adoption, and implementation of health interventions.

12 Health technology assessment (HTA) is defined as a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value. HTA focuses specifically on the added value of a new health technology in comparison to the existing standard of care in the health care system. HTA is not only used to inform local/national pricing and reimbursement decisions but also to support the development of evidence-based clinical guidelines and public health recommendations.
- Some of the European health systems are facing a shortage of health care professionals as well as a high workload for existing health care professionals that can be partly compensated by a more effective technological and decision support to health care delivery.

- Individual efforts to integrate various health technologies need a stimulus to reach the necessary critical mass of collaborations and expertise.

- The recent progress in inter-sectoral and international data sharing opens the door to more efficient use of data (including electronic health records and real-world data at large) in academic and industrial health research. However, to fully reap its potential benefits, various technological and organisational challenges have to be overcome (including insufficient interoperability, lack of common standards or ethical, legal and social aspects).

Previous Joint Undertakings such as IMI2 and ECSEL demonstrated that some of the most difficult research related to safety, efficacy and effectiveness, or investment on new research pathways can be pursued when there is strong collaboration between public and private sectors, sharing their assets and collective intelligence. Having successfully pursued public-private collaborations within individual sectors in Joint Undertakings under Horizon 2020, the industrial partners are now ready to join forces in a multi-sector partnership in the health domain.

The digital health care market is projected to exceed globally €500 billion globally by 2025\(^\text{16}\). The US accounted for $28 billion in 2017 and Europe is already worth more than €15 billion with Germany being the market leader in the EU. A remarkable growth is forecasted for the health data and data analytics market in the next 5-6 years. Some analysts have predicted that the global health data market will increase from around $14 billion in 2019 to about $70 billion in 2025\(^\text{17}\).

\(^\text{13}\) In this document, the term 'regulators' refers to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified Bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative.

\(^\text{14}\) The term “payers” as used in this document refers to tax-funded national health services (NHS) and statutory/mandatory health insurance funds (social health insurance, SHI). NHS and SHI ensure publicly financed health care (the “benefits package”). In some Member States, additional products and services can be covered by voluntary complementary/supplementary private health insurance.


In Europe, the pharmaceutical industry invested an estimated €35 billion in R&D in 2017, and directly employs approximately 750,000 people\(^{18}\). Small molecules currently account for 83\% of the revenue in the pharma sector\(^{19}\). Biologics are more complex, large molecular weight compounds and a steady growth of the biologics and bioengineered vaccines is envisaged such that 45 of the world’s top 100 selling pharmaceuticals in 2020 are expected to be biologics\(^{20}\). In addition, many blockbuster drugs are losing their exclusivity, opening up room for biosimilar companies to enter into the global market. Advanced Therapy Medicinal Products (ATMPs) are based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). ATMPs have their origin in academic research settings, and small companies have increasingly been involved. More recently, major pharmaceutical companies have invested in gene- and cell-based therapy development as well both in the EU and in the United States\(^{21}\). A study identified 939 ATMPs clinical trials, between 1999 and June 2015, and interestingly the majority (just under 75\%) of trial sponsors were non-commercial\(^{22}\).

Medical technology offers solutions for many disease areas and includes in vitro diagnostics (IVDs) and imaging. It is making a significant impact on health care as well as the economy in Europe: with about 27,000 medical technology companies in Europe (most of them are SMEs based in Germany, UK, Italy, Switzerland, Spain and France), the MedTech industry employs more than 675,000 people\(^{23}\). More patent applications (13,000) were filed in the area of MedTech with the European Patent Office than the combined field of pharmaceuticals (6,300) and biotechnology (6,300) in Europe. The European medical technology market is estimated at roughly €115 billion in 2017. Based upon manufacturer prices the European medical technology market is estimated to make up 27\% of the world market. It is the second largest medical technology market after the US (43\%). The largest device area is IVDs with solutions used to support the diagnosis, or exclusion of a disease, and also provide valuable data on prognosis, risk stratification, screening and disease progression. Overall revenues in this area across EU-28 plus EFTA reached €10,768 million in 2017, but still below the revenues recorded in 2011. The industry sector linked to ‘imaging’ according to COCIR market data and trend analysis shows that the 2018 income in this sector exceeded €300 million in Europe. Europe has a positive medical technology (excluding IVD) trade balance of €19.7 billion (2017) with largest partner being the US, China and Japan. In comparison, the US medical devices trade surplus is at €2 billion.

Regarding the future evolution of problems described above, the problems of Europe’s ageing society and prevalence of diseases are unlikely to dissipate over time. As people age, the prevalence of neurodegenerative diseases and chronic diseases is likely to increase\(^ {24}\). Our R&I agenda must, therefore, cater to these needs. In addition, there are increased expectations of EU citizens that health care must be of high quality, affordable, accessible and sensitive to their individual needs. The problem that safe and cost-effective innovations do not necessarily find the ir ways on time to users will require coordinated efforts from all stakeholders including end-users and health care systems.

If achieved, this is expected to lead to more effective health care systems better meeting public health needs. For example, easy to use and affordable innovations originated from mobile

\(^{18}\) The Pharmaceutical Industry in Figures, Key Data 2018, EFPIA
\(^{19}\) Results Healthcare. Pharma and Biotech 2017. Review of outsourced manufacturing
health technologies could reduce the pressure on health care systems both organisationally and financially. A clear beneficial impact of digital health solutions would include a reduced need to travel (e.g. to hospital) and the possibility to receive care remotely or a more effective monitoring of patients in critical condition, as it became evident during the 2019/2020 COVID-19 pandemic.

The envisaged IHI Partnership would build on lessons learnt from IMI2 Joint Undertaking (JU), a public-private partnership between the EU and the European pharmaceutical industry based on Article 187 TFEU. IMI2 JU was established under Horizon 2020, as a continuation from its predecessor IMI JU, which was established under Framework Programme 7. Close to €5 billion has been committed to the two initiatives between 2008 and 2020, making it one of the world’s largest public-private partnerships (PPPs) to accelerate drug development25.

The IMI and IMI2 JU both aimed to support the development of pre-competitive R&I activities with the aim of strengthening competitiveness and industrial leadership. The ultimate aim was to address societal challenges and help improve health and well-being in Europe. The general objective of the IMI2 JU was “to support, in accordance with Article 25 of Regulation (EU) No 1291/2013, 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 in particular as described in parts II and III of Annex I to Decision 2013/743/EU, and in particular the challenge to improve European citizens’ health and well-being”26.

The EU’s financial contribution to IMI2 JU was set at up to €1.638 billion, which would be used to match the contribution of EFPIA (at least €1.425 billion) and other Members or Associated Partners (up to €213 million; these could be industrial partners other than pharmaceutical industries e.g. technology providers or diagnostics companies, but also other entities such as charities or data handlers)27. IMI2 JU started in 2014 and will run until 31 December 2024 (with the last calls being launched by 31 December 2020). IMI2 JU participants spanned a wide range of organisations including private companies (including SMEs), higher education institutions, public-funded research centres, public bodies and others (e.g. non-profit organisations, patient associations, etc.). The analysis of funded IMI2 JU projects (until 2018) reveals that overall 39.20% of the participants were private companies, while 33.65% were higher education institutions, 17.25% were research performing organisations and 3.53% were public bodies. 15.4% (140 out of 912 participations) of beneficiaries receiving EU funding are SMEs28.

The Partnership for Health Innovation also builds on the lessons learned from the health activities in the ECSEL JU. These activities currently focus on the enabling electronics components and systems aspects. Moreover, there are several health-related activities pursued under the ECSEL JU, like e.g. the actions on the establishment of pilot production lines for smart medical devices and implants involving a range of MedTech actors, which are of high relevance for future activities under IHI. It is important to note that the IHI partnership is not

meant to be a direct continuation of IMI2 JU, rather it will have a broadened scope with new stakeholders. The proposed initiative reflects the progress in converging of health technology areas (e.g. drug development and diagnostics or medical devices and ATMPs) and a much more prominent role of digital technologies and data analytics in health research than it was the case when IMI2 JU was established. IHI will thus be responding to the recommendation of the IMI2 JU interim evaluation to “enable the active engagement of other industry sectors with the pharmaceutical industry”\(^{29}\). A key element for the linking of all these industry sectors is the necessity to avail of and share consistent and interoperable data involving innovative digital tools in order to perform people-centred translational R&I for the benefit of the European patients, health systems and society at large.

**Ever evolving understanding of diseases**

Medical science is becoming increasingly interdisciplinary: bio-health, bioinformatics, biomechanics and biochemistry, chemistry, physics, mathematics, biology, micro- and nanotechnologies, data science as well as social and behavioural sciences. Additionally, without leveraging the synergies between big data, real world data and digital tools, a great opportunity might be missed as regards, for instance, our understanding of multiple pathological conditions for many complex diseases. Many of the diseases are not completely understood in terms of what causes them, how environmental and genetic factors affect their occurrence and course, what affects treatment success, etc. Often, complex interdependencies between diseases exist, intensified in an aging society. Consequently, it is challenging to develop adequate prevention strategies, accurate diagnostics and targeted therapeutic interventions, without an interdisciplinary approach (which is particularly acute in the areas of unmet public health needs\(^7\)).

**Health research not being translated and deployed**

The EU continues to be a global leader in basic health research. However, it is much weaker when it comes to translating the outcomes of such research into products and services that will benefit the health of its citizens\(^{30}\). This is partially due to lack of adequate translational expertise (i.e. the skills and knowledge required to turn research results into products and services), differing research cultures and requirements in academia and industry, suboptimal academia-industry and industry-industry collaboration, difficulties in accessing venture capital, market failures and other barriers affecting R&D speed and success.

Factors affecting translation include low returns on investment in some health areas, e.g. infectious diseases and antimicrobial resistance and low participation from EU13 countries\(^{31}\), using IMI2 JU as an example for the latter. There is not enough involvement of health care providers, health care authorities, patients and regulators in innovation activities which may potentially be affecting the ability of researchers and innovators to target and prioritise their R&I activities adequately i.e. towards the areas of greatest need as well as more effective and implementable solutions. There is little coordination and coherence between national and EU R&I initiatives, resulting in partial overlaps and gaps, which in turn leads to inefficiencies in terms of resources and effort.


\(^{30}\) EC (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

Weak collaboration between industry sectors

An overarching organisational driver is the limited collaboration between various health-related industry sectors including pharmaceuticals, diagnostics, medical devices, imaging, biotech and digital industries\(^ {32}\). Reasons for this are competition, diverging business models and varied development timelines across sectors, as already presented in section 2.1. The interim evaluation of IMI2 JU identified specific barriers that made involvement of companies other than pharmaceutical companies difficult in IMI2 JU projects. Among other factors, cycle and business models are different, e.g. there is virtually no pre-competitive space and IP is handled differently\(^ {33}\). However, collaborations between pharma and medtech sectors start appearing within some global companies, some of them being members in several trade associations supporting this Partnership on Health Innovation.

Barriers hindering health R&D based on digitalisation and data

Lack of data standards, interoperability and accessibility, inadequate or non-existing analytical methods and tools act as barriers that diminish the EU’s ability to tap the immense potential presented by digitalisation, AI and Big Data. While ethics, privacy and security must be ensured, unsolved issues in these areas add to the complexity of the picture. The capacity to coherently access, collect, combine and analyse large, complex data sets is also variable across industry sectors and stakeholder groups. Lower investment within the EU into ICT-related skills might also be acting as a barrier to greater use of data and digitalisation in health R&D\(^ {34}\). In addition, there is often a lack of a common innovation platform that integrates the different approaches of the various health sectors, so that correlations and links between individual disease states are often not visible. As a result, health data are not adequately combined, and their potential is not used accordingly.

Market failures and lack of adequate business models

Market failures and lack of adequate business models discourage companies from investing in R&D, particularly where there is no or low return on investments. Health industries, in particular SMEs, may also encounter difficulties accessing the necessary investments from other sources as well as entering new markets and value chains, or creating partnerships and alliances because health innovation requires a broader variety of stakeholders to be involved from supply, demand and regulatory side than it would be the case for many other market sectors\(^ {35}\). All these reasons also contribute to lack of collaboration between different health-related industry sectors as described above. In addition, as previously highlighted, the issues around market barriers are exacerbated by the fact that complex and cross-sectoral innovations require the development of harmonised and adapted approaches, methods and tools not only to assess their safety and efficacy/performance but also to fully capture the added value\(^ {11}\) (incl. relative effectiveness and cost-effectiveness) they create for patients and society and to enable efficient integration into health care systems. Proper consideration of end-users’ needs and preferences is key to actually respond to people and health care systems’ needs, thus limiting market barriers to innovation.

Value of a public-private partnership


\(^{34}\)EC (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

The seamless and widespread translation of new and existing knowledge into innovative, scalable and effective products, strategies, interventions and services will require long term and coordinated support for co-operation. The life sciences, medical, digital health and biotechnology industries operate in a highly-regulated environment where innovation is research-intensive. With new developments in technology and health care delivery, technical, regulatory and ethical complexities are increasing.

IHI will become a unique platform that does not exist anywhere else, a multi-sector partnership for health innovation to break the silos between different industries first, and between industry and their respective stakeholders second. Moreover, a public-private collaboration is necessary to ensure a balance between public (including notably health care systems, payers and patients) and private interests. At the same time, improved understanding of health care needs will lower the risk for companies and encourage private investment in health R&I in Europe, thus strengthening EU competitiveness, technological sovereignty and research preparedness for upcoming health threats.

This Partnership will contribute to several overarching priorities of the European Commission:

- ‘An economy that works for people’;
- ‘A Europe fit for the digital age’;
- The Industrial Policy and the strategy for SMEs, including the Strategic Value Chain with the Smart Health theme (by increasing competitiveness of health companies of all sizes);
- Europe’s Beating Cancer Plan with the R&I mission on cancer and the European One Health Action Plan (by combining diagnostic, medical devices, data, drugs and delivery);
- The European Green Deal (by decreasing the footprint of health industries in the environment, promoting circular economy, and contributing to the greening of health care).

When preparing IHI, the following previous evaluations and assessments were considered:

**Mid-term evaluation of Horizon 2020 Joint Undertakings**, summarized in the Commission Staff Working Document "Interim Evaluation of the Joint Undertakings operating under Horizon 2020". According to this document, the key strength of the JUs was their ability to engage major industry partners globally and to overcome fragmentation in their sectors. The evaluation, based on the work of independent experts and the results of a stakeholder consultation, also identified some areas for further improvement. These include changes to Key Performance Indicators to better measure the impact of the JUs, the need for inclusion of a wider range of stakeholders either in the governance structures or in projects, increased interaction between the Governing Boards and their advisory bodies, and an improved alignment of JU activities with R&I priorities at EU, national and regional level, in particular with Smart Specialization priorities (RIS3).

**Mid-term evaluation of IMI2 JU** published in "The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020". According to this report - which concluded that the IMI2 JU remains both relevant and justified - "the main achievement of IMI2 JU on which there was general consensus, was that since the joint undertaking started, collaborations between different competing global companies, SME’s and academia became possible. These collaborations created trust and new links, including actors from a number of expertise areas, such as patient representative groups or regulatory bodies, which are essential stakeholders for medicines to enter the market with..."
quality, safety and efficacy guarantees and in the shortest possible time. Together with the available budget and long-term strategy, these collaborations were considered an important asset for European pharmaceutical research.” The report also notes that 90% of the responders to the open consultation related to the mid-term evaluation agreed or strongly agreed that the EU should cooperate with industry in the context of a public-private partnership so that the life science research brings better results to the patients and the market in Europe.

The experts drafting the report made the following recommendations for a future partnership:

**Recommendation 1:** “Make a substantial adaptation to the collaborative and funding model to enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new health care interventions.”

**Recommendation 2:** “Increase the transparency of in-kind contributions as well as the Strategic Research Agenda (SRA) and call topics generation to reflect European interest and interests of stakeholders other than EFPIA. Transparency on these issues will open up the programme for more creative and innovative thinking and trust amongst the potential participants and stakeholders.”

**Recommendation 3:** “Change the rules on the calculation of the in-kind contributions from non-European entities. To be consistent with the goal of increasing investments in Europe, in-kind contributions from activities that occur outside of the EU should not be accepted to match with the public funding, but may be accounted as additional contributions or leveraging effects.”

Building on the above recommendations:

Ad 1) The major element is that IHI is proposed as a partnership between EU and five industry sectors (pharma, medtech, biotech, imaging, vaccines), rather than only pharmaceuticals as in IMI2 JU.

Ad 2) The transparency of the initiative was maintained already at the design phase (notably, via several public consultations listed further in this document). The process of future topic generation will be made more transparent by the introduction of the Innovation Panel, bringing in the voice of various stakeholders (see below for more details).

Ad 3) The acceptance of non-EU in-kind contributions will be limited and handled according to the conditions agreed during the later phases of preparation of partnerships, to be laid down in the Council Regulation.

**Final evaluation of IMI JU** published in “The Final Evaluation of the Innovative Medicines Initiative Joint Undertaking (2008-2016) operating under the 7th Framework Programme”[^38]

When preparing future call topics, IHI will build on the following observations of IMI2 JU Scientific Committee: “IMI2 JU Scientific Committee recommendations regarding public private partnership funding – what makes a topic ultimately suitable for this kind of funding model?”[^39] and “IMI Scientific Committee Recommendation. Sustainability solutions are important criteria determining project quality and output in IMI.”[^40]

### 2.2 Common vision, objectives and expected impacts

The Partnership for Health Innovation aims to enable integration of technologies, know how, products and services to allow for well-informed and timely delivery of better health interventions of value for all actors in the health care community – prevention, diagnosis, treatment, disease & health management, for non-communicable and infectious diseases. The Partnership aims to keep EU citizens in good health, decrease disease burden for patients, care givers and health care professionals and contribute to the sustainability of health care systems and competitiveness of health industries and European health research.

The general objectives are to:

1. Create an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations;
2. Foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs currently insufficiently served by industry;
3. Drive cross-sectoral health innovation for a globally competitive European health industry.

The specific objectives that balance and converge these different societal, systemic and competitiveness imperatives are meant to:

1. Better understand determinants of health and priority disease areas (e.g. by identifying factors responsible for the predisposition to a disease or the outcomes achievable through treatments and interventions);
2. Integrate fragmented health R&I efforts across sectors and technologies, academia and industry/public and private stakeholders, focussing on unmet public health needs (e.g. through the creation of a space for knowledge and data exchange, sharing ideas and resources);
3. Deliver tools, data, platforms, technologies and processes for improved prediction, prevention, interception, treatment and management of diseases, meeting the needs of end users (e.g. using systemic approaches that pursue multiple scientific strategies);
4. Demonstrate feasibility of people-centred, integrated health care solutions along the health care pathway (e.g. by the combination of innovative products and services);
5. Exploit the full potential of digitalisation and data exchange in health care (e.g. through standards, methods and tools for interconnectivity and interoperability);

6. Deliver new and improved methodologies and models for comprehensive assessment of the added value of innovative and integrated health care solutions (e.g. by providing the tools that can support regulatory assessments).

41 Health care solution refers here to a medical product, ancillary service or tool used either alone or in combination in order to address a specific health care need, be it a medical need or an organisational need. Health care solutions to be developed within this partnership do not include organisational innovation (also known as management innovation or administrative innovation). Organisational innovation encompasses a wide range of processes, from changing professional practices and roles, to changing organisational structures and governance arrangements. While industry can propose solutions (mostly concrete goods) on organisational processes, these remain in the remit of health care authorities/organisations to consider whether and how they could be deployed in the best way.
The specific objectives are inter-dependent and sequential to some extent. For example, integrating health R&I efforts across actors and technology sectors and exploiting data and digital tools, will facilitate understanding the causes of disease (e.g. by more efficient use of data in clinical trials of medicines) as well as contribute to accelerated development of integrated health care solutions (e.g. by introducing mobile health solutions to monitor the efficacy of treatment). Providing regulators with adequate data and methodological toolboxes to facilitate regulatory assessment will enhance the health innovation pathway by improving the quality of evidence generated and shortening the time to market. This will on the one hand bring safe and effective innovative health technologies faster to end-users, and on the other hand accelerate the return on initial investment for developers. Developing methods to assess the added value of integrated, cross-sectoral innovations would indeed help to tackle both availability and accessibility issues, thus reducing barriers to market for those innovations. In addition, focusing on potential solutions able to respond to people and health care systems’ needs, i.e. matching actual needs of end-users, should help reduce barriers to uptake of innovations. In this respect, people-centred solutions are seen as key since their development implies taking into account – from the start – the needs and preferences of the patients, their carers (formal and informal) and citizens at large, rather than individual diseases (see footnote 5). In addition, implementation of the people-centred approach that aims at limiting siloed approaches across health care services will also contribute to improving collaboration across industry sectors.

The specific objectives and their targets to be reached by 2030 are summarised below. The choice of targets and their respective numbers is based on the experience of IMI2 JU42 in terms of what could be achieved by an initiative of a similar scale and broadened scope.

42 IMI2 JU Key Performance Indicators, including baselines and target values. 
<table>
<thead>
<tr>
<th>Main problem driver</th>
<th>Specific objective</th>
<th>Targets by the end of the initiative (draft)</th>
</tr>
</thead>
</table>
| Incomplete understanding of health and disease | **SO1. Better understand the determinants of health and priority disease areas** | • Explore uncharted areas of disease biology:  
  o 100 new diagnostically- and/or therapeutically-relevant hypotheses explored and tested in pre-clinical models and/or clinically  
  o new early biomarkers of disease identified and experimentally validated, in different therapeutic areas (at least 10 biomarkers)  
  o 10 new taxonomies of diseases or new stratifications to define patient subpopulations  
• expand the druggable genome by 1,000 proteins by making new pharmacological tools, therapeutic modalities and patient-derived assays openly available to the scientific community |
| Limited collaboration in health R&I across academia and industry, as well as within and across industry sectors | **SO2. Integrate fragmented health R&I efforts** across sectors and technologies, academia and industry/public and private stakeholders | • demonstrated feasibility of developing combinations of products/services, including methods for generation of clinical evidence (5 examples)  
• publications between European researchers on IHI projects (at least 1000)  
• share of projects involving civil society or patient organisations or health care professionals' associations or regulators (as participants or advisors): [the percentage requires discussion between industry and the Commission]  
• share of budget allocated to projects bringing together representatives of two or more technology sectors: [the percentage requires discussion between industry and the Commission] |
| Limited collaboration in health R&I across academia and industry, as well as within and across industry sectors | **SO3. Deliver tools, data, platforms, technologies and processes** for improved prediction, prevention, interception, treatment and management of diseases | • validated new targets for preventive or therapeutic strategy, in different therapeutic areas (at least 3 biomarkers)  
• 10 tools for prediction, prevention, diagnosis, treatment options - development, validation and use of new tools  
• Share of budget allocated to projects providing input to setting up technical standards or specifications for integrated solutions, data integration, etc.: 50%  
• Tools to increase preparedness to major epidemic outbreaks (5 examples) |
<table>
<thead>
<tr>
<th>Limited collaboration in health R&amp;I across academia and industry, as well as within and across industry sectors</th>
<th>S04. <strong>Demonstrate feasibility of people-centred, integrated, solutions</strong> (e.g. the combination of new products and services) along the health care pathway;</th>
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<tbody>
<tr>
<td></td>
<td>• demonstrated feasibility of developing people-centred, integrated health care solutions along the health care pathway (5 examples);</td>
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<tr>
<td></td>
<td>• health care solutions validated for implementation by health care authorities (5 examples);</td>
</tr>
<tr>
<td></td>
<td>• number of projects engaging regulatory acceptance processes to contribute to new or improved guidelines, methodologies (20 examples)</td>
</tr>
<tr>
<td></td>
<td>• number of projects contributing to the development of new or improved clinical guidelines (15 examples).</td>
</tr>
<tr>
<td>Limited collaboration in health R&amp;I within and across industry sectors</td>
<td>S05. <strong>Exploit the full potential of digitalisation and data exchange in health care</strong> (e.g. through standards, methods and tools for interconnectivity and interoperability);</td>
</tr>
<tr>
<td></td>
<td>• demonstrated integration of data, bringing together the public and private sectors (20 examples)</td>
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<tr>
<td></td>
<td>• Demonstration of use of artificial intelligence in health care (3 examples)</td>
</tr>
<tr>
<td>Market barriers affecting innovation in health and care</td>
<td>S06. Deliver new and improved methodologies and models for comprehensive assessment of the added value of innovative and integrated health care solutions</td>
</tr>
<tr>
<td></td>
<td>• methodologies for comprehensive assessment of the added value of combinations of products/services or combined products (including PROMs and statistical methods/tools), ready to be implemented by health care authorities and organisation (5 examples)</td>
</tr>
</tbody>
</table>
The Partnership will address these objectives by:

- **Generating high-quality, harmonised, reliable, annotated, interoperable data** that will be made available to health care and health research operators, (e.g., for larger integration, interoperability and/or where economies of scale are needed). For instance, a shift in focus to prevention of disease and diagnosis of pre-disease states, will require data on very large cohorts of healthy people that are not identified as high-risk.

- **Defining a pre-competitive space for integration of technologies and know-how to create and deliver better and safer products and ancillary services**: each individual company would leverage new science and technologies such as artificial intelligence, connected health systems, and new knowledge of genomics, robotics, micro-system and nanotechnologies, understanding of the biology of diseases to develop new products and services for disease prevention, prediction, interception, intervention and management.

- **Enabling integration of these products and ancillary services to create innovative people-centred health care solutions**: companies would combine existing and/or new products and ancillary services across the sectors and identify the needs for complementary ones where the seamless integration of those products and services along the health care pathway can offer additional value for the patients, health care professionals, health care providers, and citizens in general. This integration also includes activities to optimise the innovation pathways both within and across the sectors in terms of common standards, models, platforms, methodologies, etc. People-centred solutions are those developed around the needs and preferences of patients, their carers (formal and informal) and citizen at large rather than individual diseases (see footnote 8 for a full explanation). This approach aims at limiting siloed approaches across health care services but also across industry sectors. Development of people-centred approaches implies taking into account, from the start, the needs and preferences of the patients and health care professionals. This would in turn increase the probability of this solution to actually respond to people and health care systems needs, thus limiting market barriers to innovation.

- Laying the grounds for the development of products, tools and services to support improved operational care workflows in clinical or community setting, while considering the needs of the target populations and involving users in the design of those solutions43.

- **Proposing operational and business models for innovations involving different health industry sectors**: as companies move beyond single products to offer full-scale solutions, integrating these solutions into the entire health care system will require different operational and business models, from co-development pathways for combinations of products and services to exploring new regulatory tools, defining common outcomes across sectors and developing methods to assess the added value of innovations in collaboration with health authorities, in particular for integrated cross-sectoral innovations. A targeted outcome would be synchronising the development cycle of pharma, diagnostic and medical device and digital companies.

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43 Solutions to be proposed by industry are concrete goods (e.g. digital tools, ICT solution) or ancillary services and not organisational solutions or processes. Since the latter are solely the responsibility of health care authorities/organisations, organisational innovations are not in the scope of this partnership. However, they may be in the scope of the potential public-public partnership on Health and Care Systems Transformation. Therefore, solutions proposed in the context of IHI could accompany organisational innovations taken up by health care authorities/organisations in the context of the Health and Care Systems Transformations partnership. Moreover, the actual deployment of products or solutions in health care settings remain in the remit of individual health care organisations and in the national competence of Member States according to Art. 168 TFEU.
These specific objectives of IHI will contribute to reaching the ambitious impacts of IHI, spanning the scientific, economic/technological and societal aspects, as explained below:

<table>
<thead>
<tr>
<th>Impact area</th>
<th>Likely impacts</th>
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<tbody>
<tr>
<td>Scientific impact</td>
<td>Strengthened EU skills and capacity in academic and industrial health R&amp;I</td>
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<td></td>
<td>A thriving EU-wide cross-sectoral health R&amp;I ecosystem created</td>
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<td></td>
<td>New R&amp;D paradigms established in areas of unmet public health needs</td>
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<tr>
<td>Economic / technological impact</td>
<td>More productive and globally competitive EU health industries that create jobs</td>
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<tr>
<td></td>
<td>and growth and are able to quickly respond to health threats</td>
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<tr>
<td></td>
<td>Better, safe, effective and cost-effective health technologies, tools and digital</td>
</tr>
<tr>
<td></td>
<td>solutions</td>
</tr>
<tr>
<td></td>
<td>Increased level of public and private investments into strategic unmet public</td>
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<td></td>
<td>health needs, providing the foundation for innovative technologies to address</td>
</tr>
<tr>
<td></td>
<td>these needs</td>
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<tr>
<td>Societal impact</td>
<td>Improved health and wellbeing of EU citizens</td>
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<tr>
<td></td>
<td>Reduced health inequalities and improved access to high-quality health care in</td>
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<td></td>
<td>priority disease areas; thereby addressing unmet public health needs</td>
</tr>
<tr>
<td></td>
<td>Strengthening circular economy and mitigating the negative health impacts of</td>
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<td></td>
<td>climate change</td>
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</table>

**Scientific impacts.** Efforts to integrate the fragmented health R&I efforts within Europe will result in the diffusion of knowledge and exchange of ideas and resources across borders and sectors. Integration of efforts could create efficiencies if stakeholders, especially regulators\(^\text{44}\), HTA bodies and end-users incl. payers, are engaged early on in the agenda setting or innovation process thereby reducing the development of redundant or unrealistic innovations. Over the medium to long term, these efforts could lead to cross-sectoral collaborative networks at both European and global level.

Activities aimed at improving understanding of health and disease as well as integration of R&I activities across sectors is likely to contribute in the short term to the creation of high-quality new knowledge about the mechanisms underlying disease conditions and factors contributing to a healthy status. The new scientific paradigms established as a result could support innovation towards new and better tools and mechanisms to prevent, diagnose and treat health conditions, as well as inform regulatory standards and requirements. Knowledge

\(^{44}\text{In this document, the term “regulators” refers to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified Bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative.}\)
creation and skills development through collaborative projects is likely to lead to strengthening of human capital in R&I.

**Economic/technological impacts.** If the initiative is successful in achieving the specific objectives, health innovations will progress faster towards higher technological levels and, ultimately, to the market. Exploiting data and digitalisation technologies for health innovation will require creation and use of common standards, ethical frameworks and protocols to collect, process and analyse data. Subsequently, better, safe, effective, and cost-effective health technologies, tools and digital solutions will emerge in the short to medium term (please refer to Section 3.1). The development of innovative integrated health strategies will also require the conception of harmonised approaches for evidence generation and alignment/adaptation of regulatory processes. IHI can be expected to generate innovation-based growth in the medium to long term, in both large companies and SMEs, thanks to alternative business models, establishment of new companies and markets, increased productivity and development of new products and solutions. This should also help to increase trade and leverage investment into health R&I by the industry partners, including in areas of unmet need. IHI can make Europe an attractive place to (re)invest in health technology R&I. Taken together, the initiative could contribute to strengthening the competitiveness of Europe’s health industry, a cornerstone of Europe’s knowledge-based economy, to an increased economic activity in the production, distribution and sales of health technologies, and thus serve as a tool for increasing technological sovereignty.

The scientific and economic/technological impacts discussed above will also support the attainment of **societal impacts.** Overall, if successful, the initiative is likely to contribute to improved health for European citizens, expressed as more life-years in good health thanks to more effective prevention, a lower burden of disease, improved patient experience of care, better diagnoses and more efficient therapies. It is expected to constitute an incentive for industry to invest in unmet public health needs: More effective, cost-effective, affordable and easily implementable solutions for health care; would allow more patients to be treated more effectively and potentially with fewer resources thus further reducing operational and financial burden on health systems in the longer term. The scope of the proposed initiative would also cover innovation in manufacturing, including green manufacturing, a circular economy approach to the product lifecycle and the overall environmental footprint, thus leading to a positive effect on the climate and the ecosystem in general.

These general and specific objectives are fully aligned with the European Union’s policies and missions, namely:

- **Horizon Europe specific objectives**, including SDG3 Good health and wellbeing, by driving novel health care innovations improving patient care and wellbeing in unmet public health needs; SDG10 Reduced inequalities, by reducing the burden of disease through the development and distribution of new products and by broadening access to health care by improving the sustainability and efficiency in the system; and SDG 13 Climate action by reduced need to travel thanks to more widespread use of digital technologies and telemedicine.

- **Sustainable Europe by 2030** – the initiative aims to contribute to the resilience of health systems, enhancing health promotion and prevention (including vaccination) and fostering health coverage;

- **Industrial Strategy for Europe**\(^{45}\) – the initiative aims to support health sectors competitiveness, thereby contributing to creating a future-ready economy including resilient and competitive large and small companies. The flow of investment will be directed towards disruptive research and breakthrough innovation;

- **Digital Health Strategy and Smart Health** – the initiative aims to support European Health Data Space and make Europe an attractive environment for health research and development investments including in the field of artificial intelligence and machine learning for ethical and robust evidence for decision making, or the integration of physical and digital systems\(^{46}\).

- **European One Health Action Plan against Antimicrobial Resistance** – the initiative aims to provide industry input, including combinations of solutions, to effectively prevent and address AMR/resistant infections;

- **European Beating Cancer Plan (including the Horizon Europe Cancer mission)** – the initiative aims to implement actions which, by combining 5D (diagnostic, device, data, drugs, delivery), will support development and deployment of effective solutions to defeat cancer alongside other EU funding instruments.

- **Europe Green Deal**: The EC objective of carbon neutrality by 2050 should be considered for both the health care industry and the EU health care systems. The initiative aims to address the challenges of recyclability of products, use of critical raw materials, energy efficiency, organisation of health care, environmental and energy footprint, including green manufacturing.

In health care, many new scientific and technological advancements are either not yet used or underused because of limited translation of scientific findings into products and services, slow adoption (due to e.g. lack of methods to assess new types of interventions and mitigate related uncertainties, need to collect additional evidence to decrease those uncertainties), data analytics failing to reach its full potential, inadequate training and interdisciplinary barriers in medical science or different standards of care.

Although these new advances have transformative potential when implemented properly, integrating these new products and services into medical practice remains challenging. The main barriers include siloed approaches, lack of convergence of regulatory requirements and processes, different sets of standards and evidentiary requirements, lack of appropriate methods to demonstrate the added-value for patients and society, affordability issues, fragmentation of health care services, health care systems that focus on disease management rather than individual health but also lack of readiness of health care systems to embed new technologies. The latter aspect depends, among others, on organisational, structural, financial, regulatory and cultural factors\(^{47}\).

Access to (big) data and information is often seen as a critical enabler to transforming health care. But the potential of (big) data in terms of public health and innovation remains largely untapped due to poor data quality, missing skills and know-how to handle the data, low interoperability and interconnectivity, inconsistent standards, inefficient implementation strategies, lack of validated approaches and methods for processing and analysing this data as well as the cost of analysis. Due to the shared competence on public health between the EU and the Member States, actors within the health care sector face a fragmented policy landscape. While the EU has benefited from a strengthened framework on data protection, uncertainties remain on e.g. on secondary use of health data and de-identification creating additional complexity. For researchers, the biggest challenge is access to meaningful data at a large scale. Furthermore, security, data privacy and ethical considerations as well as issues related to bias must be at the forefront when developing any data analytics tools, including Artificial Intelligence.


\(^{47}\) While solutions to these problems are beyond reach of this public-private partnership, they would fall in scope of the candidate partnership on Health and Care Systems Transformation involving Member States who are in charge of organising their health care systems.
Further leveraging the synergies between big data and digital tools, offers a great opportunity to analyse multiple pathological conditions for many complex diseases, pointing the way towards more precise prevention, diagnosis, treatment and personalised care. This will require co-operation not just within, but across sectors. Please refer to Annex 1 for detailed references and data sources.

The specific objectives of IMI2 JU were to support the development of pre-competitive R&I activities with the aim to strengthen Europe’s competitiveness and industrial leadership and to address specific societal challenges, in particular those to improve European citizens’ health and well-being. The Council Regulation 557/2014 additionally specified that IMI2 JU should focus on priority medicines identified by WHO and increase the success rates of clinical trials.

The proposed initiative is conceived as being agnostic with regard to specific disease areas, while focussing on unmet public health needs. It intends to cover various stages in the health care pathway at which it intends to intervene, including prevention, diagnostics, treatment and disease management. This broadened technological and thematic scope compared to IMI2 JU explains the proposed new name, the Innovative Health Initiative (IHI).

The problems at stake remain valid for both the past (IMI2 JU) and the proposed initiative. However, under IMI2 JU, the problems were related to the process of pharmaceutical development (covering medicines and vaccines). This was also reflected by the constituency of the partnership, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) as the member industry association. IMI2 was able to indeed progress significantly on the underlying problems and successfully deliver on several of its objectives.

However, health challenges constantly evolve - as does R&I available to address them - and therefore, IHI is conceived to operate in a broader manner than IMI, thanks to additional technology areas covered (medtech, biotech, vaccines, digital), rather than pharma only. With this broadening, IHI will address the problems at stake in a more holistic way, capitalising on broadened experience of the new set of (industry) actors and could also focus more on prevention and preparedness. The COVID-19 crisis, and earlier the Ebola and Zika crises, have further revealed the need to address health challenges at multiple entry points, but in an agile and coordinated manner, encompassing data collection and analysis, diagnostics, prevention including by mobile health approaches, development of therapeutics and long-term prevention by vaccination – based on the specificities of the EU health research systems and industrial value chains.

To tackle its ambitious objectives, the following elements will be at the core of IHI:

- **A multi-sector initiative**, including the pharmaceutical and medical technology sectors, which will secure the expertise and active engagement in the development of new healthcare interventions, looking into prospectively planned and technology integration by design, both in individual sectors’ value chains (e.g. to optimise clinical trials in the pharmaceutical sector) and in new integrated health solutions.

- **People and system centric, rather than product centric, goals** – the focus will be the patient and citizen’s journey through health care with the help of converging the needed health technologies

- **Early engagement with public sector stakeholders for definition of priorities** should be ensured by setting up an Innovation Panel, involving all relevant public and private stakeholders from the health care ecosystem. Scientific priorities will therefore reflect the critical input from these stakeholders. This also ensures that IHI projects will better reflects the needs of health care systems.

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48 The actual thematic areas of activities will be further defined in the SRA and the resulting annual work programmes. Please see section 3.1 for further details.
- **The sustainability and impact by design** of the projects will be increased by setting concrete performance and impact targets as part of the projects’ design. This greater understanding of impact will bring more clarity on the follow-up and up-take (in collaboration with end-users, regulators, HTA bodies and payers, and relevant European Research Infrastructures). Synergies with other EU funding programmes (Horizon Europe, Digital Europe and others) will also be increased (see below in this Section).

- **Openness and inclusiveness** will be secured by incentivising and facilitating participation and contributions from investors, e.g. Associated Partners, industries/charities/foundations/others, who are not members of the founding organisations.

- **Operational model designed to enable cross-sector collaboration, diversity of expertise and to invest in pioneering areas of activity**: the funding and in-kind contributions models, as well as application of access rights and other IP rules, will be adapted to encourage the participation of all sectors.

- Clear focus on **translational research or translational research enablers**, including raising the quality and efficiency of activities aiming to deliver “industry grade” **reproducible evidence and assets compliant with regulatory standards governing scientific, regulatory and economic evaluation** of future products, services and their combinations.

**Comparison between IMI2 JU and IIII taking into account lessons from past evaluations**

<table>
<thead>
<tr>
<th>What would continue</th>
<th>What would be different</th>
</tr>
</thead>
<tbody>
<tr>
<td>A European public-private partnership based on Article 187 TFEU.</td>
<td>A cross-sectoral partnership between EU and five health care industry sectors (pharmaceutical, medtech, biotech, imaging, vaccines), rather than only pharmaceutical as in IMI2 JU.</td>
</tr>
<tr>
<td>Programme implementation supported by the dedicated Programme Office.</td>
<td>Thematic focus broadened from pharmaceutical to also other areas of health R&amp;I, including digital technologies.</td>
</tr>
<tr>
<td>The EU holds 50% of the voting rights and contributes up to 50% of the administrative and operational costs.</td>
<td>Better focus on disease prevention.</td>
</tr>
<tr>
<td>Member States (MS) and Associated Countries do not contribute financially.</td>
<td>Governance structure adapted to better incorporate views of various stakeholders involved in health care.</td>
</tr>
<tr>
<td>Member States do not have voting rights in the Governing Board but are represented in the States Representative Group.</td>
<td>All types of actors along the health value chain better involved in priority setting and in funded projects.</td>
</tr>
<tr>
<td>A jointly agreed Strategic Research Agenda based on consultation with all stakeholders.</td>
<td>Governance structure streamlined. A new governance body (‘innovation panel’) brings together representatives of EU and member industry associations as well as various other stakeholders involved in health care, to identify and review potential call topics, ensuring that they adequately address public health interest and needs of end-users.</td>
</tr>
<tr>
<td>Draft calls for proposals are published by the Programme Office, ensuring maximum transparency to all relevant stakeholders.</td>
<td>Scientific expertise is embedded in the</td>
</tr>
<tr>
<td>The partnership strives to attract investment from outside of the EU from entities being part of founding Member associations. Part of these contributions could be matched by EU funding. The partnership strives to attract investment from other actors,</td>
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*Working ideas that need further discussion between future partners and validation in the legislative act or any other documents laying down the functioning of the partnership (e.g. statutes, rules of procedure of individual governance bodies etc).*
Horizon Europe offers a great opportunity to create an integrated research continuum that enables activities addressing various facets of the same problem in the different funding instruments. This “pipeline” approach would make the progression of assets through different stages of development easier – it would also encourage the selection of the most appropriate funding instrument in relation to the foreseen objectives. Health and health technology related partnerships are probably the best place to start and test these synergies, in particular:

- **European Partnership on Health and Care Systems Transformation**, facilitating the uptake of innovative health solutions so as to improve the quality of delivered health services and to support the sustainability of health care systems. The Innovative Health Initiative will contribute to developing innovative health products, services and tools, as well as methods to assess their added value, while the candidate public-public partnership (with Member States) on Health and Care Systems Transformation will develop methods and identify organisational innovations needed to facilitate rapid implementation of those health products, services and tools into health care systems. Conversely, the Health and Care Systems Transformation partnership could formulate the needs of the health care systems so as to inform the R&I activities pursued by IHI. To achieve good complementarity between the two partnerships, the right mechanism would need to be created to ensure that research priorities defined in IHI would meet the public health and health systems needs identified in the public-public partnership. In return, health systems research carried out in the public-public partnership would address implementation challenges relevant for IHI.

- **European Partnership on Key Digital Enabling Technologies (KDT)**: The shared objective is the delivery of technology that can be used in a highly regulated biomedical environment. The foreseen extension of ECSEL’s scope to a larger number of key enabling technologies like robotics and information technologies offers new opportunities to better direct KDT towards technology that addresses the needs of the health care market and testing these solutions in an integrated context in IHI.

- **European Partnership for Photonics** may create synergies with IHI, e.g. in the technological aspects of –omics that can be used in identifying the molecular determinants of diseases, or with the development of imaging tools that can be useful e.g. for diagnostic purposes or treatment monitoring. IHI might offer test cases for the use of such technologies in clinical applications.

- **European Partnership for Metrology**: IHI may design innovative in-vitro diagnostic approaches for consideration as state-of-the-art standards or technologies of measurement useful for health applications.

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50 “Assets” may be e.g. new drug or diagnostic candidates, drug targets, biomarkers, health research tools, clinical trial methodologies, industrial processes, services etc.

51 It is important to emphasise that solutions proposed by IHI would be concrete goods or services (e.g. medicines, diagnostics, medical devices incl. digital tools etc) rather than organisational solutions. Organisational processes will be in the remit of health care authorities/organisations to consider whether and how these could be deployed in the best way.
- **European Partnership for Smart Networks and Services**: The shared objective is to enable effective collection and processing of data in real time. A similar relationship to the one with KDT (above) can be envisaged with the potential new European partnership on smart networks and services that follows on, among other initiatives, the 5G PPP, whenever connectivity challenges (speed, latency) emerge (of particular relevance in the digital health area).

- **EU-Africa Global Health Partnership**, aiming to increase health security in sub-Saharan Africa, and globally, by reducing the risk of outbreaks, pandemics or antimicrobial resistance. Infections can serve as test cases in the innovation process, including ethics and regulatory issues, which may be applicable in other health areas. Some solutions developed in IHI, for example those related to novel diagnostics or to feasibility of new clinical trials methodologies, could be relevant for, and potentially deployed at large scale in clinical trials financed through the EU-Africa Global Health Partnership.

- **European Partnership for Personalised Medicine (building on ICPeRMed and ERA PerMed)**: The objective shared by IHI with these initiatives is to enable delivery of personalised patient centric interventions. IHI will offer the possibility of taking up the research results developed in personalised medicine initiatives and putting them to work in the context of a cross-sectoral industry collaboration.

- **European Partnership on Rare Diseases (continuation of IRDIRC)**: The shared objective is to accelerate development of new patient centric solutions and enable early intervention in particular diagnosis, treatment, patient support and disease management. IHI could tackle those aspects where the close collaboration with industrial sector is beneficial.

- **European Partnership on One Health / AMR (building on JPIAMR)**, with the objective of contributing to preventing AMR. The activities of the two initiatives will be complementary, with IHI concentrating notably on the patient stratification in primary care, while One Health AMR taking a global approach to AMR in a broad variety of areas.

Interaction with other partnerships will take place at the Innovation Panel and/or meetings between partnerships (see 3.3 Governance).

Additional synergies would also be sought with the following initiatives and instruments:

- **Digital Europe Programme**: wherever large-scale deployment of products and services piloted in the Innovative Health Initiative would be envisioned.

- **European Regional Development Fund**: wherever their objectives converge in the fields of infrastructure of innovation, digital agenda, SME support, etc.

- **EIT Health & EIT Digital**: Knowledge-sharing and capacity building are shared objectives, as is the public-private nature of EIT collaborations. This offers the opportunity to operationalise the “pipeline approach” - moving assets between projects as done between IMI2 and EIT today. EIT Health through its education, training and entrepreneurship driven activities can complement the Research and Innovation activities that the Partnership would fund. The collaboration will thus support the deployment and dissemination of new solutions.

- **Mission on Cancer**: the shared objective is to align the developments in cancer prevention, prediction, detection, diagnosis and treatment including clinical expertise in these areas.

Synergies will also be sought with other Horizon Europe initiatives (EIC, ERC, etc.) as well as other EU programmes and actions, such as ESIF (in particular ERDF and ESF+), InvestEU, RSP, and notably those relevant for digital technologies (such as Robotics, Artificial Intelligence, High Performance Computing) to further support innovation pipelines.
No co-financing between this Partnership and other programmes is foreseen at this stage.

The proposed Partnership secures Europe’s future competitiveness in a world where technologies are changing rapidly and where solutions need to be brought together from all stakeholders in the value chain. Europe R&I has a long and renowned tradition of collaborative research, which provides a unique set of competence and skills all along the health care value chain. The Partnership offers a unique opportunity by driving multi-sector collaboration to accelerate the development of people-centred health care innovations in areas of clear unmet public health needs.

The Partnership will advance science and develop innovative health solutions by sharing expertise, resources and knowledge among academia and industrial players in respecting each other’s prerogatives. It would also contribute to bringing innovation to the health care systems and to increase their efficiency.

The Partnership will contribute to strengthening the competitiveness of Europe’s health industry, a cornerstone of Europe’s knowledge-based economy and a tool for sovereignty, by bringing in new business areas and lowering the risk of investing in the development of new products and services. It is likely to yield efficiency gains and to shorten the time-to-market of innovative products and services. It could directly and indirectly create highly skilled jobs, both in academia and industry. All that will help Europe recover from the economic impact of COVID-19, increase the EU technological sovereignty and create a more resilient health R&I ecosystem.

The Partnership’s activities are likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health, a lower burden of disease, improved patient experience of care, better diagnosis and more efficient therapies. It is expected to constitute an incentive for industry to invest in unmet public health needs, such as brain disorders or patient stratification in primary care in case of infections. Moreover, the Partnership could contribute to the fiscal sustainability of health care systems, address some of the challenges experienced by health care professionals and informal carers, and make innovative health interventions accessible to a broader population. Its contribution to improving the health of EU citizens will also translate into economic gains.

The Partnership will support delivery of innovative products services and tools (and their combinations) that meet people and health care systems' needs. These new solutions will facilitate early interception of disease, deliver new precision and personalised care while providing methodologies to assess the added value of health care innovation (both in terms of health and economic impacts) to optimise health care resource allocation. The Partnership will contribute to breaking silos with a view to providing people-centred continuous care even before disease occurs.

The Partnership is expected to unlock the value of data in integrating technologies and knowledge to create better knowledge, products and integrated solutions. Overall, this would promote Europe’s leadership in the digital health space. Harmonised interoperable data and widely implemented advanced analytics/artificial intelligence will contribute creating more accurate and/or rapid detection, diagnosis and treatment, leading to improved outcomes for patients. Health care providers and professionals will benefit from a better use of artificial intelligence to support decision-making. Not only can it increase the accuracy of diagnosis and efficacy of treatment, but also improve the efficiency of providing information quickly. It will be accompanied by education programmes to facilitate the uptake of AI technologies by health care professionals.

The Partnership will aim to support people-centred care by enabling solutions and products to empower citizens and patients so as to help them play a stronger role in their own care. This should materialise through improved informed shared decision-making with their health care
providers, self-management of their treatment and health, as well as collaboration in research design and conduct. The Partnership will concentrate on involving patients and citizens from the conception of new health solutions to their development and implementation in health care systems taking into account people’s needs and preferences. This will include co-design, development and testing of tools to facilitate patient engagement in R&I activities, methods and tools to support shared decision-making with health care professionals, tools to enable more efficient self-management of disease and health. The Partnership will systematically seek early input from patients into the definition of work programmes and call topics. A people-focussed approach is believed to benefit not only patients but all service users, health care professionals and the health care system more broadly. Collaborating with citizens and patients is already leading to better trials, better engagement, better communication throughout the entire life cycle of medicines, better prevention and ultimately better patient outcomes.

The Partnership will contribute to preparing the ground for evidence-based methodological approaches in Europe [disclaimer: discussions ongoing on the exact scope and terminology in this respect], thereby helping health systems in Europe become long-term sustainable, as well as contributing to the EU level goals of effectiveness, accessibility and resilience. In collaboration with academia, public authorities and health care systems, IHI would develop methods and tools for health systems decision makers to evaluate patient pathway designs and complex health care solutions in terms of impact on patient and population health as well as economic impact so as to better inform resource allocation.

The Partnership will contribute to facilitating implementation of innovative products and services delivering clear benefits to health actors including patients, health care professionals and providers, in particular by developing ancillary tools and services that might help the seamless introduction of those innovations in health care settings and by developing methods to assess the added value brought by those integrated products and services in terms of health outcomes and economic impact. This would in turn allow the EU to remain a preferred area for the health industry to bring innovation to market, and will contribute to improved access to innovation for EU citizens. The common approaches to measuring outcomes and assessing value of combinations of products, services and tools across sectors would inform future developments of HTA models, allow better identifying high-value health care interventions, and informing disinvestment in low-value care. These common approaches would also lay the grounds for business models for prevention and disease interception.

The initiative will facilitate collaboration between many different health care system stakeholders (including citizens and patients, providers, regulators, HTA bodies, payers, policy and decision makers, the industry) to address the challenges health care systems and society are facing. This will imply a widespread understanding of the societal and economic value of investing in health care. Already, several health authorities have introduced policies and changed practices driven by a people-centred approach based on the evaluation of the added value brought by health innovations to patients and society. The EU can accelerate this change and foster innovation that will support future economic growth and social cohesion. Lastly, it should lead to better care, and improved lives and wellbeing for citizens and patients.

IHI is designed as a self-standing programme, with the last calls published until approx. 2027 and projects continuing until approx. 2032-2034. The IHI Office is foreseen to function fully staffed until approx. 2031. Beyond that date, the monitoring of still running projects will be ensured either by the IHI office functioning in a limited composition, or by the relevant EC services (including by a relevant EU agency), or by the office of a potential follow-up partnership (if established), depending on decisions taken horizontally for the whole portfolio of institutionalised partnerships.

Each IHI project will be expected to develop a business plan for winding down operations or continuation without further or additional Framework Programme funding after the project’s
end, including a plan for sustainability and continuity of exploitation and dissemination activities beyond formal duration of the EU-funded project. A potential avenue for enhancing sustainability would be offered by Horizon Europe and its synergies with Structural Funds.

The preferred option will be taking up the developed assets and exploiting them - including in internal processes – when relevant or possible by industrial partners (incl. SMEs), academia, health care providers etc as who were project beneficiaries, in line with the relevant intellectual property right provisions (assets are defined as processes, standards, diagnostic tools, drugs or drug candidates, biomarkers etc that can be shown to have reached a significant milestone in the development). Certain assets are likely to be made available beyond the consortia partners, with or without fee, and these could be, e.g. databases, biobanks, in silico tools, training materials, clinical trial networks, SOPs, guidance documents, etc. If needed, the further development of assets may be continued by making use of other programmes at national or European level, or may equally involve any further partnership(s) in health, if any such a partnership is set up.

SRIA drafting process

A Strategic Research Agenda (SRA) is under preparation (its earlier version can be found at www.EUhealthPPP.org). The process of developing this agenda involved several stages:

- Initial reflection and analysis of gaps and opportunities conducted within the Industry and then with the European Commission (including based on the open public consultation on the Inception Impact Assessment, held between 30 July and 27 August 2019).
- The early ideas about scope, impact, outputs were consulted by the industrial partners with several test audiences - learned societies, research communities and main universities in several European countries umbrella patient organisations, etc.
- Preliminary draft was open for industry-run public consultation for one month (23 Oct – 24 Nov 2019) including a public webinar (4 Nov 2019). Both the consultation and information about the webinar and its outcomes were broadly publicised through (social) media. All input received is going to be made available on the consultation website, EUhealthPPP.org.
- Additional targeted consultation was held on the basis of the SRA draft in Q4 2019.
- The next SRA revision integrating comments from the public consultation will be prepared in 2020. It is expected that the draft will continue to evolve as more information about the scope of other European programmes and partnerships become available to more precisely delineate the type of activities that should be prioritised in IHI.
- The SRA will be reviewed on the occasion of the Partnership interim evaluation.

2.3 Necessity for a European Partnership

While problems such as an ageing population and increased disease burden will most probably not decrease as a result of EU action, their impact may be ameliorated through EU-supported R&I activities. The problems described are of a nature and magnitude that individual member states developing their own initiatives cannot solve. Concerted action at EU is the most appropriate option. This will allow more coherence and coordination of effort, and avoid duplication. A partnership under the aegis of the EU and the founding members of IHI would create a trustful environment for sharing expertise, resources and knowledge.

EU action is required for the following reasons:

- Current health challenges and threats are global, respecting no borders. They call for a quick and coordinated response, while health research capabilities and data are dispersed over Europe. Similarly, health R&I is increasingly a global endeavour. An EU level action would
be able to accomplish co-ordination of multiple and varied stakeholders more effectively and efficiently than individual states, thus enabling activities that will meet the planned objectives.

- Effective engagement and cross-sectoral collaboration within the health-related industry requires mobilising a very broad range of companies and other stakeholders with relevant expertise, knowledge and resources as well as patients and health care professionals, based across Europe. No Member State could mobilise these stakeholders and companies individually and reach the required critical mass of expertise and data necessary to tackle the challenges at stake.

- Most health-related companies operating in the Member States have an EU-wide presence and are governed by EU-wide legal frameworks e.g. for medicinal products, medical devices and cross-border health care. Therefore, it is logical to have a partnership focused on innovation in health at the EU level too, thereby pooling resources and expertise, and reducing duplication. Moreover, the EU is best placed to develop and implement common standards and frameworks related to health innovations applicable for the entire EU internal market.

- No Member State alone would have the legal and financial framework as well as the programme management experience to enable a multi-sectoral collaboration at the scale envisaged. Where public-private partnerships exist in individual member states, these are more limited in scope and/or scale.

**Directionality.** Compared to projects that would be enabled by Horizon Europe, a partnership will much better secure participation from several industrial sectors and implement activities needed for technology convergence. A jointly agreed R&I agenda will align with the industrial partners’ strategies, as will the Annual Work Programmes and topics published by IHI. Industry participation would help to drive public stakeholders’ research efforts towards the common objectives and applicable health innovations. This drive towards reaching the agreed objectives will be supported by the Innovation Panel (see below) safeguarding the strategic direction of call topics implementing the SRA (supporting the Governing Board who will be the only decision-making body of IHI). All this will ensure that the resulting IHI projects address real unmet health needs and deliver innovations that have more chance of being taken up by health care systems. While Member States did not express interest in contributing financially to the operational activities of IHI, they will still provide opinions and advice during the preparation of call topics via the States Representatives Group (see section 3.3 Governance), thus contributing the reaching the overarching policy objectives.

All founding members commit at the onset of the Partnership to drive the Partnership forward over its entire timeframe, which is particularly important in health research with its long development timelines. The SRA (to be approved at the first meeting of the future Governing Board) will ensure close alignment of research agendas to achieve a high-level of focus and strategic steer (directionality) to meet the strategic unmet public health needs.

Implementation of the SRA and joint progress to reaching the objectives will be supported by the Programme Office, offering high quality programme management and targeted communication capacity – including corporate IHI branding – by staff experienced in delivering such ambitious initiatives, thus providing value for money and further increasing impacts.

In line with Horizon Europe’s stated EU Added Value\(^{52}\), a European Partnership for Innovative Health would have the potential to contribute to the following:

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\(^{52}\) Horizon Europe Impact Assessment. A New Horizon for Europe. DG RTD (2018)
• The creation of critical mass to address global challenges
• Building multidisciplinary transnational networks for more impact
• Increased coordination across public and private actors and across Member States especially through the States Representative Group and its inclusion in the Innovation Panel.
• Increasing the EU’s competitive advantage vis-a-vis major competitors
• The creation of new market opportunities through collaborative multi-disciplinary teams and dissemination of results
• Leveraging private investment

Ultimately, an EU-level action will benefit all Member States and their citizens, bring about pan-European long-term structural improvement.

**Additionality.** The founding members (both private partners and the EU) commit to provide the resources for the initiative over its whole duration.

The Union’s contribution to the initiative will attract additional private sector contribution (in-kind or financial) that the industry would not have otherwise spent in strategic unmet public health areas or in cross-sectoral collaboration. This direct investment can be strengthened by activities accounted for as in-kind on additional activities (IKAA), whose level remains to be decided in the future. The total contribution made by industry associations via their members and by Associated Partners will represent at least 50% of the Partnership’s budget.

This type of commitment and pooling of resources only happens beyond the horizon and scope of individual projects and requires long-term predictability and commitment to the joint research agenda. Another pre-requisite for such an important additional investment is that industry partners have a role in co-developing and executing the SRA and Annual Work Programmes, including in programme supervision (via membership in the Governing Board with voting rights) and in communications. All these conditions are fulfilled if IHI is implemented as an Institutionalised Partnership.

### 2.4 Partner composition and target group

The initiative needs to involve all type of actors along the health value chain in priority setting and in funded projects:

• Key actors: researchers from academia and various industry sectors, to ensure the best opportunity for generating new scientific ideas and successful R&I activities;
• Users: patients and citizens, health care professionals and health care providers to provide input into the strategic design and activities of the initiative, ensuring that it addresses the needs of end-users;
• EU-wide and national regulatory authorities, HTA bodies, and health care payers to provide early input to the activities of IHI; given that health products and services are subject to evaluation of safety, effectiveness and in many cases, cost-effectiveness before being placed on the market, this early input would help avoid wasted research and would increase likelihood that the results of IHI actions will meet regulatory requirements necessary for uptake and thus for reaching societal impacts.

For details on links with other Partnership candidates and Union programmes, please refer to Section 2.2 above.
The Partnership will build on its founding members’ networks: the five trade associations represent directly and indirectly (though their associations and their members and affiliates) several thousands of health industry companies.

All partnering sectors have also developed collaborations with their upstream and downstream stakeholders including suppliers/service providers of industry (e.g. academic and clinical research, users of products and services). The initiative will encourage building upon these relationships and evolving the nature of their operational and business models.

The Partnership will build on an impressive number of already established networks. Examples include the 150+ IMI projects with more than 7000 partners, 63 projects funded under ECSEL with 6500 partners, other European partnerships and projects (e.g. Big Data PPP, ESTHER, NOBEL), RTOs, medical- and learned societies as well as hospital networks performing clinical trials and investigations.

The integrated and translational research solutions will heavily rely on research infrastructures. Early engagement with established pan European networks (such as BBMRI, ELIXIR, EATRIS, ECRIN, ERNs, etc.) as well as European Flagship Initiatives (such as the Human Brain Projects and networks set up to define roadmaps for the Human Cell Atlas, digital twin, etc) may dramatically accelerate the implementation of R&I actions.

In addition to the European Commission, the founding partners will include associations representing the pharmaceutical, biotech, vaccines, medical technologies and medical devices across Europe. The member industry sectors will be represented as follows:

- Pharmaceutical and biopharmaceutical companies will be represented by EFPIA (European Federation of Pharmaceutical Industries and Associations - www.efpia.eu). Through its direct and indirect membership EFPIA is the voice of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world. In 2018, the sector invested an estimated € 36,500 million in R&D in Europe. It directly employs some 765,000 people in Europe (of which 115,000 in R&D) and generates about four times more employment indirectly – upstream and downstream.

- The vaccines industry will be represented by Vaccines Europe (VE), covering major innovative research-based global vaccine companies as well as small and medium-sized enterprises operating in Europe. Vaccines Europe’s members invested € 2 billion in R&D spending globally in 2014 (of which 71% was invested in the Europe, covering 13 sites).

- Biotechnology companies will be represented by EuropaBio (the European Association for Bioindustries - www.europabio.org). EuropaBio represents 81 corporate and associate members and bio regions, and 15 national biotechnology associations in turn representing over 1800 biotech SMEs at a Member State level. The three main segments of Biotechnology are represented through sectoral councils: Health care (Red Biotech), Industrial (White Biotech) and Agri-Food (Green Biotech).

- Medical technology companies comprising medical devices, diagnostics and digital health will be represented by MedTech Europe (www.medtecheurope.org). MedTech Europe’s purpose is to make innovative medical technology available to more people, while helping health care systems move towards a more sustainable path. MedTech Europe is the voice of 130+ international companies and 50+ national association representing 27000 SMEs and start-ups, in 33 countries. Products typically have a lifecycle of only 18-24 months. Medtech is at the forefront of innovation with 7.9% of all patent files with the European Patent Office.

- Medical imaging, radiotherapy, health ICT and electro-medical companies would be represented by COCIR (European Coordination Committee of the Radiological, Electro-medical and Healthcare IT industry - www.cocir.org). COCIR covers 4 key industry sectors: Medical Imaging, Radiotherapy, Health ICT, Electromedical equipment. This industry leads in state-of-art advanced technology and provides integrated solutions covering the complete
care cycle. COCIR members invest on average 8% of annual revenues in R&D, with a strong in-house R&D capacity (up to 1/3 of Europe-based employees). The industry invests mostly in incremental but also radical / disruptive innovation, with innovation cycles of 1 to 7 years. This industry sector is diverse, with start-ups, SMEs, and large companies.

The Partnership will furthermore seek the involvement and contributions from companies beyond its direct membership as well as non-industry contributing members, such as foundations, charities or other non-profit organisations:

- Their participation as founding member would require that such new members are able to significantly commit to the Partnership at programme level.
- However, in order to incentivise the participation of such non-industry organisations, an Associated Partner status is planned to be offered for their participation at a topic or project level: this would allow their in-kind contribution to be acknowledged and matched with EU funding. The IMI2 JU provides a clear and recognised example of how Associated Partners can contribute to projects.

To deliver its expected impact all along the value chain of health care, this Partnership will mobilise and cooperate with a broad range of stakeholders, representing a diversity of expertise, knowledge and resources across Europe:

- The national or regional health care systems actors (e.g. regulators, HTA bodies, payers);
- The health care providers (hospitals, clinics, home carers);
- The health care professionals and informal carers;
- The patients and consumers organisations;
- Academia including research & technical universities, university hospitals and clinical research centres;
- Research and Technology Organisations;
- Learned societies;
- Pan-European research infrastructures.

Input from key stakeholders will be sought at all stages of ideation and implementation cycle:

- **Priority setting**: co-creation at scientific planning process in an open, transparent and sustainable way could be achieved through an “Innovation Panel” involving representatives from key stakeholder groups and enabling early interaction and co-design of the annual priorities, supporting decisions taken by the Governing Board (cf. section 3.4 - Openness and transparency).
- **Implementation of projects**: implementation of actions would require public private collaboration and participation of upstream innovators and downstream users from all sector from groups mentioned above.

The link with **Member States** will be ensured by the State Representative Group, which will include national representatives from ministries of research, health or industry/economy, as appointed by each individual country.

The partnership should be able to attract and partially match with EU funding the contributions from outside of the EU - both to incentivise participation of global players (public and private) to Europe-led projects, and to create a critical mass and diversity of data which will directly benefit European research and innovation actors, patients and health care systems.

This in turn will translate into increased attractiveness of Europe in terms of investments and conducting research by:

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53 A list of IMI2 JU associated partners is available at: [https://www.imi.europa.eu/get-involved/associated-partners](https://www.imi.europa.eu/get-involved/associated-partners)
- collaboration between non-EU industry branches with EU scientists on the development of cutting-edge technologies and science will further establish EU academic sites as centres of excellence with global acclaim and will therefore attract increased levels of funding and enable generation of spin-off companies in Europe;

- increased cross-fertilization of ideas and research relationships between world-wide industry partners and EU academic centres, SMEs, etc;

- preventing the perception of building barriers around Europe regarding the flow of knowledge, sharing expertise, and skills which may put the EU scientific community at a significant disadvantage in terms of leveraging global knowledge;

- increase the technological sovereignty and research capacity of the EU, making it more agile to provide an R&I response to emerging health threats, such as COVID-19.

The Partnership will strive to attract expertise and in-kind contributions from philanthropic or funding organisations that are very often operating at the global level. As an example, some key IMI2 JU projects gained a major added value via the participation (as Associated Partners) of organisations such as the Bill and Melinda Gates Foundation, ERA4TB, the Juvenile Diabetes Research Foundation, SFARI, Autism Speaks, or the Children’s Tumour Foundation. Many companies are currently seeking global collaborative opportunities through both private and public pre-competitive consortia. In the end, this will lead to increased collaboration and support of emerging SMEs.
3 Planned Implementation

3.1 Activities

With the goal to accelerate the development of safer and more effective health care interventions that respond to unmet public health needs, and that can be taken up by health care systems, the initiative will focus on cross-sectorial approaches for the creation of new products and ancillary services to prevent, intercept, diagnose, treat and manage diseases and aid recovery more efficiently. Hence, IHI will have the following operational objectives:

1. Deliver cross-sectoral R&I projects for the development of people-centred, integrated solutions and progress understanding of the determinants of health and disease;

2. Improve skills for cross-sectoral health innovations and increase involvement of patients and citizens in the generation and implementation of health innovations in Europe;

3. Create a platform for R&I collaboration in health as a safe, pre-competitive space for brokering knowledge exchange, sharing ideas and resources across the various actors in the health care pathway (e.g. academics, health industry sectors, regulators, HTA bodies, health care professionals and providers, payers, patients, informal carers, and citizens);

4. Develop tools and mechanisms to enable better access, sharing and analysis of health-related data, e.g., ethical frameworks, common standards and protocols;

5. Develop methodologies and tools that would generate high quality evidence and help better assess the added value (for patients, health care systems and societies) of cross-sectoral health innovations and people-centred, integrated health care solutions, and that would facilitate their implementation in health care systems;

6. Deliver pilots and small-scale demonstration projects to test implementability of tools, models, methodologies and innovations generated by the initiative.

These operational objectives will all contribute to reaching the specific and general objectives, as presented in Section 2.2 “Common vision, objectives and expected impacts”.

All IHI activities will have to consider the different innovation cycles of pharmaceutical and medical technology industries. While the R&I processes towards novel medicines are complex, lengthy and highly regulated, the development of medical technologies and digital solutions can be much faster. Therefore, pre-competitive activities will be primarily addressed, including demonstration pilots. IHI will cover a variety of health technology domains and therapeutic areas, with activities including but not limited to:

- discovery;
- development and testing;
- post launch studies supporting e.g. development of methodologies for assessment of safety; health outcomes or for health-economic evaluation;
- pre-standardisation activities;
- regulatory science;
- pilots/proof of feasibility.

A majority of activities will be cross-sectoral, thus reflecting the integrative nature of the partnership. The cross-sectoral activities should enable overcoming barriers such as the lack of collaboration of companies active in diagnostics and therapeutics development, or the current extremely scattered nature of large health data sets.

The operational activities will represent the implementation of the SRA, following open calls for proposals. These actions are to be performed by consortia consisting of legal entities that are part of one of the Member associations of the Partnership (at the moment of writing:...
COCI, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe), Associated Partners, and legal entities which do not belong to any partner of the partnership, but are located in the EU or in a country associated to Horizon Europe. By nature, the actions are supposed to be at the pre-competitive level, not infringing EU competition- and state-aid rules. The entities expected to perform the actions will hence be principally private companies, private or public research organisations, universities, governmental and non-governmental organisations, associations active in health area (e.g. patient associations) or regulatory bodies.

The proposed partnership is set to work in the pre-competitive R&I area of unmet health needs and as such will aim at fostering collaborations between public and private stakeholders in order to accelerate the development of health innovations.

Nevertheless, projects where late phase product development is conducted, will also address uptake, value, affordability of and equitable access to the resulting health innovations across Europe. The implementation modalities will be further discussed between the Commission and the industry associations during the preparation of the legislation for the initiative.

The call topics will be based on the SRA and reflect the scientific priorities/workplan as suggested by the Innovation Panel and decided by the Governing Board. The focus of the call topics on unmet public health needs is to be warranted by the inclusion of the relevant services of the EC, the representation of MS and public institutions and agencies.

To select focused areas for support by the partnership, two criteria will be considered: (1) the high burden of disease for patients and/or society due to the severity of the disease and/or the number of people affected by it, and (2) the high economic impact of the disease for patients and society.

Initially the areas of focus will be based on essential areas recognised by WHO/Europe as being of major importance for public health, subject to adaptations as needed during the Partnership’s lifetime.

Compared to the activities implemented by IMI2 JU under Horizon 2020:
- The scope of IHI activities will be broader, including the areas of medical technologies, imaging, vaccines, ATMPs and digital technologies;
- IHI activities will engage a broader set of participants in terms of company sizes as Member industry associations and their national member associations will bring in small- and medium enterprises, in addition to large companies;
- The composition of consortia will be different, thanks also to partial reimbursement of costs of industry participants;
- The activities will more directly respond to the future needs of end-users, such as patients and health care professionals, thanks to increased openness of the initiative and to better involvement of these stakeholders in the definition of scientific priorities and of topic texts.

With this inclusive process, IHI would address clear public health needs, increase the uptake of innovations by better reflecting the needs of the end-users and fulfil industries’ expectations in terms of return on investment in the early phases of research.

Set in the context of the Horizon Europe Pillar 2 Cluster “Health” objectives and challenges, IHI is part of the proposed R&I interventions that aim at addressing the challenge “Maintaining an innovative, sustainable and globally competitive health industry”. The Partnership will be operating in connection with several other relevant initiatives at various levels (listed in Section 2.2), so that synergies can be strengthened and duplications and waste in research minimised.

These other initiatives provide in some cases useful input to the Innovative Health Initiative and in others a fertile ground for taking up its expected outputs and results. In the Health Cluster, the strongest link to be established is with the candidate partnership on “Health and Care Systems Transformation”. As one of the main objectives of this Partnership with Member States is to develop methods and tools to facilitate implementation of technological innovations in health care systems, this initiative is essential for the Innovative Health Initiative in two ways: 1) by providing inputs for research priorities setting and 2) by acting as a catalyst for transferring developed solutions into clinical settings and ultimately health care systems.

Other closely-related initiatives are foreseen such as European Partnerships on Personalised Medicine, Rare Diseases and One Health – AMR or the ERA for Health research. The EU-Africa Global Health Partnership has a distinct, clearly defined geographical focus, nevertheless, the results of the Partnership have relevance to health security in Europe. More peripheral but important related partnership areas include Chemicals Risk Assessment and Animal Health (outside Cluster Health). Another complementary partnership is EIT Health that aims to implement health products into local and national health economies through knowledge exchange and promoting entrepreneurship.

Outside of the Health Cluster, the IHI focus on overcoming barriers that prevent exploiting the full potential of digitalisation and data exchange implies it should establish strong collaboration with the candidate Institutionalised Partnership for Key Digital Technologies\(^{55}\). Under the MFF 2021-27, the Digital Europe Programme is expected to continue to finance the deployment of cross-border exchange of patients’ health records (started under CEF Telecom programme) in the EU and deploy and expand the Cross Border eHealth Digital Service Infrastructure (eHDSI) as a leading reference to set up international standards. The Digital Europe Programme may offer opportunities to deploy and upscale the digital health solutions initiated by IHI at the level of pre-competitive collaborations, for example in the area of modernising the public health services or advancing digital skills for health and care professionals.

Duplication of efforts with other partnerships will be avoided by consultation and direct representation in the IHI Innovation Panel of representatives of other relevant initiatives, on permanent or ad hoc basis (discussions ongoing at the time of writing). Scientists members of the Innovation Panel are expected to provide information on major ongoing initiatives in the respective technological or disease areas. Finally, all draft topic texts will be consulted with the relevant services of the European Commission. This will ensure that Work Programmes are complementary. Where necessary and feasible, joint calls may be launched. Especially the health care systems / user perspective is valuable to ensure that the conducted R&I is relevant, and results are taken up.

The IHI Programme Office would lead all coordination activities to ensure internal coherence and complementarity of activities, from developing work programmes and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe.

The cross-sectoral membership composition of industry associations will not only be reflected at Partnership level but also at consortium level of the implementing actions. This will strongly reduce the risk of overlap or duplication of efforts with activities undertaken elsewhere under Horizon Europe collaborative projects, given that the involvement of large companies in H2020 collaborative R&I actions been limited so far. Another safeguard for the avoidance of overlap with other Horizon Europe initiatives is the funding model, which is different from collaborative actions and other types of EC grants, but harmonized among all public-private partnerships under Horizon Europe. The proposed unique model for pre-competitive, multi-partner collaboration is not offered by any other EU funding instrument.

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Up-take of results will be supported by a number of elements:

- The involvement of health care system representatives, health care professionals and patients will ensure that results meet the needs of users;
- Close collaboration with the candidate partnership on Health and Care Systems Transformation will facilitate the rapid up-take of solutions;
- Advisory groups including ad-hoc workshops will support dissemination of results generated in previous projects when formulating new topics;
- Valuation of in-kind contributions on additional activities (IKAA) will incentivise companies to implement results from projects;
- Impact measurements will be developed to follow up on the up-take of results in R&I, and in clinical and regulatory practice (as far as feasible);
- The funded projects will feed into the standardisation efforts (e.g. data standards, guidelines, etc.)

Integration of research outputs into industrial practice is ultimately dependent on the proposed operating model and governance system and the speed at which innovations can be developed and deployed. A robust and flexible operating system, will ensure consortia are able to follow emerging science and develop robust outcomes that will be integrated into public research strategy, industrial process and health care systems and ultimately to patients.

The States Representatives Group (composed of representatives of relevant national ministries) will be consulted on the call topic ideas and text and will provide advice on potential complementarities and overlaps with relevant national initiatives. The SRG members will need to ensure the flow of information at national level among the relevant stakeholders, notably the relevant ministries (such as the ministries of health, research or economy) or agencies (e.g. for research funding), as appropriate for the way of organisation of health R&I in a given country. The SRG Chair will have a seat in the Innovation Panel. This will make the MS voice heard both at the level of IHI strategic orientations as well as in verifying the resulting topic texts. The regional or national authorities relevant for IHI are those involved in – broadly speaking – the organisation of health care or reimbursement decisions. They would be represented in IHI governance either indirectly via the SRG representation, or directly via a seat in the Innovation Panel (see section 3.3 Governance).

### 3.2 Resources

The Partnership requires a robust and flexible financial and funding model that is operationally faster and more agile, inspired by the lessons learned from current Joint Undertakings that will bring the associations together in the best way to create ground-breaking research & innovation.

The overall budget and commitment by founding members other than the EU will be determined by several factors:

- The multiannual financial framework 2021-2027;
- Scope of the final Strategic Research Agenda;
- Definitions of
  - in-kind contributions to operational costs (IKOP) in projects,
  - in-kind contributions on additional activities (IKAA),
  - in-kind contributions from outside the EU and their eligibility for matching with EU funds;
- Details of the governance structure and operational model;
- Funding rates applicable to entities participation in projects.
Resources contributed by the private partners will consist of the following elements:

1. In-kind contributions to operational activities within IHI projects (IKOP, calculated on the basis of non-reimbursed eligible costs); the reimbursed part will have a ceiling; IKOP performed outside the EU will be limited by an overall ceiling.

2. In-kind contribution to additional activities (IKAA, described in an annex to the Annual Work Programme), contributing to the objectives of the initiative and to the implementation of the SRA. IKAA will be incurred by individual companies contributing to the objectives to the initiative.

3. Financial contribution to the administrative costs of the IHI Programme Office, proportionally to the overall contribution of members of each industry association to the programme.

4. Financial contributions that could be provided on a voluntary basis:
   a) to IHI JU, thus implementing the model of the central management of financial contributions,
   b) directly to identified projects (to one or several identified beneficiaries receiving funding and/or specific project activities, continuing the model existing in IMI2 JU – pending further discussion).

[Details and ceilings under discussion between industry and the Commission.]

The industry partners will commit to in-kind contributions to operational costs. **In-kind contribution is the condition for collaborative projects where participants provide unique assets and expertise.** Contributions from participants, in particular industry partners, are aligned with and contribute to the projects’ objectives. In-kind contributions bring significant and differential skills and expertise of industrial know-how and efforts, from which academics, health and care actors and SMEs can benefit. They are critical to enable a full translation and implementation of a scientific idea into industrial standards and product development cycles. They also ensure that projects are a true collaboration and align well with the real-life issues and needs that will ultimately benefit the patients.

- **Key principles for the funding model will be:**
  - A mandatory 50/50 ratio of in-kind vs EU funding at project level (possible exceptions to be agreed by the Governing Board for some topics/calls). It is currently foreseen that this requirement specified in the Work Programme, would be measured at the commitment or grant agreement signature level. Any exception to that ratio of in-kind contribution for a specific topic or project will require a prior agreement between founding partners at Governing Board level to secure the appropriate 1:1 balance at the programme level.
  - Public / non-profit partners and SMEs (according to EU definition) are eligible for funding up to 100% of eligible costs as per Horizon Europe rules *[disclaimer: pending further decisions at horizontal level]*;
  - In projects selected under single-stage calls, the industry partners will be eligible for funding up to a certain ceiling (including large companies and mid-caps), except large pharmaceutical companies *[disclaimer: pending conditions to be laid down in the future legislation]*. Possible exceptions to this rule could be agreed by the Governing Board for clear and pre-identified areas of unmet needs or market failure.
  - In projects selected under two-stage calls, large companies will not request EU funding *[disclaimer: pending discussions on potential eligibility for funding of mid-caps in two-stage calls]*.
  - A flexible model will be implemented at proposal/project level: applicant consortia will need to agree on the amount of funding for the project partners, as long as EU funding is equal or lower than industry in-kind contribution.
Specific methodologies for the valuation of in-kind will be required:
Limiting in-kind contributions according to internal accounting practices and methodologies would mean that some potentially very valuable contributors do not enter projects because their contributions cannot be valorised. Specific yet practical valuation methodologies must be established for specific assets, so that companies are incentivised to provide assets that are critical to the success and impact of the Partnership. The value of certain assets, such as e.g. infrastructures, commercial products and services (e.g. IT platforms, software, digital assets, diagnostics, devices, compounds, biobanks and databases – pending further definitions to be provided in the future legislation) will therefore be valorised and accounted as IKAA to encourage access and sharing across partners for the duration of the project. For industry partners providing services or equipment (e.g. assays for genome sequencing or laboratory equipment, consumables or medical devices) necessary for the project implementation and success, flexible solutions to differentiate the intended in-kind contribution (IKOP) from usual purchasing activities on the side of other consortium members are needed.

As some beneficiaries of IHI will be contributing in-kind but not receiving funding, specific tools for financial reporting must be made available for contributors not receiving EU funding (including for reporting IKAA). These participants would provide an annual consolidated report.

The Partnership for Health Innovation should attract resources from the whole world:
The future Partnership for Health Innovation will be a unique model for radical collaboration with worldwide impact. By attracting expertise and resources from around the world, Europe will benefit from deep collaboration with major industrial players in the pharmaceutical and medical technologies sectors with global input and reach, ensuring excellent science and innovation for the benefit of European citizens. Contributions incurred out of EU Member States and Horizon Europe Associated Countries will therefore be encouraged, e.g. contribution from companies’ overseas research units. Part of these non-EU contributions will be matched by the EU.

The Partnership’s leverage effect should acknowledge in-kind from additional activities:
Industry contributions to specific projects (IKOP) only reflect part of the leverage effect that will be triggered by the Partnership. Therefore, then-kind on additional activities (IKAA) with a clear link to a project’s objectives will also be valorised and accounted. These additional activities should be defined in the work programme, take place after the call launch of the related project and also include sustainability efforts after the project end. The additional in-kind activities can either be valued according to own accounting principles, specific valuation methodologies, or following eligibility rules of the funding programme.

The Partnership is also expected to attract expertise and in-kind and/or financial contributions from philanthropic or funding organisations, similar to IMI2 Associated Partners (see section 2.4 – Partner composition and target group).

In summary, the following principles related to public and private investments are proposed:

- The R&I investment provided by Members other than the Union will be at least equal to the Union contribution for this Partnership.
- It is expected that participation and additional contributions (financial and/or in kind) by entities that are not the founding members of the initiative, such as other industries,
charities, foundations, others, will be facilitated (e.g. through associated partnership status similar to their status under IMI2 JU), and matched by EU funding up to a certain ceiling.

- Due to the participation of several associations, securing the relevant level of commitment requires that a minimum **ratio of in-kind contribution is set at project level**: in-kind contributors will need to provide at least 50% of contribution in each project, including in-kind (IKOP & IKAA), direct financial contributions, etc. as appropriate, whilst the EU funding will therefore represent at most 50% of the budget at project level. Any exception to that ratio of public/private contribution for a specific topic or project will require a prior agreement between founding partners at Governing Board level to secure the 1:1 balance at the programme portfolio level.

- The industry partners will contribute predominantly **in-kind to R&I actions**. In-kind contributions bring significant and differential skills and expertise of industrial know-how and efforts from which public partners and SMEs can benefit. They are critical to enable a full translation and implementation of a scientific idea into industrial standards and product development cycles. They also ensure that projects are a true collaboration between public and private partners and align well with the real-life issues and needs that will ultimately benefit the patients.

- The Partnership should be **able to attract contributions from outside of the European Union** - both to incentivise participation of global players (public and private) to Europe-led projects, to make Europe health care systems and patients benefit from previous R&I investment abroad and to create a critical mass and diversity of data which will directly benefit European patients and health care systems. Part of these contributions would be matched by the EU funding.

- The **administrative costs** of the central office will be taken in charge by the founding members proportionally to their share of committed investments.

- Each Member association will monitor the commitment of its member companies and the overall level of commitment will be monitored on regular basis by the IHI Programme Office and presented in Annual Activity Reports.

### 3.3 Governance

The proposed Partnership will benefit both industrial and public partners and a governance system will be implemented that will address the views of all key stakeholders from both sectors and ensure suitable projects and programmes are implemented.

Without prejudice to the options available in the future model regulation for institutionalised partnerships, the governance structures will include the following elements:

- A Governing Board which will be the main decision-making body of the Partnership, composed of representatives of the Commission and of the Members other than the Union (relevant industry associations). 50% of the voting rights will be attributed to the Commission and 50% to the Members other than the Union. This ensures that the interests of both the EU and of Members other than the Union are always taken into account while each Member keeps a collective veto right. The Executive Director of the initiative will take part of the meetings as

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56 Throughout this document, "public partners" denote beneficiaries in projects funded by the initiative, who are entitled to receive EU funding and who are not founding Members, their constituent entities or their affiliated entities. In other words, "public partners" are not part of the industry associations who are going to become the private partners of IHI. This term should not be confused with public bodies, such as e.g. local, regional or national authorities (who, nevertheless, might also become project beneficiaries and thus be covered by the term "public partners").
an observer. Similarly, the Governing Board members may invite other observers to its meetings, such as e.g. representatives of organisations participating to the initiative’s activities as Associated Partners or representatives of other relevant European Partnerships, on an ad hoc basis and dependent on the scope of discussions taking place. The Governing Board will focus on strategic matters and take decisions regarding the most important issues pertaining to the JU, such as Annual Work Plans, funding decisions, membership and appointment of the Executive Director.

- An Executive Director who will be in charge of the daily operations of the IHI Office. Based on provisions of the regulation or by delegation of the Governing Board, he will be empowered to take decisions such as appointment of staff, sign the grant agreements or represent the initiative, etc.

- An Innovation Panel which will be composed of representatives of the Members of the initiative, (including both EU and industrial partners) and of other stakeholders representing constituencies such as health care authorities (e.g. regulators, HTA bodies, payers), professionals, providers, and patients, regulators, Research and Technologies Organisations, regions, scientists, Member States and ad-hoc members, totalling approx. 25-27 members. The panel will convene at designated times to advise the Governing Board on call launches without compromising overall call timelines. One of the major tasks of the Innovation Panel will be to explore, identify and/or review potential areas and topics, suitable for the scope of IHI, and which would secure sufficient in-kind commitment from the industry Members as expected under this Partnership. The members of the Innovation Panel will be expected to be in close contact with their respective constituencies and to seek expert opinion in advance to ensure openness of the initiative57. In this way, the activities of the initiative will correspond to the ultimate needs of society, public and private partners, health systems and health care workers and the patients who are end-users of the research & innovation results. The Innovation Panel will be in charge of discussing the activities of the initiative and proposing priorities for the Governing Board. In particular, it will discuss proposed future priorities. This body will also foster synergies with other programmes, including other European Partnerships and initiatives by inviting representatives of the bodies implementing them, when appropriate on ad-hoc basis. Scientific expertise/advice to the Board and IHI Office will be embedded directly in the Innovation Panel and in thematic “focus groups” to ensure a stronger role and better coordination with other inputs [disclaimer: the remits and scope of the focus groups need further discussion]. The Innovation Panel is chaired by the Executive Director of the initiative and supported by the JU Office.

- A State Representatives Group composed of representatives of the EU Member States and Associated Countries. Its task will be to provide opinions on the activities of the initiative, notably on draft Annual Work Programmes including the text of planned calls for proposals. SRG will also be expected to provide information to the IHI GB (and Innovation Panel) on related activities happening at national level. This will help to ensure more strategic coordination and avoid duplication in funding of similar activities. Member States should ensure appropriate representation from ministries of research, health or industry/economy, as appointed by each individual country. It is important to note that MS representatives in SRG will be expected to organise their internal workflows at national level to make sure that they have the adequate mandate and access to information. As crucial element for IHI will be the need to make sure that the input from both ministries of research and ministries of health is gathered and presented in a coherent manner.

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57 Innovation panel members others than the founding members, the IHI Office, and the SRG, will be selected in an open call for expression of interest with specific selection criteria to ensure the expertise and representativeness of the group.
By nature, the Commission services will play a key role in ensuring synergies and coherence with other parts of Horizon Europe such as the Health Cluster or the Partnerships related to Health, as well as Digital Europe.

To combine the research, industrial and public health agendas, the Partnership is prepared jointly between the Commission services and the trade associations who represent the private sector contributors. The first SRA proposal came from the industry partners but it was based on pre-requirements communicated by the Commission and strives to address societal needs. The SRA was open for public consultation in October and November 2019 via the EUhealthPPP.org website. The feedback received will be used to prepare a revised SRA version, taking also into account early suggestions received from the Commission services (it should be emphasized that any formal commitment or endorsement of the SRA by the Commission can only take place after the Partnership has been formally set up). The governance structure stems from a proposal of the Commission and is the result of co-design and negotiations between the latter and the industry partners. It has been conceived to address the needs of all parties while ensuring an efficient implementation of the Partnership.

The Commission and industry associations will be involved all along the implementation of the Partnership in the Governing Board and the Innovation Panel, as well as in the proceedings of other bodies such as the States Representatives Group. This will ensure that the EU public interest is taken into account at every step of the preparation and adoption of decisions. The public interest will also be ensured by the inclusion in the Innovation Panel of representatives from industry, health care authorities (e.g. regulators, HTA bodies, payers), professionals, providers, and patients, regulators, Research and Technologies Organisations, regions, scientists, Member States and finally ad-hoc members who will bring in knowledge and advice on the needs of these end-users of health innovations that will be facilitated or co-developed by IHI project participants.

The coherence with other partnerships will be ensured through several mechanisms, such as:

- Involvement of representatives (tentatively, Executive Directors) in the meetings of the Innovation Panel on an ad hoc basis
- A new idea is holding regular joint meetings between representatives of the European Partnerships relevant for health R&I in order to exchange information and identify areas for collaboration or potentially, joint calls. The frequency of such meetings remains to be decided (tentatively: twice per year).

3.4 Openness and transparency

The Commission informed potential stakeholders of the partnership project and invited them to express their ideas through open consultations. It widely advertised the project in the relevant scientific and industrial communities, including on its websites. This Partnership is in fact very open as it includes several health-related sectors and covers enterprises of all sizes, from SMEs to big companies.

The following consultations and events were held in preparation to this Partnership:

- Co-design of Horizon Europe strategic planning process, consisting of a web-based online consultation and of European R&I Days (Brussels, 24-26 September 2019)
- Open public consultation on partnerships under Horizon Europe (11 September – 12 November 2019)
- Industry-run public consultation on the draft SRA (EUhealthPPP.org, 23 October – 24 November 2019, 100+ contributions received and made public on the website)
meetings with representatives of member states in the shadow programme committee, devoted to european partnership in general (brussels, june-december 2019) and to IHI in particular (brussels, 25 november 2019)

From a geographical point of view, the participation in projects funded by the partnership is focussed in europe but is open to participants from any country. however, funding, as required by Horizon europe, is open to actors from all EU member states and associated countries. The partnership will aim to attract investments from outside europe to increase its international footprint, capture resources of global companies and benefit from other previous international investments or address specific scope (such as e.g. disease prevalence in non-eu countries, with relevance for EU population). Part of these non-eu in kind investments would be matched by the EU funding.

Access to the information about the initiative will be ensured through communication activities of the IHI Programme Office and publication of documents on its website. Additionally, the IHI Programme Office, the Commission and the industry members will organise partnering and promotion events and launch communication campaigns when appropriate. Since the future JU Programme Office will be an EU body, it will be subject to the same budgetary controls and the citizens will enjoy the right of using the “access to information” and “access to documents” procedure, thus ensuring the maximal transparency of the operations of this partnership.

Membership of the JU will be open to potential future Members, upon acceptance of the obligations of potential new Members other than the Union and upon acceptance of the Governing Board. We also foresee the participation of Associated Partners to the activities in a comparable way to IMI2 JU, where the Associated Partners demonstrate the intent of long-term commitment to JU activities by participation in several-year long projects. Additionally, all relevant stakeholders will be consulted on the activities of the Partnership, namely in the frame of the Innovation Panel discussions. Draft future scientific priorities and draft topic texts will be published in the IHI website, even before their final approval by the Governing Board, similarly to the best practice established over the years by IMI2 JU. In this way, all interested stakeholders will have early access to potential future funding opportunities.

Regarding eligibility for funding, large industry partners will benefit from a maximum reimbursement rate (maximum rate still under discussion), whereas the academia will enjoy a maximum reimbursement rate in line with the provisions of Horizon Europe Rules for Participation [disclaimer: the provisions for reimbursement rate for SMEs are under discussion at the time of writing].

Horizon Europe provisions will be the basis for the rules applicable in the Partnership regarding dissemination and access to results. Derogations to the rules are currently under discussion between contributing partners. It is expected that derogations will be limited and justified to accommodate legitimate requests of the industry partners, pending ultimate validation in the appropriate legal texts.

The composition of Members other than the Union will be established up-front in the Regulation, leaving the possibility for other potentials Members to join after the Partnership has been launched. However, already by the fact the Members other than the Union will be industry associations, the necessary flexibility and agility will be ensured without the need to frequent changes in membership. The acceptance of Associated Partners (from EU and beyond) will further enhance this dynamic adaptation to the evolution of the health research field over the initiative’s lifetime.

The establishment of the Innovation Panel precisely responds to this concern (see point 3.3). This body will involve representatives of the Members (including Commission services and industry sectors) as well as other relevant stakeholders, such as health care authorities (e.g.
regulators, HTA bodies, payers), professionals, providers, and patients, regulators, Research and Technologies Organisations, regions, scientists, Member States, other European Partnerships and finally ad-hoc members. More information on the Innovation Panel was provided above. Members States will also be consulted in parallel, through the States Representatives Group. Additional consultations may also take place out of the frame of the Innovation Panel, namely online or at specific events organised by the Partnership or its members.
Annex 1 - Key references and data sources

A. The pharmaceutical industry

- Key EFPIA figures:
  - EFPIA - The pharmaceutical industry in figures - 2019: report / data centre
  - EFPIA - Economic and social footprint of the pharmaceutical industry in Europe: Final report, Technical report

- SCRIP 100, 2018: 2016 full-year financial data from more than 650 biopharmaceutical companies: pdf / online tables

- Vantage Pharma, Biotech and Medtech 2018 in review (link)

- IQVIA, The Global Use of Medicine in 2019 and Outlook to 2023 (link)

- Vaccines Europe:
  - Infographic 2014 – Vaccines in figures: online / pdf
  - IPROVE - Strategic European Roadmap for the Vaccines of Tomorrow: roadmap + databank
  - Vaccination of 50+ adults to promote healthy ageing in Europe: The way forward (link)


- In French - Prospective study on health industries and technologies: Industrie du futur - enjeux et perspectives pour la filière industries et technologies de santé, PIPAME, June 2019: summary - report - annexes

- Research & Innovation and development pipeline
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  - EFPIA, Pipeline review of innovative therapies, July 2018 (link)
  - EFPIA Patient W.A.I.T. Indicator 2018 survey (Patients Waiting to Access Innovative Therapies) (link)
  - LEEM, Santé 2030 - Une analyse prospective de l’innovation en santé: study (in French only)

B. Medical imaging, radiotherapy, health ICT and electro-medical companies

- Medical imaging equipment, age profile & density, 2016 (link).
- Overview of COCIR’s strategy for research & innovation and technological developments:
  - COCIR Strategic Research Agenda, 2016
  - Proposal on R&I for digitization of healthcare under Horizon Europe, 2018
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  - EU Health Coalition calls upon the European Council to increase the total Horizon Europe budget to € 120 billion, 2019
  - Health industries welcome unprecedented progress leading to an adoption of Horizon Europe, its areas for missions and partnerships, 2019
  - COCIR recommendations for the implementation of the Medical Device Regulation, 2018 and 2019

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- Towards integrated care workflows, 2016
- Identity in Healthcare - A Key Enabler to Integrated Care, 2018
- Integrated Care Alliance: Multi-Stakeholder Digital Health Roadmap to support Integrated Care, 2018 – all other ICA reports are available here: http://www.integratedcarealliance.org/

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- Realising the potential of mHealth, 2016
- Beyond The Hype Of Blockchain In Healthcare, 2017
- We are all in this together: advancing eHealth interoperability, 2017
- Artificial Intelligence in Healthcare, 2019
- HMA-EMA Joint Big Data Taskforce Phase II report: Evolving Data-Driven Regulation, 2020
- COCIR presentations on The added value of AI in prevention and treatment and How can we use AI to ensure the future sustainability of our healthcare systems?
- COCIR presentations at 2019 General Assembly “How to put Artificial Intelligence into daily Healthcare?”

**Value in decision-making:**
- OECD, New Health Technologies: Managing Access, Value and Sustainability, 2017
- Expert Panel on effective ways of investing in Health (EXPH). Defining value in “value-based health care”, 2019
- HTAi 2017 Policy Forum. From theory to action: Developments in value frameworks to inform the allocation of health care resources
- The HTA Core Model ® -10 Years of Developing an International Framework to Share Multidimensional Value Assessment, Finn Børnholm Kristensen et al. Value in Health, 2017
- Managed services, innovative business and financial models, 2016
- The Value of Medical and Digital Health technology in Breast Cancer Care, 2019

**C. Medical devices, diagnostic and digital health industries**

- **Facts & Figures of medtech industry**
  - Facts and Figures
  - European IVD Market Statistics Report
  - Statistics Cardiac Rhythm Management products 2015-2019
  - Statistics for Orthopaedic Sector products, 2014-2018

- **Value based healthcare**
  - Incorporating value in investment decisions in health across Europe
  - How Procurement Unlocks Value-Based Health Care
  - Procurement: the unexpected driver of value-based health care
  - The Value of Diagnostic Information in Personalized Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems
  - Economic value as guide to invest in healthcare

- **Digital Health**
  - MedTech Europe, Call to action for an interoperable data ecosystem for digital health (position paper), July 2019, link
  - MedTech Europe, Trustworthy Artificial Intelligence (AI) in healthcare, November 2019, link
D. Challenges and specific disease areas

● OECD/EU, Health at a Glance: Europe 2018 State of Health in the EU Cycle:
  - full report [here](#)
  - annexes, tables and graphs available [here](#)
● Eurostat’s database:
  - on Health and on Science Technology & Innovation,
  - Causes and occurrence of deaths in the EU, 16 July 2019: article [here](#), data source [here](#)

a) Dementia
- Cost of illness and burden of dementia in Europe - Prognosis to 2030, Alzheimer Europe, 2009 ([link](#))
- Taking action together to ensure a brighter today and tomorrow for people with Alzheimer’s disease, EFPIA ([link](#))

b) Ageing

c) Cancer
- Comparator report on patient access to cancer medicines in Europe revisited, IHE report, 2016 ([link](#))
- Oncology Data Summit report: Unleashing the potential of data to improve cancer care, 16 June 2019 ([link](#))
- EFPIA - The oncology data landscape in Europe - 2018: Report ([link](#)), Data narrative ([link](#)), Data sources & initiatives ([link](#)), Barriers to the collection and use of health data ([link](#)), Strategic solutions ([link](#)), Country profiles ([link](#))

d) Diabetes
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e) Personalised medicine and innovative therapies
- The benefits of personalised medicine to patients, society and healthcare systems, Charles River Associates, July 2018 ([report](#))
f) Infectious disease and antimicrobial resistance

- *European One Health Action Plan on AMR* ([link](#)).
- *Supporting financial investments on R&D to de-risk antimicrobial development*, BEAM Alliance, March 2019 ([link](#)).
- "Policy Brief" document (2019) produced by WHO Europe, the Romanian Presidency of the EU and the European Observatory on Health Systems on AMR, with a focus on R&D ([link](#)).


g) Cardio vascular diseases


E. Impact and added value of Partnerships

- Relevance of public-private partnerships
  - *Public–private interaction in pharmaceutical research*, Iain Cockburn and Rebecca Henderson PNAS November 12, 1996 93 (23) 12725-12730 ([link](#)).
  - *Increased coherence and openness of European Union research and innovation partnerships*, Technopolis, June 2017 ([link](#)).

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  - IMI: Carrying the torch for medical innovation ([link](#)).
  - ‘Radical collaboration’ is shaking up the pharmaceutical industry – Carlos Moedas, Horizon - The EU Research and Innovation Magazine, June 2018 ([link](#)).