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SAN 82
TRANS 94
AVIATION 42
ENER 50
ENV 94
SOC 95
TELECOM 70
AGRI 79
SUSTDEV 22
REGIO 29
IA 22

COVER NOTE

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PART 3/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Innovative Health

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

TABLE OF CONTENTS

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS 4

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT– WHAT IS DECIDED 4

1.1. Focus and objectives of the impact assessment 4

1.2. The political and legal context 5

1.3. Why should the EU act 8

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED 9

2.1. Portfolio of candidates for Institutionalised European Partnerships 9

2.2. Assessing the necessity of a European Partnership and possible options for implementation 10

2.3. Overview of the methodology adopted for the impact assessment 14

2.4. Horizontal perspective on candidate Institutionalised European Partnerships 19

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON INNOVATIVE HEALTH 23

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT 23

1.1. Emerging challenges in the field 24

1.2. EU relative positioning in the field 26

1.3. EU policy context beyond 2021 31

2. PROBLEM DEFINITION 35

2.1. What are the problems? 35

2.2. What are the problem drivers? 37

2.3. How will the problem(s) evolve? 42

3. WHY SHOULD THE EU ACT? 43

3.1. Subsidiarity: Necessity of EU action 43

3.2. Subsidiarity: Added value of EU action 44

4. OBJECTIVES: WHAT IS TO BE ACHIEVED? 45

4.1. General objectives 45

4.2. Specific objectives 46

4.3. Intervention logic of the initiative 50

4.4. What is needed to achieve the objectives – key functionalities needed 54

5. WHAT ARE THE AVAILABLE POLICY OPTIONS? 57
5.1. Option 0: Horizon Europe calls (baseline) 58
5.2. Option 1: Co-Programmed European Partnership 59
5.3. Option 3: Institutionalised European Partnership under Article 187 TFEU 60
5.4. Options discarded at an early stage 62
6. HOW DO THE DIFFERENT POLICY OPTIONS COMPARE TO ACHIEVE THE EXPECTED IMPACTS? 62
6.1. Effectiveness 62
6.2. Efficiency 70
6.3. Coherence 73
6.4. Tabular comparison of the options and identification of the preferred option 77
7. THE PREFERRED OPTION – HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED? 81
7.1. Description of the preferred option 81
7.2. Objectives and corresponding monitoring indicators 82

Glossary

Term or acronym	*Meaning or definition*
AI	Artificial intelligence
AMR	Anti-microbial resistance
ATMP	Advanced therapy medicinal product
CPP	Co-Programmed Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIT	European Institute of Innovation and Technology
ERA	European Research Area
H2020	Horizon 2020
HTA	Health technology assessment
ICT	Information and communication technologies
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
IP	Institutionalised partnership
JU	Joint undertaking
medtech	medical technologies (sector)
MS	EU Member States
NGO	Non-governmental organisations
R&D	Research and development
R&I	Research and innovation
SME	Small- and medium-sized enterprises
SRA	Strategic Research Agenda

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT– WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I).[1] It sets out to **help decide in a coordinated manner the right form of implementation for specific candidate initiatives** based on a common approach and methodology to individual assessments[2]. It also provides an **horizontal perspective on the portfolio of candidate European Partnerships** to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.[3]

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas,** scoping the domains in which Institutionalised Partnerships could be proposed[4]. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives[5] need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.[6]

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[1] Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

[2] Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

[3] For further details on these points, see below Section 1.2.2.

[4] Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

[5] Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

[6] EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024[7], the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope[8]. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation **Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities**. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation.[9] Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "*a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses*." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the **objectives of Horizon Europe** highlight the need *to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement.* [10]

In this context, **at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action**. Furthermore, a **Strategic Plan** is co-designed with stakeholders to identify **key strategic orientations for R&I support** for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "*direct a substantial part of the funds towards the areas where we believe they will matter the most*" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

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budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that *the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships*).

[7] https://ec.europa.eu/info/strategy/priorities-2019-2024_en

[8] 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

[9] EC (2018) *A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027*. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

[10] Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**[11], a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation[12] and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

[11] Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222
Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

[12] E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to **rationalise the EU R&I funding landscape**, in particular with respect to partnerships, as well as to **re-orient partnerships towards more impact** and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward **a major simplification and reform for the Commission's policy on R&I partnerships**[13]. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a **more strategic, coherent and impact-driven approach**. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ **More systematic and transparent approach** to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (**criteria** for European Partnerships):
  - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
  - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
  - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
  - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.
- ✓ **Reinforced impact orientation:**
  - Partnerships are established only if there is evidence they support achieving EU policy objectives more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets (**directionality**) and corresponding long-term commitments from partners (**additionality**).
  - European Partnerships are expected to provide mechanisms – based on a concrete roadmap - to join up R&I efforts between a broad range of actors towards the development and uptake of innovative solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
  - They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership'[14] is defined as *"an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."*

The Regulation further specifies that European Partnerships shall adhere to the *"principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."*

[13] Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.
[14] Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.[15]

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**[16]:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

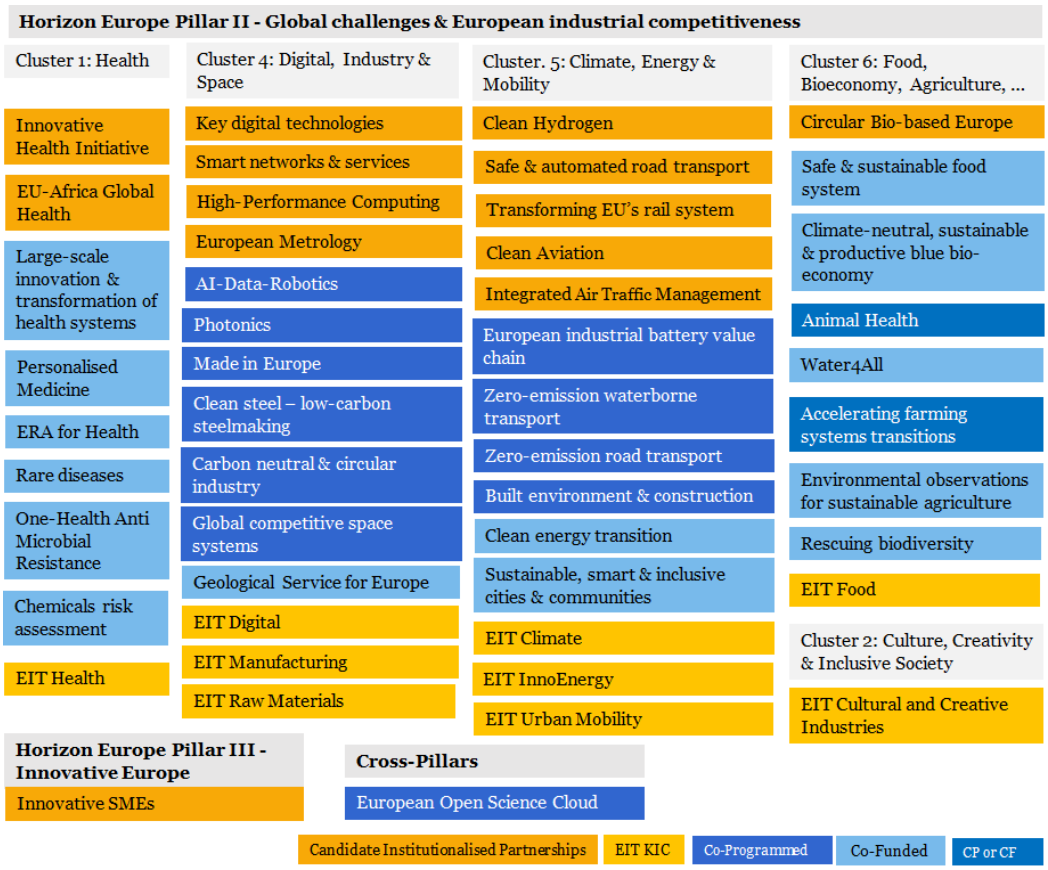
[15] Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.
[16] The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation[17], a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of **49 candidates for Co-Funded, Co-Programmed or Institutionalised European Partnerships**[18]. Out of these, **13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope**[19]. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure



Source: Technpolis group (2020)

[17] Horizon Europe Regulation (common understanding), Annex Va.

[18] Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

[19] Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into '*horizontal*' partnerships and '*vertical*' partnerships.

The **'horizontal' partnerships** have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. '**Vertical' partnerships** are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU *shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration.* At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 – Baseline option – Traditional calls under the Framework Programme
- Option 1 – Co-programmed European Partnership
- Option 2 – Co-funded European Partnership
- Option 3 – Institutionalised Partnership
    - Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
    - Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. Option 0 - Baseline option – Traditional calls

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	**Legal form**	**Implementation**
Co-Programmed	Contractual arrangement / MoU	**Division of labour**, whereby Union contribution is implemented through Framework programme and partners' contributions under their responsibility.
Co-Funded	Grant Agreement	Union provides co-funding for an **integrated programme with distributed implementation** by entities managing and/or funding national research and innovation programmes
Institutionalised based on Article 185/187 TFEU	Basic act (Council regulation, Decision by European Parliament and Council)	**Integrated programme with centralised implementation**

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon Europe calls	**Option 1: Co-Programmed**	**Option 2: Co-Funded**	**Option 3a: Institutio-nalised Art 185**	**Option 3b: Institutionalised Art 187**
Type and composition of actors (including openness and roles)				
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations
Type and range of activities (including additionality and level of integration)				
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Priority-setting process and directionality				
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (veto-right in governance) Objectives & commitments set in legal act
Coherence: internal (Horizon Europe) & external (other Union programmes, national programmes, industrial strategies)				
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes & activities

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are **based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU)** and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims

therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines[20] to evaluate and compare options with regards to their **efficiency, effectiveness and coherence**. This also integrates **key selection criteria for European Partnerships**.

Box 2 Summary of European Partnerships selection criteria[21]

- ***Effectiveness*** in achieving the related objectives and impacts of the Programme;
- ***Coherence*** and synergies of the European Partnership within the EU R&I landscape;
- ***Transparency*** & ***openness*** as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of ***additionality*** and ***directionality***;
- Ex-ante demonstration of the partners' ***long term commitment***.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high

[20] European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)
[21] For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

level of coherence and comparability of analysis, in addition to an horizontal analysis.[22] For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. Method for identifying the preferred option

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "**key functionalities needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of

[22] Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

other key selection criteria for European Partnerships (openness, transparency, directionality)[23].

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and – system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options[24].

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (**efficiency**), the thematic impact assessments broadly follow a cost-effectiveness approach[25] to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account[26]. The table below provides an overview of the cost

[23] The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

[24] In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

[25] For further details, see Better Regulation Toolbox # 57.

[26] Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the

categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.[27] The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution[28] (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution[29]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution[30]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution[31]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

[27] A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

[28] Minimum contributions from partners equal to the Union contribution

[29] Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

[30] Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

[31] Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Co-programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0	↑↑			
Set-up of a dedicated implementation structure	0			Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0	↑↑			
Ex-ante Impact Assessment for partnership	0			↑↑↑	
Preparation of EC proposal and negotiation	0			↑↑↑	
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0	↑			
Call and project implementation	0	0 In case of MS contributions: ↑	↑	↑	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				
Partners costs not covered by the above	0	↑	0	↑	↑
Additional EC costs (e.g. supervision)	0	↑	↑	↑	↑↑
Winding down costs					
EC	0				↑↑↑
Partners	0	↑	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; ↑: minor additional costs, as compared with the baseline; ↑↑: medium additional costs, as compared with the baseline; ↑↑↑: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**)[32]. In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option,** the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the '**necessity test'**.[33] The

[32] More details on the methodology can be found in Annex 4.

[33]Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

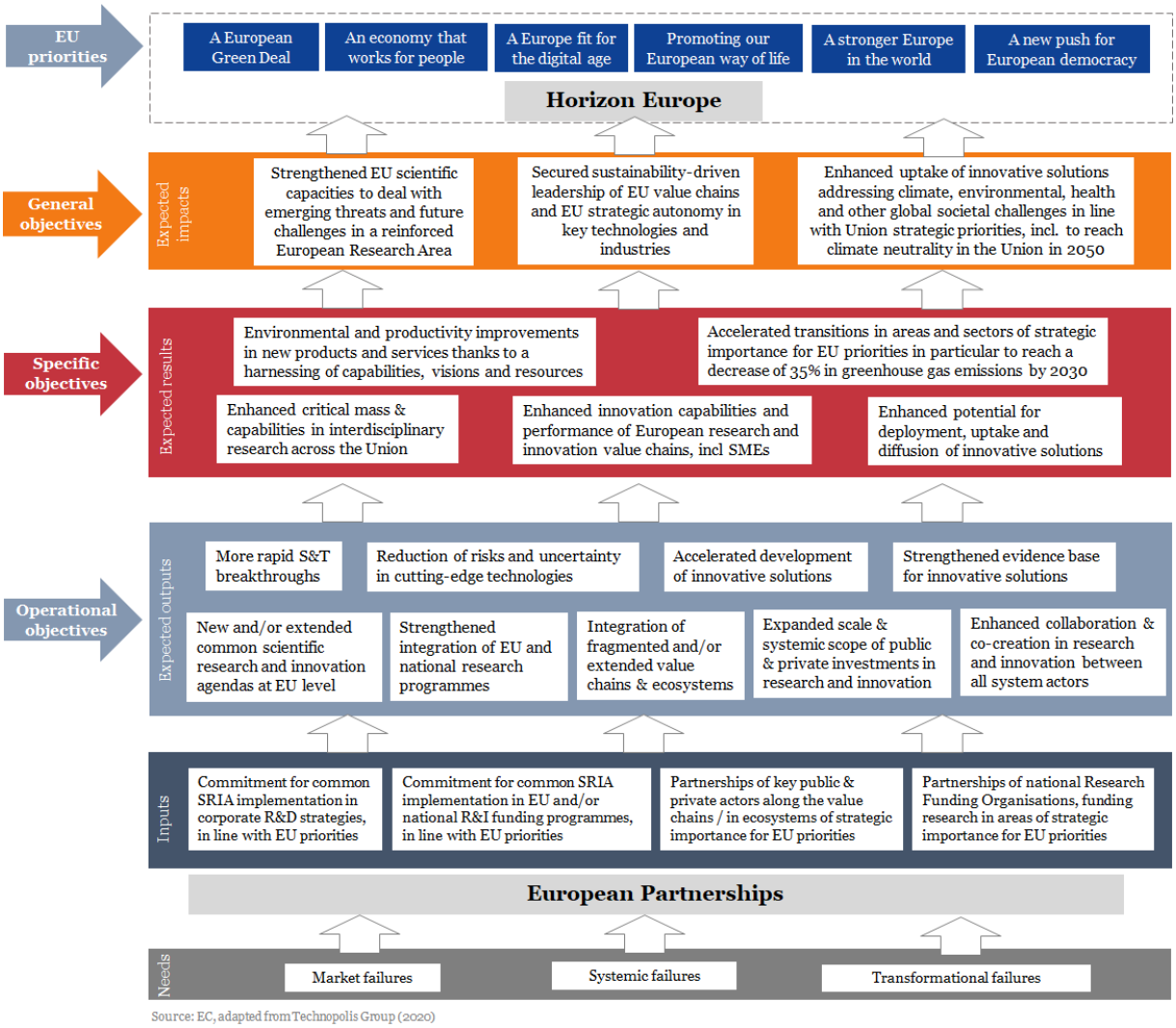
monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



Source: EC, adapted from Technopolis Group (2020)

When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

a) Strengthening EU scientific capacities to deal with emerging threats and future challenges in a reinforced European Research Area;

b) Securing sustainability-driven leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
c) Enhancing the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges in line with Union strategic priorities, including to reach climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

a) Enhance the critical mass and scientific capabilities in interdisciplinary research and innovation across the Union;
b) Accelerate the transitions in areas and sectors of strategic importance for EU priorities, in particular to reach a decrease of 35% in greenhouse gas emissions by 2030, and deliver on the digital transition;
c) Enhance the innovation capabilities and performance of European research and innovation value chains, incl. SMEs;
d) Enhance the potential for deployment, uptake and diffusion of innovative solutions;
e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking a horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- **Coherence for impact:** The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.

- **Collaboration for impact:** Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives**,** Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.

- **Efficiency for impact:** Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office[34]**.** A number of operational activities of the Joint Undertakings are of a technical or administrative

[34] See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "**digital centric**" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The **transport** sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel

and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON INNOVATIVE HEALTH

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

According to the EU Charter on Fundamental Rights, 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'[35].

In the EU, Member States hold primary responsibility for organising and delivering health services and medical care. The EU health policy serves to complement national policies, and to ensure health protection in all EU policies. In particular, EU action shall promote research into the causes, transmission and prevention of major health scourges, in line with Article 168 TFEU [36]. As regards strengthening the EU scientific and technological bases and for addressing competitiveness, the legal ground is provided by Article 179 TFEU[37].

Good health is a major determinant of quality of life, wellbeing and social participation. Along with a vibrant and dynamic health industry, it contributes to shaping a sustainable economy. A status of good health in a society depends on a multitude of actors, including private companies that develop health technologies (such as medicines and vaccines, implantable medical devices or in vitro diagnostics). Since health technologies are applied directly to individuals (for examples, medicines are distributed in the human body, whereas implantable devices are introduced at a specific body site), they are subject to very stringent regulatory mechanisms[38]. Hence, in order to develop a new health technology[39] and make it available to patients, health research and innovation (R&I) follows a long and costly pathway of pre-clinical testing and then clinical investigations on human subjects. This development pathway, which differs for medicines and medical devices, is usually conducted and financed by private companies. After obtaining necessary approvals, these companies can market such a novel development and bring it to the end-users (i.e. health

[35] Article 35, Health-Care, Official Journal of the European Union C 303/17 (2007), https://fra.europa.eu/en/eu-charter/article/35-health-care

[36] Article 168 TFEU, paragraph 1: 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention'.

[37] Article 179 TFEU, paragraph 1: 'The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties'.

[38] Directive 2001/83/EC on the Community code relating to medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

[39] Health technology refers to a pharmaceutical, a medical technology or medical and surgical/radiation procedures as well as measures for disease prevention, diagnosis or treatment used in health care (Directive 2011/24/EU).

care providers and patients). Decisions on reimbursement[40] and pricing[41] lie within the competence of Member States[42]. Such decisions are in most cases based on the evaluation of the added value[43] brought by the new technology to patients and society.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative which would focus on joint European research and innovation activities in health care under Horizon Europe.

1.1. Emerging challenges in the field

Health in the EU faces current and emerging challenges in domains ranging from the social to the economic. These challenges could be addressed, to some extent at least, through research and innovation (R&I).

Europe's health faces major challenges due to an ageing of society and the related health conditions it brings, as well as to the increasing burden of chronic diseases such as cancer, dementia, diabetes, arthritis, and to the threat of infectious diseases with resulting potential pandemics and growing antimicrobial resistance (AMR), as explained in detail in Annex 6 Section 2.1. Health R&I can help to address these demands by working towards better, safe, more effective and cost-effective solutions to promote health, to prevent, early detect, diagnose, treat and manage health conditions and to deliver health care. These opportunities are amplified by new advances in digital technologies, big data, artificial intelligence, the knowledge of human genes and advanced therapies that create opportunities to design solutions tailored to patients' specific health care needs.

However, there are still considerable knowledge and evidence gaps when it comes to understanding the underlying mechanisms of diseases and the determinants of health[44]. In addition, novel therapies, technologies and approaches face specific barriers and hurdles in R&I, implementation and scale-up before they can be useful to patients and health care systems. These barriers stem from a lack of sufficient investment, scientific knowledge and relevant R&I expertise, from the absence of appropriate standards and of frameworks for intellectual property management, as well as from high market prices of the end products.

[40] Reimbursement refers to covering the cost of health care services, including medicines, by a third-party payer (e.g. a public payer such as a social health insurance fund or national health service). European Observatory of Health Systems (a partnership hosted by WHO) (2018), Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? http://www.euro.who.int/en/about-us/partners/observatory/publications/policy-briefs-and-summaries/ensuring-access-to-medicines-how-to-stimulate-innovation-to-meet-patients-needs

[41] Pricing is the act or process of determining a price, be it by a responsible authority, the manufacturer or market forces. Idem.

[42] Article 168 TFEU, paragraph 7: 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.' and Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

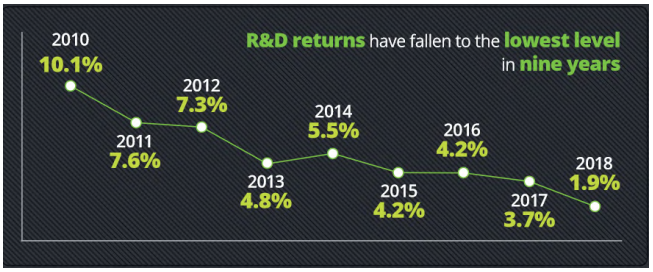
[43] Value in health care is a multidimensional concept as highlighted by the Expert Panel on effective ways in investing in Health (EXPH). Most common elements of existing value frameworks to assess health interventions include: therapeutic benefit, safety, costs, innovation level, health problem (severity 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 that to inform decision-making on the reimbursement, pricing, adoption, and implementation of health interventions.

[44] European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

Regulatory, legal and ethical aspects are also crucial elements to consider for a successful development and implementation of technological innovations[45]. For example, unlocking the potential of data and digitalisation for health-related use depends on the capacity to access, collect, distribute, combine and analyse vast amounts of data. This requires long-term investments in existing or future data infrastructure, dealing with ethical and data security concerns, and putting in place frameworks for information sharing[46]. Similarly, appropriate regulatory pathways, as well as new health technology assessment (HTA[47]) methods and tools, are required for the assessment of emerging and converging technologies. Such technologies include e.g. drug-device combination products[48], nanotechnology-enabled products and medical devices that use digital communication tools or rely on artificial intelligence (AI) or software and are often referred to as "smart" medical devices.

According to a Deloitte report[49], research and development (R&D) productivity (expected returns on R&D investments) in the biopharmaceutical sector has steadily decreased over the last decade (Figure 1), while the cost of bringing of an asset to market has significantly increased[50]. If this trend persists, the industry will see less and less incentives to invest in the risky and costly search for health innovations, which will endanger their future provision to tackle current and emerging health needs and result in fewer new treatment options being available to patients.

Figure 1. Return on R&D investment in biopharmaceutical sector over time



Health-care expenditure is enormous. It accounts for EUR 1.5 trillion in the EU annually and USD 3.6 trillion in the US or 10.0% and 17.2% of the GDP respectively[51]. It also means a vast market for health industry as one fifth of the expenditure is on medical goods[52]. Beyond the EU and US, there is a rapidly growing global market and it is essential that the

[45] European Commission Directorate General for Research and Innovation (2019), Analysis of responses to the Innovative Health Initiative, Public Consultation on the Roadmap – inception impact assessment. Consultation period 30 July – 27 August 2019.
[46] EC (2019), Strengthening strategic value chains for a future-ready EU industry.
[47] Health technology assessment (HTA) is 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 is primarily used to inform decision-making in Member States by providing a scientific evidence base for decisions on the pricing and reimbursement of health technologies.
[48] European Medicines Agency (2018), EMA Regulatory Science to 2025. Strategic reflection.
[49] Deloitte (2018), Unlocking R&D productivity, Measuring the return from pharmaceutical innovation 2018, Available at: www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health Care/deloitte-uk-measuring-return-on-pharma-innovation-report-2018.pdf.
[50] Wouters OJ et al, (2020), Estimated R&D investment needed to bring a new medicine to market, 2009-2018. JAMA. 323(9) 844-853.
[51] OECD (2018), Health at a glance.
[52] Impact Assesment report of European Partnership for Innovative Health (2020), Annex 5.

EU maintains a world-leading health industry that innovates and contributes to economic growth. The health industry is a key driver for growth through creation of high-value jobs and a positive trade balance, trading not only within Europe but also worldwide. It has the potential to attract foreign direct investment and create global companies that bring revenue to the EU. In addition, developing new solutions to improve prevention of diseases would be key to alleviate the burdens on the health care systems.

1.2. **EU relative positioning in the field**

The EU has significant monetary resources and is competitive across many industry sectors globally, allowing the EU and its Member States (MS) to make substantial investments in R&I. The EU accounts for one-fifth of the world's R&D spend and 23% of global public R&D[53]. The EU has more than 1.8 million researchers overall, compared to 1.6 million in China and 1.3 million in the United States. Building on the strengths of its community of researchers and innovators, the EU is in a position to take the lead in developing and deploying scientific breakthrough solutions to improve health and wellbeing, not only within the EU but also globally.

However, the EU has not been able to capitalize fully on its strengths. This is due to lower investment in R&D-intensive businesses and in education and skills development (e.g. ICT and economics skills), coupled with relatively weaker knowledge flows between stakeholders compared to other leading countries[54]. Furthermore, the EU health industry and market are fragmented. The different health industry sectors, e.g. pharmaceuticals, diagnostics, imaging, medical devices, etc. have diverging business models and development timelines, making collaboration difficult. This situation is exacerbated by the EU's own nature of individual Member States with varying regulatory and market access procedures and approaches applicable to health care. The EU health care systems represent a complex network and introduction of new solutions is difficult especially for SMEs that struggle to access new markets and ecosystems. One of the reasons could be a lack of knowledge and experience related to these new markets, and (perceived or real) lack of budget and time to overcome the costs associated with entering into new partnerships and markets [55]. This factor – being beyond the scope of any funding initiative under EU framework programmes – directly affects the willingness of EU companies to invest in cost- and time-intensive R&I in the EU. Hence, other world economies with more uniform health technology approval pathways become a more attractive place for health R&I and subsequent introduction of innovations to the market.

In terms of overall R&D investments, China is quickly overtaking both the EU and the US. This may be one reason why the EU is lagging behind China (and the US) in areas such as e.g. artificial intelligence (AI)[56], which has the potential to significantly increase productivity in health care. The global health data market is predicted to increase from around USD 14 billion in 2019 to about USD 70 billion in 2025[57]. The EU needs to react

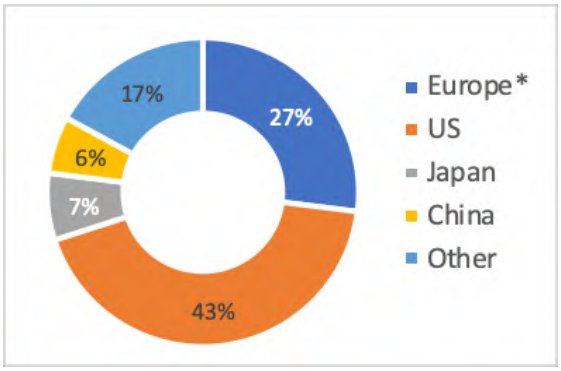
[53] European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.
[54] European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.
[55] European Commission (2018) Commission staff working document 'Enabling the digital transformation of health and care in the Digital Single Market'
[56] European Commission (2018), USA-China-EU plans for AI: where do we stand?,https://ec.europa.eu/growth/tools-databases/dem/monitor/content/usa-china-eu-plans-ai-where-do-we-stand.
[57] Statista 2019, Global healthcare big data market size in 2016 and a forecast for 2025, https://www.statista.com/statistics/909654/global-big-data-in-healthcare-market-size/.

strategically to ensure its current health data market (valued at EUR 2 billion[58]) retains sovereignty and at the same time, captures its fair share of this growth to providing European citizens with health solutions designed and produced in Europe.

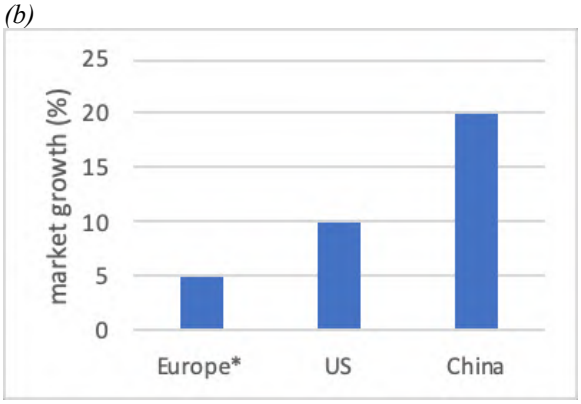
The medical technology (medtech) and pharmaceutical sectors are two of the main health-related industry sectors in Europe, they are also the crucially affected by the problems described in Section 1.1. Medtech covers many disease areas and includes in vitro diagnostics and imaging. There are about 27,000 medtech companies in Europe (mostly SMEs based in Germany, UK, Italy, Switzerland, Spain and France) directly employing over 675,000 people[59]. By comparison, the US medtech industry employs about 400,000[60]. The medtech industry is an important source of health innovation and in 2017 there were more patent applications (13,000) filed with the European Patent Office in the area of medtech than in the areas of pharmaceuticals (6,300) and biotechnology (6,300) combined. The European medtech market was estimated to be roughly EUR 115 billion in 2017 and is currently estimated to make up 27% of the world market, making it the second largest medtech market after the US (43%) (Figure 2a). Europe has a positive medtech (excluding in vitro diagnostics) trade balance of EUR 19.7 billion (2017) with the US, China and Japan being the major trade partners. In comparison, the US medical devices trade surplus is at EUR 2 billion. However, without sufficient investment in R&D, Europe's leadership position in the area of medtech may change in the future. The predicted annual growth of the industry in Europe is 5% compared to at least 20% in China and 10% in the US (Figure 2b).

*Figure 2. (a) Global market share of medtech industry and (b) anticipated annual industry growth. Source: (a) medtech Europe Facts Figures 2019. (b) Technopolis analysis of data reported in Hospodková, P, 2019[61]. *Europe includes EU28 + Norway and Switzerland.*

(a)



(b)



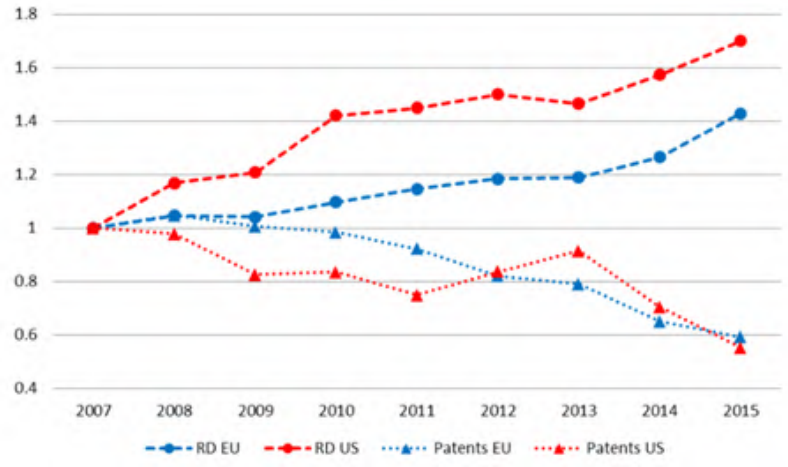
The biotech and pharma sector are a cornerstone of Europe's knowledge based economy. The pharmaceutical industry directly employs approximately 750,000 people, and the sector is Europe's second largest R&D investor with an annual EUR 40 billion spending on

[58] International Data Corporation, 2018. European Data Market Monitoring Tool.
[59] The European Medical Technology Industry in figures 2019, Medtech Europe, https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf.
[60] Hospodková, P., et al., 2019. Global centers of medical device technology: United States, Europe and China. Lékař a technika-Clinician and Technology, 48(4), pp.136-144.
[61] Hospodková, P., et al., 2019. Global centers of medical device technology: United States, Europe and China. Lékař a technika-Clinician and Technology, 48(4), pp.136-144.

R&D[62]. The innovativeness of the sector translates into high volumes of exports, generating a EUR 91 billion trade surplus[63] in 2018 for the EU.

However, this leading position is already being challenged by global competitors, notably by the US and China. Figure 3 shows that while R&D investment in the EU has continuously increased in the last decade, the pace of growth was higher in the US, which also started from a higher base.

Figure 3. Evolution of the R&D investment and number of patents in the pharma and biotech sectors for EU and US companies (base year 2007 = 1.0).



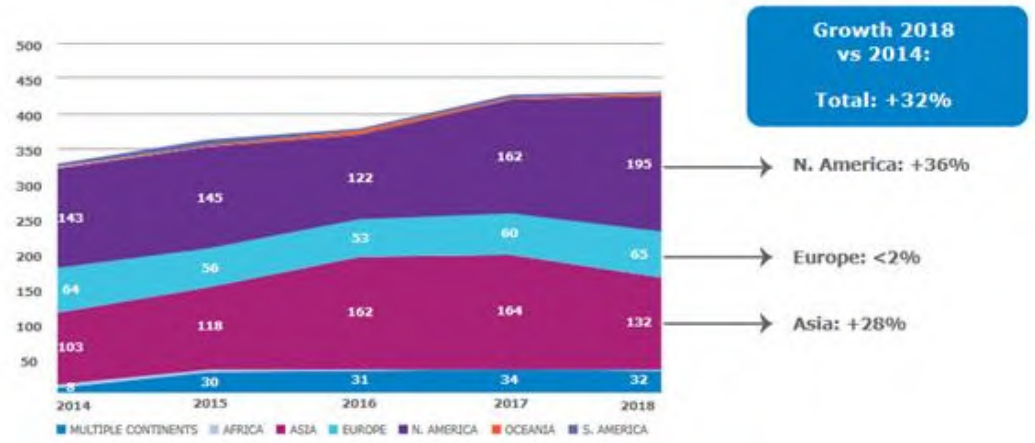
The changing pharmaceutical landscape is also evident in the development of advanced therapy medicinal products (ATMPs). ATMPs represent the new frontier of innovative health solutions; they are based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). Cell and gene therapies offer treatments, even cures for patients affected by life-threatening diseases. They not only extend life and improve the quality of life of patients, but at the same time have the potential to reduce medium and long-term the economic burden of care. While it was the EU that pioneered research in ATMPs, other regions in the world, notably the US and China, have gained momentum in the last couple of years and are initiating increasingly more clinical trials involving ATMPs[64]. The number of new clinical trials increased by 32% globally, 36% in North America, 28% in Asia, and less than 2% in Europe (Figure 4).

Figure 4. Clinical trials with ATMPs initiated Jan 2014 – June 2019, by continent and year.

[62] The 2019 EU industrial R&D investment scoreboard, https://ec.europa.eu/info/news/2019_eu-industrial-rd-investment-scoreboard-report-2019-dec-18_en.

[63] Eurostat, International trade in medicinal and pharmaceutical products (2020), https://ec.europa.eu /eurostat/statistics-explained/index.php/International_trade_in_medicinal_and_pharmaceutical_products

[64] Alliance for Regenerative Medicine: Clinical Trials in Europe: Recent Trends in ATMP Development, - https://alliancerm.org/wp-content/uploads/2019/10/Trends-in-Clinical-Trials-2019-Final_Digital.pdf.



Moreover, private investors have little economic incentives to allocate R&I resources to areas where market prospects are poor or expected return on investment is low. While some areas might indeed provide attractive market prospects, innovation is particularly challenging given the significant gaps in scientific knowledge[65].

As regards entity size, smaller companies tend to have greater R&I productivities than big companies as the former tend to focus more on new product pipelines, have less costly infrastructure and less organisational complexity (e.g. no mass-scale production facilities). On the other hand, bigger companies have more resources to take forward the costly late-phase development of promising assets, such as candidate new drugs or medical devices.

Box 1 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Under Horizon 2020, the overall budget for the 'Health, demographic change and wellbeing' Societal Challenge was EUR 7.5 billion, including Joint Undertakings (JUs).

The Innovative Medicine Initiative (IMI) was one such joint undertaking that supported R&I in the field of pharmaceutical development. For the 2014-2024 period it is named IMI2 JU to distinguish it from its predecessor IMI JU operating under the Seventh Framework Programme (FP7). IMI2 JU's total budget of up to EUR 3.276 billion makes it the world's largest public-private partnership in life sciences, with world-wide recognition. The EU's financial contribution to IMI2 JU was set at up to €1.638 billion to match the contribution of EFPIA (at least €1.425 billion) and other members or associated partners (industrial partners other than pharmaceutical industries e.g. technology providers, diagnostics companies, charities or data handlers). IMI2 JU has managed to attract significant investment from associated partners and from non-EU entities, demonstrating the attractiveness of this programme globally.

IMI contributes to improving citizens' health by speeding up the development of innovative medicines, particularly in areas where there is an unmet need. In IMI projects, a number of big industry partners (members of the European Federation of Pharmaceutical Industries and Associations, EFPIA) collaborate with public sector partners (such as

[65] OECD (2018), Pharmaceutical Innovation and Access to Medicines, OECD Health Policy Studies, OECD Publishing, Paris. https://doi.org/10.1787/9789264307391-en;

academia) and smaller companies, including SMEs.

These latter partners are funded by the EU, while EFPIA members use their own resources and do not receive EU funding. For more details about IMI, the participation patterns and achievements, please see Annex 6, Sections 2.3-2.4.

What has or is being achieved so far by IMI

Thanks to IMI, positive contributions on the drug development process have been realised.

Quoting IMI2 JU interim evaluation[66]: 'the main achievement of IMI2 JU on which there was general consensus, was that since the JU started, collaborations between different competing global companies, SME's and academia became possible'. Together with the available budget and long-term strategy, these collaborations were considered an important asset for European pharmaceutical research'. These collaborations created trust and triggered a mind shift as partners came to understand each other's needs. The quality of the research emerging from IMI projects is beyond average[67]. The initiative has international visibility and an established positive 'brand'[68].

IMI was given as an example of 'radical collaboration' where multinational companies work together and share data instead of keeping it secret, which is helping to change the model of the pharmaceutical industry and solve problems more quickly, by Carlos Moedas, the former EU commissioner for research, science and innovation[69].

IMI created important resources for drug development, used by researchers and helping patients. For example: A vaccine against Ebola Virus Disease was developed, with support by IMI's Ebola+ programme[70]. The impact of chronic obstructive pulmonary disease (COPD) on how patients experience physical activity was measured, achieving a qualification of European Medicines Agency (EMA) for novel methodologies, which opens the way for the development of more effective treatments[71]. A compact, easy-to-use diagnostic device was developed for Ebola infection that delivers results in a little over an hour[72]. Several pan-European clinical platforms were established to build clinical trial readiness, foster clinical R&I in Europe and develop innovative treatments for the European citizens, in challenging areas such as paediatrics[73], prevention of Alzheimer's disease dementia[74] and autism[75].

[66] European Commission (2017) The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

[67] The citation impact of IMI research is higher than EU and world averages. The field-normalised citation impact for all IMI papers is 1.98, compared to 0.97 for the EU and the baseline of 1 for the world. IMI2 JU Annual Activity Report 2018. https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018_final.pdf

[68] In 2018 only, IMI was mentioned in 4048 articles worldwide, including in the title or opening lines of some 7% of these articles. The tonality of the media coverage was predominantly neutral (90%), with the remaining 10% of articles registering a positive tone. Idem.

[69] https://horizon-magazine.eu/article/radical-collaboration-shaking-pharmaceutical-industry-carlos-moedas.html

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

[71] https://www.imi.europa.eu/projects-results/project-factsheets/pro-active

[72] https://www.imi.europa.eu/projects-results/project-factsheets/mofina

[73] https://www.imi.europa.eu/projects-results/project-factsheets/c4c

[74] https://www.imi.europa.eu/projects-results/project-factsheets/epad

[75] https://www.imi.europa.eu/projects-results/project-factsheets/aims-2-trials

What are the key areas for improvement and unmet challenges

The evaluations and experience so far highlighted several 'areas for improvement' for a potential future partnership:

- active engagement of other health industry sectors with the pharmaceutical industry should be enabled;
- the public interest, including accessibility of the eventually resulting products to patients, should be better taken into account,
- the transparency of the strategic research agenda and call topics development should be increased;
- the timelines from identifying R&I needs and topics to the start of resulting projects should be shortened;

More detailed information, including recommendations on the design of the present initiative and how they were addressed, can be found in Annex 6, section 2.3.1.

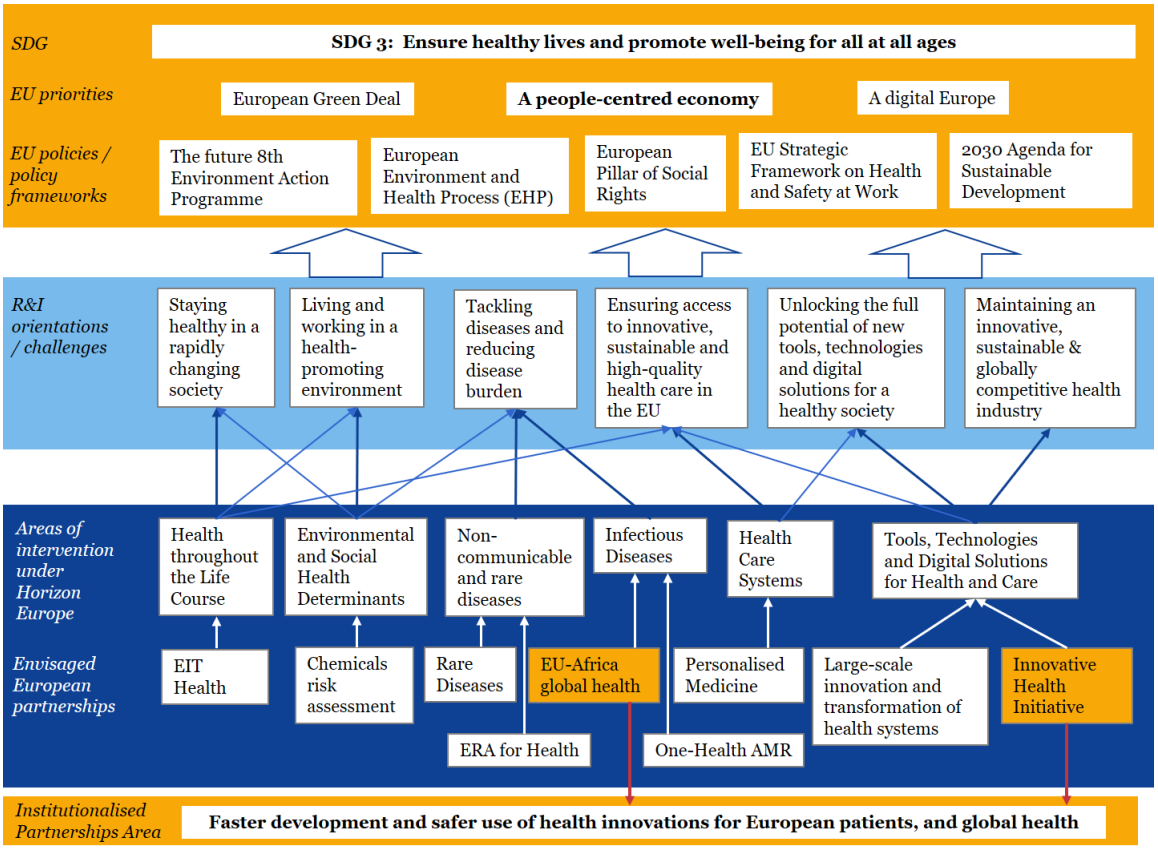
1.3. EU policy context beyond 2021

The von der Leyen Commission's political priorities for 2019-2024[76], notably 'An economy that works for people' and 'A Europe fit for the digital age', are both of high relevance to the Innovative Health Initiative (the 'European Green Deal' is also relevant albeit to a lower degree). The specific political guidance for the proposed initiative is provided in the mission letters for Commissioners Gabriel (Innovation, Research, Culture, Education and Youth) and Kyriakides (Health and Food Safety). The mission letter of Mariya Gabriel emphasises that research, policy and economic priorities have to go hand in hand, using missions and industrial strategy as a vehicle[77]. The mission letter of Stella Kyriakides highlights medical devices addressing emerging challenges and the use of e-health to provide high-quality health care, along with Europe's Beating Cancer Plan and a call for ensuring the supply of affordable medicines to meet Europe's needs whilst supporting an innovative and world-leading European pharmaceutical industry[78].

In Horizon Europe, the Innovative Health Initiative (IHI) would be part of R&I activities funded under Pillar II Cluster 1 Health, which is one of the six Horizon Europe clusters addressing global challenges and industrial competitiveness. Cluster Health is supporting the Sustainable Development Goals, notably SDG 3 'Ensure healthy lives and promote well-being for all at all ages'.

Figure 5. Innovative Health Initiative in the EU policy context. Source: Technopolis Group

[76] https://ec.europa.eu/info/priorities_en
[77] https://ec.europa.eu/commission/commissioners/sites/comm-cwt2019/files/commissioner_mission_letters/mission-letter-mariya-gabriel-2019_en.pdf.
[78] https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf.



In addition to IHI, other initiatives are put forward as possible partnerships under Horizon Europe. Within Cluster Health, the most relevant would be the Partnership on Transforming Health and Care Systems, 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. IHI could contribute to developing innovative health products, services and tools, while the candidate public-public partnership (with Member States) on Transforming Health and Care Systems could develop methods to facilitate the rapid implementation of those solutions into health care systems[79]. Conversely, the Partnership on Transforming Health and Care Systems could formulate the needs of the health care systems so as to inform the R&I activities pursued by IHI. Another relevant candidate partnership is on EU-Africa Global Health, aiming to increase health security in sub-Saharan Africa, and globally, by reducing the risk of outbreaks, pandemics or antimicrobial resistance. Some solutions developed in IHI, for example those related to novel diagnostics or to feasibility of new clinical trials methods, could be relevant for, and potentially deployed at larger scale under the EU-Africa Global Health partnership.

Beyond Cluster Health, the proposed partnership on Key Digital Technologies (successor of ECSEL JU[80]), could provide access to the latest digital technologies and data-driven tools, applicable to several fields. Some of them could prove essential for IHI due to the key role of health data for innovative, integrated health technologies.

[79] It is important to emphasise that IHI would work towards developing 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.

[80] https://www.ecsel.eu/

Other relevant initiatives include: the Connecting Europe Facility (addressing the deployment of cross-border exchange of patients' health data in the EU and enabling Cross Border eHealth Information Services as a leading reference to set up international standards) and the Digital Europe Programme (offering opportunities to deploy, implement and upscale the digital health solutions, including those possibly initiated by the proposed initiative 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). The potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe are presented in Figure 6.

Horizon Europe has introduced the novelty of missions, with cancer being one of the five mission areas, that will use the full spectrum of European R&I instruments and policies to reach their targets. The Innovative Health Initiative could play an important role in supporting the development of innovations to prevent, faster diagnose and treat cancer and thus significantly contribute to the Europe's Beating Cancer Plan[81]

Furthermore, the proposed initiative may foster the concept of 'Smart Health', an area that has been identified as one of the 'strategic value chains'[82] by a forum of industrial experts[83], with potential to drive EU's industrial competitiveness and promote technological sovereignty. Value chains are defined as a set of interdependent economic activities that add value around a product, process or service, involving a group of interlinked economic actors that operate across sectors and borders. The proposed initiative unites these features and has all elements to be considered as "strategic", i.e. revealing systemic importance and making a clear contribution to growth, jobs and competitiveness[84]. The value of IHI to serve as a precursor in this context has been further strengthened by the recently published new Industrial Strategy for Europe[85]. It may demonstrate its full potential when delivering innovative health technologies that integrate digital components, thereby preparing the ground for a potential Important Project of Common European Interest (IPCEI) on Smart Health.

Figure 6. Potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe. Source: Technopolis Group

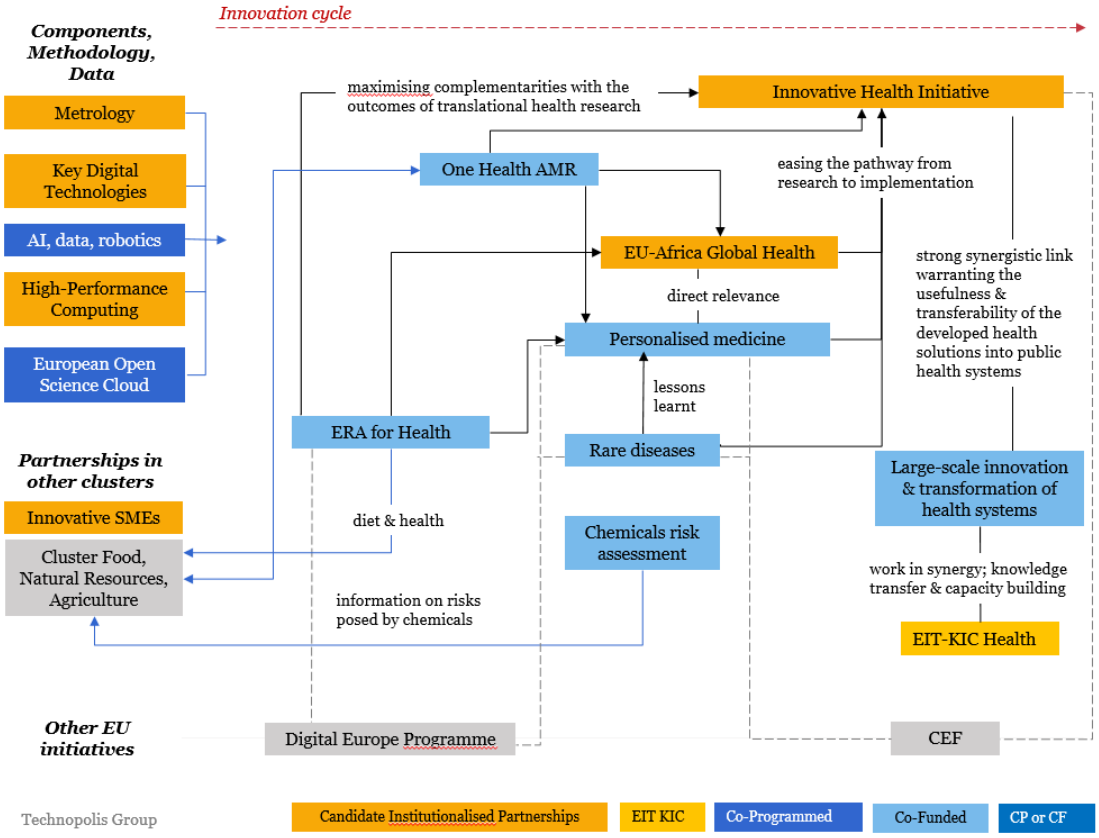
[81] https://ec.europa.eu/health/non_communicable_diseases/cancer_en

[82] European Commission (2019), Strengthening strategic value chains for a future-ready EU industry. Report and annex available at: https://ec.europa.eu/docsroom/documents/37824; factsheet available at: https://ec.europa.eu/docsroom/documents/37825

[83] Strategic Forum for Important Projects of Common European Interest: https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=StrategicForum&title=Strategic+Forum+for+IPCEI

[84] In the European political context, strategic value chains are characterised by: i) technological innovativeness; ii) economic and market potential; iii) societal and political importance for Europe; supporting Strategic Value Chains is a political priority at the interface of a number of other EU policies – R&I, industrial and the Green Deal.

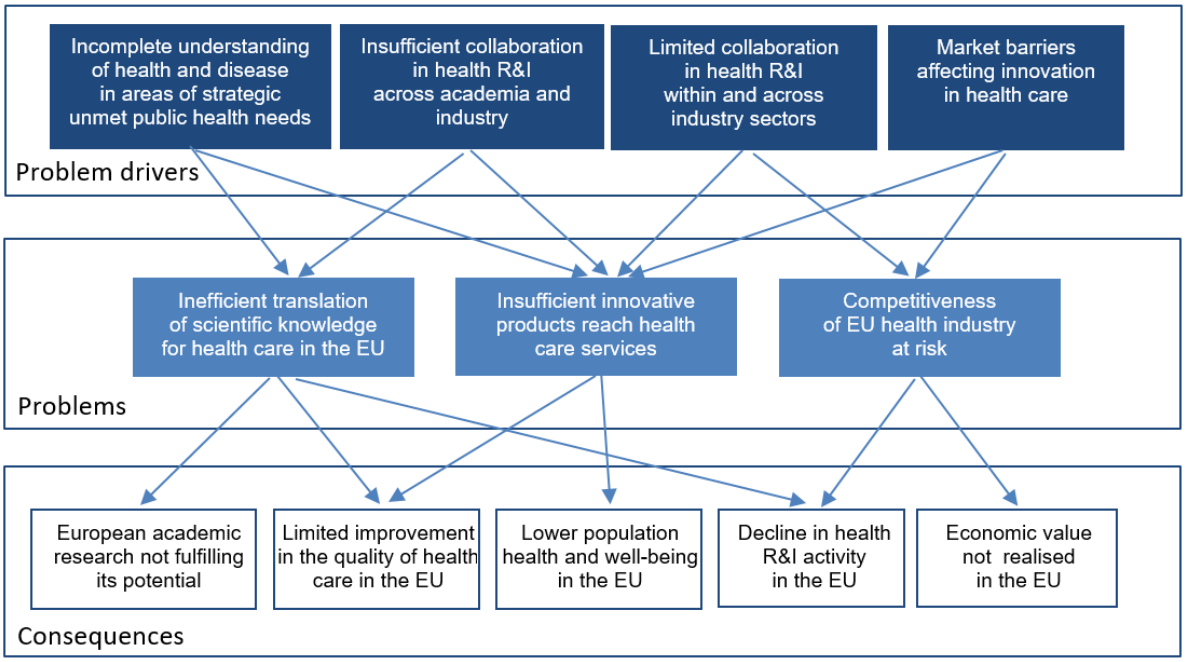
[85] COM(2020) 102 final.


Innovation cycle
Components, Methodology, Data
Metrology
Key Digital Technologies
AI, data, robotics
High-Performance Computing
European Open Science Cloud
Partnerships in other clusters
Innovative SMEs
Cluster Food, Natural Resources, Agriculture
Other EU initiatives
Digital Europe Programme
maximising complementarities with the outcomes of translational health research
Innovative Health Initiative
One Health AMR
easing the pathway from research to implementation
EU-Africa Global Health
direct relevance
Personalised medicine
strong synergistic link warranting the usefulness & transferability of the developed health solutions into public health systems
lessons learnt
ERA for Health
Rare diseases
Large-scale innovation & transformation of health systems
diet & health
Chemicals risk assessment
work in synergy; knowledge transfer & capacity building
information on risks posed by chemicals
EIT-KIC Health
CEF
Technopolis Group
Candidate Institutionalised Partnerships
EIT KIC
Co-Programmed
Co-Funded
CP or CF

2. PROBLEM DEFINITION

Given the current and anticipated challenges in the health research field and the overarching policy context, a set of problems have been identified where EU R&I in this field would have a specific role to play (Figure 7).

Figure 7. Problem tree behind an initiative for European R&I on Innovative Health



2.1. What are the problems?

The predecessor initiative, IMI2 JU, was set up to address the challenges of increasing cost, lack of incentives and decreasing productivity in drug and vaccine development. Based on the success of IMI in bringing together pharmaceutical companies and the lessons learned explained in Section 1.2, the problem definition reflects the progress in converging of health technology areas (e.g. drug development and diagnostics) 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.

2.1.1. Inefficient translation of scientific knowledge for health care in the EU

Despite Europe being a leading region in health research, a gap remains in its ability to translate this excellent health research into products and services that will make a difference to patients and reduce the burdens on health care systems[86].

The high failure rate is mostly a scientific problem due to, among others: (1) the lack of adequate translational expertise (i.e. the skills and knowledge required to turn research results into products and services under high regulatory scrutiny), (2) insufficient reproducibility of academic research[87], (3) insufficient understanding of the mechanisms of disease, (4) weak academia-industry and industry-industry collaboration, within and across different industry sectors, (5) market failures (low investment in some health areas, e.g.

[86] EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report.
[87] Friedman L.P., et al, (2015). The Economics of Reproducibility in Preclinical Research, PLoS Biol, available at https://doi.org/10.1371/journal.pbio.1002165.

infectious diseases, brain disorders and anti-microbial resistance[88], or market fragmentation).

2.1.2. Insufficient innovative products reach health care services

Even when innovation does happen, insufficient early consideration of societal or user needs and preferences acts as barrier to acceptance and uptake of the resulting products or services[89], which denotes a societal problem. Therefore, better innovation requires better involving patients, users and citizens from project design and specifications to implementation. In addition, access to products (e.g. drugs) and services (e.g. diagnostic procedures or e-health services) by patients and health care professionals may be delayed for reasons such as lack of evidence on relative effectiveness and cost-effectiveness to demonstrate their added value, high prices raising affordability issues[90], or 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[91]

For example, tapping the potential of big data, real world data and digitalisation depends on the capacity to access data, to ensure data quality, to collect, combine and analyse vast amounts of heterogeneous data; on the availability of appropriate regulatory frameworks and data infrastructures; on the fulfilment of all ethical and legal requirements[92] and on workforce skills.

2.1.3. Competitiveness of EU health industry at risk

The EU has a large health industry. However, it is struggling to maintain a leadership position in health R&D versus the US and China in many sectors, including the

[88] European Commission (2017). The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

[89] It should be noted that health products and services behave differently than it is the case in most areas of the free-market economy because: (1) the health area is subject to strict regulation at national and/or European level, depending on the actual type of products or services, (2) the pricing of these products or services does not follow the free-trade rules but is subject to reimbursement and pricing decisions which are a national competence, (3) the cost of most health products is partly or fully reimbursed by government or compulsory insurance schemes. Therefore, the aspects of 'product availability' and 'product uptake' have meanings specific to this particular area. In addition, reimbursement decisions can also include provisions on the conditions of use of the product, e.g. in certain diseases.

[90] Providing universal access to innovative medicines and other medical technologies creates tremendous social value. However, the rising prices of innovative technologies and, in particular, the proliferation of very expensive medicines in recent years have increased pressures on public health spending. Equitable access to essential, high-quality innovative health technologies depends on affordable and fair pricing and effective financing schemes. According to WHO definition, an "affordable and fair" price is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country (World Health Organization (2017). Essential medicines and health products. https://www.who.int/medicines/areas/access/en/.) Even though reimbursement and pricing are a national competence of EU Member States, research could be done at European level on the development or refinement of pricing and reimbursement instruments. This research could in turn support Member States developing and implementing their national policies. Besides pursuing affordable and fair prices, promoting cost-effective interventions is also seen as central to the achievement of universal health coverage. IHI can play a role here in developing methods and tools to assess the added-value of innovative technologies, and that can be taken-up by health care authorities/organisations if deemed relevant to inform their decisions.

[91] While solutions to these problems are beyond reach of IHI, they would fall in scope of the candidate Partnership on Transforming Health and Care Systems involving Member States who are in charge of organising their health care systems.

[92] European Commission (2019). Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

pharmaceutical and medtech (see Section 1.2.1), which is considered an economic/technological problem.

R&I creates new opportunities, supporting sustainable economic growth and the competitiveness of businesses and industries[93]. However, slow translation of scientific discoveries into tangible innovations and limited technology convergence lead to dwindling innovation pipelines. This puts Europe at risk of becoming dependent on other countries for technological developments and new health care solutions, not only endangering European competitiveness but also putting into question the future sovereignty and preparedness to face issues like e.g. shortage of essential medicines[94] or emerging pandemics.

In the **open public consultation**, 73% of respondents (77 out of 105) saw the innovation gap in translating the results of health research into the development of innovative health products and services as a very relevant problem. Insufficient consideration of societal or user needs was identified as a relevant barrier to uptake particularly by most respondents from the 15 NGOs, 5 public authorities and 6 small company/business organisations (<250 employees). Academic/research institutes and public authorities reported that ethical issues were also a barrier. Nevertheless, on average, structural and resource problems were reported as more relevant than problems in the uptake of health innovations (assessed as 'very relevant' by 56% vs 34% of all stakeholders, respectively). The need for the partnerships to contribute to EU global competitiveness was supported by most respondents (59%, 63 of 106) in the **open public consultation**, including most of the 6 respondents from business associations, the 20 respondents from industry and the 35 respondents from academic/research organisations. Only among public authorities and 'other', the majority did not cite the contribution to EU competitiveness as a need.

During **interviews**, industry representatives referred to a lack of trust between the public and industry. A positive working relationship between public and private partners could increase public trust, and therefore uptake, of new products developed by industry.

2.2. What are the problem drivers?

2.2.1. Incomplete understanding of health and disease in areas of strategic unmet public health need

Many of the diseases that are increasingly affecting the health of EU citizens, are not completely understood in terms of what causes them, how environmental and genetic factors affect the occurrence and course of the diseases, what affects treatment success, etc. Consequently, it is difficult to develop adequate prevention strategies, accurate diagnostics and targeted therapeutic interventions[95]. Further research is urgently needed to understand the causes and factors affecting development of these complex diseases[96]. Understanding of diseases should also link better to health promotion, disease prevention, prediction and staying in good health longer while aging.

[93] European Commission (2019). Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe.
[94] WHO list of essential medicines and health products, available at: https://www.who.int/topics/essential_medicines/en/
[95] The top ten leading causes of death in Europe in 2016 included dementia, in particular Alzheimer's disease, and diabetes mellitus. See Annex 6 Section 2.1 for more details.
[96] WHO data on Disease burden and mortality estimates, https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html.

The predecessor initiative, IMI, has greatly contributed to better understanding of certain diseases (e.g. by elucidating the five subtypes of diabetes rather than only two as known currently, which paves the way for proposing the adequate treatment for patients with individual disease subtypes[97]). Nevertheless, the knowledge gaps remain, due to the inherent complexity of biological processes in the human body. Such knowledge gaps are a roadblock for efficient translation into products or services and one of the root causes why no treatments are available in some therapeutic areas. These knowledge gaps must indeed be addressed by research but as regards human health, unlike in some engineering or IT areas, research can be unsuccessful, despite years of effort. For example, in the case of dementia, there is still a vast market demand as a growing proportion of the ageing population of rich countries are affected, with no available treatment. Despite this, the biggest drug companies pulled out of this area, following a string of repeated failures: between 1998 and 2017, 146 candidate medicines in clinical development for Alzheimer's were halted and did not receive regulatory approval. 18% of the failures occurred in late-stage clinical trials[98], which by then had consumed 5-10 years of R&D and USD hundreds of million, sometime over a billion in costs each. Science needs to advance and provide new therapeutic targets to industry, and industry needs to be stimulated to continue investing in this field.

Another example is the emergence of infectious diseases, demonstrated by the 2019/2020 SARS-CoV-2 (coronavirus) pandemic of unprecedented scale. Despite existing knowledge about other coronaviruses that caused earlier epidemics[99], the global spreading of COVID-19 could not be avoided.

The reason for identification of this aspect as a problem for the proposed initiative is that it is a prerequisite for being able to translate research into products. A more efficient use of various research tools or paradigms offered by new industry sectors (e.g. using innovative imaging methods or artificial intelligence) may bring a new stimulus to understanding areas not fully understood today. This persisting problem calls for continued investment into R&I on unmet health needs, intensified collaboration of academia with the main health industry sectors and the use of digital technologies in order to give a new angle to addressing these gaps.

The lack of understanding/knowledge about disease was cited as a very relevant problem by the majority within each group of respondents in the **open public consultation** with the exception of small company/business organisations. In the **feedback to the inception impact assessment**, stakeholders from business, academia, NGOs and 'others' referred specifically to antimicrobial resistance (AMR), brain disorders and neglected diseases.

2.2.2. Insufficient collaboration in health R&I across academia and industry

Collaboration between academia and industry is widely considered a key requirement for translating research into innovations but it can be inhibited by a range of factors. These include the compartmentalisation of departments within universities and hospitals; a cultural divide between academic, industry and clinical researchers; and lack of training or experience in multidisciplinary teams working among academics. In combination with these

[97] IMI's BEAT-DKD and RHAPSODY projects: https://www.beat-dkd.eu/ and https://imi-rhapsody.eu/.
[98] Researching Alzheimer's medicines (2018), http://phrma-docs.phrma.org/files/dmfile/AlzheimersSetbacksSteppingStones_FINAL_digital.pdf.
[99] SARS-CoV outbreak started in 2002 and MERS-CoV outbreaks started in 2012

factors is also a university system that rewards individual achievement rather than joint working practices[100].

Unfortunately, in the health area, the majority of European academics do not collaborate with business[101]. This is exemplified by the fact that less than 8% of participations in Societal Challenge 1 (Health, demographic change and wellbeing) Horizon 2020 collaborative projects from 2014 to 2019 were from non-SME industry partners (Table 1). The joint participation of several industry partners in one project was even less frequent.

Table 1: Proportion of non-SME private sector participation (labelled as Industry participation) in regular Horizon 2020 collaborative health R&I projects (please note that the figures exclude IMI2 JU)

Call year	Total EU funding	EU funding for industry	Total participation	Industry participation	% of industry funding	% of industry participation
2014	EUR 595,619,918	EUR 41,542,476	1609	109	6.97%	6.77%
2015	EUR 584,270,458	EUR 31,235,638	1308	98	5.35%	7.49%
2016	EUR 440,330,074	EUR 20,460,519	1111	83	4.65%	7.47%
2017	EUR 367,686,472	EUR 21,747,256	886	59	5.91%	6.66%
2018	EUR 691,315,336	EUR 51,995,267	1588	156	7.52%	9.82%
2019	EUR 796,496,156	EUR 56,131,198	1459	115	7.05%	7.88%
Total	**EUR 3,475,718,414**	**EUR 223,112,354**	**7961**	**620**	**6.42%**	**7.79%**

Source: European Commission

Differing concerns in industry and academia contribute to this frequent lack of collaboration[102]. Industry has concerns about the poor reproducibility of research, high valuation of early intellectual property, and maintaining confidentiality. Academia has concerns about the freedom to publish and about strategic changes at the industrial partner (such as change of the disease area interest, or mergers and acquisitions) which can lead to discontinuation of research projects. Furthermore, academics have less resources to comply with increasingly complex regulatory requirements compared to industry[103]. For instance, analysis of data from the EU's Clinical Trial Register shows that clinical trial results of 90% of clinical trials led by academics in Europe are not reported within a year of ending, while

[100] Fudge, N. et al. (2016) Optimising translational research opportunities: A systematic review and narrative synthesis of basic and clinician scientists' perspectives of factors which enable or hinder translational research. PLoS ONE, 11(8), pp. 1–23.
[101] Davey, T. et al. (2018). The state of university-business cooperation in Europe, https://www.ub-cooperation.eu/pdf/final_report2017.pdf.
[102] Freedman, S. and Mullane, K. (2017) The academic–industrial complex: navigating the translational and cultural divide. Drug Discovery Today, 22(7), pp. 976–993.
[103] Vesper I. (2018). Europe's academics fail to report results for 90% of clinical trials**,** Nature, Available at: https://www.nature.com/articles/d41586-018-06676-8.

70% of industry-sponsored clinical trials have published outcomes within 12 months of completion.

The situation described was significantly alleviated by the activities of IMI, as explained in Section 1.2 and in Annex 6. However, this successful outcome of IMI benefitted the collaboration mostly between academia and the pharmaceutical sector, not covering other sectors of health R&I.

Interviews with industry stakeholders indicate that while there are a few examples of large pharmaceutical companies participating in collaborative projects in Horizon 2020, this remains the exception due to low perceived success rates, small project sizes (by their standards) and time-consuming administrative requirements. In fact they prefer not to receive any funding from the EU, which is seen as a reputational risk, and rather turn to the alternative avenue offered by IMI2 JU, which allows large-scale, strategically oriented collaboration without receiving any monetary funding, while contributing own resources instead.

2.2.3. Limited collaboration in health R&I within and across industry sectors

An overarching organisational problem driver holding back the full potential of European creativity is the limited collaboration between various health-related industry sectors including pharmaceuticals, diagnostics, medical devices, imaging, biotech and digital industries[104]. Reasons for this are competition and varying definitions of pre-competitive space, different problem solving approaches, diverging business models and varied development timelines across sectors[105], further compounded by varying regulatory requirements across types of products (e.g. drugs vs. medical devices).

In the cross-sectoral digital health sector, which was less prominent at the onset of IMI2 than it is the case today, R&I is also held back by missing data standards, interoperability and accessibility; inadequate or non-existing analytical methods and tools; and issues around ethics, privacy and security[106]. All this diminishes the EU's ability to tap the immense potential presented by digitalisation, artificial intelligence (AI) and big data. The capacity to access, collect, combine and analyse large, complex data sets also varies across industry sectors and stakeholder groups resulting in a lack of collaboration[107].

In the **open public consultation**, limited collaboration and pooling of resources between industry sectors was seen as a very relevant problem across stakeholder groups (52%, 55 of 106 respondents) and in particular by business associations. Comparatively, it was more strongly agreed that limited collaborations and pooling of resources across public, private and charity sectors was a problem, with the majority of respondents (59%, 61 of 104) selecting this aspect as very relevant. During the **interviews**, stakeholders from academic/research organisations remarked on this barrier, highlighting, in particular, that the lack of data sharing between the health sector and industry was a major barrier to innovation.

[104] This problem driver for IHI is defined much more broadly than it was the case for IMI that focussed on the pharmaceutical sector only. In preparation for IHI, associations representing several health industry sectors expressed interest to enter into joint pre-competitive collaboration.
[105] The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020 (2017), Experts Group Report. Luxembourg: Publications Office of the European Union.
[106] European Commission (2019), Strengthening strategic value chains for a future-ready EU industry.
[107] European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

2.2.4. Market barriers affecting innovation in health care

Market barriers discourage companies from investing in R&D, particularly where a high return on investment is unlikely. This is a significant problem in some areas of high unmet public health need such as infectious diseases and anti-microbial resistance. In the latter area, the problem persists despite the significant and recognised achievements[108] of IMI that, however, without additional pull mechanisms, are not able to improve the attractiveness of the overall market[109].

The issues around market barriers are exacerbated by the fact that complex innovations combining different types of technologies do not easily fit into existing regulatory schemes. In addition, demonstrating their added value for patients and society poses new methodological challenges, partly because technologies converge in ways that alter the delivery of health care in ways not anticipated before and that could not be effectively addressed by predecessor initiatives. For example, mobile health offers potential for more effective and efficient provision of care, which should ultimately translate into better outcomes for patients. Such complex and cross-sectoral innovations require the development of adapted approaches, methods and tools not only to assess their safety and efficacy but also to fully capture the value they create for society and to enable efficient integration into health care systems. These novel methods would be essential for Member States to take the best informed decisions – including as regards the reimbursement and pricing policies – and put them in a stronger position to negotiate affordable prices that would in turn facilitate patient access to high-value innovations.

Health industries, in particular SMEs, may encounter difficulties in accessing the necessary investments from various sources. While IHI could serve as a source of funding to bridge possible gaps in funding between basic research grants and other financial instruments (e.g. loans) this is an issue that could also be addressed by several initiatives at EU level (e.g. by the European Innovation Council[110] or by the European Investment Bank[111]), at national level or by venture capital. However, industries may also find it difficult to enter new markets and value chains, or to create partnerships and alliances and this is precisely where IHI would have a unique role to play. 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[112].

In the **open public consultation,** there was some disagreement between small and large (>250 employees) company/business organisations about the relevance of market failure,

[108] According to the European Court of Auditors: '…despite the general withdrawal of pharmaceutical industries from antimicrobial research, JU IMI together with its partners was overall able to maintain the expected level of public-private collaboration in the ND4BB programme. While this is encouraging, there are concerns about the insufficient commercial incentives for pharmaceutical companies to invest in this field'. European Court of Auditors (2019), Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU – special report no 21, findings 60-61. https://www.eca.europa.eu/Lists/ECADocuments/SR19_21/SR_Antimicrobial_resistance_EN.pdf.

[109] Idem.

[110] Under Horizon Europe's innovation pillar, the proposed European Innovation Council (EIC) will offer grants and blended financing (grants and equity) opportunities mainly for small, highly innovative companies from early stage to development and scale-up. https://ec.europa.eu/research/eic/index.cfm.

[111] For example, InnovFin Infectious Diseases Finance Facility (IDFF) from the European Investment Bank (EIB) can provide standard debt to equity-type financing for amounts typically between EUR 7.5 million and EUR 75 million.

[112] European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

the adequacy of business models, and ethical concerns over digital tools. Small companies (9 respondents) found these problems less relevant as barriers to uptake of innovations, whereas most of the 12 stakeholders from larger companies reported these as very relevant.

The problems at stake remain valid for both the predecessor initiative, IMI2 JU, and the proposed. However, under IMI2 JU, the problems were more closely related to the process of pharmaceutical development (covering medicines and vaccines). It was also reflected by the constituency of the partnership, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) as the only member industry association. IMI2 was able to indeed progress significantly on addressing the underlying problems and successfully deliver on several of its objectives. However, the problems at stake constantly evolve and therefore, they are going to be addressed by the proposed initiative in a broader than it was the case for IMI: the Innovative Health Initiative (IHI) aims to cover several technology areas of health R&I (medtech, biotech, vaccines, digital), rather than the pharmaceutical sector only. Thanks to this broadening, the Innovative Health Initiative could address the problems at stake from a different angle, capitalising on broadened experience of the new set of industry actors.

2.3. How will the problem(s) evolve?

The problems of Europe's ageing society and prevalence of diseases are unlikely to dissipate over time. As people age, the prevalence of chronic diseases is likely to increase, thus also leading to co-morbidities[113]. In addition, in an increasingly global world, as more people continue to travel, the spread of new emerging infections and the possibility of pandemics cannot be ruled out, as clearly demonstrated by the 2019/2020 COVID-19 outbreak. All this would exert pressure on carers and health care systems.

In the baseline scenario of regular Horizon Europe calls and absence of a follow-up partnership to IMI2 JU (which exists until 2024 but launches its last calls in 2020), the problem of insufficient provision and deployment of innovations in health care, which includes both the lack of innovations itself and existing innovations not reaching users quickly enough, will persist or even worsen without intervention. However, if addressed, effective, cost-effective and easy to use innovations responding to the needs of end-users should help reduce the pressure on health care systems.

Without intervention, many of the innovative health technologies will potentially be disruptive for health care systems. They will rely on cross-sectoral collaborations and will therefore necessitate early dialogue between all relevant health care actors (including patients, developers, regulators[114], health technology assessment bodies, health authorities

[113] EC Reflection Paper (2019), Towards a sustainable Europe by 2030.

[114] 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

involved in pricing and reimbursement) to become accessible[115] to patients, at fair conditions. In addition, the increasing EU public's expectations about health care – i.e. that health care is high quality, effective, cost-effective, and accessible – is also likely to influence the burden on health care systems and how health care is delivered[116].

Overall, if left unaddressed, the problems described will result in:

- not capturing the full potential of European research, with the knowledge created by European academics not translated more efficiently into tangible innovations;
- limited improvement in the quality of health care and unsustainable health care systems that will remain reactive, addressing diseases on incident basis, rather than moving towards preventive, integrated health care that would put the person in the centre, during her/his lifetime;
- negative impact on health and wellbeing in the society (incl. increasing access barriers to novel health solutions), entailing limited preparedness to emerging health threats (such as e.g. the COVID-19 outbreak) where new diagnostics, preventive vaccines or therapeutics need to be developed quickly;
- decline in health-related R&I activity in Europe with jobs and revenue going outside the EU and economic value not being realised in Europe, leading to gradual loss of technological sovereignty and readiness to quickly respond to emerging health threats.

During **interviews**, stakeholders (including those from industry, partnerships and research infrastructures), referred to digitalisation as one of the major needs this initiative could address. This was confirmed during the **open public consultation** where respondents generally agreed (50%, 53 of 105) that insufficient digitalisation was a very relevant problem, particularly according to NGOs, business associations and EU citizens. Feedback to the **inception impact assessment** emphasised the need for integrated solutions, especially with regard to personalised health care.

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

The problems described in this document are of a nature and magnitude that EU-level concerted action will be more appropriate than individual Member States developing their own initiatives. This will enable more coherent and coordinated effort, and avoid duplication. To elaborate, EU action is required for the following reasons[117]:

- 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. No Member State alone could mobilise and engage the diverse range of

[115] Access to health care is the result of interactions between different factors, including health system coverage (i.e. who is entitled to health care), depth of coverage (i.e. what citizens are entitled to), availability of health care services and economical accessibility (affordability), based on Commission Communication on effective, accessible and resilient health systems (2014). Access also includes non-discrimination, physical accessibility, and information accessibility, in line with General Comment on the Right to Health, UN Committee on Economic, Social and Cultural Rights (2000). In addition to financial and organisational aspects, health care access may also be affected by social or cultural barriers that limit the utilisation of services.

[116] Weale A. et al. (2011), High Quality, Comprehensive and Without Barriers to Access? The Future of Healthcare in Europe. In: The Future of Healthcare in Europe (eds. Chaytor, S. and Staiger, U.), UCL: London.

[117] DG RTD (2019), Inception impact assessment of the candidate European Partnership on Innovative Health.

stakeholders and companies individually and reach the required critical mass of expertise and data that are necessary to tackle these challenges.

- Actions at Member State level would be limited in terms of industrial and academic experience available in a given country. An EU-level action is much better positioned to coordinate multiple stakeholders effectively and meet the planned objectives, at the same time avoiding duplication in research.
- Most health-related companies operating in Member States have an EU-wide presence. Their activities and products are governed by EU-wide legal frameworks, e.g. on medicinal products, medical devices and cross-border health care. Therefore, it is logical to have an initiative focused on innovation in health at the EU level. 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.
- Member States alone would not have the legal and financial framework to enable multi-sectoral collaboration with the scope and/or at the scale envisaged.

3.2. Subsidiarity: Added value of EU action

An EU initiative can help bring together a broad spectrum of stakeholders, both private and public in the health field. Industry participation would help to drive academic research efforts towards applicable health innovations, while the EU represented by the European Commission would guarantee that projects address important unmet health needs and deliver innovations that can be taken up by health care systems. An EU-level initiative has the potential to provide the necessary scale and scope of investment to attract additional, or shift existing, investment into R&I into strategic unmet public health needs where industry would not act on its own or where sufficient national funding is not available[118]. Moreover, an initiative under the aegis of the EU would create a trustful and neutral environment for sharing expertise, resources and knowledge[119]. In summary, it can provide added value in the following areas[120]:

- creation of critical mass to address global challenges;
- stability in long-term commitment and work towards common goals (directionality);
- increased industry investment into areas of unmet public health needs,
- increased coordination across public and private actors and across Member States;
- increasing the EU's competitive advantage vis-a-vis major competitors;
- creation of new market opportunities;
- leveraging more public and private investment in health-related R&I (additionality).

The proposed initiative does not go beyond what is necessary to achieve its objectives.

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[118] According to its interim evaluation, "IMI2 JU… leveraged additional funding for medicines research and development at a time when research funding was reduced in most of the European countries". European Commission (2017) The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

[119] For example, IMI2 JU AIMS-2-TRIALS project (https://www.imi.europa.eu/projects-results/project-factsheets/aims-2-trials) working on autism created a clinical trials network that covers 118 sites across 37 countries with access to over 20 000 new patients per year. The c4c project (https://www.imi.europa.eu/projects-results/project-factsheets/c4c) is setting up a paediatric clinical trial network with 19 paediatric national hub trials and national coordinators of trial sites to oversee site activity related to trials. Reaching beyond national borders facilitates the conduct of large clinical trials that would not be possible at national level.

[120] DG RTD (2018), Horizon Europe Impact Assessment. A New Horizon for Europe.

The legal basis for EU action, the same for every option discussed, is provided by Articles 168 and 179 TFEU (in addition, the legal ground for Option 3 – Institutionalised Partnership – lies in Art 187 TFEU). At the same time, Member States hold the primary responsibility for organising health services and medical care as well as for reimbursement and pricing decisions[121]. Therefore, the potential products, solutions or methodologies that might result from IHI would become subject to further independent decisions of relevant authorities and bodies, in line with relevant legislation in place.

The added value of EU action was underlined in the **open public consultation**, especially in terms of responding to: (1) the need to increase the EU's global competitiveness (selected as very relevant by 59% (63 of 106) of respondents) and the problem of limited collaboration between industry sectors (selected as very relevant by 52% (55 of 105) of respondents). Industry **interviewees** commented that investment at EU level was essential to maintain/improve the R&I competitiveness of the European health industry.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

Based on the identified problems, the general objectives of an EU action for research and innovation in health care would be to:

1. contribute towards the creation of an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations;

2. foster the development of safe, effective, people-centred[122] and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to Europe's Beating Cancer Plan;

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

General objective 1 is mainly aimed at addressing current inefficiencies in translating scientific knowledge generated in Europe into health and care innovations, such as new prevention strategies, diagnostics or drugs. **General objective 2** addresses the insufficient innovative products reaching health care services for unmet public health needs. Fostering the development of innovations that are not only safe and effective, but also people-centred and cost-effective will increase the likelihood of innovations being adopted by people and health care systems, and thus providing benefit to EU citizens and also strengthening the

[121] Elaborated in Section 1.

[122] People-centred care refers to an approach to care that consciously adopts individuals', carers', families' and communities' perspectives and sees them as participants as well as beneficiaries of health care systems that are organised around their needs and preferences rather than individual diseases.. 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. Based on: World Health Organization 2016, Framework on integrated, people-centred health services.

economy, if health care systems become more efficient. Finally, **general objective 3** is mainly aimed at addressing the risk to the global competitiveness of the EU health industry.

The general objectives align with Horizon Europe objectives, and in particular with its objective to 'strengthen the scientific and technological bases of the Union' and 'to foster competitiveness[123]. They also align with strategic EU priorities to promote health and wellbeing for all including access to innovative, sustainable and high-quality health care, and with the Sustainable Development Goal 3 of 'Ensuring healthy lives and promote well-being for all at all ages'[124]. In particular, thanks to these general objectives, the initiative will contribute to 'Europe's Beating Cancer Plan'[125] and the 'European One Health Action Plan against Antimicrobial Resistance'[126], as well as the new Industrial Strategy for Europe[127], the Pharmaceutical Strategy for Europe[128] and the SME strategy for a sustainable and digital Europe[129].

4.2. Specific objectives

The proposed partnership is conceived as being agnostic with regard to specific disease areas, while focussing on unmet public health needs[130]. It intends to cover various stages at which it intends to intervene in the health care pathways, including prevention, diagnostics, treatment and disease management[131]. This broadened technological and thematic scope compared to IMI2 JU explains the proposed new name, the Innovative Health Initiative (IHI).

With the rapid scientific and technical progress and the digital evolution, new types of products integrate the different components (such as medicines, diagnostics, treatment monitoring) in ways that has never been done before. For example, a new treatment may be accompanied by a sensor and a mobile health solution that monitors the adherence to the prescribed regime, and it may also collect data for monitoring the safety of treatment. The new possibilities for health interventions can benefit patients while offering new market opportunities to companies. At the same time, while the scientific and technical evolution is rapid and provide many new opportunities, merging of technologies must be fostered in an environment that ensures the quality and the safety of the new innovations, respecting the ethical principles. Therefore, in order to achieve the general objectives, five specific objectives are defined, that respond to the problem drivers discussed in Section 2.2.

[123] DG RTD (2018), Horizon Europe Impact Assessment. A New Horizon for Europe.
[124] European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.
[125] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan
[126] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf
[127] COM(2020) 102 final
[128] COM(2020) 761 final
[129] COM(2020) 103 final
[130] Unmet public health needs are needs currently not addressed by the health care systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease if high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life, …) and/or the number of people affected by it. For example, Alzheimer's disease.
[131] The actual thematic areas of activities will be further defined in the SRA and the resulting annual work programmes.

4.2.1. *Contribute towards a better understanding of the determinants of health and priority disease areas*

By focusing on elucidation of the mechanisms of diseases and factors contributing to health, an initiative on innovative health can provide better targets and approaches to develop new health innovations for prevention, diagnosis and therapy. In this way, this specific objective can lead to more translation of basic research into practical application, covering the priority disease areas, i.e. those of high burden to the society. This objective should result in:

- novel targets for disease prevention, diagnosis and therapy, through improved understanding of disease mechanisms in various disease areas[132];
- novel solutions for continued monitoring of health status;
- novel solutions for disease management and for efficient follow-up of treatment.

4.2.2. *Integrate fragmented health R&I efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end users*

This specific objective is related to breaking down barriers to cross-sectoral collaboration. This applies not only between academia and industry, and between different health industry sectors of different sizes, but also across all health care actors. The expected integration of actors would thus extend to patients and civil society, health care professionals, health care providers, regulators, health technology assessment bodies and health care payers. This objective should lead to:

- demonstrated feasibility of developing combination products (e.g. diagnostics + treatment), in various disease areas, focussing on unmet public health needs;
- harmonised approaches for clinical evidence generation of products combining different technologies.

To give an example, on average 10,000 substances are tested to develop one safe and efficacious medicine that can be used in health care, taking about 10-15 years using traditional approaches[133]. It is expected that the drug development process can be accelerated by using novel approaches, afforded e.g. by bespoke medical devices and machine learning algorithms[134].

4.2.3. *Demonstrate the feasibility of people-centred, integrated health care solutions*

Innovative health care solutions[135] integrating various technologies, coupled with complementary tools and services promise breakthrough solutions to tackle health issues

[132] Examples of disease areas: cardiovascular, neurological, respiratory etc.
[133] Chakravarthy R et al (2016), Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years. Therapeutic Innovation and Regulatory Science, 50(6) 759-768. http://dx.doi.org/10.1177/2168479016648730.
[134] For example, it was recently shown that pre-clinical development of candidate medicinal products can be dramatically accelerated using AI techniques: Zhavoronkov A., Ivanenkov YA., Aliper A. et al. (2019) Deep learning enables rapid identification of potent DDR1 kinase inhibitors. Nat. Biotechnol. 37, 1038–1040,doi:10.1038/s41587-019-0224-x.
[135] 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.

that cannot be effectively tackled today. Those products and services should be centred around people needs and preferences across the health care pathway, so that can be taken up by individuals and health care systems, thereby addressing the problem of insufficient knowledge translation. This objective should result in:

- demonstrated feasibility of developing people-centred, integrated health care solutions along the health care pathway, in various disease areas;
- health care solutions ready to be implemented by health care authorities or organisations.

For example, this could cover the integration of the following interventions in the case of chronic diseases, such as asthma or diabetes: (1) prevention programmes supported by apps to help people manage their health and to identify those at high risk for certain chronic diseases, (2) diagnostic tools to early detect those diseases, (3) personalised treatment for people with the disease, (4) solutions to help improve patient's adherence to treatment, (5) tools, e.g. wearables to monitor patients' health status, (6) solutions to detect and/or report adverse events, and (7) products and services supporting efficient workflows along the health care pathway, e.g. digital health solutions to facilitate communication between health care providers.

4.2.4. Exploit the full potential of digitalisation and data exchange in health care

Harnessing the full potential of big data[136] and real-world data[137] requires the digitalisation of health services, finding new ways to observe health and disease states, collecting the relevant digital biomarkers using health technologies, and developing advanced analytics/artificial intelligence approaches and software to convert data into valuable knowledge. These aspects are at the heart of data-focused approaches and could help innovators to develop more effective tools and products, including innovative, integrated solutions for preventing, diagnosing, treating and managing health conditions (e.g. tools to support real-time shared decision-making between patients and their health care providers using big data analytics platform). This objective should lead to:

- successful application of digital and data-driven solutions for health care, integrating various public and private data sources.

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.

[136] Big Data refers to extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require advanced or specialised methods to provide an answer within reliable constraints.

[137] Real world data are data regarding the effects of health interventions that are not collected in the context of conventional randomised controlled trials but prospectively and retrospectively from observations in routine clinical practice from many sources including patient registries, electronic medical records, and observational studies.

4.2.5. Enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions

There is a need for new approaches to assess the added value of novel health care solutions, thereby strengthening the overall conditions for R&I to target strategic unmet public health needs in areas where industry has traditionally been less active, due to perceived high risk and/or low return on investment.

The advent of complex and integrated solutions necessitates the development of adapted methodological approaches and tools to assess the value that these products will bring to the patient, the health care system and the society as a whole (see footnote 39 for the explanation on "value" in this context). This specific objective envisages the development of methods and tools by working transparently and collaboratively across academia, industry, regulatory and health technology assessment (HTA) bodies, health care professionals and providers, patients, informal carers and citizens. As a result of reaching this objective, health care authorities and organisations should avail of:

- methodological toolbox for the comprehensive assessment of the added value of combined products;
- methodological toolbox for assessing the added value of novel, integrated health care solutions;

The actual deployment of products or solutions in health care settings are in the remit of individual health care organisations and in the national competence of Member States according to Art. 168 TFEU. Moreover, while outputs of certain actions are supposed to serve as input to regulators, health technology assessment bodies or health care organisations to optimise their internal processes, implementation of these inputs will remain at full discretion of the bodies concerned as they need to remain independent, objective and free of conflicts of interest. The IHI objectives are focussed on pre-competitive space, therefore not infringing EU competition- and state-aid rules.

There is risk that the proposed objective would be seen as a 'push' from industry and therefore public authorities and health technology assessment bodies would be hesitant to engage. However, such approaches – if ultimately implemented in real life settings – would result in a win-win for the public and private sectors, and would lead to a shift into new areas of health innovation and eventually deployment of innovative solutions.

Interviewees were overall supportive of the initially defined specific objectives, in particular respondents coming from industry and research infrastructures. Patient associations expressed the most concern, feeling the objectives were not sufficiently patient-centric. These views were taken into account when formulating the specific objectives presented above. There were some comments across stakeholder groups that the objectives were too broad, but it was understood by stakeholders, primarily in industry and research infrastructures, that it was not possible to define specific disease areas at this stage.

In the **feedback to the inception impact assessment**, non-private actors (NGOs, academics/research institutions, and public authorities) were calling for broader stakeholder involvement. This point was stressed in particular by NGOs including patient organisations and public authorities. This was also repeated by **interviewees** who emphasised the need to include additional stakeholders beyond industry and academia.

Fulfilling the specific objectives will indeed help to address the underlying problems, improving the industry competitiveness, health status of the citizens and preparedness for future health threats. This would be achieved by focussing on pre-competitive collaboration in areas that are of strategic interest for the EU, based on the public health needs but also based on the positioning of the EU industry in the global health value chains.

IMI has delivered innovations in the pharmaceutical domain, therefore they were mainly focussed on therapy, while IHI could address health challenges in a much broader manner, with more focus on prevention strategies, preparedness and diagnostics. Compared to the scope of IMI: SO1 which was partly addressed by the predecessor initiatives from the point of view of the action of drugs but less so from the point of view of prevention; SO2 is far broader as it covers improved prediction, prevention and diagnosis; SO3 will work explicitly towards integration of various health technologies (for example, medicines and diagnostics); SO4 expects to harness new digital solutions to improve health and health care, not available to a significant extent at the time of establishing IMI2 JU; SO5 reflects the regulatory and uptake needs stemming from the emergence of combination products (e.g. medicines and mobile apps) that do not easily fit into current regulatory schemes.

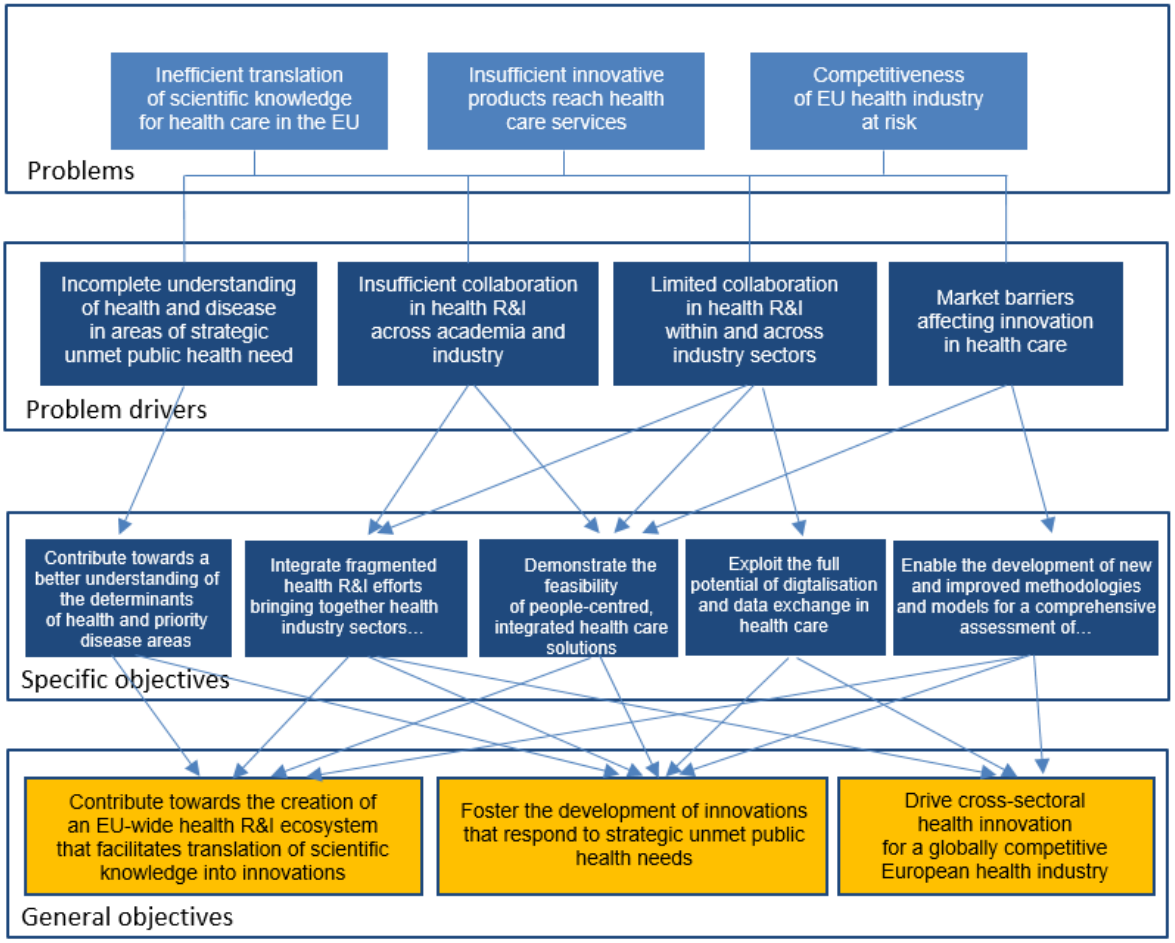
The COVID-19 crisis, as earlier the Ebola and Zika crises, have confirmed the need to address health challenges at multiple entry points, but in an agile and coordinated manner, encompassing data collection and analysis, diagnostics, prevention including by mobile health approaches, development of therapeutics and long-term prevention by vaccination – taking into account the specificities of the EU health research systems and industrial value chains.

By targeting these objectives, IHI would (a) address clear public health needs, (b) contribute to alleviate market barriers, such as those related to insufficient regulatory convergence, (b) increase the uptake of innovations by better reflecting the needs of the end-users and (d) fulfil industries' expectations in terms of return on investment in the early phases of research. The principal value of the proposed partnership for its stakeholder would be access to novel multisector collaborations at pre-competitive stage. This goes together with sharing new skills and data necessary to tackle new objectives and ultimately increasing the future competitive edge of participating companies. This opportunity is not offered at this scale by any other EU funding instrument.tar

4.3. Intervention logic of the initiative

The relationship between the general and specific objectives of the potential Innovative Health Initiative is shown in Figure 8.

Figure 8: Intervention logic for the initiative on Innovative Health



The translation of health R&I into products is a complex phenomenon that – beyond understanding the molecular basis of certain diseases – also depends on successful demonstration of safety and efficacy during the clinical phases of development, followed by regulatory steps and pricing & reimbursement decisions before innovations can reach the market and end-users, such as patients and health care professionals. In that respect, health R&I differs from a purely engineering or technological development where one outcome (e.g. a working prototype that can be up-scaled for market uptake) could directly result from one underlying intervention (e.g. a certain number of clearly defined technological improvements). For this initiative, specific objectives can be interlinked and address jointly one or more problem drivers.

For example, integrating health R&I efforts across actors and technology sectors (specific objective 2) and exploiting data and digital tools (specific objective 4), will facilitate understanding the causes of disease (specific objective 1), e.g. by more efficient use of data in clinical trials. It can also contribute to accelerated development of integrated health solutions (specific objective 3), for example by introducing mobile health solution to monitor the efficacy of treatment. Providing regulators with adequate data and methodological toolboxes to speed up regulatory uptake (specific objective 5), will also support the accelerated development of relevant health innovations (specific objective 3) by shortening the time to market and thus increasing the return on initial investment.

In particular, specific objective 4 relating to the use of data and digitalisation in health care was presented separately because it is key for linking all health industry sectors and it can

give a new angle to the process of developing new prevention or treatment strategies. Various companies indeed need and want to avail of and share consistent and interoperable data to successfully perform translational R&I but this cannot be done efficiently without inter-operable data standards, reliable data analytics tools or addressing privacy concerns. This is the reason why this initiative intends to enable a more effective, safer and ethical use digital technologies and data analytics in health research (for example, by the definition of common data exchange standards for electronic health records such that can be efficiently combined with data obtained during clinical trials of new medicines). In this way, this specific objective will help address the problems of lower R&I productivity and inefficient translation of research results into clinical practice.

The development of integrated people-centred solutions (specific objective 3) would be based on the integration of products and services developed by different industry sectors (specific objective 2), which would trigger collaboration between those sectors, thus responding to problem driver 2 "insufficient collaboration within and across industry sectors" but also problem driver 4 "market barriers affecting innovation in health care". It would indeed require addressing existing barriers to collaboration such as, for example, developing common definition of precompetitive space, looking for convergence of business models, alignment of regulatory requirements (in particular for clinical evidence generation) and developing new methodologies to assess the value of those complex and cross-sectoral health solutions.

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 122 for a full definition). This approach aims at limiting siloed approaches across health care services but also across industry sectors. In this respect, specific objective 3 would also respond to problem driver 2. In addition, 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 better responding to the needs people and health care systems, thus lowering market barriers to innovation (problem driver 4).

Specific objective 5, related to delivering new methodologies for assessing the added value of health innovations, is indeed linked to market barriers affecting innovation in health care (identified as problem driver 4) that are partly due to the lack of methods to assess the added value for patients and society of novel, cross-sectoral health solutions. Such methods are used by the industry to demonstrate the benefit brought by an innovative solution and by health care authorities/institutions to inform their decision on reimbursement and pricing. A lack of such methods has consequences on both availability and accessibility of health innovations. It negatively impacts R&I investment decisions due to increased uncertainty around the future reimbursement by health systems. It also has an impact on implementation of innovations in health care systems because such methods are essential for the public health actors to assess the added value for patients and society, decide on coverage decisions, negotiate prices with industry and determine the conditions under which to implement those innovations in order to maximise health benefit for society.

Unmet public health needs result from a lack of availability or accessibility to health care in areas of public health importance. Specific objective 5 would imply developing solutions able to tackle either availability of health care technologies (e.g., by stimulating their development and providing the necessary conditions for it) or their accessibility (e.g., by providing the support to efficiently implement those technologies in health care systems so that they are available to people). 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 (problem driver 4).

How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following expected impacts:

Scientific impacts

If successful, the initiative is expected to demonstrate various types of scientific impacts:

- Strengthened EU skills and capacity in academic and industrial health R&I;
- A thriving EU-wide cross-sectoral health R&I ecosystem created;
- New scientific paradigms established in areas of unmet public health needs.

Overall the initiative would strengthen the scientific base for the development of new prevention strategies, diagnostics and treatments. Additionally, integrating the main biomedical industry sectors is expected to lead to improved mutual understanding of particular knowledge needs of the different industry sectors and improved cost-effectiveness of R&I investment by reducing inefficiencies due to boundaries between disciplines. In the long run, this would result not only in an increased cross-sectoral collaboration at research level, but could also stimulate changes of paradigms for the actual translation of scientific findings into concrete health and care approaches. Moreover, knowledge creation and skills development through collaborative projects, especially across public and private actors, is set to strengthen Europe's human capital in health R&I.

Economic/technological impacts

If successful, the initiative is expected to demonstrate a set of economic/technological impacts:

- More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats;
- Better, safe, effective and cost-effective health technologies, tools and digital solutions;
- Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these areas.

If successful, the initiative would further lead to reduced investment risk in R&I, due to collaborations and the involvement of several industrial sectors; increased access to industrial data for academic researchers; increased efficiency of R&I investments through targeted use of biomedical research resources, both public and private. In doing so, 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. It could directly and indirectly create highly skilled jobs, both in academia and industry.

Societal and environmental impacts

If successful, the initiative is expected to demonstrate a set of societal impacts:

- Improved health and wellbeing of EU citizens;
- Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs;
- Strengthening circular economy and mitigating the negative health impacts of climate change.

Overall, if successful, the initiative is likely to contribute to improved health outcomes 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, such as brain disorders. More 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. Moreover, a more wide-spread use of digital solutions in medicine should lead to better health or disease monitoring in real life and to reduced need for travel to health care centres.

However, whether these impacts will actually be achieved and to what extent, will depend on the types of projects funded through the initiative. Digital health technologies that can be used remotely are likely to result from the initiative, leading to lowering greenhouse emissions in the long term. At the same time, the increased use of energy related to more wide-spread use of data-intensive approaches and digital tools (e.g. using energy to store, process, analyse and exchange data), may counterbalance this benefit, depending on the proportion of energy from renewable sources used to power health care.

4.4. What is needed to achieve the objectives – key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of actors to be involved

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 (and thus for reaching specific objectives 1, 2 and 3 that lead to expected scientific and economic/technological impacts);

- 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 (necessary to reach specific objectives 2 and 3, and consequently the scientific/technological and societal impacts);

- 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 (via reaching specific objectives 3 and 5, ultimately leading to societal impacts.

Based on the interim evaluation of IMI2 JU (see Annex 6 for details), a lesson to be learned is the need 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'. Therefore, the industry sectors need to cover the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area. These actors are necessary (to a varying degree, though) to achieve each of the specific objectives. As an overarching requirement, better early engagement with regulatory bodies would likely limit wasteful or inefficient research and speed up deployment, at the same time addressing a weakness identified in IMI2 JU interim evaluation (explained in Annex 6) and a recommendation from IMI2 JU Scientific Committee[138].

Member States overall (except one) did not express the wish for a tripartite partnership involving the industry, Member States and the EU[139].

Openness and flexibility to integrate players from emerging and/or adjacent technologies is vital, notably to reach specific objectives 2 and 3 to demonstrate feasibility of people centred, integrated health care solutions, as well as objective 4 aiming at harnessing the full potential of data and digitalisation for health innovations that rely on data use and on the rapidly changing field of digital technologies. Therefore, new entities should be able to join the initiative as members if emerging health challenges would so require, in this way also responding to input from targeted stakeholder consultation. This openness and flexibility should also be reflected in the participation into IHI-funded actions, notably to ensure the agility and ability to quickly mobilise all actors in the health value chain, in order to respond to newly emerging health threats, including pandemics[140].

Furthermore, it is essential to facilitate the participation of innovative SMEs in projects (thus addressing another weakness identified for IMI2 JU) to ensure reaching specific objective 2 aimed at integration of fragmented R&I across technology sectors and other stakeholder, and to help achieve the scientific and economic/technological impacts.

There are areas of health technology, data analytics and expertise in certain health conditions that are more advanced in non-EU countries (or where a higher number of people

[138] Early dialogue with regulators was identified by IMI2 JU Scientific Committee as desirable for a successful public-private collaboration. IMI2 JU Scientific Committee recommendations regarding public private partnership funding – what makes a topic ultimately suitable for this kind of funding model, https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/SCrecommendations_PPPfunding.pdf; IMI2 JU Scientific Committee recommendations regarding involvement of regulators and regulatory science, https://www.imi.europa.eu/sites/default/files/SC%20Recommendation_Involvement%20of%20regulators%20and%20regulatory%20science_FINAL.docx.pdf.

[139] Specific reasons were not provided in the structured consultation of the Member States.

[140] In the case of COVID-19 pandemic, IMI2 JU was able to – within a few weeks only – mobilise the investment of EUR 72 million of EU contribution accompanied by EUR 45 million in-kind investment from pharmaceutical companies, aimed at development of treatments and rapid diagnostic tests useful in the fight against the current and/or future outbreak. https://www.imi.europa.eu/apply-funding/open-calls/imi2-call-21.

are affected by a certain disease that also threatens EU population). Therefore, a certain openness of the initiative and participation by these international academic, industrial and regulatory actors is also desirable, in order to be able to benefit from this expertise, to respond to emerging health threats and thus realise the necessary societal impact, notably of improved health outcomes for EU citizens.

4.4.2. Type and range of activities needed

The fundamental building blocks of an initiative on innovative health would need to be collaborative R&I actions that foster academia-industry, industry-industry and cross-sectoral collaborations, particularly important for specific objectives 1, 2 and 3 (related to better understanding the determinants of health and disease, integration of R&I efforts and fostering the development of integrated health solutions). Some actions may also advance assets[141] to technology validation and the building of technology prototypes, thus benefitting from more focussed pilots, validation and demonstration activities, notably to demonstrate the feasibility of integrated health care solutions, exploit the potential of digitalisation and deliver methodologies and models for the assessment of added value of health innovations (covered by specific objectives 3, 4 and 5). The involvement of a broader set of actors, including users, is necessary, to ensure that the initiative accelerates the development of people-centred products as defined in specific objective 3. Coordination and support actions can provide useful means to conduct policy dialogues around ethics, standardisation and regulation, in line with specific objective 5.

The activities would need to focus on pre-competitive R&I, thus creating a safe space for collaboration between potential market competitors, such as pharmaceutical companies active in the same therapeutic area, e.g. cardiology or oncology, or diagnostic companies developing related technologies, e.g. for improved imaging or for rapid viral infection testing. This range of activities is important for better understanding the determinants of health and disease, integration of R&I efforts over technology areas and for making it possible to develop integrated health solutions (in line with specific objectives 1, 2 and 3), as well as for reaching the impacts of strengthened health R&I capacity in a cross-sectoral, EU-wide ecosystem. This proposed range of activities builds on the positive experience from IMI2 JU[142] that should now be expanded to cover more health industry sectors.

4.4.3. Priority setting system and level of directionality required

Reaching all the objectives requires a long-term strategic vision and committed partners working in collaborative R&I projects, aiming to achieve more than would be possible to achieve if working in isolation, in order to make a step change in accelerating the development of innovations in specific health and disease areas, for the benefit of patients, health care providers and systems. A jointly agreed strategic research agenda is therefore needed so that the shared vision aligns with the individual goals of the members of the initiative, and so that all actors have a clear understanding of how the various elements of the initiative will fit together in a coherent manner, building commitment and trust and contributing to reaching the jointly agreed objective and thus impacts. The strategic vision

[141] "Assets" may be e.g. new drug or diagnostic candidates, drug targets, biomarkers, health research tools, clinical trial methodologies, industrial processes, services etc.

[142] According to IMI2 JU interim (2014-2016) evaluation: 'the main achievement of IM2 JU on which there was general consensus, was that since the JU started, collaborations between different competing global companies, SME's and academia became possible. These collaborations created trust and new links [and] were considered an important asset for European pharmaceutical research.'

should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

The EU contribution is expected to mobilise an additional (at least 100%) private sector contribution[143] (in-kind or financial) that the industry would not have otherwise spent in strategic unmet public health areas, in particular in cross-sectoral collaboration. This type of commitment to pool resources only happens beyond the scope of individual projects and requires long-term predictability and commitment to the jointly accepted strategic research agenda. Thanks to these additional resources, the initiative would ensure the necessary leverage to be able to successfully tackle its objectives and deliver on its impacts.

4.4.4. Coherence needed with the external environment

The initiative would need to seek synergies with other Horizon Europe initiatives and partnerships in the health domain, in particular with the planned Partnership on Transforming Health and Care Systems (potential interdependencies were explained in Section 1.3). Beyond health, the 'Key Digital Technologies' initiative would likely offer complementary approaches to promote the digital transformation of the health sector, at the same time ensuring the protection of privacy and sensitive human data (relevant in particular for specific objective 4 and 5).

The EU policies on clinical trials, market authorisation of pharmaceuticals, ATMPs and medical devices would need to frame the activities from the regulatory side. The new Industrial Strategy for Europe[144], the EU Pharmaceutical Strategy for Europe[145] and the SME strategy for a sustainable and digital Europe[146] will provide an additional policy guidance for the initiative.

On digitalisation (linked in particular to specific objective 4 on exploiting the potential offered by digitalisation in health innovations), the initiative should be linked with the Digital Europe programme as regards the necessary test and experimentation infrastructures and advanced digital skills for the validation and initial deployment and uptake of digital health innovations. The initiative should be linked with the Connecting European Facility, with its eHealth Digital Service Infrastructures (eHDSI), as regards the capacities to scale up these digital health services across EU Member States via cross-border (interoperable) health data exchange and related international standards.

Effort to ensuring internal and external coherence would reflect a lesson learned from one the weaknesses identified in IMI2 JU, i.e. insufficient coherence and alignment with regional and national policies and strategies (see Annex 6).

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

[143] The leverage of IMI2 JU reached 99% in 2018, according to IMI2 JU Annual Activity Report 2018 (private commitment vs EU funding).
[144] COM(2020) 102 final
[145] COM(2020) 761 final
[146] COM(2020) 103 final

5.1. Option 0: Horizon Europe calls (baseline)

The baseline scenario used in this impact assessment is a situation without a partnership and only traditional calls of Horizon Europe. Given that there is a predecessor partnership (IMI2 JU) as well as other funding sources in the area, these will continue generating effects even if there is no new partnership. These already existing initiatives are expected to create longer-term effects on health innovations. This is taken into account in the effectiveness assessment.

IMI2 JU was established by on a Council regulation and is time-bound, without a mechanism for automatic renewal of the initiative. With no action, 2020 is the last year of launching calls and IMI2 JU will cease to exist in 2024. This justifies the choice of regular Horizon Europe calls as the baseline. Therefore, in the baseline situation, the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular (analysed in more detail in Section 6.2). This is also taken into account in the efficiency assessment.

Table 2: Key characteristics of the baseline situation - Horizon Europe calls

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	- Given the broad range of activities and actors envisaged, the Commission would need to consult extensively with a wide range of stakeholders to translate the strategic R&I agenda for health into annual work programmes. However, under this option, the setting of scientific priorities and definition of call topics would follow the usual Commission comitology procedure that does not involve formal consultation of the industry and hence tends to be more academically oriented. - The feasibility of engaging key actors: researchers from academia and various industry sectors users (patients, health care professionals, health care providers) and regulatory authorities would be low since traditional calls do not offer a structured mechanism for such engagement. Regarding specifically the necessary industry sectors (pharmaceuticals, medtech, biotech, imaging, vaccines), the likelihood of engaging the various industry participants jointly would be very low[147]
Supporting implementation of R&I agenda	- All types of funding instruments could be used. - Implementing the strategic research agenda would require the mobilisation, expertise and support of the health care industry. The calls are very open and flexible, though, enabling participation of actors along the health value chain in ad-hoc combinations, on a project basis. - Calls for proposals would be published in the work programmes of Horizon Europe. Implementation would thus rely on standard infrastructure underpinning the open calls, drawing on resources of the Commission or relevant executive agency and Commission IT systems. - Additional administrative costs for the European Commission would be low. - Dissemination of knowledge and sharing of practice would happen predominantly among partners within the project consortia.
Ensuring alignment with	- Annual work programmes developed through the comitology process are expected to cover a broad range of health issues, with fundamental discovery research prioritised.

[147] See details in Section 2.2.2.

R&I agenda	- Receiving the necessary input from representatives of all relevant stakeholders (including industry and end-users) is unlikely, in absence of a dedicated mechanism for that. - Projects delivered within and across calls may not synergise and critical mass for addressing priorities may be limited. - Annual work programmes could respond to emerging R&I needs and new technological developments in health over time but the process is less agile to adapt to unforeseen changes in a coordinated manner. - Commission input into specification and oversight of calls would help to ensure alignment with overarching policy objectives, even if full integration with other programmes would require additional coordination. In the absence of a dedicated implementing structure, traditional calls would offer less effective alignment with other key initiatives and organisations in the global health R&I arena.
Securing effective leveraging of resources	- EU grant funding would be the dominant financial contribution to projects, attracting mainly academic and SME researchers and other public sector organisations. - Traditional calls are not capable of attracting additional funds from industry; rather, the calls provide funding for industry partners. - Participation of big pharmaceutical companies would be unlikely or limited, due – among others – to those companies' aversion to accepting such public funding.
Key differences compared to the current situation	- Discontinuation of IMI2 JU without a successor, entailing the winding down costs and losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate. - Potential applicants and the general public would lose the targeted communication activities and various forms of support offered by the Programme Office after it has closed operations. - The pharmaceutical sector would lose a 'neutral platform' of collaboration in pre-competitive space.

5.2. Option 1: Co-Programmed European Partnership

Table 3: Key characteristics of Option 1 – Co-Programmed European Partnership

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	- The initiative would be based on a memorandum of understanding or a contractual arrangement between the European Commission and the private partners. - The partnership would need to consult with industry representatives and a wide range of stakeholders, including end-users, to ensure that the strategic research agenda (and ultimately the annual work programmes) is aligned with industry needs, is feasible and that it addresses strategic unmet public health needs. - It would enable participation in projects by all key public and/or private stakeholders along the entire health and care innovation pathway, across communities and technology sectors and/or value chains and where the actors have widely differing capacities and capabilities. - The composition of partners can change over time, allowing for flexibility and adaptation to emerging needs in the health R&I arena.
Supporting	- All types of funding instruments could be used.

implementation of R&I agenda	- Calls for proposals would be published in the work programmes of Horizon Europe. Implementation would thus rely on standard infrastructure underpinning the open calls, drawing on resources of the Commission or relevant executive agency and Commission IT systems. - Progress in the delivery of the R&I programme would depend on the willingness of stakeholders to support individual projects, rather than on longer term, firm commitments. - Other stakeholders would have limited control over the precise definition of the calls, limiting the extent to which calls can be adapted to the specific needs of certain end-users.
Ensuring alignment with R&I agenda	- Under the co-programmed option, a strategic roadmap is agreed between the EC and the partners involved. The work programmes are developed through a comitology process. - R&I activity would be likely to focus on the medium-term needs of partners. - This option allows for the creation of a dedicated small office to manage the initiative, financed via a Coordination and Support Action. However, this option would not allow for creation of a dedicated implementation structure and a broader coordination of programmes.
Securing effective leveraging of resources	- This option could mobilise additional private sector resources, with the likely low level of 'additionality'. Lower level industry contribution would probably be reflected in smaller overall EU commitment. - Aspirations for partners' contributions would need to be clearly defined at the outset, in line with the level of predictability of open call topics. - Projects under this option are funded under the same rules as in option 0, and thus are not attractive for certain big companies, including from the pharmaceutical sector. These firms play a key role in the targeted industry-academia and industry-industry collaborations and are the most capable of providing additional resources (in-kind or in-cash).
Key differences compared to the current situation	- Discontinuation of IMI2 JU without a successor, entailing the winding down costs and losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate. - Potential applicants and the general public would lose the targeted communication activities and various forms of support offered by the Programme Office after it has closed operations. - The pharmaceutical sector would, to a large extent, lose a 'neutral platform' of collaboration in pre-competitive space.

5.3. Option 3: Institutionalised European Partnership under Article 187 TFEU

Table 4: Key characteristics of Option 3 – Institutionalised European Partnership (Article 187 TFEU)

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	- A membership structure clearly defined from the outset allows for a binding engagement of the necessary industry partners. - Participation would be less flexible than under other options, but it might nevertheless be possible to change the composition of founding partners over time, to support new

	areas of activity in response to emerging challenges and evolving priorities. - It would provide a platform for consulting stakeholders on R&I priorities and the work programmes, ensuring that they are aligned with industry, research and end-user needs and with the agenda of other partnerships. - The integration of the needs of all relevant industry sectors and public actors would be reflected in the specification and expected delivery of the strategic research agenda. - Eligibility for participation and funding would follow Horizon Europe rules by default, the basic act may include, e.g. certain adaptations of intellectual property rules and broader participation, e.g. of international actors from non-EU countries. This has particular relevance in health R&I, since many world-leading industrial players, particularly from the UK, US and Japan, have extensive R&I activities in the EU.
Supporting implementation of R&I agenda	- Legally binding funding arrangements and dedicated administrative resources would ensure implementation of the strategic research agenda for the whole duration of Horizon Europe. - A dedicated legal entity would be created with responsibility to coordinate the implementation of the jointly agreed strategic research agenda, manage implementation of calls, monitor key indicators and report on the results. - Dissemination of knowledge and share of practices would happen among the stakeholders of the community, with potential diffusion activities managed by the Programme Office. A dedicated administrative structure would be established to coordinate the specification of R&I activity, manage implementation and report on the results (with administrative expenditure limited to a percentage of the budget).
Ensuring alignment with R&I agenda	- The partnership would be responsible for specifying work programmes in line with strategic research agenda. - The work programme would reflect the medium- and long-term needs of industry, the EU policy needs as well as the needs of end-users represented in the governance structures. - Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes and initiatives.
Securing effective leveraging of resources	- Legally binding funding requirements would be clearly defined at the outset. - High possibility for leveraging funding from industry partners as their contributions can be matched by the EU. - Risk sharing, new collaborations and EU co-financing would likely stimulate additional industry investment, not mobilised otherwise.
Key differences compared to the current situation	- Building on the current partnership albeit with a significantly broadened scope, enlarged partner composition and revised objectives to better harness cross-sectoral collaborations and the new opportunities they may offer. - Extensive explanation of similarities and differences is provided in a tabular format in Section 6.4.

This partnership type could build on the lessons learnt and achievements of the IMI's almost 15-years long history. Associations of medtech, biotech, imaging and vaccine industry sectors have indicated a strong preliminary interest in becoming members of such an Institutionalised Partnership, along with EFPIA's continued interest. The new associations have a large number of SME partners, across various geographies, which could help address

three issues of the current IMI2 JU[148]: (1) low participation of industry sectors other than pharma such as imaging, diagnostics, medical technology and ICT; (2) limited SME participation; (3) geographic disparities in participation patterns.

For big companies, this option could allow participation while refraining from receiving EU-funding, which would increase their willingness to engage. An Article 187 partnership offers strong, long-term strategic steer (directionality) and the highest additional private sector resources to reach the objectives (additionality). A pre-requisite for such a significant additional investment is that industry partners have a role in co-developing and executing the strategic research agenda (SRA), in programme supervision (via membership in the governing board with voting rights) and in communications. All these conditions are fulfilled if the initiative is implemented as an Institutionalised Partnership.

5.4. Options discarded at an early stage

A Co-Funded Partnership and an Institutionalised Partnership created under Article 185 TFEU are not considered relevant for this candidate partnership. As the initiative's objectives include facilitating innovation and boosting competitiveness of European industry, this naturally requires participation from industry at its core. The discarded options focused on public-to-public cooperation and thus would be not be appropriate for this initiative.

6. HOW DO THE DIFFERENT POLICY OPTIONS COMPARE TO ACHIEVE THE EXPECTED IMPACTS?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' – how success would look like – differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system[149].

Scientific impacts

The baseline option is expected to result in many discovery science projects, leading to the elucidation of mechanisms of various health and disease conditions, and likely to major fundamental discoveries. However, by themselves, these calls would likely not be focused on clinical development nor would deliver implementable complex health solutions. For that

[148] European Commission (2017), The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

[149] A more in depth and detailed analysis of each policy option is provided in Technopolis Group (2020)

to happen, a more strategic approach is needed, with a broader 'portfolio-level' thinking, strategic steer (directionality) towards common objectives, alignment of individual projects and the joint participation of industrial partners.

Multi-company and multi-sector collaborations are infrequent in research projects funded through regular calls so far[150] and the same is likely in the future. Horizon Europe calls would therefore miss out on the opportunity to link up SMEs, academia or public research organisations having innovative concepts with large companies that have the resources to develop these concepts further and ultimately bring solutions to market.

Moreover, under the baseline option, neither the Commission nor the partners make an upfront budgetary commitment. This also implies less political commitment and reduced visibility to the field compared to an initiative under a partnership approach. Therefore, the impact on increasing the scientific leadership in the EU, readiness to respond to new health threats and technological sovereignty would be significantly lower than in a partnership.

Stakeholder opinion

Interviews indicated that regular calls would be effective at achieving scientific impacts but would have a more limited scope due to budget and timeline constraints. Many smaller projects under regular calls could potentially result in duplication of efforts and limited internal coherence, and would be unlikely to enable the establishment of large research platforms. No respondent from the consultation on the inception impact assessment mentioned Horizon Europe regular calls as a preferred option to implement IHI.

Option 1 (Co-Programmed Partnership, CPP) would be able to attract broader communities and a diverse set of actors with differing capacities and capabilities. It is conducive to working across the public/private divide and to engagement with health professionals, health authorities, patient organisations and standards bodies to work towards common objectives (directionality). SMEs, some larger companies and other strategic partners could be engaged to some extent due to the medium-term strategic research direction. However, industry stakeholders would have more limited contribution to the detailed definition of the calls, hence restricting their interest to participate at full scale and commit financially to the initiative (especially the larger companies). The absence of an established mechanism to value private entities' contributions, such for in-kind on additional activities (established only at the level of Council regulation for Art. 187 initiatives) that increase the leverage and bring valuable resources to projects, would leave large industries' involvement and investment in projects at a very moderate level. This option therefore provides a similar potential as the baseline to lead to *strengthened EU skills and capacity in academic and industrial health R&I*, without reaching the full potential of this impact dimension. A CPP would likely focus on creating new cross-sectoral networks and opportunities for sharing expertise, resources and new knowledge. Therefore it has a similar potential as the baseline to *create a thriving EU-wide cross-sectoral health R&I ecosystem*.

The CPP would likely succeed in exploring some major scientific questions, including those that advance regulatory science to a great extent. Therefore, this option would offer similar potential as the baseline to *establish new scientific paradigms in areas of unmet public health needs*, therefore scored as 0.

[150] The main beneficiaries of the 7th Framework Programme (FP7) and Horizon 2020 health areas were academia and public research organisations. The private sector made up about one fifth of all participants, mainly SMEs plus some large companies, albeit sporadically. Further analysis of this situation can be found in the impact assessment study report Section 6.1.1.

Stakeholder opinion

Interviews indicated that a Co-Programmed Partnership was preferred to Horizon Europe regular calls in particular due to the longer term focus. However, it was felt that the commitment under the CPP option would not deliver the security needed to invest in truly innovative and risky ideas and may therefore not be attractive to some partners. Establishing common research agendas was seen as valuable but insufficient to overcome the barriers of different sectors working in isolation from one another, and the CPP would therefore not benefit from the full set of outcomes stemming from the cross-pollination of skills and knowledge under a partnership

Option 3 would have its long-term priorities enshrined in the SRA developed after broad stakeholder consultation, with the possibility to amend it when needed following a transparent process. The Institutionalised Partnership would have full responsibility for developing and implementing the annual work programmes without using the formal comitology process (the Member States' input would be secured via representation in IHI governance structures).

This option ensures the highest level of integration of stakeholders and the highest level of focus on strategic R&I questions to meet the desired specific objectives. With a high level of directionality, the strategic and potentially 'portfolio-level' approach would increase the chances of (1) integrating the currently disparate technologies of the various industry sectors and (2) creating a multi-stakeholder initiative that shares expertise, resources and knowledge for disruptive ideas of health innovation, necessary for addressing specific objectives, notably 1 and 2. In addition, option 3 offers stability with regard to funding members and financial commitments which will in turn support long-term scientific commitments. This option would thus offer a unique opportunity to bring academia, public research bodies and other actors (SMEs, but also regulators and health technology assessment bodies as well as end-users) closer to industrial partners. This would translate into good potential compared to the baseline for both *strengthened EU skills and capacity in academic and industrial health R&I* and contribute to the *creation of a thriving EU-wide cross-sectoral health R&I ecosystem* and facilitate uptake by health care systems. These two aspects would therefore be scored as +, compared to the baseline of 0 (of note, creating an R&I ecosystem is considered an endeavour of a very long time horizon, dependent on external factors such as the tax incentives or economic situation in general, preventing this option from receiving an even higher score).

This should, in principle, result in an increase in the relevance, quality and coherence of the portfolio of projects. There is, however, also a certain risk that the partnership calls for proposals will be 'over-specified' and, as a result, they will not attract the broadest array of applicants or any 'unorthodox' scientific proposals. On the other hand, this potential risk would be mitigated by the involvement of the EU in the decision-making process and ensuring sufficient openness of the call topics, and also compensated by the access of academic consortia to additional scientific expertise and valuable dataset held by the industrial partners. This would lead to equal impact potential *in establishing new scientific paradigms in areas of unmet public health needs* as the baseline[151]. Its score would therefore

[151] The citation impact of IMI research is higher than EU and world averages. The field-normalised citation impact for all IMI papers is 1.99, compared to 1.10 for the EU and the baseline of 1 for the world. IMI is also compares favourably with similar organisations such as the Wellcome Trust, the Medical Research

also be 0. At the same time, the resulting developments would likely be of higher direct relevance for the end-users, including EU citizens, health care practitioners and health care systems.

Stakeholder opinion

The proposed use of Article 187, and the establishment of a Joint Undertaking, was supported by 73% of Member States.

In the **inception impact assessment** consultation, 17 of the 18 respondents who spontaneously expressed their views on the mode of implementation were in favour of an Institutionalised Partnership, without any difference of views between the categories of respondents. Reasons cited for preferring this option were that it would enable long-term commitment of key stakeholders and ensure continuity of research ideas.

The majority of **stakeholders interviewed** felt that and Institutionalised Partnership would be the most effective means of delivering scientific impact. Stakeholders from industry saw this option as attractive because it would offer industry opportunity to co-develop research agendas. Similarly, stakeholders from other groups felt that having a diverse range of players would enable the development of research agendas that are more balanced across the needs of all actors, leading to more realistic and holistic research goals. The legally binding arrangement was seen as an advantage by providing a level of confidence to the stakeholders involved, hence facilitating the sharing of data required to achieve impact.

As for the **public consultation** on the 12 candidate Institutionalised Partnerships, respondents viewed long term commitment and long-term funding as major advantages for IHI. 55% of respondents indicated that IP was the best fit (with no difference between the views of citizens and other respondents), while only 9% supported a Co-Programmed Partnership (the remainder preferred either regular calls or a Co-Funded Partnership, a discarded option).

Economic/technological impacts

The baseline option would entail limited private sector involvement, as explained in Table 2 and in Section 6.1. Industry participation (by small, medium and large enterprises) is, however, essential to the process of advancing innovative assets (e.g. new candidate drugs or diagnostics) closer to deployment in the health care sector and international markets. The primary goal of IHI, namely to integrate the currently disjointed components of drugs, devices and software into real integrated health solutions (and thereby the specific objective 3) would not be achieved.

Under **Option 1**, the SRA could have industry contribution and therefore the Horizon Europe work programmes would be expected to have some technology focus mobilising interests from across the value chain, including the private sector.

Still, Option 1 would not offer dedicated support for managing the programme at a required scale, which is needed to ensure the proper budgetary control over industry contributions, ensuring consistency with other funding programmes, safeguard the establishment and

Council (MRC) and the Foundation for the National Institutes of Health (FNIH). IMI2 JU Annual Activity Report 2019. https://www.imi.europa.eu/sites/default/files/events/IMI%20AAR%202019_FINAL.pdf

implementation of potential intellectual property arrangements that may stem from public-private collaborations, and to offer targeted communication activities (incl. to support SMEs participation). Therefore, the longer term prize of *more productive and globally competitive EU health industries that create growth and jobs and are able to quickly respond to health threats* would be beyond reach due to low integration of stakeholders (especially across industry sectors) and hence the likely impact for these aspects remains similar to the baseline, also receiving the score of 0.

The CPP's reliance on Horizon Europe calls would place some limitation on its directionality, as discussions on its strategic direction would be conducted through the comitology process. From this perspective, the impact on developing *better, safe, effective and cost-effective health technologies* is likely be good compared to the baseline but still missing greater directionality facilitated by a dedicated implementation structure. Its score would therefore be + compared to the baseline of 0.

At the same time, openness under this option would likely favour collaborative working between the private sector and various public authorities, HTA bodies and end-users, thus contributing to improved conditions for health R&I, new adapted tools and models for value assessment and de-risking in strategic areas (notably, addressing specific objective 5). These would offer a good potential (scored as +) compared to the baseline (scored as 0) to translate into an *increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs*.

Option 3 would result in the closest alignment of research agendas, pooling of resources (including those from non-EU countries where the additional funds mobilised might be to a certain extent matched with the EU funding) and strong oversight of its project portfolio. Through a dedicated implementation structure, participants (including SMEs) would be able to benefit from adapted project support from set-up to post-R&I project activities. This should increase the likelihood of all actions delivering to their full potential.

The EU funding, combined with the high degree of directionality, would most likely attract commitment and financial leverage from the private sector supporting long-term challenges and priorities. The balance of private and public interest should be ensured through extensive stakeholder consultations prior to launching the initiative. During the partnership's lifetime, this balance would be supported by the governance structures with 50% voting rights for the EC and consultation processes to gather input from others public authorities, health care professionals and patients.

Industry could gain the long-term horizon and certainty needed to tackle risky projects in a safe environment. An Institutionalised Partnership therefore has high potential (++) compared to the baseline to develop *better, safe, effective and cost-effective health technologies, tools and digital solutions* through significant technology convergence, via fulfilling the specific objectives 2 and 3. A key element for the linking of the industry sectors is the necessity to avail of and share consistent and interoperable data, involving a wider use of innovative digital tools, leading to *more productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats* and justifying the high potential (++) of option 3 to contribute to this impact, compared to the baseline. This assessment is supported by prior experience with public-private partnerships through the Innovative Medicines Initiative (IMI JU and IMI2 JU) and ECSEL where public and private stakeholders could innovate in a safe environment. IMI and IMI2 demonstrated the capacity to mobilise resources quickly to respond to emerging

challenges, such as the Ebola outbreak[152] or COVID-19 outbreak[153]. In the biomedical research field, IMI has international visibility and 'brand' that opens doors to new collaborations; an Institutionalised Partnership on Innovative Health could achieve the same or even more, given its envisaged broader composition.

There is also a question as to whether, in the longer term, the initiative would result in an *increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs*. On one hand, under option 3, the industrial partners would provide an up-front, legally binding commitment to the jointly agreed strategic research agenda. Thanks to risk sharing with other partners, new collaborations and EU co-financing of the resulting projects, this would likely stimulate additional industry investment, not mobilised otherwise. On the other hand, the initiative would be co-financed from the part of EU research budget devoted to health, therefore attributing a 'good' potential in this impact area (scored as +), compared to the baseline of 0.

Stakeholder opinion

Interviewees indicated that investors would have more confidence contributing to a partnership with a higher degree of integration as seen in the Institutionalised Partnership. This was particularly discussed in relation to industry, whose participation would precipitate essential market knowledge needed to achieve economic impacts. It was reported that this option would enable more detailed discussion around intellectual property upfront, further increasing confidence in the partnership from the outset. The majority of feedback to the **inception impact assessment** from business associations stated that Institutionalised Partnership would be the most effective option to guarantee commitment from the different partners, in particular SMEs for which a legal framework respecting intellectual property ownership requirements was seen critical for their involvement. This point was also highlighted by public authorities.

Out of the listed economic impacts in the **public consultation**, the largest number of respondents (81%) across all stakeholder groups indicated that the Institutionalised Partnership was very relevant to 'better, safe, effective and cost-effective health technologies, tools and digital solutions for health'. This was also the case for 'highly skilled jobs' (54%), with the exception of 'other' stakeholders who generally felt this was less relevant. There was some disagreement between stakeholders from industry (business associations, company/business organisation) and non-private actors with regard to the partnership's relevance to the economic impact of 'more innovative, sustainable and globally competitive health industries', with higher rates of industry stakeholders finding this 'very relevant' compared to non-private actors whose responses were more varied.

Societal impacts

[152]https://www.imi.europa.eu/projects-results/project-factsheets/ebola;
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1248

[153] IMI2 JU was able to – within a few weeks only – mobilise the investment of EUR 72 million of EU contribution together with EUR 45 million commitment from industry, aimed at development of treatments and rapid diagnostic tests useful in the fight against the current and/or future outbreak of COVID-19. 8 project were selected from funding out of 144 proposals submitted. https://www.imi.europa.eu/apply-funding/open-calls/imi2-call-21.

Under the **baseline option**, the scale and size of these individual projects would not allow for the 'pull through' and valorisation of breakthrough discoveries in a timely manner. As discussed before, scientific breakthroughs in themselves do not create technological, economic and societal impacts. Individual projects under regular calls are unlikely to lead to significant change without strong consistency (external coherence) and the involvement of key actors, including from industry, over a more extended period of time. In the absence of strategic steer and outside contributions (directionality and additionality), the baseline option would translate to low potential for achieving societal impacts even in the longer term. In the absence of a dedicated implementation structure, traditional calls would not allow creating a common platform for large-scale collaboration between industry sectors (inherent to specific objective 2), which in turn would not allow the society to benefit from potential faster availability of new drugs or diagnostics (as targeted by specific objectives 2 and 3). This is because the 'intermediary' health technologies are not well-placed on their own to improve health promotion and disease prevention. Consequently, this option would not lead to *improved health and wellbeing of EU citizens, reduced health inequalities and improved access to high-quality health care in priority disease areas* or *strengthening circular economy and mitigating the negative health impacts of climate change*, all these impacts being scored at 0, like the baseline.

Option 1, as discussed above, offers openness and potential for engaging the entire health value chain likely favours dialogue between private sector and various public authorities and HTA bodies. As a result, option 1 offers a higher potential (scored as +) than baseline to contribute to *improved health and wellbeing of EU citizens* that would gain prominence through working more closely with public sector organisations. However, those health innovation aspects that require a longer term horizon and stronger integration of partners would not progress sufficiently towards reaching some of the more challenging types of impact sought, including *reduced health inequalities and improved access to high-quality health care in priority disease areas* and *strengthening circular economy and mitigating the negative health impacts of climate change*. This justifies only a good potential compared to the baseline in these two impact areas, hence scored at +.

Under **option 3**, the significant scale and size of Institutionalised Partnership projects have the potential to enable faster 'pull through' of breakthrough discoveries, their valorisation and translation into societal impacts. An Institutionalised Partnership offers greater strategic steer (directionality) and greater potential for outside contribution (additionality). Through the development of better health technologies and the combination of health technologies, this option offers high potential (in the long-term, compared to the baseline) to impact on *improved health and wellbeing of EU citizens*, receiving the score of ++. This is likely to happen thanks to the co-designed (public and private, including end-users) development of better health technologies and combination of health technologies, the focus of specific objective 3. This could also lead to scaling-up of health technologies that are currently of limited availability to patients and, thanks to higher efficiency of these improved health technologies, to liberating medical personnel in clinics for priority activities, e.g. in intensive care units. In addition, exploiting health data, using digital tools and rolling out the resulting digital health innovations (under specific objective 4) in areas of unmet public health needs would offer good potential for *reduced health inequalities and improved access to high-quality health care in priority disease areas*, *thereby addressing unmet public health needs,* thus scored as + compared to the baseline scored 0. Another beneficial impact of digital health solutions includes a reduced need to travel (e.g. to hospital) and the possibility to receive care remotely. This latter point was acutely demonstrated during the 2019/2020 COVID-19 pandemic when many non-coronavirus patients were delaying seeking medical advice or even emergency care (in fear of contracting the SARS-CoV-2

coronavirus when contacting other, potentially infected persons), while health care authorities were also suggesting to postpone certain visits or interventions. All this lead to worsening of their health condition as a collateral effect of the pandemic. Wider availability and use of remote care, such as remote diagnostics, would also lead to reduced burden on health care systems (and last but not least, less emissions). At the same time, decreasing the environmental footprint of health industries and promoting circular economy could contribute to the greeninig of health care. All that would lead to good potential for *strengthening circular economy and mitigating the negative health impacts of climate change.* This effect might be even stronger if the targeted R&I collaborations incentivise industries to increase their production capacities in the EU, which then in turn would improve Europe's technological sovereignty. Its score would therefore be + versus the baseline of 0.

Expected impact on fundamental rights

R&I activities leading to creation of new technologies and solutions for health care can be expected to contribute to the right to health and right to health care, the right of equitable access to preventive and treatment-related health care for all, including marginalised groups. Advances in data-based products and tools including those based on electronic health records and real-world health data could have implications on the privacy rights of citizens. The use of digital technologies in health care could make diagnosis and treatment more accessible, less invasive and accessible to all individuals, including those living in remote areas, or across borders. Digital technologies could thus contribute to access rights to preventive health care and to benefit from medical treatment as well as to a high level of human health protection[154].

Stakeholder opinion

Interviewees indicated that achieving societal impact required the involvement of a broad range of stakeholders and that an Institutionalised Partnership would be the most effective platform to create and sustain such a collaboration. In **all consultation activities**, there was a general call from respondents from the public sector for the partnership to involve of a broad scope of stakeholders beyond industry and academics, including in the partnership's governance. Examples of broader stakeholders include patients' organisations, health care payers, regulators, HTA bodies, health and social care professionals, health care providers, national health care system actors and public authorities, research and technology organisations. To a lesser extent, NGOs, civil society organisations and citizens' groups were also mentioned. Respondents explicitly asked for a balance between relevant stakeholders in strategic decision-making so that research priorities would be set according to public health needs while ensuring commitment from industry. This was considered one of the key requirements to delivering impact in relation to unmet health needs.

Out of the listed societal impacts in the **public consultation**, the largest number of respondents across all stakeholder groups indicated that the Institutionalised Partnership was very relevant to 'improved access to innovative, sustainable and high-quality health care' and 'effective health services'. An 'improved patient experience' was found to be less relevant by stakeholders from academic/research institutes, small company/business organisations and 'other' respondents.

Summary

[154] Charter of Fundamental Rights of the European Union (2012/C 326/02). Article 8 Protection of personal data, and Article 35 Health care.

Table 5 lists the scores for each of the policy options, based upon the assessments above, while also taking into account the support expressed by the different stakeholders.

Table 5: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	**Option 1: Co-Programmed European Partnership**	**Option 3: Institutionalised European Partnership Art 187**
Scientific impacts			
Strengthened EU skills and capacity in academic and industrial health R&I	0	0	+
A thriving EU-wide cross-sectoral health R&I ecosystem created	0	0	+
New scientific paradigms established in areas of unmet public health needs	0	0	0
Economic/technological impacts			
More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats	0	0	++
Better, safe, effective and cost-effective health technologies, tools and digital solutions	0	+	++
Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs	0	+	+
Societal impacts			
Improved health and wellbeing of EU citizens	0	+	++
Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs	0	+	+
Strengthening circular economy and mitigating the negative health impacts of climate change	0	+	+

Notes: Score ++ : Option presenting *high* potential compared to baseline; Score +: Option presenting *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario or under option 1, there would be winding down and discontinuation costs for the existing IMI2 JU Programme

Office. While IMI2 JU is expected to launch its last calls in 2020[155], the Programme Office as the implementation structure would be in place until the end of 2024 as set out in the Council regulation. The yearly cost of functioning of IMI2 JU Programme Office amounts to approximately EUR 10 million per year[156], hence for the period of 2021-2024 the administrative cost would likely reach approximately EUR 40 million[157]. This amount is divided equally between the EU and EFPIA, the private partner, therefore the administrative cost to the EU budget would be in the range of EUR 20 million in total until 2024. The cost savings related to the closing of the Programme Office would become visible only as of 2025[158].

On the other hand, setting up a dedicated implementation structure would require additional costs compared to the baseline option. If implemented under option 3, IHI would likely entail yearly administrative costs comparable to those of IMI2 JU (depending on several parameters, such as the operational budget of the initiative and the potential use of a common back office). The additional administrative cost would be moderate if the implementation structure is built on the existing IMI2 JU Programme Office that, with some adaptations to account for a broader industry composition or revisited governance structure, could serve IHI. Nevertheless, it is estimated that the savings on administrative costs from using option 0 instead of an existing IMI2 JU Programme Office would – in the long term – exceed the costs incurred for winding down. The score of the baseline scenario (traditional Horizon Europe calls) is therefore set to 0 as a reference point. Running costs and winding-down costs of the current JU under the future Option 1 would be similar to the baseline option. Under the future Option 3, the running costs would be the highest, hence receiving the score of (-)(-).

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) is used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy option – and the least cost-efficient – the Institutionalised Partnership

[155] In duly justified cases, calls for proposals may also be launched in 2021.
[156] For years 2014-2019, the real administrative costs of IMI2 JU ranged between EUR 8.8 and 11.2 million per year, as reported in respective IMI2 JU Annual Activity Reports. https://www.imi.europa.eu/about-imi/reference-documents.
[157] This assumption does not take into account the situation in which some staff would be released because of lower workload due to no news calls being launched, which could bring certain savings. However, the workload related to new calls being launched is only one element among many others to consider, such as the tasks related to monitoring projects launched in previous years – there are 11 IMI JU and 79 IMI2 JU projects active at the moment of writing, with approx. 20 new projects expected to be launched in 2020. The IMI Programme Office needs to maintain all the staff functions necessary for its functioning (e.g. human resources, IT, legal, audit) and cover all related costs (IT equipment, renting of premises, communications etc) that are not directly linked to the actual number of new calls launched and need to be borne until the end of existence of the Programme Office.
[158] Certain residual costs would still have to be borne by the Commission or its executive agencies to manage the "legacy" projects after 2024, as some projects IMI2 JU are expected to run until 2026-2027.

option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. However, looking at the different options in terms of their ability to attract additional private sector resources and thus leverage the EU action's investment and impact, there are significant differences.

Option 0 does not warrant a significant (or even any) in-kind or financial contribution from industry; on the contrary, in these projects industry participation would be largely financed by EU grant funding.

Under **option 1**, in-kind industry contribution is expected but its exact level would only be set in the annual work programmes. Memoranda of understanding would probably give an indication of the total contribution upfront, but such agreements have weak legal power to enforce these commitments. Stakeholder interviews also revealed that several big pharmaceutical companies would stay away from this type of partnership as the calls might not automatically offer participation without receiving EU funding (which would be preferred e.g. by large pharma industry, so as to facilitate reporting obligations and not to complicate potential pricing considerations on innovations that could ultimately result from the partnership; it is already the case in IMI where EFPIA members do not receive funding). Due to these factors, additionality in option 1 would be far smaller than in option 3.

Option 3 offers a legally binding funding arrangement laid down at the outset, with the EU providing 50% of resources to R&I activities through a financial contribution and private sector partners providing (at least) 50% of the resources, mainly through in-kind contribution but potentially also financial resources. In practice, 1 Euro of EU commitment to the initiative would bring in (at least) an additional 1 Euro from private sector partners[159]. This offsets the higher overall operating costs by orders of magnitude and thus offers the most cost-efficient option[160]. The set-up under Option 3 would also allow for leveraging the additional investment of entities other than member industries, such as charities, similarly to the 'associated partner' status already successfully implemented by IMI2 JU. While Option 3 could potentially create complexities for accessing funding, notably by start-ups and SMEs, they could be mitigated by the activities of the future JU Programme Office offering support to applicants and project beneficiaries.

Of note, Option 1 and even more so Option 0 would imply the discontinuation of IMI2 JU without a successor. Apart from the winding down cost, these options would entail losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate. These factors were also taken into account when assessing the effectiveness of the options above.

Table 6: Matrix on 'overall costs' and 'adjusted cost scoring'

[159] The leverage of IMI2 JU reached 99% in 2018, according to IMI2 JU Annual Activity Report 2018 (private commitment vs EU funding).

[160] Note that the planned EU investment for this initiative is unknown at the moment of writing the impact assessment, and depends on several factors (e.g. the Horizon Europe budget, final decisions on strategic R&I priorities and the related industry commitment). For the sake of comparison, the same EU investment was used throughout the different policy options and this is correct when comparing to the baseline. However, for a Co-Programmed Partnership (option 1) it is probable that less EU funds would be dedicated to the partnership than in the case of an Institutionalised Partnership (option 3), likely creating less prominent impacts, and the remaining funds would be deployed through traditional calls.

	Option 0: Horizon Europe calls	Option 1: Co-Programmed	Option 3: Institutionalised
Administrative, operational and coordination costs	0	0	(-)(-)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	+	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to the baseline; score (-)(-) = substantial additional costs compared to the baseline; score +: Option presenting *good* cost-efficiency compared to baseline.

The analysis above remains equally valid independent of the development of COVID-19 pandemic. The reason is that IHI was designed from the start as a collaboration of several health industry sectors, including diagnostics, pharmaceutical and vaccine areas. Providing an R&I response to emerging health threats would fall naturally in its scope.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships.

For the initiative to deliver on its ambitious specific objectives, it needs to show a high degree of internal coherence, from developing a research agenda and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe.

Under the **baseline option**, it would be challenging for individual Research and Innovation Actions to identify linkages, opportunities for coordination and communication, or to make steady progress on enabling the uptake of health innovation from the actions' limited budget. In addition, Horizon Europe would not provide dedicated support to these individual health R&I projects to put their outputs on the pathway to impact. This limitation is significant if the initiative's emphasis is on achieving shorter term impacts. Coordination and Support Actions could, to some extent, create a dedicated R&I collaborative platform that is necessary to create a 'learning' health care ecosystem but these would need to be closely linked to the collaborative research actions so that the fledging network can test innovative ideas and experiment in a safe environment. The latter is, however, hard to achieve across a multiplicity of uncoordinated calls.

Under **option 1**, a Co-Programmed Partnership would draw up its strategy in consultation with key stakeholders across the public and private sectors to ensure a high degree of internal coherence within the strategic research agenda and through linkages to other initiatives within Horizon Europe. In addition, implementation through regular calls means that it may align with and link to important parallel activities within other parts of the Horizon Europe programme. It is likely that Coordination and Support Actions could create a dedicated R&I collaborative platform that is necessary to create a 'learning' health care ecosystem and link to the (more strategic) collaborative research actions. This could also help cross-project activities to further exploit synergies and enhance potential for impacts.

Hence, this option offers good potential (score of +) to achieve internal coherence compared to the baseline (score of 0).

Under **option 3**, the Institutionalised Partnership's structure enables a high degree of internal coherence: from developing a research agenda and coordination of stakeholders to creating and/or strengthening linkages to other initiatives within Horizon Europe. This would minimise duplication and wasted research. There are a number of other candidate partnerships in the Health cluster that are closely related to innovative health but with a more thematic or geographical focus: personalised medicine, rare diseases, One Health AMR and EU-Africa Global Health partnerships. Results emerging from an Institutionalised Partnership on innovative health could be implemented and scaled up in a complex European health environment where other health initiatives (candidate Partnership on Transforming Health and Care or EIT Health) may prove complementary. Finally, the environment also seems conducive to helping the partnership achieve its goals with candidate partnerships on (1) Key Digital Technologies; (2) Artificial Intelligence, Data and Robotics; and (3) High Performance Computing. The IHI Programme Office would lead all coordination activities to ensure internal coherence, translating into high potential of option 3 (scored as ++) on this aspect versus the baseline (score of 0).

Stakeholder opinion

During the **public consultation**, the majority of respondents from all stakeholder groups reported that it would be possible to rationalise the candidate Innovative Health Initiative and its activities, and/or to better link it with other comparable initiatives. This response was less uniform among EU citizens, where a large proportion selected that they did not feel it would be possible. Of respondents who provided details for selecting 'no', a common response was that it could increase the complexity of the partnership.

Nevertheless, the overall opinion of respondents was positive: in the feedback on the **inception impact assessment**, business associations encouraged the generation of synergies between the different partnership initiatives. Similarly, there was general consensus among **interviewees** on the need for links between the partnerships including development of similar data management methodologies and establishing a flexible set of rules to facilitate collaboration.

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc.

Under **the baseline option**, Horizon Europe's work programmes are developed through a comitology process that involves several iterations of consultation with various key stakeholders, within other Commission Directorates-General and EU Member States. Health calls can also be framed to maximise their complementarity with initiatives in the wider landscape. For IHI, they would include other programmes under the 2021-2027 multiannual financial framework (e.g. Digital Europe Programme, Connecting Europe Facility) other key EU stakeholders (e.g. EUnetHTA, Heads of Medicines Agencies, Competent Authorities for Medical Devices) and research infrastructures (e.g. Elixir, BMBRI, EATRIS, ECRIN). However, it is unlikely those external programmes and networks could effectively

interact with a health initiative under Horizon Europe regular calls without the presence of a long-term dedicated strategy and central programme office.

Under **option 1**, Horizon Europe's work programmes are developed through a comitology process. A major difference compared to the baseline option is that the CPP can interact with external programmes and networks via a central administrative infrastructure (financed via a Coordination and Support Action) to bolster its long-term strategy. In addition, individual partners at a national level may have the ability to improve coherence between activities supported within the partnership and those outside of it. However, alignment with globally operating initiatives would be difficult in the absence of a dedicated implementing structure. Hence, under this option there is good potential to achieve internal coherence (scored as +), compared to the baseline option (score of 0).

Under **option 3,** the interaction with actors listed under the baseline option would be greatly enhanced by the creation of a programme management office to act as a single point of contact for all external programmes and networks. Indeed, for the partnership to meet its objectives (especially specific objective 4 'Strengthen the conditions for R&I for strategic unmet public health needs' that should lead to novel methods to assess the value of combined products and integrated health care solutions) it needs to interact with other European and international actors in the health arena, including from the regulatory side. Hence, this option offers high potential (scored as ++) to achieve external coherence compared to the baseline (score of 0).

We have also analysed the extent to which various options would lead to higher participation and larger contribution from companies active in health research, as a necessary ingredient of a successful public-private partnership.

Under **the baseline option** (regular calls of Horizon Europe), the setting of scientific priorities and definition of call topics would be done by the Commission services followed by the usual comitology procedure. This does not involve any formal step of consultation of the industry and hence tends to be more academically oriented. The limited interest of large private industries in regular calls is reflected in the limited participation in collaborative projects of large industrial entities under Horizon 2020 Societal Challenge 1 (Health, demographic change and wellbeing), with only few projects where several large companies would collaborate. Horizon Europe calls also use standard intellectual property rules that in some situations do not fully cater for all possible setups of collaborations between academia and industry, including SME.

Under **Option 1**, the implementation of programmes would follow a similar procedure as under the baseline option, differing in the industry partners would provide input on call topics to the relevant sections of the work programmes. Option 1 would not offer a dedicated staff for managing the programme at a required scale, which is needed to ensure the proper budgetary control over industry contributions, ensuring consistency with other funding programmes, safeguard the establishment and implementation of the intellectual property arrangements that may stem from public-private collaborations, and to offer targeted communication activities (incl. to support SMEs participation). Because of the limited contribution of private stakeholders to the definition of the calls, they would have only a limited interest to commit financially to the initiative. The absence of an established mechanism to value private entities' contributions, such as for in-kind on additional activities (established only at the level of Council regulation for Art. 187 initiatives) that increase the leverage and bring valuable resources to projects, would leave the investment and involvement of large industries in projects at a moderate level.

In contrast, under **Option 3**, scientific priorities would be identified by the health industries jointly with the Commission services and other stakeholders involved in health care, including end-users. The support of the Programme Office and the system of voting rights in the Governing Board would help maintain the balance of interests. Structured involvement of Member States via the States Representatives Group would help ensure consistency with national priorities and initiatives. The final decisions on the scientific priorities would be in the hands of the Governing Board, with equal representation of private (industry) and public (EU) interest. These elements, together with matching of private commitment with EU funding, would cater for the firm commitment of private industries and hence be the base for strong additionality. For example, the leverage (private commitment vs EU funding) under IMI2 JU reached 99% in 2018.

Under option 3, the industry would have a safer environment for exchanging knowledge and translating it to future products, also in case of possible adaptations of intellectual property rules, not available under option 0 and 1. The set-up under Option 3 would also allow for leveraging the additional investment of entities other than pharmaceutical industries such as charities, via the mechanism of associated partners to a future Joint Undertaking.

Stakeholder opinion

The majority of respondents from all stakeholder groups during the public consultation reported that the candidate Innovative Health Initiative would be able to link its activities with other comparable initiatives. It was discussed in both the interviews and public consultation that having a more aligned research agenda would reduce duplication and would further advancements in specific areas of research, e.g. priority disease areas. Interviewees also noted how cooperation between initiatives could enhance learning and outputs, e.g. the ECSEL Joint Undertaking (predecessor of the candidate partnership on Key Digital Technologies) could provide digital support to ensure uniform data standards and methods. It was also stated that establishing a flexible set of rules for the different initiatives could reduce bureaucratic barriers. During the consultation on the inception impact assessment, representatives of research infrastructures stressed the importance of leveraging the power and network of research infrastructures such as BBMRI, EATRIS and ECRIN. This was repeated during the interviews with stakeholders from research infrastructures.

Summary

Table 7 lists the scores for each of the policy options, based on the assessments above, while also taking into account the support expressed by the different stakeholders.

Table 7: Overview of the options' potential for ensuring and maximising coherence

	Option 0: Horizon Europe calls	Option 1: Co-Programmed	Option 3: Institutionalised Art 187
Internal coherence	0	+	++
External coherence	0	+	++

Notes: Score ++ : Option presenting *high* potential compared to the baseline; Score +: Option presenting *good* potential compared to the baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of the options and identification of the preferred option

Building upon the outcomes of the previous sections, this section compares the options' 'performance' against the three dimensions of effectiveness, efficiency and coherence (Table 8). It should be noted that the process of the preparation of the partnership has not yet been finalised (see also Section 7.1) and some quantitative data are not available, some criteria of this assessment represent a qualitative judgement rather than a full quantitative assessment.

Table 8: Scorecard of the policy options

	Criteria	Baseline: Horizon Europe calls	Option 1: Co-Programmed European Partnership	Option 3: Institutionalised European Partnership Article 187
Effectiveness	**Scientific impacts**			
	Strengthened EU skills and capacity in academic and industrial health R&I	0	0	+
	A thriving EU-wide cross-sectoral health R&I ecosystem created	0	0	+
	New scientific paradigms established in areas of unmet public health needs	0	0	0
	Economic/technological impacts			
	More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats	0	0	++
	Better, safe, effective and cost-effective health technologies, tools and digital solutions	0	+	++
	Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs	0	+	+
	Societal impacts			
	Improved health and wellbeing of EU citizens	0	+	++
	Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs	0	+	+
	Strengthening circular economy and mitigating the negative health impacts of climate change	0	+	+
Efficiency	Administrative, operational and coordination costs	0	0	(-)(-)
	Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	+	-

	Criteria	Baseline: Horizon Europe calls	Option 1: Co-Programmed European Partnership	Option 3: Institutionalised European Partnership Article 187
Coherence	Internal coherence	0	+	++
	External coherence	0	+	++

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to the baseline; score (-)(-) = substantial additional costs compared to the baseline. Score ++ : Option presenting *high* cost-efficiency compared to baseline; Score +: Option presenting *good* cost-efficiency compared to baseline; Score 0: Potential of the baseline.

The scorecard shows that the baseline performs less well against all dimensions and criteria compared to Co-Programmed and Institutionalised Partnership options, except for the net administrative cost. Even though it has a higher score in the efficiency criteria, this does not weigh up against its lower performance in the effectiveness and coherence criteria.

The scorecard also shows that benefits are clearly maximised under the Institutionalised Partnership Art 187 option. In particular, compared with the other options, option 3b would:

- Provide greater effectiveness by maximising leverage effects, allowing for greater strategic alignment among partners, and supporting a broader range of activities in research and innovation.
- Improve coherence by enhancing collaboration and alignment with the other key stakeholders.

As regards **effectiveness** in terms of the scientific impact that can be achieved, Option 3 performs better overall than Option 1 due its ability to better integrate industry sectors and as a result strengthen EU skills and innovation capacity. It also has the highest potential to contribute towards the creation of a health innovation and learning ecosystem. The baseline option, while performing well on purely addressing scientific paradigms, cannot provide a platform for cross-sectoral stakeholder collaboration effectively due to its low directionality and weak industry engagement.

As regards effectiveness in terms of the economic impact that can be achieved, Option 3 performs significantly better than either of the alternative options. This is due to an Institutionalised Partnership's ability to provide strong strategic steer (directionality) and to garner substantial outside contributions (additionality), and thanks to its dedicated implementation mechanism through which industry expertise, resources and knowledge can be best leveraged. As a result, the likelihood is highest for achieving increased productivity and growth in the EU health industry by speeding up development of health innovations in health and priority disease areas. In contrast, Option 3 has only limited benefit in terms of its contribution to a sustainable and efficient health care system.

As regards effectiveness in terms of the societal impact that can be achieved, Option 3 is most likely to deliver on the needs of the public system provided the stakeholder consultation, prioritisation exercises and call implementation mechanism are optimally set up. This is because an Institutionalised Partnership is able to make assets progress much faster and eventually help to integrate them into health products and services that can benefit patients and consumers.

On **coherence**, Option 3 is most likely to develop a coherent project portfolio to address the initiative's specific objectives. Option 3 would also be most likely to ensure the external

coherence with other initiatives, programmes and networks through its dedicated implementation structure and EU partnership.

As for **efficiency**, Option 0 (regular calls under Horizon Europe) requires the lowest administrative cost. This is due to the existence of a large-scale, highly refined overall administrative, IT and professionalised management system delivered by specialised agencies (e.g. the Research Executive Agency). Option 3 would have the highest cost, due to the need to set up a dedicated implementation structure to support the thematic area. Nevertheless, much learning can be transferred from the current IMI2 JU experience. In terms of cost-efficiency however, the higher administrative costs are offset by the additional operational funds that industry would bring to the partnership. These additional funds would leverage EU funds, offering approximately twice as much budget and impact for the same EU investment.

Option 3 would be the only one to allow setting up fully fledged Programme Office that would offer dedicated programme management as well as legal and communication expertise under one roof. The Office functions as a "neutral broker" bringing together the different industries that usually compete, to cooperate around jointly agreed objectives. It would be of particular usefulness to project participants, notably SMEs, as regards e.g. explanation of call rules or handling of intellectual property issues that can prove complex in a multi-stakeholder health research setting. The Programme Office would also offer the necessary support function to the Innovation Panel and as such, help to increase the transparency of call topics definition and to ensure that they genuinely reflect the public health needs.

In function of the **risks** of the options to deliver on the expected impacts, the **baseline option** would offer only a low certainty of delivering on the various expected impacts. A co-programmed partnership (option 1) would qualify as second in this category, while option 3 is preferred thanks to its functionalities. The ultimate success of the initiative would depend on whether the significant commitment of the industrial partners materialises and on whether the initiative is successful in attracting a high number of SMEs and academics, necessary to provide sufficient scientific expertise and innovative ideas, to multi-sector collaborations. Another risk to achieving the expected impact would be linked to the relative novelty of this type of multi-stakeholder collaboration in health and to the need of combining varying R&I development timelines that can be very long in the pharmaceutical sector but much shorter in medtech or even more so, in the digital sector.

An external risk is related to the potential post-COVID-19 slowdown of the economy. If a strong recession scenario materialises, companies' investments into R&I usually suffers the most. This factor may potentially limit the overall up-front investment of the industry members or it may affect their ability to live up to the initially declared commitment. The impact of this potential risk on the EU funding is mitigated by the fact that EU funds are committed globally on yearly basis and disbursed for individual projects only on the basis of the industry commitment. The agility of adapting the work programmes would also allow reflecting such a situation in the revised scientific priorities for future call topics. Proportionality of the preferred option is demonstrated by the fact that options 0 (baseline) or 1 would not ensure a sufficient level of directionality and additionality, while option 3 is – among the available options – the one that would best allow fulfilling these needs.

In conclusion, the scorecard analysis shows that the benefits are clearly maximised under Option 3, an Article 187 Institutionalised Partnership, and thus it is the single preferred option to deliver on the effectiveness (impacts) and coherence measures.

Comparison between the preferred option and the current partnership (IMI2 JU) taking into account lessons from past evaluations[161]

What would continue	What would be different
• A European public-private partnership based on Article 187 TFEU. • Programme implementation supported by the dedicated Programme Office. • The EU holds 50% of the voting rights and contributes up to 50% of the administrative and operational costs. • Member States (MS) and Associated Countries do not contribute financially. • Member States do not have voting rights in the Governing Board but are represented in the States Representative Group. • A jointly agreed strategic research agenda based on consultation with all stakeholders. • Draft calls for proposals are published by the Programme Office, ensuring maximum transparency to all relevant stakeholders. • The partnership strives to attract investment from outside of the EU. Part of these contributions could be matched by EU funding. • Project results are subject to the same transparency provisions as under regular Horizon Europe calls.	• 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. • Thematic focus broadened from pharmaceutical to also other areas of health R&I, including digital technologies. • More focus on disease prevention. • Governance structure adapted to better incorporate views of various stakeholders involved in health care. • All types of actors along the health value chain better involved in priority setting and in funded projects. • 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 • Industry eligible for funding up to a certain ceiling (including large companies and mid-caps), with individual industry sectors or companies entitled to opt-out from receiving funding at own discretion.

The direct continuation of IMI2 JU as it is today, i.e. a partnership between the EU and pharma sector, was not prioritised because (1) it would not capitalise on the resources, expertise and data of other health industry sectors, now ready to enter into such a collaboration; (2) it would not allow addressing more ambitious objectives of harnessing cross-sectoral collaborations to address the problem of insufficient innovative health solutions (new medicines, devices, diagnostics…) being made available to patients, (3) it would disregard the explicit recommendation of the IMI2 JU interim evaluation for a potential follow-up initiative, i.e. to ensure active engagement of other health industry sectors with the pharmaceutical industry. What was also learned from the past is that for the

[161] 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). A detailed analysis of how lessons learned were reflected in the design of the new partnership can be found in Annex 6.

underlying problems to be addressed more efficiently, the end-users need to be involved in the initiative to a greater extent than in the past.

7. THE PREFERRED OPTION – HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1. Description of the preferred option

An Institutionalised Partnership (under Article 187 TFEU) is the preferred option due to its effectiveness in delivering on the initiative's specific objectives, coherence and efficiency, and thus to achieve highest impacts. It aims to build on and learn from the current IMI2 JU's management processes and extend its know-how, international visibility and established positive brand. However, the new initiative will also bring about a step change in: (1) facilitating the integration of disparate technologies from several health industry sectors currently not collaborating to a significant extent; and (2) accelerating the development of better, safe, effective and cost-effective health products and solutions for European citizens, as part of Partnership Area 1 of Horizon Europe.

Table 9 depicts how the preferred option aligns with the selection criteria for European partnerships defined in Annex III to the Horizon Europe Regulation. The design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion at the time of writing. These include, among others (1) the budget, depending notably on the multiannual financial framework 2021-2027 negotiations, (2) strategic research agenda, planned to be adopted at the first meeting of the future governing board, (3) certain details of the governance structure and the process for call topic generation, (4) inclusion of partners from non-EU countries and the threshold for matching their contributions with EU funding, (5) intellectual property rules and questions related to the access and affordability of the resulting health innovations. Therefore, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than *ex-ante demonstration*.

Table 9: Alignment with the selection criteria for European partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	An Article 187 Institutionalised Partnership provides the closest integration of key stakeholder groups across the value chain to ensure that the initiative can respond to ambitious objectives corresponding to scientific, technological/economic and societal impacts. The mode of implementation ensures that there is sufficient scale, commitment, leverage and long-term vision for the accelerated development and deployment of health innovations. The partnership has a comprehensive set of objectives that tackle the main challenges identified and which contribute towards the creation of a health R&I ecosystem. An Article 187 Institutionalised Partnership would score significantly higher overall than the baseline option (traditional calls under Horizon Europe) and Option 1 (Co-Programmed Partnership) in terms of effectiveness.
Coherence and synergies	An Article 187 Institutionalised Partnership presents the most coherent choice to maximise synergies internally within the initiative (portfolio approach), within the EU R&I landscape and beyond. The future Programme Office, similar to the Programme Office in the current IMI2 JU, would have thematic competence in programme management and dedicated administrative support for partners and project participants to exploit such synergies and further align roadmaps between initiatives, programmes and networks.
Transparency and	An Article 187 Institutionalised Partnership aims to significantly expand the range of partners involved from health-related industries, covering the full spectrum of pharmaceutical, vaccines,

Criterion	Alignment of the preferred option
openness	biotech and medtech sectors (including diagnostics, medical devices, imaging and digital industries). In this way, relevant but currently disparate technologies (drugs, devices and software) can be usefully integrated into innovative health solutions. The partnership will maximise its impacts by being open and transparent, involving all relevant public actors (including the academic research community, patients, health care regulators, health care payers, health care providers and health care professionals) and private actors along the value chain, and by ensuring a robust governance structure. Other stakeholders may also be philanthropic organisations, charities, research infrastructures and other partnerships. Flexibility is needed in the operational processes to create trust and equity among stakeholders. Using standard Horizon Europe instruments and abiding by all the related processes (including e.g. budgetary controls, access to documents etc) will ensure that the partnership is transparent. Since a seven-year horizon is a relatively long time in a fast-moving technological R&I space, it will be important for the partnership to keep an open mind and allow entry for new actors, including those from outside the EU to allow learning across the best in class. The partnership recognises the need for broad stakeholder consultation to develop the long-term strategic directions and annual priorities. The implementation structures will provide an optimal governance, monitoring and management system.
Additionality and directionality	The legal and financial commitments made by partners at the outset of the partnership are binding and will commit partners to drive the partnership forward over the entire partnership timeframe, which is particularly important in health research with its long development timelines. The approved SRA ensures close alignment of research agendas to achieve a high-level of focus and directionality to meet the strategic unmet public health needs. No other public or private initiative is able to coordinate a similar partnership at the European level above and beyond national interests. In addition, the partnership will provide the ability to leverage other resources for the benefit of the EU.
Long-term commitment	The expectation is that in an Institutionalised Partnership on Innovative Health under Art 187, the EU and partners will be committed to pooling resources for the entire partnership period and that financial and/or in-kind contributions from partners other than the EU will represent at least 50% of the aggregated European partnership budgetary commitment.

7.2. Objectives and corresponding monitoring indicators

7.2.1. Operational objectives

Several operational objectives were identified that would enable the partnership to achieve its specific objectives:

1. improve skills for cross-sectoral health innovation;
2. increase the involvement of patients and citizens in the generation and implementation of health innovations in Europe;
3. create a platform for health R&I collaboration 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, health technology assessment bodies, health care professionals and providers, payers, patients, informal carers, and citizens);

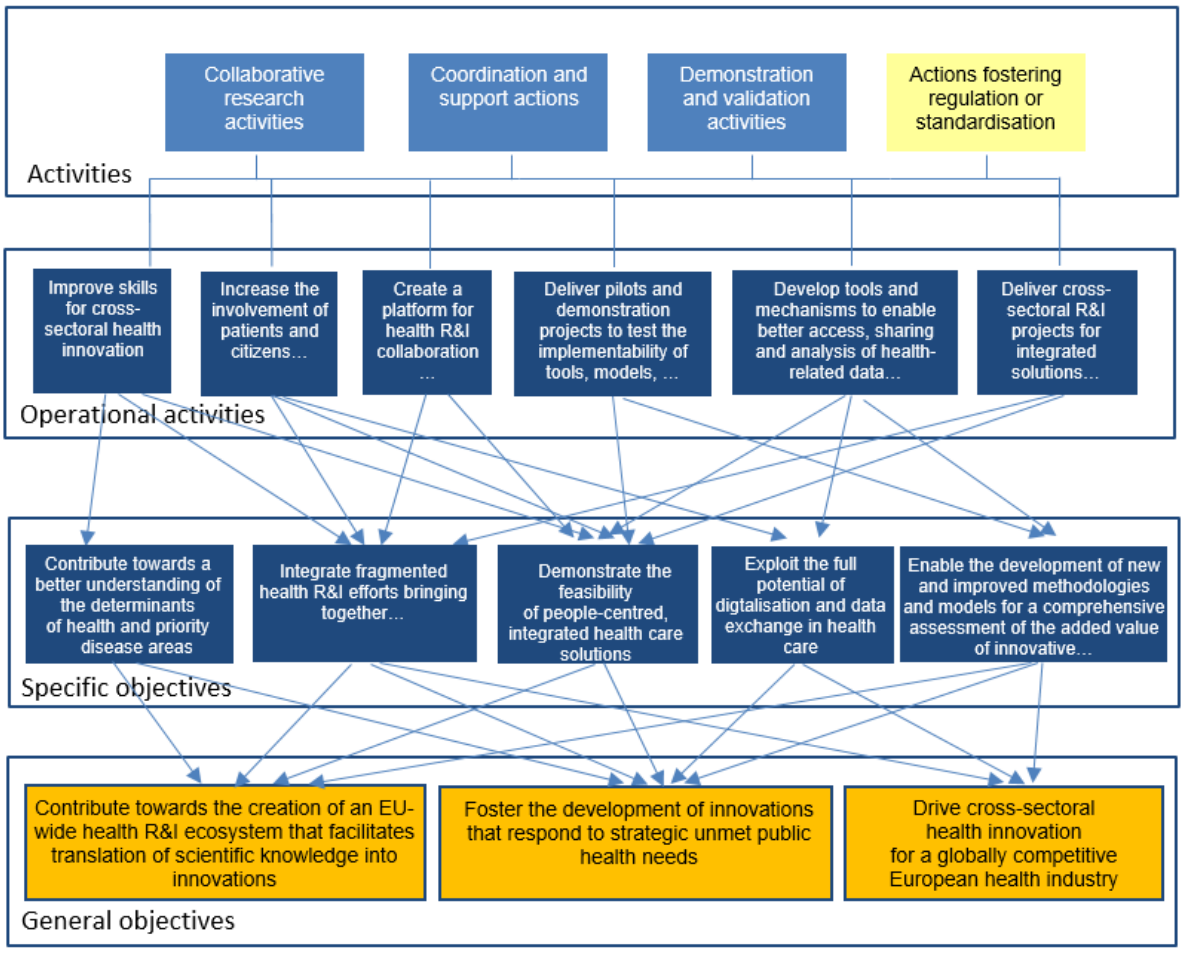
4. deliver pilots and demonstration projects to test the implementability of tools, models, methodologies and innovations generated by the initiative;

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

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

Figure 9 lists a range of actions and activities, also going beyond the R&I activities that can be implemented under Horizon Europe (highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners 'commit to jointly support the development and implementation of a programme of R&I activities, including those related to market, regulatory or policy uptake'.

Figure 9: Operational objectives of the initiative in relation to the specific and general objectives



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.

The selection of detailed areas for support would be done through an inclusive process involving a broad range of stakeholders from the public sector. Drawing on the lessons from IMI2 JU and to increase openness of this process, an improved mechanism would be put in

place with the creation of a dedicated multi-stakeholder governance body ("Innovation Panel"). This body would include not only representatives of the EU and member industry associations but also regulators, national health technology assessment bodies, health care professionals, health care providers, payers and patients as well as representatives of other relevant initiatives. The Innovation Panel would be in charge of identifying and prioritising areas for support so as to reflect needs of end-users (including patients) and public health interest. It would also help avoid overlaps and foster synergies with other programmes or initiatives.

The flexibility of choosing from a range of priorities updated at regular intervals would offer agility to adapt to new situations and needs, including public health emergencies, via adjustment of the Annual Work Programmes in line with the SRA. Such a rapid mobilisation was demonstrated by the ability of IMI to launch a fast-track call for proposals to develop therapeutics and diagnostics for current and future coronavirus outbreaks[162]. Thanks to the support of the Programme Office, the call could be designed quickly and coordinated with other global initiatives on COVID-19 to increase synergies while limiting overlaps. Of note, a similar mobilisation was possible to respond to the Ebola virus disease outbreak in western Africa in 2014. The resulting Ebola+ program led to the development of an Ebola vaccine regimen that received market authorisation in July 2020[163].

The call topics will be based on the SRA and reflect the scientific priorities/workplan as put forward by the Innovation Panel. Its opinions would validated by the Governing Board, the main decision-making body of the partnership composed of representatives of the Commission and member industry associations. The 50% of voting rights in the Governing Board attributed to the Commission would provide reassurance that the EU public interest would be adequately taken into account.

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 insufficient collaboration of companies active in diagnostics and therapeutics development, or the current scattered nature of large health data sets. At the same time, 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 very lengthy, the development of medical technologies and even more so, digital solutions, can be much faster. In order to create a safe space for collaboration of companies without affecting their commercial activities, the initiative will primarily address pre-competitive activities, including demonstration pilots.

Compared to the activities implemented by IMI2 JU under Horizon 2020:

[162] IMI2 JU Call 21 topic "Development of therapeutics and diagnostics combatting coronavirus infections" was launched on 3 March 2020 and closed on 31 March 2020. By 12 May 2020, 8 projects were provisionally selected for funding, with the total investment from the EU and from the industry partners reaching EUR 117 million. Of the eight projects, five focus on diagnostics and three on treatments. The diagnostics projects hope to develop devices that can be used anywhere, including a doctor's surgery or patient's home, and will deliver results fast (below 1 hour). The treatment projects focus primarily on the current COVID-19 outbreak but they also include efforts to prepare for future coronavirus outbreaks. The projects form part of the European Commission's wider response to the coronavirus outbreak.

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

- The scope of IHI activities will be broader, including the areas of medical technologies, imaging, vaccines, Advanced Therapy Medicinal Products (ATMPs) and digital technologies;
- IHI activities will engage a broader set of participants in terms of company sizes as Member industry associations; their national member associations will bring in small- and medium enterprises, in addition to large companies;
- The composition of consortia will be different;
- 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 thanks to better involvement of these stakeholders in the definition of scientific priorities and of topic texts.

7.2.2. Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives.

Table 10 below represents monitoring indicators proposed to track the initiative's progress towards achieving its specific objectives and targets as defined in Table 2. Health R&I is a complex and lengthy process that does not follow a 'linear' path of development and scale-up, and various intermediate steps are needed before the objectives and end targets can be reached. The proposed indicators reflect parameters that can effectively be measured for an initiative aiming to operate in a pre-competitive space of the health R&I area, during the initiative's lifetime[164]. Similarly, the short-term indicators are more activity-driven since the actual outputs of health research projects are unlikely to be visible immediately after initiative's start[165].

These proposed indicators take into account the experience gathered during the definition of IMI2 JU Key Performance Indicators[166] and will be further refined before the start of the initiative to strike a balance between defining parameters that are representative of the initiative's progress, and minimising additional reporting obligations for project participants.

[164] The medical sector is characterised by long development timelines, with uptake dependent on fulfilling stringent regulatory steps and on subsequent reimbursement and pricing decisions that remain the competence of EU Member States. Therefore, the attainment of some of the initiative's objectives would not be appreciated until after the projects have finished. The same is even more true for certain impacts that could be appreciated only long after individual projects end. Additional information is provided in Annex 3, Section 2.

[165] The quantification of expectations for individual indicators, as well as their evolution from shorter to longer term, can be done reliably when the process of defining the strategic research agenda has been advanced further.

[166] IMI2 JU Key Performance Indicators. https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf.

Table 10: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

Specific objective	Short-term indicators (typically as of year 1+)	Medium-term indicators (typically as of year 3+)	Long-term indicators (typically as of year 5+)
1. Contribute towards a better understanding of the determinants of health and priority disease areas	Share of projects covering priority disease areas	Number of international co-authorships and cross-sector publications Number of times that journal articles generated by the partnership are cited in the global literature	Number of new taxonomies of diseases and new methods of stratification Number of new early biomarkers of disease identified and validated Number of validated new targets for preventive or therapeutic strategy
2. Integrate fragmented health R&I efforts bringing together …	Share of projects bringing together representatives of two or more industry sectors Share of projects bringing together SMEs and large companies	Number of projects sharing data outside of consortia partners for further research Impact factor of international co-authorships and cross-sector and cross-institutions publications generated by IHI projects	Number of new tools shared outside of consortia partners for further research Number and types of innovations in industrial use
3. Demonstrate the feasibility of people-centred, integrated, health care solutions	Share of projects involving patient/citizen associations	Number of assets progressed through key milestones[167] Number of new or improved guidelines, methodologies, tools, technologies or solutions submitted for acceptance to regulatory authorities for use in the context of R&D, relevant for integrated, people-centred solutions	New standards and common processes adopted in official (regulatory) guidelines and in use Number of integrated health care solutions developed
4. Exploit the full potential of digitalisation and data exchange in health care		Number of projects that integrate data from public and private sectors	Number and type of digital health innovations developed
5. Enable the development of new and improved methodologies and models for comprehensive assessment of the added value of innovative and integrated health care solutions.	Share of projects addressing strategic unmet public health care needs/priority health and disease areas Number of health care stakeholders (e.g. providers, professionals, regulators) involved in projects	Number of projects developing methodological frameworks to assess the cost-effectiveness of innovation. Number of projects developing patient-reported outcome measures and/or patient-reported experience measures	Number of new tools and models ready for implementation in health care

[167] Examples of assets are drug or diagnostic candidates, targets, biomarkers or other tools that can be shown to have reached a significant milestone or pass a significant stage gate.

In addition to the above monitoring framework that will help track progress over the lifetime of the initiative, a set of targets were defined in relation to the specific objectives, against which the success or failure of the initiative could be measured. These targets are based on the experience of IMI2 JU[168] in terms of what could be achieved by an initiative of a similar financial scale and broadened scope. They will be further developed and refined during the preparation of the strategic research agenda before the start of the initiative. The necessary data would be gathered as part of the periodic project reporting as implemented for the whole of Horizon Europe, building upon what is currently done for IMI2 JU.

Table 11. Specific objectives and targets by the end of the initiative

Specific objective	Targets by the end of the initiative
SO1. Contribute towards a better understanding of the determinants of health and priority disease areas	• new tools relevant for studying new potential drug targets, e.g. new pharmacological tools, therapeutic modalities and patient-derived assays openly available to the scientific community (tools for 1,000 proteins); • new diagnostically- and/or therapeutically-relevant hypotheses tested in pre-clinical models and/or clinically (100); • new biomarkers of disease (relevant for diagnosis, efficacy, safety or prevention) identified and experimentally validated, new taxonomies of diseases or new stratifications to define patient subpopulations (at least 10 biomarkers).

[168] IMI2 JU Key Performance Indicators, including baselines and target values. https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf.

SO2. Integrate fragmented health R&I efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs...	• demonstrated feasibility of developing combination of products and services, including methods for generation of clinical evidence (5 examples); • new tools for prediction, prevention, surveillance, diagnosis, treatment options (incl. to prepare for major epidemic outbreaks) - development, validation and demonstrated deployment readiness of new tools (10 examples); • publications between European researchers on IHI projects (at least 1000); • share of projects involving civil society, patient organisations, health care professionals' associations or regulators: at least 80%; • share of budget allocated to projects bringing together representatives of two or more technology sectors: 95%.
SO3. Demonstrate the feasibility of people-centred, integrated health care solutions	• validated new targets for preventive or therapeutic strategy, in different therapeutic areas (at least 3 biomarkers); • demonstrated feasibility of developing people-centred, integrated health care solutions (5 examples); • projects engaging regulatory acceptance processes to contribute to new or improved guidelines or methodologies (20 examples);
SO4. Exploit the full potential of digitalisation and data exchange in health care	• demonstrated integration of data, provided by the public and private sectors (20 examples); • demonstration of feasibility of use of artificial intelligence in health care (3 examples).
SO5. Enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions	• methodologies for a comprehensive assessment of the added value of combinations of products/services or combined products (including PROMs/PREMs and statistical methods or tools), submitted to health care authorities and organisations (5 examples).

7.2.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.