



# Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

Independent  
Expert  
Report



Research and  
Innovation

## **Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe**

European Commission  
Directorate-General for Research and Innovation  
Directorate A — Policy & Programming Centre  
Unit A.2 — Programme Analysis & Regulatory Reform  
Contact Ann-Sofie Ronnlund  
Email [RTD-A2-SUPPORT@ec.europa.eu](mailto:RTD-A2-SUPPORT@ec.europa.eu)  
[Ann-Sofie.Ronnlund@ec.europa.eu](mailto:Ann-Sofie.Ronnlund@ec.europa.eu)  
[RTD-PUBLICATIONS@ec.europa.eu](mailto:RTD-PUBLICATIONS@ec.europa.eu)  
European Commission  
B-1049 Brussels

Manuscript completed in January 2020

This document has been prepared for the European Commission however it reflects the views only of the authors, and the European Commission is not liable for any consequence stemming from the reuse of this publication.

More information on the European Union is available on the internet (<http://europa.eu>).

Luxembourg: Publications Office of the European Union, 2020

PDF

ISBN 978-92-76-17342-7

doi: 10.2777/295096

KI-01-20-182-EN-N

© European Union, 2020

Reuse is authorised provided the source is acknowledged. The reuse policy of European Commission documents is regulated by Decision 2011/833/EU (OJ L 330, 14.12.2011, p. 39).

For any use or reproduction of photos or other material that is not under the copyright of the European Union, permission must be sought directly from the copyright holders.

Cover page image: © Lonely # 46246900, ag visuell #16440826, Sean Gladwell #6018533, LwRedStorm #3348265, 2011; kras99 #43746830, 2012. Source: Fotolia.com

# Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

**technopolis**  
group 

In collaboration with

**AECOM**

 **cambridge  
econometrics**  
clarity from complexity

**CE  
PS**

 **IDATE**  
DIGIWORLD

  
*Nomisma*  
SOCIETÀ DI STUDI ECONOMICI

**steer**

**Think**

Trinomics 

**Table of Contents**

**PART I. IMPACT ASSESSMENT STUDIES FOR THE CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS**

- 1. Overarching context to the impact assessment studies ..... 8
- 2. EU-Africa Global Health Candidate Institutionalised European Partnership ..... 33
- 3. Candidate Institutionalised European Partnership on Innovative Health ..... 156
- 4. Candidate Institutionalised European Partnership in High Performance Computing ..... 289
- 5. Candidate Institutionalised European Partnership in Key Digital Technologies ..... 415
- 6. Candidate Institutionalised European Partnership in Smart Networks and Services ..... 588
- 7. Candidate Institutionalised European Partnership in Metrology ..... 755
- 8. Candidate Institutionalised European Partnership on Transforming Europe’s Rail System .... 901
- 9. Candidate Institutionalised European Partnership for Integrated Air Traffic Management ... 1073
- 10. Candidate Institutionalised European Partnership on Clean Aviation ..... 1238
- 11. Candidate Institutionalised European Partnership on Clean Hydrogen ..... 1398
- 12. Candidate Institutionalised European Partnership on Safe and Automated Road Transport ..... 1584
- 13. Candidate Institutionalised European Partnership for a Circular Bio-based Europe ..... 1768
- 14. Candidate Institutionalised European Partnership for Innovative SMEs ..... 1945

**PART II. HORIZONTAL STUDIES**

- 1. Horizontal Analysis of Efficiency and Coherence in Implementation ..... 2088
- 2.. Impact Modelling of the Candidate Institutionalised European Partnerships ..... 2189

## Introduction

This Impact Assessment Study had the primary objective to support and provide input to the impact assessments of the first set of 13 European Institutionalised Partnerships based on Articles 185 and 187 of the Treaty on the Functioning of the EU (TFEU) that are envisaged to be funded under the new Framework Programme for Research and Innovation, Horizon Europe.

In addition, the Impact Assessment Study team contributed to future European policymaking on the overall European Partnership landscape by means of a horizontal analysis of the coherence and efficiency in the implementation of European partnerships. The purpose of this analysis was to draw the lessons learned from the implementation of the impact assessment methodology developed for this study and to formulate recommendations for the refinement and operational design of the criteria for the selection, implementation, monitoring, evaluation and phasing-out for the three types of European Partnerships. Finally, an impact modelling exercise was conducted in order to estimate the potential for longer-term future impacts of the candidate Institutionalised European partnerships in the economic and environmental sustainability spheres.

Technopolis Group was responsible for the overall coordination of the 13 specific impact assessment studies, the development of the common methodological framework, and the delivery of the horizontal analysis. It also conducted specific analyses that were common to all studies, acting as a 'horizontal' team, in collaboration with CEPS, IPM, Nomisma, and Optimat Ltd. For the implementation of the individual impact assessment studies, Technopolis Group collaborated with organisations that are key experts in specific fields covered by the candidate Institutionalised European Partnerships. These partner organisations were Aecom, Idate, Steer, Think, and Trinomics. Cambridge Econometrics took charge of the impact modelling exercise.

The Impact Assessment Study was conducted between July 2019 and January 2020. The 13 Impact Assessment Studies were conducted simultaneously, based upon a common methodological framework in order to maximise consistency and efficiency. The meta-framework reflected the Better Regulation Guidelines and operationalised the selection criteria for European Partnerships set out in the Horizon Europe Regulation. The 'Horizontal analysis of efficiency and coherence of implementation' was conducted in the same time period, building upon the information available on the 44 envisaged European Partnerships landscape as in May 2019, complemented with information on five envisaged European Partnerships as decided by the European Commission in October and November 2019.

This final report contains the reports of all individual impact assessment studies and the 'horizontal' analyses. It is structured in two parts, reflecting the two strands of analysis:

### **PART I. Impact Assessment Studies for the Candidate Institutionalised European Partnerships**

#### **1. Overarching context to the impact assessment studies**

This report sets out the overall policy context and methodological framework underlying the impact assessment studies for the candidate Institutionalised European Partnerships. It describes the changes in approach to the public-private and public-public partnerships under Horizon Europe compared to the previous EU Framework Programmes. An example is the requirement that all envisaged European Partnerships be implemented as either co-programmed, co-funded or institutionalised. The impact assessment studies will consider these three scenarios as the different options to be assessed, in compliance with the Better Regulation guidelines and against the functionalities that the candidate partnerships are expected to fulfil. The report describes the common methodological framework to assess the envisaged initiatives accordingly. The report also presents the landscape of European Partnerships at the level of Horizon Europe Pillar 2 clusters, which lay the grounds for all

of the impact assessment studies except the candidate Institutionalised European Partnership for Innovative SMEs.

## **2. EU-Africa Global Health Candidate Institutionalised European Partnership**

This initiative focuses on research and innovation in the area of infectious diseases, with a particular focus on sub-Saharan Africa. It will address the challenges of a sustained high burden of infectious diseases in Africa, as well as the (re)emergence of infectious diseases worldwide. Its objectives will thus be to contribute to a reduction of the burden of infectious diseases in sub-Saharan Africa and to the control of (re)emerging infectious diseases globally. It will do so through investments in relevant research and innovation actions, as well as by supporting the further development of essential research capacity in Africa. The study concluded that an Institutionalised Partnership under Art. 187 of the TFEU is the preferred option for the implementation of this initiative.

## **3. Candidate Institutionalised European Partnership on Innovative Health**

This initiative focuses on supporting innovation for health and care within the EU. It will address the EU-wide challenges raised by inefficient translation of scientific knowledge for use in health and care, insufficient innovative products reaching health and care services and threats to the competitiveness of the health industry. Its main objectives are to create an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations; foster the development of safe, effective, patient-centred and cost-effective innovations that respond to strategic unmet public health needs currently not served by industry; and drive cross-sectoral health innovation for a globally competitive European health industry. The study concluded that an Institutionalised Partnership based on Article 187 of the Treaty on the Functioning of the EU (TFEU) is the preferred option for the implementation of this initiative.

## **4. Candidate Institutionalised European Partnership in High Performance Computing**

The initiative focuses on coordinating efforts and resources in order to deploy a European HPC infrastructure together with a competitive innovation ecosystem in terms of technologies, applications, and skills. It will address the challenges raised by underinvestment, the lack of coordination between the EU and MS, fragmentation of instruments, technological dependency on non-EU suppliers, unmet scientific demand, and weaknesses in the endogenous HPC supply chain. The initiative has as its main objectives to enhance EU research in terms of HPC and related applications, continued support for the competitiveness EU HPC industry, and fostering digital autonomy in order to ensure long-term support for the European HPC ecosystem as a whole. The study concluded that an Institutionalised Partnership is the preferred option for the implementation of this initiative as it maximises benefits in comparison to the other available policy options.

## **5. Candidate Institutionalised European Partnership in Key Digital Technologies**

This initiative focusses on enhancing the research, innovation and business value creation of European electronics value chains in key strategic market segments in a sustainable manner to achieve technological sovereignty and ultimately make European businesses and citizens best equipped for the digital age. It will address the risks of Europe losing the lead in critical industries and services and emerging KDTs. It will also tackle Europe's limited control over digital technologies that are critical for EU industry and citizens. It has as main objectives to strengthen KDTs which are critical for the competitive position of key European industries in the global markets, to establish European leadership in emerging technologies with high socioeconomic potential and to secure Europe's technological sovereignty to maintain a strong and globally competitive presence in KDTs. The study concluded that the Institutionalised Partnership is the preferred option for the implementation of this initiative.

## **6. Candidate Institutionalised European Partnership in Smart Networks and Services**

This initiative focuses on the development of future networks infrastructure and the associated services. This includes bringing communication networks beyond 5G and toward 6G capabilities, but also the development of the Internet of Things and Edge Computing technologies. It will address the challenges raised by Europe delay in the deployment of network infrastructure and failure to fully benefit from the full potential of digitalisation. It has as main objective to ensure European technological sovereignty in future smart networks and digital services, to strengthen the uptake of digital solutions, and to foster the development of digital innovation that answers to European needs and that are well aligned with societal needs. The study concluded that an institutionalised partnership under article 187 is the preferred option for the implementation of this initiative.

## **7. Candidate Institutionalised European Partnership in Metrology**

This initiative focuses on metrology - that is the science of measurement and the provision of the technical infrastructure that underpins accurate and robust measurements throughout society; measurements that underpin all domains of science and technology and enable fair and open trade and support innovations and the design and implementation of policy and regulations. It will address challenges in the fragmentation of national metrology systems across Europe and the need to meet ever-increasing demands on metrology infrastructure to support the measurement needs of emerging technologies and important policy domains in climate, environment, energy and health. The main objective of the initiative is to establish a sustainable coordinated world-class metrology system in Europe that will increase and accelerate the development and deployment of innovations and contribute to the design and implementation of policy, regulation and standards. The study concluded that an A185 Institutionalised Partnership is the preferred option for the implementation of this initiative.

## **8. Candidate Institutionalised European Partnership on Transforming Europe's Rail System**

This initiative focuses on the development of a pan-European approach to research and innovation in the rail sector. It will address the challenges raised by the lack of alignment of research and innovation with the needs of a competitive rail transport industry and the consequent failure of the European rail network to make its full contribution to European societal objectives. It will also strengthen the competitiveness of the European rail supply industry in global markets. Accordingly, the objectives of the initiative are to ensure a more market-focused approach to research and innovation, improving the competitiveness and modal share of the rail industry and enhancing its contribution to environmental sustainability as well as economic and social development across the European Union. The study concluded that an institutionalised partnership under article 187 is the preferred option for the implementation of this initiative.

## **9. Candidate Institutionalised European Partnership for Integrated Air Traffic Management**

This initiative focuses on the modernisation of the Air Traffic Management in Europe - an essential enabler of safe and efficient air transport and a cornerstone of the European Union's society and economy. The proposed initiative will address the challenges raised by an outdated Air Traffic Management system with a non-optimised performance. The current system needs to be transformed to enable exploitation of emerging digital technologies and to accommodate new forms of air vehicle including drones. The objective is therefore to harmonise European Air Traffic Management system based on high levels of digitalisation, automation and connectivity whilst strengthening air transport, drone and ATM markets competitiveness and achieving environmental, performance and mobility goals. This would create €1,800b benefits to the EU economy if the current initiative can

be built on and accelerated. The study concluded that an Institutionalised Partnership under Art. 187 TFEU is the preferred option for the implementation of this initiative.

#### **10. Candidate Institutionalised European Partnership on Clean Aviation**

This initiative focuses on further aeronautical research and innovation to improve technology leading to more environmentally efficient aviation equipment. It will address the challenges raised by the growing ecological footprint of aviation and the challenges and barriers faced by the aviation industry towards climate neutrality. It will also strengthen the competitiveness of the European aeronautical industry in global markets. Accordingly, the objectives of the initiative are to ensure that aviation reaches climate neutrality and that other environmental impacts are reduced significantly by 2050, maintain the leadership and competitiveness of the European aeronautics industry and ensure safe, secure and efficient air transport of passengers and goods. The Impact Assessment study assessed the options for implementation that would allow for an optimal attainment of these objectives. The study concluded that an institutionalised partnership under Art. 187 TFEU is the preferred option for the implementation of this initiative.

#### **11. Candidate Institutionalised European Partnership on Clean Hydrogen**

The report assesses the impact of potential initiatives to support, through research and innovation, the growth and development of clean hydrogen, among which an Institutionalised European Partnership is one of the options assessed. The existing challenges for clean hydrogen include the limited high-level scientific capacity and fragmented research activities, the insufficient deployment of hydrogen applications, and consequently weaker EU scientific and industrial value chains. Environmental, health and mobility pressures are also driving the need for cleaner hydrogen generation, deployment and use. An initiative for clean hydrogen must have as a main objective the strengthening and integration of EU scientific capacities, to support the creation, capitalisation and sharing of knowledge. This is necessary to accelerate the development and improvement of advanced clean hydrogen applications, the market entry of innovative competitive clean solutions, to strengthen the competitiveness of the EU clean hydrogen value chains (and notably the SMEs within them), and to develop the hydrogen-based solutions necessary to reach climate neutrality in the EU by 2050. The study concluded that an Institutionalised Partnership under Art. 187 TFEU is the preferred option for the implementation of this initiative.

#### **12. Candidate Institutionalised European Partnership on Safe and Automated Road Transport**

This initiative focuses on Connected, Cooperative and Automated Mobility: the use of connected and automated vehicles to create more user-centred, all-inclusive mobility, while also increasing safety, reducing congestion and contributing to decarbonisation. With current road traffic collisions and negative local and global environmental impacts not reducing quickly enough, it will address the challenges raised by the current fragmentation of research across the field, and the threat to European competitiveness if the research agenda does not advance quickly enough. The initiative will focus on strengthening EU scientific capacity and economic competitiveness in the field of CCAM, whilst contributing to wider societal benefits including improved road safety, less environmental impact, and improved accessibility to mobility. The study concluded that a co-programmed partnership is the preferred option for the implementation of this initiative.

#### **13. Candidate Institutionalised European Partnership for a Circular Bio-based Europe**

This initiative focuses on intensifying research and innovation allowing to replace, where possible, non-renewable fossil and mineral resources with biomass and waste for the production of renewable products and nutrients, in order to drive forward sustainable and climate-neutral solutions that accelerate the transition to a healthy planet and respect



planetary boundaries. It will address the challenges raised by the fact that the EU economy does not operate within planetary boundaries, is not sufficiently circular and is predominantly fossil based. It will also address the insufficient research and innovation (R&I) capacity and cross-sectoral transfer of knowledge and bio-based solutions, as well as risks posed to the European bio-based industry's global competitiveness. The study concluded that Institutionalised European Partnership based upon Article 187 TFEU is the preferred option for the implementation of this initiative.

#### **14. Candidate Institutionalised European Partnership for Innovative SMEs**

The initiative is envisaged as a continuation of the Eurostars 2 programme which is managed by the Eureka network. The initiative focuses on international collaborative R&D of innovative companies, facilitated through a network of national funding organisations as included in the Eureka network. The funded projects are bottom-up and involve small numbers of project partners. The candidate partnership addresses a niche issue namely limited opportunities for international bottom-up collaboration. The partnership provides thus an opportunity for SMEs for international R&D collaboration but does not address specific technological, social, or environmental challenges. Its main objective is to improve the competitiveness of European SMEs through collaborative funding. The study concluded that a co-funded partnership is the preferred option for the implementation of this initiative.

### **PART II. Horizontal studies**

#### **1. Horizontal Analysis of Efficiency and Coherence in Implementation**

The focus of this report is on the coherence and efficiency in the current European Partnership landscape under Horizon Europe and the potential to enhance efficiency in the European Partnerships' implementation.

European Partnerships are geared towards playing a pivotal role in tackling the complex economic and societal challenges that constitute the R&I priorities of the Horizon Europe Pillar II and are in a unique position to address transformational failures. Multiple potential interconnections and synergies exist between the candidate European Partnerships within the clusters, but few are visible across the clusters.

As for the improvement of the efficiency in implementation of institutionalised partnerships under Art. 187, potential efficiency and effectiveness gains could be achieved with enhanced collaboration. An option for a common back-office sharing operational implementation activities is worth exploring further through a detailed feasibility study in order to assess whether efficiency gains can be made. Ideally this would be co-designed as a common Partnership approach, leading to a win-win situation for all partners.

#### **2. Impact Modelling of the Candidate Institutionalised European Partnerships**

This report presents the results of the use of a macroeconomic model to assess the economic and environmental impacts of the preferred options identified in the individual 13 impact assessment studies. The model used is E3ME. It includes explicit representation for each EU Member State with a detailed sectoral disaggregation.

The impact modelling estimated the impacts of the envisaged initiatives at an aggregated as well as individual level. In total, 14 macroeconomic models have been run, one per reviewed initiative with a time horizon of 2035 and one that combines all initiatives with a time horizon of 2050. The results of each of these models were compared with those of a baseline scenario, which corresponds to a situation where the initiatives would be funded through regular Horizon Europe calls rather than European Partnerships.

# **Part I. Impact Assessment Studies for the Candidate Institutionalised European Partnerships**

## ***1. Overarching Context to the Impact Assessment Studies***

### **Authors**

Bea Mahieu, Paul Simmonds, Maria del Carmen Calatrava, Julien Chicot,  
Diogo Machado, Stijn Zegel (Technopolis Group)

Andrea Renda (CEPS)



## **Introduction**

This report sets out the overall policy context of the impact assessment studies for the candidate Institutionalised European Partnerships and the methodological framework that was developed for the impact assessment studies.

It describes the changes in approach to the public-private and public-public partnerships under Horizon Europe compared to the previous EU Framework Programmes. An example is the requirement that all envisaged European Partnerships be implemented as either co-programmed, co-funded or institutionalised. The impact assessment studies will consider these three scenarios as the different options to be assessed, in compliance with the Better Regulation guidelines and against the functionalities that the candidate partnerships are expected to fulfil. The report describes the common methodological framework to assess the envisaged initiatives accordingly.

The report also presents the landscape of European Partnerships at the level of Horizon Europe Pillar 2 clusters, which lay the grounds for all of the impact assessment studies except the candidate Institutionalised European Partnership for Innovative SMEs. This analysis is presented in more depth in the report on the 'Horizontal analysis of efficiency and coherence of implementation' in Part II of the Impact Assessment Study report.

The report is structured around two main headings:

- Chapter 1: Background and context to European Partnerships in Horizon Europe and focus of the impact assessment– What is decided
- Chapter 2: The Candidate European Partnerships under Horizon Europe – What needs to be decided

## Table of Contents

1	Background and context to European Partnerships in Horizon Europe and focus of the impact assessment– What is decided .....	10
1.1	The political and legal context .....	10
1.2	Typical problems and problem drivers .....	14
1.3	Description of the options .....	15
2	The Candidate European Partnerships under Horizon Europe – What needs to be decided ....	18
2.1	Portfolio of candidates for Institutionalised Partnerships under Horizon Europe .....	18
2.2	Assessing the necessity of a European Partnership, possible options for implementation and their cost-effectiveness.....	20
2.3	Cross-partnership challenges in Horizon Europe clusters.....	27

## Table of Figures

Figure 1:	Targeted impacts under Horizon Europe by priority .....	11
Figure 2:	Contribution of Candidate European Institutionalised Partnerships to the Horizon Europe priorities in Pillars II and III .....	14
Figure 3:	Landscape of European Partnerships under Horizon Europe (2019) .....	20
Figure 4:	Flow of the analysis.....	22
Figure 5:	R&I priorities and higher-level objectives of the Horizon Europe Cluster 1 – Health.....	28
Figure 6:	R&I priorities and higher-level objectives of the Horizon Europe Cluster 4 – Digital, Industry and Space .....	29
Figure 7:	R&I priorities and higher-level objectives of the Horizon Europe cluster Climate, Energy and Mobility .....	30
Figure 8:	R&I priorities and higher-level objectives of the Horizon Europe Cluster 6 – Food, Bioeconomy, Natural Resources, Agriculture and Environment.....	31

## List of Tables

Table 1:	Horizon Europe selection criteria for the European Partnerships .....	21
Table 2:	Intensity of additional costs compared with HEU Calls (for Partners, stakeholders, public and EC).....	24
Table 3:	Cost-efficiency matrix.....	25

## **1 Background and context to European Partnerships in Horizon Europe and focus of the impact assessment– What is decided**

### *1.1 The political and legal context*

#### 1.1.1 Shift in EU priorities and Horizon Europe objectives

Horizon Europe is to be set in the broader context of the pronounced **systemic and holistic approach** taken to the design of the new Framework Programme and the overarching Multi-annual Financial Framework (MFF) 2021-27.

The future long-term budget will be a budget for the Union's priorities. In her Political Guidelines for the next European Commission 2019 – 2024, the new President of the European Commission put forward six overarching priorities for the next five years, which reach well beyond 2024 in scope: A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Protecting our European way of life; A stronger Europe in the world; and A new push for European democracy. These priorities build upon A New Strategic Agenda for 2019–2024, adopted by the European Council on 20 June 2019, which targets similar overarching objectives. Together with the United Nations Sustainable Development Goals (SDGs), they will shape future EU policy responses to the challenges Europe faces and will steer the ongoing transitions in the European economy and society,

The MFF 2021-27 strives to provide a framework that will ensure a more coherent, focused and transparent response to Europe's challenges. A stronger focus on European added value, a more streamlined and transparent budget, more flexibility in order to respond quickly and effectively to unforeseen demands, and above all, an effective and efficient implementation are among the key principles of the MFF. The objective is to strengthen the alignment with Union policies and priorities and to simplify and reform the system in order to "unlock the full potential of the EU budget" and "turn ambitions into reality". Investment from multiple programmes is intended to combine in order to address key crosscutting priorities such as the digital economy, sustainability, security, migration, human capital and skills, as well as support for small businesses and innovation.<sup>1</sup>

These principles underlying the MFF 2021-27 are translated in the intent for Horizon Europe "to play a vital role, in combination with other interventions, for creating new solutions and fostering innovation, both incremental and disruptive."<sup>2</sup> The new Framework Programme finds its rationale in the daunting challenges that Europe 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."

In the Orientations towards the first Strategic Plan for Horizon Europe, the need strategically to 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, "Actions under Pillar II of Horizon Europe will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union."

Figure 1, below, which gives an indicative overview of how the EU political priorities are supported under Horizon Europe, shows the major emphasis placed on contributing to the priority 'A European Green Deal', aimed at making Europe the first climate-neutral

---

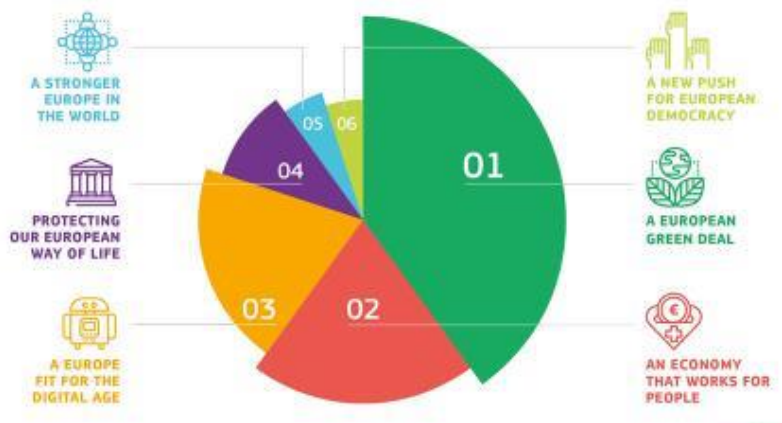
<sup>1</sup> EC (2018) *A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027*. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

<sup>2</sup> EC (2019), *Orientations towards the first Strategic Plan for Horizon Europe*.

continent in the world. At least 35 % of the expenditure from actions under the Horizon Europe Programme will address the Sustainable Development Goal 13: Climate Action.

Especially the R&I activities funded under Pillar II, including seven Partnership Areas (see below), are expected to contribute to the attainment of these objectives in an interconnected manner.

Figure 1: Targeted impacts under Horizon Europe by priority



Note: Preliminary, as described in the General orientations towards the first Strategic Plan implementing Horizon Europe.  
Source: European Commission (2019) Orientations towards the first Strategic Plan for Horizon Europe, December 2019.

### 1.1.2 Renewed ambition for European Partnerships

Reflecting its pronounced systemic nature aimed at ‘transformation’ of the European R&I system, Horizon Europe intends to make a more effective use of these partnerships with an **ambitious approach** that is impact oriented and ensures complementarity with the Framework Programme. The **rationalisation** of the partnership landscape, both in terms of number of partnership forms and individual initiatives, constituted a first step in the direction of the strategic role that these policy initiatives are expected to play in the context of Horizon Europe. Future partnerships are expected to “provide mechanisms to consistently aggregate research and innovation efforts into more effective responses to the policy needs of the Union”.<sup>3</sup> The expectation is that they will act as **dynamic change agents**, strengthening linkages within their respective ecosystems and with other related ecosystems as well as pooling resources and efforts towards the common objectives in the European, national and regional landscape. They are expected to develop *close synergies* with national and regional programmes, bring together a *broad range of actors* to work towards a common goal, translate *common priorities* into concrete roadmaps and coordinated activities, and turn research and innovation into *socio-economic results and impacts*.

The exact budget dedicated to European Partnerships under Horizon Europe will be agreed only upon decisions on the multiannual financial framework (MFF) 2021-2027 and the overall budget for Horizon Europe. In December 2017, the Council nevertheless introduced the principle of a “possible capping of partnership instruments in the FP budget”.<sup>4</sup> Accordingly, it reached the common understanding, with the European Parliament, that “the majority of the budget in Pillar II [€52.7bn] shall be allocated to actions outside of

<sup>3</sup> European Commission (2019) *Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe*. Co-design via web open consultation. Summer 2019.

<sup>4</sup> Council of the European Union (2017) *From the Interim Evaluation of Horizon 2020 towards the ninth Framework Programme*. Council conclusions 15320/17.

European Partnerships” (Article 8.2(a) of the Common Understanding on the proposal for a regulation establishing Horizon Europe).<sup>5</sup>

### 1.1.3 Key evolutions as regards the partnership approach

The European R&I partnerships were initially conceived as a means to increase synergies between the European Union and the Member States (Article 181 of the Treaty on the Functioning of the European Union TFEU). Their objectives were to pool the forces of all the relevant actors of R&I systems to achieve breakthrough innovations; strengthen EU competitiveness; and, tackle major societal challenges. The core activities of the European partnerships consist therefore of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas. They help accelerate the emergence of a programming approach in European R&I with the involvement of all relevant actors and provide flexible structures for partnerships that can be tailored to their goals.<sup>6</sup>

In the consecutive Framework Programmes up to the current Horizon 2020, the partnerships and their forms have mushroomed, leading to an increasing complexity of the partnership landscape. The Horizon 2020 interim evaluation highlighted that the overall landscape of EU R&I funding had become overly complex and fragmented, and a need to improve the partnerships’ openness and transparency. The Lamy report suggested that the European Partnerships should focus on those areas with the greatest European Added Value, contribute to EU R&I missions and would need a simplified and flexible co-funding mechanism.

The Competitiveness Council conclusions of December 2017 called on the Commission and the Member States to jointly consider ways to rationalise the EU R&I partnership landscape. In 2018, the ERAC Ad-hoc Working Group on Partnerships concluded, “the rationalisation of the R&I partnership landscape is needed in order to ensure that the portfolio of R&I partnerships makes a significant contribution to improving the coherence, functioning and quality of Europe's R&I system and that the individual initiatives are able to fully achieve their potential in creating positive scientific and socio-economic impacts and/or in addressing societal challenges”.

Horizon Europe has taken on board these concerns. The Impact Assessment of Horizon Europe gave a clear analysis of the achievements of Partnerships so far as well as the expectations for the new generation of Partnerships. Greater transparency and openness of the partnerships were considered as essential, as well a clear European added value and long-term commitments of the stakeholders involved.

A list of criteria to decide how European Partnerships will be selected, implemented, monitored, evaluated and phased-out was attached as an Annex III to the proposal to establish Horizon Europe (as revised by the partial political agreement). The rationalisation of the Partnership portfolio in Horizon Europe is expected to allow for a reduction from the current 120 to between 45 and 50 partnerships.

---

<sup>5</sup> Council of the European Union (2019) *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rule for participation and dissemination*. Common understanding 7942/19.

<sup>6</sup> European Commission (2011) *Partnering in Research and Innovation*. Communication from the Commission COM(2011) 572 final.

#### 1.1.4 Overview of legal provisions

The Horizon Europe Regulation (common understanding) defines 'European Partnership' 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." It stipulates that "parts of Horizon Europe may be implemented through European Partnerships".

The Horizon Europe Regulation (common understanding) also stipulates that the European Partnerships are expected to 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." The provisions and criteria set out for the selection and implementation of the European Partnerships reflect these principles.

#### 1.1.5 Overview of the eight Partnership areas

The Horizon Europe Regulation also identifies the following "Areas for possible institutionalised European Partnerships on the basis of Article 185 TFEU or Article 187 TFEU":

- Partnership Area 1: Faster development and safer use of health innovations for European patients, and global health.
- Partnership Area 2: Advancing key digital and enabling technologies and their use, including but not limited to novel technologies such as Artificial Intelligence, photonics and quantum technologies.
- Partnership Area 3: European leadership in Metrology including an integrated Metrology system.
- Partnership Area 4: Accelerate competitiveness, safety and environmental performance of EU air traffic, aviation and rail.
- Partnership Area 5: Sustainable, inclusive and circular bio-based solutions.
- Partnership Area 6: Hydrogen and sustainable energy storage technologies with lower environmental footprint and less energy-intensive production.
- Partnership Area 7: Clean, connected, cooperative, autonomous and automated solutions for future mobility demands of people and goods.
- Partnership Area 8: Innovative and R&D intensive small and medium-sized enterprises.

Considering the realm of these partnership areas, potential synergies exist with the future **missions**. Horizon European introduced these cross-discipline and cross-sector policy instruments as part of its core objective of stimulating further excellence-based and impact-driven R&I. In contrast with the challenges targeted in Horizon 2020, the missions aim at the achievement of well-defined goals to provide solutions, within a specified timeframe, to scientific, technological, economical and/or societal problems. As part of the preparation of Horizon Europe, the European Commission set up five boards to formulate the future missions in the following areas:

- Adaptation to climate change including societal transformation



- Cancer
- Healthy oceans, seas, coastal and inland waters
- Climate-neutral and smart cities
- Soil health and food

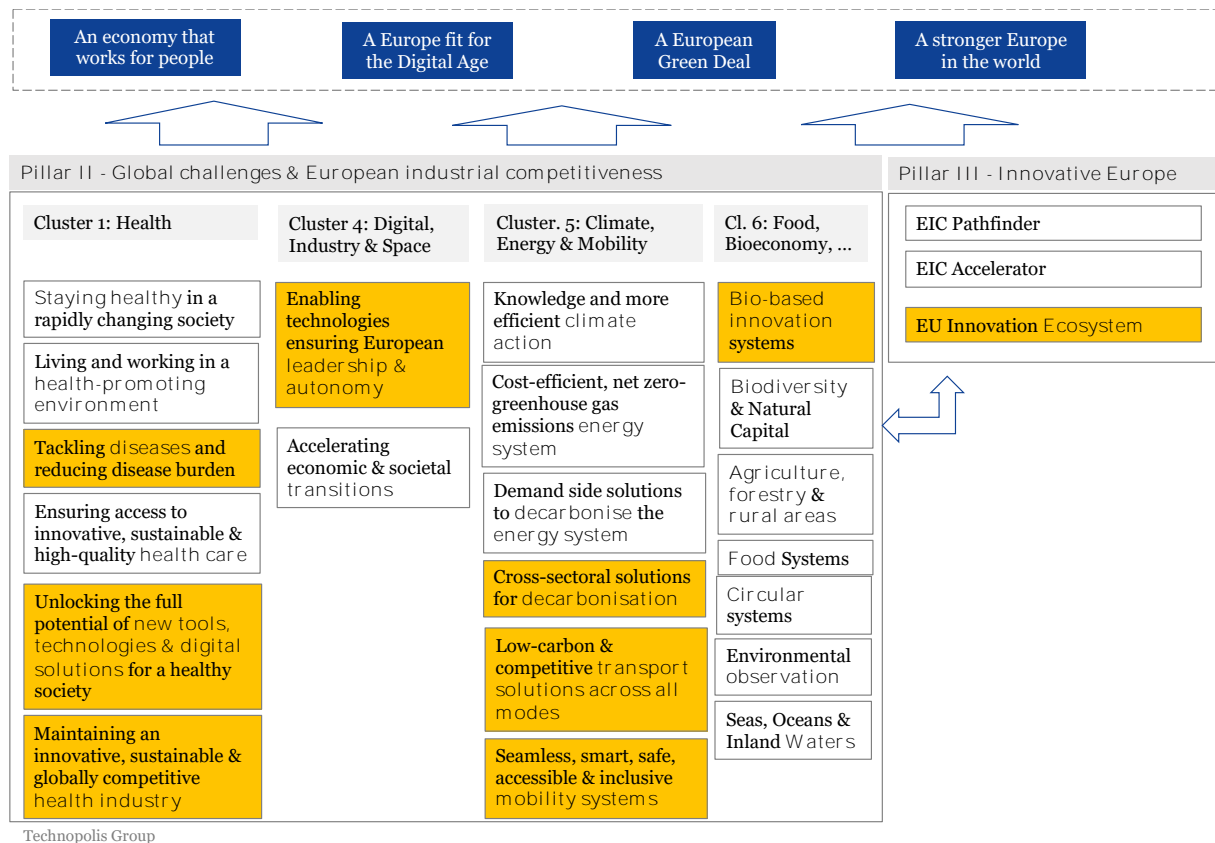
### 1.2 Typical problems and problem drivers

The European Partnerships are integral part of the framework programme and its three-pillar structure. They are predominantly funded under Pillar 2 “Global Challenges and European industrial competitiveness” and four of its thematic clusters. These clusters cover sectors and technologies, in which research and innovation activities are deemed of crucial importance in solving pressing scientific, societal or economic challenges and ensuring the scientific, technological and industrial leadership of Europe. Only one European Partnership, targeting innovative and R&D intensive SMEs, will instead act under Pillar 3 “Innovative Europe”.

The European Partnerships are intended to contribute to the attainment of the pillars’ and clusters’ **challenges and R&I priorities**. Overarching EU policy priorities addressed are predominantly the European Green Deal, a people-centred economy, the fit for the Digital Age, and a stronger Europe in the world.

In Figure 2, below, the R&I priorities in the Pillars II and III to which the candidate *Institutionalised* Partnerships intend to contribute are highlighted in yellow.

Figure 2: Contribution of Candidate European Institutionalised Partnerships to the Horizon Europe priorities in Pillars II and III



The European Partnerships under Horizon Europe most often find their rationale in addressing **systemic failures**. 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 agenda and/or R&I funding programmes.

The concentration of efforts and resources and pooling of knowledge, expertise and skills on common priorities in a view of solving complex and multi-faceted societal and economic challenges is at the core of these initiatives. Enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these policy instruments. In the light of Horizon Europe, the aim often is to drive system transitions and transformations.

Especially in fast-growing technologies and sectors such as ICT, the envisaged European Partnerships also react on 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.

**Transformational failures** addressed aim at reaching a better alignment of the strategic R&I agenda and policies of public and private R&I funders in order to pool available resources, create critical mass, avoid unnecessary duplication of research and innovation efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.

Market failures are less commonly addressed and relate predominantly to enhancing industry investments thanks to the sharing of risks.

### *1.3 Description of the options*

The proposal for a regulation establishing Horizon Europe<sup>7</sup> stipulates that parts of the Horizon Europe Framework Programme may be implemented through European Partnerships and establishes three implementation modes: Co-programmed European Partnerships, Co-funded European Partnerships, and Institutionalised Partnerships in accordance with Article 185 TFEU or Article 187 TFEU.

#### **1.3.1 Baseline option – Traditional calls under the Framework Programme**

Under this option, strategic programming for research and innovation in the field will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through traditional calls under the Framework Programme covering a range of activities, but mainly calls for R&I and/or innovation actions. Most actions involve consortia of public and/or private actors in ad hoc combinations, some actions are single actor (mono-beneficiary). There will be no dedicated implementation structures and no further support other than the Horizon Europe actions foreseen in the related Horizon Europe programme or cluster.

Strategic planning mechanisms in the Framework Programmes allow for a high level of flexibility in their ability to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving MS. The broad scope of the stakeholders providing their input to the research agenda, however, implies a lower level of directionality than what can be achieved through the partnerships. Often, the long-term perspective of the stakeholder input is limited, which risks reducing strategic capacity in addressing priorities.

The Horizon Europe option also implies a lower level of EU budgetary long-term commitment for the priority. Without a formal EU partnership mechanism, it is also less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual financial commitments beyond the single project participation.

---

<sup>7</sup> Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe - the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination - Common understanding', March 2019

### 1.3.2 European Partnership

All European Partnerships will be designed in line with the new policy approach for more objective-driven and impactful partnerships. They are based on the common criteria in Annex III of the Horizon Europe Regulation, with few distinguishing elements for the different forms of implementation. All European Partnerships will be based on an agreed Strategic Research and Innovation Agenda / roadmap agreed among partners and with the Commission. For each of them the objectives, key performance and impact indicators, and outputs to be delivered, as well as the related commitments for financial and/or in-kind contributions of the partners will be defined ex-ante.

#### 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 European Commission and the private and/or public partners. Private partners are typically represented by one or more industry association, which also functions as a back-office to the partnership. It allows for a *high flexibility* in the profile of organisation involved, objectives pursued, and/or activities implemented.

Co-programmed European Partnerships address *broader communities* across a diverse set of sectors and/or value chains and where the actors have *widely differing capacities and capabilities*. They may encompass one or more associations of organisations from industry, research, NGOs etc as well as foundations and national R&I funding bodies, with no restriction on the involvement of international partners from Associated and non-associated third countries. Different configurations are possible: private actors only, public entities only, or a combination of the two.

The basis, as for all European Partnerships, is the rationale is to create a *platform for 'concertation'*, i.e. in-depth and ongoing consultation of the relevant actors in the European R&I system for the co-development of a strategic research and Innovation agenda, typically covering the period of the next 10 years. The primary ambition is to generate *commitment to a common strategic research and innovation agenda* (SRIA). For the private actors involved, this would allow for a de-risking of their R&I investments and provide predictability of investment paths, for the public actors, it serves as a means to: inform national policy-makers on EU investments and allows for coordination and alignment of their efforts to support R&I in the field at the national level.

The *level of 'additionality is possibly lower than for other partnerships*. There is no expectation of a legally binding commitment from the partners to taking an integrated approach in their individual R&I implementation and it is based on 'best efforts'. However, the Union contribution to the partnership is defined for the full duration and has a comparable level of certainty for the partnerships than in the other forms of implementation. The priorities for the calls, proposed by the partnership members for integration in the Framework Programme Work Programmes, are subject to further input from Member States (comitology) and Commission Services. The full implementation of the Union contribution in the Framework Programme implies that the full array of Horizon Europe funding instruments in the related Pillar can be used, ranging from RIAs to CSAs and including grants, prizes, and procurement.

#### Option 2 – Co-funded European Partnership

The Co-funded Partnership is based on a Grant Agreement between the Commission and the consortium of partners, resulting from a call for a proposal for a programme co-fund action implementing the European Partnerships in the Horizon Europe Work Programme. Programme co-fund actions provide co-funding to a programme of activities established and/or implemented by entities managing and/or funding research and innovation programmes. Therefore, this form of implementation only allows to address public partners

at its core (comparable to the Article 185 initiatives below), while industry can nevertheless be addressed by the activities of the partnerships, but not make formal commitments and contributions to it. The expectation is that these entities would cover most if not all EU Member States (MS). Also 'international' funding bodies can participate as partners, which creates the potential for an efficient interaction with strategic international partners. Legal entities in countries that are not part of the programme co-fund consortium, are usually excluded from funding under the calls launched by the consortium.

The basic rationale for this partnership option is to bring MS together to invest at scale in key R&I issues of general and common interest. The joint programme of activities is agreed by the partners and with the EU and typically focuses on societal grand challenges and specifically, areas of high public good where EU action will add value while reflecting national priorities and/or policies. The ultimate intent is to create the greatest possible impact by pooling and/or coordinating national programmes and policies with EU policies and investments, helping to overcome fragmentation of the public research effort. Member States that are partners in this partnership become the 'owners' of the priority and take sole responsibility for its funding. Commitments of the partners and the European Union are ensured through the Grant Agreement.

Based on national programmes, this partnership option shows a particularly high level of flexibility in terms of activities to be implemented - directly by the national funding bodies (or governmental organisation "owning" institutional programmes), or by third parties receiving financial support (following calls for proposals launched by the consortium). The broad range of possible activities include support for networking and coordination, research, innovation, pilot actions, and innovation and market deployment actions, training and mobility actions, awareness raising and communication, dissemination and exploitation, any relevant financial support, such as grants, prizes, procurement, as well as Horizon Europe blended finance or a combination thereof.

### Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement and will be based on a Council Regulation (Article 187) or a Decision by the European Parliament and Council (Art 185) and implemented by dedicated structures created for that purpose. The legal base for this type of partnership limits the flexibility for a change in 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 agenda's in the private and/or public sectors in Europe in order to address a strategic challenge or realise an opportunity. The focus is on major long-term strategic challenges and priorities beyond the framework of a single Framework Programme where collective action – by private and/or public sectors – is necessary to *achieve critical mass* and *address the full extent of the complexities* of the ecosystem concerned.

The long-term commitment expected from the European Union and its partners is therefore much larger than for any of the other options, given the considerably higher investment in the preparation and implementation of the Partnership. As a result, this type of partnership can be selected only if 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. The commitment for contributions by the partnership members is expected to be at least equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments.

The partnership members have a high degree of autonomy in developing the strategic research agenda and annual work programmes and call topics, based on a transparent and accessible process, and subject to the approval of the Commission Services. The choice of topics addressed in the (open) calls are therefore strongly aligned with the needs defined. Normally, the strategic priorities are fully covered by the annual work programmes in the

partnership, even though it is in principle possible to keep certain topics for calls in the FP thus complementing the activities in the partnership. The full integration in the Framework Programme implies that the full array of Horizon Europe funding instruments in the related Pillar can be used, ranging from RIAs to CSAs and including grants, prizes, and procurement.

Two forms of Institutionalised Partnerships are of direct relevance to this study, influencing the constellation of partners involved.

### **Institutionalised Partnerships based upon Art 185 TFEU**

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope of partners to 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 dedicated legal entity (Dedicated Implementation Structure) for the implementation. By default, membership of non-associated Third Countries is not foreseen. Such membership is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement. Eligibility for participation and funding follows by default the rules of the Framework programme, unless a derogation is introduced in the basic act.

### **Institutionalised Partnerships under Art. 187 TFEU**

This type of Institutionalised Partnership aims at reaching the greatest possible impact by integrating the strategic R&I agendas of private and/or public actors and by leveraging the partners' investments in order to tackle R&I and societal challenges and/or contribute to Europe's wider competitiveness goals.

It brings together a stable set of 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) 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). By default, membership of non-associated Third Countries is not foreseen. Such membership is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement. Eligibility for participation and funding follows by default the rules of the Framework programme, unless a derogation is introduced in the basic act.

## **2 The Candidate European Partnerships under Horizon Europe – What needs to be decided**

### *2.1 Portfolio of candidates for Institutionalised Partnerships under Horizon Europe*

#### **2.1.1 The process for identifying the priorities for Institutionalised Partnerships under Horizon Europe**

In May 2019, the European Commission consulted the Member States on a list of 44 possible candidates for European Partnership which it had identified as part of the preparation of the first Strategic Planning of Horizon Europe. This list was also part of the

Orientations towards the first Strategic Plan implementing Horizon 2020<sup>8</sup> which served as a basis for an Open Public Consultation from July to October 2019. In October and November 2019, the European Commission and the Member States agreed on increasing the number of candidate European partnerships to 49. Subsequent discussions until the adoption of Horizon Europe will focus on ensuring the overall consistency of the EU partnership landscape and its alignment with the EU overarching priorities and on defining the precise implementation modalities.

In parallel, the European Commission completed inception impact assessments on the candidate institutionalised European partnerships. Stakeholders had the opportunity to provide their feedback on these inception impact assessments in August 2019. A web-based open public consultation to collect opinions on all candidate institutionalised partnerships (but the candidate EuroHPC partnership) was organised between September and October 2019.

### 2.1.2 Overview of the overall landscape of candidate European Partnerships subject to the impact assessment

Figure 3, below, gives an overview of all European Partnerships that are currently envisaged for funding under Horizon Europe. The candidate Institutionalised Partnerships that are the subject for this impact assessment study are coloured in dark orange.

The European Partnerships can be categorised into two major groupings: '*horizontal*' partnerships focused on the development of technologies, methods, infrastructures and resources/materials, and '*vertical*' partnerships focused on the needs and development of a specific application area, be it industrial or societal.

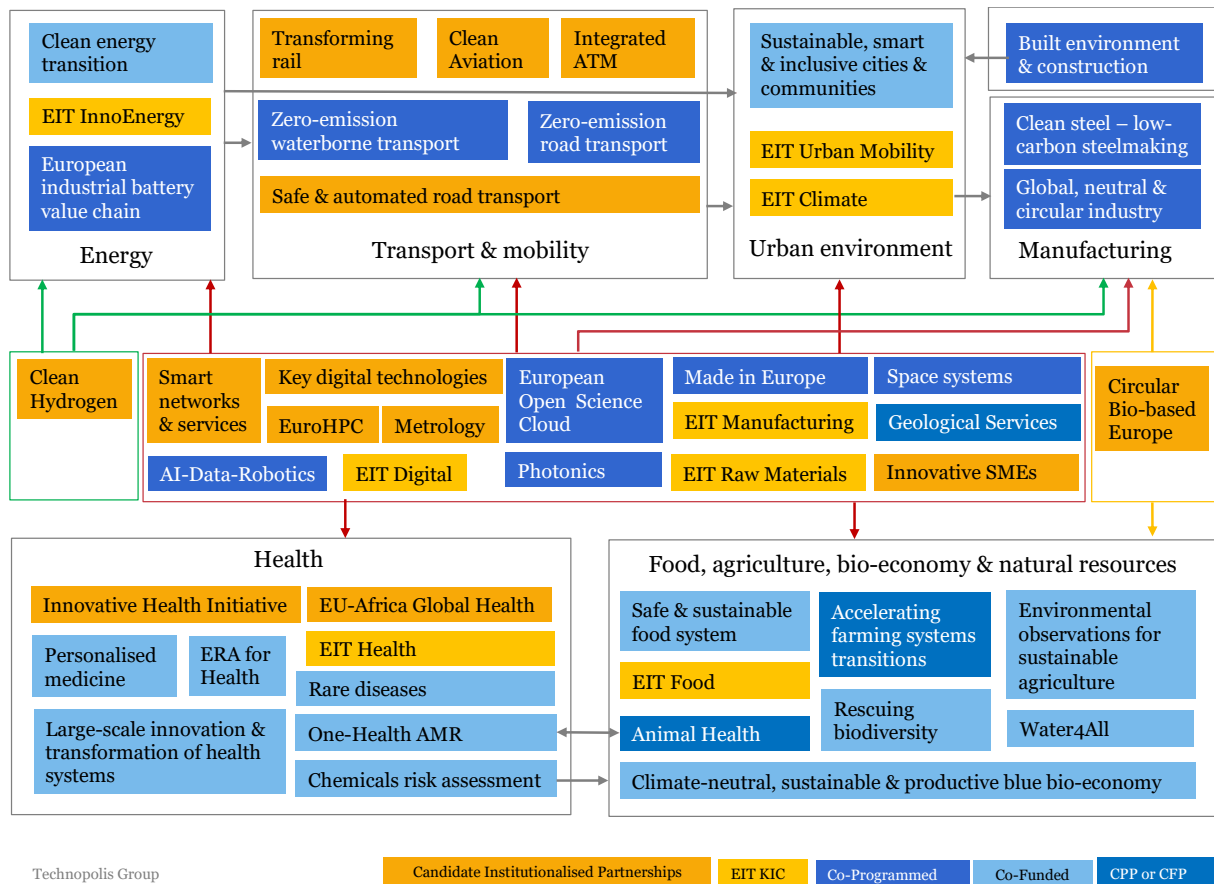
The diagram below shows the central position of the '**horizontal**' partnerships in the overall landscape, developing methodologies, technologies or data management infrastructures for application in the other priority areas. These 'horizontal' partnerships are predominantly proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs. The European Open Science Cloud (EOSC) partnership, for example, will support research partnerships by providing an infrastructure for the storage, management, analysis and re-use of research data.

The upper banner of the diagram groups the **industry-oriented 'vertical' partnerships**. Under Horizon Europe, they have in common a pronounced focus on enhancing sustainability. In this context, the banner includes also one of the most recent agreed-upon partnerships focused on the urban environment. This partnership illustrates the introduction under Horizon Europe of *challenge-oriented* cross-cluster partnerships. Multiple interconnections are envisaged among the 'vertical' partnerships in the different industry sectors covered. In the transport sector, the partnerships are predominantly proposed as Institutionalised Partnerships. In the other sectors, we see a mix of Co-Programmed Partnerships and EIT KICs. There are only two Co-Funded Partnerships.

---

<sup>8</sup> Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe, Co-design via Web Open Consultation (2019), see more here [https://ec.europa.eu/research/pdf/horizon-europe/ec\\_rtd\\_orientations-towards-the-strategic-planning.pdf](https://ec.europa.eu/research/pdf/horizon-europe/ec_rtd_orientations-towards-the-strategic-planning.pdf)

Figure 3: Landscape of European Partnerships under Horizon Europe (2019)



The lower banner includes the **'vertical' partnerships in the societal application areas**. Striking is the dominance of the Co-Funded Partnerships (to be noted that in the Food/agriculture cluster, the partnership type still needs to be decided for several envisaged partnerships). We also note the limited interconnections that are envisaged between the two areas. An exception is the newly envisaged cross-cluster European Partnerships 'One Health AMR'.

### 2.2 Assessing the necessity of a European Partnership, possible options for implementation and their cost-effectiveness

In this section we set out the methodological framework that underpins the impact assessment studies. In line with the Better Regulation Guidelines, the impact assessment is intervention logic-based and impact-oriented.

The impact assessment allowed also for the conduct of the 'necessity test' for a European Partnership as set out in the Horizon Europe regulation. Pivotal in this context was the identification of the Horizon Europe calls as Option 0 as well as Baseline Option, allowing for a comparative analysis of the three partnership forms (Options 1-3) along all of the assessment dimensions – in relation to each other as well as to the Horizon Europe calls. The options assessment therefore incorporated the required 'necessity test'.

#### 2.2.1 Assessment of the selection criteria

The common methodological framework that we defined for the 13 individual Impact Assessment studies reflects the approach defined in the Better Regulation guidelines. It also integrates the specific criteria for the use of the different types of European Partnerships as they are defined in the Horizon Europe Common Understanding (Article 8 and Annex III). Specifically this regards the **selection criteria** which have to be demonstrated as a minimum in order to justify the necessity of a European Partnership instead of regular Horizon Europe calls only and the implementation criteria in Article 8

1(a), (b) and (c) with certain elements distinguishing the use of the different partnership implementation modes (Table 1).

Table 1: Horizon Europe selection criteria for the European Partnerships

Common selection criteria and principles	Specifications
<b>More effective (Union added value) clear impacts for the EU and its citizens</b>	<ul style="list-style-type: none"> <li>• delivering on global challenges and research and innovation objectives</li> </ul>
	<ul style="list-style-type: none"> <li>• securing EU competitiveness</li> </ul>
	<ul style="list-style-type: none"> <li>• securing sustainability</li> </ul>
	<ul style="list-style-type: none"> <li>• contributing to the strengthening of the European Research and Innovation Area</li> </ul>
	<ul style="list-style-type: none"> <li>• where relevant, contributing to international commitments</li> </ul>
<b>Coherence and synergies</b>	<ul style="list-style-type: none"> <li>• within the EU research and innovation landscape</li> </ul>
	<ul style="list-style-type: none"> <li>• coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions</li> </ul>
<b>Transparency and openness</b>	<ul style="list-style-type: none"> <li>• identification of priorities and objectives in terms of expected results and impacts</li> </ul>
	<ul style="list-style-type: none"> <li>• involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness</li> </ul>
	<ul style="list-style-type: none"> <li>• clear modalities for promoting participation of SMEs and for disseminating and exploiting results, notably by SMEs, including through intermediary organisations</li> </ul>
<b>Additionality and directionality</b>	<ul style="list-style-type: none"> <li>• common strategic vision of the purpose of the European Partnership</li> </ul>
	<ul style="list-style-type: none"> <li>• approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level</li> </ul>
	<ul style="list-style-type: none"> <li>• demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators</li> </ul>
	<ul style="list-style-type: none"> <li>• exit-strategy and measures for phasing-out from the Programme</li> </ul>
<b>Long-term commitment of all the involved parties</b>	<ul style="list-style-type: none"> <li>• a minimum share of public and/or private investments</li> </ul>
	<ul style="list-style-type: none"> <li>• In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments</li> </ul>

The **Better Regulation guidelines** remained the primary point of reference for the 13 individual Impact Assessment studies. The different steps of the IA process were carried out in a consistent manner in the 13 individual IA studies, supported by horizontal analyses (i.e. common to all studies) such as bibliometrics/patent analysis, social network analysis, the partnership portfolio mapping and analysis, as well as the analysis of the Open Public Consultation data.

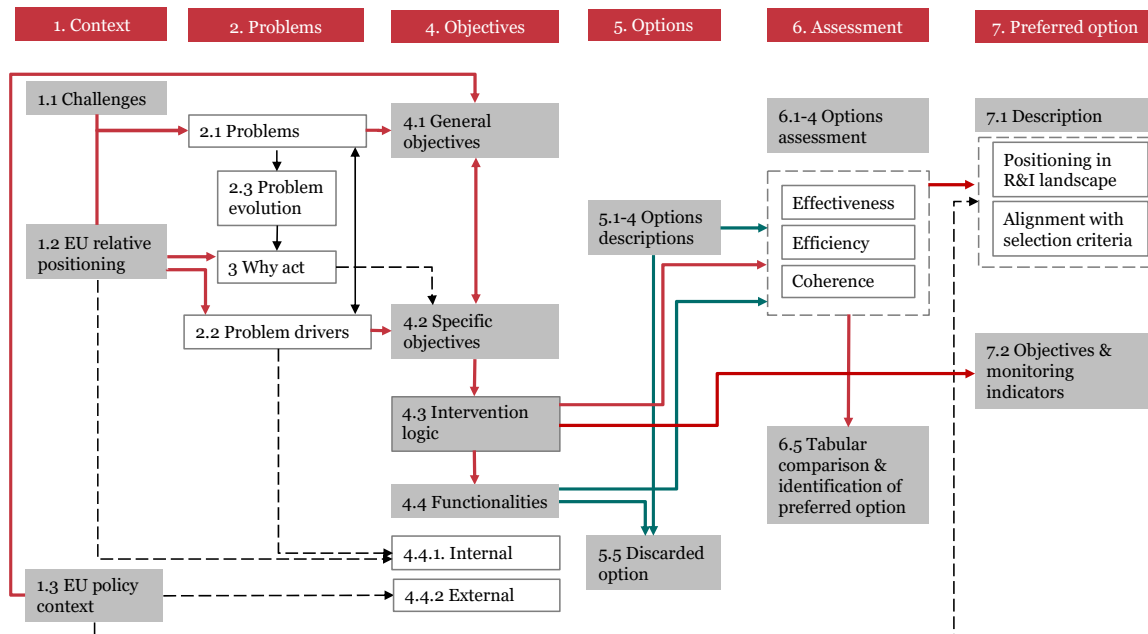


The **selection criteria** for the European Partnerships related to effectiveness and coherence fit reasonably well in the Better Regulation impact assessment structure. More problematic was the coverage of the other three criteria groupings, i.e. the criteria of Openness and Transparency, Additionality and Directionality, and the Ex-ante demonstration of commitment.

The solution was the introduction of a section on the '**Functionalities of the initiative**', in which set out our view on *how* the initiative should *concretely* respond to the selection criteria of 'coherence and synergies', 'openness and transparency' and 'additionality and directionality' in order to reach its objectives. We focused on those aspects that are not covered in other sections of this report, such as coherence and synergies, and covered those elements that from our analysis of the partnership options resulted being **key distinguishing features** of the partnership options, i.e. the composition of the partnership ('openness', including from a geographical perspective), the type of activities implemented ('flexibility'), and the level of directionality and integration of the stakeholders' R&I strategies needed ('directionality and additionality').

The logical process is summarised in Figure 4, below. The diagram shows how the 'functionality' sections constituted an important passage from the objectives and intervention logic sections to the options assessment. Building upon information collected in the previous sections (context, problem and objectives analysis) and in combination with the description of the available options, the description of the desirable 'functionalities' allowed for, on the one hand, the identification of the discarded option(s) and, on the other hand, the options assessment against coherence and against the selection criteria of 'Openness and Transparency' and 'Additionality and Directionality'. In the final chapter of the Impact Assessment report, the alignment of the preferred option with the criteria for the selection of European Partnerships was described, emphasising the outcomes of the 'necessity test'.

Figure 4: Flow of the analysis



Notes: the numbers indicate the related chapters or sections in the Impact Assessment reports

## 2.2.2 Methodological approach

### Overview of the methodologies employed

The understanding of the overall context of the candidate institutionalised European Partnerships relies on a desk research partly covering the main impacts and lessons learned

from their predecessor partnerships (if any). This was complemented with a set of quantitative analyses of the Horizon 2020-funded partnerships, or in case these did not exist, the H2020-funded projects in the field. 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 (see below).

Public consultations (open and targeted) supported the comparative assessment of the policy options. Each study interviewed up to 50 relevant stakeholders (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). They also used the results from the Open Public Consultation organised by the European Commission (Sep – Nov 2019) and the feedback on the Inception Impact Assessments of the 13 candidate institutionalised European Partnerships that the European Commission received in September 2019.

The timing of the Impact Assessment studies, in parallel to the negotiations between the European Commission and the existing Joint Undertakings on the specific implementation of the rules for the future European Partnership, as well as the ongoing discussions within the existing partnership on their future research directions, has set potential limits to the validity of the input and feedback collected from the stakeholders during the consultations.

A more detailed description of the methodology is provided in the Annexes C of each impact assessment report.

### **Method for identifying the preferred choice**

The four policy options were compared along a range of key parameters. The comparison along these parameters was carried out in an evidence-based manner. A range of quantitative and qualitative evidence was used, including ex-post evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; econometric modelling exercises producing quantitative evidence in the form of monetised impacts; reviews of academic literature on market and systemic failures and the impact of research and innovation, and of public funding for research and innovation; sectoral competitiveness studies; expert hearings; etc.

### **Options assessment related to effectiveness and coherence**

On the basis of the evidence collected and gathered, the Impact Assessment study teams assessed the effectiveness of the retained policy options along three dimensions corresponding to the different categories of likely impacts: scientific, economic and technologies, and societal (including environmental) impacts. The Impact Assessment study teams considered to which extent the retained policy options fulfilled the desirable 'functionalities' and were therefore likely to produce the targeted impacts. This analysis resulted in a scoring of the policy options along a three-point scale.<sup>9</sup> Instead of a compound score, the assessment of the effectiveness of the policy options concluded on as many scores as there are expected impacts.

Likewise, the impact assessment study teams attributed scores (using the same approach as above) reflecting the potential of each retained policy option for ensuring coherence with programmes and initiatives within (internal coherence) and beyond (external coherence) Horizon Europe.

---

<sup>9</sup> Scores vary from + to +++, where + refers to low potential for presenting a low potential for reaching the likely impacts, ++ to a good potential, and +++ to a high potential.

Scores were justified in a consistent and detailed manner in order to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation was provided of why certain scores were given to specific impacts.

When assessing the respective efficiency of the retained policy options, the Impact Assessment study teams considered the scores related to effectiveness and the identified costs to conduct a “value for money” (or cost-effectiveness) analysis. They accordingly attributed a comparative score to each of the options ranging from 1 (option with the highest costs) to 3 (options with the lowest costs).

## Options assessment related to efficiency

### **A standard cost model**

The ‘horizontal’ team has reviewed the cost categories and costs for each of the four policy options, at some length. Our first model used published data from past partnerships and Horizon 2020 calls working with the Commission’s standard accounting codes (Title 1, Title 2, Title 3). The analysis revealed wide-ranging differences in costs across partnerships and functions, which was thought to be too complex to be helpful to the current exercise. As a result, we created a static, common model using average costs as a means by which to indicate the order of magnitude of effort and thereby reveal the principal differences between each of the policy options.

The model was developed jointly with the European Commission services and is presented in the study Data report (D1.2), along with an explanation of the data sources used and the assumptions made.

It is important to note that the costs identified are theoretical and do not reflect the actual costs of any existing individual partnership. In light of this fact, and to avoid any risk of misunderstanding, we have transposed the financial estimates into a qualitative presentation using + / - system in order to compare the various cost elements for each policy option with the equivalent costs for the baseline policy options (see Table 2).

The principal differences in costs as compared with regular Horizon Europe calls relate to the European Partnerships’ one-off costs (e.g. developing the proposal and Strategic Research and Innovation Agenda), additional supervision by the European Commission and any additional programme management effort. The main difference between the three types of European Partnership are twofold: (i) the extent to which a partnership will need to run a limited or comprehensive programme management unit and (ii) the extent to which a new partnership may benefit from a pre-existing programme management unit that will greatly reduce or eliminate the set-up costs that would apply to a wholly new partnership.

Table 2: Intensity of additional costs compared with HEU Calls (for Partners, stakeholders, public and EC)

Cost items	Option 0	Option 1	Option 2	Option 3 -Art. 185	Option 3 -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0	++	++	++	++
Set-up of a dedicated implementation structure	0	0	0	Existing: + New: ++	Existing: ++ New: +++
Preparation of the SRIA / roadmap	0	++	++	++	++

Cost items	Option 0	Option 1	Option 2	Option 3 -Art. 185	Option 3 -Art. 187
Ex-ante Impact Assessment for partnership	0	0	0	+++	+++
Preparation of EC proposal and negotiation	0	0	0	+++	+++
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0	+	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	0	0	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

### ***Rationale for the comparative scoring on 'overall costs' and 'cost-efficiency' in the scorecard***

In the scorecard analysis, the scores related to the set-up and implementation costs will allow the study teams to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness).

Table 3 shows how we translated the cost analysis into a series of numerical scores.

Table 3: Cost-efficiency matrix

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 2: Co-funded	Option 3: Institutionalised
Overall cost	3	2	1	1
Cost-efficiency	3	3	2	2

For the 'overall cost' dimension, we assigned a score 1 to the option with the highest additional costs and a score 3 to the option with the lowest additional costs compared to the baseline. This was based on the following considerations:

- **Horizon Europe regular calls** will have the lowest overall cost among the policy options and have therefore been **scored 3** on this criterion, using a scale of 1-3 where 3 is best (lowest additional costs). This adjudged score is based on two facts: firstly, that Horizon Europe will not entail any additional one-off costs to set up or discontinue

the programme, where each of the other policy options will require at least some additional set-up costs; and secondly, that Horizon Europe will not require any additional running costs, where each of the other policy options will involve additional efforts by the Commission and partners in the carrying out of necessary additional tasks (e.g. preparing annual work programmes).

- A **co-programmed partnership** (Option 1 - CPP) will entail slightly higher overall costs as compared with the baseline policy option and has therefore been given a **score of 2**, using a scale of 1-3 where 3 is best (lowest additional costs). There will be some additional set-up costs linked for example with the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.
- The **Co-Funded Partnership** (Option 2 – CFP) has been **scored 1** on overall cost, using a scale of 1-3 where 3 is best (lowest additional costs). This reflects the additional set-up costs of this policy option and the substantial additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.
- The **Institutionalised Partnership** (Option 3 - IP) has been **scored 1** on overall cost, using a scale of 1-3 where 3 is best (lowest additional costs). This reflects the substantial additional set-up costs of this policy option – and in particular the high costs associated with preparing the Commission proposal and negotiating that through to a legal document – and the substantial additional running costs for the Commission associated with the supervision of this dedicated implementation model.

In relation to **cost-efficiency**, we considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when we take into account financial leverage (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 and CPP policy options – and the least cost-efficient – the CFP and IP. We have therefore assigned a score of 3 to the baseline Option 0 and CPP options for cost-efficiency (no or minor additional costs, as compared with the baseline) and a score of 2 for the CFP and IP policy options (medium additional costs, as compared with the baseline).

### ***Scorecard analysis for the final options assessment***

The scorecard analysis built a hierarchy of the options by individual criterion and overall. The scorecard exercise supported the systematic appraisal of alternative policy options across multiple types of monetary, non-monetary and qualitative dimensions. It also allowed for easy visualisation of the pros and cons of alternative options.

Each option was attributed a value of 1 to 3, scoring the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

Scores were justified in a consistent and detailed manner in order to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation was provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

The scorecard analysis allowed for the identification of a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. The final selection is a policy decision.

### 2.3 Cross-partnership challenges in Horizon Europe clusters

In this section we set the envisaged and candidate partnerships in the context of the Horizon Europe clusters and the related higher-level EU policy objectives and priorities. We focus on the evolution of the policy context including the new European Green Deal/climate neutrality objectives, the Horizon Europe Framework relevant to this cluster, and the link to the relevant Sustainable Development Goals. Seeing the focus on the Pillar II clusters, this section excludes the candidate *Institutionalised Partnership for Innovative SMEs*.

#### 2.3.1 Cluster 1 – Health

Research and innovation (R&I) actions under this cluster will aim at addressing the major socio-economic and societal burden that diseases and disabilities pose on citizens and health systems of the EU and worldwide.

The R&I activities funded under the Pillar II Cluster Health aim at contributing to the achievement of the Sustainable Development Goal 'Ensuring healthy lives and promoting well-being for all at all ages' resulting from investments in research and innovation focused on three overarching EU policy objectives: 'An economy that works for people', 'A Europe fit for the Digital Age', and 'A European Green Deal' (see Figure 5, below). The Horizon Europe proposal for a regulation defined the areas for possible institutionalised European partnerships on the basis of Article 185 TFEU or Article 187 TFEU as "*Partnership Area 1: Faster development and safer use of health innovations for European patients, and global health*".

At the core in this cluster are the R&I orientations that aim at ensuring that citizens *stay healthier throughout their lives* due to improved health promotion and disease prevention and the adoption of healthier behaviours and lifestyles, the development of *effective health services* to tackle diseases and reduce their burden, and an improved access to *innovative, sustainable and high-quality health care*. These objectives require an unlocking of the full potential of *new tools, technologies and digital solutions* and ensuring a *sustainable and globally competitive health-related industry* in the EU, allowing for the delivery of, e.g. personalised healthcare services. Last but not least, the citizens' health and well-being need to be *protected from environmental degradation and pollution*, addressing a.o. climate-related challenges to human health and health systems.

Figure 5, below, shows that the portfolio of envisaged European Partnerships in this cluster<sup>10</sup> aims to contribute to all of the R&I orientations in this cluster. However, there is a pronounced focus on the 'tackling diseases and reducing the disease burden' objective, addressed by five out of the ten partnerships (amongst which there is one candidate Institutionalised Partnership). The objectives focused on an improved exploitation of digital solutions and competitiveness of the EU health-related industry are addressed by two partnerships amongst which one is a candidate Institutionalised Partnership.

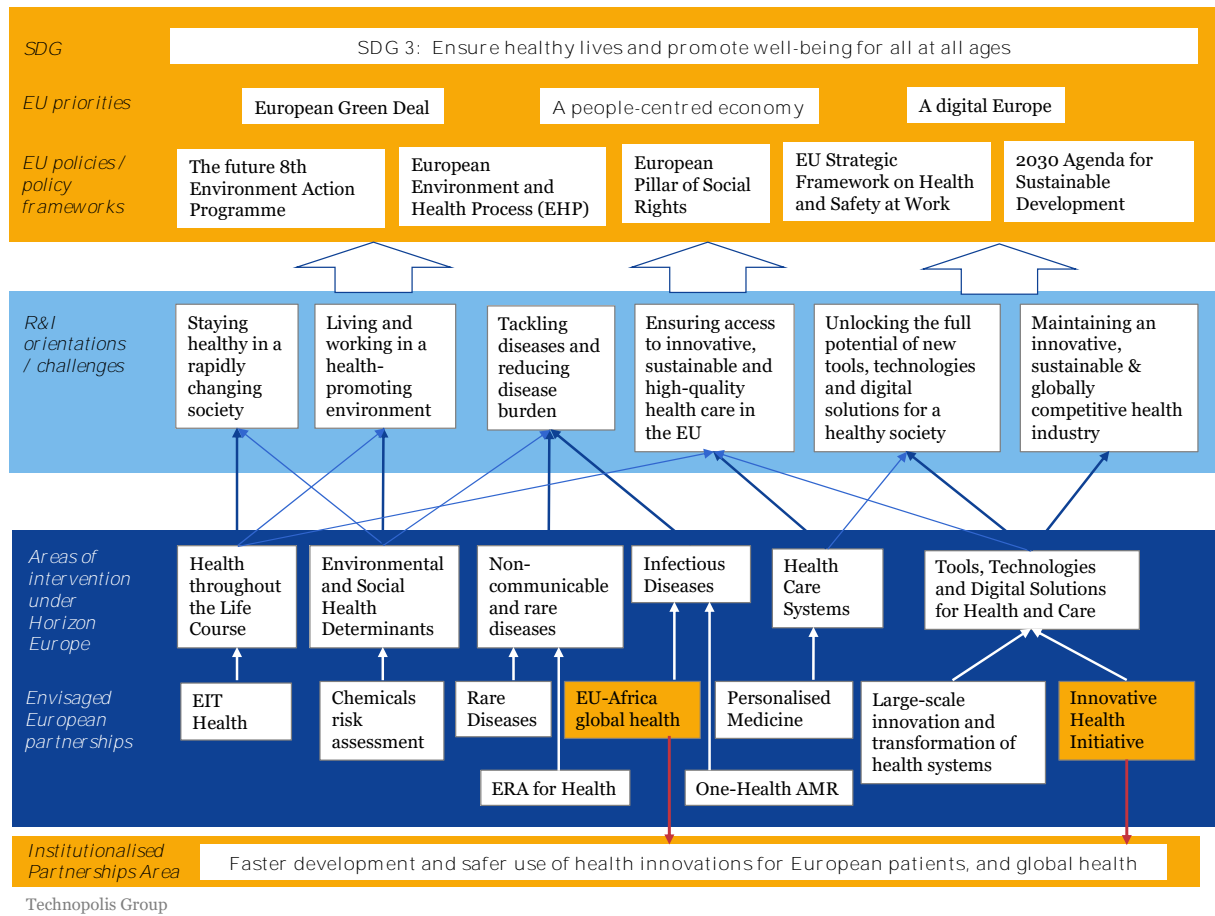
In this context, it should be noted that the portfolio of European Partnerships in this cluster predominantly encompasses Co-funded Partnerships, focused on joining the R&I programmes and investments at the national level. There is therefore overall a limited level of involvement of the private sector in the development of the SRIAs (i.e. as partners of the envisaged partnerships), be it from the supply or user side in the value chains. The only exceptions are the Innovative Health Initiative and the EIT KIC Health. European Partnerships also provide limited support for the assessment of environmental and social health determinants, uniquely addressed from a chemical risks perspective.

---

<sup>10</sup> As proposed in the Horizon Europe 'Orientations towards the first Strategic Plans', dd. December 2019

The description of the interconnections between the partnerships in this cluster and the ones funded in the context of other clusters, provided in the reports of the individual impact assessment studies, sheds more light on this topic.

Figure 5: R&I priorities and higher-level objectives of the Horizon Europe Cluster 1 – Health



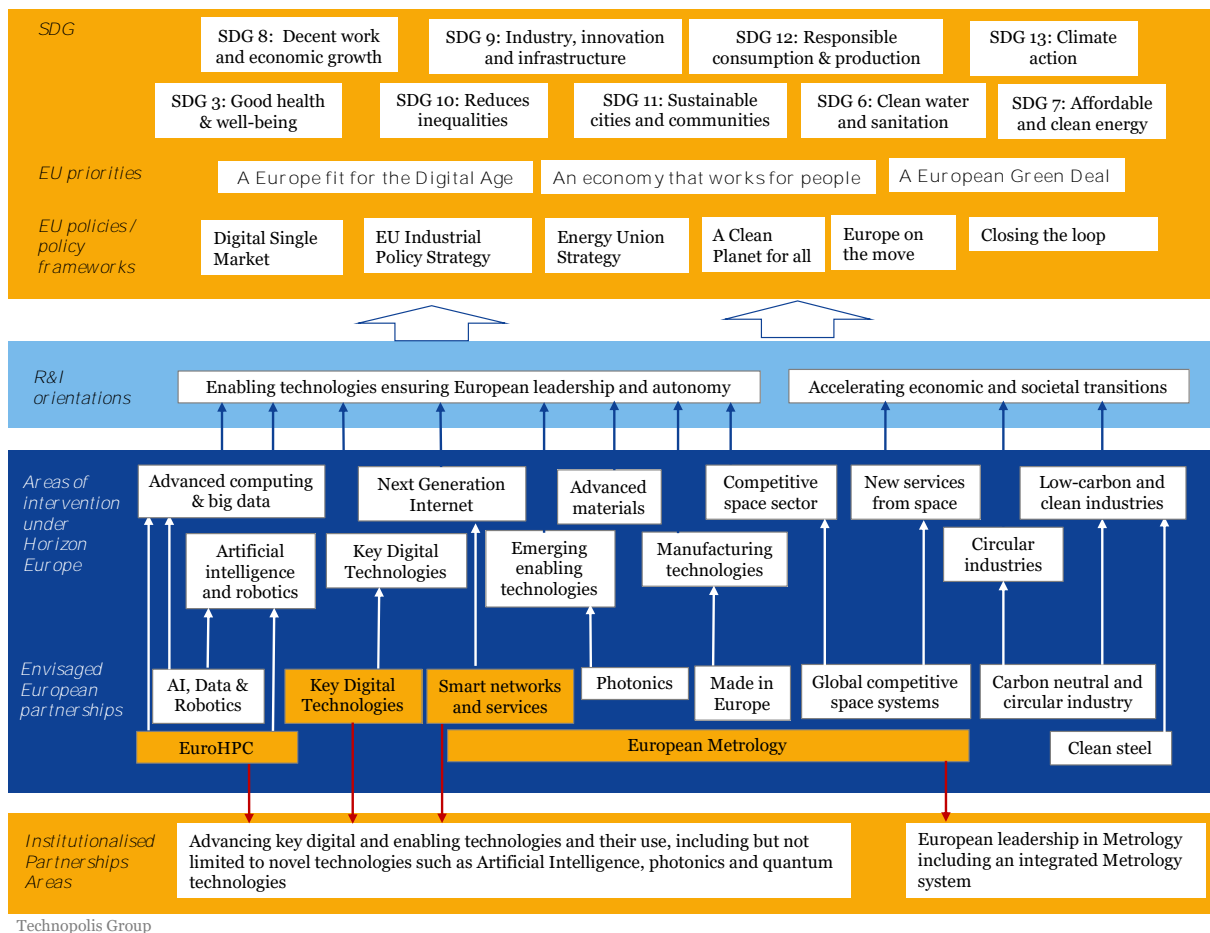
### 2.3.1 Cluster 4 – Digital, Industry and Space

In this cluster the focus is on the digitisation of European industry and on advancing key enabling, digital and space technologies which will underpin the transformation of our economy and society at large. The overarching vision for R&I investments in this cluster is “a European industry with global leadership in key areas, fully respecting planetary boundaries, and resonant with societal needs – in line with the renewed EU Industrial Policy Strategy.” The expected effects on the European economy and society imply that the R&I activities under this cluster will contribute to various Sustainable Development Goals and respond to three key EU policy priorities: ‘A European Green deal’, ‘A Europe fit for the digital age’, and ‘An economy that works for people’ (Figure 6).

The cluster pursues three objectives: 1) ensuring the competitive edge and sovereignty of EU industry; 2) fostering climate-neutral, circular and clean industry respecting planetary boundaries; and 3) fostering social inclusiveness in the form of high-quality jobs and societal engagement in the use of technologies. A human-centred approach will be taken, i.e. technology development going hand in hand with European social and ethical values.

The key R&I priorities are grouped in two general categories: (I) Enabling technologies ensuring European leadership and autonomy; and (II) Accelerating economic and societal transitions (these will be complemented by priorities of other clusters). European Partnerships envisaged to support the R&I in the specific intervention areas are mainly co-programmed partnerships. Exceptions are the three candidate Institutionalised Partnerships in the digital field and the candidate Institutionalised Partnership in metrology, reflecting their related Partnership Areas.

Figure 6: R&amp;I priorities and higher-level objectives of the Horizon Europe Cluster 4 – Digital, Industry and Space



Multiple convergences exist between the technologies that are covered in the first strand of the priorities in this cluster, i.e. “enabling technologies ensuring European leadership and autonomy”. In their function of ‘enabling’ technologies, they will also make critical contributions to the attainment of the desired ‘transitions’ in the ‘vertical’ industry sectors targeted in the second strand of priorities in this cluster as well as in the other clusters. A major contribution from this perspective can be expected from the four candidate Institutionalised Partnerships as well as from the ‘Made in Europe’ partnership, focused on manufacturing technologies.

### 2.3.2 Cluster 5 – Climate, Energy and Mobility

The main objectives of this cluster are to fight climate change, improve the competitiveness of the energy and transport industry as well as the quality of the services that these sectors bring to society. This is supportive of several Sustainable Development Goals including affordable and clean energy (SDG7); industry, innovation & infrastructure (SDG9); sustainable cities & communities (SDG11); sustainable consumption & production (SDG12); and climate action (SDG13). The cluster is most closely aligned to the EU priority for ‘A European Green Deal’ but also has synergy with two of the other five priorities; ‘An economy that works for people’ and ‘A Europe fit for the Digital Age’. This extends across various policies including a Clean Planet for all, the Energy Union strategy, Single European Railway Area, European ATM Master Plan, Single European Sky, and Europe on the Move (Figure 7).

The cluster is directly relevant to several of the areas for possible institutionalised European partnerships on the basis of Article 185 TFEU or Article 187 TFEU, namely:

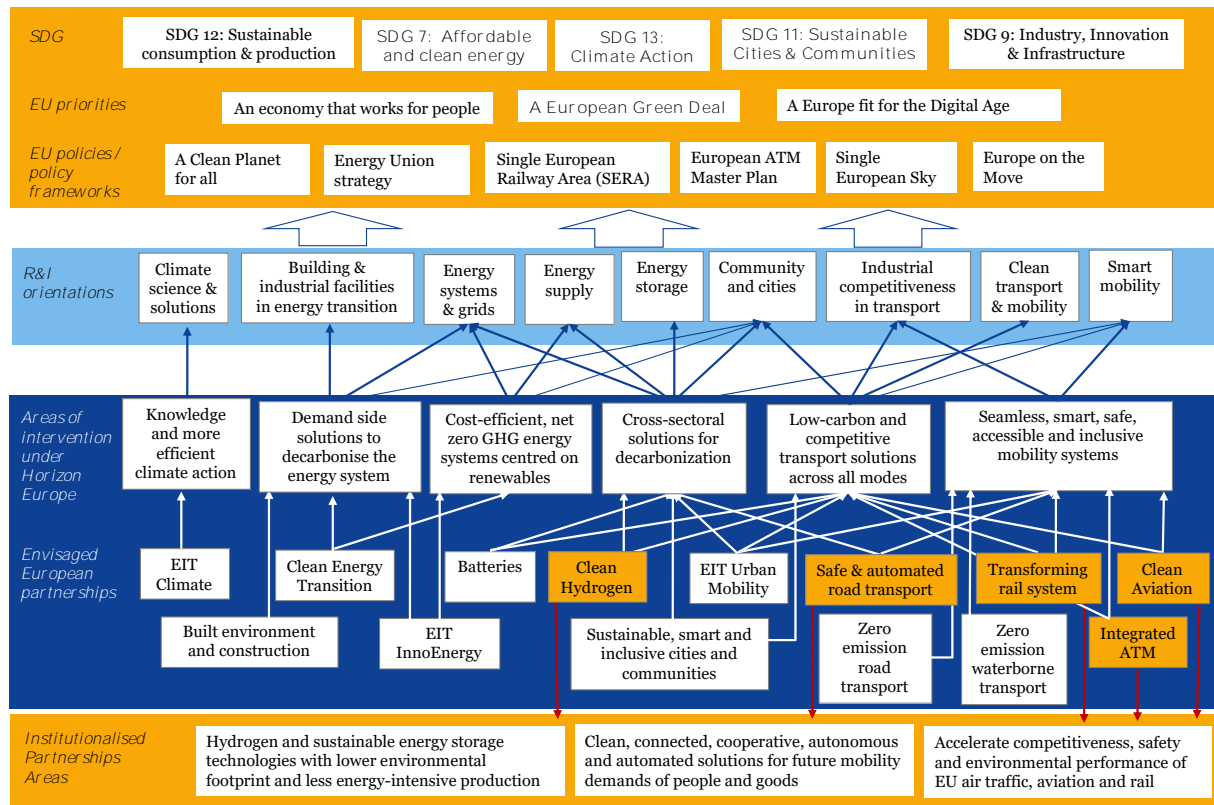
- Partnership Area 4: Accelerate competitiveness, safety and environmental performance of EU air traffic, aviation and rail



- Partnership Area 6: Hydrogen and sustainable energy storage technologies with lower environmental footprint and less energy-intensive production
- Partnership Area 7: Clean, connected, cooperative, autonomous and automated solutions for future mobility demands of people and goods

Cluster 5 is structured under six areas of intervention under Horizon Europe and nine R&I orientations. Figure 7, below, shows the portfolio of envisaged European Partnerships that are relevant to this cluster and their link to the areas of intervention.

Figure 7: R&I priorities and higher-level objectives of the Horizon Europe cluster Climate, Energy and Mobility



Technopolis Group

There are 14 candidate Partnerships that align with this cluster of which eight are possible Institutionalised Partnerships, including five Article 187 initiatives and three EIT-KICs. There are no candidate Article 185 Partnerships in this cluster. The other partnerships are envisaged as either Co-programmed and/or Co-funded Partnerships.

The diagram above shows the strong orientation of the possible Institutional Partnerships towards the mobility area and more limited direct synergies between the envisaged Partnerships and the 'climate science & solutions' priority. Of course, the climate change challenge underpins the whole of this cluster, except where the focus is on industrial competitiveness, but this will also be at least partially dependent on innovation related to clean energy and mobility products and services.

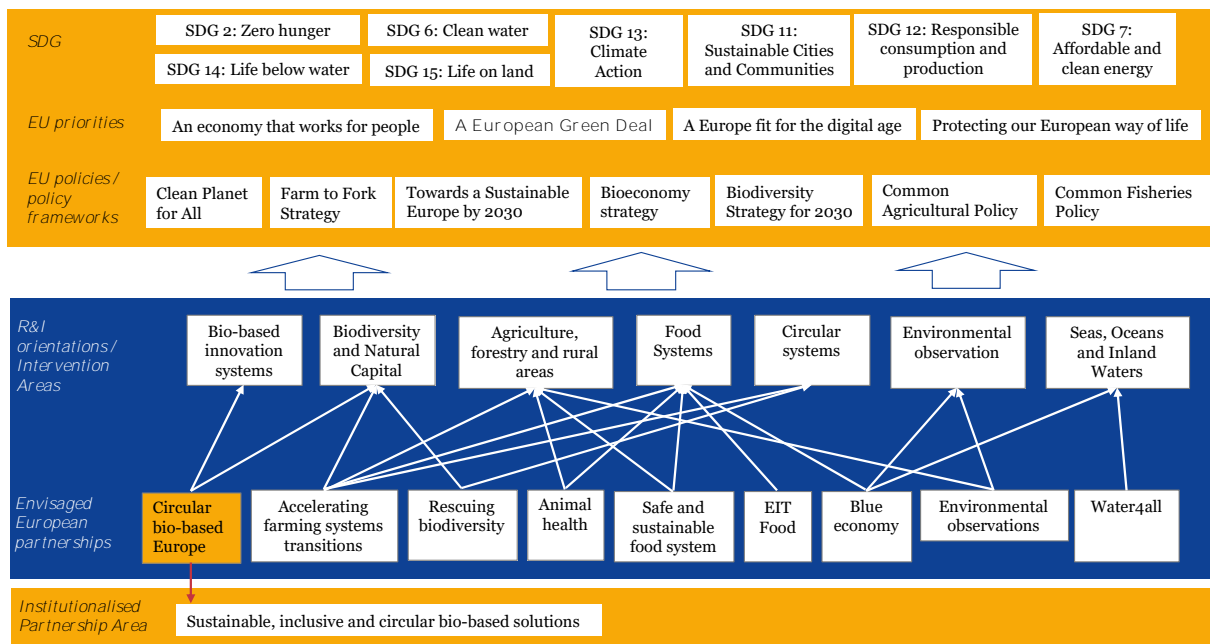
### 2.3.3 Cluster 6 – Food, Bioeconomy, Natural Resources, Agriculture and Environment

The key objective of Cluster 6, 'Food, Bioeconomy, Natural Resources, Agriculture and Environment' is to advance knowledge, expand capacities and deliver innovative solutions to accelerate the transition towards the sustainable management of natural resources (such as biodiversity, water and soils). The cluster has a large realm and aims to address a wide range of challenges relating to climate change, biodiversity and ecosystems, natural resources, and the production and consumption patterns that may affect them. It encompasses a single area for possible institutionalised European Partnerships aimed at the development of "sustainable, inclusive and circular, bio-based solutions".

The R&I activities funded under the Pillar II Cluster 6 contribute first and foremost to the ‘European Green Deal’. More precisely, they will be instrumental to the announced climate change actions, the Biodiversity Strategy for 2030, the “Farm to Fork Strategy”, the zero-pollution ambition, the New Circular Economy Action Plan, and the comprehensive strategy on Africa and trade agreements. However, through cooperation with the other clusters, Cluster 6 may make some contribution to the other EU overarching policy priorities. The R&I activities funded under this cluster therefore aim to contribute to the achievement of several United Nations SDGs including: SDG 2: Zero hunger; SDG 6: Clean water and sanitation; SDG 7: Affordable and clean energy; SDG 11: Sustainable cities and communities; SDG 12: Responsible consumption and production; SDG 13: Climate action; SDG 14: Life below water; and, SDG 15: Life on land.

Cluster 6 is structured around six targeted impacts and seven research and innovation orientations, as shown in Figure 8, below. The R&I activities funded under this cluster aim to (1) develop solutions for mitigation of, and adaptation to, *climate change*; (2) halt the *biodiversity* loss and foster the restoration of *ecosystems*; (3) encourage the sustainable (and circular) management and use of *natural resources*; (4) stimulate inclusive, safe and health *food and bio-based systems*; (5) a better understanding of the determinants of *behavioural, socio-economic and demographic changes* to accelerate system transformation; and, (6) improve solutions for *environmental observations and monitoring systems*.

Figure 8: R&I priorities and higher-level objectives of the Horizon Europe Cluster 6 – Food, Bioeconomy, Natural Resources, Agriculture and Environment



Technopolis Group

The European Commission envisages nine partnerships under Cluster 6, two of which would be institutionalised (Circular bio-based Europe and EIT Food), four would be either co-programmed or co-funded (Animal Health; A climate-neutral, sustainable and productive Blue Economy; Safe and Sustainable Food Systems for People, Planet and Climate; Water4All), and three would be co-funded (Accelerating Farming System Transition; Agriculture for Data; Rescuing Biodiversity to safeguard life on Earth).

There is seemingly a good balance between the three types of partnerships. However, industry may have some interest in being involved in the design of the Strategic Research and Innovation Agendas regarding living labs and other research infrastructure (‘Towards more sustainable Farming’ envisaged partnership) to develop solutions for accelerating the transition of farming systems, and technologies to collect agriculture data.

The proposed portfolio of European Partnerships covers the full range of R&I orientations under Cluster 6.

All but one of the proposed partnerships contribute to orienting R&I activities towards the development of food systems that will ensure both sustainable and healthy diets and food and nutrition security for all. The food system has an impact on several challenges. It directly relates to nutrition and diets, access to food, food security, and has an influence on the use of natural resources, water and soil pollution, climate change. Food waste is a key component of circular systems and biomass has strong potential to offer bio-based energy solutions. Finally, the transformation of food systems should take into consideration demographic changes and the accelerating urbanisation (which reduces lands available for food production but offers opportunities for new types of agriculture such as urban farming).

Two R&I orientations are covered by less than half of the proposed partnerships: Environmental Observations (even though achievement in this area could make significant contribution to the other areas) and Bio-based innovation systems (which is nevertheless at the core of the candidate institutionalised partnership for a circular bio-based Europe).



# **Part I. Impact Assessment Studies for the Candidate Institutionalised European Partnerships**

## ***3. Candidate Institutionalised European Partnership on Innovative Health***

### **Authors**

Peter Varnai, Anoushka Davé, Kelly Simpson



## **Abstract**

*This document is the final report of the Impact Assessment Study for the Candidate Institutionalised European Partnership on Innovative Health under Horizon Europe. The study was conducted by Technopolis Group from July to December 2019. The methodological framework reflects the Better Regulation Guidelines and operationalises the selection criteria for European Partnerships set out in the Horizon Europe Regulation.*

*This initiative focuses on supporting innovation for health and care within the EU. It will address the EU-wide challenges raised by inefficient translation of scientific knowledge for use in health and care, insufficient innovative products reaching health and care services and threats to the competitiveness of the health industry. Its main objectives are to create an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations; foster the development of safe, effective, patient-centred and cost-effective innovations that respond to strategic unmet public health needs currently not served by industry; and drive cross-sectoral health innovation for a globally competitive European health industry.*

*The study concluded that an Institutionalised Partnership based on Article 187 of the Treaty on the Functioning of the EU (TFEU) is the preferred option for the implementation of this initiative.*

## Executive Summary

This document is the final report of the Impact Assessment Study for the Candidate Institutionalised European Partnership on Innovative Health under Horizon Europe. The study was conducted by Technopolis Group from July to December 2019. The methodological framework for this study, described in Part 1 of this report, reflects the Better Regulation Guidelines and operationalises the selection criteria for European Partnerships set out in the Horizon Europe Regulation. Part 1 also sets out the political and legal context that is common to all candidate partnerships. Part 2 contains the findings of this specific study.

The Candidate Institutionalised European Partnership on Innovative Health is planned to implement the European Commission's vision for the period beyond 2020 under the Horizon Europe Pillar II, specifically the Cluster on Health. It is one of the envisaged European Partnerships in the Partnership Area "Faster development and safer use of health innovations for European patients, and global health". It will build upon and expand the activities of the Horizon 2020 Innovative Medicines Initiative Joint Undertaking.

The Innovative Health Initiative will address the EU-wide challenges raised by inefficient translation of scientific knowledge for use in health and care, insufficient innovative products reaching health and care services and threats to the competitiveness of the European health industry.

The initiative's main objectives will be to create an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations; foster the development of safe, effective, patient-centred and cost-effective innovations that respond to strategic unmet public health needs; and drive cross-sectoral health innovation for a globally competitive European health industry. The initiative will require several functionalities to meet its objectives. Firstly, it will require the involvement and alignment (e.g. pooling of investments, strategic R&I agenda and roadmap) of all actors along the health value chain including from academia, different industry sectors, third sector organisations, EU and national regulatory authorities, health technology assessment bodies, healthcare organisations and payers as well as healthcare professionals, patients and citizens. Secondly, collaborative R&I actions should be the core activity supported, but there are potential benefits from also including validation and demonstration activities as well as coordination and support actions. Finally, coordination and complementarity with EU, local, regional, national and (where relevant) international initiatives and networks will also be needed.

The relevant policy options for this assessment were Horizon Europe calls (Option 0), Co-Programmed Partnerships (Option 1) and Institutionalised Partnerships based on Article 187 of the Treaty on the Functioning of the EU (Option 3). Our conclusion is that an Institutionalised Partnership based on Article 187 is the preferred option. We conducted a comparative assessment of the three options across the criteria of effectiveness (to reach the targeted scientific, economic and societal impacts), coherence (internal and external) and efficiency. The analysis showed that benefits are clearly maximised under Option 3, the Institutionalised Partnership based on Article 187, particularly for delivering the effectiveness and coherence measures.

## Résumé exécutif

Ce document est le rapport final de l'étude de support à l'analyse d'impact de la proposition de partenariat européen institutionnalisé pour la santé innovante dans le cadre d'Horizon Europe. Cette étude a été menée par Technopolis Group entre juillet et décembre 2019. Le cadre méthodologique de cette étude, décrit dans la première partie de ce rapport, reflète des lignes directrices pour une meilleure réglementation et opérationnalise les critères de sélection des partenariats européens énoncés dans le règlement d'Horizon Europe. La première partie présente également le contexte politique et juridique commun à tous partenariats proposés. La seconde partie contient les résultats spécifiques à cette étude.

Il est prévu que le partenariat européen institutionnalisé proposé pour la santé innovante mette en œuvre la vision de la Commission européenne pour la période s'étendant au-delà de 2020 dans le cadre du deuxième pilier d'Horizon Europe, et plus précisément du cluster « Santé ». C'est l'un des partenariats européens envisagés dans le domaine de partenariat « Développement accéléré et utilisation plus sûre des innovations en matière de santé pour les patients européens, et santé mondiale ». Il développera les activités de l'entreprise commune Initiative en matière de médicaments innovants (IMI) d'Horizon 2020 tout en en tirant profit.

Cette initiative de santé innovante vise à régler les difficultés présentes dans toute l'UE dues à une traduction inefficace de la connaissance scientifique destinée à la santé et aux soins, à l'insuffisance de produits innovants parvenant aux services de santé et de soins et aux menaces portées à la compétitivité du secteur européen des soins de santé.

Les principaux objectifs de cette initiative seront de créer un écosystème de R&I en matière de santé dans toute l'UE qui permette de traduire les connaissances scientifiques en innovations ; d'encourager l'élaboration d'innovations sûres, efficaces, centrées sur le patient, rentables et qui répondent à des besoins stratégiques non satisfaits de santé publique ; et de favoriser l'innovation intersectorielle en matière de santé pour un secteur européen de la santé compétitif à l'échelle internationale. Cette initiative devra remplir plusieurs fonctionnalités pour atteindre ses objectifs. Tout d'abord, elle nécessitera l'implication et l'alignement (p. ex. mise en commun des investissements, programme de R&I stratégique et feuille de route) de tous les acteurs tout au long de la chaîne de valeur de la santé, notamment des universités, de différents secteurs de l'industrie, des organisations du secteur tertiaire, des autorités réglementaires nationales et européennes, des organismes d'évaluation des technologies de la santé, des organisations de soins de santé et des contributeurs ainsi que des professionnels des soins de santé, des patients et des citoyens. Deuxièmement, les actions collectives de R&I doivent constituer les activités principales à soutenir, mais il y a des avantages potentiels à inclure également des activités de validation et de démonstration ainsi que des actions de coordination et de soutien. Enfin, la coordination et la complémentarité avec les initiatives et les réseaux européens, locaux, régionaux, nationaux et (le cas échéant) internationaux seront également nécessaires.

Les options stratégiques pertinentes pour cette analyse étaient les appels à projets d'Horizon Europe (option 0), les partenariats co-programmés (option 1) et les partenariats institutionnalisés au titre de l'article 187 du Traité sur le fonctionnement de l'UE (option 3). Nous avons conclu qu'un partenariat institutionnalisé au titre de l'article 187 était la meilleure option. Nous avons mené une analyse comparative des trois options par rapport aux critères d'efficacité (pour atteindre les objectifs scientifiques, économiques et sociétaux ciblés), de cohérence (interne et externe) et d'efficacité. L'analyse a démontré que les avantages étaient clairement optimisés avec l'Option 3, le Partenariat institutionnalisé basé sur l'Article 187, en particulier en termes d'efficacité et de cohérence.



## Table of Contents

1	Introduction: Political and legal context .....	164
1.1	Emerging challenges in the field .....	165
1.2	EU relative positioning.....	167
1.3	EU policy context beyond 2021.....	172
2	Problem definition.....	174
2.1	What are the problems? .....	175
2.2	What are the problem drivers? .....	177
2.3	How will the problem(s) evolve? .....	181
3	Why should the EU act?.....	182
3.1	Subsidiarity: Necessity of EU action .....	182
3.2	Subsidiarity: Added value of EU action .....	183
4	Objectives: What is to be achieved?.....	184
4.1	General objectives .....	184
4.2	Specific objectives .....	184
4.3	Intervention logic and targeted impacts of the initiative.....	187
4.4	Functionalities of the initiative .....	191
5	What are the available policy options?.....	194
5.1	Option 0: Horizon Europe calls (baseline).....	194
5.2	Option 1: Co-programmed European Partnership .....	195
5.3	Option 2: Co-funded European Partnership .....	197
5.4	Option 3: Institutionalised European Partnership .....	198
5.5	Options discarded at an early stage .....	200
6	Comparative assessment of the policy options.....	200
6.1	Assessment of effectiveness.....	200
6.2	Assessment of coherence.....	209
6.3	Comparative assessment of efficiency .....	212
6.4	Comprehensive comparison of the options and identification of the preferred option .....	214
7	The preferred option .....	217
7.1	Description of the preferred option.....	217
7.2	Objectives and corresponding monitoring indicators .....	219
	Appendix A Bibliography .....	222
	Appendix B Synopsis report on the stakeholder consultation – Focus on the candidate European Partnership for Innovative Health .....	226
	Appendix C Methodological Annex.....	272
	Appendix D Additional information on the policy context .....	274

Appendix E Additional information related to the problem definition .....	280
Appendix F Additional information related to the policy options descriptions .....	283

## List of Figures

Figure 1: Global market share of MedTech industry (left hand) and the anticipated annual industry growth (right hand).....	168
Figure 2: Comparison of Europe and US - pharmaceutical R & D expenditure (left hand) and annual growth rate of expenditure (right hand).....	169
Figure 3: The envisaged partnerships in the Health cluster .....	174
Figure 4: Problem tree for the initiative on Innovative Health.....	175
Figure 5: Objectives tree for the initiative on Innovative Health.....	185
Figure 6: Impact pathway leading to scientific impacts.....	187
Figure 7: Impact pathway leading to economic/technological impacts .....	188
Figure 8: Impact pathway leading to societal impacts .....	189
Figure 9: Operational objectives of the initiative .....	220
Figure 10: Relevance of the Innovative Health Initiative in the national context.....	230
Figure 11: Possible participation and contribution to the Innovative Health Initiative, from the 17 countries that have expressed an interest to participate .....	231
Figure 12: Language of the consultation (N=1635) .....	241
Figure 13: Type of respondents (N=1635) .....	242
Figure 14: Involvement of respondents in Horizon 2020 or in the Framework Programme 7 (N=1303) .....	244
Figure 15: Role of respondents in a partnership (N=1035).....	246
Figure 16: Needs assessment (N=1363).....	250
Figure 17: Needs assessment, open answers to "Other" field (N=734) .....	251
Figure 18: Main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) (N=1551) .....	252
Figure 19: Relevant problems to address.....	253
Figure 20: Options to address challenges.....	254
Figure 21: Stakeholders to involve in setting joint long-term agenda's .....	255
Figure 22: Relevance of actors for pooling and leveraging resources .....	256
Figure 23: Assessment of the partnership composition .....	256
Figure 24: Relevance of activities to implement.....	257
Figure 25: Relevance of setting up a legal structure (funding body) .....	258
Figure 26: Assessment of the proposed scope and coverage of the candidate European Partnerships .....	259

Figure 27: Relevant impacts of future European Partnerships .....	260
Figure 28 Needs assessment (N=108).....	261
Figure 29: Needs assessment, open answers to “Other” field (N=42) .....	262
Figure 30: Main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) (N=87).....	262
Figure 31: Relevant problems to address in relation to health and health care innovation .....	263
Figure 32: Options to address the challenges .....	264
Figure 33: Open answers to explain the choice institutionalised partnership in the assessment of the Horizon Europe intervention (N=76).....	265
Figure 34: Stakeholders to involve in setting joint long-term agenda’s.....	265
Figure 35: Relevance of actors for pooling and leveraging resources .....	266
Figure 36: Relevant principles for the partnership composition .....	267
Figure 37: Relevance of activities to implement.....	267
Figure 38: Relevance of setting up a legal structure (funding body) .....	268
Figure 39: Scope and coverage proposed for the Innovative Health institutionalised Partnership.....	268
Figure 40: Scope and coverage proposed for the Innovative Health institutionalised Partnership – open question (N=41) .....	269
Figure 41: Comparable initiatives to link with the partnership (N=42) .....	270
Figure 42: Other comparable initiatives – open question (N=6) .....	270
Figure 43: Relevance of the candidate European Institutionalised Partnership to various impacts.....	271
Figure 44: Overview of participants and participations per organisation type in IMI2 (2014-2018).....	274
Figure 45: Overview of participants per EU member state in IMI2 JU (2014-2018) by organisation type .....	275
Figure 46: Preliminary mapping of the network structure of IMI2 JU by sector .....	276

## List of Tables

Table 1: Overview of the emerging challenges .....	166
Table 2: Proportion of non-SME private sector participants (labelled as industry) in regular Horizon 2020 collaborative health R&I projects (the figures exclude IMI2 JU).....	179
Table 3: Key characteristics of Option 0.....	194
Table 4: Key characteristics of Option 1.....	196
Table 5: Key characteristics of Option 2.....	197
Table 6: Key characteristics of Option 3: Institutionalised Partnership Art 185.....	198
Table 7: Key characteristics of Option 3: Institutionalised Partnership Art 187.....	199
Table 8: Likely impacts of the initiative .....	200
Table 9: Overview of the options' potential for reaching the scientific impacts .....	204
Table 10: Overview of the options' potential for reaching the likely economic/technological impacts .....	207
Table 11: Overview of the options' potential for reaching the likely societal impacts..	209
Table 12: Overview of the options' potential for ensuring and maximizing coherence	212
Table 13: Intensity of additional costs for European Partnerships compared with Horizon Europe calls (for Partners, stakeholders, public and EC) .....	212
Table 14: Matrix on 'overall costs' and 'cost-efficiency'.....	213
Table 15: Scorecard of the policy options .....	215
Table 16: Alignment with the selection criteria for European Partnerships.....	218
Table 17: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators .....	220
Table 18: Number of interviews per stakeholder category.....	233
Table 19: Country of origin of respondents (N=1635) .....	241
Table 20: Size of organisations that represent consultation respondents (N=1635)...	243
Table 21: Partnerships in which consultation respondents participated (N=1035) .....	244
Table 22: Future partnerships for which consultation respondents provide responses (N=1613).....	247
Table 23: Overview of campaigns across partnerships.....	248
Table 24: Type and composition of actors (including openness and roles) .....	283
Table 25: Type and range of activities (including flexibility and level of integration) ..	285
Table 26: Directionality .....	287
Table 27: Coherence (internal and external) .....	288

## Glossary

AI	Artificial Intelligence
AMR	Antimicrobial resistance
ATMP	Advanced Therapy Medicinal Product
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CEF	Connecting European Facility
CPP	Co-Programmed Partnership
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
EU	European Union
FP	Framework Programme
HTA	Health Technology Assessment
ICT	Information and communications technology
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
IP	Institutionalised Partnership
IT	Information Technology
IVD	In Vitro Diagnostics
JU	Joint Undertaking
MedTech	Medical Technology
MFF	Multi-annual Financial Framework
MS	Member States
PPP	Public-Private Partnerships
R&D	Research and Development
R&I	Research and Innovation
SDG	Sustainable Development Goal
SME	Small and Medium-sized Enterprise
SRIA	Strategic Research and Innovation Agenda
TFEU	Treaty on the Functioning of the European Union
TRL	Technology Readiness Level

## 1 Introduction: Political and legal context

This document presents the impact assessment study for the Candidate Institutionalised European Partnership on Innovative Health, which is one of the initiatives that will implement the Commission's vision for the period beyond 2020 under the Horizon Europe Pillar II, specifically the Cluster on Health. It is one of the envisaged European Partnerships in the Partnership Area "Faster development and safer use of health innovations for European patients, and global health".

Innovation in health is delivered as a combination of the development of new processes, tools, products and services. In this study, the term health technology is used in the broad sense and include pharmaceuticals (medicinal products), medical technologies (medical devices and in vitro diagnostics), digital and other technology-based health solutions for disease prevention, diagnosis or treatment used in healthcare. Pharmaceuticals and medical technologies are two large sectors of the health industry<sup>1</sup> that deliver innovations both to improve public health by delivering better health outcomes as well as to contribute to industrial competitiveness and economic development through job creation and growth. There are notable distinctions between these two sectors in terms of the regulatory approval and market access path for their products.

The pharmaceutical product life cycle is a closely regulated and centralised process<sup>2</sup>, from research and development (conducting clinical trials in the EU), through marketing, manufacturing and distribution authorisations, to post-authorisation pharmacovigilance measures. Medicinal products may be authorised centrally by the European Commission (following a scientific assessment by the European Medicines Agency) or by national competent authorities in Member States (MS). Following market launch, pricing and reimbursement decisions for pharmaceuticals are taken at national level, based on scientific evidence on benefits and harms provided by Health Technology Assessment (HTA) bodies, in accordance with the EU Transparency Directive.<sup>3</sup>

Medical devices are classified<sup>4</sup> into four categories, with in vitro diagnostics and implantable devices following a similar classification system. Rapidly changing technologies required the modernisation of existing Directives and led to two new EU Regulations,<sup>5</sup> which will enter into force in 2020 and 2022. The safety and performance of medical technologies are assured via a conformity assessment by designated Notified Bodies. Subsequently, the CE mark can be applied and the product can be placed on the EU market. Manufacturers must inform the Notified Bodies of changes to the medical device and once the product is commercialised, manufacturers must report any adverse events or performance issues to Competent Authorities. The market access process is more decentralised for medical technologies compared to the pharmaceutical products. HTA of medical technologies is historically less frequently performed and pricing and reimbursement decisions are usually taken via local procurement (e.g. at hospital level).

---

<sup>1</sup> The health industry is defined here as an aggregation of sectors that provide goods and services to prevent, diagnose, treat, cure and rehabilitate diseases

<sup>2</sup> For a comprehensive list of the pharmaceutical legislation, see: [https://ec.europa.eu/health/documents/eudralex/vol-1\\_en](https://ec.europa.eu/health/documents/eudralex/vol-1_en)

<sup>3</sup> Council Directive 89/105/EEC

<sup>4</sup> Council Directive 93/42/EEC

<sup>5</sup> Medical devices and in vitro diagnostics as defined by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively.

### 1.1 *Emerging challenges in the field*

Good health is of value as a major determinant of quality of life, well-being and social participation. It along with a vibrant and dynamic health industry contributes to shaping a sustainable economy. Nevertheless, health in the EU faces current and emerging challenges in domains ranging from social to economic that could be addressed to some extent at least through research and innovation (R&I).

Demographic and social changes (for example an increase in the proportion of the elderly in the population) plus the increasing burden of antimicrobial resistance (AMR), non-communicable and communicable diseases present a major challenge to health. These factors create additional socio-economic burden on EU healthcare systems, putting them under pressure.<sup>6</sup> There are still considerable knowledge and evidence gaps in terms of understanding the underlying mechanisms of diseases and the determinants of health including impacts of environmental factors such as pollution, chemicals, noise, radiation, urbanisation, climate change and work environments.<sup>7</sup>

Universal health coverage is an objective of the EU Charter of Fundamental Rights and one of the rights recognised by the European Pillar of Social Rights, and thus an important policy objective for the EU and its member states. The accessibility and affordability of health care to patients along with effectiveness and budgetary sustainability are important challenges for health systems in the EU.<sup>8</sup> In addition, citizens' expectations of and engagement with healthcare are increasing.<sup>9</sup> Healthcare providers and professionals are increasingly under pressure, and are often unable to deliver innovative solutions more widely because of organisational or financial constraints.

Health innovation can help to address these demands by enabling the creation and implementation of better and more cost-effective solutions to diagnose, treat and manage health conditions and deliver health and care. New advances in areas such as digital technologies, Big Data, artificial intelligence, genomics, personalised medicine and advanced therapies offer opportunities to create solutions tailored to the specific health and care needs of patients. However, novel therapies, technologies and approaches face specific barriers and hurdles in R&D, implementation and scale-up before they can be useful to health care systems and patients. For example, unlocking the potential of data and digitalisation for health-related use depends on the capacity to collect, distribute, combine and analyse vast amounts of data which requires long-term investments in data infrastructure, dealing with ethical and data security concerns, and frameworks for information sharing.<sup>10</sup> Similarly, appropriate regulatory pathways, as well as new HTA methods and tools, are required for assessing medical products that use nanotechnology and new materials as well as complex innovations e.g. drug-device combination products.<sup>11</sup>

---

<sup>6</sup> EC (2019) Towards a sustainable Europe by 2030. Reflection Paper.

<sup>7</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

<sup>8</sup> EC (2019) State of Health in the EU. Companion Report 2019. Available at: [https://ec.europa.eu/health/sites/health/files/state/docs/2019\\_companion\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf)

<sup>9</sup> Weale A. and Clarke S. (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.

<sup>10</sup> EC (2019) Strengthening strategic value chains for a future-ready EU industry

<sup>11</sup> EMA (2018) EMA Regulatory Science to 2025. Strategic reflection



Stakeholders providing **feedback to the inception impact assessment** identified some of the barriers in R&D and scale-up such as a lack of sufficient scientific knowledge and relevant R&D expertise, investment, absence of appropriate standards and frameworks, intellectual property as well as regulatory, legal and ethical issues.

It is also important that the EU maintains a globally competitive health industry to enable innovation and contribute to economic growth. The health industry is a key driver for growth through creation of high-value jobs and a positive trade balance through 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. However, the development of novel health technologies is associated with high financial risks (owing to the investment required and high risk of failure). In particular, SMEs may encounter difficulties to access the necessary investment sources, new markets and value-chains, or in setting-up partnerships and create alliances. Moreover, the 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. The health systems and thus available health budgets in individual EU member states also vary greatly which can make it hard to scale certain innovations.

Table 1: Overview of the emerging challenges

<p><b>Social</b></p>	<ul style="list-style-type: none"> <li>• Staying healthy in rapidly changing society (e.g. greater proportion of over-65s in the population)</li> <li>• Tackling the rising social burden of communicable and non-communicable diseases</li> <li>• Citizens increasingly playing a central role in healthcare; Rising public expectations</li> </ul>
<p><b>Technical and technological</b></p>	<ul style="list-style-type: none"> <li>• Unlocking the full potential of new tools, technologies and digital solutions for better health promotion, disease prevention and disease management</li> <li>• Creating solutions tailored to the specific health and care needs of patients</li> <li>• Making use of new advances in areas such as digital technologies, Big Data, artificial intelligence, genomics, personalised medicine and advanced therapies</li> </ul>
<p><b>Economic</b></p>	<ul style="list-style-type: none"> <li>• Tackling the rising economic burden of communicable and non-communicable diseases</li> <li>• Maintaining a sustainable and globally competitive health-related industry</li> <li>• Collaborating across different health-related industry sectors in the face of diverging business models and development timelines</li> <li>• Addressing the challenge of high prices of innovative products in relation to limited health budgets; Need for cost-efficient health solutions</li> </ul>
<p><b>Environmental</b></p>	<ul style="list-style-type: none"> <li>• Addressing knowledge and evidence gaps in terms of understanding the underlying mechanisms and impacts of environmental risk factors on health</li> </ul>



	<ul style="list-style-type: none"> <li>• Animal welfare (related to animals used for clinical experiments), management of toxic or biological waste, safe disposal of unused medicines and improving energy efficiency of R&amp;D and production</li> </ul>
<b>Political, policy and regulatory framework</b>	<ul style="list-style-type: none"> <li>• Political and policy push for better health of citizens through delivering high quality care and healthcare systems that are accessible, sustainable, resilient and efficient</li> <li>• Healthcare systems under increasing pressure</li> <li>• Need for integrated evaluation pathways and regulatory frameworks for complex health innovations</li> </ul>

Source: Technopolis Group



**Interviewees** discussed a range of emerging challenges including IT literacy, antimicrobial resistance, the ageing population and skills migration to other countries. Stakeholders providing **feedback to the inception impact assessment** additionally referred to the need for better preventative measures.

All stakeholder groups consulted during the **open public consultation**, strongly agreed that being responsive to societal needs was fully needed. Overall, 70% of respondents (74/106) agreed with this statement.

## 1.2 EU relative positioning

### 1.2.1 Competitive positioning of Europe in the field

The EU has significant monetary resources and is competitive across many industry sectors globally, allowing the EU and its MS to make substantial investments towards R&I. The EU accounts for one-fifth of the world's R&D spend and 23% of the global public R&D.<sup>12</sup> Moreover, with more than 1.8 million researchers, the EU is ahead of China and the United States, which have 1.6 million and 1.3 million researchers respectively.<sup>12</sup> Building on the strengths of its rich community of researchers and innovators, the EU is in a strong position to take the lead in developing and deploying breakthrough solutions towards improving health and wellbeing not only within the EU but also globally. However, lower investment in business R&D as well as education and skills development (e.g. ICT and economics skills) coupled with relatively weaker knowledge flows between stakeholders compared to other leading countries has meant that the EU has not been able to capitalise fully on its strengths.<sup>12</sup>

In terms of overall R&D investments, China is quickly overtaking both the EU and US. This may be one reason why the EU is lagging behind China (as well as the US) in some areas e.g. artificial intelligence (AI),<sup>13</sup> which has the potential to significantly increase productivity in healthcare. The global health data market is predicted to increase from around \$14 billion in 2019 to about \$70 billion in 2025,<sup>14</sup> and the EU needs to act

<sup>12</sup> EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report.

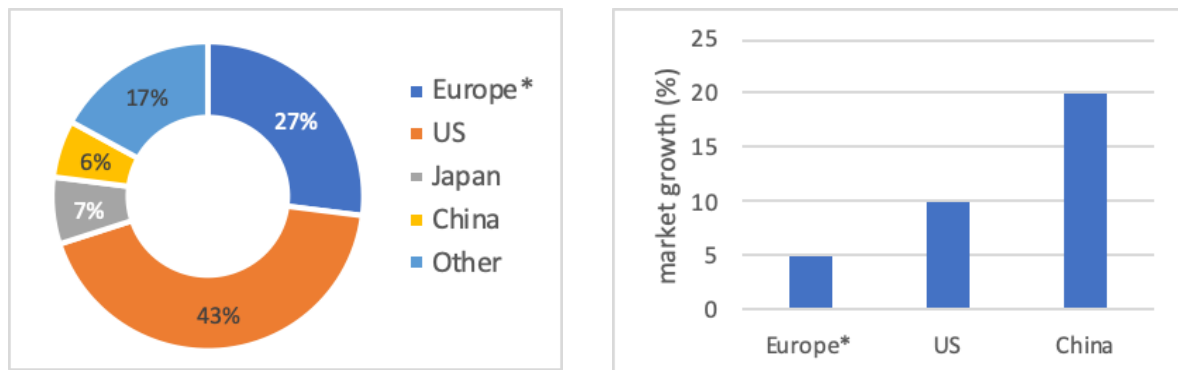
<sup>13</sup> European Commission (2018) USA-China-EU plans for AI: where do we stand?. Available at: [https://ec.europa.eu/growth/tools-databases/dem/monitor/sites/default/files/DTM\\_AI%20USA-China-EU%20plans%20for%20AI%20v5.pdf](https://ec.europa.eu/growth/tools-databases/dem/monitor/sites/default/files/DTM_AI%20USA-China-EU%20plans%20for%20AI%20v5.pdf).

<sup>14</sup> Statista (2019) Available at: <https://www.statista.com/statistics/909654/global-big-data-in-healthcare-market-size/>

strategically to ensure its current health data market (valued at €2 billion)<sup>15</sup> captures its fair share of this growth.

The medical technology (MedTech) and pharmaceutical sectors are two of the main health-related industry sectors in Europe. MedTech covers many disease areas and includes in vitro diagnostics (IVDs) 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.<sup>16</sup> By comparison, the US MedTech industry employs about 400,000.<sup>17</sup> 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 pharmaceuticals (6,300) and biotechnology (6,300) combined. The European MedTech market was estimated to be roughly €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 1). Within MedTech, the largest area is IVDs (revenues of €10,768 million in 2017 for EU-28 plus EFTA) with solutions used to confirm or exclude a disease, and provide valuable data on prognosis, risk stratification, screening and disease progression. In 2018, income of the imaging sector exceeded €300 million in Europe.<sup>18</sup> Europe has a positive MedTech (excluding IVD) trade balance of €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 €2 billion. However, Europe's leadership position in the area of MedTech may change in the future without sufficient investment into R&D. The predicted annual growth of the industry in Europe is 5% compared to at least 20% in China and 10% in the US (Figure 1).

Figure 1: Global market share of MedTech industry (left hand) and the anticipated annual industry growth (right hand)



Source: (a) MedTech Europe Facts Figures 2019. (b) Technopolis analysis of data reported in Hospodková, P, 2019.<sup>19</sup> \*Europe includes EU28 + Norway and Switzerland

The pharmaceutical industry directly employs approximately 750,000 people and has a positive trade balance of approximately €95 billion in Europe. Investment into pharmaceutical R&D in 2017 was an estimated €33 billion, much greater than the

<sup>15</sup> International Data Corporation (2018) European Data Market Monitoring Tool

<sup>16</sup> MedTech Europe (2019) The European Medical Technology Industry in figures 2019. Available at: <https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf>

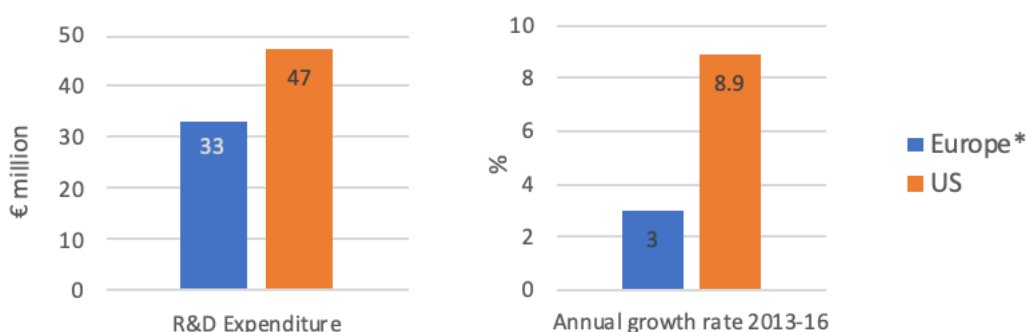
<sup>17</sup> Hospodková, P., et al. (2019) Global centers of medical device technology: United States, Europe and China. *Lékař a technika-Clinician and Technology*, 48(4), pp.136-144.

<sup>18</sup> COCIR (2019) COCIR market data and trends

<sup>19</sup> 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.

estimated €122 billion invested in Japan in 2015.<sup>20</sup> Nevertheless, the US remains a strong competitor with a greater R&D investment of approximately €47 billion (Figure 2). The gap between the European and US pharmaceutical investment is likely to increase with the annual growth of expenditure in the US (8.9%) almost three times that of Europe (3%) (Figure 2). Small molecules currently account for 83% of the revenue in the pharma sector.<sup>21</sup> However, this is expected to change with a steady growth of biologics (complex, large molecular weight molecules) and bioengineered vaccines such that 45 of the world's top 100 selling pharmaceuticals in 2020 are expected to be biologics.<sup>22</sup> In addition, many blockbuster drugs are losing their exclusivity, opening up room for biosimilar companies to enter into the global market. The changing pharmaceutical landscape is also evident in the development of Advanced Therapy Medicinal Products (ATMPs). ATMPs are based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). They originated in academic research settings, and have historically been developed in small companies but, more recently major pharmaceutical companies have also invested in gene- and cell-based therapy development in both the EU and in the United States.<sup>23</sup> Nevertheless a recent study identified 939 ATMP clinical trials, between 1999 and June 2015, with the majority (just under 75%) of trial sponsors being non-commercial.<sup>24</sup>

Figure 2: Comparison of Europe and US - pharmaceutical R & D expenditure (left hand) and annual growth rate of expenditure (right hand)



Source: Technopolis analysis of EFPIA Pharma Figures 2018. \*Europe includes EU28 + Norway and Switzerland

To allow innovative solutions to reach the market, R&I funding needs to be complemented with a strategic approach to investment, for instance, capital intensive and high-risk investments.<sup>25</sup> The EU has mechanisms for this such as the European Fund for Strategic Investments and the proposed European Innovation Council that help support top-class innovators, start-ups, small companies and researchers to successfully translate research into interventions that will improve the health and wellbeing of EU citizens, and enable them to be accessed more widely by potential users. It should also be noted that the EU

<sup>20</sup> EFPIA (2018) The Pharmaceutical Industry in Figures, Key Data 2018

<sup>21</sup> Results Healthcare (2017) Pharma and Biotech 2017. Review of outsourced manufacturing

<sup>22</sup> Evaluate Pharma (2014) World Pharma 2014, outlook to 2020. Available at: <http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EP240614.pdf>

<sup>23</sup> De Wilde S. et al (2016) Clinical development of gene- and cell-based therapies: overview of the European landscape. *Molecular Therapy — Methods & Clinical Development* 3

<sup>24</sup> Hanna E. et al (2016) Advanced therapy medicinal products: current and future perspectives. *J Market Access & Health Policy* 4: 31036

<sup>25</sup> EC (2019) Towards a sustainable Europe by 2030. Reflection Paper.

has updated the legal framework as regards medical devices and IVDs in order to reflect the scientific progress of the sector and ensure more transparent rules for patient safety.<sup>26</sup>

The EU has set some of the highest social and environmental standards and has put in place some of the most ambitious policies to protect human health. The EU-27 member states have the second highest score on average for the main health-related SDG 3 (Ensure healthy lives and promote well-being for all at all ages).<sup>25</sup> All this has been enabled by public and private investments in skills, innovation and emerging technologies, which has helped to drive sustainability within the economy as well as society.

### 1.2.2 Support for the field in the previous Framework Programme

Under Horizon 2020, overall budget for the “Health, demographic change and wellbeing” Societal Challenge was €7.5 billion which included joint undertakings (JUs).<sup>27</sup> The Innovative Medicine Initiative was one such JU that supported R&I in the health field. 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).<sup>28</sup>

The general objective of the IMI2 JU was to support the development and implementation of pre-competitive research and of innovation activities of strategic importance to the EU’s competitiveness and industrial leadership or to address specific societal challenges, in particular the challenge to improve European citizens’ health and well-being”.<sup>28</sup>

The specific objectives were to:<sup>28</sup>

- increase the success rate in clinical trials of priority medicines identified by the World Health Organization (WHO)
- where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases
- develop new therapies for diseases for which there is a high unmet need,<sup>29</sup> such as Alzheimer’s disease and limited market incentives, such as antimicrobial resistance
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators
- reduce the failure rate of vaccine candidates in phase III clinical trials through identifying new biomarkers for initial efficacy and safety checks
- improve the current drug development process by providing support for the development of tools, standards and approaches to assess the efficacy, safety and quality of regulated health products.

IMI2 JU participants spanned a wide range of organisations including private companies (including SMEs), higher education institutions, public-funded research centres, public bodies and others (e.g. non-profit organisations, patient associations, etc.). Private companies and higher education institutions accounted for almost three-fourths (73%) of

---

<sup>26</sup> EC (no date) New regulations. Available at: [https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)

<sup>27</sup> EC (2014) Horizon 2020 in brief.

<sup>28</sup> Council of the European Union (2014) Council regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking. Official Journal of the European Union 169, p. 54-76.

<sup>29</sup> It is not clear how IMI assesses high unmet need. Technopolis conducted a brief analysis of WHO data and available in section 2.2.1 Strategic unmet public health needs not served by industry

the participants. Higher education institutions also accounted for the most funding (around 55% of the total net requested EU contributions between 2014 and 2018).<sup>30</sup> Constituent and affiliated entities of EFPIA (European Federation of Pharmaceutical Industries and Associations) did not get any reimbursement from the JU.<sup>31</sup> The UK accounted for almost one-fifth of the participants, followed by Germany, France, the Netherlands and Belgium. Participation from EU13 was low (2%). Notably, the most frequently collaborating organisations were the private companies, Janssen Pharmaceutica NV, Novartis Pharma AG, Eli Lilly and Company and Pfizer.

Features of the IMI2 JU<sup>32,33</sup> experience included: (1) low participation of industry sectors other than pharma such as imaging, diagnostics, medical technology and ICT; (2) limited SME participation; (3) insufficient engagement with advisory bodies; and (4) insufficient coherence and alignment with regional and national policies and strategies. Accordingly, recommendations for future health innovation-related initiatives included adapting the collaborative and funding model to enable active engagement of industry sectors other than the pharmaceutical industry; and increasing the transparency of in-kind contributions, agenda setting and call topics generation to reflect wider stakeholder and European interests for the development of new healthcare interventions.<sup>34</sup> The involvement of civil society organisations in Horizon 2020 in general remains low,<sup>35</sup> which means that there is a gap to be filled in terms of bringing R&I closer to the public, which will be important if people-centred and personalised innovations are the aim.



Other recommendations based on lessons learned were also articulated in **Member State consultations**.<sup>36</sup> Herein, respondents identified that SME involvement could be improved through measures such as a legal framework for respecting IP ownership requirements for SMEs and simpler processes and administration. Further, comments in the consultations reinforced the need for the inclusion of wider stakeholders such as national authorities, healthcare providers, regulatory bodies and users in roles ranging from governance and priority setting to participation in projects. More transparency with regard to public and private sector contributions (including in-kind), data produced (open access to research results) and prices paid in public and private sectors was also requested. The importance of addressing ethical and data privacy issues, harmonisation of standards and approaches, better coordination with academia to support research translation, facilitating synergies with

<sup>30</sup> Technopolis analysis of IMI2 JU data

<sup>31</sup> Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014 establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in 'Horizon 2020 the Framework Programme for Research and Innovation (2014-2020)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking OJ L 174, 13.6.2014, p. 7-11 ; Financial Rules of the Innovative Medicines Initiative 2 Joint Undertaking

<sup>32</sup> 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

<sup>33</sup> Meulien P. (2017) The Innovative Medicines Initiative: taking open innovation to the next level. The European Files 49: 14-15.

<sup>34</sup> 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

<sup>35</sup> European Commission (2017) Commission staff working document. In-depth interim evaluation of the Horizon 2020. Brussels: Publications Office of the European Union

<sup>36</sup> European Commission (2019) European Partnerships under Horizon Europe: results of the structured consultation of Member States. Draft report for the meeting of the Shadow Configuration of the Strategic Programme Committee on 27 June 2019.

other EU and national programmes and implementing “green technology solutions” in drug manufacturing were also highlighted.

### 1.3 EU policy context beyond 2021

Health and well-being of Europeans is a central aim of the EU, which is reflected in its policies and programmes. According to Article 168 of the Treaty on the Functioning of the EU, “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”. The European Pillar of Social Rights has laid the foundation of a social model for all European citizens that is fairer, inclusive and more social and fit for the challenges of the 21<sup>st</sup> century. This includes providing all European citizens with access to good-quality affordable, preventive and curative health care, through dedicated legislation, policies and programmes. Guaranteeing access to high-quality healthcare is a key public health objective in EU countries and accounts for the largest share of social expenditure after pensions.<sup>37</sup> These aims also relate to the key Sustainable Development Goal ‘Ensuring healthy lives and promote well-being for all at all ages’.<sup>38</sup>

The future EU policy context will be further shaped by the President of the European Commission, Dr Ursula von der Leyen, and her team. Among the President’s six main ambitions for Europe,<sup>39</sup> the European green deal, a people-centred economy and a digital Europe are most likely to intersect with innovation in health. In fact, there are already plans for the Executive Vice-President for the European Green Deal<sup>40</sup> and the Commissioners for Internal Market,<sup>41</sup> Environment and Oceans,<sup>42</sup> and Health<sup>43</sup> to collaborate on a new action plan for circular economy. There could be opportunities to create synergy between research and innovation in health and missions and initiatives such as the cancer mission, the European Health Data Space and the European One Health Action Plan (under the responsibility of the Commissioner for Health<sup>43</sup>) as well as the new industrial policy and the strategy for SMEs (under the joint responsibility of Executive Vice-President for a Europe fit for the Digital Age<sup>44</sup> and An Economy that Works for People,<sup>45</sup> and the Commissioner for Internal Market)<sup>41</sup>.

<sup>37</sup> EC DG EMPL (no date) Health care. Available at: <https://ec.europa.eu/social/main.jsp?catId=754&langId=en>

<sup>38</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

<sup>39</sup> von der Leyen, U. (2019) Political Guidelines for the next European Commission 2019-2024: A Union that strives for more. My agenda for Europe. [https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf)

<sup>40</sup> European Commission (2019) *Frans Timmermans: Executive Vice-President for the European Green Deal*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-frans-timmermans-2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-frans-timmermans-2019_en.pdf)

<sup>41</sup> European Commission (2019) *Thierry Breton: Commissioner for Internal Market*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-thierry-breton\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-thierry-breton_en.pdf)

<sup>42</sup> European Commission (2019) *Virginijus Sinkevičius: Commissioner for Environment and Oceans*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-virginijus-sinkevicius\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-virginijus-sinkevicius_en.pdf)

<sup>43</sup> European Commission (2019) *Stella Kyriakides: Commissioner for Health*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf)

<sup>44</sup> European Commission (2019) *Margrethe Vestager: Executive Vice-President for a Europe fit for the Digital Age*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-margrethe-vestager\\_2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-margrethe-vestager_2019_en.pdf)

<sup>45</sup> European Commission (2019) *Valdis Dombrovskis: Executive Vice-President for An Economy that Works for People*. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-valdis-dombrovskis-2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-valdis-dombrovskis-2019_en.pdf)

Furthermore, the “Smart Health” strategic value chain,<sup>46</sup> which has been prioritised for strengthening based on its potential for driving EU’s industrial competitiveness and helping to realise EU’s climate ambitions will be important in the context of digital health innovation. Smart health will comprise solutions blending healthcare and digital technologies, digital media, mobile devices and biomedical engineering. To strengthen this value chain and help create a European industry that is “fit for the future”, recommendations involve creating a European Health Data Space, EU Investment Platform and European Smart Health Innovation Hub. Such infrastructure would be a great enabler for any EU initiative encouraging innovation for health. In addition, there will be complementarities with Digital Europe, which will boost investments in supercomputing, artificial intelligence, cybersecurity and advanced digital skills to ensure a wide use of digital technologies across the economy and society, including in health.

As set out in Part 1 Section 2.3.1 of this report, the R&I activities funded under the Pillar II Cluster 1 –Health aim at contributing to the Commission President’s priorities highlighted above. Multiple interconnections exist between the envisaged and candidate partnerships in the health cluster, both in terms of research topics covered and stakeholders involved. Their positioning along the innovation cycle in Figure 3, below, with the more research-oriented to the left and the more innovation-oriented ones to the right allows for a clearer view of the nature of possible interconnections.

The mapping in Figure 3, below, shows the central role of the candidate partnership in Innovative Health. On one hand, it is expected to “ease the pathway from research to implementation” for the Translational Health, Personalised Medicine, EU-Africa Global Health and Rare Diseases initiatives. On the other hand, clear synergies can be noted with the envisaged Large-Scale Innovation and Transformation of Health Systems in a Digital and Ageing Society Partnership and EIT Health, both of which are expected to address and involve similar industry actors along the health innovation value chains (the pharmaceutical industry, MedTech, and Health ICT providers). The figure also shows that other envisaged partnerships such as Translational Research and One Health AMR can be expected to produce research results that will feed into the R&I activities of many other initiatives. One Health AMR, the cross-cluster research initiative on AMR, for example, could support the EU-Africa Global Health and Innovative Health Initiatives in their efforts to accelerate the development and uptake of health care technologies and innovations addressing infectious diseases and the ageing society.

---

<sup>46</sup> EC (2019) Strengthening strategic value chains for a future-ready EU industry

Figure 3: The envisaged partnerships in the Health cluster

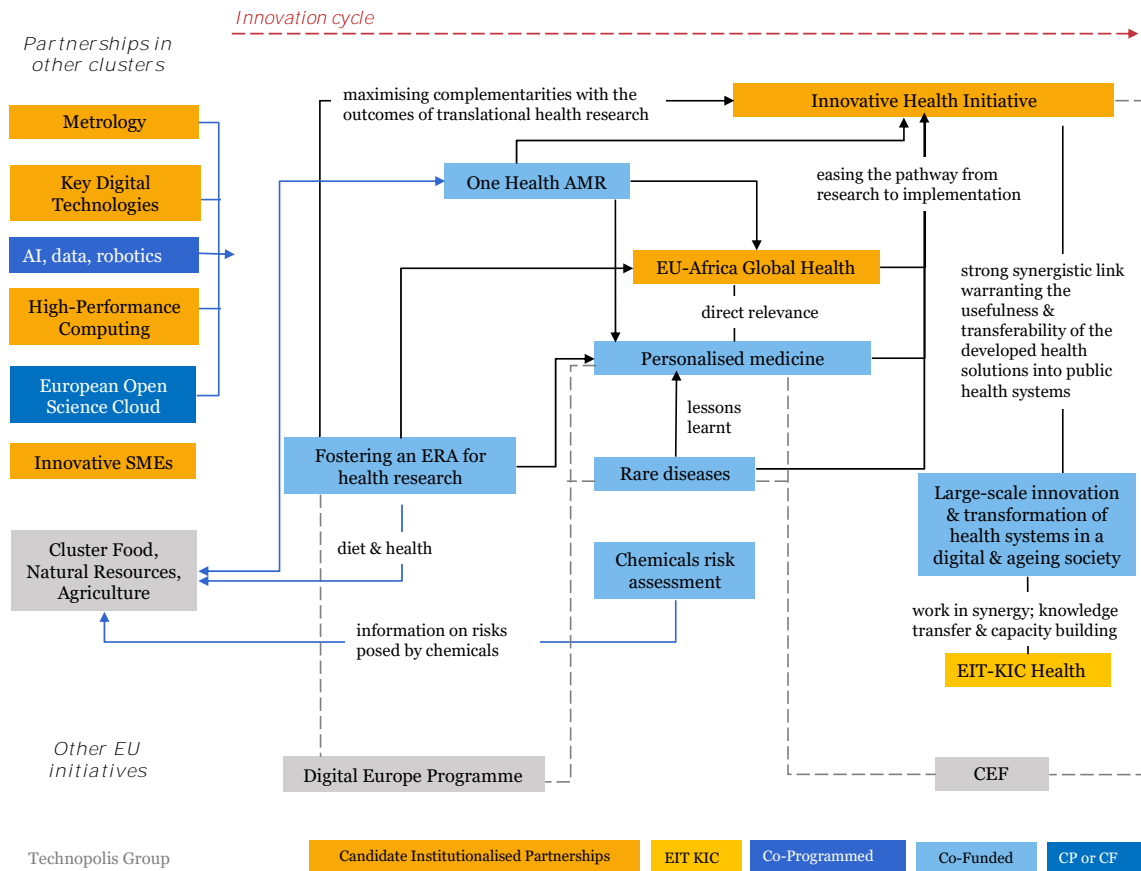


Figure 3 also illustrates potential for interplay with technological partnerships. For instance, the Key Digital Technologies Candidate Institutionalised Partnership could help contribute to innovation towards Smart Health solutions and the AI-data-robotics Co-Funded Partnership could help deliver new solutions for healthy ageing. Tapping developments in key digital technology areas for improving population health and healthcare systems in Europe would help realise the EU priority of maximising the potential of the Digital Age.

Interconnections between the envisaged partnerships in the Health cluster and the Food, Natural Resources and Agriculture cluster relate to the One Health concept owing to the common fight against AMR, the link between health and diet and the health risks posed by chemicals.

Finally, the envisaged partnerships in Health could potentially be supported by other EU initiatives, especially in terms of connectivity between hospitals, medical centres and research centres (the Connecting Europe Facility); and deployment of common digital data solutions and reinforcement of digital infrastructure and skills (Digital Europe Programme).<sup>47</sup>

## 2 Problem definition

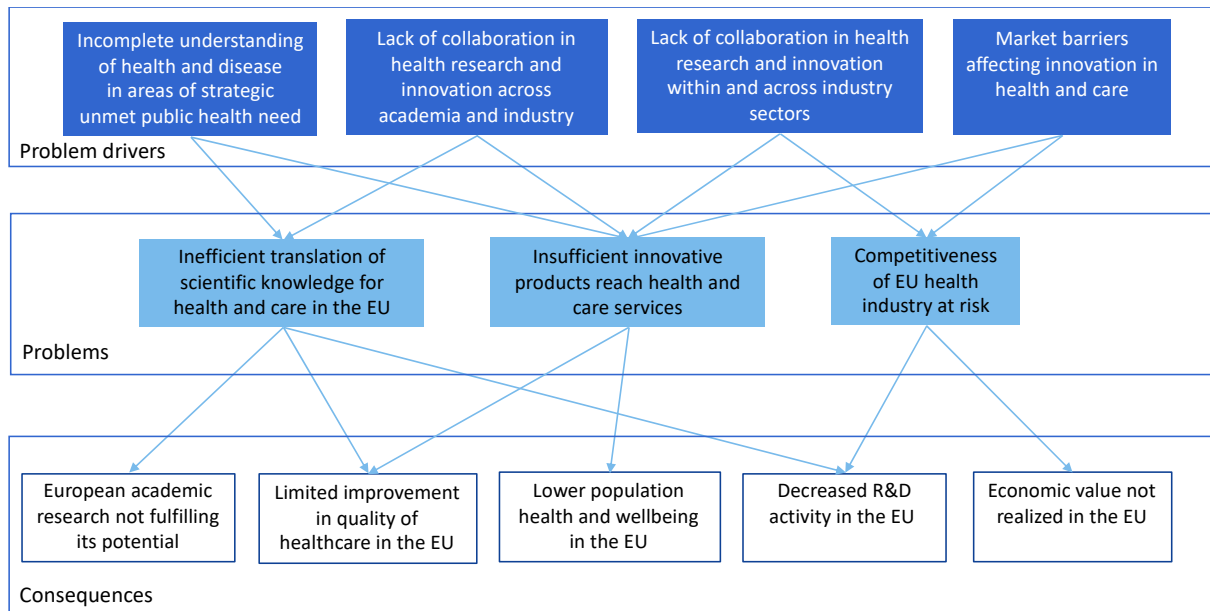
This chapter provides a discussion of the problems to be addressed in relation to the emerging challenges presented in Section 1.1, drawing on evidence from desk research and the findings of the stakeholder consultations undertaken as part of this study. These will serve as the basis for the formulation of the objectives and understanding of the likely impacts.

<sup>47</sup> EC (2018) A New Horizon for Europe. Impact Assessment of the 9th EU Framework Programme for Research and Innovation



A problem tree portraying the problems, their drivers and consequences (if the problems are not addressed) is presented in Figure 12 and described in detail in the following sections. The three problems identified are aligned with the Horizon Europe framework: insufficient translation of scientific knowledge is mainly a scientific problem; insufficient innovative products available for healthcare is mainly a societal problem; and the risk of competitiveness of EU health industry is mainly an economic problem.

Figure 4: Problem tree for the initiative on Innovative Health



Source: Technopolis Group

## 2.1 What are the problems?

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

Despite Europe being a leading region in health research, there remains a gap in terms of the ability to translate this excellent health research into products and services that will make a difference to patients and healthcare professionals.<sup>48,49</sup> The high failure rate is due to 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), lack of reproducibility of academic research,<sup>50</sup> lack of understanding of the mechanisms of disease, weak academia-industry and industry-industry (within and across different industry sectors) collaboration, market failures (low investment in some health areas e.g. infectious diseases, brain disorders and AMR)<sup>51</sup> and other barriers affecting R&D speed and success. Faster translation from discovery to market further needs involvement of a variety of additional stakeholders along the health research and innovation value chain, including regulators, payers and healthcare providers.

<sup>48</sup> EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report.

<sup>49</sup> The Scientific Panel for Health (2018) Building the future of health research. Proposal for a European Council for Health Research.

<sup>50</sup> Friedman L.P., Cockburn I.M. and Simcoe T.S. (2015) The Economics of Reproducibility in Preclinical Research, *PLoS Biol* 13(6): e1002165. doi:10.1371/journal.pbio.1002165

<sup>51</sup> European Commission (2017) The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

### 2.1.2 Insufficient innovative products reach health and care services

In view of the EU's commitment to the SDGs, health systems, in particular, need to evolve so that they are easily accessible and affordable to all, which means concentrating on improved access to medicines, more patient-centred healthcare, and a strong focus on health promotion and disease prevention.<sup>52</sup> This can be supported by innovation which helps provide new tools, technologies and digital solutions with the potential to improve health outcomes, address unmet health needs and inform regulatory standards and requirements. However, insufficient consideration of societal or user needs act as a barrier to acceptance and uptake, limiting the extent to which the full potential of novel innovative products can be realised. In addition, health systems need better tools for planning and forecasting workforce deployment and enabling broader use of cost-effective health innovations including digital health technologies. For example, tapping the potential of Big Data, Real World Data and digitalisation depends on the capacity to collect, combine and analyse vast amounts of data; the availability of appropriate regulatory frameworks and data infrastructures; and the fulfilment of all ethical and legal requirements.<sup>53</sup>

Access to products and services by patients and healthcare professionals may also be delayed<sup>54</sup> for reasons such as affordability or lack of preparedness of healthcare systems owing to organisational, structural and cultural factors. New innovations can sometimes have high prices, e.g. innovative anticancer medicines,<sup>55</sup> which can impact on the finances of a health system and its ability to provide individuals access to preventive, diagnostic and therapeutic innovations. In order to address the above-mentioned challenges and opportunities and to balance various interests, health technology assessment (HTA) has become an increasingly important tool to assist Member States in creating and maintaining sustainable health care systems and to stimulate innovation that delivers better outcomes for patients. Therefore, methods and tools to assess the added value of innovations need to be further developed to help Member States (MS) take appropriate reimbursement and pricing decisions. Consideration is also needed for reconciling different amortization periods for pharmaceuticals (long) and medical devices (short)<sup>56</sup> in payment models, particularly in the context of the emergence of complex health innovations.

### 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 against the US and China in many sectors including the pharmaceutical, MedTech and digital sectors (see Section 1.2.1).

R&I creates new opportunities, thus supporting sustainable economic growth and the competitiveness of businesses and industries.<sup>57</sup> However slow translation of discovery science 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 and care solutions, putting European competitiveness at risk. Health industries, including SMEs, based in Europe can increase their productivity and

---

<sup>52</sup> EC (2019) Towards a sustainable Europe by 2030. Reflection Paper.

<sup>53</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

<sup>54</sup> DG RTD (2019) Inception Impact Assessment of the candidate European Partnership on Innovative Health.

<sup>55</sup> Wilking N., Bucsecs A., Kandolf Sekulovic L., et al (2019) Achieving equal and timely access to innovative anticancer drugs in the EU: summary of a multidisciplinary CECOG-driven roundtable discussion with a focus on Eastern and South-Eastern EU countries. *ESMO Open*;4:e000550. doi: 10.1136/esmoopen-2019-000550

<sup>56</sup> Attenstetter C. (2017) Medical Devices: European Union Policymaking and the Implementation of Health and Patient Safety in France

<sup>57</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe.

sustainability by developing health innovations that can be taken up by users and healthcare systems worldwide. For this, it will be important for Europe to exploit the full potential of the convergence of pharmaceutical, digital and medical technologies; personalised medicine; and data- and digitalisation-driven health innovation. Alternative business and R&I funding models will also help contribute to more value captured in the EU, further contributing to competitiveness.



In the feedback to the inception impact assessment, academic stakeholders referred to the need to address pressures on the healthcare system due to non-communicable diseases and the ageing population. It was discussed that there is a need to consider the health systems when developing innovations to ensure efficient and appropriate integration.

The innovation gap in translating the results of health research for the development of innovative health products and services was highlighted by the majority of stakeholders (73%, 77 of 105) as a very relevant problem during the **open public consultation**. Insufficient consideration of societal or user needs was identified as a relevant barrier to uptake particularly by the majority of the respondents from the 15 NGOs, five public authorities and six small company/business organisations (<250 employees). Academic/research institutes and public authorities reported that ethical issues were also a barrier. Nevertheless, on average, stakeholders reported that structural and resource problems were more relevant than problems in the uptake of health innovations (an average of 56% of all stakeholders chose “very relevant” for structural and resource questions compared to an average of 34% for questions on problems with uptake of health innovation). The need for the partnerships to contribute to EU global competitiveness was supported by most stakeholders (59%, 63 of 106) in the **open public consultation**, including the majority of the 6 respondents from business associations, the 20 respondents from industry and the 35 respondents from academic/research organisations. Public authorities and ‘other’ were the only stakeholder groups where the majority did not state contribution to EU competitiveness as a need.

During **interviews**, industry representatives referred to a lack of trust between the public and industry. It was also felt that 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?

The key problem drivers affecting R&I performance in the health sector in Europe are discussed in more detail in the following paragraphs.

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

Communicable (diseases that can spread from one person to another) and non-communicable (those that do not spread from one person to another) diseases<sup>58</sup> are responsible for a large number of premature deaths and disabilities in the EU and elsewhere, thus presenting a large societal and economic burden and putting healthcare systems under financial and organisational pressure. For instance, mental illnesses and neurodegenerative diseases are responsible for up to 80% of EU healthcare costs,<sup>59</sup> while

<sup>58</sup> Communicable diseases can spread from one person to another (includes some infectious diseases), while non-communicable diseases do not spread from one person to another. Their burden, causes, treatment and prevention are very different. Hence, they are usually reported separately.

<sup>59</sup> EC (2017) State of Health in the EU Companion Report. Available at: [https://ec.europa.eu/health/sites/health/files/state/docs/2017\\_companion\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2017_companion_en.pdf)

infectious diseases account for about 5% of the total burden.<sup>60</sup> Moreover, AMR is becoming a major threat to public health with an estimated 33,000 deaths per year in the EU, costing €1.5 billion per year in healthcare costs and productivity losses.<sup>61</sup> Further, with Europeans living longer than ever before, the increased likelihood of chronic diseases with co-morbidities put additional pressure on health systems.<sup>61</sup>

Europe's ageing society, communicable and noncommunicable diseases and factors such as AMR contribute to important unmet public health needs. In 2017, 1.6% of people in the EU reported unmet needs for medical care, compared to 3.4% in 2011.<sup>61</sup> While the situation is improving, costs and long waiting lists remain the main reasons for unmet health needs. Unmet healthcare needs may result in people forgoing healthcare and may increase health inequalities if such unmet needs are concentrated among specific demographic groups e.g. people with low socioeconomic status or the elderly. Importantly however, advances in medical science give rise to new demand for health care by increasing the capacity to prevent, diagnose, treat, cure and rehabilitate diseases.<sup>62</sup> This demand is further increased by higher expectations of citizens with regard to the quality and timeliness of their healthcare as those who use health services get accustomed to higher standards.<sup>62</sup>

Many of the diseases that are increasingly affecting the health of EU citizens including infectious diseases and non-communicable diseases 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. For example, the top ten leading causes of death in Europe in 2016 included Alzheimer's disease, other dementia and diabetes mellitus, and further research is urgently needed to understand the causes of these complex diseases.<sup>63</sup> Understanding of diseases should also link better to prevention, prediction and healthy ageing.

## 2.2.2 Lack of collaboration in health research and innovation 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, such as 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 team working among academics (combined with a university system that rewards individual achievement rather than joint working practices).<sup>64</sup>

In recent years, there has been a steady rise in the number of large multi-stakeholder public-private consortia active in the pre-competitive space.<sup>65</sup> Academia predominantly takes on the higher risk, early phase trials and hence de-risks investment for industry. Industry on the other hand runs later-stage, more expensive trials often by hiring contract

---

<sup>60</sup> Institute for Health Metrics and Evaluation (2018) Global Burden of Disease Study 2017. Available at: [http://www.healthdata.org/sites/default/files/files/policy\\_report/2019/GBD\\_2017\\_Booklet.pdf](http://www.healthdata.org/sites/default/files/files/policy_report/2019/GBD_2017_Booklet.pdf)

<sup>61</sup> EC (2019) Towards a sustainable Europe by 2030. Reflection Paper.

<sup>62</sup> Jakubowski E. and Busse R. (1998) Health care systems in the EU: A comparative study. Working Paper. Luxembourg: European Parliament.

<sup>63</sup> WHO (no date) Disease burden and mortality estimates. Data available at: [https://www.who.int/healthinfo/global\\_burden\\_disease/estimates/en/index1.html](https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html)

<sup>64</sup> 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. doi: 10.1371/journal.pone.0160475.

<sup>65</sup> Lim, M. D. (2014) Consortium Sandbox: Building and Sharing Resources. *Science*, 6(242), pp. 1–8.

research organisations to recruit and run trials effectively. An analysis of the completion rates for non-industry sponsored trials versus industry-sponsored trials shows mixed results across the phases.<sup>66</sup> The probability of success of drug development projects however increases when non-industry partners are involved, underlining the benefits of enhanced collaboration.<sup>66</sup>

However, the majority of European academics do not collaborate with business.<sup>67</sup> Indeed, less than 8% of participations in SC1 (Health, demographic change and wellbeing) Horizon 2020 collaborative projects from 2014 to 2019 were from non-SME industry partners (see table below).

Table 2: Proportion of non-SME private sector participants (labelled as industry) in regular Horizon 2020 collaborative health R&I projects (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	€ 595,619,918	€ 41,542,476	1609	109	6.97%	6.77%
2015	€ 584,270,458	€ 31,235,638	1308	98	5.35%	7.49%
2016	€ 440,330,074	€ 20,460,519	1111	83	4.65%	7.47%
2017	€ 367,686,472	€ 21,747,256	886	59	5.91%	6.66%
2018	€ 691,315,336	€ 51,995,267	1588	156	7.52%	9.82%
2019	€ 796,496,156	€ 56,131,198	1459	115	7.05%	7.88%
<b>Total</b>	<b>€ 3,475,718,414</b>	<b>€ 223,112,354</b>	<b>7961</b>	<b>620</b>	<b>6.42%</b>	<b>7.79%</b>

Source: European Commission



Interviews with industry stakeholders suggest that while there are examples of large pharmaceutical companies participating in collaborative projects in Horizon 2020, this remains limited due to low perceived success rates, time-consuming administrative requirements and the availability of the alternative of IMI2 JU.

Differing concerns in industry and academia contribute to this lack of collaborations.<sup>68</sup> Industry is concerned with poor reproducibility of research, high valuation of early IP, and maintaining confidentiality, while academia is concerned with the freedom to publish and strategic changes at the industrial partner which can lead to discontinuation of research projects. Further, evidence suggests that academics are less able to comply with increasingly complex regulatory requirements compared to industry.<sup>69</sup> For instance, analysis of data from the European Union's Clinical Trial Register shows that clinical trial

<sup>66</sup> Wong, C. H., Siah, K. W., Lo, A. W. (2019) Estimation of clinical trial success rates and related parameters. *Biostatistics*, 20(2), pp. 273–286. Available at: <https://academic.oup.com/biostatistics/article/20/2/273/4817524>

<sup>67</sup> Davey, T., Meerman, A., Galán-Muros, V. et al. (2018) The state of university-business cooperation in Europe.

<sup>68</sup> Freedman, S. and Mullane, K. (2017) The academic-industrial complex: navigating the translational and cultural divide. *Drug Discovery Today*, 22(7), pp. 976–993. doi: 10.1016/j.drudis.2017.03.005.

<sup>69</sup> Vesper I. (2018) Europe's academics fail to report results for 90% of clinical trials, *Nature*, DOI: 10.1038/d41586-018-06676-8.

results of 90% of clinical trials led by academics in Europe are not reported within a year of ending, while 70% of industry-sponsored clinical trials have published outcomes within 12 months of completion.

### 2.2.3 Lack of collaboration in health research and innovation within and across industry sectors

An overarching organisational problem driver to exploit 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.<sup>70</sup> Reasons for this are competition, diverging business models and varied development timelines across sectors. The interim evaluation of IMI2 JU identified specific barriers that made involvement of companies other than pharmaceutical companies difficult in IMI2 JU projects. Firstly, technology providers tend to be SMEs with limited resources and prefer to apply for grants to fund R&I projects rather than support them with in-kind contribution; and secondly, their product development stage and business model are vastly different from the pharmaceutical sector, i.e. their precompetitive activities are more limited and IP is handled rather differently.<sup>71</sup>

For example, COCIR members in 2015 felt that IMI2 JU IP rules were less conducive to collaborative R&I than general Horizon 2020 rules.<sup>72</sup> Participants were not required to share results or background material in their ownership with other participants who might require that information to exploit the IP. Besides, there was an obligation to provide licenses to third parties to allow them access to results and background for third-party research purposes. As such the consensus was that there was limited scope for the exploitation of IP generated from an IMI2 JU project. It was difficult to recoup investments under these IP rules and hence COCIR members did not want to engage in any collaborative R&I involving generation of new IP.

Lack of data standards, interoperability and accessibility; inadequate or non-existing analytical methods and tools; and issues around ethics, privacy and security are barriers that diminish R&I in the cross-sectoral digital health sector.<sup>73</sup> This diminishes the EU's ability to tap the immense potential presented by digitalisation, AI and Big Data. The capacity to collect, combine and analyse large, complex data sets is also variable across industry sectors and stakeholder groups resulting in a lack of collaboration.<sup>74</sup>

### 2.2.4 Market barriers affecting innovation in health and 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 AMR. This is exacerbated by the fact that methodologies and models to demonstrate the market value of complex health interventions are lacking.<sup>70</sup> Health industries, in particular SMEs, may also encounter difficulties to access the necessary investments from other sources as well as new markets and value chains, or in creating partnerships and alliances because health innovation requires a broader variety of stakeholders to be involved from supply, demand and

---

<sup>70</sup> DG RTD (2019) Inception Impact Assessment of the candidate European Partnership on Innovative Health.

<sup>71</sup> 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.

<sup>72</sup> COCIR (2015) Outline of COCIR position towards IMI-2.

<sup>73</sup> EC (2019) Strengthening strategic value chains for a future-ready EU industry

<sup>74</sup> EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report.

regulatory side.<sup>75</sup> All these reasons also contribute to lack of collaboration between different health-related industry sectors as described above.

In 2013, the chief technology officers of Philips, GE and Siemens articulated the difference between innovation in the medical technology industry and pharma industry, highlighting that “R&I timescales and market access mechanisms are quite different.”<sup>76</sup> On the other hand, pricing of new innovations is a major issue for healthcare payers and policy-makers. Therefore, new methods and tools to support reimbursement and pricing decisions including new models for value-based pricing or other ways of estimating the full lifetime value of an innovation to the healthcare system are needed to support Member States (in HTAs or health system/organisations performance assessments).



The lack of understanding/knowledge about disease was agreed to be a very relevant problem by the majority within each stakeholder group in the **open public consultation** with the exception of small company/business organisations where the majority (out of 9 respondents) felt this was less relevant. In the **feedback to the inception impact assessment**, stakeholders from business, academia, NGOs and ‘others’ referred specifically to AMR, brain disorders and neglected diseases.

Limited collaboration and pooling of resources between industry sectors was seen as a very relevant problem across stakeholder groups (52%, 55 of 106 respondents) in the **open public consultation**. Stakeholders from academic/research organisations, small company/business organisations, EU citizens and NGOs put less weight on this point. 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 stakeholders (59%, 61 of 104 respondents) 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.

In the **open public consultation**, there was some disagreement between small and large (>250 employees) company/business organisations in terms of the relevance of market failure, adequacy of business models, and ethical concerns related to digital tools. Small companies (9 respondents) found these problems less relevant as barriers to uptake of innovations compared to the majority of the 12 stakeholders from larger companies that reported these as very relevant.

### 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 neurodegenerative diseases and chronic diseases is likely to increase leading to co-morbidities.<sup>77</sup> In addition, in an increasingly global world, as more people continue to travel, the spread of new emerging infections and the possibility of a pandemic cannot be ruled out. However, increased use of social media and telecommunications may help educate people with regard to the risk factors, prevention and treatment, which would help manage the disease burden more effectively. In addition, AI tools, for example, based on social media could alert us to emerging infections and new digital health solutions (that are being developed already)

<sup>75</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

<sup>76</sup> COCIR (2015) Outline of COCIR position towards IMI-2.

<sup>77</sup> EC (2019) Towards a sustainable Europe by 2030. Reflection Paper.

could help with the monitoring and management of disease conditions remotely, thus relieving the pressure on healthcare systems.

The problem of insufficient innovations for health and care, which includes lack of innovation as well as innovations not reaching users on time, will persist without intervention, and will require efforts from all stakeholders including those in the health system and end-users. However, if addressed, easy to use and affordable innovations should help reduce the pressure on healthcare systems both organisationally and financially. In addition, increasing expectations with regard to healthcare from EU citizens – that healthcare is high quality, affordable, effective and accessible – is also likely to influence the burden on and delivery of healthcare.<sup>78</sup>

Personalised medicine is another area that is set to revolutionise healthcare. The right personalised medicine solutions will not only address the problems presented by an ageing society and increased disease burden, but also reduce pressure on health systems, help ensure health and wellbeing for all and reduce health inequalities if they are easy to implement and cost-effective in the long run.<sup>79</sup>

Overall, the problems described if left unaddressed will result in limited improvement in the quality of healthcare and unaffordable/unsustainable health systems which will negatively impact on health and wellbeing in the society. Besides, lack of translation, innovation and an internationally competitive health industry could lead to a decline in health-related R&D activity in Europe with jobs and revenue going outside the EU, and economic value not being realised in Europe. Furthermore, without improvements in the efficiency of translation of scientific knowledge created by European academics and the level of subsequent innovation activity, the full potential of European academic research will not be captured.



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 by stakeholders consulted during the **open public consultation** who 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 regards to personalised healthcare.

### 3 Why should the EU act?

A similar argument for EU action in supporting the European HPC ecosystem was made in the EuroHPC Impact Assessment of 2018 and subsequent regulation establishing the EuroHPC JU. In it, the EU considered it must act to eliminate the fragmentation of investments in HPC by MS, which requires coordinated action in support of the European HPC ecosystem, as stated by the European Parliament in 2017, in response to the lack of HPC capacity in Europe.<sup>80</sup> This argument remains valid. The following sections provide further justification to the subsidiarity and added value questions.

#### 3.1 Subsidiarity: Necessity of EU action

The problems described are of a nature and magnitude that EU-level concerted action will be more appropriate compared to individual Member States developing their own

<sup>78</sup> Weale A. and Clarke S. (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.

<sup>79</sup> EC (2018) Precision Medicine. Targeted scenario N°14. Glimpses of the future from the BOHEMIA study.

<sup>80</sup> Briefing on EU Legislation in Progress – EuroHPC Joint Undertaking, June 2018



initiatives. This will allow more coherence and coordination of effort, and avoid duplication. To elaborate, EU action is required for the following reasons:<sup>81</sup>

- Effective engagement and cross-sectoral collaboration within the health-related industry sectors requires mobilising a very broad range of companies and other stakeholders with relevant expertise, knowledge and resources as well as patients and healthcare professionals, based across Europe. No Member State could mobilise these stakeholders and companies individually and reach the required critical mass.
- Health R&I is increasingly a global endeavour. An EU-level action would be able to accomplish co-ordination of multiple and varied stakeholders more effectively and efficiently than individual states, thus enabling activities that will meet the planned objectives.
- Most health-related companies operating in Member States have an EU-wide presence and are governed by EU-wide legal frameworks, e.g. medicinal products, medical devices and cross-border healthcare. Therefore, it is logical to have a partnership focused on innovation in health at the EU level too, thereby pooling resources and expertise, and reducing duplication. Moreover, the EU is best placed to develop and implement common standards and frameworks related to health innovations as it is a regulatory body in this area.
- No Member State alone would have the legal and financial framework as well as the programme management experience to enable a multi-sectoral collaboration at the scope and/or scale envisaged.

### 3.2 *Subsidiarity: Added value of EU action*

An EU initiative can help bring together a broad spectrum of stakeholders, both private (large and mid-size companies, SMEs) and public (academia and research organisations; charity organisations; patients; regulators; Health Technology Assessment organisations; healthcare payers, providers and professionals) in the health field. Industry participation would help to drive academic research efforts towards applicable health innovations, while public partners would guarantee that projects address important unmet health needs and deliver innovations that can be taken up by healthcare systems. An EU level initiative has the potential to provide the necessary scale and focus of investment to attract additional, or shift existing, investment into R&I addressing strategic unmet public health needs, especially where industry would not act on its own. Having an initiative under the aegis of the EU would create a trustful environment for sharing expertise, resources and knowledge, contributing to the building of multidisciplinary transnational networks engaged in innovation. In summary, it can provide added value in terms of:<sup>82</sup>

- Creation of critical mass to address global challenges
- Increased coordination across public and private actors and across Member States
- Increasing the EU's competitive advantage vis-a-vis major competitors
- The creation of new market opportunities
- Leveraging more public and private investment in health-related R&I

---

<sup>81</sup> DG RTD (2019) Inception Impact Assessment of the candidate European Partnership on Innovative Health.

<sup>82</sup> DG RTD (2018) Horizon Europe Impact Assessment. A New Horizon for Europe.



The added value of EU action was further underlined by stakeholders in the **open public consultation**, especially in terms of responding to 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 the EU level was essential to maintain/improve the R&I competitiveness of the European health industry. Several stakeholders, predominantly from the 'other' category, repeated this notion in the **feedback to the inception impact assessment**.

## 4 Objectives: What is to be achieved?

### 4.1 General objectives

We have identified three general objectives corresponding to the main problems discussed in Section 2.1, i.e. Inefficient translation of scientific knowledge for health and care in the EU, insufficient innovative products reaching health and care services, and risk to the global competitiveness of the EU health industry. The general objectives of an EU action should therefore be to

- Create an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations
- Foster the development of safe, effective, patient-centred and cost-effective innovations that respond to strategic unmet public health needs currently not served by industry
- Drive cross-sectoral health innovation for a globally competitive European health industry

General objective 1 is mainly aimed at addressing, through the scientific impact pathway, current inefficiencies in translating the scientific knowledge generated in Europe into health and care innovations. The second objective addresses the lack of sufficient innovative products reaching health and care services and addressing unmet public health needs. Fostering the development of innovations that are not only safe and effective, but also patient-centred and cost-effective will increase the likelihood of innovation being adopted by health systems, and thus provide benefit to EU citizens. Finally, general objective 3 is mainly aimed at addressing, through the economic impact pathways, the risk to the global competitiveness of the EU health industry.

The general objectives align with Horizon Europe objectives to "strengthen the scientific and technological bases of the Union" and "to foster competitiveness",<sup>83</sup> as well as strategic EU priorities to promote health and wellbeing for all including access to innovative, sustainable and high-quality healthcare and the Sustainable Development Goal of "Ensuring healthy lives and promote well-being for all at all ages".<sup>84</sup>

### 4.2 Specific objectives

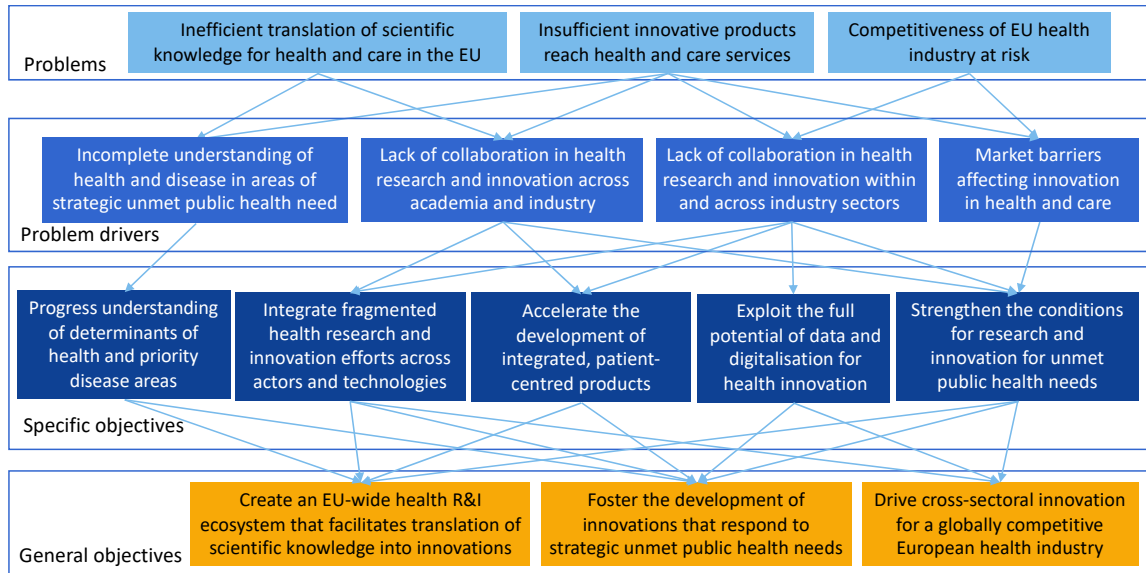
In order to achieve the general objectives, we defined five specific objectives. These specific objectives respond to each of the problem drivers discussed in Section 2.2. The relationship between the general and specific objectives is shown in Figure 5. It should be noted that specific objectives are inter-dependent and sequential to some extent. For example, integrating health research and innovation efforts across actors and technologies and exploiting data and digitalisation will facilitate progress in understanding the determinants of health and priority disease areas as well as contribute to accelerated

<sup>83</sup> DG RTD (2018) Horizon Europe Impact Assessment. A New Horizon for Europe.

<sup>84</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

development of integrated health solutions. Strengthening the conditions for research and innovation for strategic unmet public health needs will also support the accelerated development of relevant health innovations.

Figure 5: Objectives tree for the initiative on Innovative Health



Source: Technopolis Group

By achieving the specific objectives, some of the key push and pull factors of innovation can be addressed and the underlying problem drivers diminished, driving cross-sectoral innovation for a globally competitive European health industry (general objective of the initiative). While accelerating the development of integrated, patient-centred solutions and supporting the development of data- and digitalisation-driven innovation for health, the initiative also has the potential to improve the way healthcare is delivered across Europe as well as improve the effectiveness and cost-effectiveness of healthcare (through better and more targeted prevention, diagnosis and treatment). Moreover, through strengthening conditions for research and innovation, the initiative is expected to lead to greater acceptance and uptake of innovations in healthcare systems and society and thus help alleviate the pressure on healthcare systems and fulfil unmet public health needs.

Note that the Innovative Health Initiative (IHI) was conceived to be agnostic to specific disease areas or stages at which it intends to intervene in the health and care pathways: it may cover prevention, diagnostics, treatment or diseases management.

### Progress understanding of the determinants of health and priority disease areas

By focussing on improving the understanding of health and disease states through elucidation of the mechanisms of diseases and factors contributing to health, R&I activities undertaken through the initiative 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 and provide a starting point for further R&I activities.

### Integrate fragmented health research and innovation efforts across actors and technologies

This specific objective is expected to contribute to the general objectives by breaking down barriers to cross-sectoral collaboration not only between academia and industry and between different health industry sectors of different sizes but across all actors in the healthcare pathway including patients and civil society, healthcare professionals, healthcare providers, regulators, HTA bodies and payers.

## Accelerate the development of integrated, patient-centred solutions that can be taken up by individuals and systems along the healthcare continuum

Innovative health products that integrate technologies across drugs, devices and software promise breakthrough solutions to tackle health. Better collaboration and integration of fragmented R&I efforts between different actors in the EU health R&I ecosystem can be expected to accelerate innovation. However, to ensure that the innovation activity is faster and impactful, novel approaches that can accelerate the process and issues that might affect uptake also need to be considered at the outset.

To give an example, on average 10,000 substances are tested to develop one safe and efficacious medicine that can be used in the healthcare system, taking about 10-15 years using traditional approaches. It is expected that the development process can be accelerated by using novel approaches afforded by bespoke medical devices and machine learning algorithms. For example, it was recently shown that pre-clinical development of candidate medicinal products can be dramatically accelerated using AI techniques.<sup>85</sup>

## Exploit the full potential of data and digitalisation for health innovation

The use of Big Data and Real-World Data requires the digitalisation of health data, finding new ways to observe health and disease states, collect the relevant digital biomarkers using health technologies and develop new analytics and software to convert data into valuable knowledge. These aspects are at the heart of data-focussed approaches and these will help innovators to develop more effective tools and products for preventing, diagnosing, treating and managing health conditions, including innovative, integrated solutions.

## Strengthen the conditions for research and innovation for strategic unmet public health needs

Importantly, innovations tailored to meet the needs of patients, health professionals and payers will more likely be taken up by healthcare systems, provided the necessary implementation strategies and wider infrastructure are in place at health and care organisations.

There is however a need for strengthening the conditions for R&I specifically to target strategic unmet public health needs where industry traditionally has not been active due to perceived high risk and/or low return on investment. The advent of complex and integrated solutions necessitates new ways of assessing the value these products bring to the patient and the overall health system. Recognising value at the appropriate level will serve as a balanced incentive for the industry to innovate and for public health systems to provide high quality and cost-effective care. This specific objective envisages the development of new concepts, methods and tools by working transparently and collaboratively across academia, industry and regulatory and HTA bodies.



Overall, stakeholders were supportive of the specific objectives in the **interviews**. Those from industry and research infrastructures, in particular, were the most supportive of the specific objectives during the **interview** consultation. Patient associations shared the most concern specifically with regards to feeling the objectives were not sufficiently patient-centric. 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 or topics at this stage.

<sup>85</sup> Zhavoronkov A., Ivanenkov YA., Aliper A. et al. (2019) Deep learning enables rapid identification of potent DDR1 kinase inhibitors. *Nat. Biotechnol.* 37, 1038–1040. Available at: doi:10.1038/s41587-019-0224-x

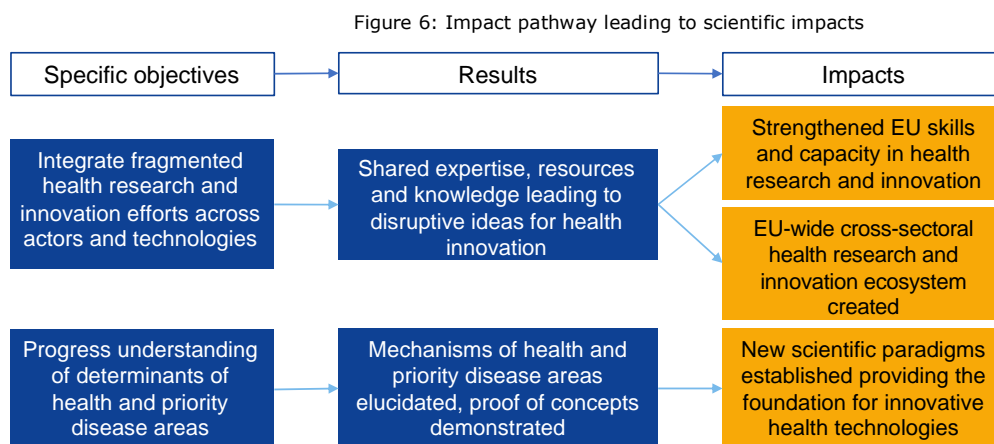
In the **feedback to the inception impact assessment**, non-private actors (NGOs, academics/research institutions, and public authorities) made comments calling for broader stakeholder involvement, particularly patient organisations and healthcare payers. This was repeated by **interviewees** who discussed the need to include additional stakeholders beyond industry and academia.

In line with the objective to “Integrate fragmented health research and innovation efforts across actors and technologies”, the **open public consultation** revealed strong support for collaborative R&I projects (selected as very relevant by 71% [75 of 105] of respondents). This included the majority of the 35 academic/research institutions, 6 business associations, 12 large companies and 15 NGOs. EU citizens and small companies also showed support for collaborative R&I projects but reported more varied levels of how relevant these are to achieve the objectives.

### 4.3 Intervention logic and targeted impacts of the initiative

#### 4.3.1 Likely scientific impacts

The initiative is likely to lead to three key scientific impacts, as illustrated in Figure 6 and further described below.



Source: Technopolis Group

Efforts to integrate the fragmented health R&I efforts within Europe will result in the **diffusion of knowledge** and exchange of ideas and resources across borders and sectors. Integration of efforts could create efficiencies if stakeholders, especially users and regulators, were engaged early on in the agenda setting or innovation process thereby reducing the development of redundant or unrealistic innovations. Over the medium to long term, these efforts could lead to cross-sectoral collaborative networks. Should projects include overseas partners, the networks could be spread out globally.

Activities aimed at improving understanding of health and disease as well as integration of R&I activities across sectors is likely to contribute in the short term to the **creation of high-quality new knowledge** about the mechanisms underlying disease conditions and factors contributing to a healthy status. The new scientific paradigms established as a result could support innovation towards new and better tools and mechanisms to prevent, diagnose and treat health conditions as well as inform regulatory standards and requirements.<sup>86</sup> Knowledge creation and skills development through collaborative projects is likely to lead to **strengthening of human capital in R&I**.

<sup>86</sup> European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe.

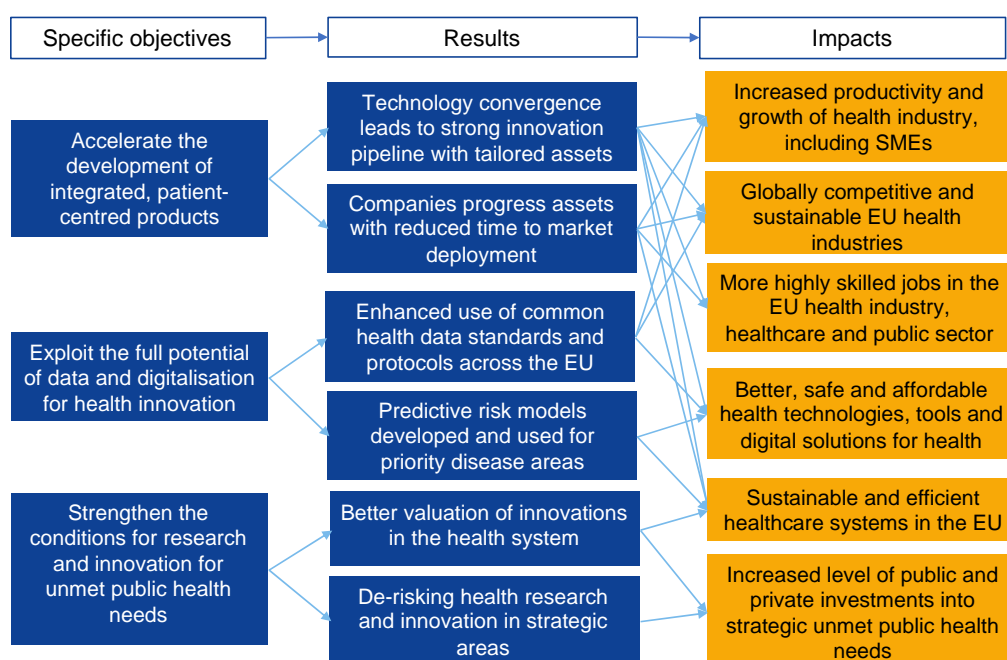


In the **interview** consultation, the majority of the 22 industry, seven European Commission and five 'other' stakeholders mentioned that they expected the initiative to drive more innovative and high-quality research outputs and methodologies. Similarly, the majority of the 35 stakeholders across the industry, academia, research infrastructures and 'other' groups felt that the initiative would help forge efficiencies in health R&I. These quality and efficiency impacts were attributed to the diversity of skills and knowledge that a diverse range of stakeholders would bring to a partnership.

In the **feedback to the inception impact assessment**, the majority of the nine academic/research organisation stakeholders agreed that the aforementioned scientific impacts could be realised from the initiative. They anticipated major impacts from the expansion of the initiative to industries beyond pharmaceutical sector. Likely economic/technological impacts

The likely key economic/technological impacts of the initiative are mapped in Figure 7.

Figure 7: Impact pathway leading to economic/technological impacts



Source: Technopolis Group

If the initiative is successful in implementing the specific objective on acceleration of development of integrated, patient-centred solutions facilitated by the integration of R&I activities across health-related sectors, technological convergence, creation of new complex health innovations, and progression of innovations towards higher technological levels and the market will occur faster. Exploiting data and digitalization approaches/technologies for health innovation will require creation and use of common standards, ethical frameworks and protocols to collect, process and analyse data. Subsequently, better, safe and affordable health technologies, tools and digital solutions will emerge in the short to medium term. The emergence of novel integrated and complex health solutions will also require appropriate regulatory and HTA standards and requirements.

The IHI can be expected to **generate innovation-based growth** in the medium to long term. Alternative business models, establishment of new companies and markets; increased productivity and **creation of jobs** in the industrial, healthcare and public sector on the back of the innovation; and development of new products and solutions will contribute to this growth. This should also help to increase trade and **leverage**

**investment** into health R&I including in areas of unmet need from both the EU and industry partners. Taken together, all these impacts can help drive the **sustainability and competitiveness of the EU health industry** in the long term.

Moreover, uptake of the new and potentially better and cost-effective innovations in the healthcare system will likely have wider economic benefits for society in terms of lower healthcare costs and fewer days lost to ill health, resulting in more sustainable healthcare systems in the long term.



A common sentiment reported by **interviewees** was that due to the synergies achieved through the partnership, economic benefits would be felt by all stakeholders along the health value chain. Nevertheless, SMEs were identified as key beneficiaries by the majority of the seven European Commission, five academic and two partnership stakeholders. Stakeholders, especially those from existing partnerships, felt that the investment would help increase the global competitiveness of the EU.

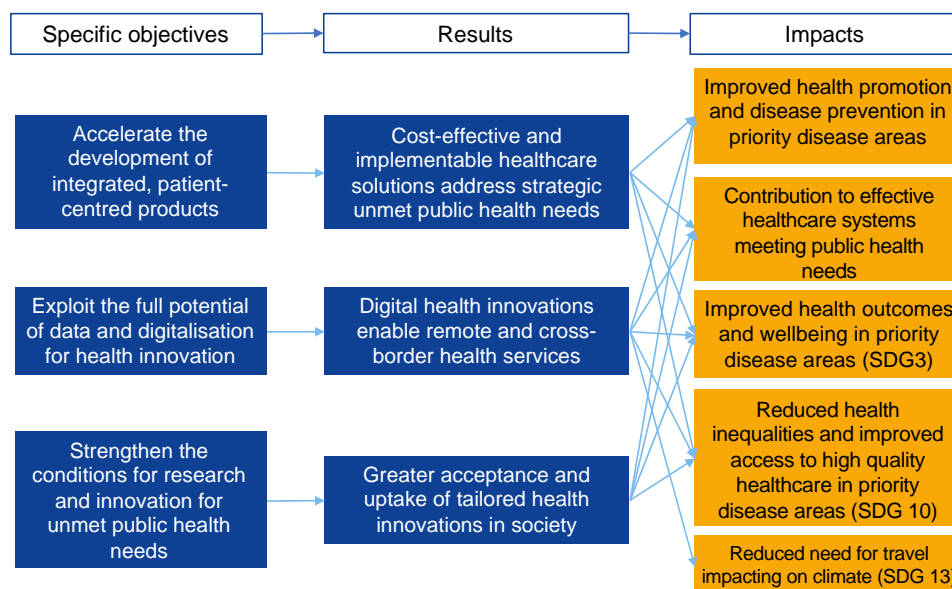
Job growth was a commonly discussed impact during the **interviews**, particularly with stakeholders from industry, academia, research infrastructures and the 'other' category, but responses varied as to the extent and nature of job growth.

New health tools and technologies were also raised as potential impacts during **interviews**. Stakeholders from academia and industry discussed this in relation to prevention and personalised medicine and stakeholders from research infrastructures discussed this in relation to diagnostics. The new technologies were expected to decrease the burden on health care systems and contribute to a healthier population resulting in economic benefits to MS.

#### 4.3.2 Likely societal impacts

The scientific and economic/technological impacts discussed above will also support the attainment of societal impacts as shown in Figure 8.

Figure 8: Impact pathway leading to societal impacts



Source: Technopolis Group

## Likely environmental impacts

The IHI has the potential to impact on the following sustainable development goals:<sup>87</sup>

- SDG 12 responsible consumption and production by reducing waste and improving environmental safety through less environmentally toxic drugs; developing medicines with a longer, more stable shelf life; and more robust waste management procedures
- SDG 13 climate action by reducing the need to travel for healthcare due to better digital technologies (e.g. telemedicine, e-health or m-health solutions) and adopting green manufacturing practices, thereby reducing greenhouse emissions
- SDG 16 Peace and justice by improving animal welfare through reducing reliance on animal testing. This could be achieved through research conducted within the partnership as well as working with regulators to establish alternative standards/protocols

However, whether these impacts will be achieved will depend on the types of projects funded through IHI. Digital health technologies that can be used remotely are most likely to emerge from the IHI's current specific objectives, leading to impact on carbon emissions in the long term.

## Likely social impacts

More effective, affordable and easily implementable solutions for healthcare, 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 medium to long term. **Uptake of new innovations** in healthcare systems and by individuals will be facilitated by activities undertaken to strengthen conditions for market deployment such as the development of methodological approaches and tools to assess the added value of innovations that can be used by HTA bodies, healthcare payers, and policy-makers to support pricing and reimbursement decisions. Effective healthcare systems that meet public health needs and improved health promotion and disease prevention will lead to improved health outcomes (longer life-years, reduced burden of disease, better patient experience) and well-being in the long term. Thus, R&I activities within IHI have the potential to simultaneously **address EU policy priorities** for health and wellbeing (see Section 1.3) and the following Sustainable Development Goals:<sup>88</sup>

- SDG 3 Good health and wellbeing by driving novel healthcare innovations improving patient care and wellbeing in unmet public health needs
- SDG 10 Reduced inequalities by reducing the burden of disease through the development and distribution of new products; and by broadening access to healthcare by improving the sustainability and efficiency in the system

## Likely impacts on simplification and/or administrative burden

The initiative is unlikely to create impacts in terms of simplification or administrative burden of the R&I activities supported under Horizon Europe.

## Likely impacts on fundamental rights

R&I activities leading to creation of new technologies and solutions for healthcare can be expected to contribute to the fundamental right of equitable access to preventive and

---

<sup>87</sup> EC DG International Cooperation and Development (no date), The Sustainable Development Goals. Available at: [https://ec.europa.eu/europeaid/policies/sustainable-development-goals\\_en](https://ec.europa.eu/europeaid/policies/sustainable-development-goals_en)

<sup>88</sup> EC DG International Cooperation and Development (no date), The Sustainable Development Goals. Available at: [https://ec.europa.eu/europeaid/policies/sustainable-development-goals\\_en](https://ec.europa.eu/europeaid/policies/sustainable-development-goals_en)



treatment-related healthcare 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 majority of the 48 **interviewees** agreed that the IHI would contribute to improved health and wellbeing. In this context, industry stakeholders referred most commonly to benefits from addressing AMR whereas ‘other’ stakeholders expected benefits from developments in personalised medicine. Stakeholders from patient associations felt that inclusion of end users in health R&I would lead to positive impacts on patient and citizen wellbeing.

A common societal impact raised in the **feedback to the inception impact assessment** was the reduction of health inequalities. **Interviewees** also concurred that this aspect could be partially addressed in the IHI by developing innovations that account for variations in digital literacy, ageing and geographical diversity across Europe. **Interviewees** also discussed potential positive environmental impacts, referring in particular to reduced carbon emissions associated with a shift towards digital health solutions.

#### 4.4 Functionalities of the initiative

This section outlines the functionalities that need to be considered when assessing the policy options in Chapter 6, reflecting the selection criteria for European Partnerships defined in the Commission proposal for the Horizon Europe Regulation.<sup>89</sup> In the following paragraphs, we discuss the implications of the criteria relating to the type and composition of the actors involved, the range of activities to be undertaken and the directionality required if the initiative is to deliver the objectives discussed above. We also consider the complementarities

##### 4.4.1 Internal factors

#### Type and composition of the actors involved

This functionality relates to the criterion: “Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness”. It concerns the need to involve the full range of stakeholders that can usefully contribute to delivering the future R&I agenda.

The objectives of the initiative are ambitious and multi-faceted, and thus it requires the involvement of all types of actors along the health value chain. The key actors are researchers from academic and various industry sectors as well as third sector organisations and foundations performing essential R&I activities.

The orientation of the research needs to be informed, and possibly co-delivered and disseminated, by the potential users of the eventual health solutions. These include patients and citizens, healthcare professionals and healthcare providers. They can contribute with important information on context and provide crucial health data and pilot/demonstrator sites to ensure that the R&I activities in the initiative are fit for purpose. Member States and Associated Countries could also play a role in setting the joint long-term agenda.<sup>90</sup>

<sup>89</sup> European Commission (2018) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018PC0435&from=EN>

<sup>90</sup> Just over 50% of respondents to the public consultation on the IHI Roadmap Inception Impact Assessment thought this role was relevant or very relevant for Member States and Associated Countries

It is also relevant to engage, and as far as feasible involve, EU and national regulatory authorities, HTA bodies and healthcare payers, who assess the quality, safety and efficacy of complex health innovations, and ultimately pay for the delivery of those to patients. Their needs and requirements would be best considered early in the planning and implementation of the R&I initiative so as to maximise the potential for alignments and future exploitation of outputs. In addition, standards developing organisations should be usefully involved, especially in digital health.<sup>91</sup>

The industry sectors need to cover the biopharmaceutical, biotechnology, medical technology, and other digital companies that can work together to integrate currently disparate technologies, including drugs, devices and software, into integrated health solutions. Since technologies advance ever faster and new challenges may arise during the lifetime of the initiative, the relevant processes should allow for new entities to join the initiative if needed. In particular, it is essential to facilitate the participation of innovative SMEs that often lack the necessary infrastructure and experience to collaborate with large enterprises otherwise.

While the EU has a strong and broad health research sector to build on, there are areas of health technology, data analytics and expertise in particular health conditions that are more advanced in non-EU countries. Therefore the inclusion of international actors is necessary in these specific areas to progress scientific and technological agendas and provide a critical opportunity for mutual learning. These actors may come from academic and industrial organisations, as well as foundations and regulatory authorities. This flexibility and openness is required so that European patients have early access to the best available health solutions and European companies remain at the forefront of health innovations. For example, a number of actors from the UK, Switzerland, US, Norway and Israel were coordinators or participants in past IMI2 projects.

### Type and range of activities

This functionality relates to the criterion “Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances”. It concerns the types of activity that the initiative is intended to encourage, such that it is able to respond effectively to the problems described in Chapter 2.

**Collaborative R&I** actions will be crucial for meeting the objectives of the initiative. This constitutes R&I projects that potentially cover testing new interventions in pre-clinical, clinical and real-world environments to generate novel biomarkers, better understanding of health and disease states, experimental proof of concepts etc. to better prevent, diagnose, intercept or treat disease. Some actions may also advance assets to technology validation and building technology prototypes. The latter could benefit from more focussed **validation and demonstration activities**, with involvement of broader set of actors, including users.

The initiative requires the close cross-sectoral collaboration of the two main industry sectors: pharmaceuticals and medical technologies. It is therefore important to have R&I themes where such interaction can accelerate innovation: either directly through project co-design and co-delivery or indirectly through a portfolio-approach where project deliverables contribute to a subsequent integrated health solution. It will also help partners develop skills through training activities (in collaborative R&I actions) and contribute to retaining talents in Europe.

---

<sup>91</sup> NHS Digital has recently published its new framework that sets out the core standards on technology and data by which all IT systems and digital services in the NHS will need to abide: <https://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards>

**Coordination and Support Actions** are foreseen to help integrate the fragmented health R&I landscape through the development of a dedicated collaboration platform. This is an essential step towards building a well functioning health R&I ecosystem in Europe. These actions will help exchange existing knowledge, co-design new innovative projects, drive collaborative R&I actions and ultimately strengthen the EU's capacity to respond to public health challenges. Coordination and support actions can provide a useful means to conduct policy dialogues around ethics, standardisation and regulation. However, more specific external actions may be needed to cooperate with existing external networks and programmes, if standardisation for health data exchange (e.g. with Connecting Europe Facility/eHDSI) or regulatory science collaboration (e.g. with Heads of Medicines Agencies, EUnetHTA and Competent Authorities for Medical Devices) is needed.

### Directionality and additionality required

This functionality relates to the criteria "Common strategic vision of the purpose of the European Partnership" and "Creation of qualitative and significant quantitative leverage effects". The former highlights the importance of ensuring that all participating stakeholders have a common understanding of the purpose of the policy intervention and the intended direction of the R&I activity. The leverage effects relate to spillover effects from the knowledge gained as well as the crowding-in effects on private investments in R&I – both among participating stakeholders and in the broader community, and/or the pooling of resources from EU Member States.

The objectives of the initiative are ambitious and these clearly indicate the need for more holistic solutions for strategic unmet public health needs not served by industry. This requires significant alignment of all actors involved in the health value chain towards the common objectives. Actors need to bring together their specific scientific, technical and contextual expertise; skills; knowledge; facilities and investments so that the initiative succeeds. It also requires a long-term strategic vision and committed partners working in collaborative R&I projects to make a step change in accelerating the development of innovations in specific health and disease areas. A strategic R&I agenda and roadmap are therefore needed so that all actors have a clear understanding of how the various elements of the initiative will fit together in a coherent manner.

When research agendas, expectations and commitments are aligned across public and private stakeholders, there is a real potential for sharing risks related to health R&I and attract additional resources. The Union's contribution to the initiative is expected to crowd-in additional (at least 50%) private sector contribution (in-kind or financial) that the industry would not have otherwise spent in strategic unmet public health areas. This type of commitment to pool resources however only happens beyond the horizon of individual projects and potentially requires long-term predictability and commitment to the joint research agenda.

#### 4.4.2 External factors

The proposed Regulation for Horizon Europe also identifies the need to consider "Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions" when assessing the case for a partnership. It concerns the potential for linkages with other relevant R&I initiatives proposed or planned for the forthcoming Framework Programme, at the EU level in the context of the MFF 2021-27, and beyond.

Two external factors are relevant for the success of the initiative: (i) the ability of the data and digitalisation agenda to reach all actors; and (ii) the development of a value assessment model of complex health innovations built on consensus and with the involvement of all interested parties. These factors point to the need to work with external regional and pan-EU networks and existing EU programmes.

In terms of digitalisation, the Digital Europe Programme should provide the necessary test and experimentation infrastructure and advanced digital skills for the validation and initial deployment of digital health innovations. The Connecting European Facility with its eHealth Digital Service Infrastructures (eHDSI) should provide the means to scale up these digital health services across EU Member States via cross-border (interoperable) health data exchange and related international standards.

Incentives and affordability of health innovations are essential for successful deployment of R&I outputs of the initiative. The academic and industry sectors cannot on their own develop a suitable model and strong engagement from external networks is needed. The Heads of Medicines Agencies,<sup>92</sup> EUnetHTA<sup>93</sup> and Competent Authorities for Medical Devices<sup>94</sup> are examples of established networks which should provide the necessary environment for this aspect of the initiative to succeed.

## 5 What are the available policy options?

In this chapter, we provide an overview of the key characteristics of the policy options for this initiative. The Horizon Europe regulations put forward three forms of European Partnerships that constitute the policy options for this initiative; standard Horizon Europe calls are a fourth option that also act as a baseline against which the three partnership options will be compared.

To ensure correct assessment of the different options and their effectiveness, it is crucial to take into consideration both the objectives and the functional requirements outlined in Section 4. The descriptions of the options in the sections below therefore focus on the implications of the options' characteristics for these functionalities. The options' characteristics related to the functionalities are listed in Section 4.4. A full description of the options is provided in Section 1.3 of the Common Part of the impact assessment.

### 5.1 Option 0: Horizon Europe calls (baseline)

Under this option, strategic programming for R&I in health will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through traditional open calls under the Health Cluster in Pillar 2 (Global Challenges and Industrial Competitiveness) and Pillar 3 Open Innovation in the Framework Programme.

Table 3: Key characteristics of Option 0

	Implications of option
<b>Enabling appropriate profile of participation (actors involved)</b>	<ul style="list-style-type: none"> <li>The Commission would need to consult extensively with a wide range of stakeholders to translate the strategic R&amp;I agenda for health into annual work programmes.</li> <li>It would allow sufficient time for forming matching consortia of public and/or private actors in ad hoc combinations, from academia and industry (including SMEs) to regulators/HTA bodies, health care providers and patients.</li> </ul>

<sup>92</sup> The Heads of Medicines Agencies (HMA) is a network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. The HMA co-operates with the European Medicines Agency (EMA) and the European Commission in the operation of the European medicines regulatory network and it is a unique model for cooperation and worksharing on statutory as well as voluntary regulatory activities.

<sup>93</sup> EUnetHTA is a network for Health Technology Assessment (HTA) across Europe; it contributes information to HTA and supports collaboration between national and regional HTA bodies in Europe.

<sup>94</sup> Competent Authorities for Medical Devices is umbrella group, under which the national competent authorities in the EU work to enhance the level of collaborative work in what is a single market for medical devices.

	Implications of option
	<ul style="list-style-type: none"> <li>• Call specification could reflect the need for an evolving profile of participation, with different project consortia forming at different stages to take different types of activity forward.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (<i>activities</i>)</b>	<ul style="list-style-type: none"> <li>• Implementation would rely on standard infrastructure underpinning the open calls procedure, drawing on resources of executive agencies and Commission IT systems.</li> <li>• Calls could cover a range of activities<sup>95</sup>: collaborative R&amp;I and/or innovation actions, as well as coordination and support actions could support the objectives of the health initiative.</li> <li>• Transparency and open publication of results would ensure their availability and accessibility to interested parties.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (<i>directionality</i>)</b>	<ul style="list-style-type: none"> <li>• Annual work programmes developed through the comitology process are expected to cover a broad range of health issues.</li> <li>• R&amp;I activity is expected to focus primarily on the needs of the public sector, with fundamental discovery research prioritised.</li> <li>• Projects delivered within and across calls may not synergise and critical mass for addressing priorities may be limited.</li> <li>• Industry participation would increasingly be required for clinical research (beyond pre-clinical studies), demonstration activities and where continuity with the IMI JU is desired.</li> <li>• Annual work programmes could respond to emerging R&amp;I needs and new technological developments in health over time but the process is less agile to adapt to unforeseen changes.</li> <li>• Commission input into specification and oversight of calls would help to ensure alignment with overarching policy objectives but full integration with other programmes would require additional coordination.</li> </ul>
<b>Securing leveraging effects (<i>additionality</i>)</b>	<ul style="list-style-type: none"> <li>• EU grant funding would be the dominant financial contribution to projects, attracting mainly academic and SME researchers and other public sector organisations.</li> <li>• No expectation of significant in-kind or financial contribution from industry, with lower level of long-term financial commitment available to strategic areas.</li> </ul>

Source: Technopolis Group

## 5.2 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 European Commission and the private and/or public partners. It would provide for focused input from partners into the determination of the R&I agenda while continuing to rely on the Commission and/or executive agencies for administration. At the same time, while it would allow for flexibility in the stakeholder

<sup>95</sup> DG RTD (2018) Horizon Europe Impact Assessment. A New Horizon for Europe.

profile, 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 commitments.

Table 4: Key characteristics of Option 1

	Implications of option
<b>Enabling appropriate profile of participation (<i>actors involved</i>)</b>	<ul style="list-style-type: none"> <li>• The partnership would need to consult with industry sector representatives and a wide range of stakeholders to ensure that the strategic R&amp;I agenda, and ultimately the annual work programmes, were aligned with industry and strategic unmet public health needs.</li> <li>• 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.</li> <li>• It would offer the flexibility to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (<i>activities</i>)</b>	<ul style="list-style-type: none"> <li>• Implementation would rely on standard administrative infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems.</li> <li>• Calls for proposal would be published in the annual work programmes of Horizon Europe.</li> <li>• Calls could cover a range of activities<sup>96</sup>: collaborative R&amp;I and/or innovation actions, as well as coordination and support actions supporting the objectives of the health initiative.</li> <li>• Transparency and open publication of results would ensure their availability to interested parties.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (<i>directionality</i>)</b>	<ul style="list-style-type: none"> <li>• Proposals for call topics by partnership members for integration in the Horizon Europe annual work programmes are subject to further input from MS (comitology) and Commission services.</li> <li>• The partnership would be responsible for ensuring that priorities for Horizon Europe open calls were specified in line with the partnership's long-term common strategic R&amp;I agenda.</li> <li>• For partnership members this would provide predictability about open call topics. For industry, it would allow for alignment with their investment paths and lowering some of the associated risks, and for public actors it would provide sufficient lead time to inform national stakeholders about EU investments and coordinate their R&amp;I efforts at the national level.</li> <li>• R&amp;I activity would nevertheless be likely to focus on the medium-term needs of industry and public stakeholders; expected to cover a range of problem areas.</li> <li>• Industry participation would increasingly be required for clinical research (beyond pre-clinical studies), demonstration activities and where continuity with the IMI JU is desired.</li> </ul>

<sup>96</sup> DG RTD (2018) Horizon Europe Impact Assessment. A New Horizon for Europe.

	Implications of option
	<ul style="list-style-type: none"> <li>Health Programme Committee would need to ensure alignment with overarching policy objectives and coordination with related programmes.</li> </ul>
<b>Securing leveraging effects (<i>additionality</i>)</b>	<ul style="list-style-type: none"> <li>Aspirations for partners’ contributions would need to be clearly defined at the outset, in line with the level of predictability of open call topics.</li> <li>The Union contribution to the partnership may be defined for the full duration, while the expected in-kind contributions from the private sector would need to be identified in the annual work programmes.</li> </ul>

Source: Technopolis Group

### 5.3 Option 2: Co-funded European Partnership

The Co-funded Partnership is based on a *Grant Agreement* between the Commission and the consortium of partners resulting from a call for proposal for a programme co-funded action implementing the European Partnerships in the Horizon Europe Work Programme.

Table 5: Key characteristics of Option 2

	Implications of option
<b>Enabling appropriate profile of participation (<i>actors involved</i>)</b>	<ul style="list-style-type: none"> <li>Partners could include any national funding body, governmental research organisation or other types of actors such as charities and foundations.</li> <li>Industry or private sector entities and associations cannot be partners.</li> <li>Countries would need to have substantial national R&amp;I programmes related to innovation in health to participate, so there might be limited participation from all MS.</li> <li>Only legal entities from countries that are part of the consortium of partners could apply to calls launched by the partnership, under national rules.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (<i>activities</i>)</b>	<ul style="list-style-type: none"> <li>Activities could range from R&amp;I, pilot, deployment actions to training and mobility, dissemination and exploitation, conducted according to national programmes and rules.</li> <li>Implementation would be either by the partners via institutional funding programmes, or by ‘third parties’ following calls for proposals.</li> <li>The scale and scope would depend on the participating programmes. The resulting funded R&amp;I actions are expected to be smaller in scale than FP projects.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (<i>directionality</i>)</b>	<ul style="list-style-type: none"> <li>The partners and the EC would agree the strategic R&amp;I agenda/roadmap while the annual work programme drafted by the partners would have to be formally approved by the EC.</li> <li>Objectives and commitments would be set out in the Grant Agreement.</li> <li>Coherence among partnerships and with the annual work programme of the FP could be achieved by the partners and EC.</li> </ul>

	Implications of option
	<ul style="list-style-type: none"> <li>Strong synergies with national/regional programmes and activities could be achieved owing to the central role of MS in developing the R&amp;I agenda and work programme. However, synergies with other European programmes or industrial strategies would be limited.</li> </ul>
<b>Securing leveraging effects (additionality)</b>	<ul style="list-style-type: none"> <li>Leveraging investment from industry/private sector would be unlikely as they would not have a say in the decision making.</li> </ul>

Source: Technopolis Group

## 5.4 Option 3: Institutionalised European Partnership

### 5.4.1 Institutionalised Partnerships under Art 185 TFEU

Article 185 of the TFEU is a complex arrangement and is based on a Decision by the European Parliament and Council and implemented by dedicated structures created for that purpose. It allows the Union to participate in programmes jointly undertaken by MS and Associated Countries.

Table 6: Key characteristics of Option 3: Institutionalised Partnership Art 185

	Implications of option
<b>Enabling appropriate profile of participation (actors involved)</b>	<ul style="list-style-type: none"> <li>Partners could include MS and Associated Countries, but not industry/private sector.</li> <li>Non-associated third countries could only be included as partners if foreseen in the basic act and subject to conclusion of dedicated international agreements.</li> <li>Participating countries would need to have substantial national R&amp;I programmes for innovation in health.</li> <li>By default, FP rules would apply for eligibility for funding/participation, but subject to derogation only legal entities from Participating States would probably be able to apply to calls launched by the partnership, under national rules.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (activities)</b>	<ul style="list-style-type: none"> <li>All Horizon Europe's standard actions from R&amp;I to uptake could be supported.</li> <li>Subject to derogation, implementation could be based on national rules.</li> <li>Integration of national and Union funding for the joint funding of projects would be possible.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (directionality)</b>	<ul style="list-style-type: none"> <li>The partners and the EC would agree the strategic R&amp;I agenda/roadmap while the annual work programme drafted by the partners would have to be formally approved by the EC.</li> <li>The objectives and commitments would be set out in the legal base. This includes the obligation for financial contributions.</li> <li>Coherence among partnerships and with the annual work programme of the FP can be ensured by the partners and EC.</li> </ul>



	Implications of option
	<ul style="list-style-type: none"> <li>Potentially, strong synergies with national/regional programmes and activities as well as with other programmes could be achieved, but not with industrial strategies.</li> </ul>
<b>Securing leveraging effects (<i>additionality</i>)</b>	<ul style="list-style-type: none"> <li>Leveraging investment from industry/private sector would be unlikely as they would not be directly involved in the partnership.</li> </ul>

Source: Technopolis Group

#### 5.4.2 Institutionalised Partnerships under Art. 187 TFEU

An Institutionalised Partnership established under Article 187 of TFEU would provide a structured framework for bringing together the capabilities of all stakeholders contributing to health-related R&I under Horizon Europe. This would include dedicated administrative resources to support the development of the strategic R&I agenda for the whole duration of Horizon Europe and legally binding funding arrangements.

Table 7: Key characteristics of Option 3: Institutionalised Partnership Art 187

	Implications of option
<b>Enabling appropriate profile of participation (<i>actors involved</i>)</b>	<ul style="list-style-type: none"> <li>It would allow for the integration of the needs of all relevant industry sectors and public actors in the specification and expected delivery mechanism of the common strategic R&amp;I agenda.</li> <li>It would provide a forum for broad stakeholder consultation on strategic R&amp;I priorities and annual work programmes, ensuring alignment with industry and public health needs.</li> <li>Eligibility for participation and funding follows by default the rules of the FP, nevertheless the basic act may foresee broader participation, e.g. international actors from third countries.</li> <li>It has a clearly defined membership structure from the outset, but it might nevertheless be possible to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (<i>activities</i>)</b>	<ul style="list-style-type: none"> <li>The partnership would take an integrated approach towards establishing a dedicated legal entity with responsibility to coordinate the specification of R&amp;I activity, manage implementation of calls, monitor key indicators and report on the emerging results.</li> <li>The work programme could build on learnings and achievements of the IMI JU, but not be constrained by the current programme, to ensure new technology areas can be effectively integrated to achieve maximum impact for the initiative.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (<i>directionality</i>)</b>	<ul style="list-style-type: none"> <li>The partnership would jointly be responsible for the development of its work programme, in line with the R&amp;I priorities identified by the industry and approved by the Commission.</li> </ul>

	<ul style="list-style-type: none"> <li>• The work programme would be closely aligned with the medium to long-term strategic needs of industry and the public health sector, drawing on the perspectives of different stakeholders along the entire health and care innovation pathway.</li> <li>• 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.</li> </ul>
<p><b>Securing leveraging effects (<i>additionality</i>)</b></p>	<ul style="list-style-type: none"> <li>• The partnership members would have a strong commitment to achieving the strategic objectives of the initiative.</li> <li>• A legally binding funding arrangement would be defined at the outset, with the Union providing 50% of resources to R&amp;I activities through financial contribution and private sector partners providing (at least) 50% of the resources through mainly in-kind contribution but potentially also financial resources.</li> </ul>

Source: Technopolis Group

### 5.5 Options discarded at an early stage

The Co-Funded Partnership and Institutionalised Partnership created under Article 185 are not relevant for this impact assessment because they focus on public-to-public cooperation and do not allow for participation of industry and private sector stakeholders, which will be essential for meeting the IHI’s objectives. Our comparative analysis will therefore focus on a three-way comparison of the baseline option, Co-programmed European Partnership and an Institutionalised European Partnership based on Article 187 of the TFEU.

## 6 Comparative assessment of the policy options

### 6.1 Assessment of effectiveness

Based on the intervention logic, the initiative aims to deliver scientific, economic/technological and societal (including environmental) impacts through a set of pathways (Section 4.3), which require a set of critical factors in place to be achieved in the best possible way (Section 4.4).

This section assesses the extent to which each retained policy option has the potential to allow the attainment of the likely impacts in the scientific, economic/technological and societal sphere (Chapter 5). At the end of each section we summarise the outcomes of the assessment by assigning a non-numerical score to each option for each impact desired.

The assessments in this section set the basis for the comprehensive *comparative* assessment of all retained options against all dimensions in Section 6.4. Table 8 lists the desired impacts in the three impact areas.

Table 8: Likely impacts of the initiative

Impact area	Likely impacts
<p><b>Scientific impact</b></p>	<p>Strengthened EU skills and capacity in health research and innovation</p>
	<p>EU-wide cross-sectoral health research and innovation ecosystem created</p>
	<p>New scientific paradigms established providing the foundation for innovative health technologies</p>

Impact area	Likely impacts
<b>Economic / technological impact</b>	Increased productivity and growth of health industry, including SMEs
	Globally competitive and sustainable EU health industries
	More highly skilled jobs in the EU health industry, healthcare and public sector
	Better, safe and affordable health technologies, tools and digital solutions for health
	Sustainable and efficient healthcare systems in the EU
	Increased level of public and private investments into strategic unmet public health needs
<b>Societal impact</b>	Improved health promotion and disease prevention in priority disease areas
	Contribution to effective healthcare systems meeting public health needs
	Improved health outcomes and wellbeing in priority disease areas (SDG3)
	Reduced health inequalities and improved access to high quality healthcare in priority disease areas (SDG 10)
	Reduced need for travel impacting on climate (SDG 13)

Source: Technopolis Group

### 6.1.1 Scientific impacts

#### Option 0: Horizon Europe calls (baseline)

Horizon Europe is large in scale and its regular calls provide the opportunity for broad collaborative R&I across a wide-range of disciplines and application areas. Successive Framework Programmes have invested widely in health-related R&I, mainly through its Health programme. FP7 funded over 1000 projects for a total project costs of €6.4 billion (without IMI).<sup>97</sup> The majority of the projects (73%) were funded under the small- or medium-scale focused research projects funding instrument, with large-scale integrating projects representing only 13% of projects overall. The main beneficiaries of FP7 Health were academia and public research organisations, representing 73% of all participants and 75% of the total project costs. In contrast, the private sector was made up of about one fifth of all participants, mainly SMEs. Investment under Horizon 2020 into health (SC1: Health, Demographic Change and Wellbeing) increased, yet participation of large companies remains low. It is also very rare to find multiple companies in a research project funded through regular calls and therefore missing out on the opportunity to link up SMEs with innovative concepts with large companies that have the resources to bring solutions to market.

This option is therefore expected to have good potential to *strengthen EU skills and capacity in health research and innovation* but due to the aforementioned limitations in terms of participant types, despite openness and flexibility, the full potential of this impact dimension is not achievable.

---

<sup>97</sup> European Commission (2017) Ex-post evaluation of the health theme in FP7 (2017). Available at: <http://doi.org/10.2777/70014>

Horizon Europe will continue to provide opportunities for broad collaboration across research; however the average scale of the projects, both in terms of budget and time available, partly restricts the challenges research projects under regular calls can tackle. For FP7 Health,<sup>97</sup> the average EU contribution per project was €4.8m with an average of 11 participants; nevertheless regular calls also supported 132 large-scale integrating projects with an average EU contribution per project of €11.4m. This shows that while there are no formal limits on project size and participation level, regular calls may not be able to support the scale and scope of projects expected for the IHI.

Further, while call themes have extensive input from the public sector through the comitology process (possibly leading to a low level of directionality), input from industry is very limited. Other factors hindering private sector engagement include the perceived success rate of funding via regular calls and the protracted time from call publication to the eventual project start. The overall success rate for FP7 Health<sup>97</sup> projects was 20%, dropping to 13% for horizontal topics for collaborative projects. This historical rate is however not a guide, target or legal requirement. There is also an expectation of peer-reviewed publications and full access to research outputs which would be seen by industry as unfavourable to accelerated innovation and technology development. Taken together, regular calls (even with coordination and support actions) cannot integrate fragmented R&I efforts at the required level, and the various industry sectors foreseen to participate are unlikely to use this mode of implementation. Therefore the anticipated impacts from *the creation of an EU-wide cross-sectoral health R&I ecosystem* would be low.

Regular calls under Horizon Europe are expected to lead to many exploratory, discovery science projects, bringing together the best in academia, public research organisations and SMEs. These research projects attract scientific excellence and can lead to the elucidation of mechanisms of various health and disease conditions, and likely to major fundamental discoveries. Therefore, there would be a high potential to *establish new scientific paradigms*.

These new scientific paradigms provide the basis for further R&I but by themselves will not deliver implementable complex health solutions. For that, a more strategic approach is needed, with 'portfolio-level' thinking, directionality towards common objectives and alignment of individual projects through coordination. Meeting scientific objectives should however also include advancing regulatory science and developing novel economic models, which are harder to achieve through disparate research projects. In fact, FP7 Health projects involved only 5% participation by regulators and other public bodies<sup>97</sup> (excluding research and education organisations), limiting the direct regulatory understanding and acceptance of new research evidence.

### **Option 1: Co-Programmed**

The Co-Programmed Partnership (CPP) will rely on concerted activity of public and private partners for developing a joint Strategic Research and Innovation Agenda with medium-term priorities. Therefore, the partnership is expected to aim at accelerating the development of health technologies to meet unmet public health needs. Calls may shift to some degree towards industry applications, except where scientific goals also constitute commercially important markets.

In terms of openness and flexibility, the innovative health CPP will be able to attract broad communities and a diverse set of actors with differing capacities and capabilities during the timeframe of the initiative. It is particularly constructive to working across the public/private divide and engage health professionals, health authorities, patient organisations and standards bodies to work towards common objectives. It is also expected that private research performing organisations (both SMEs and some larger companies) and other strategic partners will be engaged to some extent according to the medium-term strategic research direction. While the predictability of research funding is increased, the

calls still constrain industry to participate at full scale (especially the larger companies) due to the limited directionality achievable through the comitology process. This option therefore provides good potential to *strengthen EU skills and capacity in health research and innovation* but would not reach the full potential of this impact dimension.

The CPP will likely focus on creating new cross-sectoral networks and opportunities for sharing expertise, resources and new knowledge through training and collaborative research projects. Therefore, it has good potential to *create EU-wide cross-sectoral health R&I ecosystem*.

The CPP would likely succeed in exploring major scientific questions, as well as those that advance regulatory science and develop novel economic models, to a great extent. By aligning with various EU strategies, research projects would attract scientific excellence and achieve significant increase in our understanding of various health and disease conditions. Therefore under this option there would be a high potential to *establish new scientific paradigms providing the foundation for innovative health technologies*.

### Option 3: Institutionalised Art 187

The Institutionalised Partnership (IP) has its long-term priorities enshrined in a Strategic Research and Innovation Agenda (SRIA) proposed by industry after broad stakeholder consultation. It targets pre-competitive research and accelerating the development of health technologies and applications where the unmet public health need is the highest but where industry would not act by itself. The IP has full responsibility for developing and implementing the annual work programme without using the comitology process. The Commission approves the SRIA and the annual work programmes (including calls for proposals) via its representatives in the Governing Board.

This option ensures the highest level of integration of stakeholders and focus on strategic research questions to meet the objectives of the initiative. With high level of directionality, the strategic and potentially a 'portfolio-level' approach enhances the chance to integrate the currently disparate technologies of the various industry sectors and create a multi-stakeholder initiative that shares expertise, resources and knowledge for health innovation. The IP thus has a unique opportunity to break down silos across the entire value chain. It needs however to carefully balance the needs of the different industry sectors: those with long product development timelines and high R&D investment (typically the pharmaceutical sector) and those with shorter product development timelines and low R&D investment (typically the MedTech sector). It is also important to provide support to SMEs so that they are able to link up with larger industry players and contribute with their own scientific ideas to the partnership. In addition, there are other stakeholders whose play a role in various defined phases of the R&I process as discussed above. This would translate into high potential for both *strengthened EU skills and capacity in health research and innovation* and contributing to the *creation of an EU-wide cross-sectoral health R&I ecosystem*.

This should, in principle, result in an increase in the relevance and quality of the portfolio of projects. There is however also a risk that the partnership calls will be 'over-specified' and expedited and as a result they will not attract the broadest array of applicants or any 'unorthodox' scientific proposals. The more top-down approach even with an optimal governance structure and high level of directionality would not be able to ensure simultaneously that the highest scientific excellence is attracted. This would lead to good, but not high, impact potential that this option generates a radical breakthrough in our understanding of the mechanisms of health and disease and *establishing new scientific paradigms providing the foundation for innovative health technologies*.



**Interviewees** indicated that regular calls would be effective at achieving scientific impacts but would have a more limited scope due to budget and timeline constraints. It was felt that 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.

In the **feedback to the inception impact assessment**, the majority of the 9 respondents from academic/research institutions agreed that an IP would be the preferred option. They felt that this option would enable a long-term commitment of key stakeholders and, in agreement with comments made during the **interviews**, would ensure continuity of research ideas.

There was a strong agreement across all stakeholder groups in the **open public consultations** that scientific impacts would be very relevant under an Institutionalised Partnership. Specifically 74% (78 of 105) and 76% (80 of 105) felt that 'New scientific knowledge and reinforcement of EU scientific capabilities' and 'Scientific collaboration networks' respectively, were very relevant impacts to deliver.

## Summary

Table 9, below, lists the scores we assigned for each policy option based on the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 9: Overview of the options' potential for reaching the scientific impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 187
Strengthened EU skills and capacity in health research and innovation	++	++	+++
EU-wide cross-sectoral health research and innovation ecosystem created	+	++	+++
New scientific paradigms established providing the foundation for innovative health technologies	+++	+++	++

Notes: Score +++ : Option presenting a *high* potential; Score ++: Option presenting a *good* potential; Score +: Option presenting a *low* potential

Source: Technopolis Group

### 6.1.2 Economic/technological impacts

#### Option 0: Horizon Europe calls (baseline)

In the previous section on scientific impacts, it was discussed that under this option, the private sector involvement would be limited. Industry participation (of small, medium and large enterprises) is however essential to progress innovative assets closer to deployment in the health and care sector and international markets. The primary goal of the initiative, namely to integrate currently disjointed components of drugs, devices and software into real integrated health solutions through long-term strategic planning would not be achieved. The low level of industry participation would result in a low level of 'crowding-in'

effects and additionality, leading to *low potential for achieving most technological and economic impacts*.

For example, without the development of tools, technologies and digital solutions, it is hard to stimulate increased productivity and growth of the EU health industry (including SMEs), and reach global competitiveness. Equally, without medium to long-term commitment and industry sharing relevant health data with the academic and public (regulatory) sector, health R&I in strategic areas cannot be effectively de-risked. This will impede tackling unmet public health needs currently not addressed by industry and the burden on the healthcare systems will remain.

It should however be noted that the recent 'Fast Track to Innovation' programme under the Enhanced European Innovation Council pilot aims to attract industry sectors that normally do not participate in the FP and to shorten development time of innovations. Another EU initiative is the Future and Emerging Technologies (FET) Flagship that aims to bring together stakeholders to address grand challenges over a 10-year period (e.g. the Human Brain Project).

### **Option 1: Co-Programmed**

The SRIA developed in a CPP will have industry contribution and therefore the Horizon Europe work programmes are expected to have some technology focus mobilising interests from across the value chain, including the private sector. Leveraging effects through in-kind contribution would result in progress towards meeting economic and technological objectives.

In particular, openness under this option likely favours collaborative working between the private sector and various public authorities and HTA bodies, thus contributing to improved conditions for health R&I, new adapted tools and models for value assessment and de-risking in strategic areas. These have a good potential to translate into *increased level of public and private investments into strategic unmet public health needs*.

The CPP's reliance on Horizon Europe calls will place some limitation on directionality as the strategic direction must be decided through the comitology process and a broad consensus needed on the scale and timing of the work programme. It will nonetheless provide a platform for a portfolio of interrelated projects, helping to ensure an internally more coherent and determined response to the identified problems and defined objectives. From this perspective, the impact on *new highly-skilled jobs, increased productivity, growth of the health industry (including SMEs)* and developing *better, safe and affordable health technologies for health* will likely be good but a high potential for impact will not be possible without a dedicated implementation structure and a higher level of directionality.

The longer term prize of a *globally competitive and sustainable EU health industry* and contribution to *sustainable and efficient healthcare systems* would be beyond reach through the intermediate integration of stakeholders (especially across the industry sectors) in a CPP and hence the likely impact in these aspects remains low.

### **Option 3: Institutionalised Art 185 / Art 187**

The option to implement the initiative as an IP under Article 187 would result in the closest alignment of research agendas, pooling of resources (including those from non-EU countries) 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.

Given the strong need for innovative health solutions, both from the public health and EU competitiveness perspectives, we expect strong support for an IP from the stakeholders across the value chain. The Union funding levels combined with the high degree of

directionality would most likely attract commitment and leverage effects from the private sector, supporting long-term challenges and priorities. Balance of private and public members' needs would be ensured through extensive stakeholder consultations (and approved by the Governing Board).

An IP affords industry the safe environment, long-term horizon and certainty needed to tackle risky projects. It allows focus on technology integration for areas of strategic unmet public health needs. The IP therefore has high potential to develop *better, safe and affordable health technologies, tools and digital solutions* through significant technology convergence; data-driven approaches will lead to *increased productivity, growth and competitiveness in the health industry (including SMEs)*. *Creation of more highly skilled jobs not just in the private sector but across healthcare and public sector* is expected as a result of new health innovations reaching the market.

There is risk that the objective around developing economic models to assess market value would be seen as a 'push' from the industry and therefore public authorities and HTA bodies would not engage. However, better models – if ultimately implemented in real life settings – would result in a win-win for the public and private sector, and would lead to a shift into new areas of health innovation and eventually deployment of innovative solutions in the healthcare system.

There is also prior experience with public-private partnerships through the IMI and ECSEL. These JUs have the capacity to mobilise resources quickly to respond to changing challenges, and create new tools and platforms. They have the international visibility and 'brand' that opens doors to new collaborations and an IP on innovative health could achieve the same. Ultimately, under this option the initiative has high potential to contribute to *globally competitive and sustainable EU health industries*. Nevertheless, due to the time to market from pre-competitive R&I, only a 'good' level of impact is envisaged in terms of contributing to *sustainable and efficient healthcare systems in the EU*. It is also unclear if, in the longer term, the initiative would result in *increased level of public and private investments into strategic unmet public health needs*. Therefore, this impact is currently classed as having 'good' potential.



**Interviewees** indicated that investors would have more confidence contributing to a partnership with a higher degree of integration as seen in the IPs. In the **feedback to the inception impact assessment**, the majority of the 7 respondents from business associations commented that an

IP would be the most effective option to guarantee commitment from the different partners.

Out of the listed economic impacts in the **open public consultation**, the largest number of respondents across all stakeholder groups (77%, 81 of 105) indicated that the IP was very relevant to 'better, safe and affordable health technologies, tools and digital solutions for health'. This was also the case for 'highly skilled jobs' with the exception of 'other' stakeholders who comparatively felt this was less relevant. There was some disagreement between stakeholders from industry (business associations, company/business organisations) and non-private actors regarding the relevance of IPs to 'more innovative, sustainable and globally competitive health industries', with more of the 27 industry stakeholders finding this 'very relevant' compared to the 56 non-private actors whose responses were more varied.



## Summary

Table 10, below, lists the scores we assigned for each of the policy options, based on the assessments above and the support expressed by the different stakeholders.

Table 10: Overview of the options' potential for reaching the likely economic/technological impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 187
Increased productivity and growth of health industry, including SMEs	+	++	+++
Globally competitive and sustainable EU health industries	+	+	+++
More highly skilled jobs in the EU health industry, healthcare and public sector	+	++	+++
Better, safe and affordable health technologies, tools and digital solutions for health	+	++	+++
Sustainable and efficient healthcare systems in the EU	+	+	++
Increased level of public and private investments into strategic unmet public health needs	+	++	++

Notes: Score +++ : Option presenting a *high* potential; Score ++: Option presenting a *good* potential; Score +: Option presenting a *low* potential

Source: Technopolis Group

### 6.1.3 Societal impacts

#### Option 0: Horizon Europe calls (baseline)

Scientific breakthroughs in themselves do not lead to technological, economic and societal impacts. The EU FPs provide funding through regular calls for the best scientific ideas, but the scale and size of these individual projects do not allow 'pull through' of breakthrough discoveries in a timely manner, leading to unexploited societal potential of Health programme projects. In the absence of directionality and additionality, implementation under this policy option will translate to low potential for achieving societal impacts even in the longer term, considering that the 'intermediary' health technologies are not in place to *improve health promotion and disease prevention and consequently health outcomes in priority disease areas, or reduce health inequalities for people across the EU*. Nevertheless, regular calls may target very specific aspects of health R&I that would involve aspects of exploiting existing data and technologies to enable digital health innovations for remote and cross-border health services, reducing climate impact of associated travel. Individual projects under regular calls are however unlikely to lead to significant change without strong external coherence and the involvement of key actors over a more extended period of time.

#### Option 1: Co-Programmed

The CPP enables progress toward societal impacts outlined in the logic model for the initiative. As discussed above, openness under this option and potential for engaging the entire health value chain likely favours collaborative working between the private sector, public authorities and HTA bodies, thus having a high potential for contribution to *effective*

*healthcare systems meeting public health needs*. There would be good potential for delivering other societal impacts, including *improved health promotion and disease prevention*, possibly through working more closely with public sector organisations. However, without a longer term horizon and stronger integration of partners, progress towards some of the more challenging impacts, including *improved health outcomes and wellbeing for all*, would be unlikely. There could however be knowledge spillovers from collaborating across the public and private sectors, which should in turn, see public institutions, patients and regulators improve their processes for a more effective health care system.

### Option 3: Institutionalised Art 187

The scale and size of IP projects have the potential to enable faster 'pull through' of breakthrough discoveries towards societal impacts. With higher directionality and additionality, and through the development of better health technologies, implementation under this option presents high potential (in the long term) for impact on *improved health promotion, disease prevention, and health outcomes in priority disease areas*. In addition, exploiting data and digitalisation would have good potential to lead to *improved access to high quality healthcare* and rolling out digital health innovations in Europe. Further, digital health solutions could result in reduced need to travel to hospital (and hence less emissions) and effective healthcare systems that meet public health needs.



**Interviewees** indicated that a broad range of stakeholders was required to achieve societal impact and that IPs would be the most effective platform to create and sustain such a collaboration. The need for a diverse, cross-sectoral partnership was reiterated by NGOs in the **feedback to the inception impact assessment** as a key requirement for impact in relation to unmet health needs.

The majority of the 5 'other' respondents in the **feedback to the inception impact assessment** felt that IPs would be the only way to ensure that proper governance structures were in place. NGOs cited a good governance structure as a key characteristic of a successful partnership.

In the **open public consultation**, the largest number of respondents across all stakeholder groups indicated that the IP was very relevant to 'improved access to innovative, sustainable and high-quality health care' (78%, 82 of 105) and 'effective health services' (77%, 80 of 104). 'Improved patient experience' was seen as less relevant by stakeholders from academic/research institutes, small company/business organisations and the 'other' category.

### Summary

Table 11, below, lists the scores we assigned for each of the policy options based on the assessments above and the support expressed by the different stakeholders.

Table 11: Overview of the options' potential for reaching the likely societal impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<b>Improved health promotion and disease prevention in priority disease areas</b>	+	++	+++
<b>Contribution to effective healthcare systems meeting public health needs</b>	+	+++	++
<b>Improved health outcomes and wellbeing in priority disease areas (SDG3)</b>	+	++	+++
<b>Reduced health inequalities and improved access to high quality healthcare in priority disease areas (SDG 10)</b>	+	++	++
<b>Reduced need for travel impacting on climate (SDG 13)</b>	+	++	++

Notes: Score +++ : Option presenting a *high* potential; Score ++: Option presenting a *good* potential; Score +: Option presenting a *low* potential

Source: Technopolis Group

## 6.2 Assessment of coherence

### 6.2.1 Internal coherence

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

#### Option 0: Horizon Europe calls (baseline)

To deliver a step change in areas of unmet public health needs not currently addressed by industry requires high degree of internal coherence of the initiative: from developing a research agenda and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe.

Horizon Europe calls will routinely signal the existence of other major platforms, programmes and initiatives where there may be value in further cooperation or coordination, to share information and increase opportunities for synergy. Horizon Europe application guidelines invite bidders to reflect on such issues and the evaluation panels are also invited to consider the extent to which research applications have understood their position in the broader Horizon Europe portfolio.

Under this option, it will be challenging for individual collaborative R&I actions to identify linkages, opportunities for coordination and communication, and measures to enable the uptake of their health innovation with their limited budget. Horizon Europe will also not offer dedicated support for individual projects to put their outputs on the pathway to impact. This limitation may be significant if the initiative puts emphasis on achieving shorter term impacts.

Coordination and Support Actions can to some extent create a dedicated R&I collaborative platform, however, 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.

### Option 1: Co-Programmed

The innovative health CPP will define its strategy in consultation with key stakeholders across the public and private sectors to ensure a high degree of internal coherence within the SRIA and linkages to other initiatives within Horizon Europe. In addition, the implementation of its work programmes through Horizon Europe calls means it will align with and link to important parallel activities within the wider EU Research FP, as described above for the baseline option.

It is likely that under this option, Coordination and Support Actions can create a dedicated R&I collaborative platform and link to the (more strategic) collaborative research actions. Such support actions can also help cross-project activities further exploit synergies and enhance potential for impacts. Hence, under this option, there is good potential to achieve internal coherence.

### Option 3: Institutionalised Art 187

The structure of the IP enables a high degree of internal coherence: from developing a research agenda and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe. This is to minimise duplications and waste in 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 or EU-Africa Global Health. Results emerging from the innovative health IP will need to be implemented and scaled up in a complex European health environment and other health initiatives may prove complementary such as the large-scale innovation and transformation of health systems initiative and EIT Health. Finally, the Key Digital Technologies, Artificial Intelligence, Data and Robotics, and High Performance Computing partnerships would provide an environment that enables the IP to achieve its goals. The programme office will lead all coordination activities to ensure internal coherence. Hence, under this option there is a high potential to achieve internal coherence.



During the **open public consultation**, the majority of the 91 respondents across the stakeholder groups reported that it would be possible to rationalise the candidate IHI and its activities, and/or to better link it with other comparable initiatives. This contrasted with EU citizens where a large proportion of the 16 respondents did not feel this would be possible. A common explanation for this response was that it could increase the complexity of the partnership.

Nevertheless, in the **feedback on the inception impact assessment**, the overall opinion of stakeholders was positive, with business associations encouraging synergies between the different partnerships. 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.

#### 6.2.2 External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with EU-level programmes and initiatives beyond the Framework.

### Option 0: Horizon Europe calls (baseline)

Horizon Europe's work programmes are developed through a comitology process that involves several iterations of consultation with various key stakeholders, within other Commission's Directorate Generals and EU member states. Those exchanges will also involve discussions with other European and international actors in the health arena, which means the Health calls can be framed to maximise their complementarity with initiatives in the wider landscape, including other programmes under the MFF 2021-27 (e.g. Digital Europe Programme, Connecting Europe Facility) other key EU stakeholders (e.g. EUnetHTA, Heads of Medicines Agencies or regional networks) and research infrastructures (e.g. Elixir, BMBRI, EATRIS, ECRIN). However, it is unclear how those external programmes and networks could interact with a health initiative under Horizon Europe regular calls without the presence of a long-term dedicated strategy and central administrative infrastructure. Hence, under this option there is a low potential to achieve external coherence.

### Option 1: Co-Programmed

As described for 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's Directorate Generals and EU member states. Those exchanges will also involve discussions with other European and international actors in the health arena, which means the Health calls can be framed to maximise their complementarity with initiatives in the wider landscape, including other programmes under the MFF 2021-27 (e.g. Digital Europe Programme, Connecting Europe Facility) other key EU stakeholders (e.g. EUnetHTA, Heads of Medicines Agencies, Competent Authorities for Medical Devices, the EIB<sup>98</sup> and regional networks) and research infrastructures (e.g. Elixir, BMBRI, EATRIS, ECRIN). A major difference compared to the baseline option, the CPP can interact with external programmes and networks via a central administrative infrastructure (financed via CSA) to bolster its long-term dedicated strategy. Hence, under this option there is a good potential to achieve internal coherence.

### Option 3: Institutionalised Art 187

For the IP to meet its objectives (especially standardisation, demonstration, and developing a value-based assessment model) it needs to interact with other European and international actors in the health arena. It will include programmes under the MFF 2021-27 (e.g. Digital Europe Programme, Connecting Europe Facility) other key EU stakeholders (e.g. EUnetHTA, Heads of Medicines Agencies, Competent Authorities for Medical Devices or regional networks) and research infrastructures (e.g. Elixir, BMBRI, EATRIS, ECRIN). This interaction is greatly enhanced by the set-up of a programme management office that act as a single point of contact for all external programmes and networks. Hence, under this option there is a high potential to achieve external coherence.



The majority of respondents (86%, 78 of 91 respondents) from all stakeholder groups in the **open public consultation** reported that the candidate IHI would be able to link its activities with other comparable initiatives. In both the **interviews** and **open public consultation**, stakeholders stated that 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. ECSEL could provide digital support to ensure uniform data standards and methods. In the **feedback on the inception impact assessment**, research

<sup>98</sup> Ernst & Young and Technopolis Group (2019) Health Sector Study EU. Report for the European Investment Bank and European Commission DG SANTE. Available at: <https://eiah.eib.org/publications/attachments/report-health-sector-study-20180322-en.pdf>

infrastructures stressed the importance of leveraging the power and network of research infrastructures such as BBMRI, EATRIS and ECRIN. Stakeholders from research infrastructures reiterated this point during **interviews**.

## Summary

Table 12, below, lists the scores we assigned for each of the policy options based on the assessments above and the support expressed by the different stakeholders.

Table 12: Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<b>Internal coherence</b>	+	++	+++
<b>External coherence</b>	+	++	+++

Notes: Score +++ : Option presenting a *high* potential; Score ++: Option presenting a *good* potential; Score +: Option presenting a *low* potential

Source: Technopolis Group

### 6.3 Comparative assessment of efficiency

In order to compare the policy options under common standards, we developed a standard cost model for all 13 candidate Institutionalised Partnership studies. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.2.2.

Table 13, below, shows the intensity of additional costs against specific cost items for the various options as compared to the baseline, i.e. Option 0 (Horizon Europe calls). In this table we have taken into account that for Option 3 (Institutionalised Partnership) there would be moderate additional costs for setting up of a dedicated implementation structure seeing that such a structure is already existing in IMI JU. For Option 1 (Co-programmed), we did not consider an additional cost for the call and project implementation as MS would not be providing contributions.

Table 13: Intensity of additional costs for European Partnerships compared with Horizon Europe calls (for Partners, stakeholders, public and EC)

Cost items	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 187
<b>Preparation and set-up costs</b>			
Preparation of a partnership proposal (partners and EC)	0	++	++
Set-up of a dedicated implementation structure	0	0	++
Preparation of the SRIA / roadmap	0	++	++
Ex-ante Impact Assessment for partnership	0	0	+++

Cost items	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 187
Preparation of EC proposal and negotiation	0	0	+++
<b>Running costs (Annual cycle of implementation)</b>			
Annual Work Programme (AWP) preparation	0	+	+
Call and project implementation	0	0	+
Cost to applicants	0	0	0
Partners costs not covered by the above	0	+	+
Additional EC costs (e.g. supervision)	0	+	++
<b>Winding down costs</b>			
EC	0	0	+++
Partners	0	+	+

Notes: 0: no additional costs, as compared with the baseline; +: minor additional costs, as compared with the baseline; ++: high additional costs, as compared with the baseline; +++: very high additional costs, as compared with the baseline

Source: Technopolis Group

The scores related to the costs set out above will allow for a “value for money” analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4. For this purpose, in Table 14 where we provide the scores for the scorecard analysis, based on our insights and findings and based on the scores above, we assign a score 1 to the option with the highest costs and a score 3 to the lowest.

Table 14: Matrix on ‘overall costs’ and ‘cost-efficiency’

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 187
<b>Overall cost</b>	3	2	1
<b>Cost-efficiency</b>	3	3	2

Notes: Score 1 = Substantial additional costs, as compared with the baseline; score 2 = Medium additional costs, as compared with the baseline; score 3 = No or minor additional costs, as compared with the baseline

Source: Technopolis Group

We considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when we take into account financial leverage (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 Option 0 and the Co-Programmed policy options – and the least cost-efficient option– the Institutionalised

Partnership policy option. We have therefore assigned a score of 3 to the Option 0 and the Co-Programmed policy options for **cost-efficiency** and a score of 2 for the Institutionalised Partnership policy options.

It should be noted that the potential for the creation of crowding-in effects for industry has been taken into account when assessing the effectiveness of the policy options above.

#### 6.4 Comprehensive comparison of the options and identification of the preferred option

Building upon the outcomes of the previous sections, this section presents a comparison of the options' 'performance' against the three dimensions of effectiveness, efficiency and coherence.

In Section 6.4.1, we first compare the policy options against each other for each criterion in the effectiveness and coherence dimensions, resulting in a scorecard with scores from 1 to 3 where 3 stands for a substantially higher performance. Combined with the results from the comparative assessment for efficiency in Section 6.3, above, the final scorecard will allow for the identification of the preferred option in Section 6.4.2, taking all dimensions and criteria into account.

##### 6.4.1 Comparative assessment

#### Effectiveness

Regarding effectiveness to deliver on the scientific impacts, among the three options each has its distinct individual benefits. It is clear that while Option 0 has the highest potential to generate scientific excellence. Nevertheless, it is unlikely to be able to create critical mass and address systemic effects in priority health and disease areas and integrate not only the technology sectors but across actors the health value change. Option 1 would have similar potential to Option 0 to generate scientific excellence, and through its balanced stakeholder membership a higher potential to enable a health innovation and learning ecosystem. Option 3 would have the highest potential to integrate fragmented health research and innovation efforts across actors and technology sectors, nevertheless its more directive approach would make it less likely to deliver breakthroughs in new proof of concepts related to health and diseases states. The scorecard below reflects these individual attributes.

Regarding effectiveness to deliver on the economic/technological impacts, Option 0 performs the least well, considering the low level of directionality and thus limited engagement of industry in regular calls. In comparison, Option 1 performs better on most impact dimensions as industry is involved in developing the medium-term strategy for the partnership. Nevertheless, the predictability and engagement are not as high as in Option 3 where the highest impacts are expected. Even so, contribution to sustainable health systems and increase in investment into strategic areas is only marginally improved compared to the baseline option. The scorecard below reflects these individual attributes.

Regarding effectiveness to deliver on societal impacts, Option 0 perform again the least well, considering that it is the least likely to garner critical mass around a few strategic health and disease areas and accelerate the speed of health innovation. Option 1 is expected to perform better but ultimately it is Option 3 that has the highest potential to impact on key areas of health innovation. The scorecard below reflects these individual attributes.

#### Coherence

Regarding internal coherence, there is a clear trend of improvement from Option 0 through Option 1 to Option 3, as policy options increasingly enhance the initiative's strategic focus and ability to create cross-project synergies through a portfolio approach.



Regarding external coherence, it is also following a similar trend to internal coherence, Option 3 having the highest potential to ensure interaction with other initiatives, programmes and networks through a dedicated implementation structure. For final scores, see Table 15 below.

Table 15: Scorecard of the policy options

	Criteria	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 187
<b>Effectiveness</b>	<b>Scientific impacts</b>			
	Strengthened EU skills and capacity in health research and innovation	2	2	3
	EU-wide cross-sectoral health research and innovation ecosystem created	1	2	3
	New scientific paradigms established providing the foundation for innovative health technologies	3	3	2
<b>Effectiveness</b>	<b>Economic/technological impacts</b>			
	Increased productivity and growth of health industry, including SMEs	1	2	3
	Globally competitive and sustainable EU health industries	1	1	3
	More highly skilled jobs in the EU health industry, healthcare and public sector	1	2	3
	Better, safe and affordable health technologies, tools and digital solutions for health	1	2	3
	Sustainable and efficient healthcare systems in the EU	1	1	2
	Increased level of public and private investments into strategic unmet public health needs	1	2	2
	<b>Societal impacts</b>			
	Improved health promotion and disease prevention in priority disease areas	1	2	3
	Contribution to effective healthcare systems meeting public health needs	1	3	2
	Improved health outcomes and wellbeing in priority disease areas (SDG3)	1	2	3
	Reduced health inequalities and improved access to high quality healthcare in priority disease areas (SDG 10)	1	2	2

	Criteria	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 187
	Reduced need for travel impacting on climate (SDG 13)	1	2	2
Coherence	<b>Internal coherence</b>	1	2	3
	<b>External coherence</b>	1	2	3
Efficiency	<b>Overall cost</b>	3	2	1
	<b>Cost-efficiency</b>	3	3	2

Notes: Scores for effectiveness and coherence: 3 = *substantially higher performance*; 2 = *higher performance*; 1 = *lower performance*. Scores for efficiency: 1 = *substantial additional costs*, as compared with the baseline; 2 = *medium additional costs*, as compared with the baseline; 3 = *No or minor additional costs*, as compared with the baseline

Source: Technopolis Group

#### 6.4.2 Identification of the preferred option

Regarding scientific effectiveness, the scorecard in Table 15 shows that overall Option 3 performs marginally better than Option 1 due its ability to integrate industry sectors better and as a result strengthen EU skills and capacity as well having the highest potential to contribute to the creation of a health R&I ecosystem. Option 0 while performs well on purely addressing scientific paradigms, due to the low directionality and weak industry engagement, it cannot provide a platform for cross-sectoral stakeholder platform effectively.

Regarding economic effectiveness, the scorecard clearly indicates that Option 3 preforms significantly better than either of the alternative policy options. This result is due to the ability of an Institutionalised Partnership to provide strong directionality and additionality and through a dedicated implementation mechanism 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 through the acceleration of development of health innovations in health and priority disease areas. In terms of contribution to a sustainable and efficient healthcare system, Option 3 has only a marginal benefit.

Regarding societal effectiveness, the scorecard shows that Option 3 is most likely to deliver on needs of the public system provided the stakeholder consultation, prioritisation exercises and call implementation mechanism are optimally set up. This result is due to the ability of an Institutionalised Partnership to progress assets much faster and eventually integrate those into health products and services that can impact of patients and consumers.

Regarding coherence, the scorecard shows that Option 3 is most likely to develop a coherent project portfolio to address the initiative's specific objectives and through the

dedicated implementation structure and EU partnership ensure the external coherence with other initiatives, programmes and networks.

Regarding efficiency, the scorecard shows that Option 0, the regular calls under Horizon Europe, require the lowest cost and achieve the most cost-efficient implementation as a result of 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). The highest cost and lowest cost-efficiency is attributed to Option 3, due to the need for setting up a dedicated implementation structure to support the thematic area. We consider however that much management learning can be transferred from the current IMI JU experience to optimise the set-up, running and discontinuation processes. In addition, Option 3 is best placed to carry forward and extend the know how, visibility and brand that had been built during the IMI JU period.

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

## **7 The preferred option**

### *7.1 Description of the preferred option*

The Institutionalised Partnership (Art 187) represents the preferred option for achieving the overall highest impacts in terms of effectiveness to deliver on the initiative's specific objectives, coherence and efficiency. It aims to build on and learn from the current IMI JU's management processes and extend its know how, visibility and brand. However, the new initiative will also bring about a step change in terms of facilitating the integration of disparate technologies from industry sectors currently not collaborating to a significant extent and accelerating the development of safe and effective health products and solutions for European patients, as part of the Partnership Area 1.

It was remarked that the IHI is agnostic to specific disease areas or stages at which it intends to intervene in the health and care pathways – by design. Nevertheless, it is important to recognise the tension between breadth and depth and coverage and impact. During the development of the SRIA with broad stakeholder consultation, it will be important to ask what would be feasible or realistic within the timeframe of the initiative and where the partnership can add the most value. Areas to consider are where industry has not and would not innovate on its own and where there is a clear need for a pre-competitive partnership. A prioritization exercise will need to consider disease burden in Europe as well as where strategic unmet public health needs lie. One of the key goals of the partnership and a unique opportunity is the integration of technology sectors (drugs, devices and software) and the creation of a health innovation ecosystem. This requires a careful assessment of where partners want to invest their limited resources. It should not, of course, require each and every project to have equal contribution from the pharma and MedTech sectors. The initiative should manage an active portfolio and design it in a way that considers associated risks in the process; portfolio projects should complement and build on each other, and in most cases, partnership members should co-design projects and transparently communicate (also with broader stakeholders) the intermediate results, success and challenges.

It should also be noted that the logic model would need to be tested further with the stakeholders in interactive workshops and amended if necessary. There are a number of assumptions in the final governance and implementation mode of the partnership that are currently unknown but may crucially influence the impact that can be expected from the partnership.

In Table 16, below, we indicate the alignment of the preferred option with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation. Seeing that 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, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Table 16: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
<b>Higher level of effectiveness</b>	<p>Institutionalised Partnership Art 187 provides the closest integration of key stakeholder groups across the value chain to ensure that the initiative can respond to the ambitious objectives corresponding to scientific, technological/economic and societal impacts. The implementation mode 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 contribute to the creation of a health R&amp;I ecosystem. According to the analysis presented, Institutionalised Partnership Art 187 would score significantly higher overall than the baseline policy option (traditional calls under Horizon Europe) and option 1 (Co-Programmed Partnership) in terms of effectiveness.</p>
<b>Coherence and synergies</b>	<p>Institutionalised Partnership Art 187 presents the most coherent choice to maximise synergies internally within the initiative (portfolio approach), within the EU R&amp;I landscape and beyond. The programme office provides dedicated administrative support for partners and project participants to exploit such synergies and further align roadmaps between initiatives, programmes and networks.</p>
<b>Transparency and openness</b>	<p>Institutionalised Partnership Art 187 aims to significantly expand partners involved from health-related industries, covering the full spectrum of pharmaceutical, vaccines, biotech and MedTech sectors (including diagnostics, medical devices, imaging and other digital industries), so that relevant but currently disparate technologies (drugs, devices and software) can be usefully integrated into innovative health solutions.</p> <p>The partnership will maximise its impacts by being open and transparent, involving all relevant public (including academic research community, patient and consumer groups, healthcare regulators, healthcare payers, healthcare providers and healthcare professionals) and private actors along the value chain, and ensuring a robust governance structure. Stakeholders may also be philanthropic organisations, charities, research infrastructures and product development 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 rules will ensure that the partnership is transparent.</p> <p>Since a 7-year horizon is a relatively long time in a fast-moving technological R&amp;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 roadmap, and implementation structures including an optimal governance, monitoring and management system.</p>
<b>Additionality and directionality</b>	<p>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. The approved SRIA ensures close alignment of research agendas to achieve a high-level of focus and directionality to meet the strategic unmet public health needs not served by industry. No other public or private initiative is able to coordinate a similar partnership at the European level above and beyond national interests.</p>

Criterion	Alignment of the preferred option
<b>Long-term commitment</b>	The expectation is that in the Institutionalised Partnership on Innovative Health under Art 187 the Union and partners will be committed to pool resources for the entire partnership period and at least 50% of the aggregated European Partnership budgetary commitments will represent financial and/or in-kind contributions from partners other than the Union.

Source: Technopolis Group

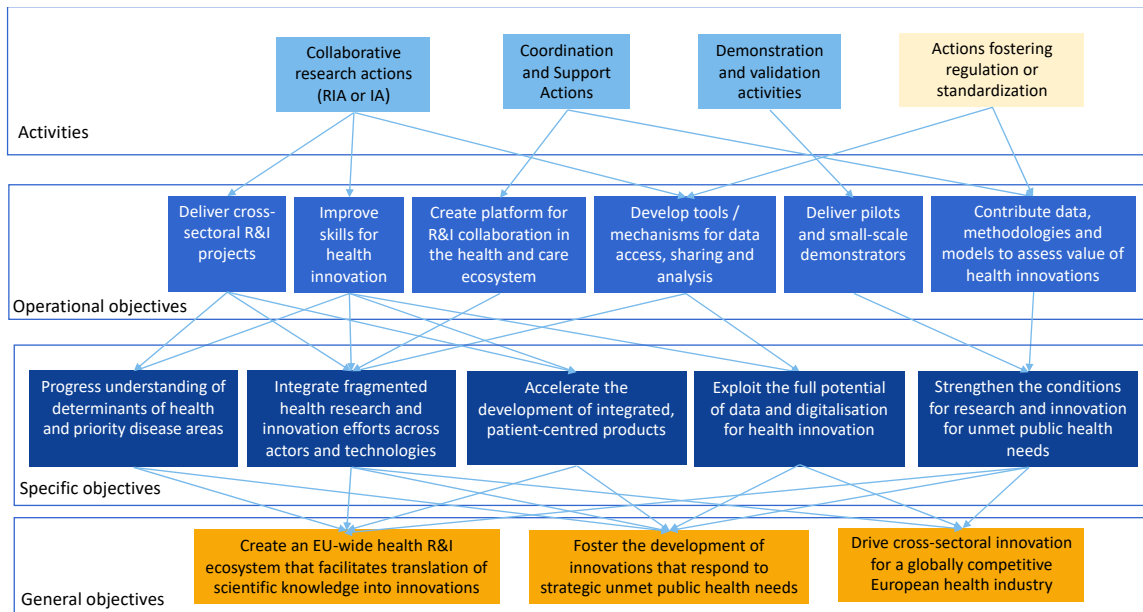
## 7.2 Objectives and corresponding monitoring indicators

Operational objectives Figure 9, below, 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 research and innovation activities, including those related to market, regulatory or policy uptake.” It also shows the links between the actions, operational objectives and the specific and general objectives of the initiative.

To elaborate, the operational objectives are to:

- Deliver cross-sectoral R&I projects for the development of integrated, patient-centred solutions and progress understanding of the determinants of health and disease
- Improve skills for health innovation in Europe
- Create a platform for R&I collaboration in health as a safe, pre-competitive space for brokering knowledge exchange, sharing ideas and resources across the various actors in the healthcare pathway e.g. academics, health industry sectors, healthcare payers, regulators, HTA bodies, and users
- Develop tools and mechanisms to enable better access, sharing and analysis of health-related data, e.g., ethical frameworks, common standards and protocols
- Contribute data, methodologies and economic models to better assess the value of complex health innovations for healthcare systems
- Deliver pilots and small-scale demonstration projects to test implementability of tools, models, methodologies and innovations generated in the initiative

Figure 9: Operational objectives of the initiative



Source: Technopolis Group

### 7.2.1 Monitoring indicators

Table 17 below represents monitoring indicators that could be used to track progress of the initiative towards its targeted impacts in addition to the ones identified for the Horizon Europe key impact pathways. Indicators represent either proxy measures (short and medium term) or metrics for long-term assessment of impacts beyond project end. Some of these indicators require further specifications with stakeholders involved in the development of the strategic R&I agenda and associated monitoring framework. Ideally, the framework would be implemented at the outset of the partnership and baseline data would be collected to understand before/after effects and the added value of the partnership. Annual data reporting requirements at least 5 years beyond the funded project period should be enshrined in the legal requirements and enforced accordingly.

Table 17: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact	Number of projects by participant type (academia, industry sectors, patients, healthcare professionals/organisations, regulators/HTA bodies)	Number of international co-authorships and cross-sector publications	New or improved scientific approaches/proof of concepts developed for progressing preventive, diagnostic and therapeutic innovations New tools and data shared outside of consortia partners for further research New taxonomies of diseases and new stratifications developed New networks formed/synergies with other programmes

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Technological / economic impact	<p>Share of projects bringing together representatives of two or more industry sectors</p> <p>Share of projects bringing together SMEs and large companies</p> <p>Share of projects addressing strategic unmet public health and care needs/priority health and disease areas</p>	<p>Number of assets progressed through key milestones</p> <p>New standards and common process adopted in international (regulatory) guidelines and in use</p> <p>Availability of independently scrutinised business plan for post project period to ensure continuity of research</p>	<p>Degree of increase in public and private investment in areas of strategic unmet public health needs (not addressed by industry previously)</p> <p>Number and types of innovations with regulatory approval/CE marking</p> <p>Number and types of innovations' cost-effectiveness demonstrated</p> <p>Number and types of innovations in practice or industry use</p>
Societal impact		<p>Number and type of innovations addressing strategic unmet public health needs</p>	<p>Implementation of new tools and models generated by projects</p> <p>Number and type of innovations available and accessible in Member States</p> <p>Changes of mortality rates / Number of lives saved/Patient experience improved - in priority disease areas</p>
Incl. Environmental/ sustainability impact		<p>Number and share of digital health innovations developed</p>	<p>Adoption of digital health innovations developed contributing to reduction in patient/health professional travel</p>

Source: Technopolis Group

## **Appendix A Bibliography**

Alttenstetter C. (2017) Medical Devices: European Union Policymaking and the Implementation of Health and Patient Safety in France

COCIR (2015) Outline of COCIR position towards IMI-2.

COCIR (2019) COCIR market data and trends – confidential paper

COCIR, EBE, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe (2019) Health PPP industry update – Draft 13 June 2019. Presentation.

Council of the European Union (2014) Council regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking. Official Journal of the European Union 169, p. 54-76.

Council of the European Union (2019) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe - the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination - Common understanding, Interinstitutional File: 2018/0224(COD) – available at: <https://www.consilium.europa.eu/media/38902/st07942-en19.pdf>

Davey, T., Meerman, A., Galán-Muros, V. et al. (2018) The state of university-business cooperation in Europe.

De Wilde S. et al (2016) Clinical development of gene- and cell-based therapies: overview of the European landscape. Molecular Therapy – Methods & Clinical Development 3

DG RTD (2018) Horizon Europe Impact Assessment. A New Horizon for Europe

DG RTD (2019) Inception Impact Assessment of the Analysis of the network structure of the current partnerships (Social Network Analysis) European Partnership on Innovative Health.

DG RTD (2019) Inception Impact Assessment of the candidate European Partnership on Innovative Health.

Ernst & Young and Technopolis Group (2019) Health Sector Study EU. Report for the European Investment Bank and European Commission DG SANTE. Available at: <https://eiah.eib.org/publications/attachments/report-health-sector-study-20180322-en.pdf>

EC (no date) New regulations. Available at: [https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)

EC (2014) Horizon 2020 in brief.

EC (2017) State of Health in the EU Companion Report. Available at: [https://ec.europa.eu/health/sites/health/files/state/docs/2017\\_companion\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2017_companion_en.pdf)

EC (2018) A New Horizon for Europe. Impact Assessment of the 9th EU Framework Programme for Research and Innovation

EC (2018) Precision Medicine. Targeted scenario N°14. Glimpses of the future from the BOHEMIA study.

EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report

EC (2019) State of Health in the EU. Companion Report 2019. Available at: [https://ec.europa.eu/health/sites/health/files/state/docs/2019\\_companion\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf)

EC (2019) Strengthening strategic value chains for a future-ready EU industry



EC (2019) Towards a sustainable Europe by 2030. Reflection Paper

EC DG EMPL (no date), Health care. Available at: <https://ec.europa.eu/social/main.jsp?catId=754&langId=en>

EC DG International Cooperation and Development (no date), The Sustainable Development Goals. Available at: [https://ec.europa.eu/europeaid/policies/sustainable-development-goals\\_en](https://ec.europa.eu/europeaid/policies/sustainable-development-goals_en)

EFPIA (no date) The Pharmaceutical Industry in Figures, Key Data 2018

EMA (2018) EMA Regulatory Science to 2025. Strategic reflection

European Commission (2017) A European One Health Action Plan against Antimicrobial Resistance (AMR). Available at: [https://ec.europa.eu/health/amr/sites/amr/files/amr\\_action\\_plan\\_2017\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf)

European Commission (2017) Commission staff working document. In-depth interim evaluation of the Horizon 2020. Brussels: Publications Office of the European Union

European Commission (2017) Ex-post evaluation of the health theme in FP7 (2017). Available at: <http://doi.org/10.2777/70014>

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.

European Commission (2018) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018PC0435&from=EN>

European Commission (2018) USA-China-EU plans for AI: where do we stand?. Available at: [https://ec.europa.eu/growth/tools-databases/dem/monitor/sites/default/files/DTM\\_AI%20USA-China-EU%20plans%20for%20AI%20v5.pdf](https://ec.europa.eu/growth/tools-databases/dem/monitor/sites/default/files/DTM_AI%20USA-China-EU%20plans%20for%20AI%20v5.pdf).

European Commission (2019) European Partnerships under Horizon Europe: results of the structured consultation of Member States. Draft Report for the meeting of the Shadow Configuration of the Strategic Programme Committee on 27 June 2019

European Commission (2019) Frans Timmermans: Executive Vice-President for the European Green Deal. Mission Letter. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-frans-timmermans-2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-frans-timmermans-2019_en.pdf)

European Commission (2019) Innovative Health Partnership. Inception Impact Assessment; European Commission (2019), Innovative Health Partnership. Fiche for the consultation with Member States.

European Commission (2019) Margrethe Vestager: Executive Vice-President for a Europe fit for the Digital Age. Mission Letter. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-margrethe-vestager\\_2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-margrethe-vestager_2019_en.pdf)

European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe.

European Commission (2019) Progress report 2017 EU AMR action plan. Available at: [https://ec.europa.eu/health/amr/sites/amr/files/amr\\_2018-2022\\_actionplan\\_progresreport\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_2018-2022_actionplan_progresreport_en.pdf)

European Commission (2019) Stella Kyriakides: Commissioner for Health. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf)

European Commission (2019) Thierry Breton: Commissioner for Internal Market. Mission Letter. Available at: [https://ec.europa.eu/commission/commissioners/sites/comm-cwt2019/files/commissioner\\_mission\\_letters/president-elect\\_von\\_der\\_leyens\\_mission\\_letter\\_to\\_thierry\\_breton.pdf](https://ec.europa.eu/commission/commissioners/sites/comm-cwt2019/files/commissioner_mission_letters/president-elect_von_der_leyens_mission_letter_to_thierry_breton.pdf)

European Commission (2019) Valdis Dombrovskis: Executive Vice-President for An Economy that Works for People. Mission Letter. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-valdis-dombrovskis-2019\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-valdis-dombrovskis-2019_en.pdf)

European Commission (2019) Virginijus Sinkevičius: Commissioner for Environment and Oceans. Mission Letter. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-virginijus-sinkevicius\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-virginijus-sinkevicius_en.pdf)

European Medicines Agency (no date) Human medicines: regulatory information. Available at: <https://www.ema.europa.eu/en/human-medicines-regulatory-information>

Evaluate Pharma (2014) World Pharma 2014, outlook to 2020. Available at: <http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EP240614.pdf>

Food and Agriculture Organization of the UN (FAO) (2016) Antimicrobial resistance and our food systems: challenges and solutions. Available at: <http://www.fao.org/3/a-i6106e.pdf>.

Freedman, S. and Mullane, K. (2017) The academic–industrial complex: navigating the translational and cultural divide. *Drug Discovery Today*, 22(7), pp. 976–993. doi: 10.1016/j.drudis.2017.03.005.

Friedman L.P., Cockburn I.M. and Simcoe T.S. (2015) The Economics of Reproducibility in Preclinical Research, *PLoS Biol* 13(6): e1002165. doi:10.1371/journal.pbio.1002165

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. doi: 10.1371/journal.pone.0160475.

Hanna E. et al (2016) Advanced therapy medicinal products: current and future perspectives. *J Market Access & Health Policy* 4: 31036

Health-Holland (no date) Available at: <https://www.health-holland.com/calls/tki-match>

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.

IMI (2019) Annual Activity Report 2018. Available at: [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018\\_final.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018_final.pdf)

Institute for Health Metrics and Evaluation (2018) Global Burden of Disease Study 2017. Available at: [http://www.healthdata.org/sites/default/files/files/policy\\_report/2019/GBD\\_2017\\_Booklet.pdf](http://www.healthdata.org/sites/default/files/files/policy_report/2019/GBD_2017_Booklet.pdf)

International Data Corporation (2018) European Data Market Monitoring Tool

Jakubowski E. and Busse R. (1998) Health care systems in the EU: A comparative study. Working Paper. Luxembourg: European Parliament.

Lim, M. D. (2014) Consortium Sandbox: Building and Sharing Resources. *Science*, 6(242), pp. 1–8.

MedTech Europe (2019) The European Medical Technology Industry in figures 2019. Available at: <https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf>

Meulien P. (2017) The Innovative Medicines Initiative: taking open innovation to the next level. *The European Files* 49: 14-15.

Results Healthcare (2017) Pharma and Biotech 2017. Review of outsourced manufacturing

Scottish Government (no date), Available at: <https://www2.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health>

Statista (2019) Available at: <https://www.statista.com/statistics/909654/global-big-data-in-healthcare-market-size>

The Scientific Panel for Health (2018) Building the future of health research. Proposal for a European Council for Health Research.

Vesper I. (2018) Europe's academics fail to report results for 90% of clinical trials, *Nature*, DOI: 10.1038/d41586-018-06676-8.

von der Leyen U. (2019) Political Guidelines for the next European Commission 2019-2024: A Union that strives for more. My agenda for Europe. [https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf)

Weale A. and Clarke S. (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.

WHO (no date) Disease burden and mortality estimates. Data available at: [https://www.who.int/healthinfo/global\\_burden\\_disease/estimates/en/index1.html](https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html)

Wilking N., Bucsics A., Kandolf Sekulovic L., et al (2019) Achieving equal and timely access to innovative anticancer drugs in the EU: summary of a multidisciplinary CECOG-driven roundtable discussion with a focus on Eastern and South-Eastern EU countries. *ESMO Open*; 4:e000550. doi: 10.1136/esmoopen-2019-000550

Wong, C. H., Siah, K. W., Lo, A. W. (2019) Estimation of clinical trial success rates and related parameters. *Biostatistics*, 20(2), pp. 273–286. Available at: <https://academic.oup.com/biostatistics/article/20/2/273/4817524>

Zhavoronkov A., Ivanenkov YA., Aliper A. et al. (2019) Deep learning enables rapid identification of potent DDR1 kinase inhibitors. *Nat. Biotechnol.* 37, 1038–1040. Available at: doi:10.1038/s41587-019-0224-x

## **Appendix B Synopsis report on the stakeholder consultation – Focus on the candidate European Partnership for Innovative Health**

*Disclaimer: the views expressed in the contributions received are those of the respondents and cannot under any circumstances be regarded as the official position of the Commission or its services.*

### **B.1 Introduction**

Following the European Commission's proposal for Horizon Europe in June 2018,<sup>99</sup> 12 candidates for institutionalised partnerships within 8 partnership areas have been proposed, based on the political agreement with the European Parliament and Council on Horizon Europe reached in April 2019.<sup>100</sup> Whether these proposed institutionalised partnerships will go ahead in this form under the next research and innovation programme is subject to an impact assessment.

In line with the Better Regulation Guidelines,<sup>101</sup> the stakeholders were widely consulted as part of the impact assessment process, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019,<sup>102</sup> gathering 350 replies for all 12 initiatives;
- A structured consultation of Member States performed by the EC services over 2019;
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A total of 608 Interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

This document is the synopsis report for the initiative “Innovative Health”. It provides an overview of the responses to the different consultation activities. A full analysis of the results is provided in the study Data Report.

---

<sup>99</sup> [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_18\\_4041](https://ec.europa.eu/commission/presscorner/detail/en/IP_18_4041)

<sup>100</sup> [https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT\\_19\\_2163](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_19_2163)

<sup>101</sup> [https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation\\_en](https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en)

<sup>102</sup> The full list of inception impact assessments is available here. They were open for public feedback until 27 August 2019.

## **B.2 Feedback to the inception impact assessment on candidate initiatives for institutionalised partnerships**

Following the publication of the inception impact assessment, a feedback phase of 3 weeks allowed any citizen to provide feedback on the proposed initiatives on the “Have your say” web portal. In total 350 feedbacks were collected for all initiatives.

For the initiative “Innovative Health” 44 individual feedbacks were collected, mainly from non-government organisations (NGOs).<sup>103</sup> Among the elements mentioned were:

- Several needs and barriers the initiative could address. For example, the potential for the initiative to address the need for better preventative measures, and the need for greater coordinated efforts in response to the rising threat of antimicrobial resistance;
- Aspects the initiative should take into account such as pressures on the healthcare system due to non-communicable diseases and the ageing population, and the need to consider how interventions, in particular personalised health, would be integrated into existing health systems. It was highlighted that leveraging the power and network of research infrastructures was important;
- The potential for major scientific impacts to be realised from this initiative, especially if the initiative was to include industries beyond the pharmaceutical sector. This was particularly discussed by the academic/research stakeholders;
- The potential for EU-level funding to maintain or improve the competitiveness of the European health R&I industry. It was commented that broader stakeholder involvement was a key component of strengthening the R&I industry;
- The potential for the initiative to realise societal impacts, in particular the possibility to reduce health inequalities;
- The agreement that an institutionalised partnership would be the preferred option referring to the potential for this structure to support a long-term commitment of key stakeholders, which would better enable a continuity of research ideas. This was discussed particularly by stakeholders from business associations. It was felt by ‘other’ stakeholders that this structure would be the only way to ensure that adequate governance structures were in place. In support of this, NGOs cited good governance structure as a key characteristic of a successful partnership;
- An overall positive opinion of the proposed initiative with business associations encouraging synergies with the different partnerships.

## **B.3 Structured consultation of the member states on European partnerships**

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the preparatory work for the candidate initiatives (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.

The feedback provided by 30 countries (all Member States, Iceland and Norway) has been analysed and summarised in a report, with critical issues being discussed at the Shadow Strategic Programme Committee meetings.

---

<sup>103</sup> Feedback on inception impact assessment to be found on [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972449/feedback\\_en?p\\_id=5722347](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972449/feedback_en?p_id=5722347)

Key messages overall for all candidate Institutionalised Partnerships, as taken directly from the report<sup>104</sup>:

*B.3.1 Key messages overall for all candidate Institutionalised Partnerships are the following:*

### **Overall positive feedback on the proposed portfolio, but thematic coverage could be improved**

The results indicate a high level of satisfaction with the overall portfolio, the level of rationalisation achieved, and policy relevance. While delegations are in general satisfied with the thematic coverage, the feedback suggests the coverage could be improved in cluster 2 "Culture, creativity and inclusive society" and cluster 3 "Civil Security for Society".

### **Large number (25) of additional priorities proposed for partnerships by delegations**

Despite high satisfaction with the portfolio and candidates put forward by the Commission, countries put forward a high number of additional priorities to be considered as European Partnerships. A closer examination suggests that these additional proposals are motivated by very different reasons. Whilst some proposals are indeed trying to address gaps in the portfolio and reach a critical mass, then, others are driven by the wish to maintain existing networks, currently not reflected in the Commission proposal (e.g. those based on JPIs, ERA-NETs). In addition, some proposals reflect worries over some topics not being sufficiently covered in the existing proposals, but could be possibly well covered within the scope of existing partnerships, or by traditional calls under the Framework Programme.

### **Critical view on the high number and openness of Joint Undertakings**

Country feedback suggests dissatisfaction with the high number of proposed Article 187 TFEU partnerships. Notably smaller as well as EU-13 countries raise concerns with regards to the potential insufficient transparency and openness of the partnership model. In the feedback, countries either directly support or ask to carefully analyse whether the objectives of this proposal could be reached with the co-programmed model.

For those partnerships that will be set up on the basis of Article 187, the country feedback stresses the need to ensure a clear shift towards openness in the governance, membership policy and allocation of funding of these partnerships. Notably, it is emphasised that the JU rules should not have any limitations or entry barriers to the participation of SMEs and other partners, including from academia.

Although the feedback suggests a general criticism, there are few concrete and broadly supported proposals, including to reduce the number of institutionalised partnerships mergers or by alternative implementation modes.

### **Lack of cross-modal perspective and systematic approach to mobility**

The current proposal foresees 5 partnerships in the area of transport (for rail, air traffic management, aviation, connected and automated driving, zero-emission road transport), and 2 that in closely related technologies for radically reducing carbon emissions (hydrogen, batteries). Several delegations would wish to see a systemic approach to developing mobility and addressing related challenges (optimisation of overall traffic, sustainable mobility solutions for urbanisation), and do not support a mode-dependent view only. This suggests the need to discuss how to ensure greater cooperation between

---

<sup>104</sup> European Partnerships under Horizon Europe: results of the structured consultation of Member States, analysis written and performed by Joerg Niehoff, Maria Reinfeldt, Andrei Lintu and Margareta Olson

transport modes and cross-modal approaches in establishing partnerships in the area of mobility.

### **Partnership composition: the role of Member States in industry partnerships**

The composition and types of partners is an important element for the success of a partnership, e.g. to ensure the right expertise and take-up of results. Ensuring broad involvement without overly complicating the governance of the partnership remains an important an important challenge in the design of future partnerships.

In the feedback, several Member States express their interest to join as a partner in partnerships that have traditionally been industry-led. However, individual comments suggest there are different views on what their involvement means in practice, with some countries expressing readiness to commit funding, while others support limiting their involvement to alignment of policies and exploiting synergies. This suggests the need to discuss further what the involvement of Member States means in practice (notably in terms of contributions, in the governance), and what would be possible scenarios/options in Horizon Europe. There is special interest in testing and deployment activities, in synergies with Cohesion Funds and CEF priorities and investments.

Although it is too early to determine the interest of industry/ businesses in the topics proposed for partnerships where the main partners are public authorities, their involvement in in public centric partnerships will also be an important question in the design and preparation of future proposals.

### **Some proposals are more mature than others**

The analysis of feedback per partnership candidates suggests that some proposals are more mature, while others would need more time to determine the scope, objectives, partner composition and contribution and appropriate mode of implementation. This relates to in particular to partnerships with no predecessors and those where the main partners are public. It suggests that the proposals would need to be developed at different paces in order to achieve good quality, and thus, not all partnership proposals may be ready for implementation at the start of Horizon Europe.

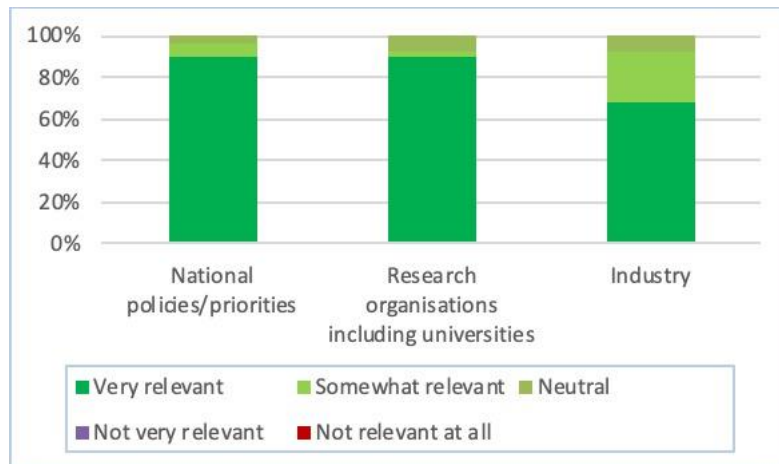
The feedback provided by 30 countries (all Member States, Iceland and Norway) has been analysed and summarised in a report, with critical issues being discussed at the Shadow Strategic Programme Committee meetings. For the initiative "Innovative Health" the following overall feedback was received from Member States.

#### *B.3.2 Overall feedback for the initiative "Innovative Health"*

### **Relevance and positioning in a national context**

Overall the results of the Member State consultation confirm the relevance of the proposed Innovative Health Initiative, with 89% considering it very relevant and 7% somewhat relevant for national policies and priorities. Equally there is a very strong confirmation of the overall relevance for research organisations, including universities, as well as for industry (Figure 10).

Figure 10: Relevance of the Innovative Health Initiative in the national context



On the question of existing national/regional R&I strategies, plans and/ or programmes in support of the proposed Innovative Health Initiative, 28 countries (93 %) report to have relevant elements in place. National R&I strategies or plans were identified most frequently (89%, AT, BE, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, PL, PT, RO, SK, SI, UK, IS, NO), followed by national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (79%, AT, BE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LU, LV, MT, PL, PT, RO, SK, SI, UK, NO) and regional R&I and/or smart specialisation strategies (75%, AT, CY, DK, EE, ES, FR, HR, HU, IE, LU, LV, MT, PL, PT, RO, SK, SI, NO). Dedicated funding programmes exist in 57% of the countries.

Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities. There is a general call for better SME participation, including more favourable IPR rules for them. Other comments address e.g.:

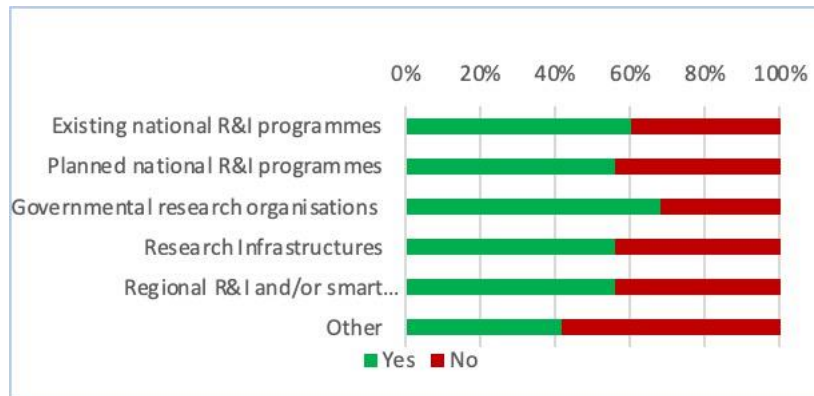
- stronger role of national authorities in the governance to address the public health need and to allow for synergies with national programs;
- inclusion of health care providers;
- clear link to national health systems and an early dialogue with regulatory bodies;
- structured coordination with academia to support the translational process;
- reinforcement of the European digital industry with regard to global competitors;
- need to ensure that the agenda setting supports joint, converging industry collaboration;
- including research on vaccines, including method development for the quality control of vaccines, as well as the implementation of “green technology solutions” in the manufacturing of drugs;
- education and training of users, incentives for healthcare providers.

A majority of countries, 17, have expressed an interest to participate (BE, EE, ES, FR, HR, HU, IE, IT, LU, LV, MT, RO, SE, SK, SI, UK, NO), and only 3 countries have at this stage expressed there is no national interest to participate (AT, DE, PT).

Identified elements for their participation covers broadly existing or planned national R&I programmes, governmental research organisations, research infrastructures, as well as regional R&I and/or smart specialisation strategies (Figure 11). All countries expressed interest in having access to results produced in the context of the partnership.



Figure 11: Possible participation and contribution to the Innovative Health Initiative, from the 17 countries that have expressed an interest to participate



### Feedback on objectives and impacts

Overall there is a strong agreement (82%) on the use of a partnership approach for innovative health issues. There is broad agreement (89%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, and an important small degree (53%) that it would contribute to improving the coherence and synergies within the EU R&I landscape. No country expresses any disagreement.

Countries indicate good agreement with the proposed objectives at short, medium and long term (96% agree or strongly agree) and the expected scientific, economic and societal impacts at European level (93% agree or strongly agree), with the remaining ones remaining neutral. The vast majority of countries (85%) consider the impacts very relevant in the national context. There is good agreement (56%) with the envisaged duration of the proposed partnership, but an important share (22%) that consider the duration too long and request clear exit strategies.

Additional comments suggest a clearer articulation between the Innovative Health Initiative and other Partnerships, and the need to clarify the role of IT aspects. A request is made to better focus on the sustainability of healthcare systems and on health promotion and preventive interventions.

### Views on partners, contributions and implementation

The majority (66%) agree on the type and composition of partners, and 15% disagree. Many comments support the shift towards other industrial sectors and would welcome better inclusion of health care providers. Most countries (65%) would need more information on contributions and level of commitments expected from partners, while 31% agree with the proposal. Individual comments relate to the following issues:

- The role of Member States in the agenda setting and governance should be strengthened;
- Ensure realistic commitments from industry, including meaningful financial contributions, with regards to the scale and budget of the initiative;
- Support industries in jointly addressing common and growing operational, regulatory and economic challenges;
- Ensure sufficient representation of health ICT companies and research organisations;
- Impact on promoting EU competitiveness should be at the forefront of the initiative, by limiting contributions from non-EU legal entities, or even limiting it to EU and Associated countries;

- Funding to industry in accepted projects should be possible, to allow for peer-to-peer collaborations between academia, RTOs and industry partners;
- Important to strengthen the role of healthcare providers in the agenda setting.

The proposed use of Article 187, and the establishment of a Joint Undertaking, is supported by around the majority (73%), while one country disagrees, with the rest expecting more details in order to be able to make an informed decision. One country would support a tripartite partnerships with Industry, Member States and the Union, while another country excludes any national co-funding. Furthermore the issue is raised how to ensure sufficient Member State and stake holder involvement in the agenda setting and set-up of the programme in order to achieve people centred healthcare.

#### ***B.4 Targeted consultation of stakeholders related to the initiative "Innovative Health"***

In addition to the consultation exercises coordinated by EC services, the external study thematic teams performed targeted consultations with businesses, research organisations and other partners on different aspects of potential European Partnerships.

##### *B.4.1 Approach to the targeted consultation*

The objective of the programme of interviews was to provide an insight into the views of key stakeholders with regard to the context, problem definition, objectives, policy options, impact analysis, coherence and monitoring of the new initiative. Interviews were voluntary and information provided served as evidence of perceptions of key stakeholders about the initiative. Not all questions could be answered by all interviewees – in fact, interviewees felt unable to reliably quantify any potential impact.

The interviewees were selected based on consultations with the study's Expert Panel and Commission's Steering Group. The list of stakeholders was balanced between different sectors along the value chain of Innovative Health and represented a mix of geographies. Stakeholders included researchers from different disciplines; public, industry and third sector organisations; end-user groups and patient associations; and regulators.

Interviewees were contacted directly by personalised emails which included an overview of the purpose and scope of the interview and a letter of support from the Commission. Interviewees were invited to suggest times and dates that were convenient to them. All interviewees were provided with a briefing document that introduced the nature of the interview and the general topics that would be discussed.

Only one representative per organisation was contacted. Priority was given to the more senior members of the organisation. Email reminders were sent approximately two weeks later. In cases where the priority contact had not replied a week after the second reminder, an email was sent to the second contact from that organisation. A third and final email reminder was sent approximately one month after the initial email was sent.

Semi-structured interviews were conducted using a tailored interview topic guide and were subsequently transcribed/summarised and analysed.

##### *B.4.2 Overview of respondents to the targeted consultation*

Interviews were conducted with representatives from industry, the European Commission, academic research institutions, research infrastructures, patient associations, existing partnerships, regulators, HTA bodies and payers.

Industry made up the largest stakeholder category, reflecting the diversity of industry stakeholders expected to engage in the new initiative. Stakeholders in this category represented the MedTech, pharmaceuticals, imaging, and biotechnology/biopharmaceuticals sectors and ranged across different business types

including SMEs, large companies and industry associations. The next largest category was the European Commission comprising interviewees from DG SANTE, DG CNECT and DG RTD. Stakeholders from research institutes included representatives from organisations at both the national and European levels.

Table 18: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
Industry	22	45.8
European Commission	7	14.6
Academic, research institutes and experts	5	10.4
Research infrastructures	3	6.3
Patient associations	4	8.3
Partnerships	2	4.2
Other (including Regulators, HTA bodies and payers)	5	10.4
TOTAL	48	100

### B.4.3 Key results/messages from the targeted consultation

#### Problem definition

While problems and problem drivers were not explicitly discussed during the interviews, several interviewees shared their thoughts on what problems could be addressed with this investment. These included antimicrobial resistance, ageing populations and skills migration to other countries. It was felt that Europe was struggling to maintain its leadership position in health R&D compared to US and China.

It was discussed that the fragmentation of the healthcare systems including differences in capacities, standards of care and cultural expectations leads to challenges implementing health innovations uniformly across Europe and may act as a barrier to uptake. In particular it was discussed that uneven IT literacy across Europe and poor public perception of industry were hindering uptake.

#### Objectives: What is to be achieved

##### General objective

The general objective was not considered specifically in the interviews so there were only a handful of comments from interviewees. These included questions around what was meant by 'patient-centred' and 'uptake to healthcare systems'. Overall, the general objective was supported by interviewees.

##### Specific objectives

A large proportion of interviewees were satisfied with the specific objectives. Any comments were typically minor in nature.

There was some discussion around the broad nature of the objectives and the potential difficulty of measuring the associated outcomes, however it was generally agreed this was a strategic decision to encompass the needs of the variety of stakeholders likely to be involved.

The need for more stakeholder groups (e.g. patient representatives, payers, regulators) to be listed alongside academia and industry among the groups that will share knowledge and resources in the IHI was also commonly discussed. Further to this, a number of interviewees had questions on where/how their own stakeholder group would fit in the initiative. More minor points were the need to reference ethics along with digitalisation and data exchange as areas where barriers need to be overcome and the need to include “standardisation” of the methodologies and models to better assess market value.

There was also some positive feedback around the push for a patient-centred approach in the initiative.

## **Intervention logic and targeted impacts of the initiative**

### **Likely scientific impacts**

The majority of interviewees felt that an investment in the initiative would lead to more efficient development processes and more innovations. The increase in efficiency of research would stem from involving stakeholders with expertise from different stages of the development process, and ensuring that innovations are designed to truly meet a need, are likely to be accepted by the health systems/patients and would have a realistic transition to market. Having this engagement at the outset would reduce the development of redundant or unrealistic innovations. Similarly, standardisation of tools, methods and workflows across the different types of partners was discussed as an important dimension to enhance efficiencies.

It was felt that having a broad range of expertise would drive cross-pollination of ideas and creativity leading to novel and innovative health solutions that would not be possible from a more siloed approach.

Scientific advancements associated with overcoming barriers of data exchange was a frequently discussed impact. In particular it was felt that timely and efficient data sharing would lead to a better understanding of the drivers of disease and would help in the development of digital technologies through for example training of machine learning algorithms that could be used in diagnostics, preventative treatment and healthcare delivery. It was discussed that inclusion of policy makers in the discussion on data exchange was vital to ensure patient data was being shared ethically.

Specific areas where it was felt scientific impacts would be felt were antimicrobial resistance, oncology and early diagnostics.

### **Likely economic and technological impacts**

The majority of interviewees discussed that bringing together stakeholders from across the innovation value chain would also lead to economic benefits. These impacts would flow from more efficient and relevant innovations reducing the cost of development and cost to the end users. As discussed above, investing in partnerships between diverse stakeholders is expected drive a better understanding of supply and demand resulting in a higher return on investment and more successful products. Input from regulators, in particular, was seen as an important driver of efficiency and market access.

The economic benefits to end users discussed were two-fold. Firstly, it was felt that more efficient development processes may lead to lower cost innovations, although it was acknowledged that market price is influenced by more than development costs alone. Secondly, the economic benefits associated with new innovations, particularly in relation

to personalised medicine, prevention and early detection, would decrease the burden on health care systems. Interviewees also commented that a healthier population would be able to contribute more to the economy as a whole.

It was discussed that the development of digital platforms and technologies coupled with effective data exchange would also have economic benefits to the healthcare system. For example, eHealth platforms containing diagnostic data would reduce the need to duplicate diagnostic tests across multiple healthcare sites and digital health technologies could be used to shift from expensive hospital care to community-based facilities. Development of these technologies was also discussed as a method to boost the global competitiveness of the European industry.

Job growth was a commonly discussed impact but responses varied in the extent and nature of job growth expected. Some interviewees felt that any boost in the economy would lead to a general growth in jobs, others referred to jobs that would be created as a direct result of carrying out the IHI project or from the products that would be created. This was particularly discussed in reference to start-ups and SMEs. Skill development, in particular data skills, was a key aspect of this growth and it was suggested by a number of interviewees that education or training activities within the partnership project would enhance this impact. The cross-pollination of ideas and knowledge between the different participating sectors was also expected to foster skill development and job opportunities. Retention of existing talent was also discussed. It was felt that the opportunity to participate in the partnerships or work with the innovations resulting from IHI were potential incentives for skilled workers to stay within the European market, helping to maintain the region's competitive edge.

A number of interviewees felt that due to the synergies that would be developed as part of the partnership, the economic benefits of the investment would be felt by all stakeholders along the value chain. Nevertheless, SMEs were identified as key beneficiaries and it was felt that business growth of SMEs was a driver for innovation and global competitiveness in health R&D.

It was felt by interviewees that the partnerships have the potential to attract additional investment. It was shared that private investors would be attracted to expanding their R&D portfolio and working with a broad range of stakeholders, but it was acknowledged that in many cases value would need to be demonstrated first. Philanthropic funding was also discussed but it was generally agreed that an element of flexibility was required to engage with these funders.

Interviewees generally agreed that it was difficult to estimate the timeframe and extent of impacts due to the wide range of variables (e.g. scope of partners, healthcare focus etc). Overall, impacts were anticipated in the short, medium and long term and a positive return on investment was cited.

### **Likely societal impacts**

The majority of interviewees agreed that IHI would lead to improved health and wellbeing. Many of the discussions were general in nature suggesting that the specific impacts would be determined by the nature of the projects. Some interviewees did provide specific expected outcomes that would impact health and wellbeing including:

- improvements in diagnostic capabilities due to AI
- New tools to deal with AMR e.g. vaccinations
- Personalised medicine
- Fewer hospital visits due to alternative non-invasive diagnostics and data exchange

- Disease prevention innovations

Positive environment impacts were discussed primarily with regards to reduced need for travel and less/better waste management. Reduced need for travel would stem from advancements in remote testing and monitoring. It was discussed that this would also have a positive impact on patient wellbeing. It was envisioned waste could be reduced via enhanced data exchange replacing the need to duplicate tests or technological innovations as solutions to single use products. Some interviewees raised concern that there are also negative environmental impacts of digital technologies e.g. energy consumption of datacentres and extraction of raw materials, suggesting it would be important to consider the net environmental impact.

It was generally agreed that IHI would also impact society through increasing the uptake of innovations. This would be primarily driven by engaging stakeholders at the end-user stage of development, ensuring that the innovations were needed and relevant to the target groups and that the end-users were trained sufficiently to use the innovation. It was also felt that innovations would be readily taken-up once there was a clear benefit demonstrated to the end-users.

Interviewees shared a number of other societal aspects that could be impacted by IHI. Inequality was discussed as a major barrier to healthcare that could be partially addressed in the partnerships by developing innovations that account for variations in digital literacy, ageing and geographical diversity. It was also felt that a positive working relationship between public and private partners would increase public trust, and therefore, uptake of new products produced by industry.

## Functionalities of the initiative

### Internal factors

Interviewees strongly felt that a broad range of stakeholders was required to make the partnership a success. In particular they encouraged the involvement of regulators, patient representatives, and representatives of healthcare systems to strengthen the impact and uptake of innovations. Opening up membership to partners from overseas was mentioned as a way to help increase the quality and impact of the outputs.

### External factors

In general, there was strong support for working synergistically with other EU initiatives, in particular since health is complex and feeds into many aspects of other initiatives. Developing similar data management methodologies or use of similar platforms was discussed as a key way to ensure findings were able to be shared between initiatives. It was also discussed that cooperation between initiatives could enhance learning e.g. ECSEL could provide digital support to projects to ensure that data is collected, and platform development is run in a uniform manner, enhancing data exchange and reducing unnecessary duplication. Establishing a flexible set of rules for the different initiatives would reduce bureaucratic barriers that have prevented past collaborations.

It was also discussed that there was an opportunity for projects, partners or ideas to flow between different funding initiatives such as Horizon Europe regular calls and IHI in order to exploit the sequential needs of the project.

### Future stringent requirements

- Increasing the transparency of the institutionalised partnership's decision-making, financing and activities

Interviewees agreed that increased transparency was good. It was felt that this could increase public confidence in the initiative.

- Broadening the membership of the institutionalised partnerships geographically and sectorially across Europe and keeping open that membership to potential future partners across its lifetime

In general, it was felt that a broader membership would be a positive change, but it was discussed that membership should be based on research/knowledge excellence rather than geographical representation. There was strong support for keeping membership open to potential future partners as this would enable development to be more flexible and could address previously unknown gaps in membership that may develop later in the partnership.

- Ensuring the results of the partnership's RDI activities are widely disseminated and made available for re-use by others, across Europe

There was support for this requirement as it was felt that better dissemination would enable more efficient research in future. But it was discussed that intellectual property was an important consideration and sharing of results should not compromise the development of IP. There were also some concerns around GDPR and patient data.

- Increasing the level of private partners' contributions, ideally to a point that the Union financial contribution amounts to around 25% of the total investment

There were mixed responses to this requirement. Some interviewees supported this requirement provided there was a strong agreement across industry. On the other hand, it was felt that it may make IHI less attractive to industry and that a true partnership should be 50/50. There were also some concerns about the public perception and the shift in balance to industry in determining the research agendas.

- Increasing the level of private members financial contributions, ideally to a point where around 10% of all private members contributions are financial rather than in-kind

This requirement also led to a mix of responses. Some interviewees felt that in-kind was a more valuable contribution than cash as the knowledge and expertise of industry is where the true value of the partnership lies. Others felt that a financial contribution would lead to a stronger commitment from industry partners. Some felt that a flexible, case-by-case approach would be most suitable suggesting that commitments may change over time once industry had the opportunity to assess the value of the partnership.

## **Comparative assessment of the policy options**

### **Horizon Europe Regular Calls**

It was generally felt that Horizon Europe has an important place in the funding landscape through regular calls and is effective in achieving impacts in smaller projects and enhancing academic excellence.

However, it was discussed that the structure would not be able to enable large-scale collaboration between a broad range of stakeholders as would be required to achieve the abovementioned impacts. There were concerns that it would not be very attractive to industry due to a reduced role in setting research priorities and a potentially less binding agreement. Projects under Horizon Europe were viewed as having a smaller scope so would not be able to holistically evaluate digital platforms or comparable technologies. This would have to be accomplished by combining many smaller Horizon Europe projects, leading to fragmentation and inefficiencies. The timeframe of regular calls was also discussed as being insufficient to adequately achieve the objectives.

### **Co-programmed Partnership**

Co-programmed partnerships were preferred to Horizon Europe Regular Calls in particular due to their longer-term focus. Co-programming was seen as suitable for a partnership structure where a more flexible arrangement was desirable such as involving pre-existing

partnerships or for projects of a smaller scope. There were, however, concerns over co-programming delivering an in-depth partnership of diverse stakeholders. It was felt that the commitment under this option would not deliver the security needed to invest in truly innovative and risky ideas and may therefore not be attractive to some partners. Furthermore, some interviewees felt that industry would have less input in developing research agendas under this option. Establishing common research agendas was seen as valuable but insufficient to overcome the barriers of different sectors working in silos and would therefore not benefit from the full set of outcomes stemming from the cross-pollination of skills and knowledge under a partnership. For these reasons, it was felt that a co-programmed partnership would not be as effective in delivering the impacts described above.

### **Institutionalised Partnership**

Institutionalised partnerships were generally seen as more integrated partnership structure. The most frequently discussed advantage of Institutionalised partnerships over the other policy options was that this structure would attract and enable a broader scope of actors to engage. Diversity of stakeholders along the value chain was seen as an essential component to achieve impacts. Similar to a co-programmed partnership model, the longer-term outlook was also seen as a key advantage of this option.

It was discussed that this arrangement would be attractive to industry because there would be the 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 because it provided a level of confidence to the stakeholders involved and it was also viewed as an important conduit to facilitate the sharing of data that would be required to achieve the impacts. It was discussed that this integrated approach would also enable a more detailed discussion around intellectual property upfront further increasing confidence in the partnership from the outset. This in turn could lead to greater commitments from private partners since the risk of investment is shared leading to more innovative and potentially more impactful outcomes.

It was discussed that institutionalised partnerships may suffer from a large administrative burden however it was also felt that this was a necessary component of such a complex arrangement and that the administrative burden of Horizon Europe and co-programmed partnership was likely to be similar. Nevertheless, it was suggested that this could be a barrier to smaller companies, i.e. SMEs and start-ups, that may not have the capacity to meet the administrative needs.

### **Description of the preferred option**

Overall the majority of interviewees felt that Option 2: institutionalised partnership would be the most effective means of delivering the impacts discussed above. Commonly given reasons for this were the broader range of stakeholders engaged, stronger commitment from all parties, flexibility on setting research agendas and the longer-term outlook.

A smaller number of interviewees felt that a mix of options would be appropriate, reflecting that different structures may be appropriate in different circumstances. There were also a few interviewees that felt co-programming would be most suitable due to the greater flexibility of membership under this arrangement.



## KPIs

It was acknowledged that health and wellbeing of citizens should be the primary focus but that investment from the private sector would be bolstered with evidence of a return on their investment.

In general, KPIs such as publications and patents were seen as easy to measure but limited in showcasing the impact of the partnership. Instead it was suggested to focus be on indicators such as adoption into healthcare systems, uptake of citizens and ultimately a change in health outcomes or the burden of disease.

It was discussed that health and economic KPIs would be difficult to measure and would require a well-defined baseline at the start of the project that was tailored to the specific project objectives.

Some specific KPIs were:

- Health and wellbeing: disease prevalence, QALYs, probability of treating disease, life expectancy, time in hospital, cost of treatment
- Economic: job growth, number of new SMEs/start-ups, business performance, product development, follow-on funding
- Scientific: publications (but acknowledged this is insufficient alone)

There was also a discussion on monitoring the success of IHI overall. This could be measured by examining the number of stakeholder types involved, how representative each partnership was, meeting timeline goals, development of products and follow-on partnerships.

A number of interviewees stressed it was important to focus on a small number of high-quality KPIs. Some even suggested establishing a small project dedicated to defining the most effective KPIs for each project and IHI overall.

### ***B.5 Open public consultation on the Candidate institutionalised European Partnerships***

#### *B.5.1 Approach to the open public consultation*

The consultation was open to everyone via the EU Survey online system<sup>105</sup>. The survey contained two main parts and an introductory identification section. The two main parts collected responses on general issues related to European partnerships (in Part 1) and specific responses related to 1 or more of the 12 candidate initiatives (as selected by a participant).

The survey contained open and closed questions. Closed questions were either multiple choice questions or matrix questions that offered a single choice per line, on a Likert-scale. Open questions were asked to clarify individual choices.

The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French. It was advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

The analysis of the responses was conducted by applying descriptive statistic methods to the answers of the closed questions and text analysis techniques to the analysis of the answers of the open questions. The keyword diagrams in this report have been created by

---

<sup>105</sup> <https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope>

applying the following methodology: First, the open answer questions were translated into English. This was followed by cleaning of answers that did not contain relevant information, such as "NA", "None", "no comment", "not applicable", "nothing specific", "cannot think of any", etc. In a third step, common misspellings were corrected, such as "excellence" instead of "excellence", or "partnership" instead of "partnership". Then, the raw open answers were tokenised (i.e. split into words), tagged into parts of speech (i.e. categorised as a noun, adjective, preposition, etc) and lemmatised (i.e. extraction of the root of each word) with a pre-trained annotation model in the English language. At this point, the second phase of manual data cleaning and correction of the automatic categorisation of words into parts of speech was performed. Finally, the frequency of appearance and co-occurrences of words and phrases were computed across the dataset and the different subsets (e.g. partnerships, stakeholder groups). Data visualisations were created based on that output.

The keyword graphs in the following sections have been built based on the relationships between words in the open responses of the survey participants. It features words that appear in the same answer either one after the other or with a maximum distance of two words between them. Each keyword is represented as a node and each co-occurrence of a pair of words is represented as a link. The size of the nodes and the thickness of the links vary according to the number of times that keywords are mentioned and their co-occurrence, respectively. In order to facilitate the visualisation of the network, the keyword graphs have been filtered to show the 50 most common co-occurrences. Although the keywords do not aim to substitute a qualitative analysis, they assist the identification of the most important topics covered in the answers and their most important connections with other topics, for later inspection in the set of raw qualitative answers.

### *B.5.2 Overview of respondents to the open public consultation*

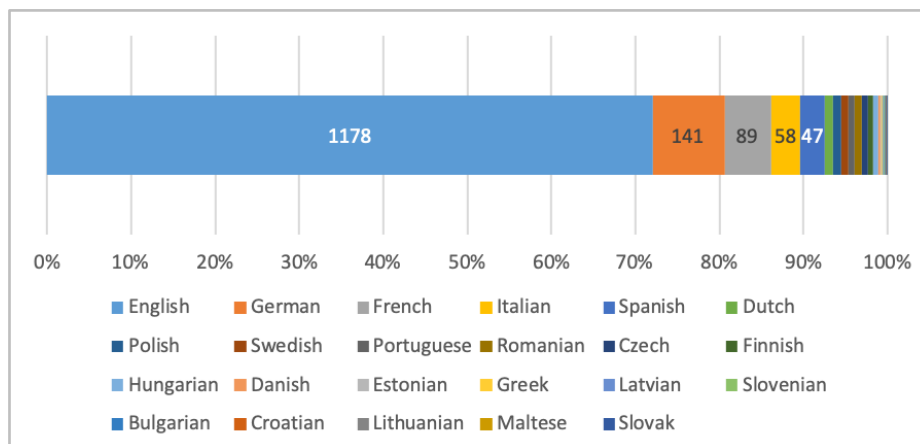
#### **Profile of respondents**

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as '*campaigns*', segregated and analysed separately and from other responses. In total 11 campaigns were identified. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not analysed separately from the general analysis.

Among the 1635 respondents, 1178 (72.05%) completed the online consultation in English, 141 (8.62%) in German, 89 (5.44%) in French, 58 (3.55%) in Italian and 47 (2.87%) in Spanish, see Figure 3. Respondents that belong to the 11 campaigns follow the same pattern of language distribution, with English being the dominant language of respondents in that group. Table 2 shows that over 50% of respondents come from 4 Western and Southern European countries – Germany, Italy, France and Spain. Overall, the number of respondents from Eastern and Northern Europe is lower, while among non-EU countries the greater number of respondents come from Switzerland, Norway and Turkey, which are countries associated to the Framework Programme. In the group of respondents labelled as campaigns, most respondents are from Germany (48 respondents or 17.65%), France (39 respondents or 14.34%), Italy (37 respondents or 13.6%), Belgium (23 respondents or 8.46%), the Netherlands (21 respondents or 7.72%) and Spain (17 respondents or 6.25%). Hence, a similar pattern of country of origin is observed in the entire sample of respondents and for the campaigns.

Across all respondents 40.80% indicated to answer to the open public consultation in a public way (non-anonymous) and 20.67% of all respondents indicated their Transparency Register number.

Figure 12: Language of the consultation (N=1635)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

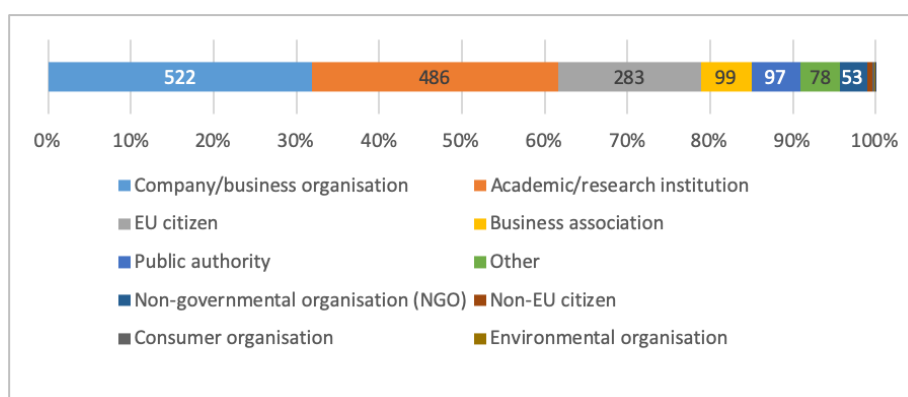
Table 19: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%

Country	Number of respondents	Percentage of respondents
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

According to Figure 13, the three biggest groups of respondents are companies and business organisations (522 respondents or 31.93%), academic and research institutions (486 respondents or 29.72%) and EU citizens (283 respondents or 17.31%). Business associations, representing multiple businesses, were the fourth largest responding group (99 respondents or 6.05%), no other types of associations were presented amongst the selectable options for respondents. Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely companies and business organisations (121 respondents or 44.49%), academic and research institutions (54 respondents or 19.85%) and EU citizens (42 respondents or 15.44%).

Figure 13: Type of respondents (N=1635)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

Respondents were asked to indicate the organisational size of the companies, organisations and institutions they work for. Based on Table 20, a greater number of respondents work in large companies and business organisations (295 respondents out of 522 or 56.51%) and large academic and research institutions (348 respondents out of 486 or 71.60%). A greater number of respondents that are employed by business associations and NGOs indicated an organisation size of 1 to 9 employees. Among the group of respondents that are marked as campaigns, a greater number of respondents work in large companies and business organisations (82 respondents out of 121 or 67.77%) and academic and research institutions (39 out of 54 respondents or 72.22%).

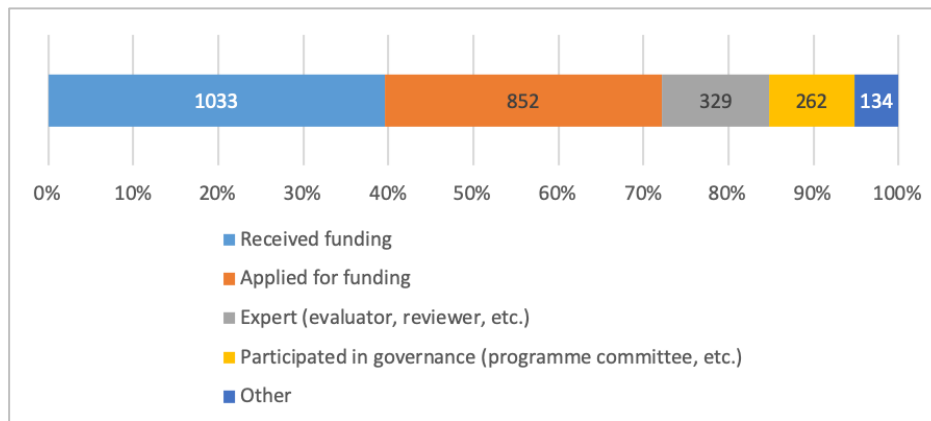
Table 20: Size of organisations that represent consultation respondents (N=1635)

Type of respondents' organisations	Organisation size			
	Large (250 employees or more)	Medium (50 to 249 employees)	Small (10 to 49 employees)	Micro (1 to 9 employees)
Company/business organisation	295	66	90	71
Academic/research institution	348	95	31	12
Business association	15	6	34	44
Public authority	58	33	6	0
Non-governmental organisation (NGO)	7	9	11	26
Consumer organisation	1	0	2	1
Environmental organisation	0	0	1	0
Trade union	0	0	1	0
Other	24	16	19	19

Among all consultation respondents, 1303 (79.69%) have been involved in the on-going research and innovation framework programme Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated that they were a beneficiary (1033 respondents or 39.58%) or applicant (852 respondents or 32.64%).

The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents (see distribution in Figure 14). However, a few stakeholder categories have mainly been involved in the capacity of "Received funding" and/or "Applied for funding", this applies to business associations, NGOs and public authorities.

Figure 14: Involvement of respondents in Horizon 2020 or in the Framework Programme 7 (N=1303)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

Among those who have been involved in the on-going research and innovation framework programme Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4, the table also show the key stakeholder categories for each partnership.

Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

Table 21: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations	Company/business organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19

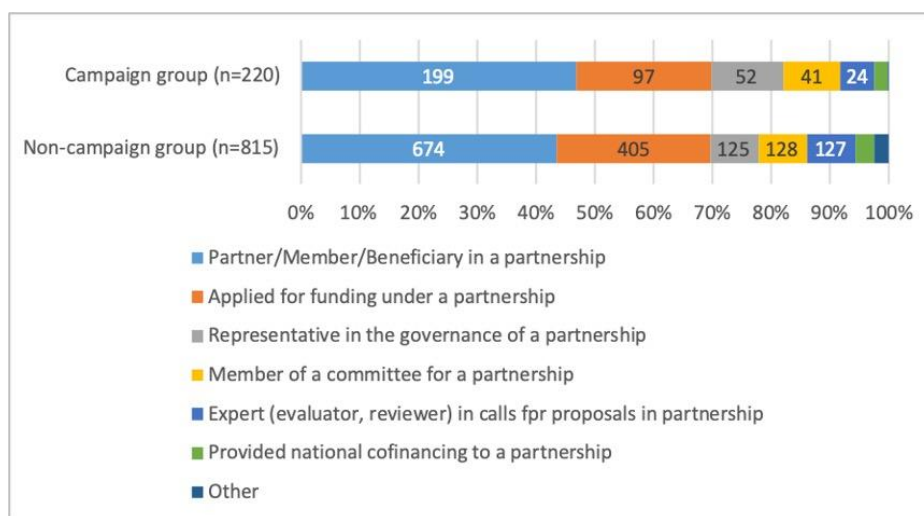
Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations	Company/business organisations	EU citizens	NGOs	Public authority
and Research (EMPIR)									
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations	Company/business organisations	EU citizens	NGOs	Public authority
Countries Clinical Trials Partnership									
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High-Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

When respondents were asked in which role(s) they participate(d) in a partnership(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership (see, Figure 15). The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

The few respondents that selected “Other” as their role were provided with the opportunity to outline their role. A total of 25 people did provided description. The answers provided were very varied and could not be clustered in sub-groups, a few examples are: former communication and stakeholder relationship officer, chair of steering board, system engineer, grant manager, Joint Programming Initiative (JPI), or a role in advocacy of the partnership.

Figure 15: Role of respondents in a partnership (N=1035)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

In the open public consultation respondents could provide their views on each of the candidate Institutionalised European Partnerships, and each respondent could select



multiple partnerships to provide their views on. The table below presents the number and percentage of respondents for each partnership. It is visible that the majority of respondents (31.37%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% of all respondents provided their views for the candidate partnerships European Metrology, Clean Aviation and Circular bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 22: Future partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
Clean Hydrogen	506 (31.37%)	382 (28.49%)	123	21		55	74	8	13
European Metrology	265 (16.43%)	225 (16.78%)	112	3	21	11	34	3	28
Clean Aviation	246 (15.25%)	191 (14.24%)	57	5	21	34	54	3	8
Circular bio-based Europe: sustainable Innovation for new local value from waste and biomass	242 (15%)	215 (16.03%)	63	19	36	35	31	7	13
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)	29	14	23	39	31	2	7
Key Digital Technologies	182 (11.28%)	162 (12.08%)	55	13	20	22	35	5	7
Innovative SMEs	111 (6.88%)	110 (8.20%)	19	12	39	4	14	4	10
Innovative Health Initiative	110 (6.82%)	108 (8.05%)	35	6	9	12	16	16	5
Smart Networks and Services	109 (6.76%)	107 (7.98%)	34	9	12	17	21	2	6
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)	25	12	11	19	10	3	9
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)	8	7	4	24	9	2	7
EU-Africa research partnership on	49 (3.04%)	47 (3.50%)	15	2	4	3	12	6	4

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
health security to tackle infectious diseases – Global Health									

### Campaigns per candidate Institutionalised European Partnership

As was mentioned above, 11 campaigns were identified, the largest of them includes 57 respondents. The table below presents the campaigns that replied for each candidate partnership. As presented, the candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few partnerships, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships, therefore, campaign #2 and #6 feature in several partnerships.

Table 23: Overview of campaigns across partnerships

Name of the candidate Institutionalised European partnership	Number of a campaign group (total number of respondents in a campaign)	Number of respondents that provided views about a partnership
Clean Hydrogen	Campaign #1 (57 respondents)	57 respondents
	Campaign #2 (41 respondents)	25 respondents
	Campaign #7 (18 respondents)	18 respondents
	Campaign #9 (14 respondents)	13 respondents
	Campaign #11 (10 respondents)	9 respondents
Clean Aviation	Campaign #2 (41 respondents)	17 respondents
	Campaign #6 (19 respondents)	19 respondents
	Campaign #8 (14 respondents)	13 respondents
Integrated Air Traffic Management	Campaign #2 (41 respondents)	10 respondents
	Campaign #6 (19 respondents)	12 respondents
European Metrology	Campaign #3 (36 respondents)	35 respondents
Circular bio-based Europe: sustainable Innovation for new local value from waste and biomass	Campaign #5 (20 respondents)	20 respondents
Transforming Europe's rail system	Campaign #4 (31 respondents)	29 respondents

Name of the candidate Institutionalised European partnership	Number of a campaign group (total number of respondents in a campaign)	Number of respondents that provided views about a partnership
Key Digital Technologies	Campaign #10 (12 respondents)	12 respondents
Innovative SMEs	-	-
Innovative Health Initiative	-	-
Smart Networks and Services	-	-
Safe and Automated Road Transport	-	-
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	-	-

### B.5.3 Responses to the open public consultation at programme level

The following section of the report presents the analysis of responses at programme level, meaning all respondents (excluding campaigns) were included, independent of which candidate European Partnerships respondents selected to provide their views on. The results for responses as part of campaigns are presented separately.

#### Characteristics of future candidate European Partnerships

Respondents were asked to assess what areas, objectives, aspects need to be in the focus of the future European Partnerships under Horizon Europe and to what extent. According to Figure 16, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs (companies with less than 250 employees) value role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs.

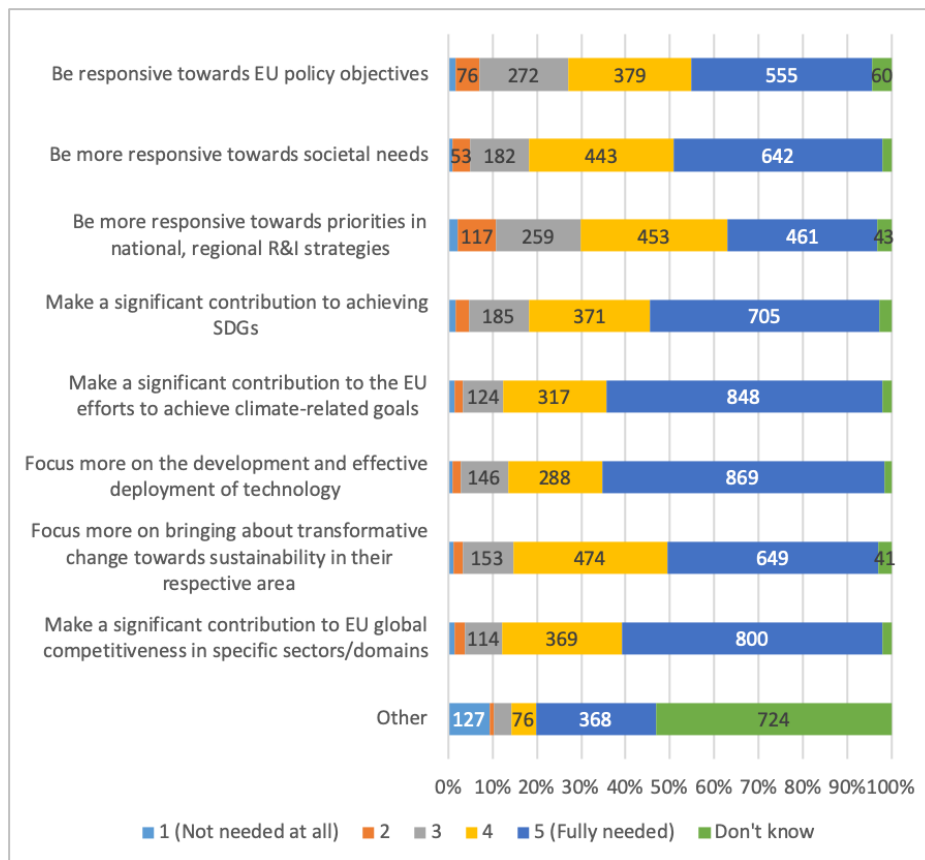
The views of citizens (249, or 18.27%), both EU and non-EU citizens, that participated in the open public consultation do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of

the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN’s Sustainable Development Goals.

Among 272 respondents that are classified as **campaigns**, the majority (86.76%) indicated that the future European Partnerships should focus more on the development and effective deployment of technology. Other categories of presented needs that received a high score among many campaign respondents are the need to make a significant contribution to the EU efforts to achieve climate-related goals, Sustainable Development Goals and to EU global competitiveness in specific sectors/domains. The least number of campaign respondents valued the need to be more responsive towards priorities in national, regional R&I strategies (54 respondents gave a score “5 Fully needed”, or 19.85%) and to be more responsive towards societal needs (71 respondents gave a score “5 Fully needed”, or 26.10%).

Similarly as for non-campaign respondents, we find only minor differences between the main stakeholder categories amongst campaign respondents. Academic/research institutions indicated that the future European Partnerships need to focus a little less on development and effective deployment of technology than other respondents. On the contrary, large companies find the focus on the development and effective deployment of technology a little more needed than other respondents, as do public authorities. Furthermore, large companies feel responsiveness towards priorities in national, regional R&I strategies is a little less needed than other respondents. Public authorities, however, value the responsiveness towards societal needs and priorities in national, regional R&I strategies more than others.

Figure 16: Needs assessment (N=1363)



Notes: Question: “To what extent do you think that the future European Partnerships under Horizon Europe need to ...”; Non-campaign replies; Aggregation of responses of all candidate initiatives

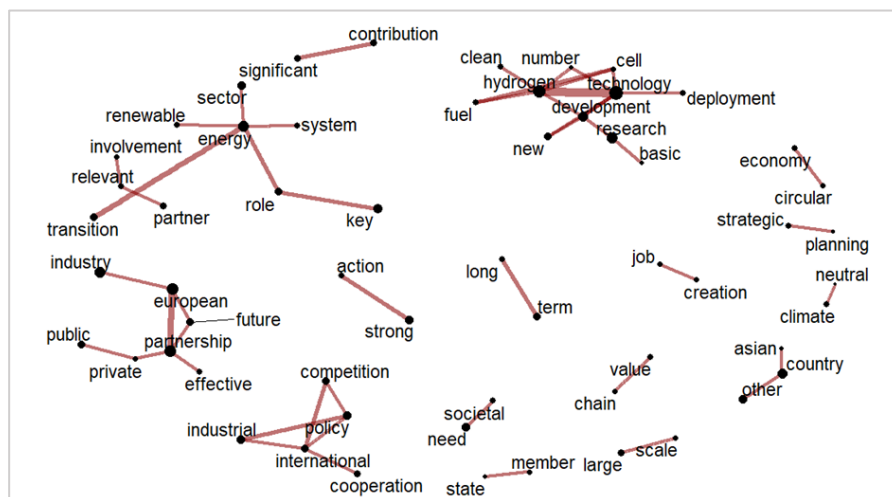
The analysis of the open answers provided to explain the “Other” field show that many respondents included the set-up of public-private European partnerships and the link

between industrial policy and international competition and cooperation (see Figure 17). This is confirmed through qualitative analysis of answers, many of which mention the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals. Against this backdrop, fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are deemed as priorities. Next to that, many respondents provided answers related to the fields of hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate European Partnership specific questions related to these topics.

Many of the respondents that are classified as campaigns took the opportunity of the "Other" field to underline their key messages. The main aspects mentioned were:

- The global positioning of Europe: outlining the role of global competition (including the role of technology), the importance of autonomy for Europe and the ability of Europe to act as a key player at the global level.
- The balance between policy objectives and private sector interests: Partnerships are regarded as an instrument to secure industry commitments due to the stability required for investments that serve policy goals.
- The importance of the transition between research and innovation (implementing research results in the market).
- The importance of multidisciplinary, and specifically cross-sectoral/cross-partnership collaboration.
- The importance of the long-term commitment of a wide range of relevant stakeholders.

Figure 17: Needs assessment, open answers to "Other" field (N=734)



Notes: Question: "To what extent do you think that the future European Partnerships under Horizon Europe need to ..."; 50 most common co-occurring keywords; Non-campaign replies; Aggregation of responses of all candidate initiatives

Next to that many respondents as part of campaigns stressed the importance of the energy transition, hydrogen and the environment, which corresponds to the high number of respondents that provided answers to the candidate European Partnership specific questions related to these topics.



- System complexity
- Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation
- Lower funding percentage compared to regular Horizon Europe projects
- Cash contributions
- Administrative burdens
- Potential for IPR constraints

### Relevance of EU level efforts to address problems in selected areas of Partnerships

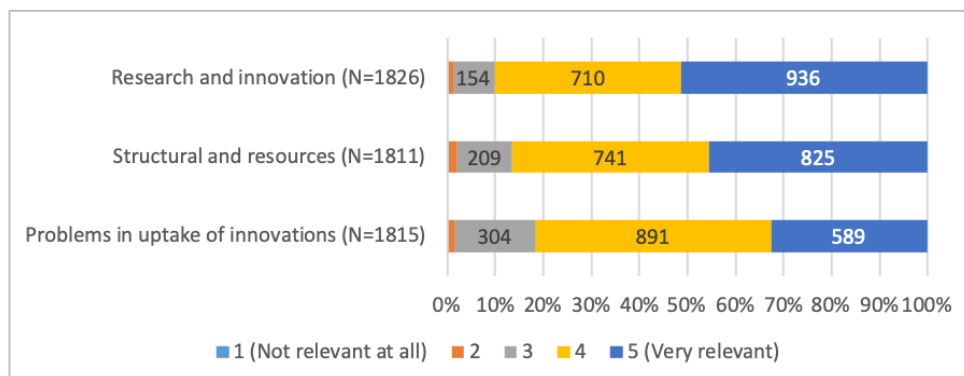
Per candidate European Partnership respondents were asked to rate the relevance of partnership specific problems in three main areas: Research and innovation problems, Structural and resource problems and Problems in the uptake of innovations. To aggregate results the average of the responses on partnership specific problems were calculated.

As presented in Figure 19, research and innovation related problems were rated as most relevant by the respondents across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant.

Only minor differences were found between the main stakeholder categories of respondents. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find it slightly more relevant to address problems in uptake of innovation than other respondents.

The views of citizens, both EU and non-EU citizens, are the same as other respondents (no significant differences). Respondents that are/were directly involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) find, however, the uptake of innovation problems slightly more relevant than other respondents.

Figure 19: Relevant problems to address

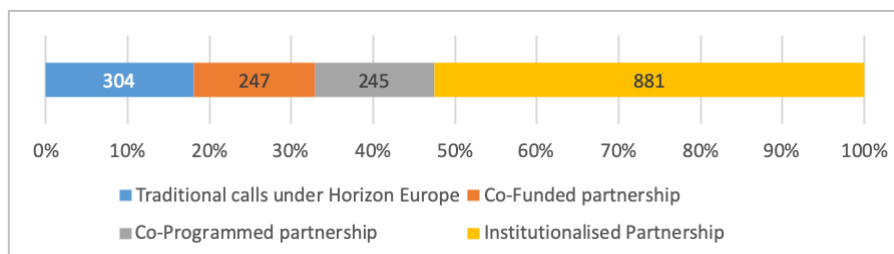


Notes: Question: "To what extent do you think it is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

## Horizon Europe mode of intervention to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 20, just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, however, relatively strong differences between stakeholder categories were found. The intervention of institutionalised partnerships was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens, compared to other respondents, indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, however, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 20: Options to address challenges



Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

When asked to reflect on their answers, respondents that pointed to the need for using the "institutionalised partnership" intervention mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Respondents that referred to possible approaches, sometimes gave examples of good experiences in with other interventions:

- Traditional calls because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy premier. This was mentioned by 94 participants, evenly distributed across companies (25 of them), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).

## Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

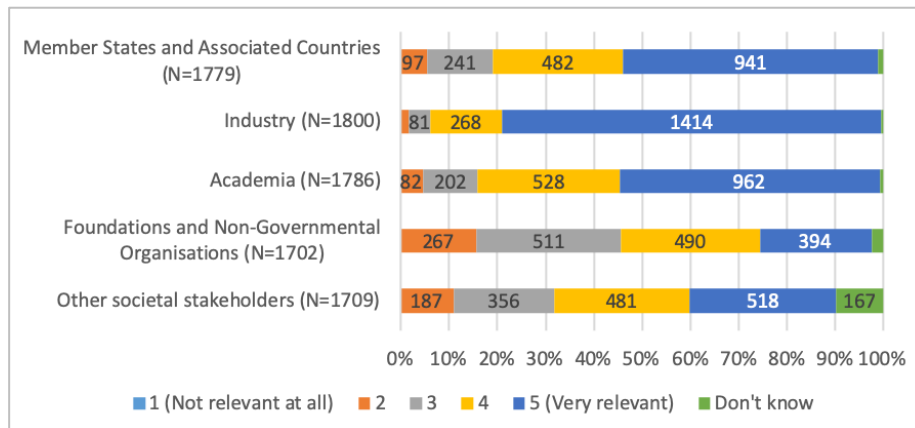
### Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. As presented in Figure 21, collectively all respondents see stakeholders



from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents.

Figure 21: Stakeholders to involve in setting joint long-term agenda's



Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of:"; Non-campaign replies; Aggregation of responses of all candidate initiatives

When looking at the differences between the answers of the main stakeholder categories only minor differences could be found. Overall, it could be observed that most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve. Academic/research institutions find it more relevant to involve academia and less relevant to involve industry when compared to other respondents. The other way around large companies, SMEs and business associations find it more relevant to involve industry and less relevant to involve academia, Member States and Associated Countries and NGOs. The involvement of Member States and Associated Countries was found more relevant by academic/research institutions and public authorities. NGOs also values their own involvement and those of other societal stakeholders more than other respondents. The views of citizens also show a slightly higher relevance for foundations and NGOs. This is less so the case for respondents that are/were directly involved in a current/preceding partnership (most predominantly companies and academia).

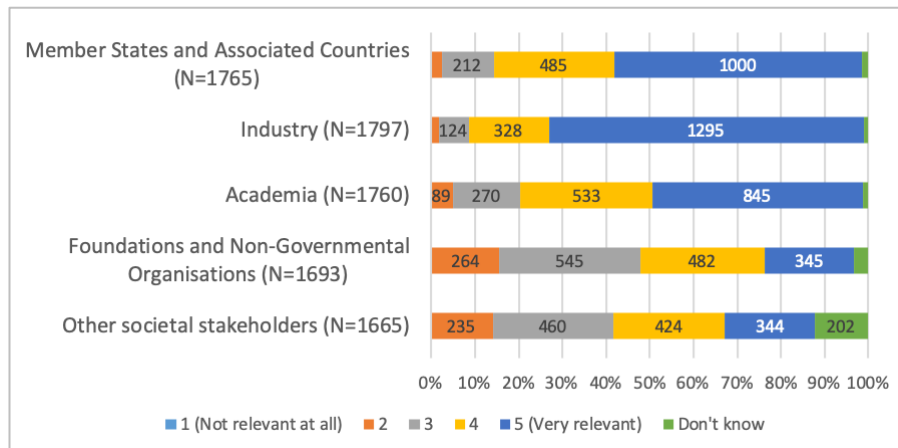
### Pooling and leveraging resources through coordination, alignment and integration with stakeholders

Respondents were also asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. As shown in Figure 22 - similarly as for the previous questions, respondents also see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents.

Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor. As such, academic/research institutions see the relevance of academia higher, while large companies, SMEs and business association indicated a lower relevance of academia than other respondents. Similarly, these private sector stakeholders valued the relevance of industry higher than others while valuing the relevance of NGOs and other societal

stakeholders less. NGOs value themselves and other societal stakeholders however higher than other respondents, and also public authorities indicated a higher relevance for Member States and Associated Countries than other respondents. Citizens mainly put more emphasis on the role of NGOs and other societal stakeholders than other respondents.

Figure 22: Relevance of actors for pooling and leveraging resources



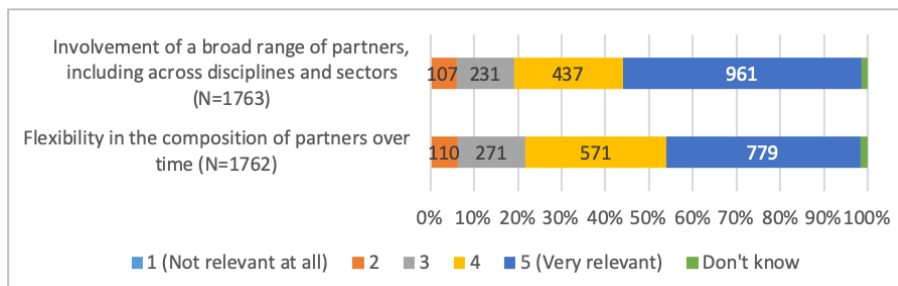
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with:"; Non-campaign replies; Aggregation of responses of all candidate initiatives

### Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 23).

When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

Figure 23: Assessment of the partnership composition

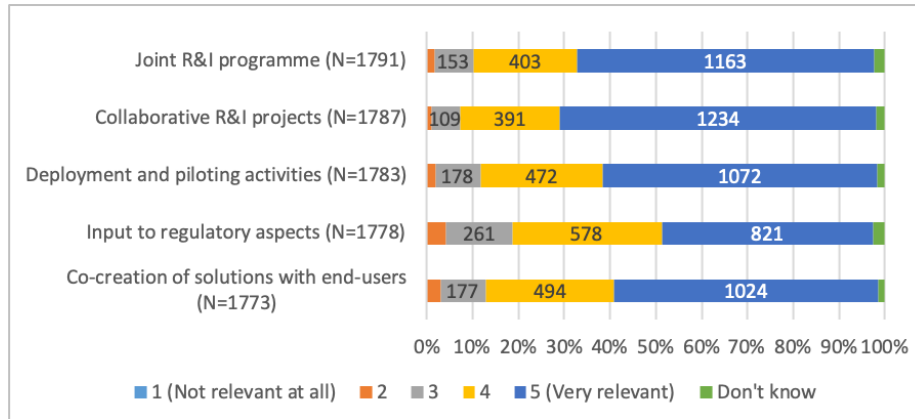


Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition"; Non-campaign replies; Aggregation of responses of all candidate initiatives

## Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives (see Figure 24).

Figure 24: Relevance of activities to implement



Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities"; Non-campaign replies; Aggregation of responses of all candidate initiatives

Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities shown in Figure 24, above.

## Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

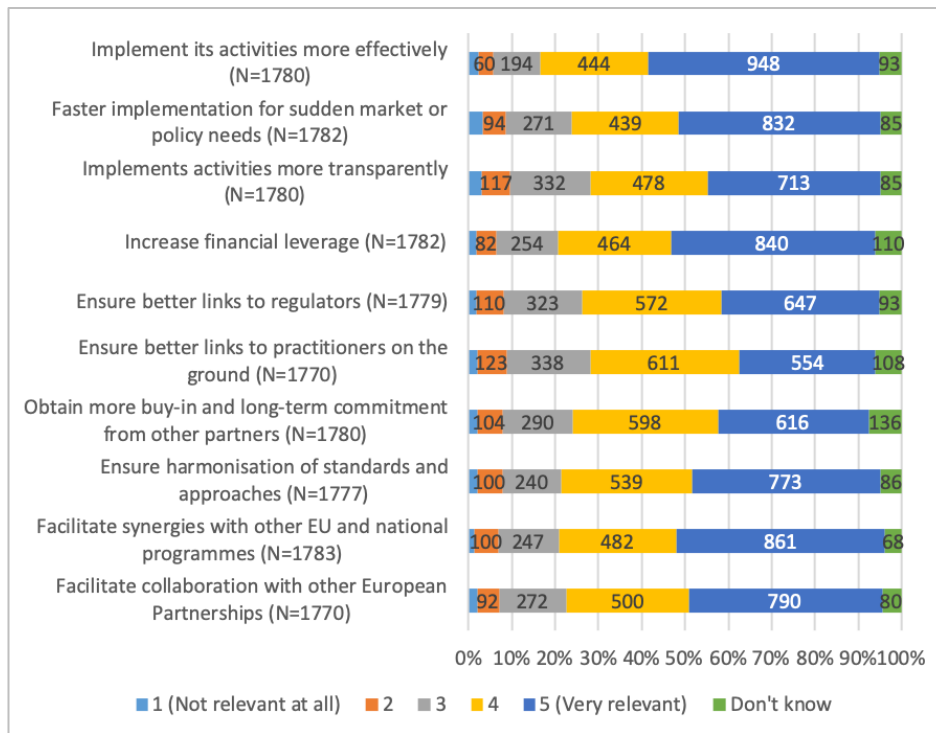
Respondents were then asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as presented in Figure 25. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. The legal structure was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

When comparing the main stakeholder categories, we found minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships than other open consultation respondents. NGOs find it slightly more relevant to implement activities faster for sudden market or

policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents.

The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Quite different results are shown for respondents that are/were directly involved in a current/preceding partnership when compared to respondents not involved in a current/preceding partnership, they indicated a higher relevance across all elements presented in Figure 25.

Figure 25: Relevance of setting up a legal structure (funding body)



Notes: Question: "In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

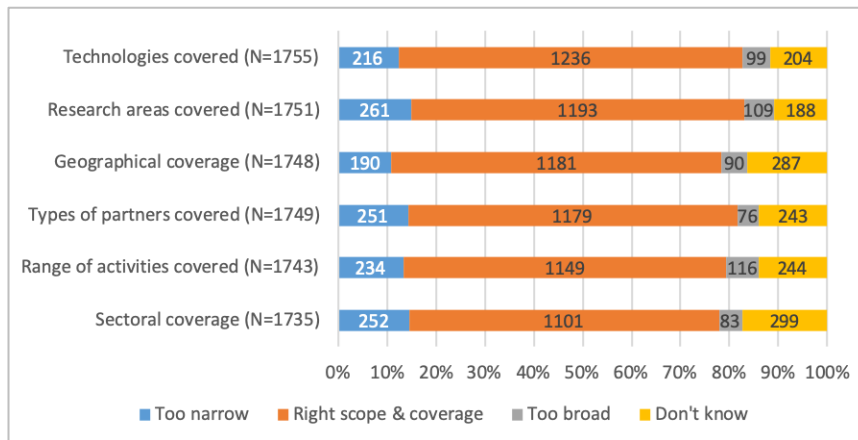
### Scope and coverage of the candidate European Partnerships based on their inception impact assessments

The response regarding the scope and coverage for the partnerships, based on inception impact assessments, shows that the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. Figure 26 shows the results. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". In the open answers respondents mostly reflected on specific aspects of the geographical and sectoral scope and coverage of the specific candidate European Partnerships, no overall lessons could be extracted.

Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" than other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow" when compared to other respondents. Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents.

The views of citizens are the same as for other respondents. Most notably, respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, more often indicated that the candidate institutionalised European Partnership have the “right scope & coverage”.

Figure 26: Assessment of the proposed scope and coverage of the candidate European Partnerships



Notes: Question: “What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment?”; Non-campaign replies; Aggregation of responses of all candidate initiatives

### Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered “Yes” (1000, or 62.15%), while over one third answered “No” (609, or 37.85%). Nearly no differences were found between the main stakeholder categories, only large companies and SMEs indicated slightly more often “Yes” in comparison to other respondents.

The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated “No” more often, the balance is about 50/50 between “Yes” and “No” for this group.

In the open responses respondents often referred to specific similar/comparable and complementary initiatives discussing the link with a specific candidate European Partnership, no overall lessons could be extracted, but more detailed results can be found in the partnership specific result sections.

### Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

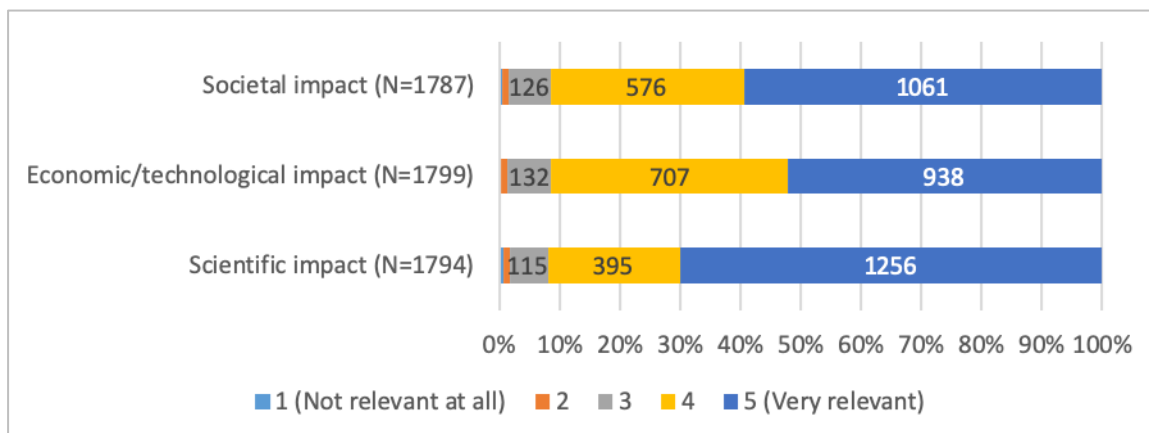
Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal impacts, Economic/technological impacts and Scientific impacts. To aggregate results the average of the responses on partnership specific impacts were calculated.

As presented in Figure 27, overall, all three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that these impacts were (very) relevant.

Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important.

Citizens, both EU and non-EU citizens, did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 27: Relevant impacts of future European Partnerships



Notes: Question: "In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

## **B.6 Responses to the open public consultation for the candidate partnership "Innovative Health"**

### **B.6.1 Introduction**

This chapter outlines the results of the Open Public Consultation for the candidate European Partnership on Innovative Health. The chapter outlines the following:

- Results on general questions, segregated for this candidate European Partnership:
  - Views on the needs of the future European Partnerships under Horizon Europe
  - Views on the advantages and disadvantages of participation in an Institutionalised European Partnership
- Results on specific questions for this candidate European Partnership:
  - Relevance of research and innovation efforts at the EU level to address problems
  - Views on Horizon Europe interventions to address these problems
  - Views on the relevance of elements and activities in:
    - setting a joint long-term agenda;
    - pooling and leveraging resources;
    - partnership composition;
    - implementation of activities.
  - Views on setting up a specific legal structure (funding body)
  - Views on the proposed scope and coverage of this candidate European Partnership
  - Views on the alignment of the European Partnership with other initiatives
  - Relevance of this candidate European Partnership to deliver impacts

### B.6.2 Characteristics of respondents

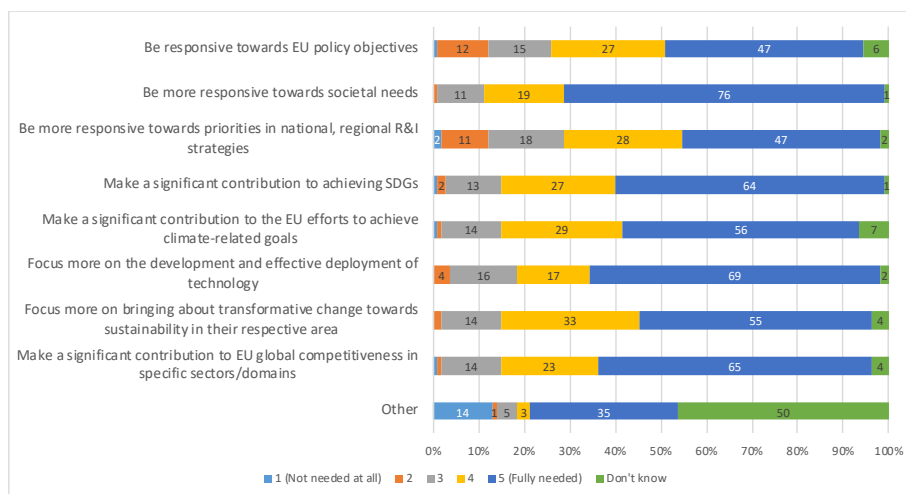
In total, 108 respondents provided views about the Innovative Health Initiative Partnership. Among them, 35 respondents (32.41%) are representatives of academic and research institutions, 19 respondents (19.44%) are company/business organisations, and 17 respondents (15.74%) are citizens. The majority of respondents, namely 77 (71.30%), have been involved in the on-going research and innovation framework programme, while 49 respondents (63.64%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

### B.6.3 Characteristics of future candidate European Partnerships – as viewed by respondents to the Innovative Health initiative

At the beginning of the consultation, the respondents of this partnership indicated their views of the needs of the future European Partnerships under Horizon Europe. Overall, respondent indicated that many of these needs were fully needed. The need where most respondents indicated this, was be more responsive towards societal needs (76, 70.37%) Aside from 'other', the needs where the least respondents indicated that these needs were fully needed, are being more responsive towards EU policy objectives and being more responsive towards priorities in national and/or regional R&I strategies, but even for these answers 47 (43.52%) respondents indicated that this was fully needed. The only options where less than 30% of respondents indicated that options were fully needed, was in response to be more responsive toward priorities in national and/or regional R&I strategies and for the other category. With regard to Other, it is likely that respondents did not have a concrete idea of other needs of the future European Partnerships.

No statistical differences were found between the views of citizens and other respondents.

Figure 28 Needs assessment (N=108)



Notes: Question: "To what extent do you think that the future European Partnerships under Horizon Europe need to ..."

The respondents also had the option to indicate other needs. The results of the analysis resulted in the chart shown in Figure 29 showing the co-occurrences of keywords. The results show that respondents have indicated needs around investment in long term European partnership, extensive support and the value chain.



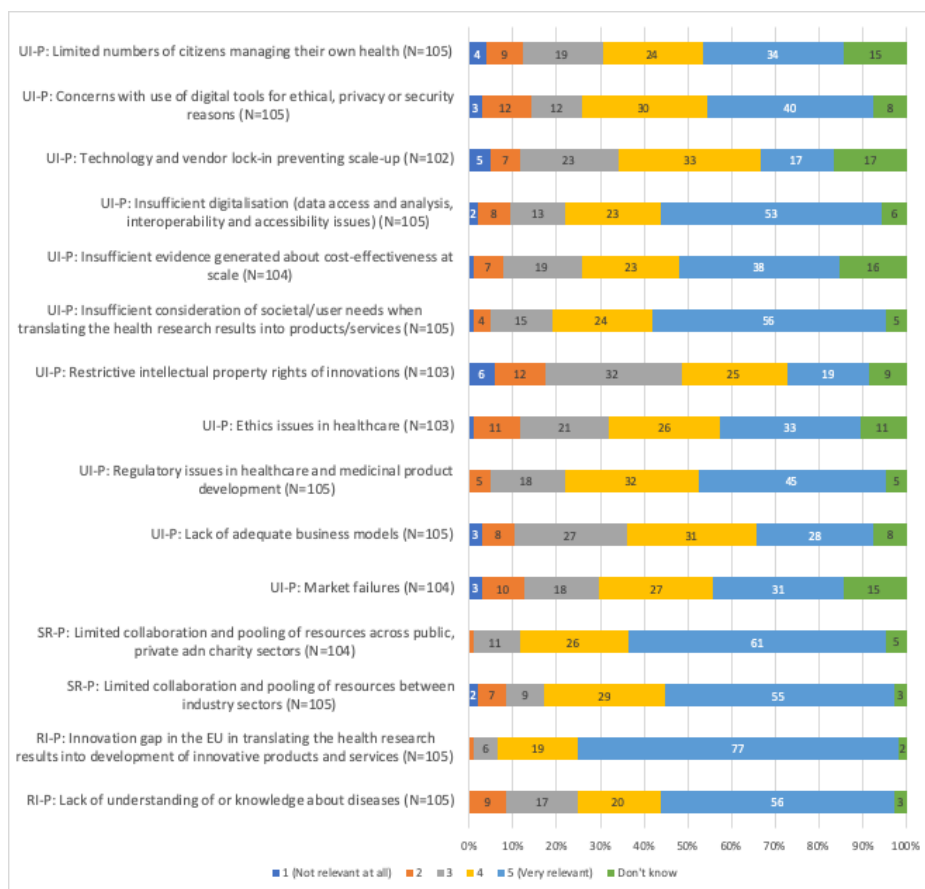


advantages citing increased cohesion and alignment between different stakeholders as a means to reduce duplication of efforts and enable knowledge transfer. Academic respondents gave a more balanced view, indicating that collaboration and cooperation between partners would maximise impact on shared societal issues but highlighted concerns that the partnership could be overly bureaucratic and heavily administrative.

### B.6.5 Relevance of EU level efforts to address problems in relation to the Innovative Health initiative

In the consultation, respondents were asked to provide their view on the relevancy of research and innovation efforts at EU level to address the following problems in relation to health and health care innovation, specifically on three types of problems: problems in uptake of health innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 31 the responses to these answers are presented.

Figure 31: Relevant problems to address in relation to health and health care innovation



Notes: Question: "To what extent do you think it is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question?"

With regard to the uptake in innovation problems, the answered that received the most 5 (Very relevant) answers is insufficient consideration of societal or user needs when translating the results of health research into better health products and services for its citizens (56, 53.33%). This option was closely followed by Insufficient digitalisation (data access and analysis, interoperability and accessibility issues) (53, 50.48%). The option that has received the least 5 (very relevant) answers is the technology and vendor lock-in preventing scale-up (17,16.67%).

With regard to structural and resource problems, the answers to the two questions are fairly similar. Limited collaboration and pooling of resources across public, private and

charity sectors is considered slightly more relevant, with 61 respondents indicating that this is very relevant (58.65%). Overall respondents have indicated that on average, structural and resource problems are more relevant than the uptake of health innovation problems.

Finally with regard to Research and innovation problems, the innovation gap in the EU in translating the results of health research into the development of innovative health products and services has received the most 5 (very relevant) answers, of all of the problems that the respondents were asked to reflect on (77, 73.33%).

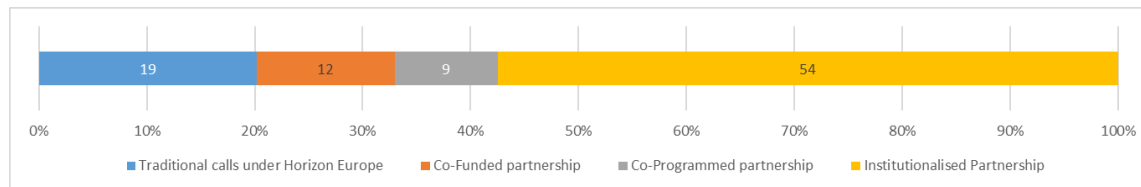
No statistical differences were found between the views of citizens and other respondents.

#### B.6.6 Horizon Europe mode of intervention to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 32, just over 55% of respondents indicated that institutionalised partnerships were the best fitting intervention.

No statistical differences were found between the views of citizens and other respondents.

Figure 32: Options to address the challenges

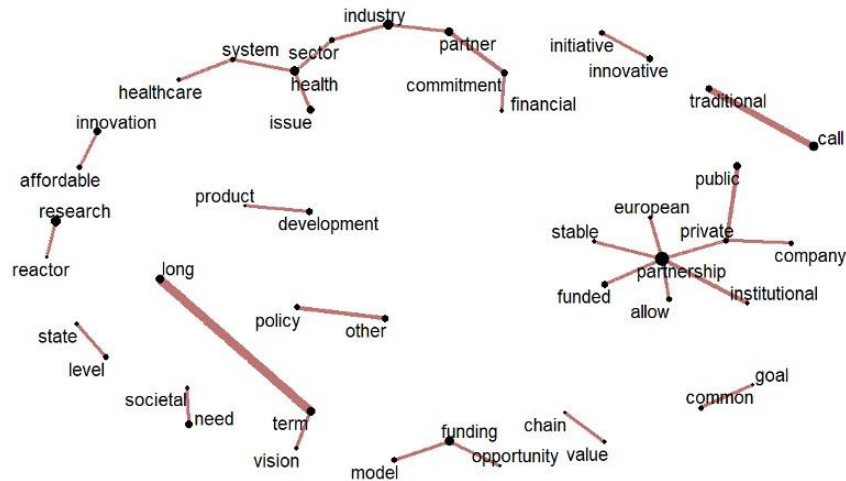


Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"

The respondents were asked to briefly explain their answers to the question above. People who stated that an institutionalised partnerships was the best fitting answer mentioned long term collaboration, global health issues and financial commitment (Figure 33). Respondents who did not select institutionalised partnership as their preferred intervention (N=47) mentioned traditional calls, industry partners and collaborative research as crucial for innovation (not pictured).

Qualitative analysis of responses revealed that stakeholders felt the coordinated and collaborative nature of the partnership was an important feature that would be able to address key challenges. The long-term perspective was also frequently discussed as a driver of innovation.

Figure 33: Open answers to explain the choice institutionalised partnership in the assessment of the Horizon Europe intervention (N=76)



Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"

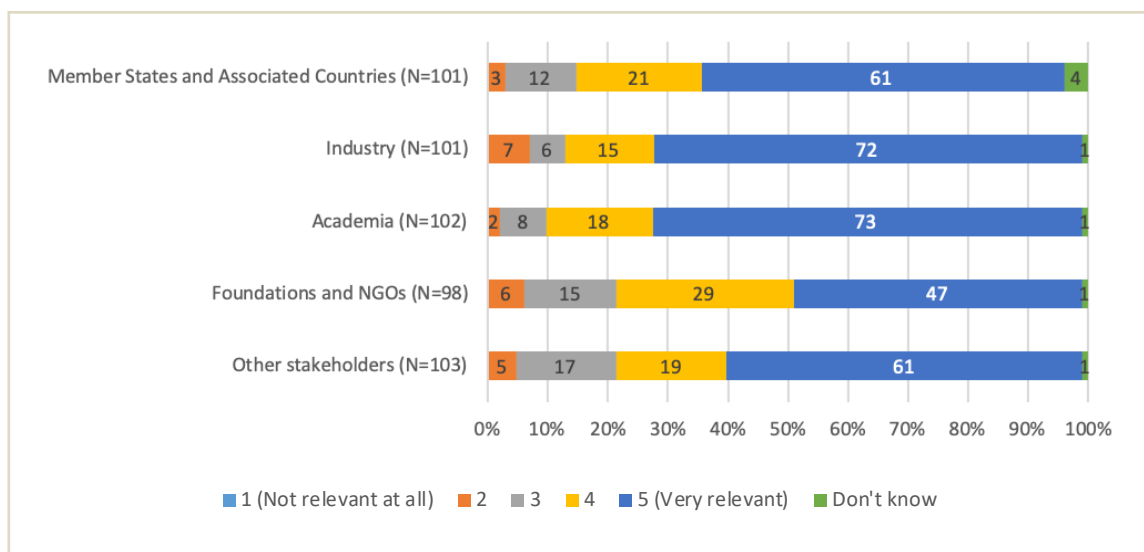
**B.6.7 Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives**

**Setting joint long-term agendas**

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives. According to Figure 34, a higher number of respondents consider that the involvement of academia and industry is highly relevant for reaching objectives of the Innovative Health Initiative Partnership. In contrast, the importance of involvement of foundations and NGOs in setting joint long-term agenda is considered lower, as only 47 respondents (47.96%) view them as highly relevant actors for setting the agenda.

No statistical differences were found between the views of citizens and other respondents. Respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) find industry a more important stakeholder to involve in joint long-term agenda setting than other respondents.

Figure 34:: Stakeholders to involve in setting joint long-term agenda's

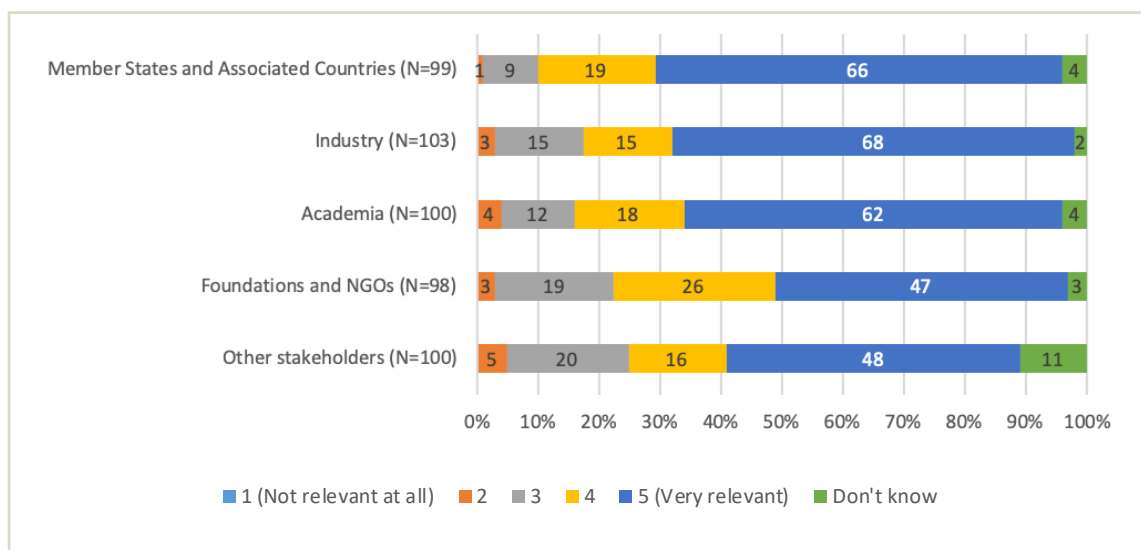


## Pooling and leveraging resources through coordination, alignment and integration with stakeholders

When respondents were asked about the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise, to meet the Partnership objectives, their views reflect the significant perceived role of Member States and Associated Countries. On a scale from 1 (not relevant at all) to 5 (very relevant), 85.86% of respondents consider Member States and Associated Countries relevant (score – 4) and very relevant (score – 5). The importance of involvement of other actors, such as industry and academia, is also considered relatively high by respondents. In contrast, the role of foundations, NGOs and other stakeholders in pooling and leveraging resources, is seen less relevant. See Figure 35, below.

A slight statistical difference was found between the views of citizens and other respondents. Citizens show slightly less relevance for industry, for other categories views show no statistical differences.

Figure 35: Relevance of actors for pooling and leveraging resources



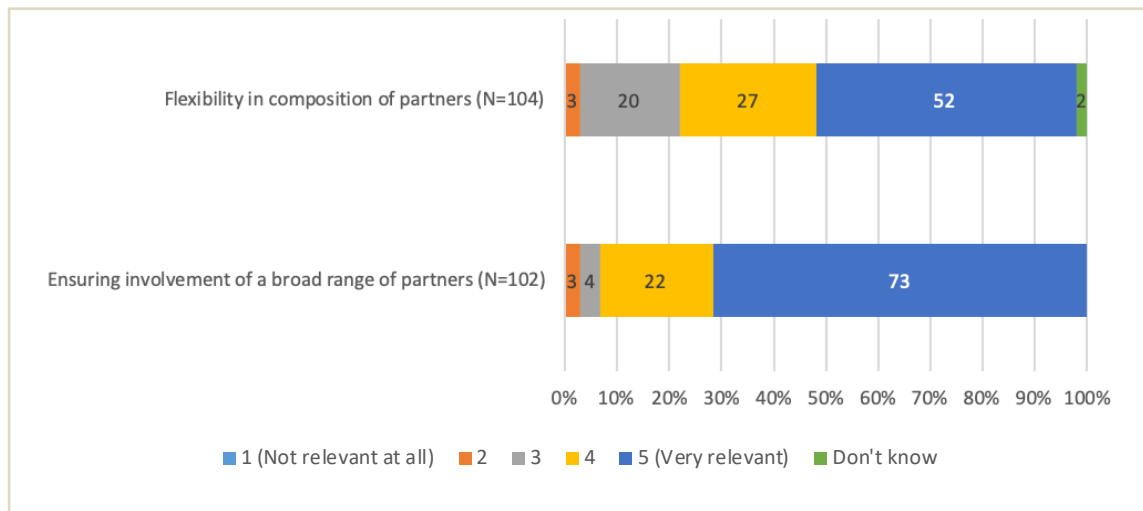
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with:"

## Relevance of elements and activities for the partnership composition

Respondents were asked about the relevance of Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. Based on views of respondents, the involvement of a broad range of partners is considered more relevant to meet the objectives of the Partnership than the flexibility in composition of partners over time, as 73 of respondents (71.57%) versus 52 (50%) respectively consider them very relevant.

No statistical differences were found between the views of citizens and other respondents.

Figure 36: Relevant principles for the partnership composition

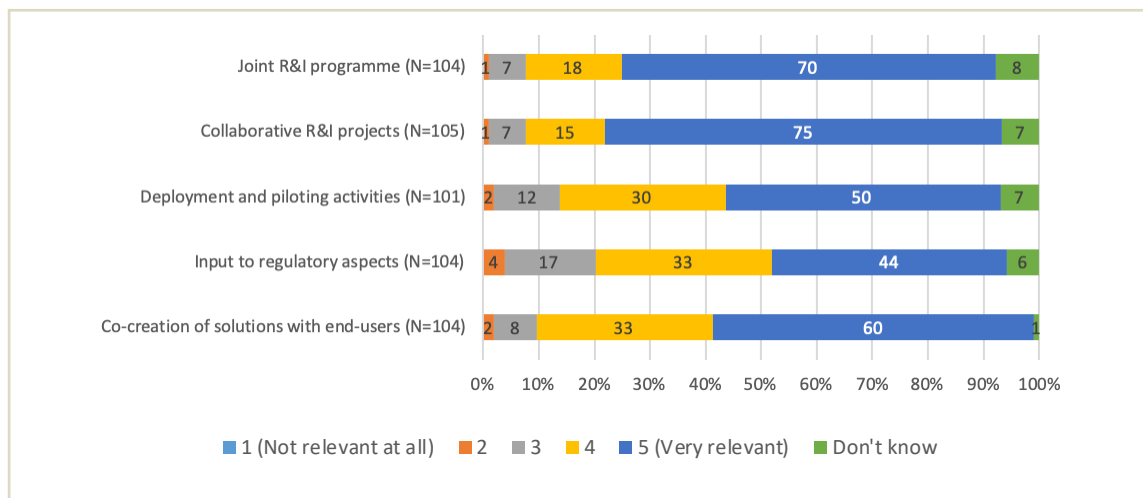


### Relevance of implementation of activities

Respondents were asked to provide opinions on relevance of implementation of several activities for meeting objectives of the Innovative Health Initiative. According to Figure 37, over 67% of respondents consider collaborative and joint R&D projects very relevant for reaching the objectives of the Partnership. The least number of respondents, namely 44 (42.31%), view the input to regulatory aspects relevant for meeting objectives.

No statistical differences were found between the views of citizens and other respondents.

Figure 37: Relevance of activities to implement



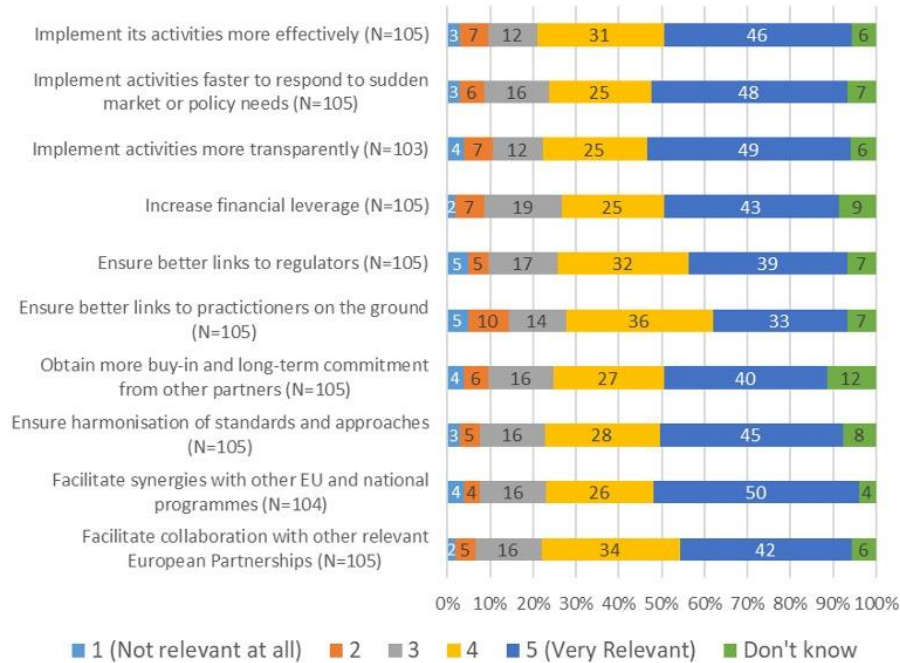
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities"

### B.6.8 Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several objectives. The opinions of respondents reveal that the legal structure would be equally beneficial for most listed activities, as Figure 38 reflects a similar pattern of responses. However, the least number of respondents suggest that the legal structure would be very relevant for ensuring better links to practitioners on the ground and to regulators.

No statistical differences were found between the views of citizens and other respondents.

Figure 38: Relevance of setting up a legal structure (funding body)

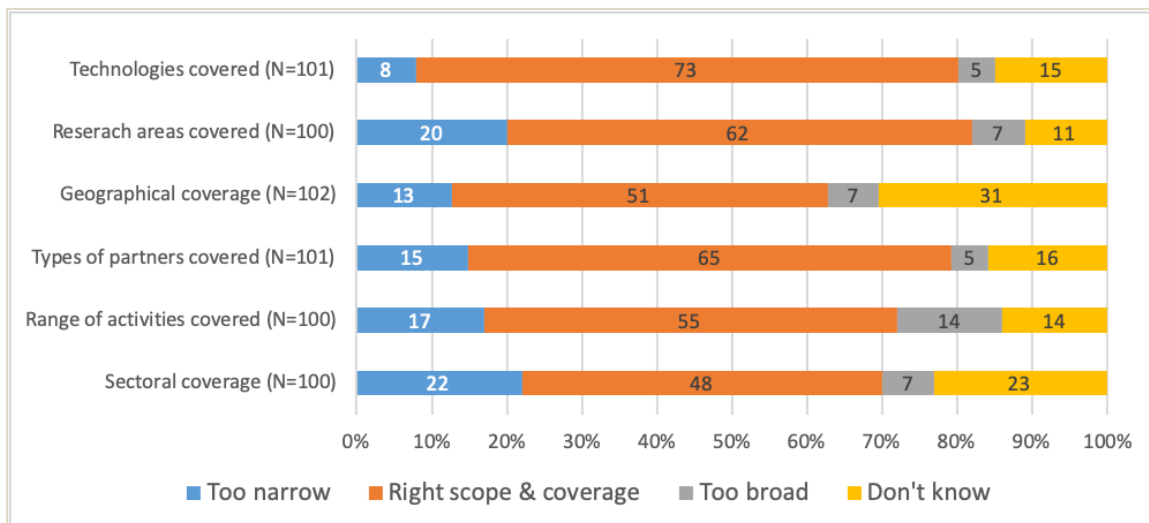


**B.6.9 Scope and coverage of the candidate European Partnerships based on their inception impact assessments**

Respondents were asked to assess the scope and coverage of the proposed Innovative Health Initiative Partnership, based on its inception impact assessment. According to Figure 39, 73 respondents (72.27%) consider that the coverage and scope of technologies is right, while the least number of respondents, namely 51 out of 102 (50%), think that the proposed sectoral and geographical coverage and scope are right. Moreover, 20 respondents (20%) indicated that the research areas covered are too narrow.

No statistical differences were found between the views of citizens and other respondents.

Figure 39: Scope and coverage proposed for the Innovative Health institutionalised Partnership

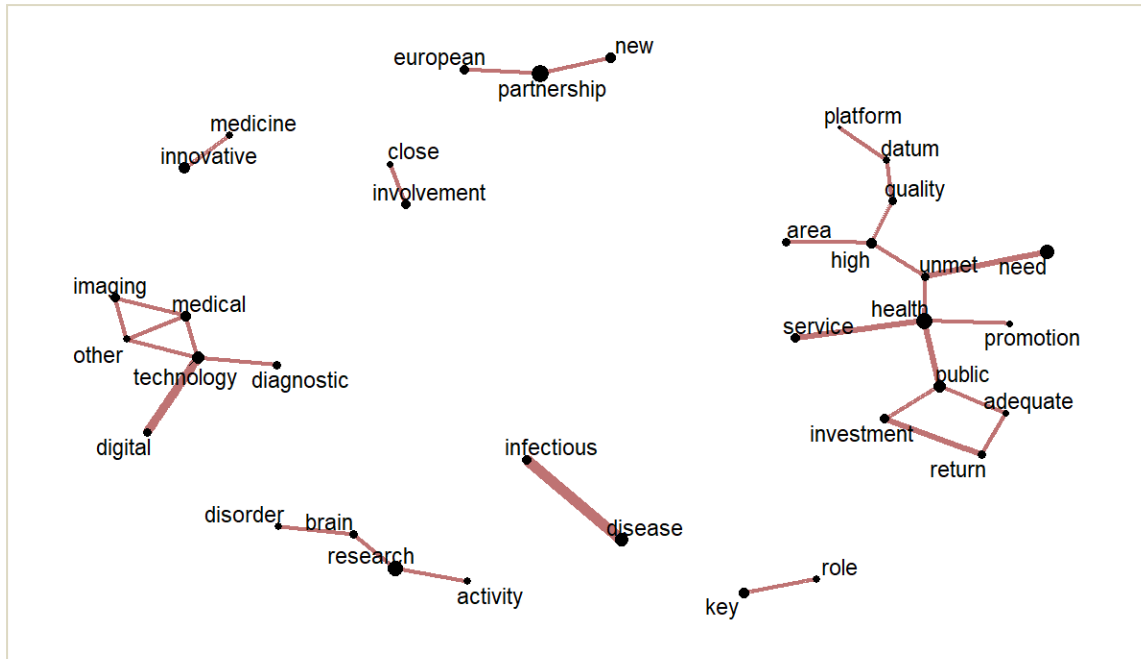


Notes: Question: "What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment?"

Aside from this multiple choice question, the respondents were also asked to provide any comment that they may have on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword analysis used for open questions resulted in the

graph shown in Figure 40. This analysis showed the respondents used this question to talk about infectious diseases, the scope of the partnership with regard to global health, the health system and public health.

Figure 40: Scope and coverage proposed for the Innovative Health institutionalised Partnership – open question (N=41)



Notes: 30 most common co-occurring keywords

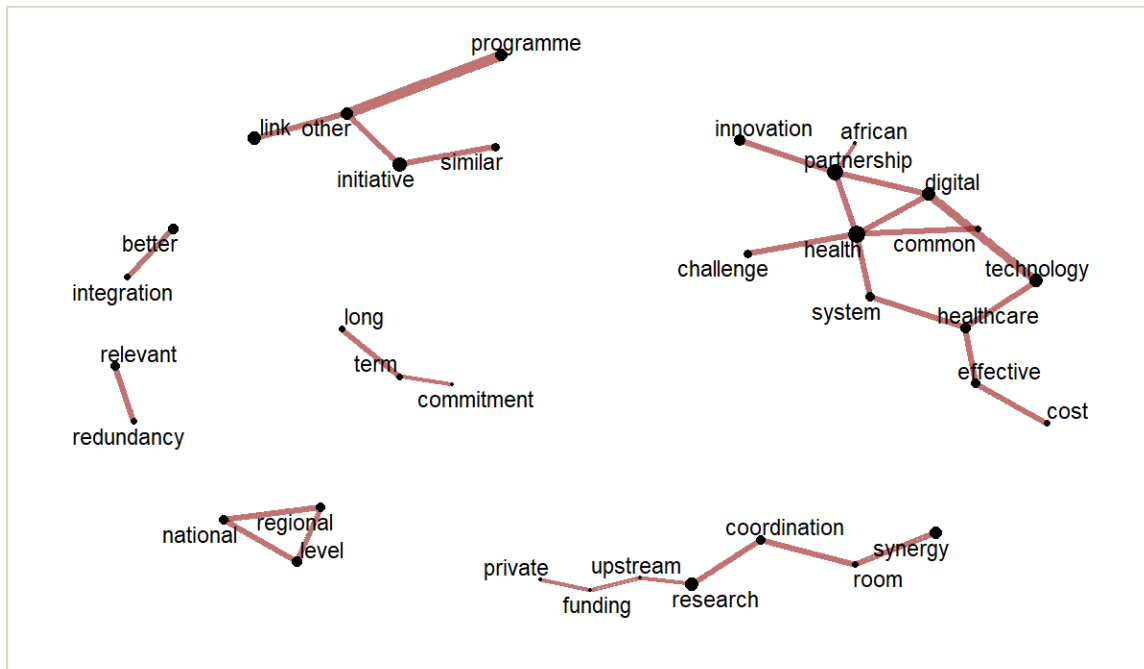
In the qualitative analysis of responses, prevention and new technologies were identified as key areas that should be within scope. It was discussed that including a broad range of stakeholders was important to drive innovation, but this was also raised as concern that too broad a scope would be difficult to manage administratively. Including stakeholders from non-European countries in cases where their expertise and participation was warranted was also seen as important.

*B.6.10 Scope for rationalisation and alignment of candidate European Partnerships with other initiatives*

Out of 91 respondents, 78 (85.71%) think that it be possible to rationalise the candidate Innovative Health Initiative and its activities, and/or to better link it with other comparable initiatives.

The respondents who answered affirmative, were asked which other comparable initiatives it could be linked with. The results of the analysis resulted in the chart shown in Figure 41 showing the co-occurrences of keywords. The results show that respondents mention other programmes, complementary initiatives, health system partnerships and digital technology.

Figure 41: Comparable initiatives to link with the partnership (N=42)

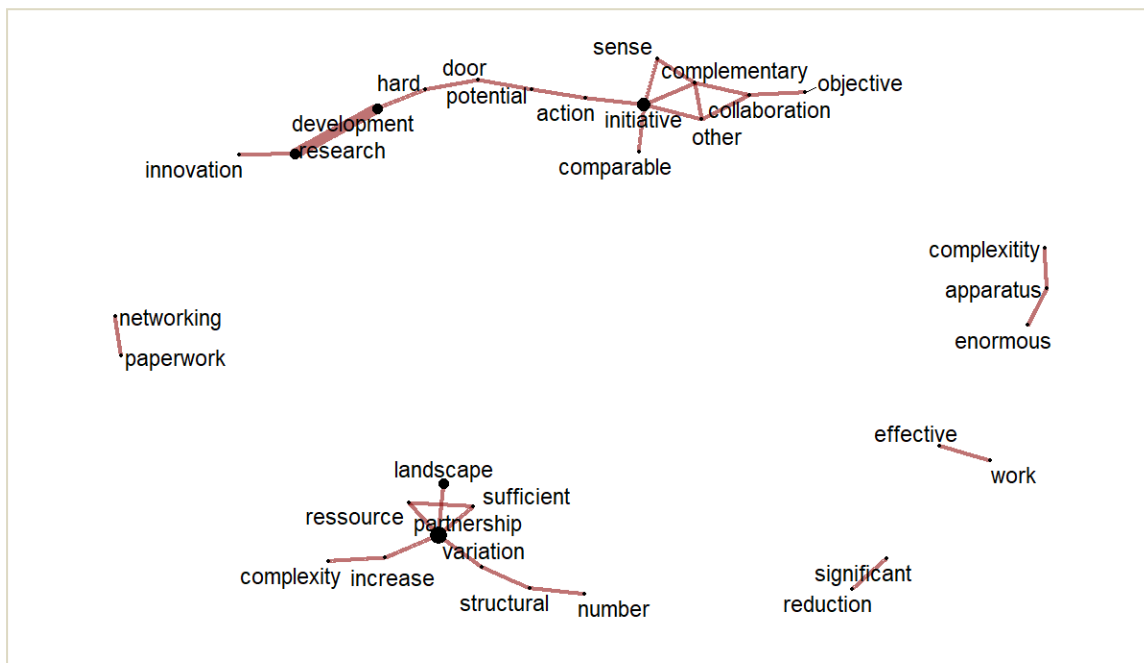


Notes: Open question: "Which other comparable initiatives could the partnership be linked with?"; 30 most common co-occurring keywords

Qualitative analysis of responses from stakeholders who felt that this initiative could be rationalised with comparable initiatives revealed that streamlined research processes and a reduction in duplication were key drivers. Some of the comparable initiatives listed were Key Digital Technologies, EDCTP, One Health EJP and national initiatives.

For the respondents who answered negatively on the previous question, the results of the analysis resulted in the chart shown in Figure 42 showing the co-occurrences of keywords. The results show that respondents mention other complementary initiatives, sufficient knowledge and resources and research and development.

Figure 42: Other comparable initiatives – open question (N=6)



Notes: Open question: "why other comparable initiatives are not suitable to be linked?"; 30 most common co-occurring keywords



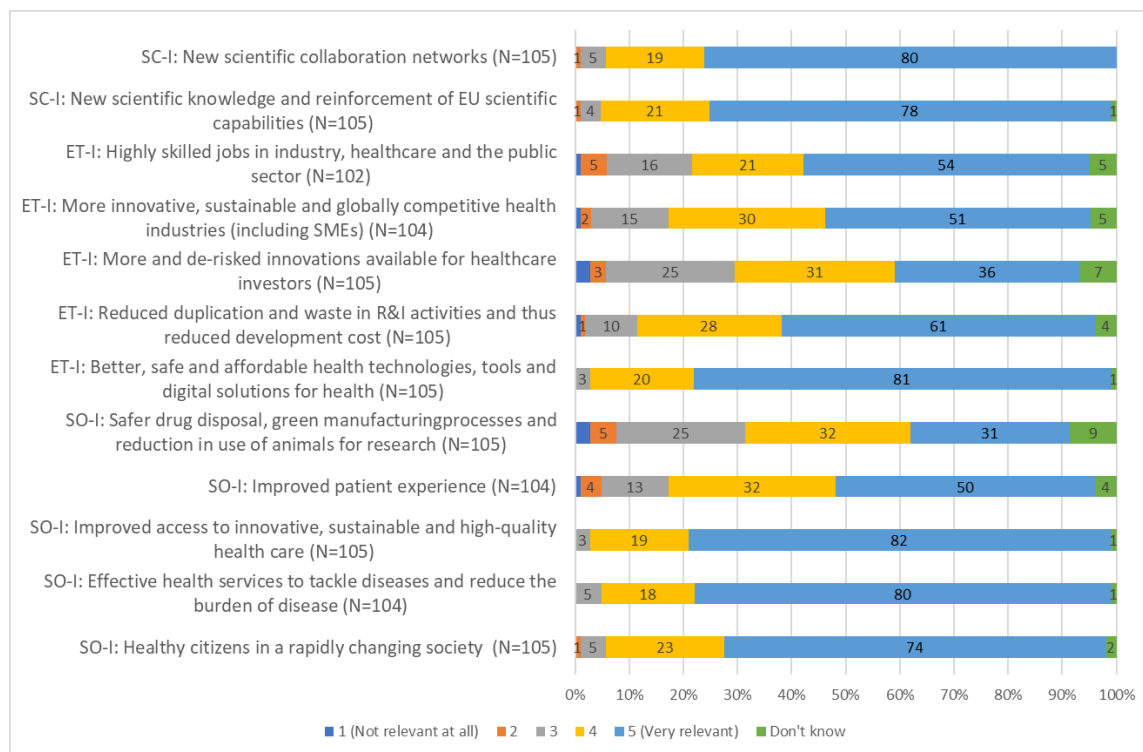
Qualitative analysis of responses revealed that an increase in complexity was a major concern of those who felt that the institutionalised partnership should not be linked to comparable initiatives. It was however, felt that there could be benefits from learning and working with other initiatives if the complexity was managed.

*B.6.11 Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts*

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed impacts. According to Figure 43, the candidate Partnership is expected to be 'very relevant' for improving access to innovative, sustainable and high-quality health care, for ensuring effective health services to tackle diseases and reduce the burden of disease, and for ensuring that there are healthy citizens in a rapidly changing society. Among listed economic and technological impacts, a greater number of respondents (81 out of 105, or 77.14%) indicated that the candidate Partnership would make a significant contribution towards better, safe and affordable health technologies, tools and digital solutions for health. The results for listed scientific impacts are very similar and positive, reflecting high expectations about potential impacts of the candidate Partnership.

No statistical differences were found between the views of citizens and other respondents for most of the discussed impacts. The economic and technological impact regarding the availability of more and de-risked innovations for healthcare investors was found more relevant by respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7).

Figure 43: Relevance of the candidate European Institutionalised Partnership to various impacts



Notes: Question: "In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts?"

## Appendix C Methodological Annex

The Impact Assessment studies for all 13 candidate institutionalised European Partnerships mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. The Impact Assessment Study Teams went through grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for their candidate partnerships. The review of official documentations, especially from the European Commission, additionally helped understand the main EU policy proprieties that the initiatives under assessment could contribute to achieve.

Almost no candidate institutionalised European Partnership is intended to emerge ex nihilo. Partnerships already existed under Horizon 2020 and will precede those proposed by the European Commission. In the assessment of the problems to address, the Impact Assessment Study Teams therefore considered the achievements of these ongoing partnerships, their challenges and the lessons that should be drawn for the future ones. For that purpose, they reviewed carefully the documents in relation to the preceding partnerships, especially their (midterm) evaluations conducted. The bibliography in Annex A gives a comprehensive overview of the documents and literature reviewed for the present impact assessment study.

Finally, the description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. The European Commission services and, where needed the ongoing Joint Undertakings or implementation bodies of the partnerships under Article 185 of the TFEU, provided data on the projects that they funded and their participants. These data served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to the countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and to the industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS. We used the NACE codification up to level 2. These data enabled identified the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that will need to be involved (further) in the future partnerships.

The horizontal teams also conducted a Social Network Analysis using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing European partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided by the European Commission finally served a bibliometric analysis aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

All together, these statistical analyses will complement the desk research for a comprehensive definition of the context in which the candidate institutionalised European Partnerships are intended to be implemented. The conclusions drawn on their basis will be confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European partnerships received in August 2019
- The open public consultation organised by the European Commission from September to November 2019
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020.

For instance, in all three exercises, the respondents were asked to reflect on the main challenges that the candidate institutionalised European Partnerships should address. In the open public consultations, they mainly reacted to proposals from the European Commission like when they were given to opportunity to give feedback to the inception impact assessment.

The views of stakeholders (and experts) were particularly important for determining the basic functionalities that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the Study Teams confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation. Annex B includes also the main outcomes of these three stakeholder consultation exercises.

The comparison of different options for European partnerships additionally relied on a cost-effectiveness analysis. When it comes to research and innovation programmes, the identification of costs and benefits should primarily be aimed at identifying the “value for money” of devoting resources from the EU (and Member States) budget to specific initiatives. Based on desk research and consultation with the European Commission services, the horizontal study team produced financial estimates for different types of costs (preparation and setup costs, running costs and winding down costs) and per partnership option. The costs were common to all candidate European Partnerships. The results of the cost model were displayed in a table, where each cost was translated on a scale using “+” in order to ease the comparison between the partnership options.

A scorecard analysis, which allocated each option a score between 1 and 3 against selected variables, was used to highlight those options that stand out as not being dominated by any of the other options in the group: such options are then retained as the preferential ones in the remainder of our analysis. It also allowed for easy visualisation of the pros and cons of alternative options.

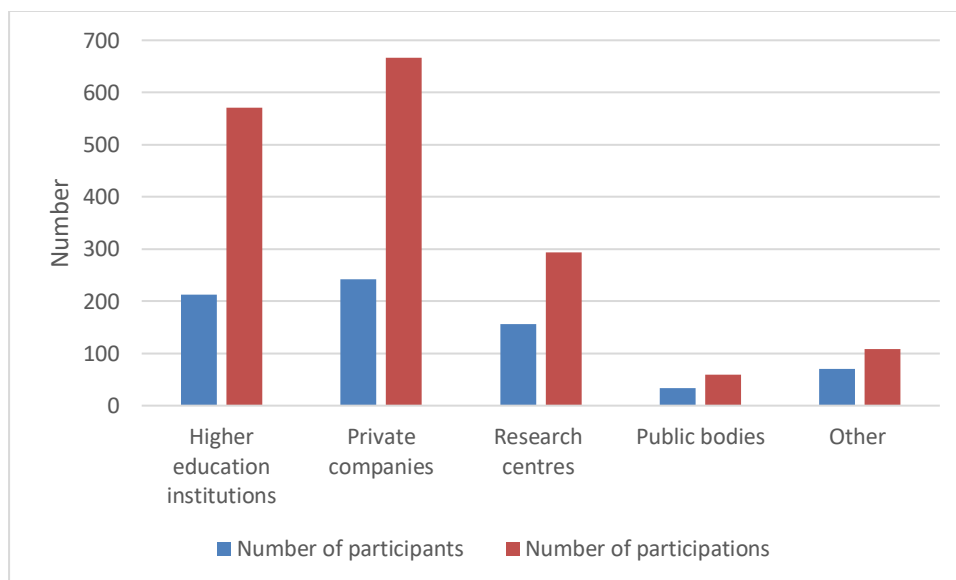
## Appendix D Additional information on the policy context

### D.1 IMI2 Joint Undertaking

#### D.1.1 Stakeholder analysis

Stakeholder analysis sets the basis for considering which stakeholders to involve in the future initiative. IMI2 JU participants spanned a wide range of organisations including private companies (including SMEs), higher education institutions, public-funded research centres, public bodies and others (e.g. non-profit organisations, patient associations, etc.). Based on our analysis of funded IMI2 JU projects (until 2018), overall 39.20% of the participants were private companies while 33.65% were higher education institutions, 17.25% were research performing organisations and 3.53% were public bodies (see Figure 44). From the data available to us, it was unclear how many beneficiaries were SMEs. However, analysis by the IMI JU management team shows that 15.4% of beneficiaries receiving EU funding are SMEs.<sup>106</sup> It should be noted that EFPIA members did not receive EU funding.

Figure 44: Overview of participants and participations per organisation type in IMI2 (2014-2018)



Source: Technopolis Group

In terms of the size of funding, higher education institutions accounted for the most funding, totalling around €447 million or 55% of the total net requested EU contributions between 2014 and 2018.<sup>107</sup> This was followed by €222 million (27%) for research centres, €87 million (11%) for private companies, €23 million (3%) for public bodies and €40 million (5%) for other types of organisations. However, it should be noted that constituent and affiliated entities of EFPIA (European Federation of Pharmaceutical Industries and Associations) that participated in projects did not get any reimbursement from the JU<sup>108</sup> and hence that funding is not represented among these figures.

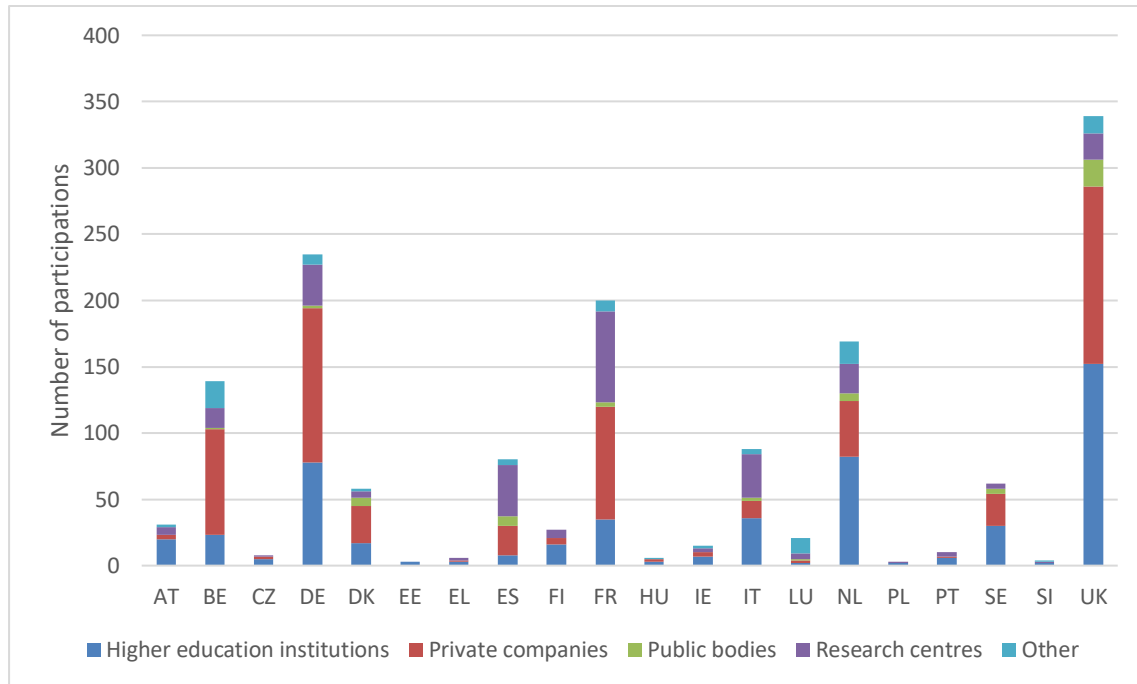
<sup>106</sup> IMI (2019) Annual Activity Report 2018. Available at: [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018\\_final.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018_final.pdf)

<sup>107</sup> Technopolis analysis of IMI2 JU data

<sup>108</sup> Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014 establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in 'Horizon 2020 the Framework Programme for Research and Innovation (2014-2020)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking OJ L 174, 13.6.2014, p. 7-11 ; Financial Rules of the Innovative Medicines Initiative 2 Joint Undertaking

The maximum number of participants (including all public and private sector participants and non-EU participants) were from the UK (19.95%, n=339) followed by Germany (13.83%, n=235), France (11.77%, n=200), the Netherlands (9.95%, n=169) and Belgium (8.18%, n=139) (see Figure 45). The EU15 member states dominated participation accounting for 87% of participations and 90% of the total net requested EU contributions. In turn, EU13 accounted for only 2% of the participations and 1% of the total EU contributions. There was participation from associated member states (7%; 3% of contributions) and other international partners (4%; 5% of contributions) as well.

Figure 45: Overview of participants per EU member state in IMI2 JU (2014-2018) by organisation type

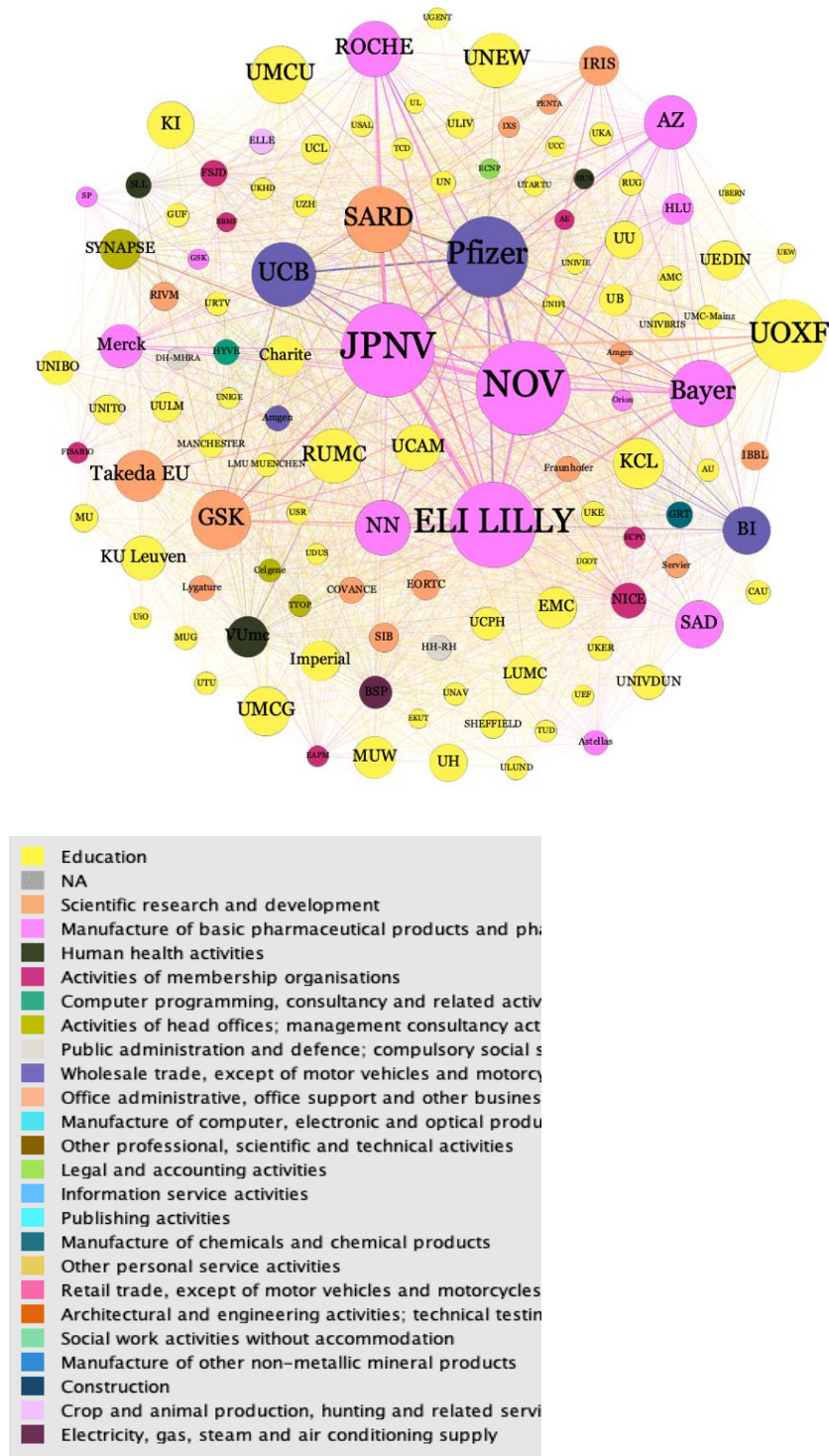


Source: Technopolis Group

Based on IMI2 JU participation data, we mapped the level of participation of individual organisations. Figure 46 below outlines a preliminary mapping of the IMI2 JU network according to organisations' NACE<sup>109</sup> industry sector (classified according to colour) with the bubble size indicating the frequency of participation (the bigger the bubble, the more frequent participation). The lines ('ties') between two organisations display the frequency of collaboration among the concerned organisations. The figure shows that the private companies, Janssen Pharmaceutica NV, Novartis Pharma AG, Eli Lilly and Company and Pfizer participated in the most number of IMI2 JU projects (see JPNV, NOV, ELI LILLY and PFIZER in Figure 46 below).

<sup>109</sup> NACE (Nomenclature of Economic Activities) is the European statistical classification of economic activities. NACE groups organisations according to their business activities. Statistics produced on the basis of NACE are comparable at European level and, in general, at world level in line with the United Nations' International Standard Industrial Classification (ISIC).

Figure 46: Preliminary mapping of the network structure of IMI2 JU by sector



Source: Technopolis Group

### D.1.2 Lessons learned

Health interventions are notoriously complex to design and implement and stretch the full spectrum of the health and care pathway: from prevention, through diagnosis and treatment to management of diseases and end of life care. While they can significantly contribute to addressing health and care challenges, we know that many innovations are

currently slow to reach patients and healthcare professionals.<sup>110</sup> For too long, the academic, industry and health sectors have worked in relative segregation, without an opportunity to collaborate on integrated solutions where drugs, devices and software are seamlessly combined into personalised and adaptable solutions. It is anticipated that such solutions would not only meet public health needs in Europe but also provide a strong base to attract, retain and grow competitive companies in Europe that excel in global markets.

Some of these features were also observed in IMI2 JU<sup>111,112</sup> and lessons have been learned. For instance, there was low participation of industry sectors other than pharma such as imaging, diagnostics, medical technology, ICT; limited SME participation; insufficient engagement with advisory bodies; and insufficient coherence and alignment with regional and national policies and strategies. The involvement of civil society organisations in Horizon 2020 in general remains low<sup>113</sup>, which means that there is a gap to be filled in terms of bringing R&I closer to the public, which will be important if people-centred and personalised innovations are the aim.

The lessons learned were also articulated in the form of recommendations for what future IMI-like joint undertakings should do. These are to:<sup>114</sup>

- Substantially adapt the collaborative and funding model to enable the active engagement of other industry sectors with the pharmaceutical industry for the development of new healthcare interventions.
- Increase the transparency of in-kind contributions as well as the Strategic Research Agenda and call topics generation to reflect European interest and interests of stakeholders other than EFPIA
- Change the rules on the calculation of the in-kind contributions from non-European entities. As increasing investments in Europe is usually the goal, in-kind contributions should not be accepted for matching with EU funds if activities are occurring outside the EU, but could be counted as additional contributions or leveraging effects.

These recommendations were made in 2017 and the first recommendation in particular is being taken into account for the new candidate partnership, IHI.

Other recommendations for a new partnership based on lessons learned were articulated in member state consultations. Herein, respondents identified that SME involvement could be improved through measures such as more favourable IP rules for SMEs.<sup>115</sup> Other areas for action were identified albeit to a lower extent to achieve better outcomes from a future partnership. These included:

---

<sup>110</sup> DG RTD (2019) Inception Impact Assessment of the proposed European Partnership on Innovative Health.

<sup>111</sup> 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

<sup>112</sup> Meulien P. (2017) The Innovative Medicines Initiative: taking open innovation to the next level. The European Files 49: 14-15.

<sup>113</sup> European Commission (2017) Commission staff working document. In-depth interim evaluation of the Horizon 2020. Brussels: Publications Office of the European Union

<sup>114</sup> 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

<sup>115</sup> European Commission (2019) European Partnerships under Horizon Europe: results of the structured consultation of Member States. Draft report for the meeting of the Shadow Configuration of the Strategic Programme Committee on 27 June 2019.

- A stronger role for national authorities in the governance to address public health needs and allow synergies with national programmes
- Including healthcare providers in projects and linking to national health systems and regulatory bodies
- Coordinating with academia to support the translation of research findings into products, policy or practice
- Reinforcing the European digital industry in the face of global competition
- Supporting industry collaboration through strategic agenda setting and jointly addressing operational, regulatory and economic challenges
- Vaccine research, including method development for quality control
- Implementing “green technology solutions” in drug manufacturing
- Education and training of users
- Incentives for healthcare providers
- Ultimately, if achieving the SDGs is desired, an impact-focused and/or mission-oriented approach is warranted according to the interim evaluation of Horizon 2020,<sup>116</sup> which might be something to consider for the proposed IHI partnership.

## **D.2 IMI success stories**

Since its inception, IMI has resulted in a range of outcomes and impacts on healthcare, health systems and patient wellbeing. A selection of these success stories is highlighted here.

### *D.2.1 Empowering patients*

The European Patients' Academy on Therapeutic Innovation (**EUPATI**) is a programme centred on patient engagement.<sup>117</sup> EUPATI has helped address a key knowledge gap in patient and public knowledge by providing information on how medical research and development is conducted. Outputs from this project include the Patient Expert Training Course, a toolbox on medicines R&D, guidance documents for the engagement of patient organisations, and annual conferences and workshops. The Patient Expert Training Course is up to its fourth cohort having trained almost 100 patients from 32 countries across 58 disease areas. The R&D toolbox has been used by more than 500,000 people worldwide.

### *D.2.2 Better use of big data*

Big Data for Better Outcomes (**BD4BO**) is an IMI programme aiming to integrate detailed personal and biological data to uncover insights that will improve outcomes for patients. Within BD4BO is the European Health Data and Evidence Network (**EHDEN**) project that brings together large-scale clinical data to answer real world problems. The power of this concept was recently demonstrated when the EHDEN project team successfully analysed 20 years of clinical data in just 5 days emulating results from a clinical trial in knee-surgery.<sup>118</sup> This is the first milestone from this project, and it is anticipated that this will further stimulate this type of research in Europe.

---

<sup>116</sup> European Commission (2017) Commission staff working document. In-depth interim evaluation of the Horizon 2020. Brussels: Publications Office of the European Union

<sup>117</sup> <https://www.imi.europa.eu/projects-results/project-factsheets/eupati>

<sup>118</sup> <https://www.ehden.eu/ehden-knee-replacement-study-results-published-in-lancet-rheumatology-truly-elevating-observational-data/>



### *D.2.3 Faster diagnostics*

The lengthy diagnostic process was a major shortcoming in containing the 2014-15 west Africa Ebola outbreak. IMI's **Mofina** project aimed to address this problem by developing an alternative diagnostic test. The project resulted in the development of a compact, easy-to-use diagnostic device that can be deployed in the field and deliver results in a little over an hour.<sup>119</sup> The device is now validated and commercially available. The test can be used to diagnose Ebola and other *Filoviridae* such as Marburg virus with future plans to expand this to other WHO priority pathogens such as dengue and Lassa fever. The project partners report that the collaboration between public and private stakeholders was a key element to the success of the project.

### *D.2.4 Greener pharmaceuticals*

The project **CHEM21** aimed to address inefficiencies and sustainability in the manufacturing processes of pharmaceuticals. In doing so the project developed a new metric-based tool for use in the early stages of process development that has embedded 'green chemistry' in the overall approach to chemical development with EFPIA members.<sup>120</sup> The toolkit assesses how green a chemical reaction is by using a combination of qualitative and quantitative criteria. The project also delivered a range of new, cleaner catalysts which are currently being used by EFPIA members and facilitated the expansion of an SME into new areas of chemistry production.

---

<sup>119</sup> <https://www.imi.europa.eu/projects-results/project-factsheets/mofina>

<sup>120</sup> <https://www.imi.europa.eu/projects-results/project-factsheets/chem21>

## Appendix E Additional information related to the problem definition

### E.1 Taxonomy of failures requiring policy intervention

Market failures	
<b>Market power</b>	Inadequate market structures due to the degree of competition and barriers to entry such as strongly concentrated / closed industry sectors or markets
<b>Externalities</b>	Low return on investments due to difficulties, for innovators, appropriating the outcomes of their investments and limiting undesired spillovers to the benefit of competitors. Those externalities often cause low (private) investments, especially for uncertain and risky R&D activities.
<b>Information asymmetry</b>	Actors within a particular market (or system) have uneven access to information. Some may lack the information they need to develop and exploit their innovative products/services.
Systemic failures	
<b>Capability</b>	Factors related to the individuals' and organisations' absence or shortage of the necessary capabilities to acquire and absorb new knowledge, to adapt to new and changing circumstances, to grasp (technological) opportunities, and to switch from old to new (technological) trajectories. At a systemic level, it relates to 'sufficient scale' or 'critical mass'
<b>Network</b>	Interactions between a set of actors are too dense to allow for novel insights or inspirations to emerge. Strong dependence on few partners may lead to lock-in phenomena. <i>Weak network failure</i> : Too limited exchange and collaboration between organisations and individuals, which limit co-creation and co-development of new products and services,
<b>Institutional</b>	Norms and rules (regulatory framework) hinder innovation; social norms and values, and culture hinder innovation
<b>Infrastructural</b>	Lack of the physical (R&D facilities, ICT infrastructure, transport etc.) and knowledge (knowledge, skills, database etc.) infrastructures needed to enable and stimulate innovation activities.
Transformational failures	
<b>Directionality</b>	Lack of shared vision regarding the goal and direction of the required system transformation process. No coordination between the actors involved in system transformation. Absence of targeted funding for R&I activities and infrastructures, which would define collectively accepted trajectories of development.
<b>Demand articulation</b>	A deficit in anticipating and learning about user needs and constraints. Insufficient use of public demand to orient and leverage wider demand and influence innovation activities. Lack of mechanisms to articulate the demand from various groups of actors.

<b>Policy coordination</b>	Missing or weak coherence between the activities of national, regional, sectoral and technological institutions: lack of coordination between innovation and sectoral policies; lack of coordination between ministries and implementing agencies; no alignment between public and private organisations; mismatches in the timing of policy intervention
<b>Reflexivity</b>	Insufficient ability to monitor progress of (transformative) policy interventions towards the achievement of their objectives, to develop adaptation strategies, to anticipate changes (e.g. by developing strategies with open options taking into consideration uncertainty), and to involve a wide range of actors in the governance process. Absence of opportunities for experimenting policy instruments.

Source: Technopolis Group (2018), Modified from Weber & Rohracher (2012)

## E.2 Categorisation of the problem drivers for the Innovative Health Initiative

<b>Market failures</b>	
<b>Market power</b>	<ul style="list-style-type: none"> <li>• Business and R&amp;I funding models vary greatly between different health industry sectors</li> </ul>
<b>Externalities</b>	<ul style="list-style-type: none"> <li>• Limited scope for the exploitation of IP generated for some health industry sectors. Hence, it can be difficult to recoup investments resulting in lower engagement in any collaborative R&amp;I involving generation of new IP.</li> <li>• Some diseases or challenges e.g. infectious diseases and anti-microbial resistance also have low returns on investment.</li> </ul>
<b>Systemic failures</b>	
<b>Capability</b>	<ul style="list-style-type: none"> <li>• Capacity to collect, combine and analyse large datasets vary across industry sector and stakeholder types</li> </ul>
<b>Network</b>	<ul style="list-style-type: none"> <li>• Different health industry sectors (such as pharma, imaging, diagnostics, medical technology, ICT) not sufficiently collaborating with each other</li> </ul>
<b>Infrastructural</b>	<ul style="list-style-type: none"> <li>• Lack of interoperable data infrastructures across industry sectors and stakeholder types</li> </ul>
<b>Transformational failures</b>	
<b>Directionality (related to the direction and coordination of the targeted system transformation)</b>	<ul style="list-style-type: none"> <li>• Lack of sufficient collaboration and coordination between the industry sectors and stakeholder types (academia, large or SME industry, MSs, regulators, healthcare providers etc)</li> <li>• Lack of feedback loops in the system – healthcare providers, patients, regulators not informing prioritisation and innovation activities</li> </ul>

	<ul style="list-style-type: none"><li>• Member states can have different views of what involvement is required in practice.</li></ul>
<b>Policy coordination</b>	<ul style="list-style-type: none"><li>• Lack of policy coordination leading to partial overlap or gaps between EU initiatives e.g. those covering innovation in health and care and digital solutions</li><li>• Lack of coherence between related national and EU initiatives resulting in inefficiencies</li></ul>
<b>Reflexivity (ability to monitor progress of and adapt policy interventions)</b>	<ul style="list-style-type: none"><li>• Insufficient ability to monitor socioeconomic outcomes and impact with pre-defined SMART KPIs</li></ul>

Source: Technopolis Group

## Appendix F Additional information related to the policy options descriptions

### F.1 Degree of coverage of the different functionalities by policy option

Table 24: Type and composition of actors (including openness and roles)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b> Any legal entity in a consortium can apply to Horizon Europe calls in ad hoc combinations Calls are open to participation from across Europe and the world (not all entities from third countries are eligible for funding)</p>	<p><b>What is possible?</b> Partners can include any national funding body or governmental research organisation, Possible to include also other type of actors, including foundations.</p>	<p><b>What is possible?</b> Partners can include MS and Associated Countries.</p>	<p><b>What is possible?</b> Suitable for all types of partners: private and/or public partners, including MS, regions, foundations. By default open to AC/ 3<sup>rd</sup> countries, but subject to policy considerations. Can cover a large and changing community. HE rules apply by default to calls included in the FP Work Programme, so any legal entity can apply to these.</p>	<p><b>What is possible?</b> Suitable for all types of partners: private and/or public partners, including MS, foundations. By default open to legal entities from AC/ 3<sup>rd</sup> countries, but subject to policy considerations. In case of countries participating non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements HE rules apply by default, so any legal entity can apply to partnership calls.</p>
<p><b>What is limited?</b> Systematic/ structured engagement with public authorities, MS, regulators, standard making bodies, foundations and NGOs.</p>	<p><b>What is limited?</b> Requires substantial national R&amp;I programmes (competitive or institutional) in the field. Usually only legal entities from countries that are part of the consortia can apply to</p>	<p><b>What is limited?</b> Non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements. Needs good geographical coverage – participation of at least 40% of Member States is required</p>	<p><b>What is limited?</b> If MS launch calls under their responsibility, usually only legal entities from countries that are part of the consortia can apply to these, under national rules</p>	<p><b>What is limited?</b> Requires a rather stable set of partners (e.g. if a sector has small number of key companies). Basic act can foresee exceptions for participation in calls / eligibility for funding.</p>

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
	calls launched by the partnership, under national rules.	Requires substantial national R&I programmes (competitive or institutional) in the field.  While by default the FP rules apply for eligibility for funding/participation, in practice (subject to derogation) often only legal entities from countries that are Participating States can apply to calls launched by the partnership, under national rules.		
<p><b>What is not possible?</b> To have a joint programme of R&amp;I activities between the EU and committed partners that is implemented based on a common vision.</p>	<p><b>What is not possible?</b> To have industry/ private sector as partners.</p>	<p><b>What is not possible?</b> To have industry/ private sector as partners.</p>	<p><b>What is not possible?</b></p>	<p><b>What is not possible?</b></p>

Table 25: Type and range of activities (including flexibility and level of integration)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b></p> <p>Horizon Europe standard actions that allow <i>broad range of individual activities</i> from R&amp;I to TRL 7 or sometimes higher.</p> <p>Calls for proposals published in the Work Programmes of Horizon Europe (adopted via comitology).</p>	<p><b>What is possible?</b></p> <p>Activities may range from R&amp;I, pilot, deployment actions to training and mobility, dissemination and exploitation, but according to national programmes and rules.</p> <p>Decision and implementation by “beneficiaries” (partners in the co-fund grant agreement) e.g. through institutional funding programmes, or by “third parties” receiving financial support, following calls for proposals launched by the consortium.</p>	<p><b>What is possible?</b></p> <p>Horizon Europe standard actions that allow a broad range of coordinated activities from R&amp;I to uptake.</p> <p>In case of implementation based on national rules (subject to derogation) Activities according to national programmes and rules.</p> <p>Allows integrating national funding and Union funding into the joint funding of projects</p>	<p><b>What is possible?</b></p> <p><i>Horizon Europe standard actions</i> that allow a broad range of coordinated activities from R&amp;I to uptake.</p> <p>The association representing private partners allows to continuously build further on the results of previous projects, including activities related to regulations and standardisation and developing synergies with other funds</p> <p>Union contribution is implemented via calls for proposals published in the Work Programmes of Horizon Europe based on the input from partners (adopted via comitology).</p> <p>Open and flexible form that is simple and easy to manage.</p>	<p><b>What is possible?</b></p> <p><i>HE standard actions</i> that allow to build a portfolio with broad range of activities from research to market uptake.</p> <p>The back-office allows dedicated staff to implement integrated portfolio of projects, allowing to build a “system” (e.g. <i>hydrogen</i>) via pipeline of support to accelerate and scale up the take-up of results of the partnership, including those related to regulations and standardisation and developing synergies with other funds. E.g. setting up biorefinery plants and promoting their replication by additional investments from MS/private sector.</p> <p>Procuring/purchasing jointly used equipment (e.g. HPC)</p> <p>Allows integrating national funding and Union funding into the joint funding of projects</p>
<p><b>What is limited?</b></p>	<p><b>What is limited?</b></p> <p>Scale and scope of the programme the resulting funded R&amp;I actions and depend on the participating programmes, typically</p>		<p><b>What is limited?</b></p> <p>Limited control over precise call definition, resulting projects and outcomes, as they are implemented by EC agencies.</p>	<p><b>What is limited?</b></p> <p>Limited flexibility because objectives, range of activities and partners are defined in the Regulation, and negotiated in the Council (EP).</p>

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
	smaller in scale than FP projects			
<p><b>What is not possible?</b></p> <p>To design and implement in a systemic approach a portfolio of actions.</p> <p>To leverage additional activities and investments beyond the direct scope of the funded actions</p>				

Source : Technopolis Group



Table 26: Directionality

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b> Strategic Plan (as implementing act), annual work programmes (via comitology). Possible also to base call topics on existing or to be developed SRIA/roadmap</p>	<p><b>What is possible?</b> Strategic R&amp;I agenda/roadmap agreed between partners and EC Annual work programme drafted by partners, approved by EC Objectives and commitments are set in the Grant Agreement.</p>	<p><b>What is possible?</b> Strategic R&amp;I agenda/roadmap agreed between partners and EC Objectives and commitments are set in the legal base. Annual work programme drafted by partners, approved by EC Commitments include obligation for financial contributions (e.g. to administrative costs, from national R&amp;I programmes).</p>	<p><b>What is possible?</b> Strategic R&amp;I agenda/roadmap agreed between partners and EC Objectives and commitments are set in the contractual arrangement. Input to FP annual work programme drafted by partners, finalised by EC (comitology)  Commitments are political/best effort, but usually fulfilled</p>	<p><b>What is possible?</b> Strategic R&amp;I agenda/roadmap agreed between partners and EC Objectives and commitments are set in the legal base. Annual work programme drafted by partners, approved by EC (veto-right in governance) Commitments include obligation for financial contributions (e.g. to administrative costs, from national R&amp;I programmes).</p>
<p><b>What is limited?</b> No continuity in support of priorities beyond the coverage of the strategic plan (4 years) and budget (2 years Annual work programme).</p>				
<p><b>What is not possible?</b> Coordinated implementation and funding linked to the concrete objectives/ roadmap, since part of overall project portfolio managed by agency</p>				

Source: Technopolis Group

Table 27: Coherence (internal and external)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b> Coherence between different parts of the Annual Work programme of the FP ensured by EC</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities Synergies with other programmes</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC If MS participate: Synergies with national/regional programmes and activities Synergies with industrial strategies</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with other programmes or industrial strategies If MS participate: Synergies with national/regional programmes and activities</p>
<p><b>What is limited?</b> Synergies with other programmes or industrial strategies</p>	<p><b>What is limited?</b> Synergies with other programmes or industrial strategies</p>	<p><b>What is limited?</b> Synergies with industrial strategies</p>	<p><b>What is limited?</b> Synergies with other programmes</p>	
<p><b>What is not possible?</b> Synergies with national/regional programmes and activities</p>				

Source: Technopolis Group





Publications Office  
of the European Union