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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 February 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2021) 37 final - Part 4/19
Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe European Partnership on Innovative Health

Delegations will find attached document SWD(2021) 37 final - Part 4/19.

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EUROPEAN
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Brussels, 23.2.2021
SWD(2021) 37 final

PART 4/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

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

European Partnership on Innovative Health

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

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5302

2. ORGANISATION AND TIMING

Institutionalised Partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for Institutionalised Partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential Institutionalised Partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 15 May 2020, the Staff Working Document has been revised as presented in Figure 1. These revisions were endorsed by the Inter Service Steering Group on 20 January 2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate Institutionalised Partnerships[1] (Technopolis Group, 2020). It consisted of a horizontal analysis and individual thematic analyses for each of the initiatives under review.

[1] Technopolis Group, 2020, forthcoming.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

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

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board – main considerations	**Actions taken for the Staff Working Document**
(1) The report does not sufficiently explain how the problems and challenges addressed by the new partnership differ from those addressed by the present one.	More information on the problems and challenges was added in Sections 2.2.1 (page 36) and 2.2.4 (page 40), and the differences in scope and activities were further highlighted in Section 7.2.1 (pages 82-83).
(2) The report does not clearly explain to what extent the different partnership types are likely to attract health industry partners (small or big) and why.	More detail on the expected attractiveness of the various forms of partnerships to industry was provided in Sections 5 (page 56) and 6 (notably 6.3.2, pages 61 and 73-74).
(3) The report does not provide sufficient information about how the partnership would be implemented in practice.	Information was added in Section 7.2.1, notably on the selection of the actual areas for support (pages 81/82), practical functioning of the initiative and comparison of IHI activities with those of IMI2 JU (pages 82-83).

Furthermore, the whole text was revised to provide more clarity on the aspects raised in the "Further considerations and adjustment requirements" section of RSB opinion. The main of these revisions are listed below:

- The presentation of stakeholder views in all sections were re-visited (throughout the whole text).
- The reasons for the change of scope from IMI2 JU further were explained (section 6.4, pages 82/83).
- The definitions of specific and general objectives were adjusted to better convey the intended content (Sections 4.1 and 4.2 in pages 43-46, and in related figures).
- The intervention logic was revisited to provide more clarity and to better explain the interdependencies between objectives, problems and their drivers (Sections 4.2 and 4.3, pages 48-50).
- The differences between the various partnership forms considered in the report were explained in more detail, notably for an Institutionalised Partnership (Sections 5 and 6, page 58, 59, 70, 73-74).
- Discrepancies in the scoring of options were removed and further explanation was added to justify certain conclusions and scores (throughout Section 6).
- The analysis of the options is better linked to the objectives (Sections 5 and 6).
- A clear justification for the choice of Horizon Europe calls as baseline, rather than a continuation of the current partnership, was provided in Section 5.1 (page 56).
- The advantages of a dedicated Programme Office were presented in Section 6.4 (page 77).
- The analysis of risks and uncertainties of the final choice was provided in Section 6.4 (page 77).
- Targets by the end of the initiative were presented together with the proposed monitoring indicators in Section 7.2 (pages 84-86).
- A statement was added to clarify that the comparison and choice of the options is a qualitative judgement rather than a quantitation (Section 6.4, page 75).
- Numerous revisions were made to increase readability and strengthen the argumentation, also using more examples, and taking into account various technical comments received from the RSB. The content of the text was also updated to reflect developments in the preparation of the partnership that took place since the RSB assessment (throughout the whole text), including making the general objectives (page 43), the operational objectives (pages 80-81), the indicators and targets (pages 84-86) more measurable and representative of the partnership.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,[2] the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for Institutionalised Partnerships, 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, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (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.
- 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 targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system[3]. The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. 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, the largest of them includes 57 respondents[4]. In addition,

[2] https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en
[3] https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope
[4] The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

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 excluded from the general analysis.

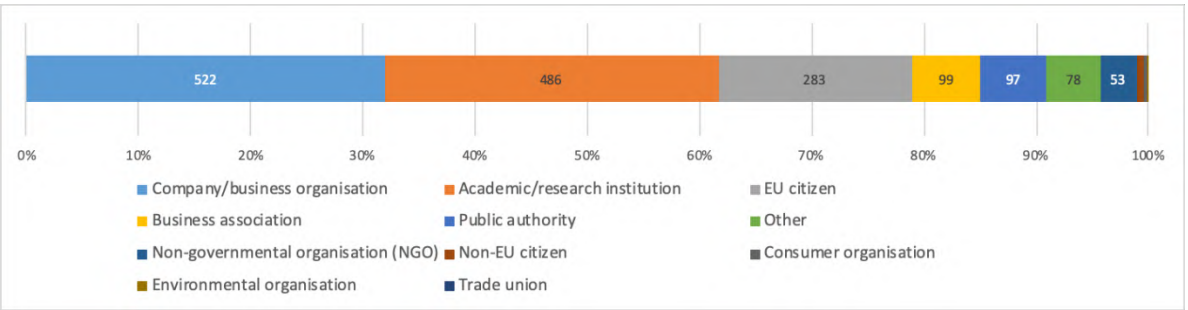
Table 1: Country of origin of respondents (N=1635)

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%
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%

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

Figure 2. Type of respondents (N=1635) - For all candidate initiatives



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 Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). 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.

Among those who have been involved in 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 2, 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.

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. 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.

Table 2: 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 (<250)**	**Company/business organisations (250+)**	**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 and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
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
Eurostrars-2	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6

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 (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
(supporting research-performing small and medium-sized enterprises)									
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 Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
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

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for 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 3: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups	Number and % of respondents from a non-campaign

	(n=1613)	group (n=1341)
Clean Hydrogen	506 (31.37%)	382 (28.49%)
European Metrology	265 (16.43%)	225 (16.78%)
Clean Aviation	246 (15.25%)	191 (14.24%)
Circular bio-based Europe	242 (15%)	215 (16.03%)
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)
Key Digital Technologies	182 (11.28%)	162 (12.08%)
Innovative SMEs	111 (6.88%)	110 (8.20%)
Innovative Health Initiative	110 (6.82%)	108 (8.05%)
Smart Networks and Services	109 (6.76%)	107 (7.98%)
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)

1.2.2. Characteristics of future candidate European Partnerships

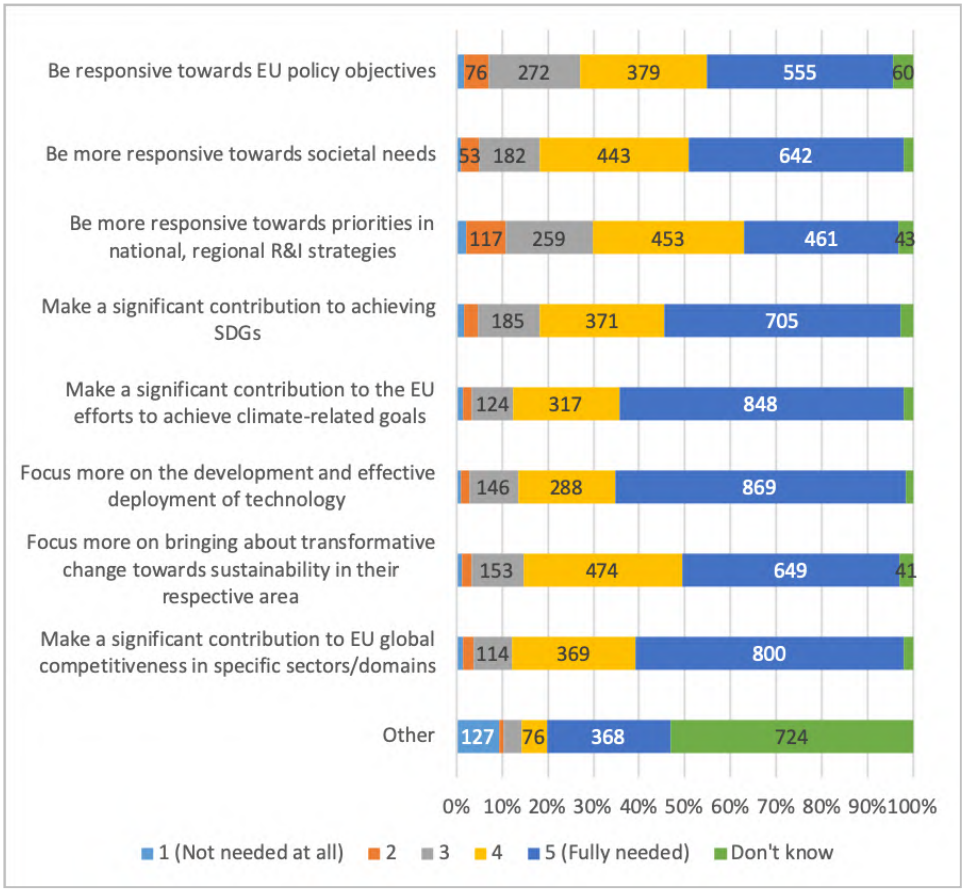
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is '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 value the 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 18.3%) 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.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which 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 needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 3: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment.

Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

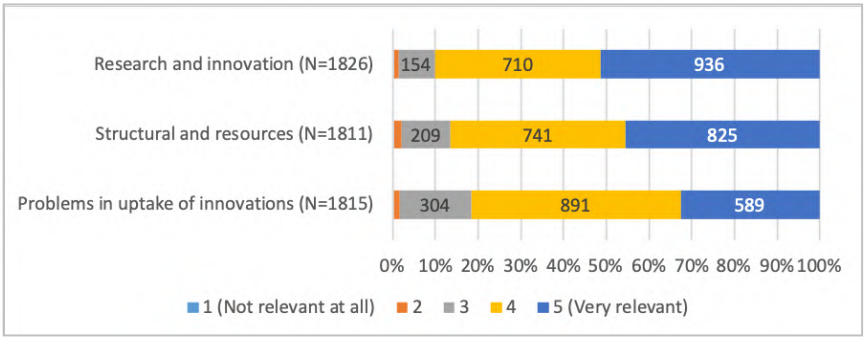
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; 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.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the **relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships**. Research and innovation related problems were rated as most relevant 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 stakeholder categories. 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 slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

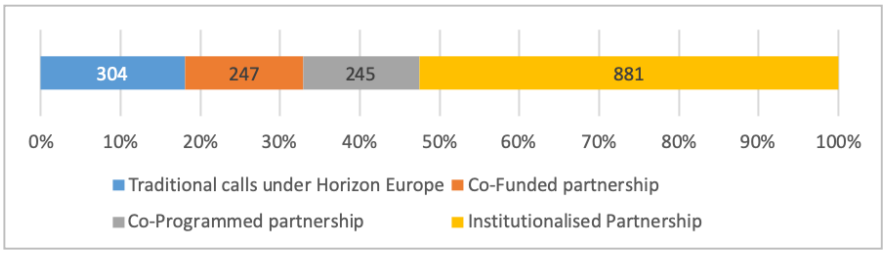
Figure 4: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through **Horizon Europe intervention**. Just over 50% of all respondents indicated that Institutionalised Partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership 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 indicated slightly less often that Institutionalised Partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the Institutionalised Partnership intervention in far higher numbers (nearly 70%).

Figure 5: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



When asked to reflect on their answers, respondents that pointed to the need for using Institutionalised Partnership 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. Others shared positive experiences with other modes of interventions:

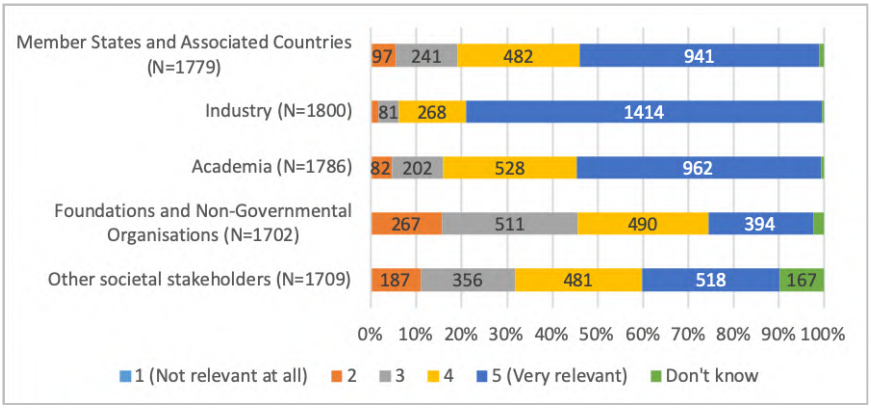
- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism 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).

1.2.6. 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. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. 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. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

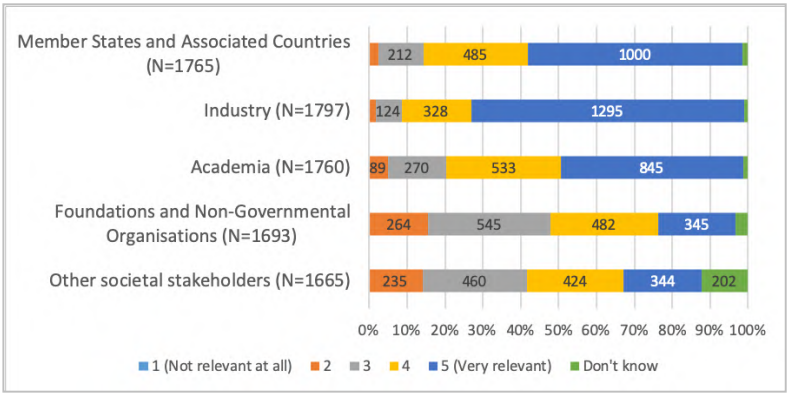
Figure 6: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



Pooling and leveraging resources through coordination, alignment and integration with stakeholders

Respondents were 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. 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 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.

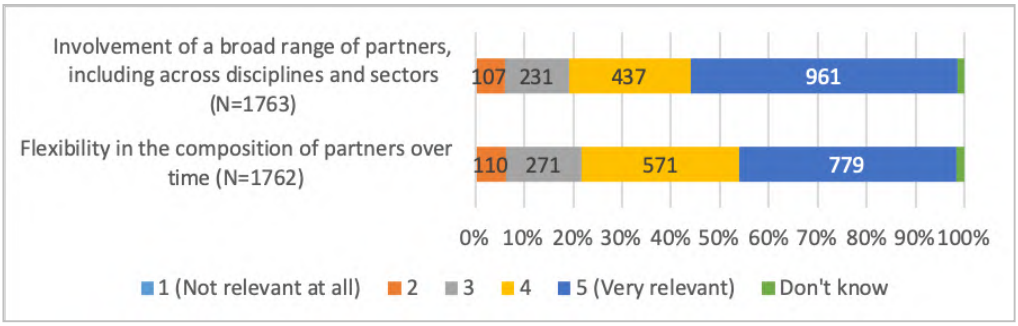
Figure 7: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For 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 6). 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 8: 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

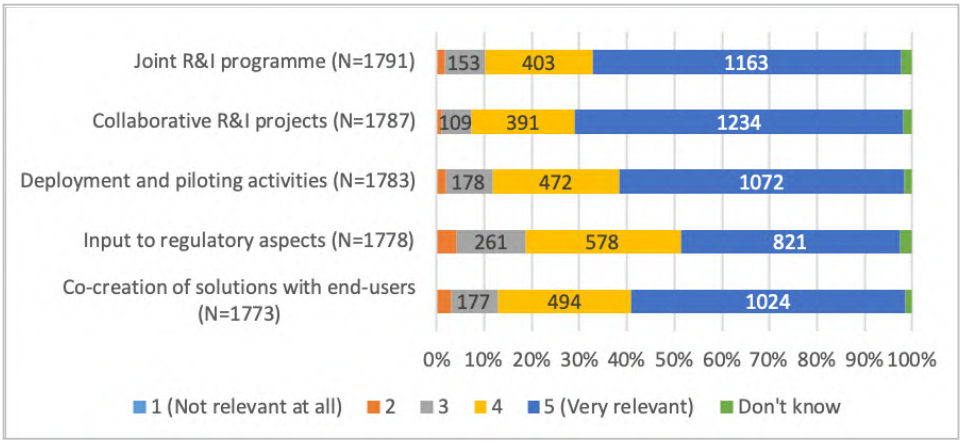


Implementation of activities

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. 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.

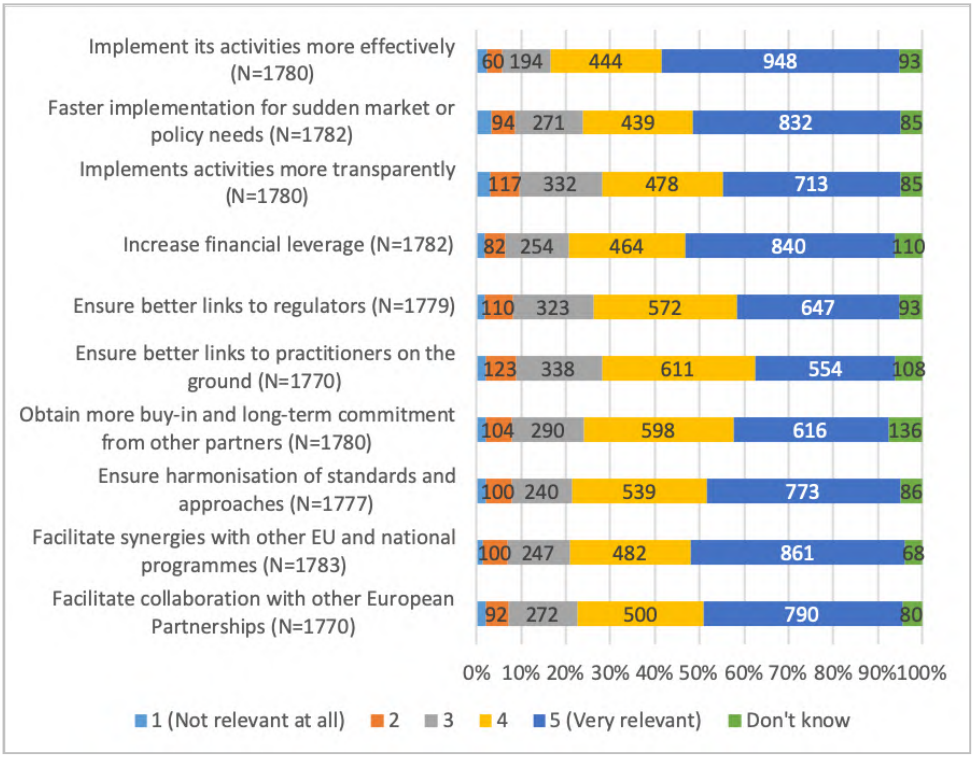
Figure 9: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It 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.

Figure 10: 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



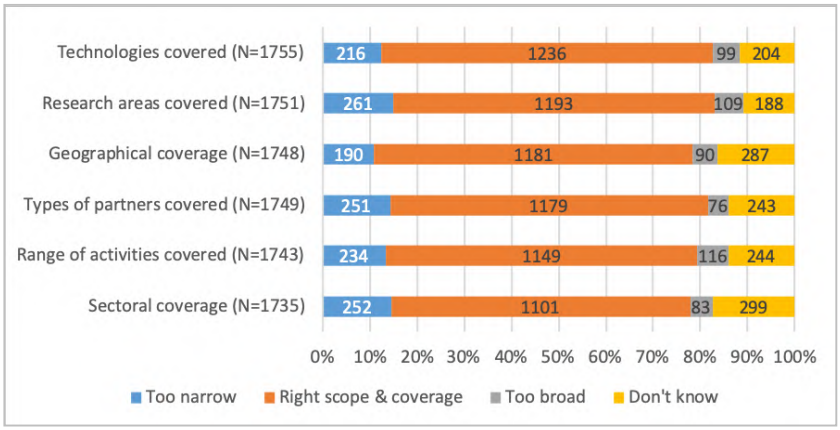
When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding 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. 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. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. 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”. 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" then 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". 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. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate Institutionalised European Partnership have the "right scope & coverage".

Figure 11: 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



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

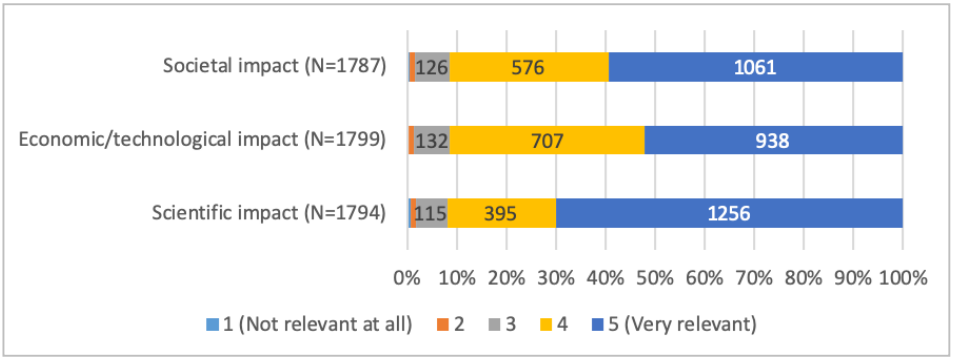
When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between 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.

1.2.10. 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; Economic/technological; and Scientific impacts. 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 this as (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 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 12: 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



1.3. Stakeholder consultation results for the Innovative Health Initiative

An overview of the number and description of participants in each consultation activity targeting this specific initiative is available in Table 2. Participants were clustered into five categories: academic/research institutions, companies/business associations, Non-Governmental Organisations (NGOs), public authorities and European citizens. European patient organisations, health care professionals' organisations, organisations promoting the interest of specific groups of the population (e.g. people aged 60 and above), organisations of social health care payers were included among NGOs. Respondents from companies and business associations covered the various sectors potentially involved in IHI: pharmaceutical, biotech and vaccines, medical devices, imaging, in-vitro diagnostics and digital technologies. In addition to Member States, feedback has been received from the entire scope of all relevant stakeholders, in particular researchers, industry, health care professionals, patients, payers and public authorities.

Table 2. Participation in the various consultation activities

Consultation activity	**Consultation period**	**Participation and profile of participants**
Structured consultation of Member States	June 2019	26 Member States (all but Lithuania and Bulgaria), Iceland and Norway
Public consultation on IHI Inception Impact Assessment	July – August 2019	43 respondents: - 12 academic/research institutions (28%) - 9 companies/business associations (21%) - 14 NGOs (32%) - 5 public authorities incl. the German government (12%) - 3 EU citizens (7%)
Targeted consultation of stakeholders	September – December 2019	48 interviewees: - 8 academic/research institutions/research infrastructures (17%) - 22 companies/business associations (46%) - 4 NGOs: patient associations (8%) - 5 public authorities incl. regulators, HTA bodies and payers (10%) - 7 European Commission officials (15%) - 2 members of the management team of the current public-private partnership (4%)
Open public consultation	September – November	108 respondents:

	2019	- 35 academic/research institutions (32%) - 19 companies/business organisations (19%) - 17 EU citizens (16%)

In terms of methods, public consultations were based on structured questionnaires also including open questions and offering the possibility to hand in position papers with additional information. If needed, depending on the number of replies, responses were first scanned using text-mining technique to facilitate further analysis.

1.3.1. Feedback to the inception impact assessment

Following the publication of the inception impact assessment, a feedback phase of 3 weeks allowed any citizen to provide input on the proposed initiatives on the "Have your say" web portal. In total 43 individual feedbacks were collected from NGOs (14; 32%), academic/research institutions (12; 28%), business associations (9; 21%), public authorities including the German government (5;12%) and EU citizens (3; 7%).

Relevance of the initiative and implementation mode

Three quarters of the respondents (32/43, 74%) explicitly expressed their support to the initiative (around 90% among business associations and academic/research institutions and 60% of public authorities and NGOs). No respondent gave a negative opinion on the proposed roadmap. Among the 18 respondents who explicitly expressed their preference regarding the implementation mode, all but one were in favour of an Institutionalised Partnership and one in favour of a co-programmed partnership.

Comments made from the respondents of the public and private sectors varied in terms of focus:

- public actors called for broader stakeholder involvement, transparency, open access to research results, public return on investment, and increased participation of SMEs;
- business associations called for flexibility in various aspects of the partnership: topic generation process, funding models, in-kind contributions from industry, legal framework for intellectual property management, and better involvement of SMEs.

This feedback is presented below according to the following categories: stakeholder involvement (in governance including priority setting, and in programme implementation), involvement of SMEs, transparency issues, participation from third countries, funding models, open access to research results, intellectual property right management, public return on investment, synergies with other initiatives, ethics and data privacy issues, sustainability of projects' results, and comments related to the R&I content of the potential partnership.

Stakeholder involvement

There was a general call from respondents of the public sector for the involvement of a broader variety of stakeholders in the partnership beyond industry and academics: patients' organisations, health care payers, regulators, health and social care professionals, health care providers, national health system actors and public authorities, Research and Technology

Organisations, and to a lesser extent, civil society organisations and citizens' groups were mentioned. A broader stakeholder involvement is expected at different levels: in the governance of the partnership, including in research priority setting, and in the implementation of the programme itself, including topic generation and participation in projects.

Regarding governance and priority setting, respondents from the public sector requested a model that would enable multi-stakeholder collaboration with a balance of relevant stakeholders in strategic decision-making and a stronger role of the Commission and national authorities. Respondents highlighted the need to put in place mechanisms ensuring that priorities will be set according to public health needs.

Regarding programme implementation including generation of call topics, there was a call for an inclusive process of topic generation involving patients, health care providers, health care professionals, and regulatory agencies. Respondents indicated the need for a balanced role of partners within the projects, in particular in projects addressing highly sensitive areas (e.g. projects on regulatory research).

Involvement of SMEs

Improved involvement of SMEs was strongly supported, in particular by business associations. The unique contribution of SMEs to the development of innovative health solutions was stressed by several respondents. To facilitate the participation of SMEs, the following measures were suggested: a legal framework respecting intellectual property ownership requirements for SMEs, a limitation of the administrative burden (and therefore a limitation of topics' scopes to limit consortia sizes), and process simplification (simple formats for proposals, fast feedback, simple reporting).

Transparency

Respondents form the public sector and in particular NGOs explicitly called for greater transparency with regard to decision-making processes (including in agenda-setting process) and in-kind contribution related to operational activities provided by the industry.

Participation of third countries

Business associations strongly advocated for eligibility of in-kind contributions without limitation for non-EU legal entities while the German government argued that the core of the activities and of the industry contributions needed to remain in Europe, even though international partners could provide valuable input to the initiative especially in the field of global health.

Industry contribution and funding models

Business associations asked for a funding model that encourages diverse in-kind contributions. Some companies were in favour of a flexible funding model where industry could be eligible for receiving funding, including large companies and mid-caps. Financial contribution from industry partners was suggested by some respondents form the public sector (NGO and public authority).

Open access to research results

Respondents from the public sector and in particular NGOs strongly called for open access to research results (mandatory and free) with derogations restricted to rare circumstances.

Intellectual property rights management

Some NGOs asked that ownership of publicly funded R&I results be driven by public interest and that various forms of intellectual property management and licensing be explored, including equitable licensing. Other respondents including business associations, and the German government, advocated for a revision of the rules for intellectual property rights to facilitate the involvement of the new industrial sectors with different business models and to offer better opportunities for SMEs to participate.

Public return on investment

Some NGOs called upon public return on investment by ensuring complete transparency regarding the costs of research, development and production and by safeguarding equitable access to publicly funded biomedical R&I: "Parties receiving EU biomedical R&I funding should agree on provisions to tackle the end product's affordability, accessibility, availability and efficiency along all the R&I stages".

Ethics and data privacy issues

Respondents highlighted the importance of addressing ethics and data privacy issues in the programme. One respondent called for ethical debates on the limits of digitalization, robotisation and the use of AI in the provision of health care so that to pave the way for a human-centred use of new technologies.

Synergies with other initiatives

Respondents highlighted the need for alignment, synergies and collaborations with i) national and regional initiatives and ii) other EU funded programmes, especially other candidate partnerships such as EU-Africa Global Health, Health and Care Systems Transformation, Personalised Medicine and Rare Diseases.

Sustainability of project results

The issue around sustainability of project results beyond the lifetime of individual projects was mentioned at several occasions. Solutions were asked in particular for sustainability of data infrastructures (e.g., through models of financing large equipment and data access handling).

Comments related to the R&I content of the partnership.

Specifically, respondents requested a better focus on and consideration of the following:

- health promotion and preventive interventions including personalised prevention, and early diagnostics in healthy population;
- sex and gender aspects (e.g. impact of digitalisation of services, implementation of artificial intelligence) as well as specific needs of subgroups of the population;
- improved cooperation between research and clinical practice;
- regulatory research;
- implementation research: methodologies to achieve large scale deployment of health care solutions and technologies;

- research in health economics;
- implementation of “green technology solutions” in the manufacturing of drugs and European Union Strategic Approach to Pharmaceuticals in the Environment.

In addition, comments were received on specific disease areas that should be considered as priorities (e.g. neglected diseases, paediatric cancer, asthma, brain disorders).

1.3.2. Structured consultation of the Member States

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.

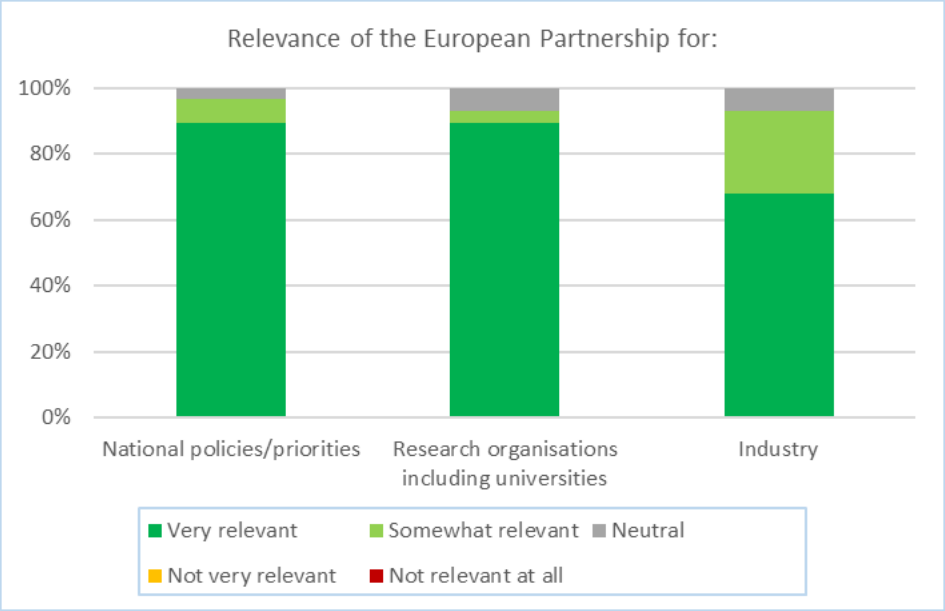
The feedback provided by 30 countries (all Member States, Iceland and Norway) was analysed and summarised in a report, with critical issues discussed at the Shadow Strategic Programme Committee meetings.

During the structured consultation of Member States, there was overall a strong endorsement of the Innovative Health Initiative, including the proposed implementation via the Institutionalised Partnership with the participation of several industry sectors.

Relevance and positioning in a national context

Overall the results of the Member States consultation confirmed 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 was a very strong confirmation of the overall relevance for research organisations, including universities, as well as for industry (Figure 1).

Figure 1. 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 %) reported to have relevant elements in place. National R&I strategies or plans were identified most frequently (89%), followed by national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (79%) and regional R&I and/or smart specialisation strategies (75%). Dedicated funding programmes exist in 57% of the countries.

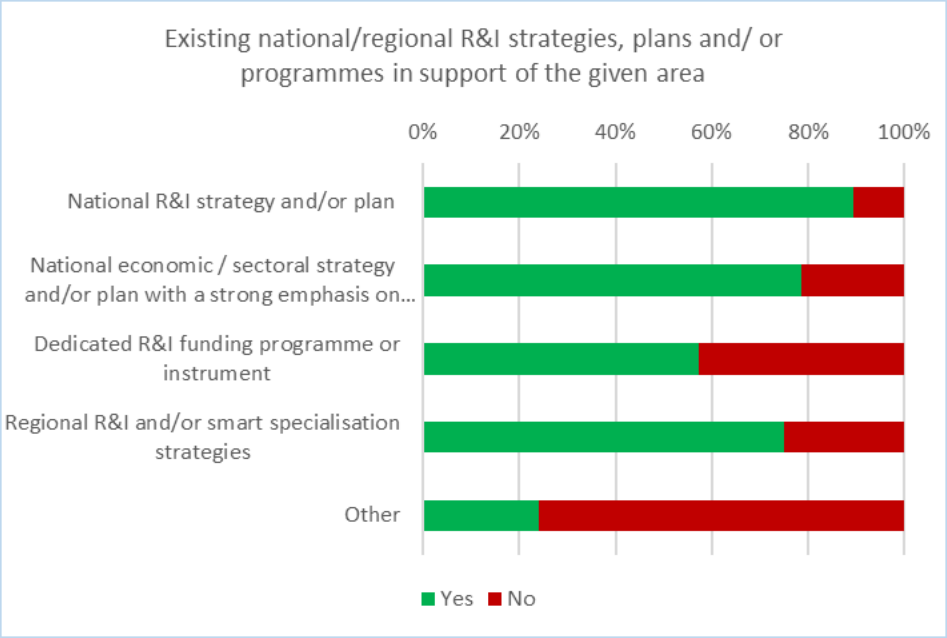
Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities. There was a general call for better SME participation, including more favourable intellectual property rights for them. Other comments address 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 health care providers.

A majority of countries, 17, have expressed an interest to participate (it should be noted that the question did not allow to draw conclusion on the exact nature of participation – see also

below under 'Views on partners, contributions and implementation), and only 3 countries at this stage expressed no national interest to participate. Identified elements for their participation covered 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). All countries expressed interest in having access to results produced in the context of the partnership.

Figure 2. Possible participation and contribution to the Innovative Health Initiative, from the 17 countries that have expressed an interest to participate.



Objectives and impacts

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

Countries indicated 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 rest remaining neutral. The vast majority of countries (85%) considered the impacts very relevant in the national context. There was agreement (56%) with the envisaged duration of the proposed partnership, but an important share (22%) considered the duration too long and requested clear exit strategies.

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

Views on partners, contributions and implementation

The majority (66%) agrees on the type and composition of partners, and 15% disagreed. Many comments supported 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% agreed with the proposal. Individual comments related 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 health care providers in the agenda setting.

The proposed use of Article 187, and the establishment of a Joint Undertaking, was supported by the majority (73%), while one country disagreed, 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 explicitly excluded any national co-funding. Furthermore, the issue was raised of how to ensure sufficient Member State and stakeholder involvement in the agenda setting and set-up of the programme in order to achieve people-centred health care.

1.3.3. Targeted consultation of stakeholders

In addition to the consultation exercises coordinated by EC services, the external study thematic team performed a targeted consultation with key stakeholders on different aspects of the Innovative Health Initiative. The objective of the programme of interviews was to provide an insight into the views of these key stakeholders on the context, problem definition, objectives, policy options, impact analysis, coherence and monitoring of the new initiative. Semi-structured interviews were conducted using a tailored interview topic guide and were subsequently transcribed/summarised and analysed.

Forty-eight interviews were conducted with representatives from industry (22; 46%), the European Commission (7; 15%), academic and research institutes (5; 10%), research infrastructures (3; 6%), patient associations (4; 8%), members of the management team of existing partnerships (2; 4%), regulators, HTA bodies and payers (5; 10%).

Key results/messages from the targeted consultation are presented below.

Problems and problem drivers

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&I compared to US and China.

It was discussed that the fragmentation of the health care 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 mentioned that uneven IT literacy across Europe and poor public perception of industry were hindering uptake.

Other 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.

Objectives

Interviewed stakeholders expressed an overall support for IHI general objectives. A large proportion of interviewees were satisfied with the specific objectives with positive feedback around the push for a people-centred approach. There was some discussion around the broad nature of the objectives and the potential difficulty of measuring the associated outcomes. Nevertheless, it was generally agreed as a strategic decision to encompass the needs of the variety of stakeholders likely to be involved.

Expected impacts

- In terms of **scientific impacts**, bringing together a broad range of expertise and actors from across the innovation value chain was seen as instrumental for the majority of interviewees. In their opinion, such a configuration would allow: i) to support the development of innovations that would meet patients and health systems needs while having a realistic transition to market, ii) to drive cross-pollination of ideas and creativity leading to innovative health solutions that would not be possible from a more siloed approach, and iii) to foster scientific advancements by overcoming barriers of data exchange.

- According to the majority of interviewees, **economic impacts** would result from more efficient development processes, thus reducing the cost of development that may in turn contribute to lower innovation cost to the end users. It was also discussed that the development of digital platforms and technologies coupled with effective data exchange would also have economic benefits to the health care system (e.g. eHealth platforms containing diagnostic data would reduce the need to duplicate diagnostic tests across multiple health care sites). Regarding the impact on job growth, some interviewees felt that any boost in the economy would lead to a general growth in jobs, while others referred to jobs that would be created as a direct result of carrying out IHI 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 a number of interviewees suggested that education or training activities within the partnership project would enhance this impact. Many interviewees indicated 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 the business growth of SMEs was considered as a driver for innovation and global competitiveness in health R&I.

- In terms of **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 actual IHI projects. Societal impact would also be achieved through increased uptake of innovations. This would be primarily driven by engaging end-users, ensuring the relevance of innovations to the target groups and sufficient training of end-users to benefit from the innovations. It was also discussed that inequality in health care access could be partially addressed in the partnership by developing innovations that account for variations in digital literacy, ageing and geographical diversity.

- Positive **environmental impacts** were discussed primarily with regard to reduced need for travel (via advancements in remote testing and monitoring) and less/better waste management (e.g. via enhanced data exchange replacing the need to duplicate tests). 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 that the net environmental impact would be important to consider.

Stakeholder involvement

It was strongly felt that a broad range of stakeholders alongside academia and industry was required to make the partnership a success. In particular the involvement of regulators, patient representatives, and representatives of health care systems to strengthen the impact and uptake of innovations was encouraged.

Synergies with other EU initiatives

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 that findings can be shared between initiatives. It was also discussed that cooperation between initiatives could enhance learning. Establishing a flexible set of rules for the different initiatives would reduce bureaucratic barriers that have prevented past collaborations. An opportunity was noted 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.

Transparency

Interviewees were in favour of increased transparency of the initiative in terms of decision-making, financing and activities, as a means to increase public confidence in the initiative.

Broadening the membership of the partnership

It was generally 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 a token of flexibility and to help address gaps in membership that may develop later in the partnership.

Dissemination of results and re-use by others across Europe

This notion was supported as it was felt that better dissemination would enable more efficient future research. At the same time, sharing of results should not compromise the development of intellectual property. There were also some concerns around GDPR and patient data.

Increased level of private partners' contributions

Some interviewees supported the increased level of private partners' contributions 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 have a 50/50 contribution ratio. There were also some concerns about the public perception and the shift in balance to industry in determining the research agendas.

Increased level of private partners' financial contributions

Interviewees were asked whether they would support an increased level of private partners' contributions, ideally to a point where around 10% of all private members' contributions are financial rather than in-kind. This question 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 others felt that a flexible, case-by-case approach would be most suitable suggesting that commitments may change over time once industry has the opportunity to assess the value of the partnership.

Implementation mode

The majority of interviewees felt that Institutionalised Partnership would be the most effective option of delivering scientific, economic and societal impacts. 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.

- 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, is was discussed that the structure would not be able to enable large-scale collaboration between a broad range of stakeholders as 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 structures. The most frequently discussed advantage of Institutionalised Partnerships over the other policy options was that this structure would attract and enable a broader set 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 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 to be 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.

Key Performance Indicators (KPIs)

In general, KPIs such as publications and patents were seen as easy to measure but limited in showcasing the partnership's impact. Instead, it was suggested to focus on indicators such as adoption into health care 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, tailored to the specific project objectives.

Some proposed KPIs were:

- health and wellbeing: disease prevalence, Quality Adjusted Life Years (QALYs), probability of treating disease, life expectancy, time in hospital, cost of treatment;
- economic: job growth, number of new SMEs/start-ups, business performances, product development, follow-up on funding;
- scientific: publications (but acknowledged as 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, meeting timeline goals, and development of products.

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.

1.3.4. Open Public Consultation

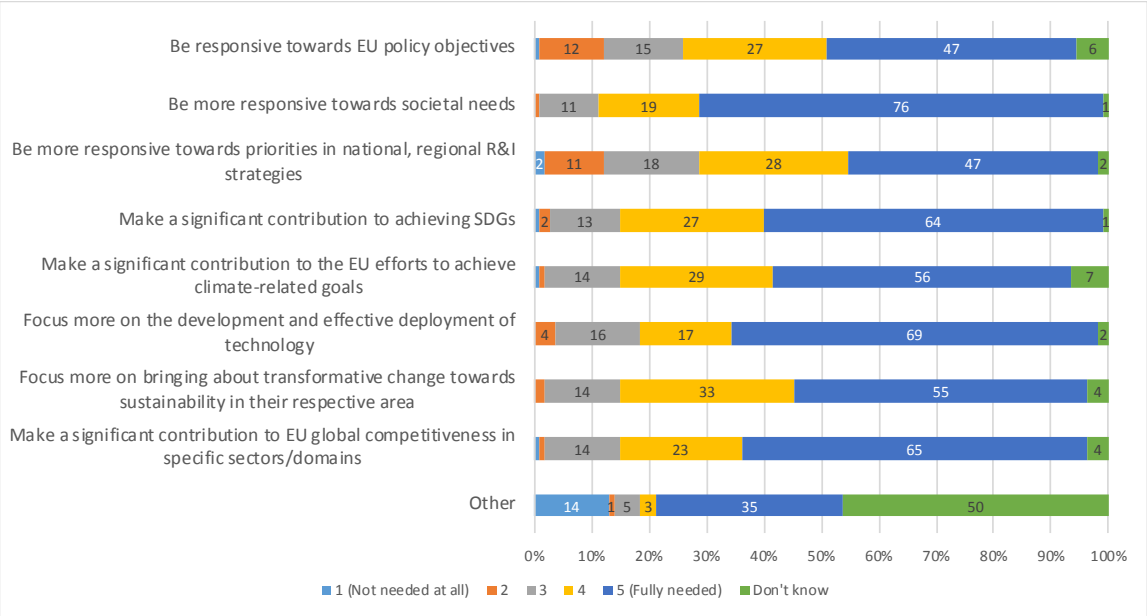
This section outlines the results of the Open Public Consultation for the candidate European Partnership on Innovative Health Initiative.

There were 108 respondents who provided views about the Innovative Health Initiative Partnership. Among them, 35 respondents (32%) are representatives of academic and research institutions, 19 respondents (19%) are company/business organisations, and 17 respondents (16%) are citizens. The majority of respondents, namely 77 (71%), have been involved in the on-going research and innovation framework programme, while 49 respondents (64%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Relevance of efforts of the Innovative Health Initiative to address problems

At the beginning of the consultation, the respondents indicated their views regarding the needs of the future Innovative Health Initiative (Figure 3). Overall, respondents indicated that many of the options presented were relevant. The option where most respondents indicated this, was “be more responsive towards societal needs” (76; 70%). No statistical differences were found between the views of citizens and other respondents. Other needs indicated were those around investment in long term European partnership, extensive support and the value chain.

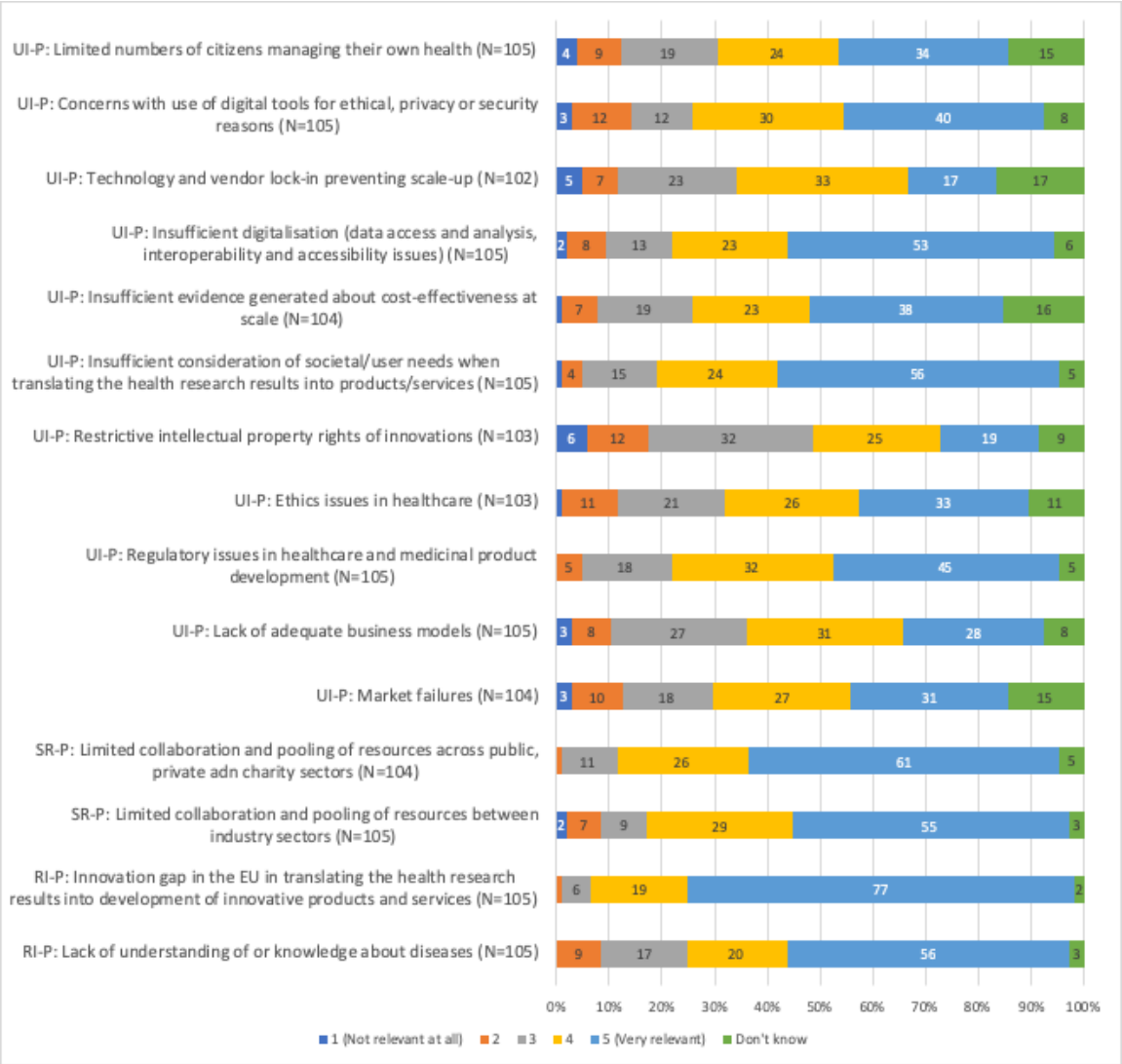
Figure 3. Views of the respondents in regard to the needs of future Innovative Health Initiative under Horizon Europe (N=108)



Relevance of R&I efforts at the EU level to address problems in relation to health and health care innovation

Respondents were asked to provide their view on the relevance of R&I efforts at EU level to address 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). Responses are presented in Figure 4.

Figure 4. Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to health and health care innovation



With regard to uptake of health innovations (UI-P), the issue for which EU-level R&I efforts were considered very relevant by the greatest amount of respondents (56; 53%) is "insufficient consideration of societal or user needs when translating the results of health research into better health products and services". This option was closely followed by "Insufficient digitalisation (data access and analysis, interoperability and accessibility issues)" (53; 50%).

With regard to structural and resource problems (SR-P), the answers to the two proposed options ("Limited collaboration and pooling of resources - across public, private and charity sectors or - between industry sectors") are fairly similar, with the majority of respondents considering those two problems as very relevant to be addressed at EU-level.

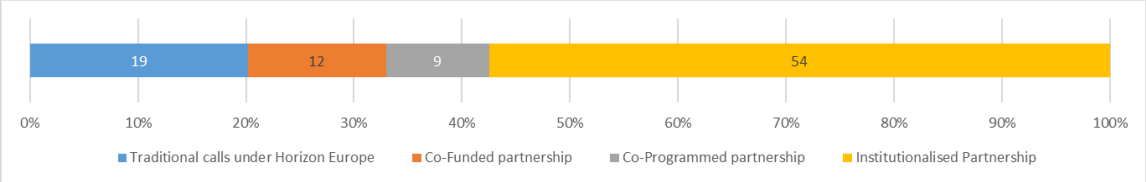
With regard to R&I problems (RI-P), "Innovation gap in the EU in translating the results of health research into the development of innovative health products and services" was considered by the greatest number of respondents (77; 73%) as a very relevant issue to be addressed at EU-level.

No statistical differences were found between the views of citizens and other respondents.

Horizon Europe interventions to address problems

As shown in Figure 5, 57% 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 5. Assessment of Horizon Europe intervention

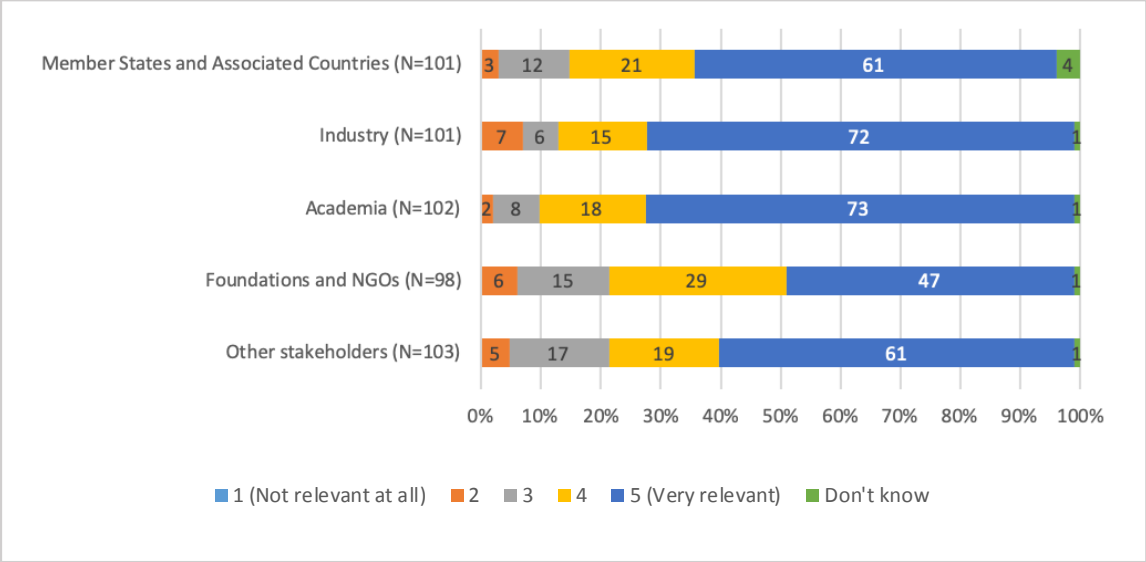


People who stated that an Institutionalised Partnership was the best fitting answer mentioned long term collaboration, global health issues and financial commitment. Respondents who did not select Institutionalised Partnership as their preferred intervention (N=47) mentioned traditional calls, industry partners and collaborative research as crucial for innovation.

Involvement of actors in setting joint long-term agenda

A higher number of respondents consider that the involvement of academia and industry is highly relevant for reaching the 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, with 47 respondents (48%) viewing them as highly relevant actors for setting the agenda. 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. No statistical differences were found between the views of citizens and other respondents.

Figure 6. Views of respondents on relevance of actors in setting joint long-term agenda



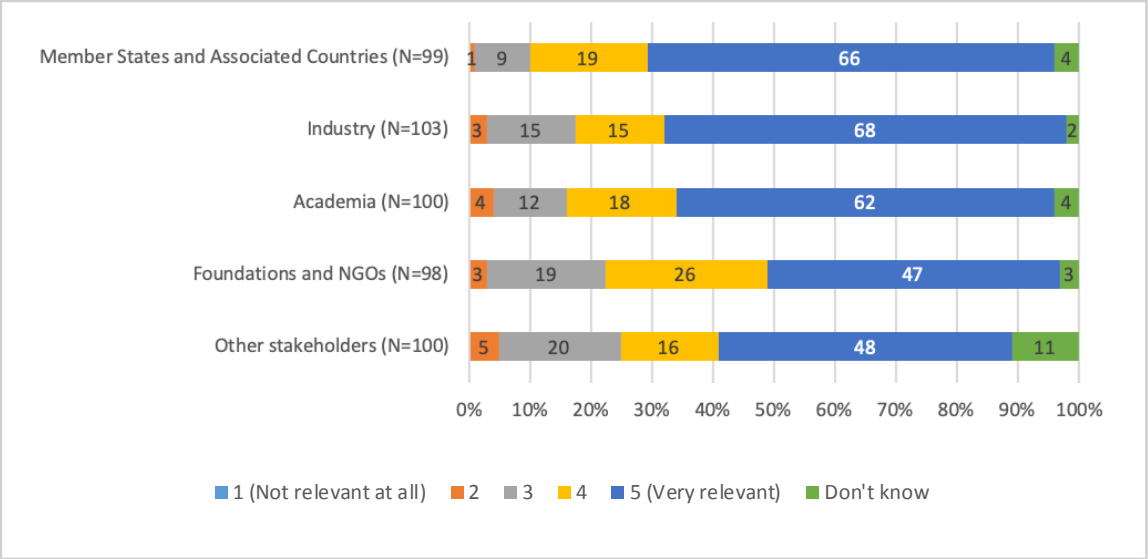
Relevance of actors in pooling and leveraging resources

The role of Member States and Associated Countries is perceived as relevant or very relevant by 86% of respondents. The importance of involvement of other actors, such as

industry and academia, is also considered high by 81% and 80% of respondents, respectively. The role of foundations and NGOs as well as other stakeholders in pooling and leveraging resources, is seen as less relevant (74% and 64%, respectively).

A slight statistical difference was found between the views of citizens and other respondents. Citizens show slightly less relevance for industry, for other categories the views show no statistical differences.

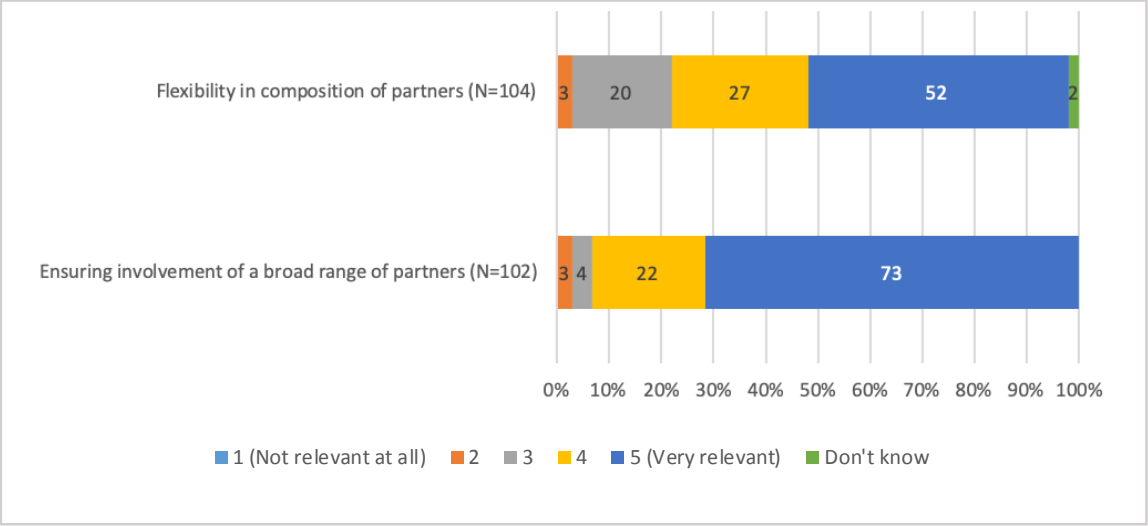
Figure 7. Views of respondents on relevance of actors for pooling and leveraging resources



Partnership composition

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 respondents (72%) versus 52 (50%) respectively consider them very relevant.

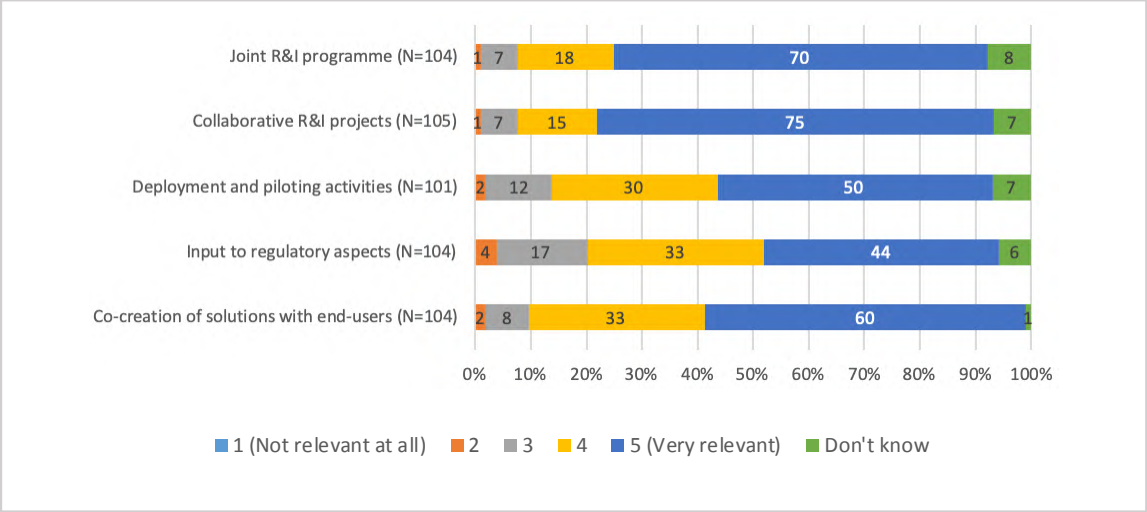
Figure 8. Views of respondents on relevance of partnership composition elements



Implementation of activities

Over 67% of respondents consider collaborative and joint R&I projects very relevant for reaching the objectives of the Partnership. The least number of respondents, namely 44 (42%), view the input to regulatory aspects as relevant for meeting the objectives. No statistical differences were found between the views of citizens and other respondents.

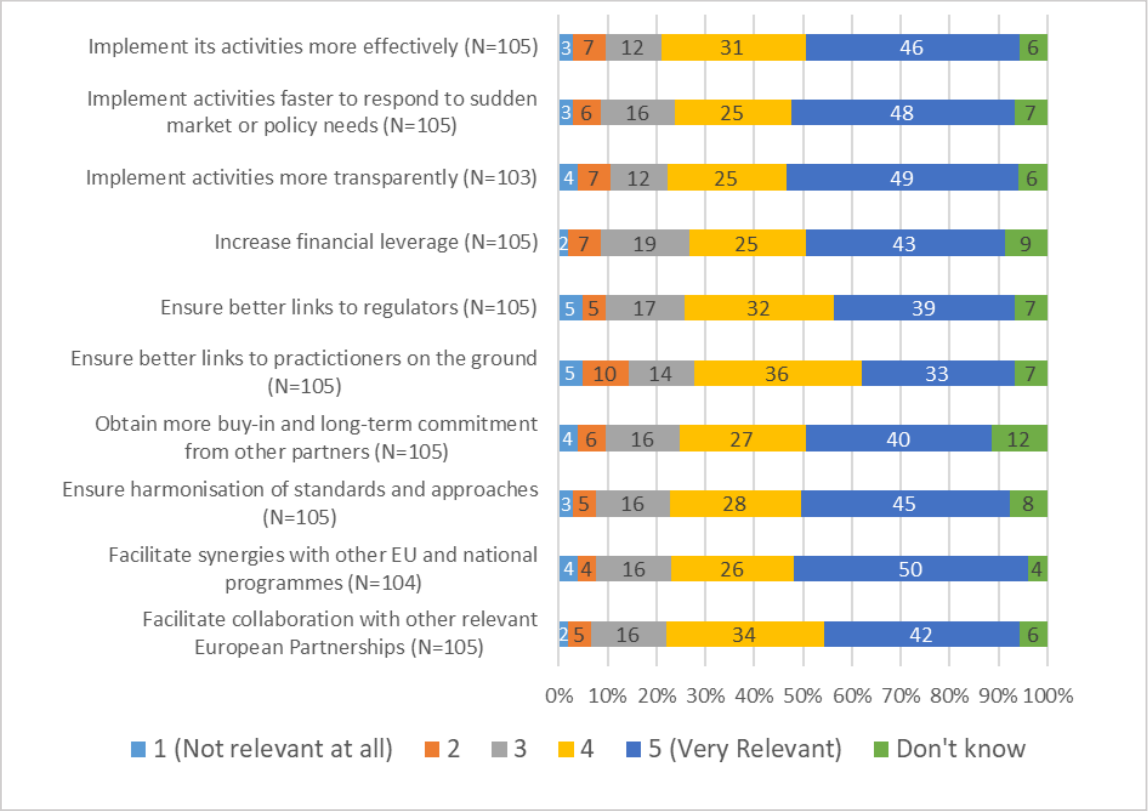
Figure 9. Views of respondents on relevance of implementation of the following activities



Relevance of a legal structure (funding body) to achieve specific objectives

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 10 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.

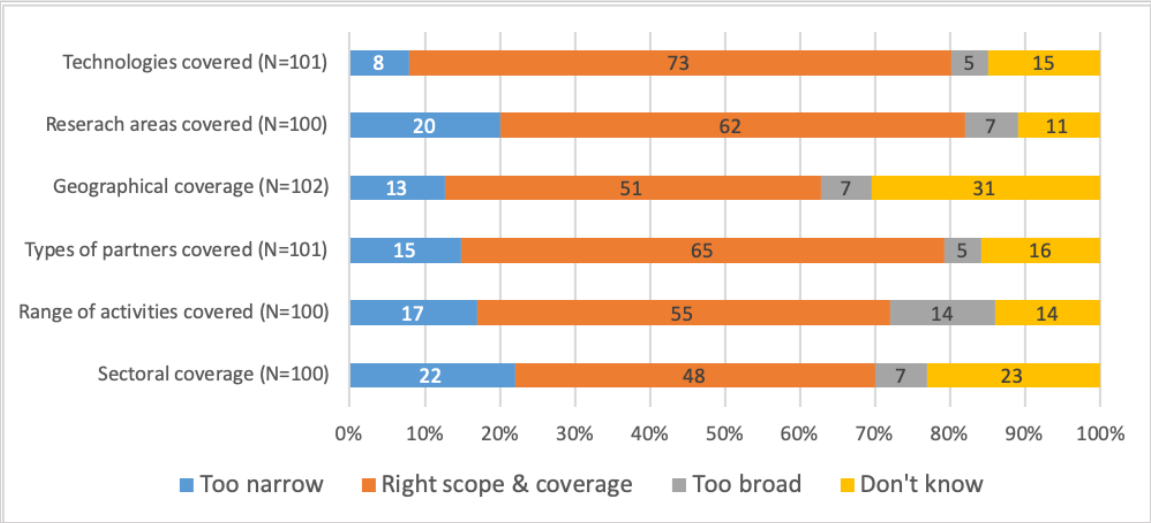
Figure 10. Views of respondents on relevance of a specific legal structure



Scope and coverage

Respondents were asked to assess the scope and coverage of the proposed Innovative Health Initiative, based on its inception impact assessment. As presented in Figure 11, 73 respondents (72%) consider that the coverage and scope of technologies is right, while the least number of respondents, namely 51 (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 11. Views of respondents on the scope and coverage proposed for the Innovative Health Institutionalised Partnership



Aside from this multiple choice question, the respondents were also asked to provide comments on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword analysis showed the respondents used this open question to talk about infectious diseases, the scope of the partnership with regard to global health, the health systems and public health.

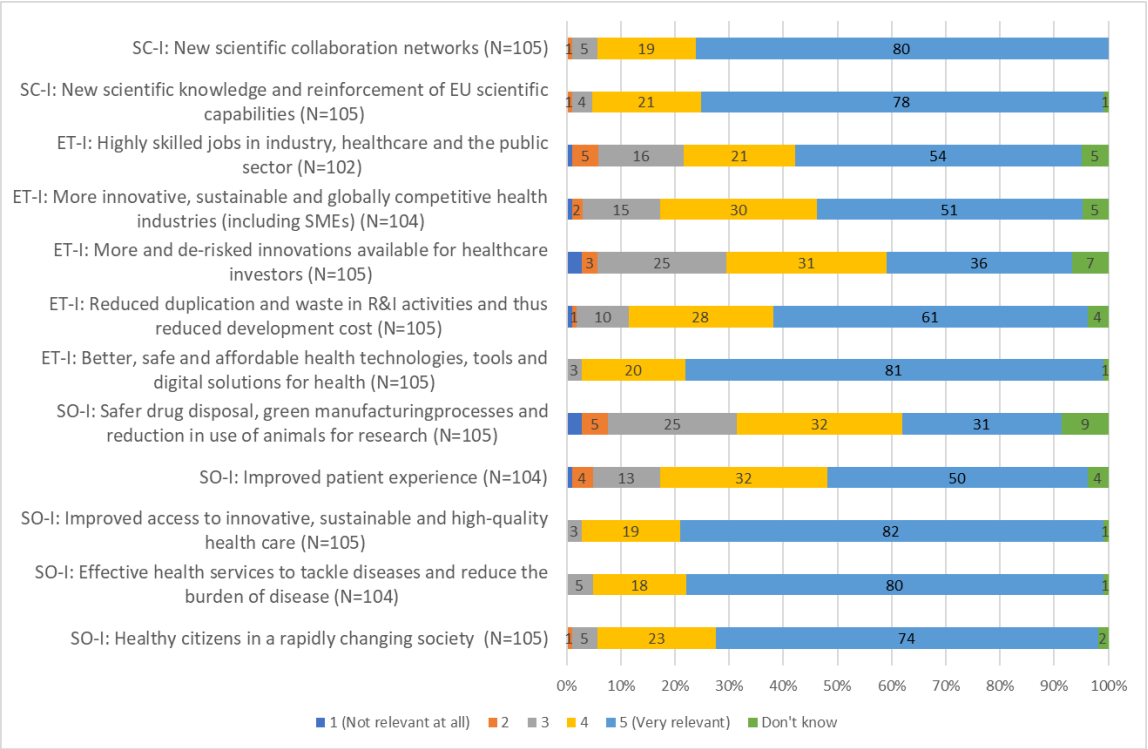
Alignment of the European Partnership with other initiatives

Out of 91 respondents, 78 (86%) think that it is possible to rationalise the candidate Innovative Health Initiative and its activities, and/or to better link it with other comparable initiatives. Respondents mentioned other programmes, complementary initiatives, health systems partnerships and digital technology.

Relevance of the Candidate European Partnership to deliver impacts

According to Figure 12, the candidate Partnership is expected to be 'very relevant' for "improved 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; 77%) 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. The economic and technological impact regarding "more and de-risked innovations available for healthcare investors" was found more relevant by respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7). No statistical differences were found between the views of citizens and other respondents for most of the discussed impacts.

Figure 12. Views of respondents on the relevance of the candidate European Institutionalised Partnership to various impacts



1.3.5. Integration of feedback received in the preparation of the partnership[5]

- **Stakeholder involvement**

To address the request for broader involvement of stakeholders in IHI governance, a separate body ('Innovation Panel') is envisaged. It would be composed of the representatives of EU and member industry associations, as well as of various other stakeholders such as representatives of patients, health care professionals, patients, health care providers, academia, research and technology organisations, research infrastructures, other partnerships and ad-hoc members as necessary. One of the major tasks of the Innovation Panel will be to identify and review potential areas and topics, ensuring they are suitable for the scope of IHI, they adequately address public health interest and needs of end users, and that they have a chance of securing sufficient in-kind commitment from the industry. The members of the Innovation Panel will be expected to be in close contact with their respective constituencies and to seek expert opinion in advance, thus maintaining openness of the initiative and at the same time, ensuring smooth operation.

[5] This chapter provides information on various measures and solutions that could be proposed to address the feedback received. It should be noted that these ideas need validation in the legislative act or any other legal documents laying down the functioning of the partnership (e.g. statutes or rules of procedure of individual governance bodies).

Member States and Associated Countries would be represented in the States Representatives Group. Its task will be to provide opinions on the activities of the partnership and information on related activities at national level. The proposed partnership will thus benefit both industrial and public partners and the governance system will ensure representation of the views of all key stakeholders.

- **Involvement of SMEs**

To encourage SMEs involvement in the partnership, dedicated support and communication actions and could be offered by the Programme Office, benefitting from the implementation mode as an Institutionalised Partnership.

- **Transparency**

Regarding the transparency of research priority setting and the topic generation process, the revised governance structure would better incorporate views of various stakeholders involved in health and care thanks to the Innovation Panel. As regards the transparency of in-kind contribution provided by the industry in relation to operational activities, detailed requirements for its valuation would be defined in documents laying down the functioning of the initiative. The project results are going to be subject to the same transparency provisions as under regular Horizon Europe calls. Access to the information about the initiative will be ensured through communication activities and publication of relevant documents on its website. Additionally, appropriate partnering/promotion events and communication campaigns may be organised.

- **Participation of industry from third countries**

EU Member States expressed a strong wish to strengthen competitiveness of Europe's health technology industry. At the same time, health research goes beyond national borders and the necessary global dimension of the partnership should be ensured. The partnership will aim to attract investments also from outside Europe to increase its international footprint, capture resources of global companies and benefit from other previous international investments or address specific scope (such as e.g. disease prevalence in non-EU countries, with relevance for EU population). In order to balance these needs, in-kind contributions committed out of EU or Horizon Europe Associated Countries might be accounted for and eligible for matching with EU funds, albeit to a certain extent. If formalised in the relevant legal provisions, this approach would follow the practice established under IMI2 JU.

- **Funding models**

To address the need for financial flexibility requested by some industrial sectors, industry could be eligible for funding up to a certain ceiling (including large companies and mid-caps), and could also be entitled to opt-out from receiving funding at their discretion. The detailed arrangements will be laid down in the relevant legal provisions.

- **Open access to research results**

As a principle, general Horizon Europe provisions will apply.

- **Intellectual property rights management**

As a principle, general Horizon Europe provisions will apply.

- **Public return on investment**

The proposed partnership is set to work in the pre-competitive R&I area of unmet health needs and as such will aim at fostering collaborations between public and private stakeholders in order to accelerate the future development of health innovations. As a principle, the partnership does not envisage engaging mechanisms to influence pricing and reimbursement as these are a national competence. Nevertheless, in case the partnership would conduct research at a significant scale in the competitive area, a mechanism could be foreseen so that products or services developed by the partnership are accessible at fair conditions.

- **Synergies with other initiatives**

The partnership will be operating in connection with several other relevant initiatives at various levels so that synergies can be strengthened and waste in research minimised. Duplication of efforts with other partnerships could be avoided by consultation and potential direct representation in the IHI governance structures (the Innovation Panel) of representatives of other relevant initiatives, such as e.g. the potential future public-public partnership on "Health and Care Systems Transformation". Draft topic texts will be consulted with the relevant services of the European Commission and approved by the Governing Board that will include EC members. To ensure coherence with national/regional initiatives, the States Representatives Group (composed of representatives of relevant national ministries) is foreseen to be represented in the Innovation Panel, will be consulted on future call topics and will provide advice on potential complementarities and overlaps with relevant national initiatives.

- **R&I content of the partnership**

The comments related to the content of the partnership were taken into account when designing the proposed objectives and are going to be further considered during the elaboration of the Strategic Research Agenda.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The Institutionalised Partnership implementing the Innovative Health Initiative will be offering funding and collaboration opportunities to those interested in it, on a voluntary basis. As a result, it will not impose any obligations generally applicable to citizens, businesses including SMEs or administrations. Certain obligations will be imposed, though, on industry associations who will become formal Members of the initiative as enshrined in the legislative act, and on stakeholders directly involved in the funded actions because of obligations resulting from signed grant agreements.

The impact on national public administrations will be limited to the allocation of human and financial resources to attend the States Representatives Group meetings (approx. 3-4 per year, in Brussels) and ensuring the flow of information at national level between stakeholders, notably between the relevant ministries. These processes are similar to those required for attending various Horizon Europe programme committees but an additional effort will be needed for a separate channel of communication activities to national stakeholders. Such activities are usually organised by National Contact Points as the main structure existing at the Member States level to provide guidance, practical information and assistance on all aspects of participation in EU funding programmes. A similar impact can be expected on various stakeholder groups such as health care professionals, providers, patient associations or research and technology organisations, to ensure their potential input into the governance and priority setting process.

Industry associations who are formal members of the Partnership will be bound by the various obligations stemming from the Regulation establishing the initiative. Due to their representation in the partnership's Governing Board, these associations will need to organise their internal workflows for efficient decision making and allocate representatives to attend Board meetings, and to follow-up on the Governing Board's decisions taken by written procedures.

For all other enterprises active in health R&I, some limited additional costs may be linked to understanding the rules of the new funding programme and allocating staff to follow up calls as they are prepared and published, and to networking and finding collaboration opportunities. SMEs might find these costs to be proportionally higher (versus their overall staff effort) as such activities are not directly linked to the entity size. Overall, these costs and effort will be lower for those already familiar with other private-public partnerships, such as ECSEL or IMI Joint Undertakings.

As the major positive impact, all stakeholders interested to take part in the initiative and respond to calls for proposals will stand a chance of benefiting from funding opportunities and access to new scientific ideas, intellectual property and collaborators beyond their usual interlocutors. For industries – including SMEs – this will enhance business viability and speed up the path of designing products or services that better respond to the needs of end-users: patients, health care professionals and health care systems.

2. SUMMARY OF COSTS AND BENEFITS

It is not possible to quantify – with an acceptable level of confidence – how this initiative would lead to the reduction or increase of costs of developing health innovations, or to the health status of EU citizens.

The development cost and timelines in the field of health play a crucial role. In the pharmaceutical area, successful development of a new drug takes on average 10 to 15 years, far beyond the typical duration of projects seen e.g. in IMI2 JU (usually 4-6 years). The cost of development is, in most cases, shared between various funding sources, such as private investors and governments that complement various phases of product development pathway[6]. While the success of drug development process is variable between areas, such as oncology versus infectious disease vaccine development[7], a common feature is that the cost of failures needs to be factored in the cost (and ultimately, market price) of products that will successfully enter the market.[8].

Furthermore, the funding made available by this initiative can only make a partial contribution to the important development costs of medical interventions. A recent independent analysis[9] demonstrates that (after accounting for the costs of failed trials) the median capitalized R&D investment to bring a new drug to market was estimated at approx. USD 985 million (mean investment approx. USD 1.3 billion). The figures vary greatly between therapeutic areas: median between USD 765.9 million for nervous system agents and USD 2.7 billion for antineoplastic and immunomodulating agents. Earlier estimates – based on different type of input data – suggested that out-of-pocket cost per approved new drug reached approx. USD 1.4 billion (2013), with fully capitalised costs reaching approx. USD 2.6 billion[10].

This analysis gets inevitably more complex in the case of a cross-sector partnership such as IHI that will bring together the several technology sectors: medical devices, pharmaceuticals, biotechnology, imaging and vaccines. Indeed, it is expected that the majority – if not all – projects funded under IHI will operate in the thematic areas of two or more sectors. Moreover, various sectors have varying development timelines and disparate definitions of pre-competitive space, where this partnership actually intends to intervene. The combination products (such as e.g. diagnostics + treatment) that could result from the partnership in the long term, would also reflect these underlying complexities.

The direct monetary benefit for citizens cannot be quantified, either, because the status of health is influenced by numerous factors, such as e.g. income and social status, education, environment, social support networks, genetic factors, the place where one lives, access to

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[6] Chakravarthy R et al (2016) Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years. Therapeutic Innovation and Regulatory Science, 50(6) 759-768. http://dx.doi.org/10.1177/2168479016648730

[7] Wong CH, Siah KW and Lo AW (2018) Estimation of clinical trial success rates and related parameters. Biostatistics (February) 1-14. http://dx.doi.org/10.1093/biostatistics/kxx069

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

[9] Wouters OJ, McKee M, Luyten J (2020): Estimated R&D investment needed to bring a new medicine to market, 2009-2018. JAMA. 323(9) 844-853. doi:10.1001/jama.2020.1166 https://jamanetwork.com/journals/jama/fullarticle/2762311

[10] DiMasi JA et al (2016): Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics 47, pp. 20-23.

health care services and many others[11]. Majority of these factors are beyond the control of any funding initiative, including this one.

For all these reasons, the ensuing analysis will provide a qualitative assessment and some estimates, while refraining from computing potential gains or loss values, as these would be based on too many assumptions to warrant credibility.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation***	***Comments***
Direct benefits		
Strengthened EU skills and capacity in academic and industrial health research and innovation	New scientific paradigms, new high-impact publications[12].	
EU-wide cross-sectoral health research and innovation ecosystem created	Easier interactions between potential new collaborators: across stakeholder types (e.g industry with academia, SMEs with large industry…) and across sectors (e.g. pharma with medtech). A neutral platform created for interactions between academia, industry, end-users and regulators.	
New scientific paradigms established providing the foundation for innovative health technologies	New health solutions (e.g. drugs, diagnostics, combination products) available to citizens. Potential new business opportunities for industry, incl. SMEs	Potential new solutions might be entering the market in the future, thus changing the competitive position of companies, incl. SMEs.
Indirect benefits		
More productive and globally competitive EU health industries that create jobs and growth	Positive impacts on European economy, including access to new markets for companies.	Potential salary increase for highly-skilled jobs and/or increase of high-salary employment in health sectors.
Better, safe, effective and cost-effective health technologies, tools and digital solutions for health	EU citizens will benefit.	Companies may need to adapt to changing landscape and new business models.
Increased level of public and private investments into strategic unmet public health	EU citizens will benefit.	For companies, need to adapt to new business models and areas.

[11] https://www.who.int/hia/evidence/doh/en/

[12] The citation impact (which measures how many times a paper is cited in subsequent papers) for all IMI papers is 2.03 (compared to 1.14 for the EU and the baseline of 1 for the world). https://www.imi.europa.eu/sites/default/files/news/Brochure_ResultsImpact.pdf

needs		
Improved health outcomes and wellbeing in priority disease areas (SDG3)	EU citizens will benefit.	Health care systems might need to shift focus from treatment to prevention.
Reduced health inequalities and improved access to high quality health care in priority disease areas (SDG 10)	EU citizens will benefit.	For companies, need to adapt to new business models and areas.
Reduced need for travel impacting on climate (SDG 13)	EU citizens will benefit.	Lowered revenues for certain enterprises active in the travel sector.

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs						EUR 4,7 million[13]
	Indirect costs						
Personnel costs	Direct costs						EUR 6.3 million[14] to cover the cost of 56 staff
	Indirect costs						

[13] Figure for IMI2 JU in 2019, based on IMI2 JU Annual Activity Report 2019, Title 2 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

[14] Figure for IMI2 JU in 2019, based on IMI2 JU Annual Activity Report 2019, Title 1 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

All these individual costs and benefits are likely to contribute to, or even trigger, changes in the health care systems. For individual citizens, this could mean that the health care will shift from disease/incident-based treatments to more holistic care throughout the lifetime.

REFIT Cost savings table

Not applicable for the proposed Innovative Health partnership. The initiative will build on the existing implementation structure (the Programme Office) already in place for IMI2 JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines[15] to evaluate and compare options with regards to their **efficiency, effectiveness and coherence**. This is complemented by integrating the **conditions and selection criteria for European Partnerships**, as well as requirements for setting up Institutionalised Partnerships.[16]

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis [17] (Technopolis Group, 2020).

All impact assessment 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. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

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. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, 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 analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the

[15] European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

[16] A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

[17] Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I 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 finally served a bibliometric analysis run by the contractor 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.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were 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;
- 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 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) 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 external contractors 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 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "**functionalities**". These are

used to reflect *what is needed in terms of implementation* for each candidate initiative to be able to deliver on its objectives. The functionalities are the **distinguishing factors** between the different options and are directly linked to the European Partnerships' selection criteria of openness and transparency, additionality and directionality (see Annex 6). Based on the objectives identified and the targeted impact, functionalities describe what this requires in terms of implementation. Each form of implementation is then assessed to establish to which degree it would allow for these functionalities to be covered, e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of stakeholders' R&I strategies[18]; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with other EU, national or regional policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options and allows a structured comparison of the options against the selection criteria for European Partnerships.

Figure 1. Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	**Option 1: Co-programmed**	**Option 2: Co-funded**	**Option 3.1: Institutionalised Article 185**	**Option 3.2: Institutionalised Article 187**
Type and composition of actors (including openness and roles)				
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations
Type and range of activities (including additionality and level of integration)				
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality:	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of

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

Baseline: Horizon Europe calls	Option 1: Co-programmed	Option 2: Co-funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
projects Limitations: No systemic approach beyond individual actions	s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Additionality: National funding	projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Directionality				
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal (Horizon Europe) and external (other Union programmes, national programmes, industrial strategies)				
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes and activities

On the basis of the evidence collected, the thematic impact assessments evaluate the **effectiveness** of the various policy options along three dimensions corresponding to the

different categories of likely impacts: scientific, economic and technological, and societal (including environmental). Each impact assessment considers to which extent the different policy options fulfil the desirable 'functionalities' and are therefore likely to produce the targeted impacts. In addition, where specific impacts (e.g. on fundamental rights) are relevant for a candidate Partnership, these are assessed in the corresponding report and according to the Better Regulation Guidelines and Toolbox. This analysis results in a scoring of the policy options with a three-point scale. Scores vary from + to +++, where + refers to low potential for reaching the likely impacts, ++ to a good potential, and +++ to a high potential. The effectiveness assessment of the different options does not use a compound score but concludes on as many scores as there are expected impacts. This is done to increase transparency and accuracy in the assessment of options. Qualitative and quantitative evidence is provided to motivate each score.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence corresponds to the consistency between a given implementation mode and the other actions under Horizon Europe. External coherence refers instead to the alignment with other initiatives at EU, national and international level beyond Horizon Europe that are relevant to a thematic area. Each option (implementation mode) is assessed following a three-point qualitative scale.

To compare the expected costs and benefits of each option (**efficiency**), the thematic impact assessments broadly follow a cost-effectiveness approach[19] to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account[20]. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.[21] The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for

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

[20] Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

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

the overall investment).

- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%),[22] but lead to an additional R&I investment of at least the same amount than the Union contribution[23] (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution[24]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).[25]
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution[26]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution[27]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 2 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Co-programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0	↑↑			
Set-up of a dedicated implementation structure	0			Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0	↑↑			
Ex-ante Impact Assessment for partnership	0			↑↑↑	
Preparation of EC proposal and negotiation	0			↑↑↑	
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0	↑			

[22] Specifically, some additional set-up costs linked for example to 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.

[23] Minimum contributions from partners equal to the Union contribution.

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

[25] These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

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

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

Cost items	Baseline: traditional calls	Option 1: Co-programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Call and project implementation	0	0 In case of MS contributions: ↑	↑	↑	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				
Partners costs not covered by the above	0	↑	0	↑	↑
Additional EC costs (e.g. supervision)	0	↑	↑	↑	↑↑
Winding down costs					
EC	0				↑↑↑
Partners	0	↑	0	↑	↑

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

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

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

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

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in Figure 3. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (- -) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (+ +) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common

Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options, a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option[28].

Figure 3: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	**Option 1: Co-programmed**	**Option 2: Co-funded**	**Option 3a: Institutionalised 185**	**Option 3b: Institutionalised 187**
Administrative, operational and coordination costs	0	(0)	(-)	(- -)	(- -)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. *cost-efficiency*)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline. ; score (+) = lower costs compared to baseline

[28] The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space). The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe - the future EU research and innovation (R&I) programme for 2021-2027, according to which, "*European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme*". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[29]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[30] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[31] sets out the areas for which the Unions has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?

[29] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[30] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[31] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[32]:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the Sustainable Development Goals (SDGs).

[32] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?
The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[33] or significantly damage the interests of other Member States?
As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

[33] https://europa.eu/european-union/about-eu/eu-in-brief_en

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact,

the proposed initiative should be seen as complementary and reinforcing national and sub-national initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve

satisfactorily on their own, and where the Union can do better?
The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.
(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?
For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)
The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.