EUROPEAN
COMMISSION

Brussels, 23.2.2021
SWD(2021) 37 final

PART 2/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

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

EU- Africa Global Health Partnership

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

ANNEXES

TABLE OF CONTENTS

ANNEX 1 PROCEDURAL INFORMATION 4

ANNEX 2 STAKEHOLDER CONSULTATION 10

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS 10

1.1. Introduction 10

1.2. Horizontal results of the Open Public Consultation 10

1.2.1. Profile of respondents 10

1.2.2. Characteristics of future candidate European Partnerships 14

1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships 15

1.2.4. Relevance of EU level to address problems in Partnerships' areas 16

1.2.5. Horizon Europe mode of intervention to address problems 17

1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives 17

1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements 20

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments 21

1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives 22

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts 22

1.3. Stakeholder consultation results for this specific initiative 23

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships 23

1.3.2. Structured consultation of the Member States on European partnerships 23

1.3.3. Targeted consultation of stakeholders 26

1.3.4. Open Public Consultation 31

ANNEX 3 WHO IS AFFECTED AND HOW? 42

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE 42

2. SUMMARY OF BENEFITS AND COSTS 43

3. OVERVIEW **OF** COSTS 46

ANNEX 4 ANALYTICAL METHODS 48

4. OVERVIEW OF THE METHODOLOGIES EMPLOYED 48

5. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES ... 49

6. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS ... 54

ANNEX 5 SUBSIDIARITY GRID ... 56

ANNEX 6 ADDITIONAL BACKGROUND INFORMATION ... 64

1. BACKGROUND INFORMATION FOR ALL INITIATIVES ... 64

1.1. Selection criteria of European Partnerships ... 64

1.2. Overview of potential functions for a common back office among Joint Undertakings ... 65

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE ... 67

2.1. Implementation of the EDCTP2 ... 67

2.2. Recommendations of the First Interim Evaluation of the EDCTP2 programme ... 69

2.3. Actions taken in response to the EDCTP2 Interim Evaluation Recommendations ... 72

2.4. Strengths, Weaknesses, Opportunities and Threats of the EDCTP programmes ... 76

2.5. Progress towards EDCTP2's objectives (2014-2019) ... 78

2.6. Success stories of the EU funding through FPs and EDCTPs programmes ... 79

2.7. Specific African countries consultation on GHP-EDCTP3 ... 81

Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5240

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 13 May 2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20 January 2020.

On 15 May 2020 the Regulatory Scrutiny Board (RSB) gave a positive opinion with reservations to a draft version of the EU-Africa Global Health Partnership candidate impact assessment. The revision was done to ensure that the assessment relies on a solid methodology that meets the RSB standards. The Board's recommendations covered the following key aspects: (1) The report defines the problem too widely in view of what the EU-Africa health partnership aims to achieve. It does not sufficiently focus on informing the choice of form of the candidate partnership. (2) The added value of the preferred option over an alternative type of partnership is not sufficiently demonstrated. (3) The report does not

sufficiently explain which players the new partnership can attract in its upgraded form and what they will contribute to delivering on its objectives.

The core text and annexes of the EU-Africa Global Health Partnership candidate impact assessment report were adjusted following the recommendations of the RSB. In particular to focus the problems in view of what the partnership aims to achieve, and to properly inform the choice of form of the candidate partnership, demonstrating the added value of the preferred option over an alternative type of partnership and explaining in a more detailed manner which players the new partnership can attract in its upgraded form and what they will contribute to delivering on its objectives.

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

Comments from the Regulatory Scrutiny Board	**Actions taken for the Staff Working Document**
The report defines the problem too widely in view of what the EU-Africa health partnership aims to achieve. It does not sufficiently focus on informing the choice of form of the candidate partnership The logic of the intervention presented in the report should be clarified to support the analysis. It should focus on the central theme of the impact assessment, i.e. the choice of partnership form. In doing so, the report should better clarify the relationship between the problems, the 'functionalities', 'expected impacts', and the specific objectives. Impacts should be assessed with respect to the specific objectives. In the particular case of establishing a partnership for EU-Africa research health cooperation, the report should narrow down the problem definition. This should build on the experience gathered with the previous research programmes with and in African countries and focus on supporting clinical trials and enhancing research capacities.	The context of the initiative has been shortened to focus on the aim of the Impact Assessment, in particular on the analysis of the types of partnerships that can be created in the specific area of research cooperation with African countries and other global partners. The intervention logic has been revised based on a better definition for the two main problems the partnership aims to address - the lack of suitable health technologies and the emergence and spread of infectious diseases – analysing the problem drivers, their corresponding specific objectives and expected impacts. For each policy option, the different functionalities have been detailed and assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('*openness*'); the range of activities that can be performed (including *additionality and level of integration*); the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (*internal coherence*), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (*external coherence*).

	It has been highlighted that the new partnership builds on the success and experience gathered by its predecessors, the EDCTP and EDCTP2 programmes.
The added value of the preferred option over an alternative type of partnership is not sufficiently demonstrated. The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct inconsistencies in terms of expected impacts. The report should justify any deviations from the common efficiency analysis. On this basis, the report should better explain the advantages of an institutionalised Article-187 partnership over other organisational forms. This should include the prospective participation of national, international and private organisations or donors. It should also include the financial requirements and the needed time horizon of the commitment to support clinical trials and grow research capacity in sub-Saharan Africa.	The scoring system applied when assessing the options has been better explained as well as the relative importance of the different criteria and the deviations from the common efficacy analysis. The discrepancies between the text and the tables and inconsistencies in terms of expected impacts have been corrected. The report should justify any deviations from the common efficiency analysis. The advantages of the institutionalised Article-187 partnership over other organisational forms has been explained. The main added value of the partnership based on an Article 187 of the Treaty of the European Union is that the African countries' contribution can count towards matching the EU contribution. This new approach provides a strong recognition of the political and the operational importance of the African countries in the partnership. In addition, Article 187 provides the framework within which philanthropies, industry and other third countries can also join and contribute to the partnership, allowing the EU to collaborate with different key global health players. Moreover, under an Article 187, the EU is a full partner and co-owner in the endeavour. This means that the Commission is an active actor in the policy dialogue and the governance mechanism of the partnership. With its broader, multi stakeholder partnership, an article 187 partnership would be a powerful actor to address global health and it would be able to deliver at the necessary speed and scale ensuring that public interests are at the core of the partnership. The quantitative information on the required budget have been indicated including for the envisaged set up and running costs.
The report does not sufficiently explain which players the new partnership can	The report has been revised to better explain which players can be attracted to the

attract in its upgraded form and what they will contribute to delivering on its objectives. The report should expand on how the preferred form of the partnership would attract private industry and donors. It should explain how it would coordinate with similar global initiatives.	partnership. The motivation for the **EU, European and African countries** comes mainly from the successes of the EDCTP and EDCTP2 partnerships. These partnerships have shown that European and African governments can join forces with the EU around common objectives, creating an environment within which results were achieved that individual countries or the EU research framework programme alone, would not have managed to obtain. **Philanthropies**, such as the Bill and Melinda Gates Foundation or Wellcome Trust, have realised that alone they cannot bear the costs of late stage clinical trials for the development of medicines or vaccine for poverty related diseases (e.g. phase IV of the RTS,S malaria vaccine candidate) and they are therefore seeking partners to join forces with. The Ebola epidemics in West Africa and the Democratic Republic of Congo has contributed to raise the interest of the **pharma industry** and vaccine in investing in infectious diseases threats affecting Africa and they are actively reaching out to potential partners. Also, for some of these industries, investing in research that is relevant to Africa is part of their corporate social responsibility (e.g. Johnson & Johnson[1], GSK[2]) with a commitment to fair pricing. Including pharma industry in the partnership will also allow to produce at scale and cover the whole value chain. Here also a partnership under Article 187 would better harness industry's contribution as it can be matched. While industry has already taken part in some projects under EDCTP2. The industry that would participate in this partnership, is the industry that has a research agenda that is relevant to infectious diseases in low and middle income countries.

[1] https://www.jnj.com/responsibility/

[2] https://www.gsk.com/en-gb/responsibility/

Additional changes to the Core Impact Assessment Staff Working Document	Introductory paragraphs to the Figure 6 and 7 have been added. Following suggestions from the GHP Working Group on African Involvement additional information has been added to the problem drivers. In the General and Specific objectives, points 4.1 and 4.2 references to the specific African countries consultation have been added. The target to measure the objective of strengthening the capacity of sub-Saharan Africa for epidemic preparedness has been better defined. In point 4.4, under 'Type and composition of the actors to be involved' and 'Type and range of activities needed' a reference to the specific African consultation has been added. Under the 'Coherence needed with the internal and external environment', more information has been added to better explain Figure 9. Under point 7.1 The preferred option, a paragraph has been adapted to avoid the repetitions. The Table 14 on Monitoring indicators has been adapted to include additional indicators from the Draft EDCTP3 Strategic Research and Innovation Agenda.
Additional changes to the Annex of the Impact Assessment Staff Working Document	The 'Overview of costs' (Annex 3.3) has been revised based on the DG BUDG average costs to be used for the estimates on 'Human resources' in the legislative financial statements. The 'specific African consultation on GHP/EDCTP3' has been added (Annex 6.2.7).

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 [3] (Technopolis Group, 2020). It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

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.

[3] Technopolis Group, 2020, forthcoming.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,[4] 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.[5] 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[6]. In addition, 162

[4] https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en
[5] https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope
[66] 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.

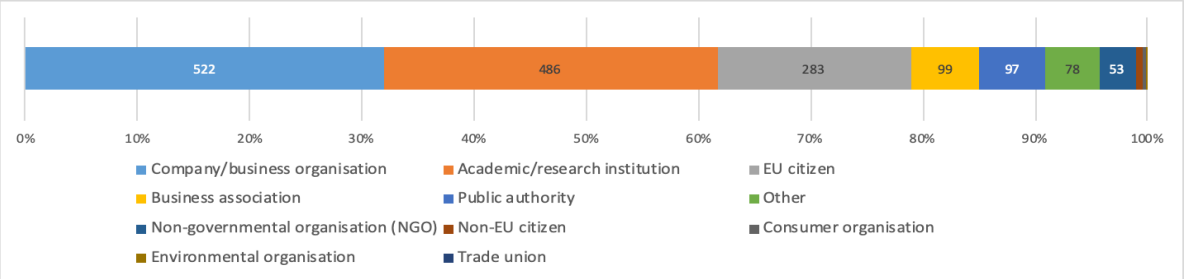
respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

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 4, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

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 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations	Company/business organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation 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 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing 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 5: 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 (n=1613)**	**Number and % of respondents from a non-campaign 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

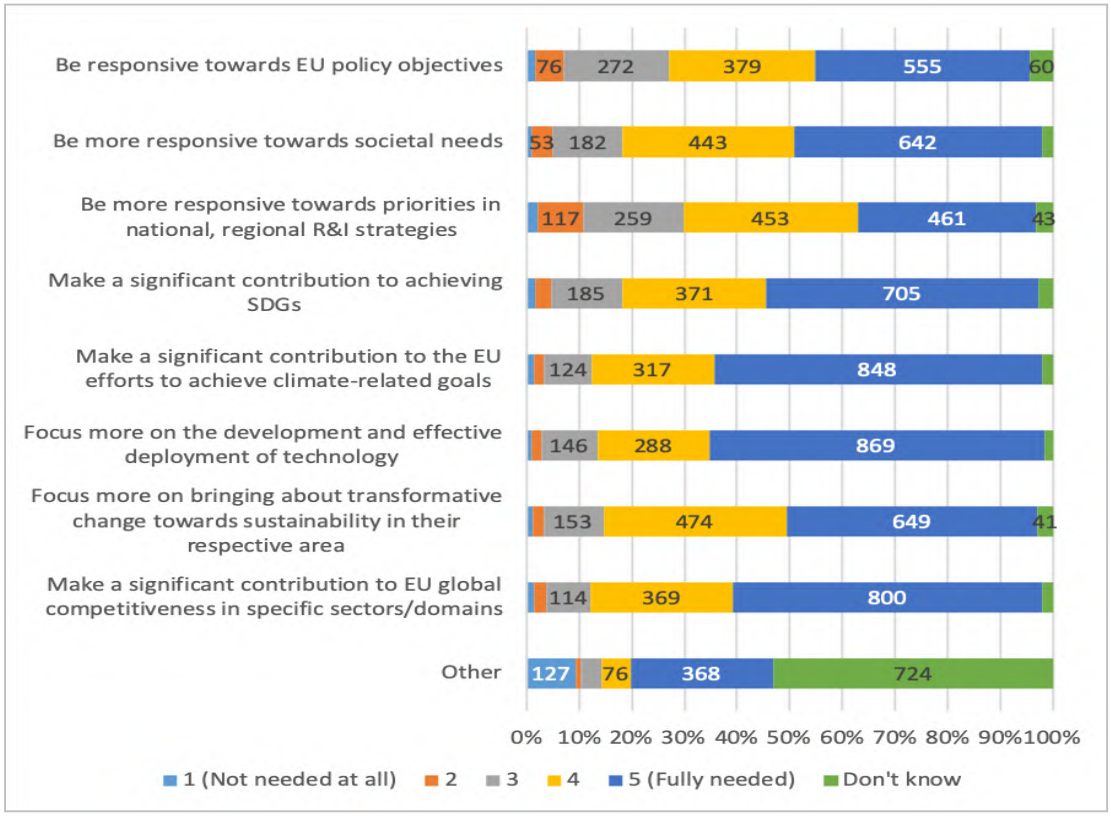
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is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

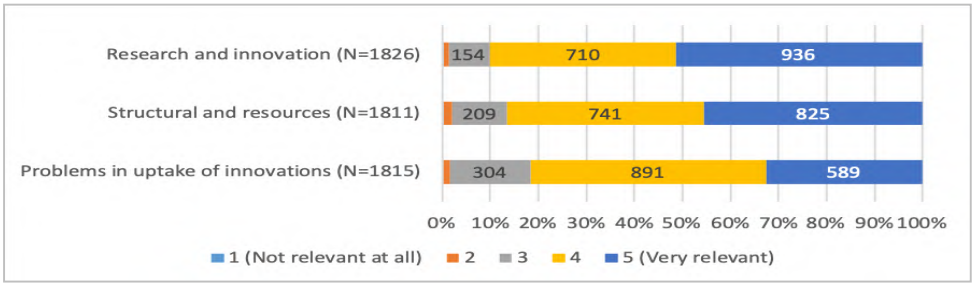
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels 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.

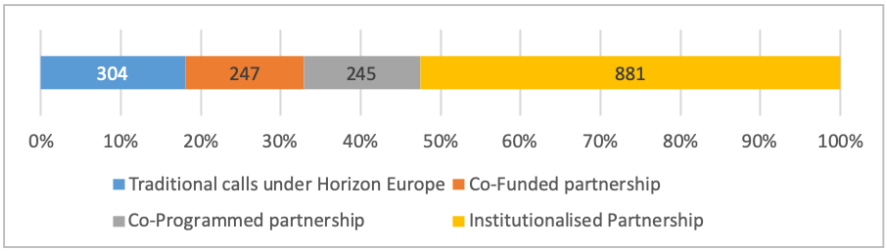
Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



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 10: 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).

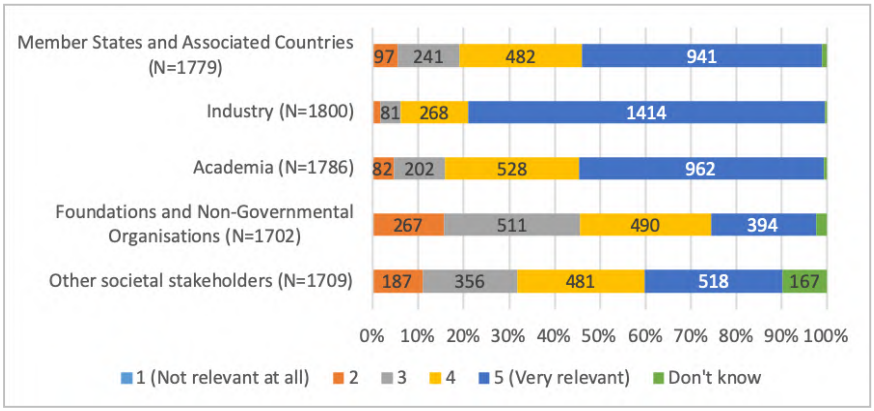
1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

<u>Setting joint long-term agendas</u>

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.

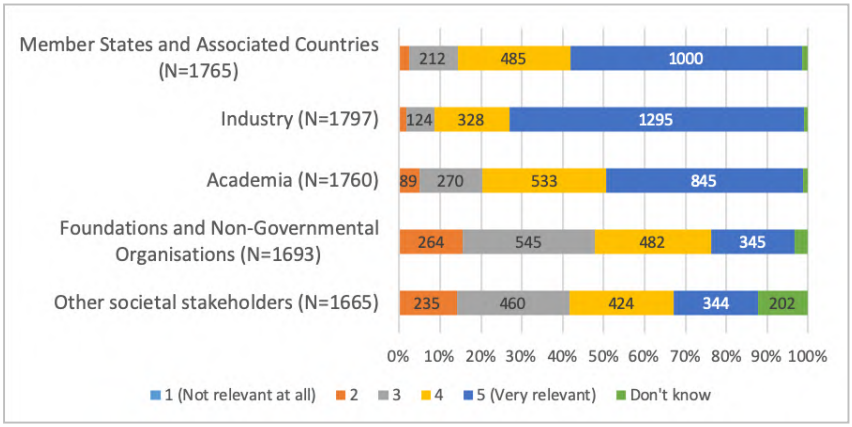
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



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.

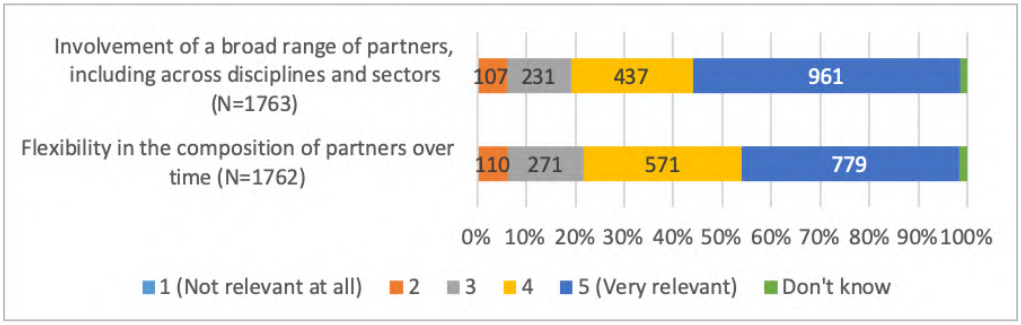
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign 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 13). 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.

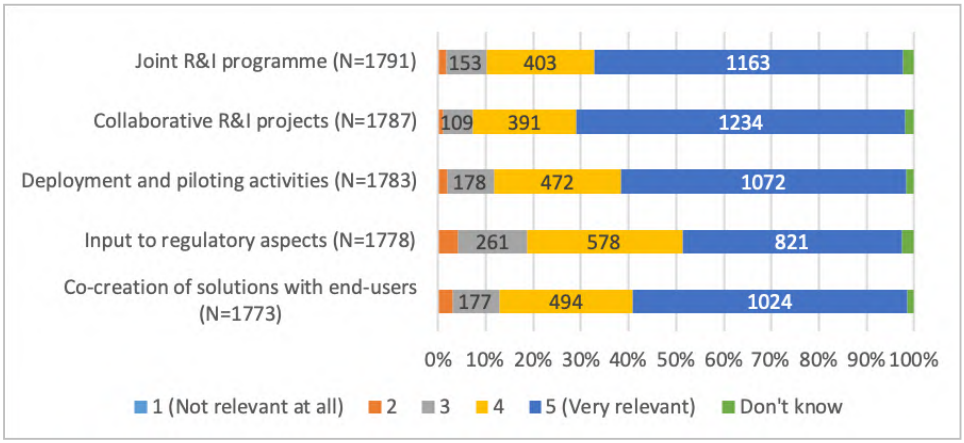
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



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.

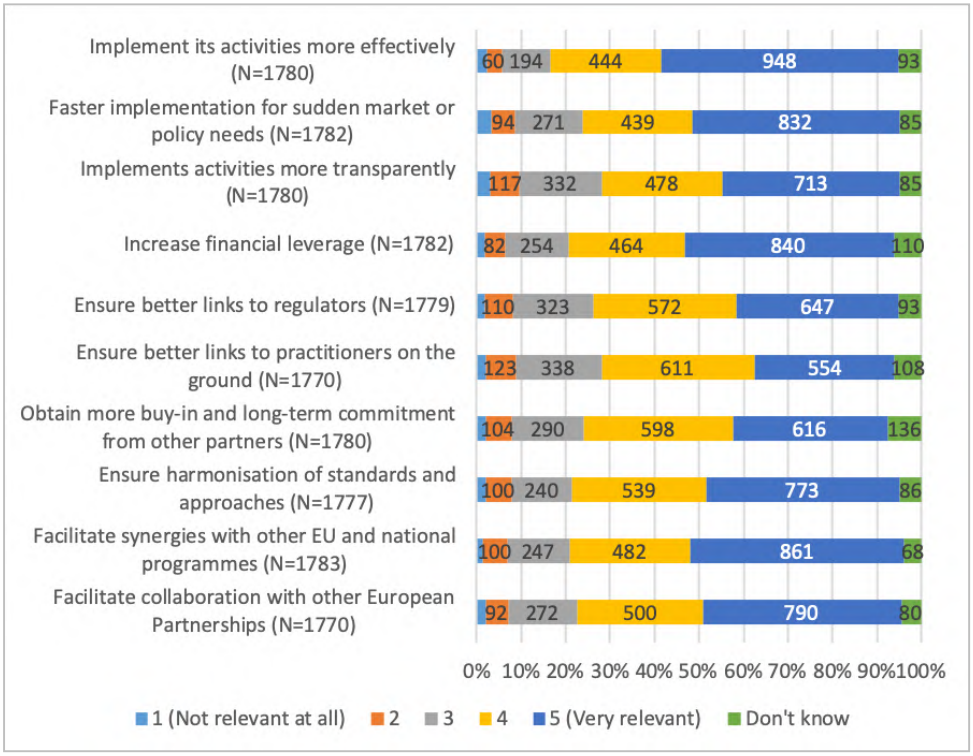
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



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 15: 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

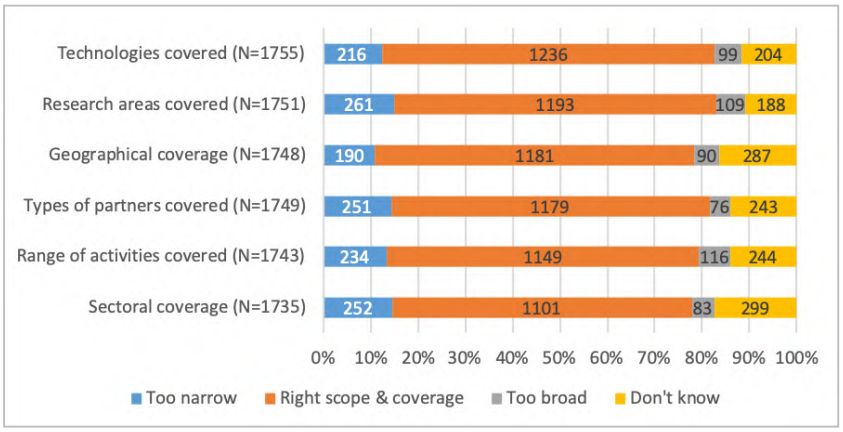


When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding 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 16: 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



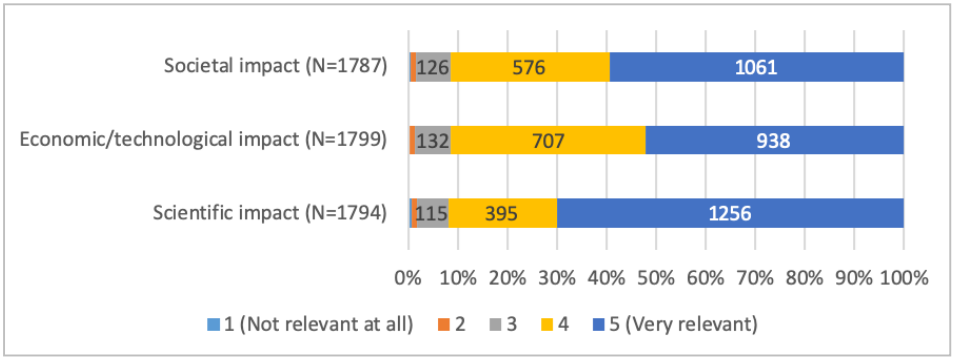
1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

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 17: 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 this specific initiative

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of three weeks allowed any citizen to provide feedback on the proposed initiative on the "Have your say" web portal[7]. In total 34 responses were collected for the initiative "EU-Africa Global Health", mainly from academic/research institutions, non-governmental organisations, EU and non-EU citizens, industry associations, and public authorities.[8] Among the elements mentioned were:

- The scope of the initiative should cover late-stage clinical trials for infectious diseases, especially those poverty-related and neglected as well as emerging diseases in sub-Saharan Africa. Capacity building and education of African scientists should also be prioritised in the scope of the partnership.
- The partnership needs to guarantee a strong involvement of non-EU countries, particularly the African partners, in decision-making, strategic planning, and funding allocation.
- The partnership is expected to facilitate a coordinated scientific agenda for tackling infectious and emerging diseases.
- Funding decisions should follow public health needs in Sub-Saharan Africa, and research priority areas.
- Flexibility in funding decisions should be increased, possibly through adopting a portfolio-based funding approach.
- Efforts should be made to prevent brain-drain from Africa through strengthening local research systems and creating opportunities for researchers to continue their academic career in Africa.
- An increase (over €1.3 billion) in financial support from the EU is needed to ensure that the development of new technologies can be supported. Contributions of European and African partners need to be increased, while financial accounting needs to be simplified.
- Public-private collaboration should be boosted though stronger engagement of private partners and in-kind and financial investments. This would allow to pool adequate resources for the ambitious goals.
- The partnership should become a platform for EU science diplomacy in Africa to strengthen the ties between the continents.
- Stakeholders indicate that Institutionalised Partnership under Article 187 would allow a greater flexibility to attract a variety of stakeholders to achieve the goals of the partnership and should therefore be preferred.

1.3.2. Structured consultation of the Member States on European partnerships

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the

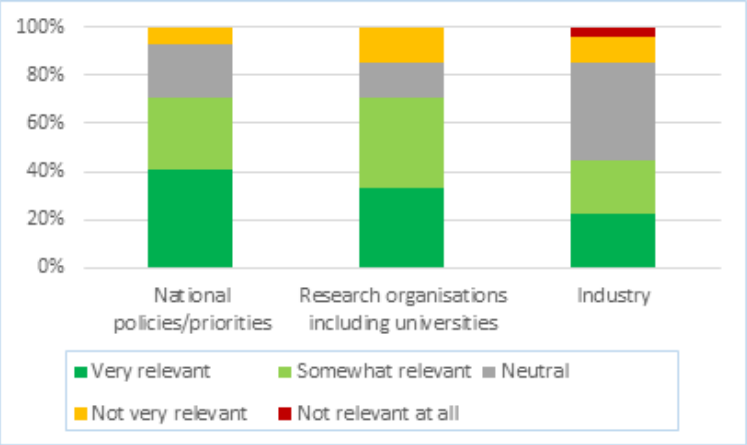
[7] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11907-EU-Africa-Global-Health-Partnership/public-consultation

preparatory work for the candidate initiatives, in line with the Article 4a of the Specific Programme of Horizon Europe. For the initiative "EU-Africa Global Health" the following overall feedback was received from Member States.

Relevance and positioning in a national context

Overall the results of the Member State consultation confirm the relevance of the proposed EU-Africa partnership on health security to tackle infectious diseases, with 69% considering it relevant for national policies and priorities, and 70% for their research organisations, including universities. The proposed partnerships is considered less relevant for industry by most countries (46% relevant), see Figure 18.

Figure 18: Relevance of the EU-Africa partnership on health security to tackle infectious diseases in the national context



On the question of existing national/regional R&I strategies, plans and/or programmes in support of the proposed EU-Africa Partnerships, 21 countries (70 %) report to have relevant elements in place. National R&I strategies or plans were identified most frequently (56%, BE, DE, EE, ES, HR, IT, LV, MT, PL, RO, SE, SI, UK, NO), followed by national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (48%, DK, EE, ES, HR, LV, NL, PL, RO, SE, SI, UK, NO) and dedicated R&I funding programmes or instruments (44%, AT, DE, ES, FR, HR, LV, PL, RO, SE, UK, NO).

Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities. These are all individual comments, with few common elements, e.g.[4]:

- The zoonotic origin of many tropical diseases should be strongly re-enforced and studies on vectors of tropical diseases included;
- Better definition of the role of AMR, also in relation to other partnerships candidates;
- Extension to investigating health behaviour. The fight against infectious diseases in Africa is more effective when it is approached systematically, not only from the clinical perspective;
- Increase the scope of infectious diseases covered, and geographical coverage (e.g. Latin America);
- Include major threats in terms of global burden such as diarrheal, respiratory diseases and meningitis as major causes of death for children under 5, or vector-borne diseases;

- Better alignment with policies in relation to sexual reproductive health and rights. Also, a clear gender analysis and approach;
- Increased efforts for engagement of more partners from the parts of Africa that have weak research culture (areas of greatest impact);
- Better involvement of countries that are not contributing with funding;

The majority of countries (52%) are at this stage undecided concerning their interest to participate, and 4 countries have expressed there is no national interest to participate (CY, CZ, HU, IS). At this stage 7 countries (DE, FR, IT, MT, SI, UK, NO express interest to join as a partner. National R&I programmes and governmental research organisations are identified are main potential partners or contributors. A number of countries express that their interest to participate would increase if their comments would be taken into account. While most are undecided concerning their participation, many countries (74%) expressed interest in having access to results produced in the context of the partnership.

Feedback on objectives and impacts

Overall there is a strong agreement (84%) on the use of a partnership approach in addressing health security tackling infectious diseases. There is broad agreement (76%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, and only to a small degree (36%) that it would contribute to improving the coherence and synergies within the EU R&I landscape.

Countries indicate good agreement with the proposed objectives at short, medium and long term (84%) and the expected scientific, economic and societal impacts at European level (88%), with the remaining ones remaining neutral. Slightly less (72%) consider the impacts relevant in the national context. There is good agreement (80%) with the envisaged duration of the proposed partnership, but strong request for exit strategies, given that the initiative has started in 2003.

Additional comments made by individual delegations reiterate points made previously under elements to be reinforced. On the scope there are diverging views, between those that want to maintain the proposed focus, and others that want to expand the geographical and thematic scope.

Views on partners, contributions and implementation

There is no clear view between countries on the type and composition of partners, yet few comments (e.g. doubts on the inclusion of industry or foundations) are made that further elaborate their assessment. At this stage most countries (68%) would need more information on contributions and level of commitments expected from partners, while 24% agree with the proposal.

The proposed change of the implementation, from the use of Article 185 to the use of Article 187, and the establishment of a Joint Undertaking, is supported by around one third of countries (36%), while 24% disagree, with the rest expecting more details in order to be able to make an informed decision. Arguments made in relation to either implementation relate to the following:

- Article 185: Political aspects (role of the European Parliament), continuation of implementation that is considered well-working, future role of the UK (currently UK is the major contributing country in EDCTP2); positive experience with the current governance model;
- Article 187: more possibilities for private and NGO partners and reduced liability issues for Member States, need to be clear about role of industry (limitation to ad-hoc participation seems more acceptable), ensuring the programme is developed by the public domain, consideration to enhance the territorial scope beyond African countries.

1.3.3. Targeted consultation of stakeholders

The objective of this targeted consultation based on interviews was to collect stakeholder insights on the different issues. These included the functionalities of the initiative required to attain the objectives, the commitment of Member States and other stakeholders to the initiative, the costs of eventual future partnership, the leveraged R&D investments from stakeholders and the impacts and differentiators to take into account for the options assessment. The interview questions were based on the objectives, scope, type of partnership, partner engagement, governance, coherence, funding sustainability and impact.

Overview of respondents to the targeted consultation

The number of interviews with representatives in each stakeholder category, along with their percentage share is shown in Table 2. Within the category "country representatives to the EDCTP GA", a number of interviewed (European and African) representatives are affiliated with research institutions. Thus, the number of interviewed academics exceeds the number of interviews shown in the category 'academia'. Furthermore, a number of interviews were performed as group interviews with two or more participants.

1. Table 2: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
EDCTP Secretariat and Scientific Advisory Committee	7	18.9%
Country representatives to the EDCTP General Assembly	9	24.3%
European Commission and related bodies	6	16.2%
Academia	3	8.1%
Product Development Partnerships (PDPs)	3	8.1%
Charitable foundations	2	5.4%
Industry	3	8.1%
International organisations	2	5.4%
Other	2	5.4%
TOTAL	37	100%

Political and legal context

Although no interview questions directly cover issues of political and legal context directly, interviewees were vocal in expressing their views on the subject. Interviewees discussed areas where Africa has achieved substantial progress, such as scale up of e-health technologies, and overall digitalisation of the continent. However, respondents state that, much still needs to be done. Issues of emerging infectious diseases, climate change, and antimicrobial resistance were highlighted as external factors that may shape future policy priorities for global health.

Problem definition and drivers

What are the problems? Interviewees across all categories agree that the burden of infectious disease is still high in sub-Saharan Africa. The EDCTP Secretariat, EC, PDPs, industry, and others highlighted that emerging diseases also constitute a problem that needs to be addressed. They also mention the lack of accessible and affordable technologies as a driver for this burden, as well as the limited commercial interest in the area of infectious diseases. Interviewees, from all stakeholder categories, stress that there remains a large unmet need for effective, affordable and safe treatments, vaccines and diagnostic tools to combat infectious diseases. The large majority of stakeholders across all categories believe that limited capacity of African countries to conduct clinical research for disease is a major problem driver.

Why should the EU act? Interviewees unanimously agree that there is a strong need for the EU to address the identified problems. Many stakeholders (across all stakeholder groups) believe that the Candidate Initiative is unique to address the needs. Many stakeholders (from EDCTP, country representatives, PDPs, academia, international organisations) stress the added value the initiative brings to African countries in terms of strengthened research capacity and infrastructure. Interviewees (EDCTP Secretariat and SAC, academia, other) emphasise that the partnership format is effective in promoting long-term commitments from all partners, including African countries.

Since the costs of conducting late-stage clinical trials can be extremely high, many of them (EDCTP and SAC, country representatives, EC, academia, PDPs) state that the Candidate Initiative would be essential to achieve a critical mass in terms of funding, as the expected costs are beyond the capacities of national funders. They (EDCTP and SAC, EC, academia,) also state that the Candidate Initiative could enhance coherence between national research programmes funded by EU Member States. Furthermore, some stakeholders (academia, other) believe that the large financial contributions made into EDCTP could be (partially) lost if no successor initiative is in place.

Many stakeholders (EC, country representatives, academia, product development partnerships, charities, international organisations, others) also stress the political commitment of EU to fund actions for research and innovation in Africa and the need to keep up with other international players. EU commitment to SDGs and human right principles are discussed. A few stakeholders have pointed out that supporting development of Africa is in line with European values and feel that EU has a moral obligation to do so.

Objectives: What is to be achieved?

General objectives Across all stakeholder groups, interviewees strongly favour a clear focus on diseases affecting sub-Saharan Africa, in particular on infectious diseases. It is viewed that there is still much to be done in this area and that it will be crucial to sustain and continue the progress made to date. Several interviewees – including representatives of the EC, charitable foundations, and industry – have also highlighted the rise of non-communicable diseases in Africa. However, numerous interviewees have indicated that a broadening of the scope of the Candidate Initiative, compared to that of EDCTP2, would necessitate a concomitant increase in funding.

Interviewees widely agree that the primary focus of the Candidate Initiative should be on sub-Saharan Africa. Nonetheless, some interviewees – in particular those working on emerging infectious diseases and diseases with a high prevalence in other parts of the world – have underscored that it should include other regions and collaborate with other relevant initiatives.

Specific objectives All interviewees were familiar with the type of activities that were supported under EDCTP and have expressed that the Candidate Initiative should support a similarly wide range of activities and support the development of new or improved health technologies to tackle infectious diseases. Furthermore, several interviewees – including EDCTP staff, representatives of PDPs and academics – have expressed a desire for the Candidate Initiative to increase support for implementation research, aimed at improving uptake and effective use of existing health technologies. A limited number of interviewees – in particular those working at a more overarching global health policy level – have underscored the need to promote and support integration of research efforts in the field and to convene stakeholders across the world. Interviewees also indicate the need of sustained support for capacity strengthening. At the same time, several interviewees indicate that various sub-Saharan African countries have already developed substantial capacity and now focus should be on areas where this is most needed, thus capitalising effectively on previous success and South-South networking and cooperation.

A number of stakeholders recognise emerging infectious diseases as a growing problem, affecting not only sub-Saharan Africa but also other parts of the world, including the EU. These stakeholders are in favour of bolstering capacity in the African region to timely detect and respond to such diseases, recognising that existing systems are often weak. At the same time, a number of interviewees are somewhat cautious about the extent to which the Initiative should engage in this area, where already several other initiatives are active. Whilst overall there is support among stakeholders for this specific objective, it is widely seen as one that necessitates collaboration and coordination.

Targeted impacts

Interviewees widely agree that, by supporting research in the field of infectious diseases, the Candidate Initiative has a clear and strong potential to contribute to scientific impact, in the form of new knowledge generated and new health technologies developed. Another area where the Candidate Initiative is generally expected to deliver scientific impact is in the strengthening of research capacity.

Across stakeholder groups, interviewees anticipate that any new technologies developed could have important societal impacts, by reducing the burden of infectious diseases in the African region. This is universally viewed as the ultimate goal of the Candidate Initiative. At

the same time, most interviewees have realistic expectations about the potential for the Candidate Initiative to deliver such societal impacts, recognising both the significant challenges associated with health technology development, and the broader socio-economic context of the African continent.

A number of interviewees from academia have seen first-hand what impacts EDCTP has had on career development opportunities for African researchers. They are therefore optimistic that the Candidate Initiative would likewise achieve such positive impacts if it supports a similar, or extended range, of activities.

None of the interviewees have discussed the potential for the Candidate Initiative to deliver economic impact by increasing the production, distribution and sales of health technologies for infectious diseases. That is not to say that they would not deem such impacts likely, but rather reflects the fact that this form of economic impact is not seen as a goal in itself. This similarly applies to other possible areas of economic impact, such as those on EU-Africa trade and sustainable investments, or on increased research spending in Sub-Saharan Africa. Rather, interviewees are focused on tackling the burden of infectious diseases itself, thereby reducing the associated economic burden.

Functionalities

Across the different stakeholder groups, there is unanimous recognition that to achieve impact the Candidate Initiative needs to encompass a broad range of stakeholders, including European and African countries, research institutions, industry, charitable and international organisations. The extent of participation, particularly stakeholders' involvement in the General Assembly, voting rights and funding decisions have been widely discussed among interviewees. There is no consensus on the format of participation.

Representatives of national governments stress the importance of European and African country participation, and their ability to "steer the processes". Interviewees encourage third party participation, in the form of private entities, associated countries, and charitable foundations. In case of industry participation, they welcome their involvement but express a need for transparency in their participation and contributions as well as limited mandate in order to ensure that public interests are at the core of the Candidate Initiative.

Interviewees uniformly indicate that funding and implementation of research should be the primary focus of the Candidate Initiative. In particular, they view late-stage clinical trials as the primary area where the Candidate Initiative can deliver direct impacts.

A number of interviewed representatives of the EC, as well as some members of the EDCTP Association, have expressed frustration with what they perceive as 'free riding' under EDCTP: the ability for countries that are not part of the EDCTP Association to participate in all EDCTP-supported activities. They argue that this provides limited incentive for countries to formally commit to and align activities. They thus suggest that certain activities should be accessible only to active participants in the Candidate Initiative.

Comparative assessment of policy options and preferred option

Effectiveness

All interviewees expect an institutionalised partnership approach to be most effective to achieve the objectives of the Candidate Initiative. Opinions are, however, somewhat divided

on whether this should take the form of an Article 185 partnership or an Article 187 partnership. Many acknowledge, or even embrace, the advantages an Art.187 set-up would bring to the partnership, arguing that it allows for more meaningful inclusion of a greater range of stakeholders, creates more financial certainty, and would allow for a leaner and more efficient organisational structure. Others, however, have concerns about what this would mean for the relationships built with and between current EDCTP members and for the level of control that EC would have over the partnership, possibly at the expense of the representation of current members. This group of interviewees contains in particular current representatives to the General Assembly of EDCTP, both those from Europe and those from Africa.

Among many interviewees, particular representatives from African countries, there are also concerns that countries that cannot substantially contribute to the partnership financially will be left out of the decision-making. However, several interviewees acknowledge that they do not fully understand the respective advantages and disadvantages of these two options.

Coherence

Numerous interviewees have pointed out the importance of ensuring alignment with other initiatives and programmes in the field of global health and infectious disease. However, they do so mostly in rather general terms rather than by singling out specific areas or initiatives.

A few interviewed stakeholders, including those from within the EC, have indicated that there is space for improved coordination across different Directorates-General within the EC. In particular, this relates to the role of DG DEVCO in health systems strengthening and that of DG ECHO and DG SANTE in epidemic preparedness. Other initiatives named include the Joint Programme for Anti-Microbial Resistance and the Innovative Medicines Initiative. However, these interviewees did not always seem to be fully aware of the exact focus or scope of activities supported by these activities.

Stakeholders also widely agree that the Candidate Initiative should coordinate its efforts with other key stakeholders in the field, but again often without being specific. A few suggest that there has been a proliferation of initiatives that appear to share focal areas with the Candidate Initiative. In addition to EC programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and funders such as the Bill & Melinda Gates Foundation. These interviewees indicate that it will be important for the Candidate Initiative to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities

Efficiency

Few interviewees expressed any views on the comparative efficiency of the different policy options, as many lack the detailed understanding of the options to be able to comment on this meaningfully. Representatives of the EC, both in interviews and during meetings of the PSG, have expressed concerns that any change compared to the Art. 185 partnership that has been in place for EDCTP will result in loss of momentum and expertise. The main reason for this view is the fact that under any other arrangement, the current EDCTP Secretariat will

effectively cease to exist[9]. This is expected to result in important knowledge being lost, which cannot easily be found within the current EC services, and the breakdown of relationships that have been built with stakeholders and partners. Similar concerns have been voiced by members of the EDCTP Secretariat themselves.

1.3.4. Open Public Consultation

Approach to the open consultation

As part of its better regulation agenda, the Commission listens more closely to the views of citizens and stakeholders. The aim is to make evidence-based proposals of EU policies that address their needs. The consultation was open to everyone via the EU Survey online system.[10] The survey contained two main parts and an introductory identification section. The two main parts collected responses on general issues related to European partnerships (in Part 1) and specific responses related to 1 or more of the 12 candidate initiatives (as selected by a participant).

The survey contained open and closed questions. Closed questions were either multiple choice questions or matrix questions that offered a single choice per line, on a Likert-scale. Open questions were asked to clarify individual choices.

The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French. It was advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

The analysis of the responses was conducted by applying descriptive statistic methods to the answers of the closed questions and text analysis techniques to the analysis of the answers of the open questions. The keyword diagrams in this report have been created by applying the following methodology: First, the open answer questions were translated into English. This was followed by cleaning of answers that did not contain relevant information, such as "NA", "None", "no comment", "not applicable", "nothing specific", "cannot think of any", etc. In a third step, common misspellings were corrected. Then, then raw open answers were tokenised (i.e. split into words), tagged into parts of speech (i.e. categorised as a noun, adjective, preposition, etc) and lemmatised (i.e. extraction of the root of each word) with a pre-trained annotation model in the English language. At this point, the second phase of manual data cleaning and correction of the automatic categorisation of words into parts of speech was performed. Finally, the frequency of appearance and co-occurrences of words and phrases were computed across the dataset and the different sub-sets (e.g. partnerships, stakeholder groups). Data visualisations were created based on that output.

The keyword graphs in the following sections have been built based on the relationships between words in the open responses of the survey participants. It features words that appear in the same answer either one after the other or with a maximum distance of two words

[9] A change from an Article 185 into an Article 187 initiative would also affect the legal structure of the Dedicated Legal Structure

[10] https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

between them. Each keyword is represented as a node and each co-occurrence of a pair of words is represented as a link. The size of the nodes and the thickness of the links vary according to the number of times that keywords are mentioned and their co-occurrence, respectively. In order to facilitate the visualisation of the network, the keyword graphs have been filtered to show the 50 most common co-occurrences. Although the keywords do not aim to substitute a qualitative analysis, they assist the identification of the most important topics covered in the answers and their most important connections with other topics, for later inspection in the set of raw qualitative answers.

Open public consultation for the candidate European Partnership on EU-Africa Global Health

The chapter outlines for the candidate European Partnership on EU-Africa Global Health the type of respondents; the views on the needs of the future European Partnerships under Horizon Europe and on the advantages and disadvantages of participation in an Institutionalised European Partnership.

It also analyses the results on the views to specific questions related to: Relevance of research and innovation efforts at the EU level to address problems; Horizon Europe interventions to address these problems; Relevance of elements and activities in setting a joint long-term agenda; Pooling and leveraging resources; Partnership composition; and Implementation of activities; Setting up a specific legal structure (funding body); Proposed scope and coverage of this candidate European Partnership; Alignment of the European Partnership with other initiatives; and on Relevance of this candidate European Partnership to deliver impacts.

Profile of respondents

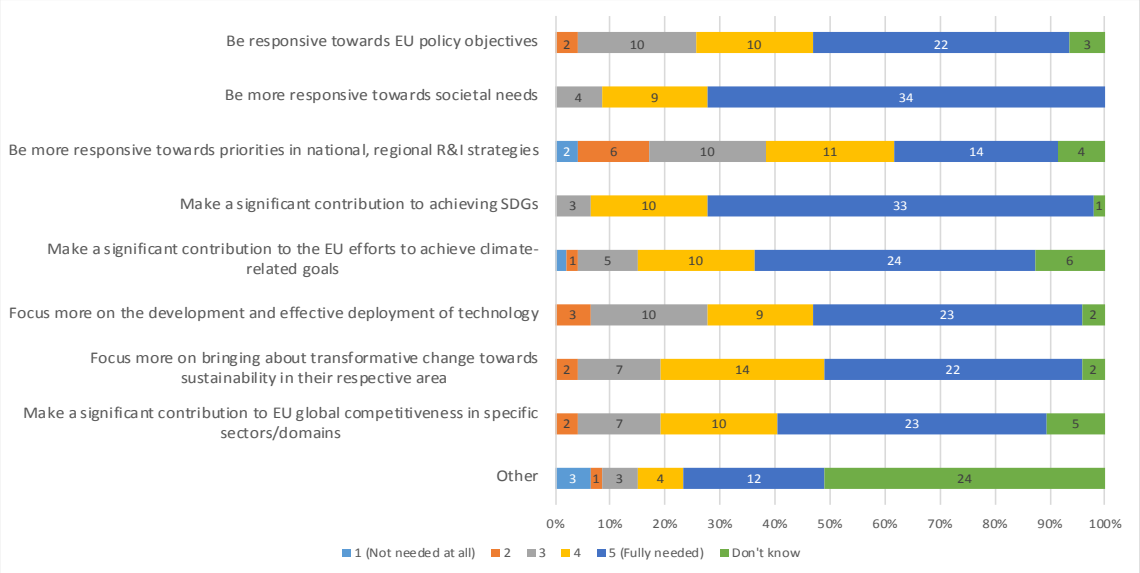
Only 47 respondents provided views on the EU-Africa Global Health partnership. Among them 13 respondents (27.66%) are citizens. The group is dominated by respondents from academic and research institutions (15 respondents or 31.91%), citizens and company/business organisations (7 respondents or 14.89%). The majority of respondents, namely 35 (74.47%), have been involved in the on-going research and innovation framework programme, while 31 respondents (88.57%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Characteristics of future candidate EU-Africa Global Health initiative as viewed by respondents

At the beginning of the consultation, the respondents of this partnership indicated their views of the needs of the future European Partnerships under Horizon Europe. There were two options for which many respondents indicated that they were fully needed, namely be more responsive towards societal needs (34, 72,34%) and make a significant contribution to achieving SDGs (33, 70.32%). The only options where less than 30% of respondents indicated that options were fully needed, was in response to be more responsive toward priorities in national and/or regional R&I strategies and for the other category. With regard to Other, it is likely that respondents did not have a concrete idea of other needs of the future European Partnerships.

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

Figure 19: Views of respondents in regard to the needs of future European Partnerships under Horizon Europe (N=47)



The respondents also had the option to indicate other needs. The results of the analysis show that respondents have indicated needs around extensive support linkage and the development and scaling of technology.

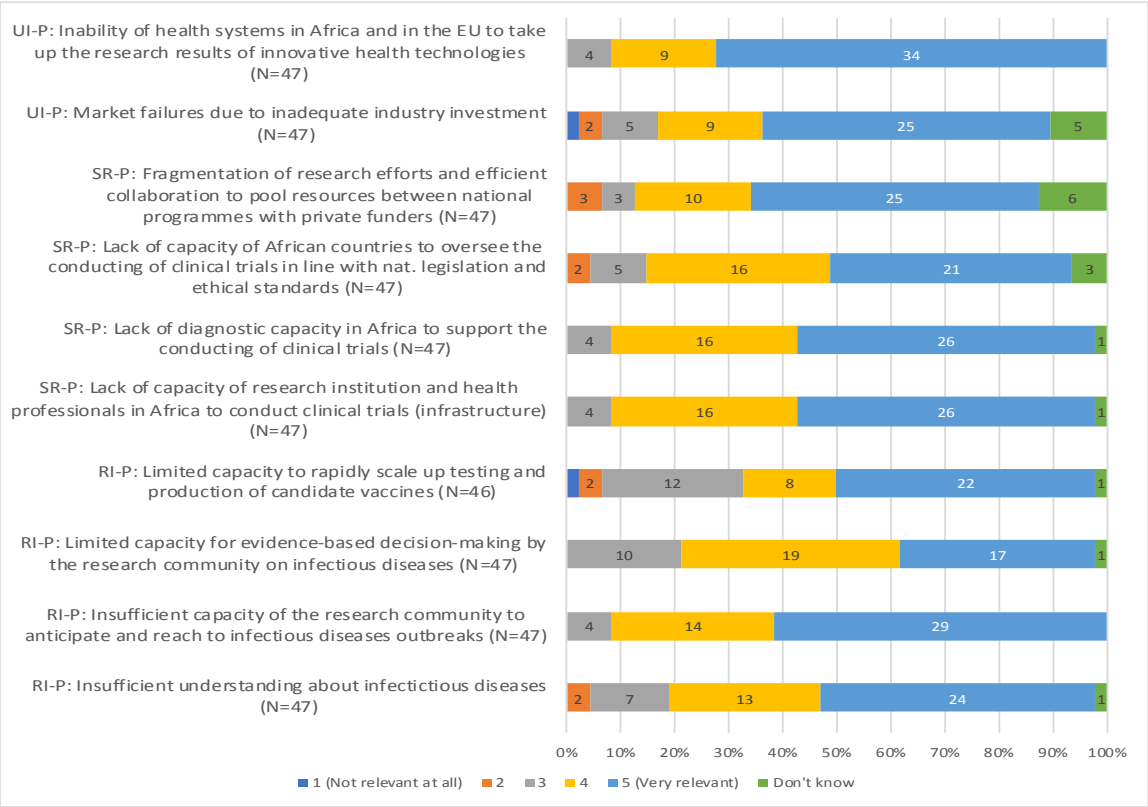
Main advantages and disadvantages of Institutionalised European Partnerships

The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. The keyword analysis used for open questions showed the respondents viewed a network as the main advantage of the institutionalized partnership, as well as long term funding.

Relevance of EU level efforts to address problems in relation to Global Health

In the consultation, respondents were asked to provide their view on the relevance of research and innovation efforts at EU level to address the following problems in relation to global health, specifically on three types of problems: problems in uptake of health innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 20 the responses to these answers are presented.

Figure 20: Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to global health



With regard to the uptake in innovation problems, the inability of health systems in Africa and in the EU to take up the research results of innovative health technologies was highlighted as the main area of concern (34 respondents, 72.34%, indicated it as very relevant).

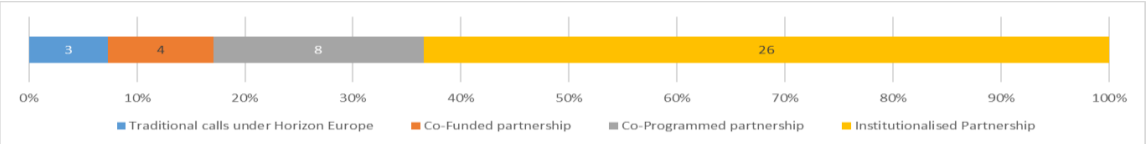
With regard to structural and resource problems, the answers are fairly similar. 26 respondents (55.32%) have indicated that both the lack of capacity of research institutions and health professionals in Africa to conduct clinical trials and the lack of diagnostic capacity in Africa to support the conducting of clinical trials are very relevant.

Last, with regard to research and innovation problems, 29 respondents have indicated that they view insufficient capacity of the research community to anticipate and react to infectious diseases outbreaks as a very relevant problem (61.70%). Limited capacity for evidence-based decision-making by the research community on infectious diseases outbreaks has received the least amount of very relevant answers out of all the problems presented, as 17 respondents have indicated that it is relevant for research and innovation efforts at the EU level to address this issue (36.17%). No statistical differences were found between the views of citizens and other respondents.

Horizon Europe mode of intervention to address problems

To the question on how the challenges could be addressed through HE intervention, just over 60% 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 21: Assessment of Horizon Europe intervention



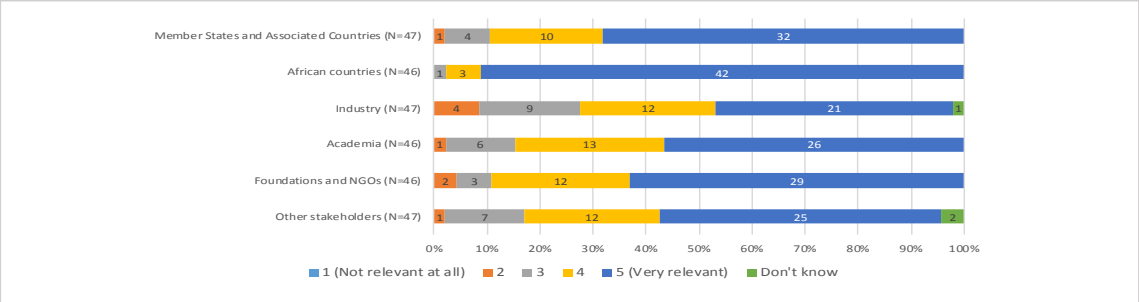
The respondents were asked to justify their answers. An in-depth analysis of the open responses shows that those in favour of an institutionalised partnership viewed this as offering the greatest stability, with long-term political and financial commitments. These respondents view the institutionalised partnership as the best way to pool resources, foster collaboration between a wide range of partners and other stakeholders, with coordination and alignment of efforts. It was also noted that this partnership form best allows for a pipeline or portfolio management approach to selecting projects for funding. The small number of respondents in favour of a co-programmed partnership believe that this option would allow for inclusion of a greater range of actors, including non-EU countries and SMEs, and comes with the lowest administrative cost. The respondents opting for the co-funded partnership approach mentioned flexibility and transparency reasons. There are no significant differences between different groups of respondents.

Relevance of elements and activities to ensure meeting of objectives

Setting joint long-term agendas

To the question on how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives, over 90% of respondents consider that the involvement of African countries is very relevant (Figure 22). Over 60% of them suggest that the participation of Member States and Associated Countries, as well as, foundations and NGOs is very relevant. The least number of respondents (21 respondents or 44.68%) suggested that industry should be involved in setting a joint long-term agenda. No statistical differences were found between the views of citizens and other respondents.

Figure 22: Views of respondents on relevance of actors in setting joint long-term agenda



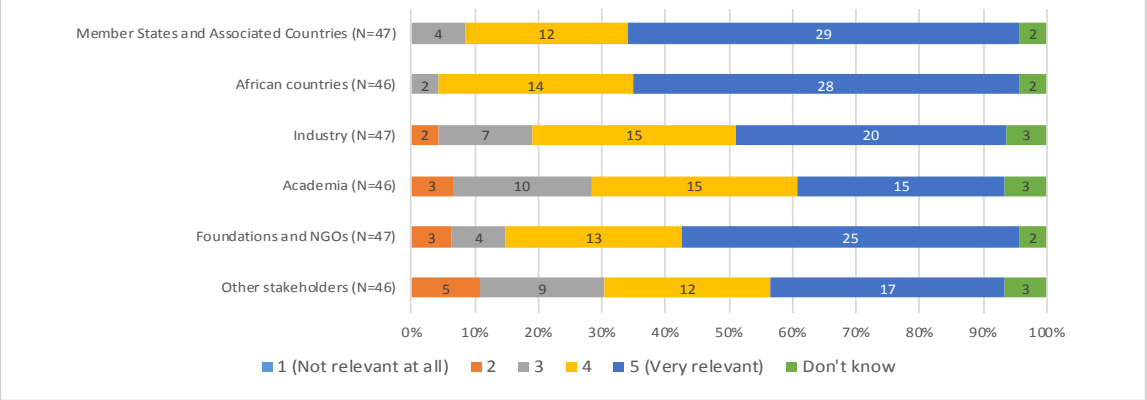
Relevance of elements and activities in pooling and leveraging resources

With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, and in-kind expertise to meet the candidate Partnership objectives, over 50% of respondents indicated Member States and Associated Countries, African countries, foundations and NGOs are most relevant. Based on the opinions of respondents, the role of academia is considered smaller for pooling and leveraging resources, in contrast to setting a

long-term agenda, as only 15 respondents consider that their involvement is very relevant to pool and leverage resources.

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

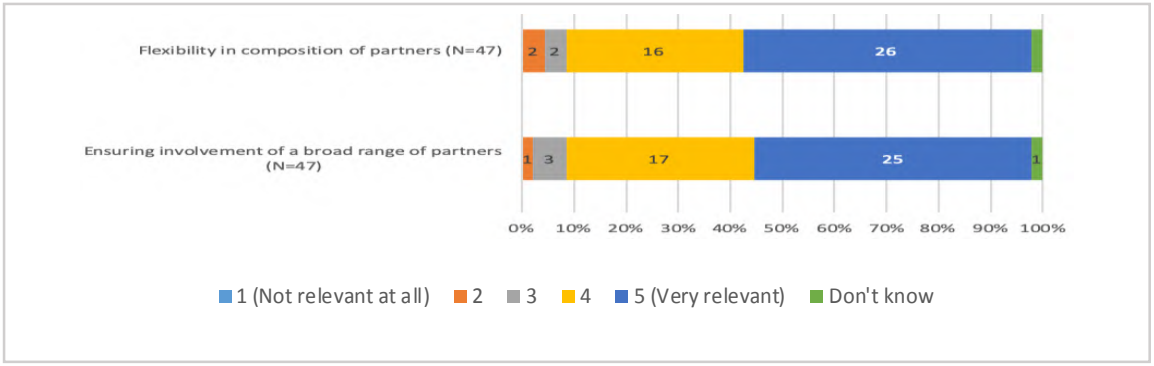
Figure 23: Views of respondents on relevance of actors for pooling and leveraging resources



Relevance of elements and activities for the partnership composition

Around 55% of respondents consider that both the flexibility in partners' composition and a broad range of partners (including across disciplines and sectors) are very relevant to reach the Partnership's objectives. Less than 10% of respondents consider these elements as not very relevant (Figure 24). No statistical differences were found between the views of citizens and other respondents.

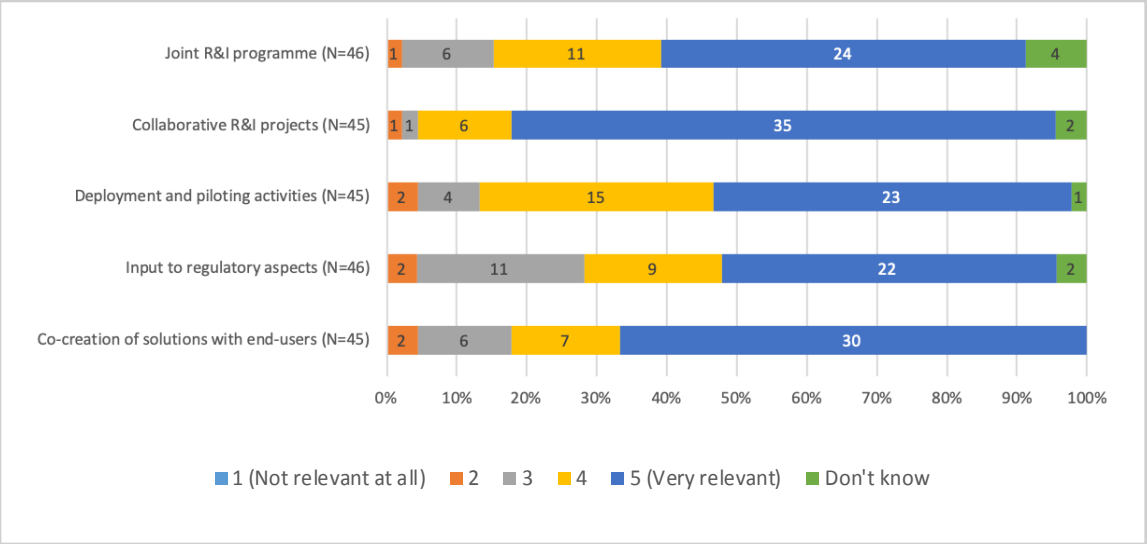
Figure 24: Views of respondents on relevance of partnership composition elements



Relevance of implementation of activities

Concerning the relevance of implementation of several activities for meeting objectives, the activities listed included: joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects (i.e. to developers of medicines or health technologies on approvals and pre-qualifications) and co-creation of solutions with end-users (e.g. national health systems). Out of 45 respondents, 77.8% indicated that collaborative R&D projects are very relevant. The co-creation of solutions with end-users is also considered as very relevant by a large number of respondents (66.6%). In contrast, deployment and piloting activities, and input to regulatory aspects is considered less relevant. Overall, citizens provided similar views, but found Joint R&I programme more relevant.

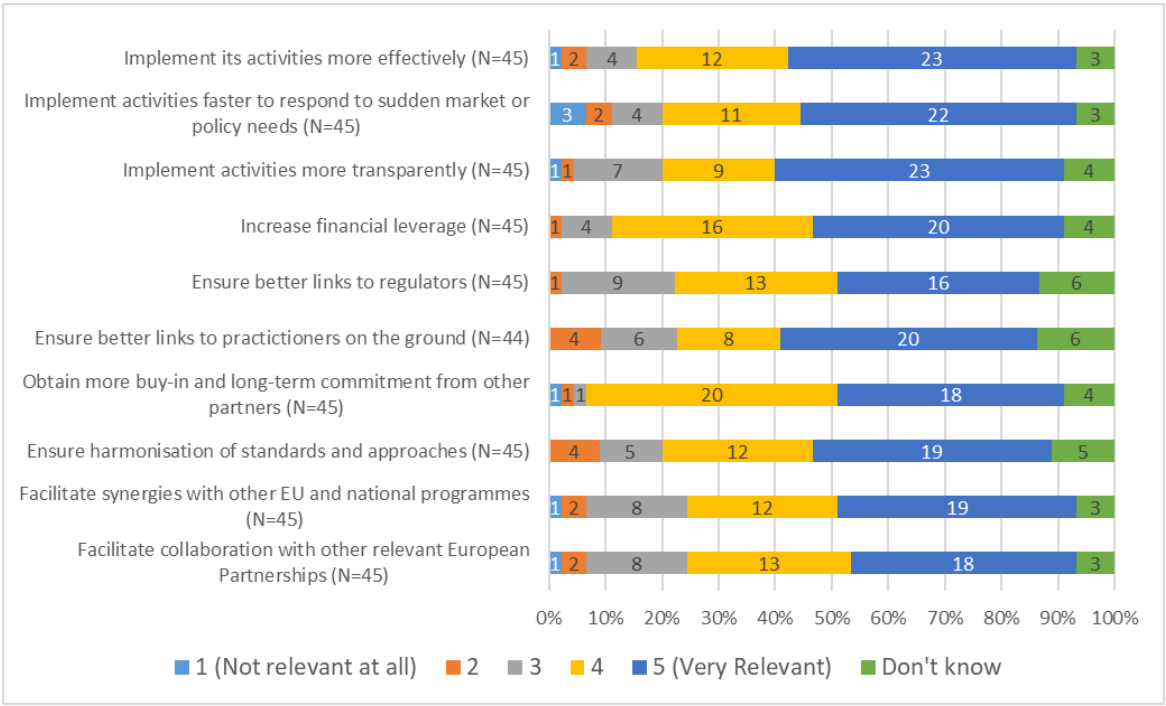
Figure 25: Views of respondents on relevance of implementation of the following activities



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

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 26, a greater number of respondents indicated that the legal structure would be needed to obtain more buy-in and long-term commitment from other partners, to increase financial leverage and to implement activities more effectively. In contrast, the least number of respondents suggest that the legal structure would assist in ensuring better links to regulators, as only 16 respondents indicated that it would be very relevant for this purpose. No statistical differences were found between the views of citizens and other respondents.

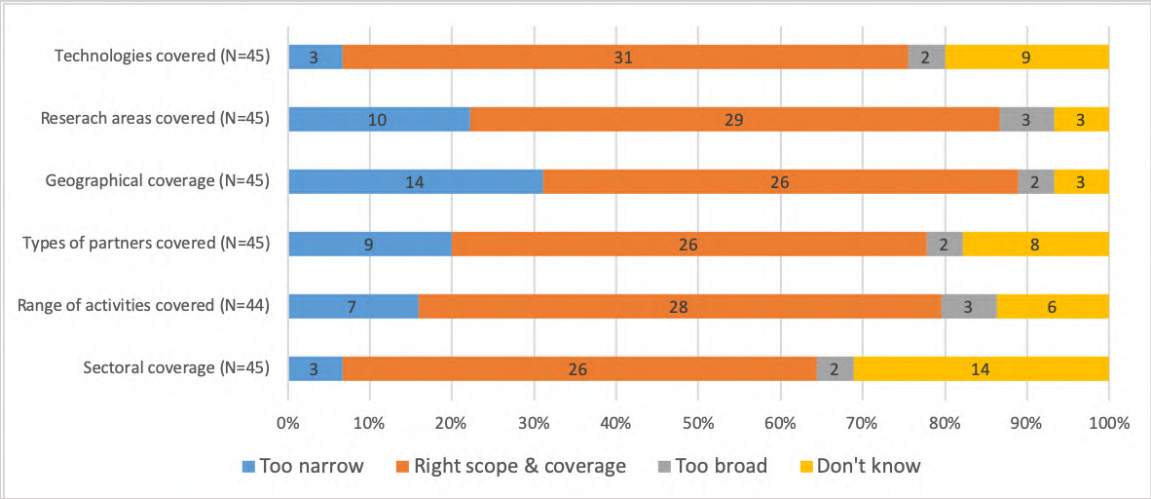
2. Figure 26: Views of respondents on relevance of a specific legal structure



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

The majority of the respondents consider that the proposed scope and coverage of the Partnership is right in terms of technologies, research areas, geographical coverage, types of partners, range of activities and sectors. However, among listed areas, a higher share of respondents (14 respondents or 31.11%) indicated that the geographical coverage might be too narrow. No statistical differences were found between the views of citizens and other respondents.

Figure 27: Views of respondents on the scope and coverage proposed for the Global Health institutionalised Partnership



Respondents were also asked to comment on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword in-depth analysis used for open questions of these responses shows that some suggested expanding the scope, compared to that proposed, to include also anti-microbial resistance and hospital-acquired infections, as well food-, water- and vector-born diseases and zoonoses. This effectively calls for inclusion of a 'One Health' approach.

Other research areas suggested for inclusion were non-communicable diseases, health systems research, and social and behavioural determinants of health. On the spectrum of research and development to be covered, comments were mixed. Whereas some suggested a full coverage from early stage research to bringing products to market, others advocated for keeping the focus on Phase I and II clinical trials. In terms of geographical scope, a small number of respondents suggested including areas other than sub-Saharan Africa, in particular the Middle East and South America.

Other respondents, however, emphasised that sub-Saharan Africa continues to carry a disproportionate burden of poverty-related infectious diseases and thus argue that this focus remains appropriate. It is furthermore cautioned that expanding the scope of the partnership, both in terms of geography and disease areas covered, would dilute resources and focus, thereby jeopardising potential impact. In all cases, the number of clarifying comments was too small and answers were too heterogeneous to determine any significant differences between different groups of respondents.

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

Among 39 respondents, 31 (79.49%) consider that it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives. No statistical differences were found between the views of citizens and other respondents.

The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. The analysis of the results show that respondents mention scientific capability, infectious diseases, other programmes and new partnerships as well as clinical trials.

A more in-depth analysis of the comments shows that several respondents, mostly from academic organisations, see potential for collaboration or alignment with, in particular, WHO-TDR, the candidate 'One Health Partnership', the candidate Innovative Health Initiative, the candidate Key Digital Technologies Partnership and European vaccine development initiatives like Transvac2, as well as national initiatives (not specified). A NGOs nevertheless highlighted the need to make strategic investment decisions and to dedicate predetermined budget envelop to the development of products to heal specific diseases. A representative of the industry sector similarly reported the need to ensure the sustainability of new products by ensuring, through alignment with other initiatives, the engagement of multiple types of stakeholders.

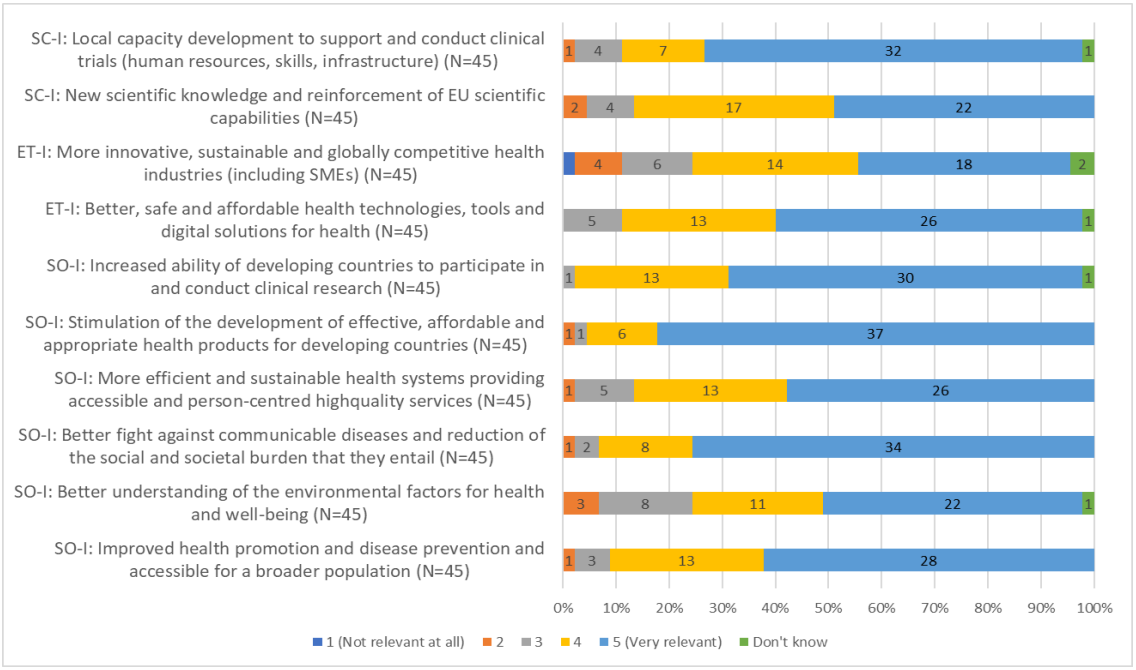
For the four respondents who answered negatively on the question, the analysis shows that they mention capacity building, broader initiatives, sufficient knowledge and specific objectives.

All respondents highlighted that the candidate partnership has very specific objectives and that, like its predecessors, it is unique, so that there should not be any risk of duplication of research and innovation efforts. A representative from the industry sector, in the same line, stated that the candidate partnership could learn from other initiatives, but it should be given the full freedom of adapting its specific objectives to the circumstances. An EU citizen added that EDCTP would not have achieved its goals if it had had broader objectives.

Relevance of the candidate to deliver targeted scientific, economic/technological and societal impacts

Respondents were asked to assess the relevance of the candidate Partnership to deliver on listed impacts. Based on results, among societal impacts, it is expected to be 'very relevant' for stimulation of the development of effective, affordable and appropriate health products for developing countries and for fighting against communicable diseases and reduction of the societal and societal burden that they entail (Figure 28). Among presented economic impacts, a greater number of respondents, namely 26 out of 45 (57.78%), indicated that the candidate Partnership would be 'very relevant' for ensuring better, safe and affordable health technologies, tools and digital solutions for health. The majority of respondents (32 out of 45, or 71.11%) suggest that the initiative would have a significant effect on local capacity development to support and conduct clinical trials. Overall, citizens provided similar views, but found the societal impact regarding 'More efficient and sustainable health systems' more relevant.

Figure 28: Views of respondents on the relevance of the candidate Partnership to various impacts


SC-I: Local capacity development to support and conduct clinical trials (human resources, skills, infrastructure) (N=45)
1 4 7 32 1
SC-I: New scientific knowledge and reinforcement of EU scientific capabilities (N=45)
2 4 17 22
ET-I: More innovative, sustainable and globally competitive health industries (including SMEs) (N=45)
4 6 14 18 2
ET-I: Better, safe and affordable health technologies, tools and digital solutions for health (N=45)
5 13 26 1
SO-I: Increased ability of developing countries to participate in and conduct clinical research (N=45)
1 13 30 1
SO-I: Stimulation of the development of effective, affordable and appropriate health products for developing countries (N=45)
1 1 6 37
SO-I: More efficient and sustainable health systems providing accessible and person-centred highquality services (N=45)
1 5 13 26
SO-I: Better fight against communicable diseases and reduction of the social and societal burden that they entail (N=45)
1 2 8 34
SO-I: Better understanding of the environmental factors for health and well-being (N=45)
3 8 11 22 1
SO-I: Improved health promotion and disease prevention and accessible for a broader population (N=45)
1 3 13 28
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
1 (Not relevant at all)
2
3
4
5 (Very relevant)
Don't know

Annex 3 Who Is Affected And How?

1. Practical implications of the initiative

The ultimate beneficiaries of the EU-Africa Global Health partnership will be **people in sub-Saharan Africa who will gain access to potentially life-saving interventions**. However, the programme will also directly and indirectly deliver benefits to the EU and sub-Saharan Africa in multiple ways:

- Global leadership: The partnership will be a demonstration of the EU's commitment to the health and well-being of disadvantaged populations in sub-Saharan Africa, and its pursuit of the SDGs.
- Health security: By addressing key global threats to health such as emerging and re-emerging infections and antimicrobial resistance, the partnership will help to ensure the health security of Europe as well as in sub-Saharan Africa.
- Global influence: The partnership will enable the EU to undertake activities beyond the capacity of individual countries. It will provide a powerful voice for Europe in global health research, as well as an important mechanism to promote European objectives and values, including open access to research findings.
- Industrial competitiveness: By sharing the risks of new product development with companies and product development partnerships, it is helping to create sustainable markets for products and safeguarding a strategically important industrial sector in Europe and promoting it in sub-Saharan Africa.
- Scientific competitiveness: International networking will benefit researchers in Europe and sub-Saharan Africa. Strengthening ties with sub-Sahara Africa, these networks will enable researchers, from Europe and sub-Saharan Africa, to focus their research on global priority questions and achieve greater impact.

2. Summary of benefits and costs

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
Direct benefits		
Delivering on EU commitments to tackle global challenges	Infectious diseases have a profound economic impact on countries (healthcare costs and lost productivity). The partnership will make an important contribution by advancing in the development of new or improved health technologies to combat these diseases.	The initiative under 187 would be able to incorporate not only Member States and Associated States contributions but also additional contributions from the sub-Saharan countries and other third countries, private charitable foundations and the pharma industry. Some examples from the current initiative would help to understand the benefits of the proposed initiative: During the period, 2014-2019 EDCTP supported 84 large-scale clinical trials and other clinical research activities with €526 million. The PredART trial provided the first evidence of a strategy to reduce the risk of fatal complication when HIV-infected patients begin antiretroviral treatment while being treated with tuberculosis therapy. TB-NEAT consortium generated evidence on new tuberculosis diagnosis.
Boosting scientific excellence and Europe's global competitiveness in research and innovation	The initiative will further increase the EU's global influence within the international research community.	Between 2003 and 2011, over 90% of publications from EDCTP-funded projects were published in high-impact journals. Moreover, papers from Europe-wide or Europe–sub-Saharan Africa collaborations typically have high citation rates and research impact.
Developing the evidence base for national and international health policy-making (bridging the gap between science and policy for health)	The initiative will support multiple studies that will be able to influence national and international health policy and practice.	The predecessor EDCTP, supported the WANECAM study that demonstrated the safety and efficacy of an antimalarial formulation for children, paving the way for its approval by the European Medicines Agency and recommendation by the WHO. EDCTP-UK studies contributed to Paediatric European Network for Treatment of AIDS (PENTA) guidelines. EDCTP established the Pan African Clinical Trials Registry (PACTR), which is the only WHO-endorsed primary registry in Africa, with >1,000 clinical trials registered. EDCTP is a member of the African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. EDCTP also has a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF). In order to boost country ownership and alignment with specific national health research needs in sub-Saharan Africa, EDCTP has been collaborating with WHO-AFRO on a National Health Research Systems (NHRS) survey project for the assessment of NHRS, informing progress towards the achievement of Universal Health Coverage.
Providing mechanisms to	Globalisation and broad access to	EDCTP has invested € 23.43 million to support preparedness

prepare for and respond to public health emergencies in Africa and Europe	international travel coupled with the emergence of new communicable diseases highlight the importance of doing local field research to address public health risks.	to respond to infectious disease outbreaks in sub-Saharan African countries, including two large multidisciplinary consortia, ALERRT and PANDORA-ID-NET, involving 22 institutions in 18 sub-Saharan African countries and 16 institutions in 6 European countries. Each consortium has actively responded to disease outbreaks in the region (Lassa fever, Ebola, plague, monkeypox, Coronavirus) as well as redirected their research to immediately address the COVID-19 pandemic in sub-Saharan Africa, and jointly enhanced the capacity of African regions to detect, prepare, and to carry out clinical research in emergency situations. Joint calls with the World Health Organisation have developed capacity in responding to Ebola outbreaks, clinical research and implementation research.
Creating and retaining a new generation of African scientists	Africa's potential in science and innovation is handicapped by a shortage of trained scientists. The partnership will contribute to the research capacity building by supporting the researchers' careers in Africa and strengthening national health research systems. .	The majority of EDCTP-funded clinical studies include a capacity-building work package that supports long- and short-term training, including PhDs and Master's degrees, in addition to improving site infrastructure and equipment. 7,488 people have participated in EDCTP project-related trainings and workshops to improve the capacity to conduct clinical trials, on topics such as study protocol, specimen collection, research and administration, Good Clinical Practice and epidemics preparedness. In addition a comprehensive EDCTP fellowship programme is focused on the career development of individual African researchers and already supported 126 individual fellowships (€ 31.28 million). Since its inception in 2003 the EDCTP has supported more than 500 African researchers, including fellows and MSc/PhD candidates, with 90% continuing their research career in Africa.
Supporting integrated capacity building for health research in Africa	As well as a training scientific workforce and leadership, the partnership will contribute to other key aspects of health research capacity by supporting Networks of Excellence in African regions enabling the sharing of research experience, expertise and knowledge, and developing sustainable capabilities; and by supporting for the establishment of functional regulatory systems and capacities for ethical review of clinical research. The partnership will make efforts to address gender, language and regional research and related capacity disparities.	EDCTP has supported the creation of 4 Networks of Excellence across 63 institutions in 42 sub-Saharan African institutions in 28 countries, in Central Africa CANTAM, Western Africa WANETAM, Southern Africa TESA and Eastern Africa EACC, to address disparities between countries in terms of clinical research capacity. EDCTP is supporting 57 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa (EUR 51.28 million), including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice. Moreover EDCTP is contributing to the strengthening of national health research systems in sub-Saharan Africa. They have received EDCTP support for the establishment of functional regulatory systems and capacities for ethical review of clinical research. EDCTP is also developing innovative fellowship approaches (such as tandem fellowships), offering grant writing workshops in different languages (English, French and Portuguese) and project and financial management training, amongst other activities. It is also supporting the development of a standardised Financial Management Assessment Tool for assessing the financial capacity of beneficiaries and the international standard for Good Financial Grant Practice for better financial governance.
Developing European and African capacities in clinical research against	The partnership will encourage interdisciplinary and cross-disease approaches, enabling institutions to	EDCTP is encouraging collaboration between its Participating States' Initiated Activities and the centrally-managed activities in order to optimise investments in infectious

poverty-related infectious diseases	build and diversify their expertise to combat infectious diseases and to build skills in managing global collaborative projects.	diseases R&D and maximise the impact of the limited financial resources. EDCTP also collaborates with The Global Health Network to develop online tools to facilitate open source clinical trials and data sharing. This includes a data management tool for better clinical data management; a Clinical Trial Protocol builder for open source development of clinical trial protocols; and a one-stop data sharing portal called EDCTP Knowledge Hub to provide free access to a virtual research community.
Indirect benefits		
Contributing to the achievement of the African Union Agenda	The partnership will contribute to reduce the economic and social impact of infectious diseases on African countries which is central to delivering the Sustainable Development Goals (SDG 3) and Aspiration 1 of African Union Agenda 2063	EDCTP contributes to the Sustainable Development Goals and to African Union Agenda 2063.
Contributing to the provision of safe medical interventions	The partnership will contribute to better national pharmaco-vigilance systems as the safety of new interventions needs to be monitored when they are introduced into routine care and are used by much larger numbers of people.	EDCTP has supported several projects building national and international expertise, from WHO international drug monitoring programme to Uppsala monitoring centre, to strengthen pharmaco-vigilance systems, to build national capacities to detect and respond to possible adverse events and to maintain public confidence. In addition EDCTP is promoting development of cooperation between academic researchers and product developers (PDPs and Pharmaceutical industry), thus matching scientific excellence with efficiency in advancing products along the product development value chain.

3. Overview of costs

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative cost (a)	Direct costs					EUR 0.1 million[11] (1FTE)	EUR 0.9-1.0 million[12]/year
	Indirect costs						
Personnel costs	Direct costs					EUR 0.2 million[13] (2FTE)	EUR 5.0-6.0 million/year (46 FTE)
	Indirect costs						

Notes to the administrative budget summary:

1. Missions: the costs budgeted under this category exclude the travel costs of expert groups (Scientific Advisory Committee and Scientific Review Committee) and for specific events, which are budgeted for under other EU-funded activities (chapter 3).
2. Consumables and supplies: the costs budgeted for under this category include bank charges incurred in making fund transfers to beneficiaries, postage and courier costs, office utilities, office consumables and stationery.
3. Service contracts (including non-recoverable taxes): the costs budgeted for under this category include annual audit fees in relation to secretariat's annual financial reports and statutory accounts, office cleaning, IT support services, office rent (for the EDCTP Association offices in The Hague and Cape Town), and other hosting costs.

REFIT Cost savings table

Not applicable for the proposed EU-Africa Global Health Partnership. The initiative would benefit from the experience of the existing organisation/structure already in place (e.g. the EDCTP Secretariat) which has implemented efficiently the EDCTP2 keeping that programme's administrative costs do not exceed 6% of the European Union's financial contribution of EUR 683 million (i.e. EUR 40.98 million).[14] However, as there

[11] Indicative one-off administrative costs associated for the setting up the Joint Undertaking (logistic structures to adapt from Art 185 to Art 187)

[12] Indicative yearly figure based on draft EDCTP2 Annual Activity Report 2019 (Table 41 Comparison of actual and budget for 2019 Administrative costs). Under Article 185, the EDCTP2 administrative direct costs amount covered the expenses incurred by the EDCTP Secretariat in implementing the EDCTP2 programme. The administrative and personnel costs of the initiative will depend on several factors, including the total budget of the initiative.

[13] Indicative one-off personnel costs associated to the setting up the Joint Undertaking (organisation of selection of personnel, etc.)

[14] The EDCTP2 Interim Evaluation Panel strongly recommended that in addition to the 6% eligible administrative costs, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions

will be a change of partnership from an Article 185 to an Articled 187 initiative, some limited additional costs would be necessary to set up the Joint Undertaking from the EDCTP Secretariat. These limited additional costs will be compensated by the savings from the simplification of procedures, as the Commission will be part of the decision Board of the JU, which will simplify the adoption of the annual work plans and the JU will be benefiting from the common support of the Horizon Europe for proposal submission, evaluation and selection, as well as other dissemination services like Cordis. In addition, there will be also (training) savings from the possibility to recruit knowledgeable and experienced staff from the current EDCTP2 programme implementing structure that will be progressively closing down.

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]

4. 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].

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

[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.

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.

5. 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 "**key functionalities needed**" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis

of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)[18].

Figure 29: 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 projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Directionality				

[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
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

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact

framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options[19].

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

To compare the expected costs and benefits of each option (**efficiency**), the thematic impact assessments broadly follow a cost-effectiveness approach[20] 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[21]. 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.[22] The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

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

[19] In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.
[20] For further details, see Better Regulation Toolbox # 57.
[21] 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.
[22] 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).

overall investment).

- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%),[23] but lead to an additional R&I investment of at least the same amount than the Union contribution[24] (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[25]. 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).[26]
- For an Article 185 initiative the additional R&I investment by Member States 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 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[28]. 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 30 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

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

[23] 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.

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

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

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

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

[28] 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
		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.

6. 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 31. 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[29].

Figure 31: 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

[29] 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[30]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[31] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[32] sets out the areas for which the Unions has competence only to support the actions of the Member States.*

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

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[33]:

- 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

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

Sustainable Development Goals (SDGs).
(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[34] 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)

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

vary across the national, regional and local levels of the EU?
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.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

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

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

1. **The justification for implementing a priority with a European Partnership** to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 – Baseline).

2. **The justification for the use of the form of Institutionalised Partnership**: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 32: Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective (Union added value) clear impacts for the EU and its citizens	Delivering on global challenges and research and innovation objectives
	Securing EU competitiveness
	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and	Within the EU research and innovation landscape

Common selection criteria & principles	Specifications
synergies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality and directionality	Common strategic vision of the purpose of the European Partnership
	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term commitment of all the involved parties	A minimum share of public and/or private investments
	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back-office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs Some HR facilities are procured	More generic resources and expertise for HR matters More consistency in HR policy	Ensuring consistency with EC HR policies is already in place

	from external contractors Some JUs have a Service Level Agreement with COM for HR	Shared HR investment for specialised expertise (IP and legal)	
Financial management	Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e-Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

2.1. Implementation of the EDCTP2

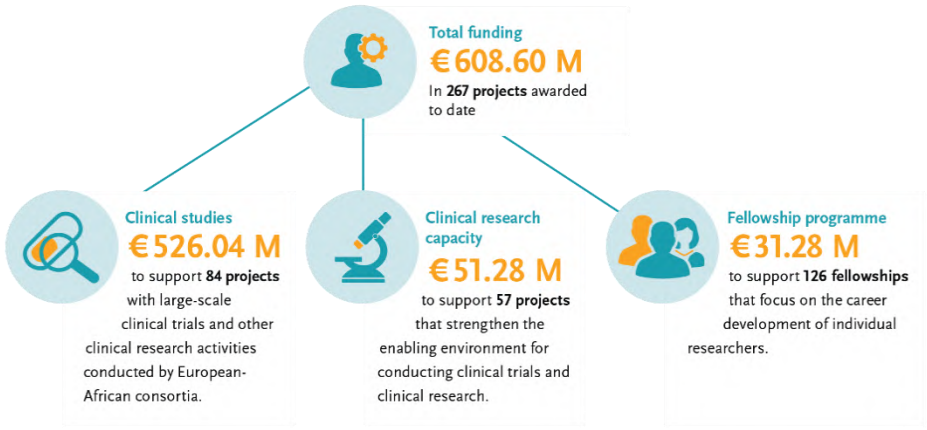
Between 2014 and 2019, the EDCTP2 programme has committed €608.6m funding (as at November 2019). A total of 347 institutions are involved in EDCTP2 projects, including 198 sub-Saharan African institutions and 137 in Europe. In addition, 147 private entities have been involved in EDCTP2 projects, receiving support of EUR 68m, while contributing matching co-funding of a higher amount in-kind through various product development services and supply of investigational products. The number of countries participating in EDCTP2-funded activities has risen to 65 – of which 37 are from Africa, 20 from Europe and eight from elsewhere. A total of 211 clinical studies have been funded, including 123 clinical trials.

The EDCTP2 European Participating States have so far contributed EUR 159.0m in cash to the EDCTP2 programme and EUR 556.3m on Participating States Initiated Activities (in-kind contributions) by the end of 2018. These national activities include 144 clinical studies as well as support for capacity development, ethics and regulatory activities, operational and implementation research, and health systems strengthening. More than 465 publications have been reported as resulting from Participating States Initiated Activities-funded research. Moreover, Participating States have also reported that these activities have resulted in significant policy change and positive influence on national or international guidelines.

EDCTP2 has so far leveraged an additional €300m funding from third parties, including global funders such as the US National Institutes of Health (NIH), philanthropic donors such as the President's Emergency Fund for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID), global funders such as the Bill and Melinda Gates Foundation, Product Development Partnership, such as the TB Alliance and Medicines for Malaria Venture, and pharmaceutical companies.

EDCTP has an integrated approach to capacity development for health research in Africa as a means of ensuring sustainable development of the research environment and increasing its preparedness for conducting clinical research according to ethical principles and regulatory standards. This is done through comprehensive fellowship programmes, 126 African researchers are being supported through fellowships, and more than 6000 have benefited from training opportunities, 57 ethics and regulatory projects have been funded in 27 African countries, including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice, also under infectious disease outbreak conditions and through collaborative research networks.

Figure 33: EDCTP2 funding (from January 2014 up to November 2019).



Joint initiatives have been launched with WHO/TDR, Fundacion Mundo Sano-Espana, African Research Excellence Fund and GlaxoSmithKline. Further joint initiatives are planned with the Coalition for Epidemic Preparedness Innovations (CEPI), the Novartis Foundation, Fondation Botnar, and the Africa Centres for Disease Control and Prevention.

EDCTP2 funding has been well spread across priority disease areas, with the greatest number of grants and funding going towards TB projects (Figure 34).

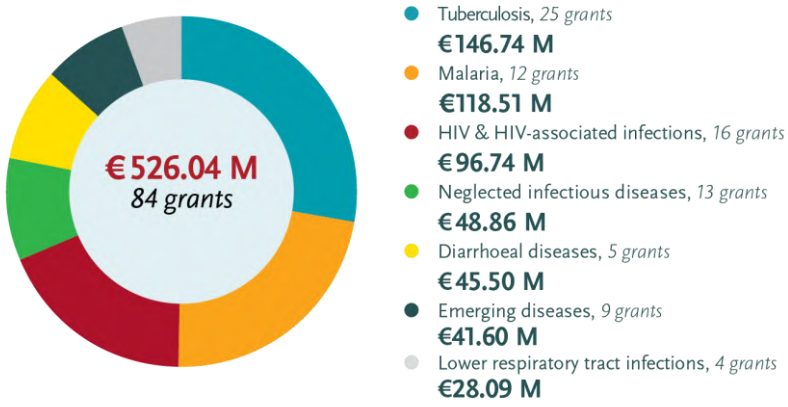


Figure 34 *Allocation of EDCTP2 funding up to November 2019.*

Of the clinical trials funded, 58% are phase II and III studies of drugs and vaccines, providing key data on safety and efficacy; 16% are phase IV post-licensing studies designed to inform policymaking and practice.

In terms of priority populations, 14% of projects focus on pregnant women and new-born babies, 35% involve children, and 43% adolescents.

2.2. Recommendations of the First Interim Evaluation of the EDCTP2 programme[35]

Living up to the potential of EDCTP

- To reach its full potential and the ambitious goals outlined in the Strategic Business Plan, EDCTP should assume a position as a proactive key strategic player and change agent in sub-Saharan Africa. This effort will require a reinvigorated strategic approach not only by EDCTP management but also by the PSs and the EC. The Panel recommends EDCTP to develop a strategic policy plan.
- As a priority, we propose EDCTP catalyse the development and strengthening of national health research plans of African PSs.
- A change in 'mindset' will be required within EDCTP and at the heart of EDCTP, which is the PSs. The establishment of an effective partnership arrangement among PSs needs to be further developed.
- Being part of the EDCTP programme must be viewed as an added value. The Panel thus recommends that EDCTP membership should be a requirement for applying to EDCTP calls.
- EDCTP will need to understand the goals and priorities of PSs and work with them to align EDCTP strategy and programmes. EDCTP should thus actively support the PSs in developing their own national research agendas.
- The Panel views the EDCTP regional networks as a critical element of institutional capacity in sub-Saharan Africa. The strategic role of the EDCTP regional networks should be broadened and clearly defined.
- The EDCTP regional networks should develop a plan that includes a focus on its capacity building activities, with emphasis across the spectrum of scientist career development, and their support of weaker institutions and regions.
- The capacity for active participation in the EDCTP program varies significantly across sub-Saharan Africa. It is important to ensure a more equitable distribution of EDCTP activities and investments so the benefits of EDCTP impact weaker institutions and regions. A strategy must be developed to incentivise wealthier PSs to engage with less resourceful African nations in all EDCTP activities.
- To support the networks in achieving this next phase of their evolution, the level of funding for networks should increase.
- EDCTP should adopt a more comprehensive and catalytic funding approach for supporting the career path of young talented African investigators and to build African scientific leadership. Particular attention should be paid to gender balance.
- EDCTP should assess opportunities in this area to strategically align with other funders and programmes on career development.

Strengthening coherence and added value of the EDCTP programme

- Based on a thorough analysis of existing programmes and active international funders, EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged, and complementary programmes aligned for greater impact and reach.
- EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships.
- The EU would benefit by having a high level strategy across programmes and policies to facilitate alignment, coordination and collaboration where opportunities exist. This approach would be most effective with the appointment of a specific coordinator responsible for coherence among EU initiatives and policies
- The strategic value of the EDCTP target to obtain at least €500M in additional public or private contributions is questionable. The EU should, together with the PSs, reconsider this rather high €500M target so that EDCTP can focus on more relevant aspects of partnerships.

EDCTP visibility and advocacy

[35] http://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf

- EDCTP should put considerably more focus on external strategic communication and advocacy efforts. The current communication strategy should not only be aimed at delivering information but also become more focused on building relationships and dialogue with PSs' governments and European and International funders and stakeholders.Communication functions and strategies must better reflect the fact that EDCPT2 is a programme that PSs own collectively. Currently, this joint ownership, coordination and support of EDCTP are not evident in programmes or in advocacy and communication efforts. This lack of co-leadership weakens the overall potential and effectiveness of EDCTP2.
- To determinedly implement the communication strategy, the function of strategic communication and advocacy within EDCTP should be elevated to the highest level of leadership. This role within EDCTP will require considerable networking and coordination across PSs to identify synergies and to achieve better alignment and coordination with PSIAs. Closer coordination and planning between the EC leadership and the EDCTP Secretariat and GA will also help to achieve the level of communication and advocacy needed. These coordinated leadership roles will require a mindset change across organizations and individual leaders.
- To achieve the advocacy goals of EDCTP2 to execute the communication strategy, clear objectives, tactics, timelines, and milestones to describe how EDCTP will achieve its advocacy goals is needed. Opportunities to align messaging and programmes with PSs should be prioritized for communications and advocacy.

Improving instruments to advance research in sub-Saharan Africa

- Adopting a portfolio approach: EDCTP should take on a portfolio approach in order to use its funding instruments (including competitive calls) more strategically. This would enhance the value-add of EDCTP and maximize impact.
- EDCTP should adopt a more flexible funding approach that, after careful analysis of the current conditions, would include both broad and more specific calls. The analysis should incorporate considerations of disease burden, the potential for improving health equity and also the global funding landscape.
- Grant Funding Reference Group: In order to ensure high quality and credibility of the grant application process, EDCTP and the EC should jointly initiate an external review of the processes related to funding, including launch of calls, peer-review, evaluation and selection. EDCTP should consider establishing a 'Grant Funding Reference Group' which could mimic the approach already taken by the EC. For example, inviting Independent Observers to assess the peer review process and its implementation (e.g. 1-2 observers for each call). Alternatively, another mechanism could involve members of the research community obtaining information on how the funding strategy and funding instruments are perceived on a regular basis.
- Modifying the process of PSIAs: EDCTP and the EC should jointly modify the entire process around PSIAs to improve efficiency and to enhance impact. The aims of PSIAs must be articulated with consideration given to how they can be used to enhance strategic value-add of both EDCTP and the PSs. A more efficient way to bring in the Participating States' engagement in EDCTP, and to effectively obtain the co-funding that is conditional to the EU co-funding, should be developed.
- EDCTP should initiate a process for in-depth analysis of the outcome of the activities initiated by the PSs in order to identify synergies, gaps and overlaps. PSIAs should be prospectively and strategically integrated with EDCTP programmes and calls in order to minimize gaps. In addition, PSIAs should be strategically integrated among themselves to efficiently maximize their impact.
- The EC should jointly with EDCTP analyse the possible effects of the United Kingdom's decision to withdraw from the EU and develop mitigating strategies.

Governance for reaching long-term objectives and sustainability

- General Assembly (GA): The EC and EDCTP should jointly define the responsibilities and expectations for both the PSs and their General Assembly representatives.

- The PSs should enhance the executive and political level of GA representatives and ensure that representatives are clear on their responsibility to report back to their respective government agencies that have the mandate to deliver on their governments' commitment to EDCTP.
- Scientific Advisory Committee (SAC): EDCTP must further develop Scientific Advisory Committee and its critical role of providing strategic scientific advice as stated in the EDCTP Decision.
- Strategic Advisory Group: EDCTP should create a separate, Strategic Advisory Group, a high-level strategic group to advise on matters of policy, coherence and partnership to achieve value-add of EDCTP2, to align efforts of EDCTP2 with other significant global funders and with politically driven goals and directions. A strategic policy plan needs to be urgently developed. As a high priority, EDCTP should catalyse the development and strengthening of national health research plans especially for African PSs.
- 3-year work plans: EDCTP and the EC should jointly and urgently review and modify the process of approving the annual work plans so that the entire process is completed prior to the year of operation.
- The process should be changed so that EDCTP submits a 3-year work plan for approval by the EC but with annual milestones that are to be reported and evaluated on an annual basis so that timely adjustments can be made.
- Executive Director: EDCTP should further strengthen the position of the Executive Director by emphasizing his/her role to proactively initiate and implement strategic work and high-level advocacy as well as to engage in long-term planning and sustainability issues. To support the Executive Director, EDCTP should create the position of a Deputy Executive Director. The subsequent recruitment and appointment process should reflect the imperative for an improved gender balance at the high-level management.

Financial contribution

- According to the Terms of Reference, the Panel should also discuss the level of financial contribution to EDCTP2. With effectively two years of data, it is essentially impossible to evaluate this aspect of the programme. Provided that in-kind contributions stay at a level similar to today and provided that PSIAs are effectively and strategically integrated with the EDCTP programme, the current level may be appropriate.
- The Panel strongly recommends that in addition to the 6% eligible administrative costs, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions

2.3. Actions taken in response to the EDCTP2 Interim Evaluation Recommendations

Recommendation	Recommendation involve	Actions taken (until March 2020)
Living up to the potential of EDCTP	• Supporting development and strengthening of national health research plans of African EDCTP2 Participating States	• National Health Research Systems (NHRS) assessment has been launched in collaboration with WHO-Afro to establish baseline data for guiding planning to strengthening health research capacity within sub-Saharan Africa: o Survey to determine the barometer scores for NHRSs in the 17 African countries that are members of the EDCTP Association (completed, see here) o Development of strategies for uptake of survey results (Consultative meeting held on 17-18 October 2019 in Brazzaville, Republic of Congo and on-going).
	• Improving gender ratio and achieving more equitable distribution of activities and funding across countries/ regions	**Improving gender ratio of EDCTP-funded activities**: • Workshop *Enhancing networking among African and European scientists to close regional and gender disparities experienced in EDCTP1 and EDCTP2 funded health research capacity activities in sub-Saharan Africa* (completed Nov 2019) • Scientific Advisory Committee working group on gender (activities ongoing) initial report presented to the EDCTP General Assembly (June 2019) • Expansion of monitoring efforts to track and analyse gender balance (ongoing, with completed analysis on *EDCTP2 Evaluation Procedures and Gender Balance*) • Independent evaluation of Sida support to EDCTP assessing, among others, gender balance in the areas of research supported by EDCTP[36] (completed) **Achieving more equitable distribution of activities and funding across SSA countries/ regions**: • Launch of Senior Fellowships Plus 2019 call aimed to engage less resourced African countries (completed with proposal evaluation ongoing, see here) • Independent evaluation of EDCTP Regional Networks activities (completed)[37]

[36] The Sida evaluation concluded that: "The gender balance across projects that have received Sida funding overall is very good. Across different capacity building programmes, the balance has an average of 43% of project staff being female (…) EDCTP are making efforts to address gender issues. This has become more visible in 2018 and 2019 with reviews being commissioned on the make-up of evaluation panels/ the gender dimensions of proposal review processes together with an evaluation of the barriers to female researchers in Africa being commissioned. The Scientific Advisory Committee (SAC) also now has a gender working group. We have not been able to investigate the degree of training given to researchers on gender equality and/or how to design research taking into account gender equality issues. However, at least one project is highly gender aware (PANDORA) and includes gender issues in its research design and evaluation".

[37] EDCTP Networks evaluation concluded that the EDCTP Networks are a strong brand with increasing goodwill. It was therefore recommended that in order to sustain the achievements the EDCTP Networks have made to date, it is important that EDCTP continues to financially and operationally support, and politically advocate for their sustainability. Increasing funding would strengthen

		• Three 'grant writing' workshops held in Gabon, Ivory Coast and Mozambique (targeting Portuguese-speaking and French speaking scientists) for young African scientists (completed) with a total of number of 96 participants • Funding to large multi-country consortia pursuing inter and intra-regional research cooperation (ongoing projects): Four Regional Networks addressing disparities between SSA countries in terms of clinical research capacity EDCTP; Two epidemic preparedness consortia with governance and management structures organised to promote equitable decision-making and execution of research activities. • An EDCTP Alumni Platform[38] has been launched to facilitate networking of sub-Saharan Africa researchers and to make the professional profiles of all current and past EDCTP fellows easily accessible. It facilitates reflection and collaboration among them. Working groups on HIV, tuberculosis, malaria, and neglected or emerging infectious diseases have also been established.
Strengthening (internal) coherence and added value of the EDCTP programme	• Improving alignment of Participating States activities with EDCTP-centrally managed activities	• Facilitating Participating States to launch joint or aligned activities (e.g. Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme for implementation research on infectious diseases of poverty-funded by Germany, Sweden and the UK • Facilitating Participating States in aligning reporting and data sharing: in the UK Department Health Social Care's evidence mapping[39], independent evaluation of Sida funding, data sharing initiatives such as G-FINDER, World RePORT, and the WHO Global Observatory on Health R&D. • Creation of a dedicated webpage with the Analysis of Participating States Initiated Activities (PSIAs) and sharing of information of both centrally managed activities and PSIAs via EDCTP participating states profiles have been done to facilitate easy sharing of information[40].

clinical trials and researcher support, networking of the Networks, as well as development and implementation of digital platforms, all of which are important for data generation and sharing. Reducing funding would limit EDCTP's contribution to generation of big data and health research ecosystems capacity building broadly, which is invaluable for reducing the burden of the diseases targeted by EDCTP. Stopping the financial support towards the EDCTP Networks would reverse the gains of a model that has so far proved useful for clinical trials capacity building in Africa through North-South and South-South collaborations. Evaluation of the EDCTP Regional Networks Report: http://www.edctp.org/edctp-regional-networks-2015/

[38] https://edctpalumninetwork.org/

[39] https://eppi.ioe.ac.uk/cms/Default.aspx?tabid=73

Strengthening (external) coherence and added value of the EDCTP programme	• Strategic partnership building with other programmes and inititives	**Strategic partnership building** • Launching EDCTP Strategic grant scheme (6 calls completed as part of WPs 2015-2018 resulting in EUR 323.87 M in direct project funding from third-parties (international organisations, industry and private funders) and several collaboration agreements have been concluded with WHO-TDR Special Programme on Research and Training in Tropical Diseases, Mundo Sano Foundation, GSK, Novartis Global Health, Botnar Foundation, Leprosy Foundation. Efforts are underway to finalise a cooperation agreement with WHO-AFRO • Two High-level policy dialogue meetings with African States to consult on the EDCTP strategy (Dakar and Lisbon) • EDCTP has contributed to strengthening national health research systems (NHRS). The report 'WHO African Region – progress towards universal health coverage' shows that between 2014 and 2018, the majority of the countries participating in EDCTP have improved their NHRS[41]. • WHO fully supports EDCTP's plans to develop a follow up programme and has nominated WHO observers to both the EDCTP Scientific Advisory Committee and General Assembly (WHO Director General's letter of 29 08 2019).
	• Coordination with other EU initiatives and national development agencies	**Engagement with DG DEVCO and other EU programmes and development agencies**: • Appointment of an additional observer at the EDCTP General Assembly, representing DG DEVCO. • Launch of two strategic calls requiring cofounding from development cooperation agencies : *Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives* (completed with 2 projects ongoing) and Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives (planned as part of work plan 2020) • Outreach through active participation events and meetings: DEVCO info point, European Development Days, side meeting at the EU Africa High Level Policy Dialogue
Visibility and advocacy	• Strategic communications aimed at building relationships and dialogue with Participating States' governments and European and International funders and stakeholders	• Nomination of two High Level Representatives with a strategic programme each to promote and encourage higher financial commitment and active participation of Participating States in Europe and sub-Saharan Africa. • Communications strategy has increased focus in involving Participating States' Initiated Activities in the overall EDCTP communication activities. • Dedicated pages for each Participating State are under preparation for the EDCTP website to presenting their involvement under the EDCTP2 programme. • More informative and user-friendly communication resources have been introduced such as: scaled up use of interactive online annual reports, case studies summarising ongoing activities and success stories,

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6660673/

		summary documents highlighting the added value of EDCTP to Europe and Africa.
Improving instruments to advance research in sub-Saharan Africa	• Introducing portfolio funding and diversification of funding approach	• Grant to PAMAfrica consortium to support a portfolio of projects developing new treatments for malaria in the most-at-risk populations (ongoing 5-year project under portfolio funding, see here) • Narrow thematic (e.g. malaria vaccine) and fairly broad (e.g. diagnostics) calls launched. There are however, limits to the flexibility of allocation of EU funding, as H2020 rules must be followed, limiting the possibilities of very targeted funding (to a specific organisation or product candidate)
	• Establishment of a grant funding reference group involving independent observers	• Involvement of independent observers in call for proposals evaluations, their reports and recommendations are followed up providing quality and transparency (ongoing)
	• Improving the process of the Participated States Initiated Activities	• Establishing a General Assembly-Scientific Advisory Group Working Group on Participating States Initiated Activities Meetings organized in 2018 and 2019 to improve efficiency and to enhance impact. Draft report presented to the General Assembly of November 2019
	• An in-depth analysis of the outcome of the activities initiated by the PSs to identify synergies, gaps and overlaps	• Mapping and analysis of Participating States Initiated Activities (PSIAs) to identify overlaps and opportunities for synergies with EDCTP-centrally managed activities in relation to the EDCTP2 Strategic Research Agenda (ongoing: Draft report presented to the EDCTP General Assembly Nov. 2019)
Governance for reaching long-term objectives and sustainability	• Strengthening the role of Scientific Advisory Committee (SAC) in providing strategic (policy) advice to the General Assembly (GA) • Improving support for the Executive Director and gender balance in EDCTP Senior Management	• Secretariat restructuring in 2018 (completed) • Created position of Executive Governance Officer to facilitate coordination of EDCTP constituencies • Two High Level Representatives for Africa and Europe scaled up their work to support the ED on advocacy and fundraising activities • The recruitment of current and future members of the SAC takes into account their dual role of providing both scientific and strategic advice • The interaction between SAC and GA has been strengthened and thus facilitating the sharing of information between the two constituencies.

2.4. Strengths, Weaknesses, Opportunities and Threats of the EDCTP programmes

Strengths	Weaknesses
ORGANISATION • Established a presence and visibility in sub-Saharan Africa • Covered a key gap in the funding landscape; few other private and public bodies fund large late-stage clinical trials in sub-Saharan Africa • Supported scientific excellence, with projects generating major publications in high-profile publications • Focused research activity on underserved populations, addressing key market failures • Integrated capacity-building into grants • Developed African scientific leadership • Established new African networks • Strengthened the regulatory and ethics review capabilities of multiple African countries • Expanded the range of African countries with capacity to carry out clinical research • Facilitated formation of enduring global partnerships **PORTFOLIO** • Impactful HIV studies, particularly prevention of mother-to-child transmission, paediatric HIV treatment • Influential trials on HIV co-infections, particularly HIV–TB and HIV–malaria co-infections and opportunistic infections (e.g. Cryptococcus) • Significant advances in TB diagnostics • Major studies in TB drug development and vaccine evaluation, with globally important collaborations and innovative trial methodologies • Landmark studies on malaria treatment during pregnancy, in children, and in co-infected patients • Capacity developed in malaria vaccine evaluation • Advances in diagnostics for neglected infectious diseases	**ORGANISATION** • Relatively small player, in terms of funds available per pathogen, compared with some funders in global health research • General lack of visibility/awareness • Fewer funding partners than initially envisaged, especially with pharmaceutical companies • Lack of flexibility in funding approach can be an obstacle to joint initiatives with other funders • Challenges leveraging additional cash funding from PSs • Lack of incentives to join EDCTP Association • Challenges aligning funding strategies of EU PSs • Lack of support to enable researchers from French- and Portuguese-speaking countries with weaker research systems to submit high-quality applications. **PORTFOLIO** • Disappointing results in early microbicide and HIV vaccine trials • Large range of pathogens covered resulted in limited funding per disease category in EDCTP2 thus far, particularly for the newly incorporated diseases
Opportunities	**Threats**
ORGANISATION • Enhanced global networking and engaged new partners • Additional engagement with newer EU 'EU13' Member States • Alignment with other global health agendas (e.g. outbreak preparedness, antimicrobial resistance, universal health coverage and design of people-centred health systems) • Alignment with other EU initiatives (e.g. other Horizon Europe initiatives, Joint Programming Initiative on Antimicrobial Resistance, Innovative Medicines Initiative). • Increased synergies and better coordination of the PSs' own contributions to research activities within EDCTP's scope (PSIAs). • Additional joint funding initiatives and co-funding schemes • Increased proportion of projects led by African and	**ORGANISATION** • Insufficient funds to support all highly ranked projects • Expanded scope to include non-communicable diseases or other bigger thematic areas could spread resources too thinly • Ineffective global collaboration could lead to both duplication of efforts and missed opportunities • Inappropriate use of funds by recipients could damage confidence and cause reputational harm to EDCTP • Insufficient funding to support activities of the growing EDCTP Alumni Network and its integration with the EDCTP Regional Networks **PORTFOLIO** • Major disease outbreaks could overwhelm country response capacity and undermine research efforts on priority diseases

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: CDMA 00/175 - Tel. direct line +32 229-51143

Inmaculada.Penas-Jimenez@ec.europa.eu

female researchers
- Increased collaboration among emerging research leaders funded by EDCTP

PORTFOLIO
- Improved pipelines offer more scope for later-phase studies and head-to-head comparisons
- Scope for additional implementation studies and synergy with health system strengthening in pursuit of universal health coverage
- Co-infections and co-morbidities associated with longer survival
- Maternal vaccination
- Drug repurposing
- Multiplex diagnostic platforms
- New digital and other technologies, to enhance diagnosis, delivery of interventions and design of people-centred care
- Opportunities for greater multi-disciplinary input, e.g. from social and behavioural sciences, anthropology
- Repurposing of platforms/infrastructure to address new threats, including emerging infectious disease threats and antimicrobial resistance
- Innovative trial designs for faster and more flexible clinical evaluation

- Rising antimicrobial resistance could compromise use of therapeutics
- Civil unrest and conflict could compromise countries' ability to conduct clinical research
- Public rejection of research or experimental interventions could threaten research and implementation
- Major adverse reactions to a new intervention could trigger negative public attitudes to clinical research
- Significant global funding gaps could compromise achievement of challenging global targets
- Insufficient local investment could threaten sustainability of newly developed research capacity

2.5. Progress towards EDCTP2's objectives (2014-2019)

Medical interventions

New or improved medical interventions against poverty-related infectious diseases.

217
is the total number of clinical studies supported by EDCTP2 since 2014. Of these, 59% (130) are interventional (clinical trials) and 41% (87) are non-interventional studies.

57% (71)
of interventional studies are phase II and III trials of drugs and vaccines which aim to deliver key evidence on safety and efficacy. The phase III trials also aim to provide data to support product registration.

15% (18)
of the interventional studies involve post-license (phase IV) studies with a view to influencing health policies and practice and optimising the delivery of medical interventions for the wide range of sub-Saharan health systems and diverse populations.

10% (21)
of all studies target pregnant women and their children. Other key populations are also involved in the studies, such newborns and infants (35;17%), children (64; 31%) and adolescents (60; 29%).

32
sub-Saharan Africa countries host recruitment sites of EDCTP-funded collaborative clinical studies.

Collaboration and capacity development

Increase cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards.

€51.07 M
is the total grant investment to support 57 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa.

27
sub-Saharan African countries have received EDCTP support for the establishment of functional regulatory systems and capacities for ethical review of clinical research.

€23.43 M
has been invested to support preparedness of 6 sub-Saharan African countries in the fight against Ebola outbreaks.

130
fellowships that focus on the career development of researchers.

42
sub-Saharan African institutions in 28 countries participate in the EDCTP-supported Networks of Excellence: CANTAM (Central Africa), WANETAM (Western Africa), TESA (Southern Africa) and EACCR (Eastern Africa).

7468
people have participated in EDCTP project-related trainings and workshops on topics such as study protocol, specimen collection, research and administration, Good Clinical Practice and epidemics preparedness.

European coordination

Improve coordination, alignment and integration of European National Programmes.

30
researchers from sub-Saharan Africa received funding from the 'Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme for implementation research on infectious diseases of poverty launched in 2017. The call was supported through a partnership between Germany, Sweden and the UK.

€158.8 M
the total cash received from the European Participating States to the EDCTP programme.

External partnerships

Increase international cooperation with public and private partners.

16
sub-Saharan African countries are full members of the EDCTP Association. These members have contributed to a total of €1.21 million by end of 2018 through the Participating States' Initiated Activities (PSIAs) – research activities within the scope of the EDCTP programme that are funded and implemented by one or more member countries.

65
countries participate in EDCTP-funded activities: 37 sub-Saharan African countries and 20 European countries.

371
institutions are involved in EDCTP projects: 198 sub-Saharan African institutions and 137 European institutions.

57%
of the total EDCTP grant value is allocated to sub-Saharan African institutions (€302 million).

EU cooperation

Increase interaction with other EU initiatives, including those linked to development assistance.

162
private sector entities are involved in EDCTP projects. By end of 2018, these organisations have received €89.26 M in grant value.

3
grant consortia were established through an EDCTP call to support health systems/service optimisation research capacities in cooperation with development assistance'. Two of these consortia received funding from international development cooperation partners (SIDA and USAID).

17
EDCTP African member countries participated in a survey to inform the development of a strategic policy plan for strengthening health research system capacities of countries in sub-Saharan Africa. This project is a joint initiative between EDCTP and WHO AFRO.

2.6. Success stories of the EU funding through FPs and EDCTPs programmes

The EU funding has contributed to:

- The generation of new knowledge through development research publications, best practices and guidelines:

  As a result of the NeutNET (FP6) project, seven novel and reproducible types of neutralisation assays were developed, thus contributing to the advancement of scientific and medical knowledge and aiding future vaccine research; STOPPAM (FP7) provided valuable information with respect to a revision of the current administration regimen of Intermittent Preventive Therapy in pregnancy, to date the most effective and most widely adopted strategy for combatting pregnancy malaria; IDAMS (FP7) led to advancements in clinical knowledge about variables affecting dengue presence, and developed tools, strategies and treatments in order prevent the spread of dengue. New insights generated by the project led the WHO to revise their estimates of dengue prevalence and guidelines for outbreak protocol

- Development of new drugs, devices, diagnostics, vaccines and vector control methods:

  NIDIAG (FP7) successfully developed a new Rapid Diagnostic Test for human African trypanosomiasis, which is now commercially available. CHAPAS (EDCTP) provided evidence in support of the current WHO guidelines for first-line paediatric antiretroviral therapy; the results also led to licensed combinations for treatment of children. GeneXpert (EDTCP) developed diagnostics technology that could potentially improve health care providers' ability to diagnose tuberculosis and could thereby lead to improved health systems. PanACEA (EDCTP) developed better treatments for tuberculosis. Anti-malarials for pregnant women PREGVAC (EDCTP) and for children 4ABC (EDCTP); MCD (FP7) developed the eave tubes a low-cost device and frugal innovation to control malaria mosquitoes in tropical settings with significant impact on disease prevention.

- Capacity building, primarily in relation to research and education system strengthening, but some evidence of health system strengthening:

  EUROPRISE (FP6) brought together a new network of HIV/AIDS researchers from 32 institutions across the fields of vaccines and microbicides. The project developed the FluoroSpot essay that is now commercially available and could, in future, be an efficient tool for vaccine trials in low and middle income countries; COSMIC (FP7) brought health services closer to the people and used village health workers to provide an antimalarial prevention to women. Through training community health workers involved in the case management of malaria, it increased the capacity to test and treat women in Burkina Faso. SILVER (FP7), where leading international virologists, medicinal chemists and bio-informaticians across Europe, Russia, China and Africa joined forces to design small molecule inhibitors against emerging and neglected RNA viruses, including dengue. ELAN2LIFE (FP6) facilitated knowledge exchange and capacity

development through North-South and South-South research cooperation, with more than a thousand South American participating scientists; EACCR (EDCTP) achieved success in terms of capacity building and staff training, as well as in terms of research outputs, playing a pivotal role in supporting South-South cooperation in Africa.

- Generating evidence of later stage development and commercialisation**:**

  EARNEST trial (EDCTP) provided strong support for the current WHO guidelines to switch antiretroviral therapy in a limited-resource setting for people with HIV; Kesho Bora study (EDCTP) identified ways to prevent mother-to-child transmission of HIV and findings of the study strongly influenced the WHO's 2010 Guidelines ; 4ABC trials (EDCTP) contributed to key evidence on safety and efficacy of an antimalarial combination therapy that now is registered with the European Medicines Agency and recommended by the WHO for uncomplicated malaria.

- Improved access, affordability, equity and equality, or informing the revision of the World Health Organisation (WHO) guidelines:

  WANETAM (EDTCP) developed a molecular line probe assay technology for rapid detection of multi-drug resistant tuberculosis in Ghana, which is now a unique asset to identify second-line anti-TB drugs. The new approach, promoted by the WHO, has contributed to changing policies regarding treatment of patients who had failed a first, standard therapy. The TB CHILD (EDCTP) was a proof of concept study to identify children with active tuberculosis, which could help to better diagnose TB in children in future.

2.7. Specific African countries consultation on GHP-EDCTP3

As the EU-Africa Global Health Partnership is addressing the clinical research of infectious diseases affecting sub-Saharan Africa in partnership with the sub-Saharan countries, an additional consultation was launched addressed to the African countries.

1. Executive Summary

On May 5, 2020, member states of the African Union and relevant stakeholders, including grantees and scientific advisors outside Africa, were invited to participate in an online survey about the future orientation of the European & Developing Countries Clinical Trials Partnership (EDCTP).
A short, user-friendly instrument of 25 items, was developed and disseminated by the government of South Africa.

A total of 161 people accepted to participate in the survey, but only 150 completed the online survey form. Responses were received from 26 countries in Africa, 12 countries in Europe and one in America.

Among the 130 participants who responded to the question about expertise in global health research, 59 indicated expertise in Epidemiology, 59 in Clinical trials, 58 in Public health, and 49 in Biomedical research.

Political will and awareness through education were perceived as the most important drivers for advancing Universal Health Coverage (UHC) in Africa.

Among the 115 participants that responded to the question about the benefit of EDCTP association membership, 89 (77.4%) considered membership to be beneficial to their countries.

'Mentorship programme for science writing' was ranked as most important by 42 (35.6%) of 118 responders addressing additional activities that could further facilitate the implementation of the current EDCTP2 programme. It was followed closely by 'simplification of the processing of calls' which was given the highest rank by 38 responders (32.2%). Most of the responders (74.8%) thought specific calls for female scientists was the most important driver for gender equity in health research in sub-Saharan Africa.

Increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones; and strengthening cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials, were identified as the two most important objectives of EDCTP2.

When asked about how EDCTP3/GHP can bring onboard countries that are not currently members of the EDCTP Association, 38.7% of 119 responders considered 'Demonstrate benefit for African countries with limited capacities for health research' as the most important action, followed by 'Enhance South-South collaboration' (29.4%) and 'Enhance EU-Africa collaborations to achieve UHC in all countries' (25.2%).

The same responders identified the critical role of regional entities like Africa Centres of Disease Control (Africa CDC) and World Health Organisation – Regional Office for Africa (WHO-AFRO), as the most important lesson learnt so far from COVID-19 pandemic. Examples cited of important regional entities, networks and consortia that have been important during the COVID-19 pandemic include all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP-supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities in the African region.

For EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, 'contributing to the regional and global health research agenda' was considered the most important factor.

An overwhelming majority (81.7%) of 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector, including industry and foundations. However, most of the responders thought it was a highly risky venture. The main risk identified is that relating to conflicts of interest and loss of control.

Conducting the survey during the COVID-19 pandemic was timely as it allowed input on the relevance of working for the global good and the importance of south-south networking, coordinated by EDCTP Regional Networks of Excellence, regional economic communities and key institutions like Africa CDC and WHO-AFRO. However, the COVID-19 outbreak also posed some limitations to the outcome of the survey. With most people working from home during lockdowns, there was limited access to the internet. Administering the survey form in English, targeting responders in all AU member states, met some language barriers, especially in Central Africa, where most of the AU members have French as the official language.

2. Background

This Report on the Global Health Partnership online consultation forms part of the deliberations regarding the successor to the second European & Developing Countries Clinical Trials Partnership programme (EDCTP2).

During the last EU-AU High Level Policy Dialogue on Science, Technology and Innovation (HLPD), held in Addis Ababa, Ethiopia in November 2019, senior officials called 'on all European and African Union Member States to consider the questions for reflection on the future orientation of the European & Developing Countries Clinical Trials Partnership (EDCTP), and proposed the convening of a consultation event'. The South African Department of Science and Innovation (DSI) offered to host the consultation. DSI and the EDCTP Secretariat duly set out to co-host a high-level consultative dialogue on EDCTP3/GHP, as part of the ongoing discussions and public consultation about the framework concerning the EDCTP2 successor programme.

The current EDCTP2 programme started in November 2014 and is expected to end in 2024. The proposed third EDCTP programme (EDCTP3/GHP) under Horizon Europe, the EU Framework Programme of Research and Innovation, is envisaged as a partnership between the European Union (EU), European countries and sub-Saharan Africa countries as well as other potential partners like private industry and foundations and other third countries. EDCTP3/GHP seeks to contribute to the United Nations global agenda for sustainable development, the sustainable development goals (SDG), by contributing to better health for all (SDG 3) and poverty reduction (SDG 1).

On 9 March 2020, the European Commission (EC) and the High Representative for Foreign Affairs and Security proposed the basis for a new strategy with Africa. In her address, the European Commission President, Ursula von der Leyen, said: "Today's Strategy with Africa is the roadmap to move forward and bring our partnership to the next level. Africa is the European Union's natural partner and neighbour. Together we can build a more prosperous, more peaceful and more sustainable future for all."

The renewed cooperation on the EU-Africa Global Health partnership (EDCTP3/GHP) proposed will build on the EDCTP2 programme, the public consultation launched in 2019 and the ongoing consultations with African partners, including the partners in global health security. The proposed EU-Africa Global Health Partnership (EDCTP3/GHP) will promote development of diagnostics, medical devices, medicines, and vaccines to combat infectious diseases including those of epidemic potential, and to improve national and global health security. This goal could not have been timelier given the COVID-19 pandemic that has clearly unveiled the research, human resources, infrastructure and coordination gaps on the Africa continent and globally.

It is noted that the first evaluation of EDCTP2 conducted in 2017 'positively assessed the EDCTP programme and acknowledged it as highly relevant as the challenges addressed by the EDCTP persist.'

3. Method

The consultative dialogue was to take the form of a workshop on 16 March 2020 at the Protea Breakwater Lodge, Cape Town, South Africa.

DSI, the EDCTP Africa Office and the Directorate General Research and Innovation (DG RTD) of the EC proceeded to organise the event to share views, and ideas, and to pave a way forward for the next programme.

Unfortunately, the COVID-19 pandemic led to the postponement of the event. Therefore, the consultative dialogue accordingly took the form of an online survey that was coordinated by the DSI in collaboration with the EDCTP Africa Office and the DG RTD of the EC. DSI, through a Project coordinator based at South African Medical Research Council (SAMRC), disseminated the instrument which was developed with assistance from the EDCTP secretariat. On 5 May 2020, invitations to participate in the survey were sent to member states in the African Union and strategic partners relevant to the EDCTP3/GHP programme.

The main objective of the online consultation is to explore the views of sub-Saharan Africa States, the African Union, and other key stakeholders on how practically to galvanise Africa-EU cooperation in global health research and innovation. The consultation informs the scope and possible modalities of the EU-Africa GHP/EDCTP3.

A questionnaire with 25 survey items (SI) was developed and hosted on the survey monkey™ platform (see Appendix). The EDCTP Secretariat disseminated the instrument with the undertaking of confidentiality. Although the South African Protection of Personal Information Act was not mentioned, the associated legislation applies to the retention of personal information.

Aside from standard biodata (SI 1-5), fourteen items were completed by means of pre-assigned options of drop-down menus. SI 17, SI 20, SI 24 and SI 25 elicited free text responses.

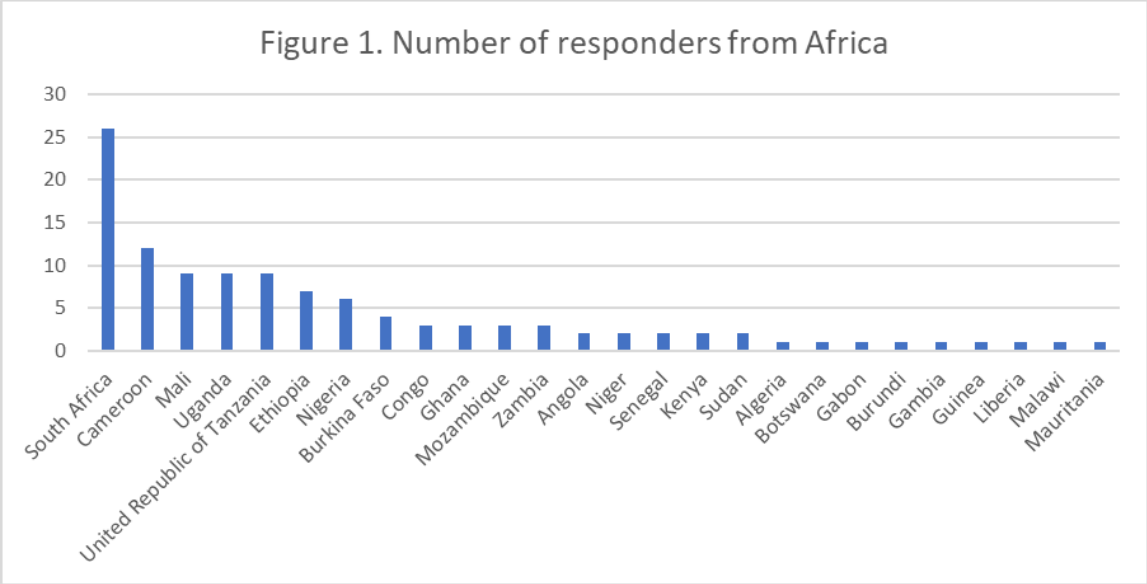
The free text responses were examined, interpreted, coded, and then clustered thematically.

All interpretation was anonymised. The author had no access to the individual questionnaire returns.

6. Results

General response

A total of 161 people accepted to participate in the survey but only 150 people completed the online survey form. Responses were received from 26 countries in Africa, 12 countries in Europe and the United States of America. All African member countries of EDCTP Association, including Angola (an aspirant member), participated in the survey. Out of the total 150 who participated in the survey, 113 (75.3%) were from Africa, 34 (22.7%) from Europe and 3 (2%) from USA. The number of responders per country in Africa is shown in Figure 1.



26 African countries participated in the survey, including 10 from West Africa, 5 from East Africa, 6 from southern Africa, 4 from Central Africa and 2 from North Africa, including Sudan. The highest number of responses (36) came from southern Africa, including 26 from South Africa. The total number of responses from Central, East, North and West Africa were 16, 29, 2 and 30 respectively.

Respondents from all 16 EDCTP African member states, and the aspirant member state (Angola) participated in the survey. Two or more people participated from each of the 16 EDCTP participating states except for Gabon and Gambia which returned one response each. There were two responders from Angola.

Responders from African countries outside the EDCTP Association came from Algeria, Burundi, Botswana, Guinea, Liberia, Malawi, Mauritania and Sudan.

All responses associated with African countries were from African participants because SI 1 specifically asked for country of origin. More than 73% of the African responders were from public institutions. The number of participants from EDCTP African participating states (102) accounted for 68% of all responders (150). While it was not possible to associate responses with countries of origin in most cases, it is clear from the 115 people who provided written text in their responses to SI 24 and SI 25 that the participants were overwhelmingly from Africa or promoters of the African interest.

The participants included 102 (68%) males, 46 (31%) females and two with unspecified gender.

Profiles of responders

Figure 2 shows responses for SI 7 about primary area of research expertise. Among the 130 participants who responded to SI 7 about expertise in global health research, 59 indicated expertise in Epidemiology, 59 in Clinical trials, 58 in Public health, and 49 in biomedical research. Expertise in Ethics was indicated by 25 people, followed by Policy (18), Data (12), Social Science (11) and Advocacy (7). The 'other responses' included research translation, product development and management. There was one response for Entomology.

Figure 2. Profiles of responders to SI7: What is your primary area of research expertise? (More than one can be selected)

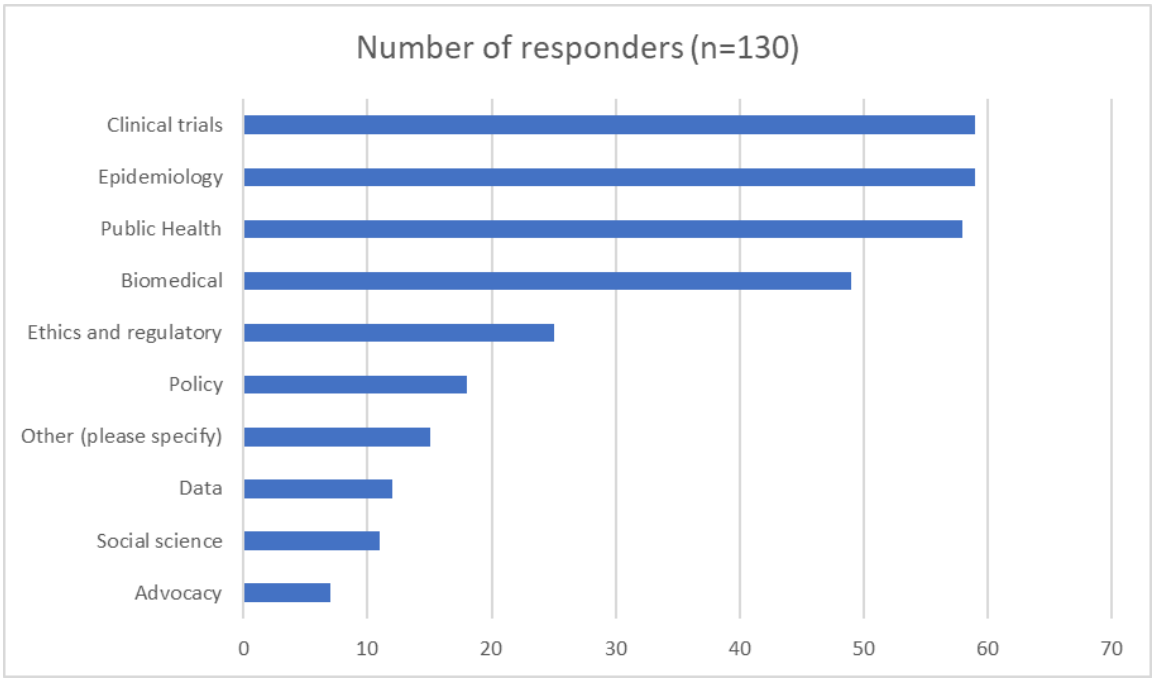
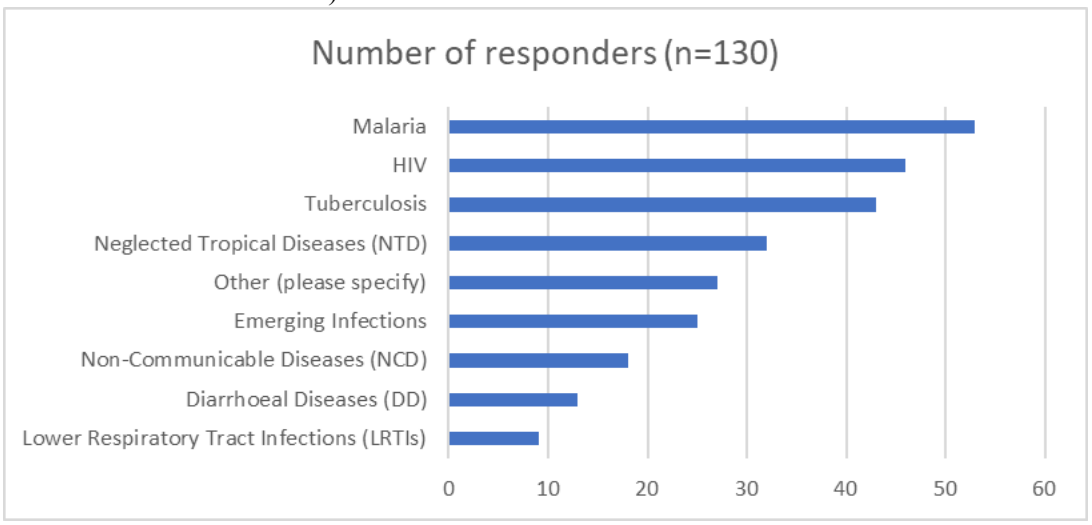


Figure 3 shows the number of responses indicating expertise in specific disease areas as asked in SI 8. Most responders to SI 8 indicated expertise in the malaria space (53), followed by HIV (46), tuberculosis (43), NTDs (32), Other (27), emerging infections (25), Non-Communicable Diseases (18), Diarrhoeal Diseases (13) and Lower Respiratory Tract Infections (9). The 'Other' category with 27 responders included management, public health and care, and research.

Figure 3. Profile of responders to SI 8: What is your primary area of health expertise? (You can select more than one choice)



Responders involvement in EDCTP2 Programme

The question about involvement in the EDCTP2 programme (SI 3) received the highest response rate. Over 99% (149) of the 150 participants responded to this survey item and 94 (63.1 %) indicated an association with the current programme in various capacities as shown in Table 1 below. Only 38 of the 94 responders indicated that they were nationals of EDCTP participating states even though 102 had indicated an African EDCTP member country as country of origin.

Current or previous EDCTP grantees accounted for 42% (63) of the 149 participants that responded to SI 3.

Strategic partners in Africa, including the Africa Union Commission for Social Affairs, Africa CDC, AUDA-NEPAD and WHO-AFRO participated in the survey.

Table 1: Number of responders (94) who answered yes to involvement with the EDCTP2 programme in various capacities. Some were involved in more than one capacity

Are you associated with EDCTP in these capacities?	**Yes**
National of an EDCTP2 participating state	38
Current resident of an EDCTP2 participating state	20
Member of the EDCTP General Assembly	17
EDCTP High Representative	2
Member of the EDCTP Scientific Advisory Committee	4
Member of the AU Secretariat (Commissions)	1
Member of other organs of the AU	3
Member of WHO	1
Reviewer of EDCTP grants	11
Current EDCTP grantee	47
Independent researcher	7
Previous EDCTP Grantee	16
Have applied for EDCTP grants	25
Private sector (Industry, NGO)	6
Funder (Contributed to joint calls)	3

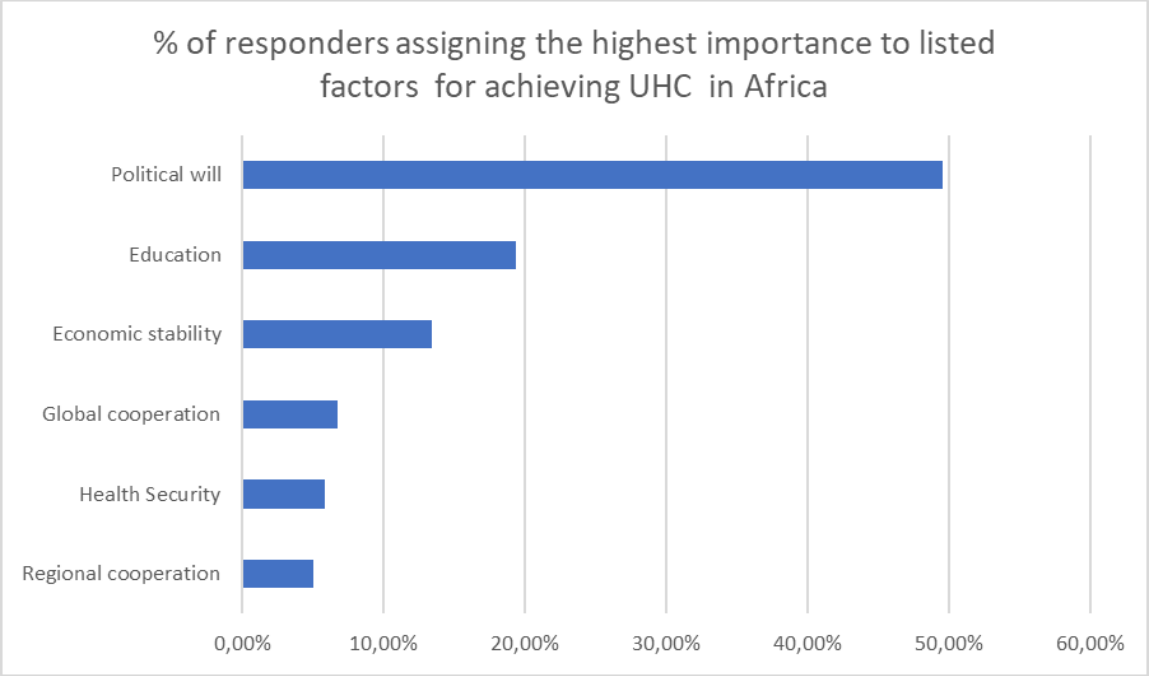
Among the 115 participants that responded to the question about the benefit of EDCTP Association membership (SI 21), 89 (77.4%) considered the membership to be beneficial to their countries, two responders (oen from Africa) thought it was not beneficial, and 24 (20.9%) responders had no comments.

Achieving Universal Health Coverage and SDG3 in Africa

SI 10 asked responders about the most important contextual factors for achieving Universal Health Coverage (UHC) in Africa, and what could be the role of EDCTP3/GHP in the transformation process in Africa.

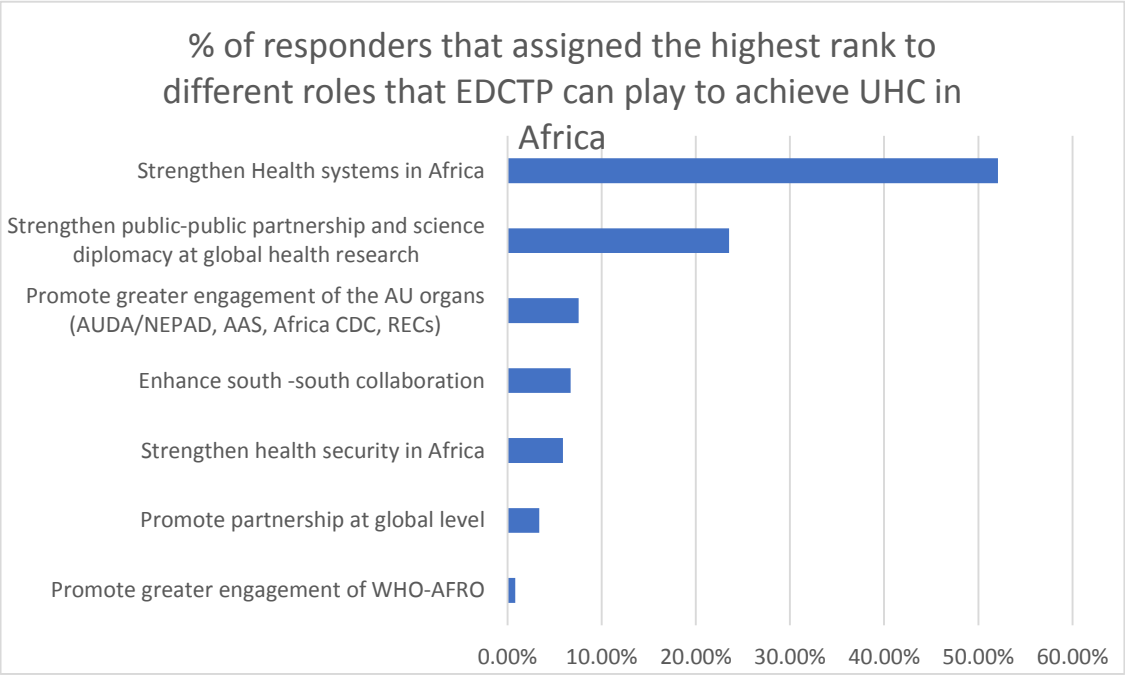
Given the choice to rank six factors indicated in Figure 4, in order of importance, for achieving UHC, almost half (49.9%) of the 119 responders considered ‘Political will’ to be the most important factor. ‘Education’ was ranked highest by 20% of responders. Only 13.5% considered ‘Economic stability’ as the most important factor. More responders (6.7%) ranked ‘Global cooperation’ as the leading factor than ‘Regional cooperation’ (5.0%). Strengthening ‘Health Security’ was considered the most important factor for achieving UHC by 5.9% of responders.

Figure 4. Percentage (%) of responders assigning the highest importance to listed factors affecting UHC in Africa (n=119).



More than half of the 119 responders (52.1%) to SI 11 considered 'Strengthening health (research) systems' as the most important role EDCTP can play to achieve UHC in Africa (Figure 5). This was followed by 'Strengthen public-public partnership and science diplomacy in global health research' which 23.5% of responders gave the highest ranking. The proportion of responders that ranked the other options as most important varied from 0.8% for 'Promoting greater engagement with WHO-AFRO' to 6.7% for 'Enhancing South-South collaboration'.

Figure 5. Percentage (%) of responders assigning the highest importance to listed roles that EDCTP can play to achieve UHC in Africa (n=119)



Achieving SDG3 (Good health and well-being)

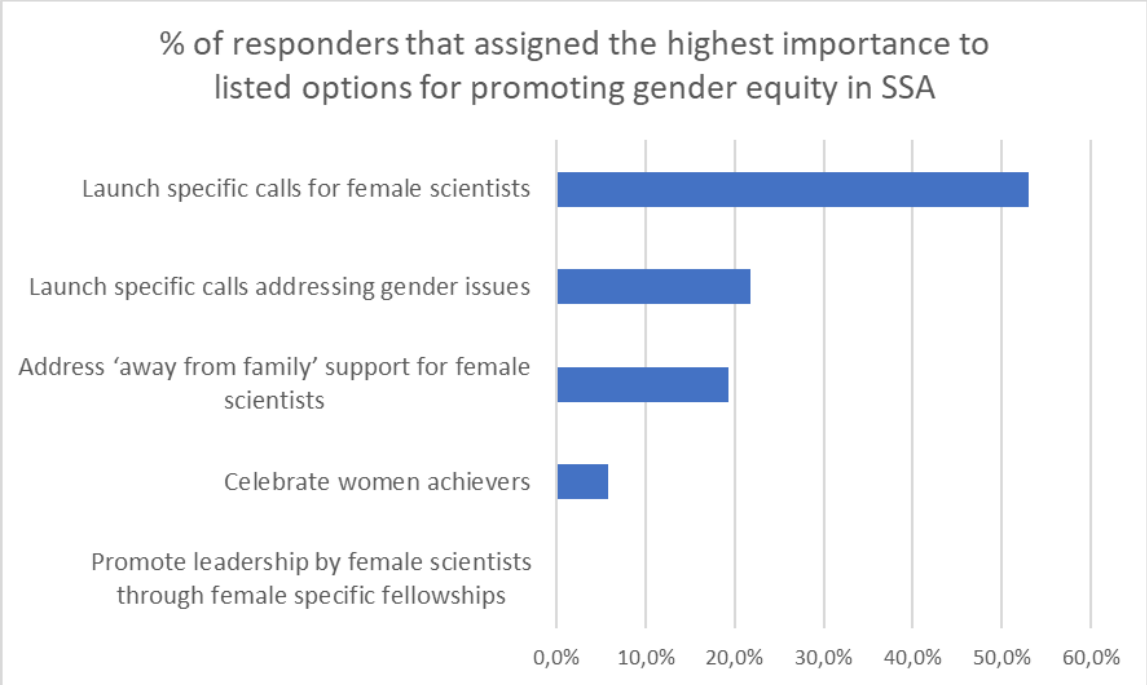
In response to SI 12, a large majority (83.2%) of the 119 responders agreed that achieving the following objectives will, to a large extent, facilitate meeting the SDG 3 (Good health and well-being):

- Reduction of the social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe.
- Development and uptake of new or improved interventions against infectious diseases.
- Enhancement of health security in sub-Saharan Africa, and by extension in Europe and worldwide, in the context of environmental and climate change, by reducing the risk of outbreaks, pandemics or antimicrobial resistance.

Promotion of gender equity in global health research in sub-Saharan Africa (SSA)

Figure 6 shows the results for the level of importance 119 responders assigned to a list of options for promoting gender equity in global health research in Africa (SI 13). Most of the responders (74.8%) thought specific calls for female scientists was the most important driver for gender equity in health research in SSA. More than half of the responders (52.9%) considered launching specific calls for female scientists as the most important driver. This was followed by specific calls addressing gender issues (21.0%). Addressing 'away from family' support for female scientists was assigned the highest rank by 19.3% of the responders.

Figure 6. Percentage (%) of responders assigning the highest importance to listed options for promoting gender equity in sub-Saharan Africa (n=119).



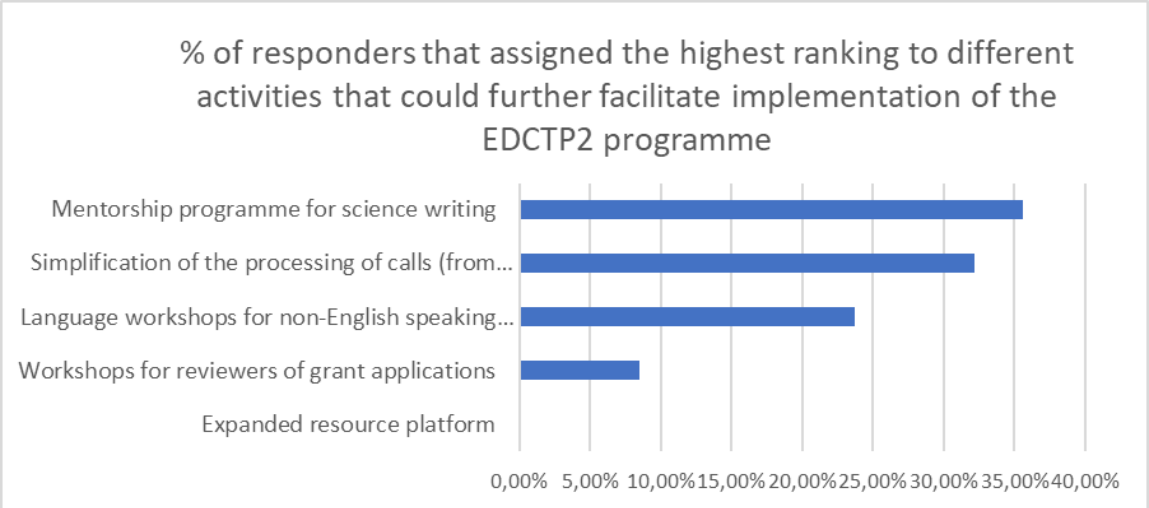
Additional activities to facilitate implementation of EDCTP2

A total of 118 participants responded to SI 18 about the additional activities that could further facilitate implementation of the current EDCTP2 (Figure 7).

'Mentorship programme for science writing' was ranked as most important by 42 (35.6%) responders, followed by 'simplification of the processing of calls' which was ranked highest by 38 responders (32.2%). Not far behind was 'Language workshops for non-English speaking applicants' which got 28 votes (23.7%) for the most important activity that accelerate the implementation process for the EDCTP2 programme. Only 10 (8.5%) responders assigned the

highest ranking to conducting 'Workshops for reviewers of grant applications'. 'Expanding the resource platform' was considered the least important of the five options provided for SI 18.

Figure 7. Ranking of additional activities that that could further facilitate implementation of the current EDCTP2 (n=118)



Objectives of the current EDCTP2

SI 9 requested participants to rank the EDCTP2 objectives in Figure 8 below in order of importance. Most of the 130 responders (51.5%) considered "Increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones' as the most important objective. 'Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials' was ranked the highest by 34.6% of the responders. Each of the other objectives were ranked as most important by less than 10% of the responders. 'Extended international cooperation with other public and private partners' received the least number of votes as the most important. It was ranked top by only 2.3% of responders.

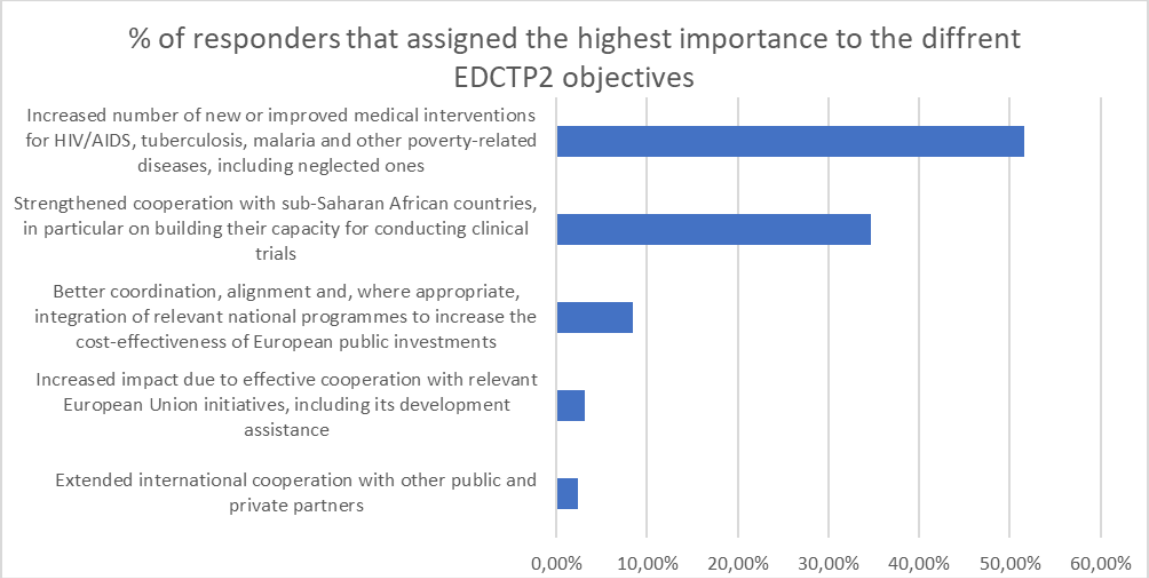


Figure 8: Percentage (%) of responders assigning the highest importance to the different EDCTP2 objectives (n=130)

How to increase countries participation in the EDCTP3/GHP Programme.

To address SI 14, 119 participants responded to the question 'How could the EDCTP3/GHP bring onboard countries that are not currently members of the EDCTP Association?

Among the options listed for ranking, 38.7% gave the highest rank to 'Demonstrate benefit for African countries with limited capacities for health research', followed by 'Enhance South-South collaboration' (29.4%) and 'Enhance EU-Africa collaborations to achieve UHC in all countries' (25,2%). Only 6.7% of the responders considered 'Demonstrate benefit for EU countries' as the most important factor in bringing onboard countries that are not members of the EDCTP Association.

Additional areas to be tackled by EDCTP3/GHP

In response to the question 'Do you think that EDCTP3/GHP should tackle additional areas than the ones currently tackled by the EDCTP2 programme? (SI 15), 86.6 % (107) of the 119 responders answered in the affirmative. Among those that answered 'yes', 'Clinical epidemiology' was considered the most important area by 28.6% of the 119 responders. This was closely followed by 27% for 'Vector control' and 24.0% for 'Social science'. 'Climate change' was considered the most important additional area by only 20% of responders.

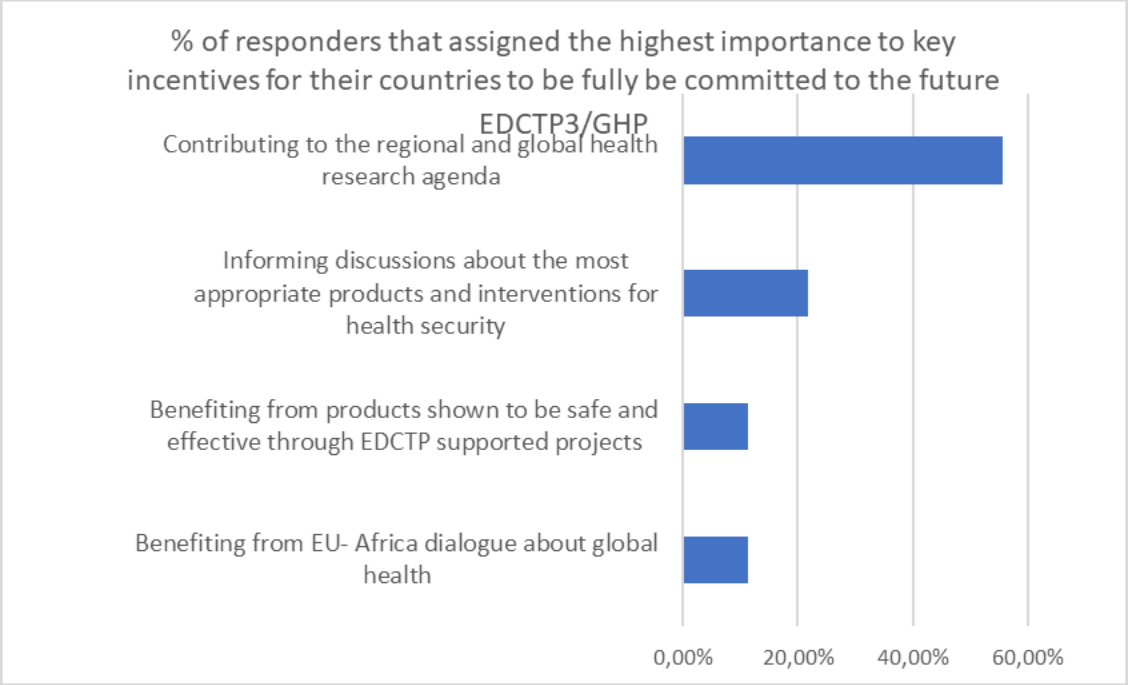
Lessons learned from COVID-19 pandemic

In response to SI 19, the most important lesson learnt from COVID-19 pandemic that could inform the EDCTP3/GHP funding scope, 'regional entities like Africa CDC and WHO-AFRO are critical for managing public health emergencies' was ranked number 1 by 43.2 % of responders. However, this was just marginally higher than the number of responders who thought that the roles of EDCTP Regional Networks of Excellence should be expanded with increased funding to accommodate regional entities (36.4%). One in five responders (20.3%) considered EDCTP3/GHP support for regional platforms (e.g. AVAREF and WAHO) to implement ethics and regulatory activities was the most important lesson learnt. The examples indicated of regional entities, networks and consortia that have been important during the COVID-19 pandemic include all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities (RECs) in the African region. Also mention were H3Africa, COHRED, REACTing and Red Cross.

Incentives to commit to EDCTP3/GHP

Among the key incentives listed in Figure 9 for EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, 'contributing to the regional and global health research agenda' was assigned the highest ranking by 64 (55.7%) out of 115 responders. 'Informing discussions about the most appropriate products and interventions for health security' was considered the most important by 25 (21.7%) responders. The other two options were each given high importance by 13 (11.3%) responders.

Figure 9. Importance of incentives for country commitment to EDCTP3/GHP (n=115)



Private sector involvement (industry and foundations)

In response to SI 23, 94 (81.7%) of the 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector including industry and foundations. The others did not think so. However, the majority of the responders thought it was a highly risky venture. The main risk identified is that relating to conflicts of interest and loss of control. The various narratives about the risk of engaging private partners are best exemplified by these three:

1. "For most Africa, the private sector is poorly regulated rendering highly risky for investment in terms of grants. However fostering Private-Public sector partnerships might be beneficial"

2. "In my opinion, membership in the private sector will rather contribute to strengthening the association by mobilizing financial resources. But as a risk I fear that c sector will want to change the orientations of the association for purposes other than those it has set for itself".

3. "Increased risk for competing priorities of the private sector may not be UHC but as an expansion of their profit margins by the health hazards. If the private sector is to be involved, the regulations and ethical acumen should be updated to ensure the Public Health good is the priory and not otherwise"

5. Discussion

The primary goal of the online consultation was to explore the views of African institutions, including public and private initiatives, and member states of the African Union, about how EU-Africa cooperation in global health research and innovation might be enhanced through the envisaged EDCTP3/GHP initiative. To this end, a short, user friendly online instrument was developed, disseminated, collated and analysed.

African involvement

The majority of the 150 responders were from Africa. Respondents from all 16 current African member states of the EDCTP Association, and the aspirant member state (Angola) participated in the online consultation. Fewer responses were received from non-English speaking countries, particularly Francophone countries in central Africa. The low response rate from these countries may be because the questionnaire was available only in English. A similar low response rate, from Lusophone and Francophone, was reported by WHO-AFRO for a recent online survey, conducted in English, about ethics and regulatory capacities in Africa (https://www.edctp.org/news/avaref-survey-highlights-edctps-role-supporting-ethical-regulatory-oversight-africa/). Most of the African participants were from public institutions, including government departments/ministries, national research institutions, the AU Commission for Social Affairs, the African CDC, the African Union Development Agency (AUDA-NEPAD) and the Regional Economic Communities (RECs). Responders were mainly epidemiologists and clinical trialists, but some had expertise in ethics and regulatory activities, social science, health policy, data, knowledge translation and advocacy. One was an entomologist.

Achieving Universal Health Coverage (UHC) in Africa

Political will and awareness through education were perceived as the most important drivers for advancing UHC in Africa. Most responders thought EDCTP can accelerate this process by strengthening health (research) systems and promoting public-public partnership and science diplomacy in global health research. There was an overwhelming agreement among participants that the sustainable development goal for health and well-being (SDG3) will be met largely through a reduction of the social and economic burden of infectious diseases in sub-Saharan Africa. Meeting the SDG3 targets can be accelerated by the development and uptake of new or improved interventions against infectious diseases in Africa and globally to reduce the risk of outbreaks, pandemics or antimicrobial resistance. To achieve UHC leaving no one behind, there were suggestions for closing the gender gap. Most of the responders advocated for specific calls for female scientists to enhance equity in health research in sub-Saharan African and 'away from family' support for female scientists.

The EDCTP2 Programme

All 150 participants, except one, responded to the question about involvement in the EDCTP2 programme. Most of the responders, mainly grantees, were associated with the EDCTP2 programme in various roles, but many of them were from countries that are not members of the EDCTP Association, indicating that responders outside the EDCTP participating states considered membership of the association to be beneficial to their countries. However, there was little enthusiasm for extending international cooperation with other public and private partners outside the EU-Africa network.

Increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones; and strengthening cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials, were identified the two most important objectives of EDCTP2.

To further enhance the EDCTP2 programme, the participants thought that a mentorship programme for science writing should be implemented and the processing of calls should be simplified and presented in different languages.

Two responders did not think that the EDCTP2 programme was beneficial to their countries, but no reason was given except from one whose the country of origin was not in Africa which could be established through the free text narrative.

EDCTP3/GHP programme

There was a general consensus that for the EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, it should be seen firstly as 'adding value to the regional and global health research agenda' and by 'providing current information about the most appropriate products and interventions for health security'. An overwhelming majority of responders (86.6%) wanted EDCTP3/GHP to embrace additional areas not addressed in the EDCTP2 programme. As the survey was conducted during the COVID-19 outbreak, Clinical epidemiology was the favourite new topic; followed closely, and in order of importance, by Vector control, Social science and Climate change. Vector control has become popular since the Zika outbreak, and more recently with the use of medicines for vector control to tackle vector-borne diseases like malaria and filariasis.

The coordinating role played by regional entities like Africa CDC and WHO-AFRO in managing public health emergencies was considered the most important lesson learnt so far from the COVID-19 pandemic that could inform the EDCTP3/GHP funding scope. But equally important are the emerging critical networking activities of the EDCTP Regional Networks of Excellence (NoE). The responders thought the support for EDCTP Networks of Excellence should be expanded with increased funding to accommodate more regional entities. The list, they provided, of regional entities, networks and consortia that have been important during the COVID-19 pandemic included all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities (RECs) in the African region. Also listed were AVAREF, H3Africa, COHRED, REACTing and Red Cross.

Extending EDCTP3/GHP membership to the private sector, including industry and foundations was considered beneficial by most responders. However, many thought it was a highly risky venture because of conflicts of interest and loss of control. The following text about the risk of engaging private partners can best illustrate most of the views expressed

"For most Africa, the private sector is poorly regulated rendering highly risky for investment in terms of grants. However, fostering Private -public sector partnerships might be beneficial"

Conclusion

The views expressed in the online consultation process came from a wide range of strategic entities from across Africa. Key influencers in Africa, including the African Union Commission, Africa CDC, Africa Union Development Agency, and the WHO-AFRO shared their views on the way forward for EDCTP3/GHP. There was a consensus about demonstrating value addition to the regional and global health research agenda through support for the most appropriate products and interventions for health security. Conducting the survey during the COVID-19 pandemic was timely as it allowed input on the relevance of working for the global good and the importance of south-south networking, coordinated by EDCTP regional networks of excellence, regional economic communities and key institutions like Africa CDC and WHO-AFRO. Extending EDCTP3/GHP membership to the private sector, including funders and foundations was considered beneficial but should be managed carefully to avoid conflicts of interest and mitigate risks related to profits from products. EDCTP might also explore the best ways to determine country capabilities for health research and through resources like the WHO Joint External Evaluations, and the WHO-AFRO national health research systems barometer that is partly supported by EDCTP. Such analysis might assist in shaping the EDCTP3/GHP yet further in light of the COVID-19 pandemic.

Limitations

The online consultation survey had some limitations. Administering the survey form in English, targeting responders in all AU member states, met some language barriers, especially in Central Africa, where most of the AU members have French as the official language. Moreover, the online survey was performed during a public health emergency, with people observing lockdown restriction and working from home with limited access to the internet. The number of invitations sent out were also were limited by access to contact details due to privacy and data protection policies.

The visibility of EDCTP in Africa has been perceived as suboptimal, and it is not clear from the online survey what the leadership of strategic partners in health in Africa think about EDCTP as a valued partner going forward with the proposed EDCTP3/GHP programme. High-level engagements with leaders in the African Union, EU, Africa CDC and WHO-AFRO, after the survey, provided some indicators about the role of EDCTP in supporting health research in Africa. Their thoughts have been summarised in Appendix 2 in this report.

Questionnaire

1. Accept/reject conditions

2. Country of origin (Please add your country of origin, or that of your organisation when responding on behalf of one)

3. Gender

4. Current employer
- Government
- Public institution
- Private institution
- Multilateral institution
- Other (please specify)

5. Have you been involved in the on-going European and Developing Countries Clinical Trials Partnership (EDCTP2) programme? [Yes/No]

6. If yes, please identify in which capacity (You can select more than one choice)
- From an EDCTP 2 participating State
- Current resident of an EDCTP2 participating state
- Member of the EDCTP General Assembly
- EDCTP High Representative
- Member of the EDCTP Scientific Advisory Committee
- Member of the AU Secretariat (Commissions)
- Member of other organs of the AU (e.g. AUDA/NEPAD, AAS, Africa CDC, RECs).
- Member of WHO
- Reviewer of EDCTP grants
- Current EDCTP grantee
- Independent researcher
- Previous EDCTP Grantee
- Have applied for EDCTP grants
- Private sector (Industry, NGO)
- Funder (Contributed to joint calls)

7. What is your primary area of research expertise? (You can select more than one)
- Epidemiology
- Public health

- Clinical trials
- Biomedical
- Policy
- Data
- Advocacy
- Social science
- Ethics and regulatory
- Other (please specify)

8. What is your primary area of health expertise? (You can select more than one choice)
- Malaria
- TB
- HIV
- NTD
- LRTI
- Diarrhoeal diseases
- NCD
- Emerging infections
- Other (please specify)

9. Please rank, in order of importance, the specific objectives of the current EDCTP2 programme:
a. Increased impact due to effective cooperation with relevant Union initiatives, including its development assistance
b. Increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones
c. Better coordination, alignment and, where appropriate, integration of relevant national programmes to increase the cost-effectiveness of European public investments
d. Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials
e. Increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance
f. Extended international cooperation with other public and private partners

10. What are the most important contextual factors in your opinion for achieving Universal Health Coverage (UHC) in Africa? Rank the choices below:
a. Political will
b. Economic stability
c. Education
d. Health Security
e. Regional cooperation
f. Global cooperation

11. What role can the EDCTP3/GHP programme play to achieve the UHC in Africa. Rank the choice below
a. Strengthen public-public partnership and science diplomacy at global health research
b. Strengthen Health (research) systems in Africa
c. Strengthen health security in Africa
d. Promote partnership at global level
e. Enhance south -south collaboration
f. Promote greater engagement of the AU organs (AUDA/AUDA-NEPAD, AAS, Africa CDC, RECs).
g. Promote greater engagement of WHO-AFRO.

12. To what extent will achieving these objectives facilitate meeting the SDG 3 (Good health and well-being). The proposed EDCTP3/GHP general objectives are:

- Reduction of the social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe
- Development and uptake of new or improved interventions against infectious diseases;
- Enhancement of health security in sub-Saharan Africa, and by extension in Europe and worldwide, in particular in the context of environmental and climate change, by reducing the risk of outbreaks, pandemics or antimicrobial resistance.
- Large extent
- Limited extent
- None

13. In your opinion, how could EDCTP3/GHP promote gender equity in sub-Saharan Africa? Rank choices below

a. Launch specific calls for female scientists
b. Promote leadership by female scientists through female specific fellowships
c. Address 'away from family' support for female scientists
d. Launch specific calls addressing gender issues
e. Celebrate women achievers

14. How could the EDCTP3/GHP bring onboard countries that are not currently members of the EDCTP Association? Rank the choices below

a. Enhance EU-Africa collaborations to achieve UHC in all countries
b. Enhance South-South collaboration
c. Demonstrate benefit for African countries with limited capacities for health research.
d. Demonstrate benefit for EU countries

15. Do you think that EDCTP3/GHP should tackle additional areas than the ones currently tackled by the EDCTP2 programme ? Yes/No

16. If yes, rank the choices below for other areas in order of importance.

a. Climate change
b. Vector control
c. Clinical Epidemiology
d. Social Science

17. If no, give reasons

18. In your opinion, what additional activities could further facilitate implementation of the current EDCTP2? Please rank the choices below in order of importance:

a. Expanded resource platform
b. Language workshops for non-English speaking applicants
c. Mentorship programme for science writing
d. Workshops for reviewers of grant applications
e. Simplification of the processing of calls (from launch, review to outcome)

19. What lessons do you think we have learnt from the recent and ongoing Global Health Emergencies that should inform the EDCTP3/GHP future funding approach? Rank the choices below

a. Regional entities like Africa CDC and WHO-AFRO are critical for managing public health emergencies
b. The roles of EDCTP Regional Networks of Excellence should be expanded with increased funding to accommodate regional entities.
c. EDCTP3/GHP should support regional platforms (e.g. AVAREF and WAHO) for ethics and regulatory activities

20. If appropriate, please give examples of regional entities, networks and or consortia that have been active during PHE (Max 50 words)

21. If your country is currently a member of the EDCTP Association, do you think that being part of the EDCTP Association is beneficial for your country?

- Yes
- No
- No comments

22. What are the key incentives for your country to be fully be committed to the future EDCTP3/GHP? Rank choices below.

a. Contribution to the regional and global health research agenda
b. Benefiting from EU- Africa dialogue about global health
c. Informing discussions about the most appropriate products and interventions for health security
d. Benefiting from products shown to be safe and effective through EDCTP supported projects

23. In your opinion, can EDCTP3/GHP benefit from extending membership to the private sector including funders and foundations?

- Yes
- No

24.In your view/opinion, what are the risks of extending membership to the private sector? (Max 50 words)

25. Please add any other comments, views or information you deem important, and that have not been tackled in this online consultation, which should be considered when developing the future EDCTP3/GHP (Max 200 words)

Post-survey engagements with AU, EU, Africa CDC and WHO-AFRO

High-level engagements with the African Union, EU, Africa CDC and WHO-AFRO after the survey provided some indicators about role of EDCTP in supporting health research in Africa. Members of the EDCTP secretariat contributed to important high-level discussions about EDCTP's role and value addition to the public health space in Africa. EDCTP was mentioned in speeches by African Ministers of Health, the AU commissioner for Social Affairs, the Regional Director for the WHO Africa Region and the Director of Africa CDC.

24 & 25 June 2020: Africa's Leadership in COVID-19 vaccine development and access

The role of EDCTP in research in vaccine development in Africa was highlighted during the virtual meeting of Africa's Leadership in COVID-19 vaccine development and access held on 24 and 25 June 2020 (https://africacdc.org/download/africas-leadership-in-covid-19-vaccine-development-and-access-highlights-day-1-2/).

The meeting, which was opened by H.E. President Cyril Ramaphosa, Chairperson of the African Union and President of the Republic of South Africa brought together African leaders, public health professionals, policymakers, the media, civil society, community leaders, private sector representatives, pharmaceutical industry experts, and partners to discuss a roadmap for the development of safe, efficacious, affordable, equitable and accessible COVID-19 vaccine in Africa, with the involvement of Africans.

During the closing session there were presentations by the Executive Director of UNAIDS, H.E. Amira Elfadil Mohammed, Commissioner for Social Affairs, African Union Commission and Dr Leonardo Simao, EDCTP High representative for Africa.

Dr Leonardo Simao, said that the conference was timely because it will ensure that Africa is not left behind in COVID-19 vaccine development. He highlighted some of the activities of EDCTP

in Africa since 2003. He reminded the participants EDCTP is engaged in high level dialogue in Africa, Europe and globally to find solutions to the vaccine challenge and they will continue working with partners as we move into the next phase of the programme.

16 July 2020: European Union (EU) - African Union (AU) Research & Innovation Ministerial meeting

The first ever EU - AU Research & Innovation Ministers' Meeting took place on 16 July 2020, under the framework of the EU-AU High-Level Policy Dialogue (HLPD) on Science, Technology and Innovation (https://ec.europa.eu/info/news/european-union-and-african-union-research-and-innovation-ministers-meet-first-time-2020-jul-16_en)
The policy discussions on public health focused on the human health impacts and the more far reaching socioeconomic effects of COVID-19. The two main discussion points for public health were i) the emergency call for expressions of interest launched by the EDCTP to support COVID-19 research activities and ii) the impact of COVID-19 on ongoing EDCTP Projects.

The ministers advocated for international cooperation (north-south and south-south), and better support for EDCTP and the successor, the planned Global Health Partnership (GHP). Some AU Ministers called for increasing the EDCTP membership by African countries currently not represented, giving the Partnership a whole of Africa approach. The Ministers (or their representatives) of non-EDCTP participating states, including Hungary, Egypt, Romania that advocated for additional financial resources for the EDCTP/GHP.

EDCTP was represented in the meeting by Dr Michael Makanga, EDCTP Executive Director; Dr Leonardo Simao, EDCTP High Representative Africa, and Professor Marcel Tanner, EDCTP High Representative Europe.

11-12 August 2020: 34th session of the African Advisory Committee for Health Research and Development (AACHRD) Meeting.

EDCTP participated in the 34th session of the WHO-AFRO African Advisory Committee for Health Research and Development (AACHRD) on 11-12 August 2020. The theme of the meeting was 'Health Research in the context of COVID-19' but the regional health research agenda for Africa was presented and discussed with inputs from EDCTP and strategic partners. The key partners included NEPAD, TDR, Africa CDC and the Regional economic Communities. More than 50 people participated in the meeting, including many that were invited to the proposed Cape Town meeting on EDCTP/GHP. The main goal of AACHRD is to provide advice to the Regional Director on the WHO core function of shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge in Africa.

The WHO-AFRO Regional Director, Dr Matshidiso Moeti, in her opening remarks acknowledged the presence of EDCTP and highlighted the valuable recent outputs from joint activities that informed the MOU between WHO-AFRO and EDCTP signed in June 2020.

Professor Moses Bockarie gave an overview of the emergency call launched by EDCTP in April 2020 to support COVID-19 research activities, and the impact of COVID-19 on ongoing EDCTP Projects. Professor Bockarie also presented the roadmap for strengthening National Health Research Systems in Africa that was developed during the EDCTP-WHO joint meeting held in Brazzaville on in October 2019 (https://publications.edctp.org/nhrs-consultative-meeting-report/cover).

Recommendations and action points

The participants resolved to develop and implement a work plan around the following recommendations of the 34th AARCHD:

1. Leadership, governance and innovation in health research

3. Develop a collaboration framework to guide engagement with stakeholders.
4. Promote indigenous innovations from the region.
5. Develop guidance document on access options should a vaccine be available.
6. Finalise the strategy for strengthening the use of evidence information and research for policy making in the WHO/AFRO region for presentation at the 2021 regional committee meeting.
7. In the context of COVID 19, the AACHRD, resolved to go beyond the advisory capacity, to assist WHO-AFRO through collaborating with other partners in terms of shaping the research agenda and ensure the quality of ongoing research around COVID 19.
8. Encourage participation of African countries (and communities) in vaccine trials.
9. Put in place mechanism of accessing vaccines once available and in collaboration with partners (e.g. Africa CDC).
10. Encourage regulatory bodies and governments to be engaged actively in trials.
11. Orient research beyond the biomedical and public health areas spheres and address research questions in multiple sectors including social economic status, social sciences/ground realities and advise government based on the evidence.

2. Strengthening national health research systems

12. Develop COVID-19 research agenda for Africa.
13. Conduct deliberative dialogues that will identify topics for policy briefs.
14. Support and strengthen work on policy briefs.
15. Set up standing subcommittee to review policy briefs.
16. Endorse and strengthen work of AVAREF
17. Develop a regional health research directory.
18. Develop guideline for rapid ethics review.
19. Promote multisectoral, transdisciplinary, social science, health (research) systems, implementation and operational research.
20. Develop reports on COVID-19 best practice and research agenda from member states.

1. 3. Harmonisation and co-ordination of research

21. An expansive list was generated; further discussion on prioritising for WHO-Afro while also allowing country specific priorities
22. Consider interventions for prevention that are beyond the health care system.
23. Use of the Health systems building blocks to organise the priorities, as this is widely used as a conceptual framework and is well known.
24. Consider emerging and re-emerging infections.
25. Include social science among research priorities.