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IMPACT ASSESSMENT

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}

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Acronyms

AMR	Anti-Microbial Resistance
CD	Communicable disease
CSA	Coordination and Support Action
DIS	Dedicated Implementation Structure
EC	European Commission
EDCTP	European and Developing Countries Clinical Trials Partnership
EIT	European Institute of Innovation & Technology
EU	European Union
ERA	European Research Area
FTE	Full Time Equivalent
GA	EDCTP General Assembly
GHIT	Global Health Innovative Technology Fund
H2020	Horizon 2020 - EU Framework Programme of Research and Innovation - 2014-2020
HE	Horizon Europe - EU Framework Programme for Research and Innovation 2021-2027
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
ID	Infectious disease
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
JU	Joint Undertaking
LMIC	Low and Middle-Income Countries
MDG	Millennium Development Goals
MOU	Memorandum of Understanding
MS	EU Member States
NCD	Non-Communicable Diseases
NGO	Non-Governmental Organisations
NTD	Neglected Tropical Diseases
OPC	Open Public Consultation
PDP	Product Development Partnership
PRND	Poverty Related and Neglected Disease
R&D	Research and Development
R&I	Research and Innovation
RIA	Research and Innovation Action
SDG	Sustainable Development Goals
SME	Small- and Medium-Size Enterprises
SRIA	Strategic Research and Innovation Agenda
SSA	Sub-Saharan Africa
TFEU	Treaty of Functioning of the European Union
TMA	Training and Mobility Actions
WHO	World Health Organisation

Definitions

For the purposes of the GHP/EDCTP3 impact assessment, the following definitions apply:

Clinical trial: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.[1]

Disease outbreak: The occurrence of disease cases in excess of normal expectancy. The number of cases varies according to the disease-causing agent, and the size and type of previous and existing exposure to the agent. Disease outbreaks are usually caused by an infection, transmitted through person-to-person contact, animal-to-person contact, or from the environment or other media.[2]

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.[3]

Health intervention: An act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.[4]

Infectious diseases: Those diseases caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another.[5]

Phases of a clinical trial: A trial of experimental drug, treatment, device or behavioural intervention may proceed through four phases:[6]

- Phase I Clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).
- Phase II Clinical trials study the biomedical or behavioural intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- Phase III Studies investigate the efficacy of the biomedical or behavioural intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

[1] https://www.who.int/ictrp/en/
[2] https://www.who.int/environmental_health_emergencies/disease_outbreaks/en/#:~:text=A% 20disease%20outbreak% 20is%20the,or%20to%20radioactive%20materials
[3] https://www.who.int/health-technology-assessment/about/healthtechnology/en/
[4] https://www.who.int/classifications/ichi/en/
[5] https://www.who.int/topics/infectious_diseases/en/
[6] https://www.who.int/ictrp/glossary/en/#TrialPhase

- Phase IV Studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Zoonotic diseases: Infectious diseases of animals that can cause disease when transmitted to humans. [7]

[7] https://www.who.int/topics/infectious_diseases/en/

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

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

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I).[8] It sets out to **help decide in a coordinated manner the right form of implementation for specific candidate initiatives** based on a common approach and methodology according to individual assessments[9]. It also provides an **horizontal perspective on the portfolio of candidate European Partnerships** to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or philanthropies) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the Horizon Europe programme.[10]

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

The Horizon Europe Regulation defines **eight priority areas,** scoping the domains in which Institutionalised Partnerships could be proposed[11]. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives[12] need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.[13]

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

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

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

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

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

[13] EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that *the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships*).

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024[14], the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope[15]. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation **Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities**. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation.[16] Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "*a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses*." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the **objectives of Horizon Europe** highlight the need *to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement.* [17]

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

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

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby

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

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

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

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

the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**[18], a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation[19] and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

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

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.

- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.

- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

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

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

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

The impact assessment of Horizon Europe identifies therefore the need to **rationalise the EU R&I funding landscape**, in particular with respect to partnerships, as well as to **re-orient partnerships towards more impact** and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward **a major simplification and reform for the Commission's policy on R&I partnerships**[20]. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a **more strategic, coherent and impact-driven approach**. Key related changes that apply to all forms of European

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

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

Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Under Horizon Europe, a 'European Partnership'[21] is defined as *"an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including philanthropies and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."*

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

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

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.[22]

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**[23]:

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

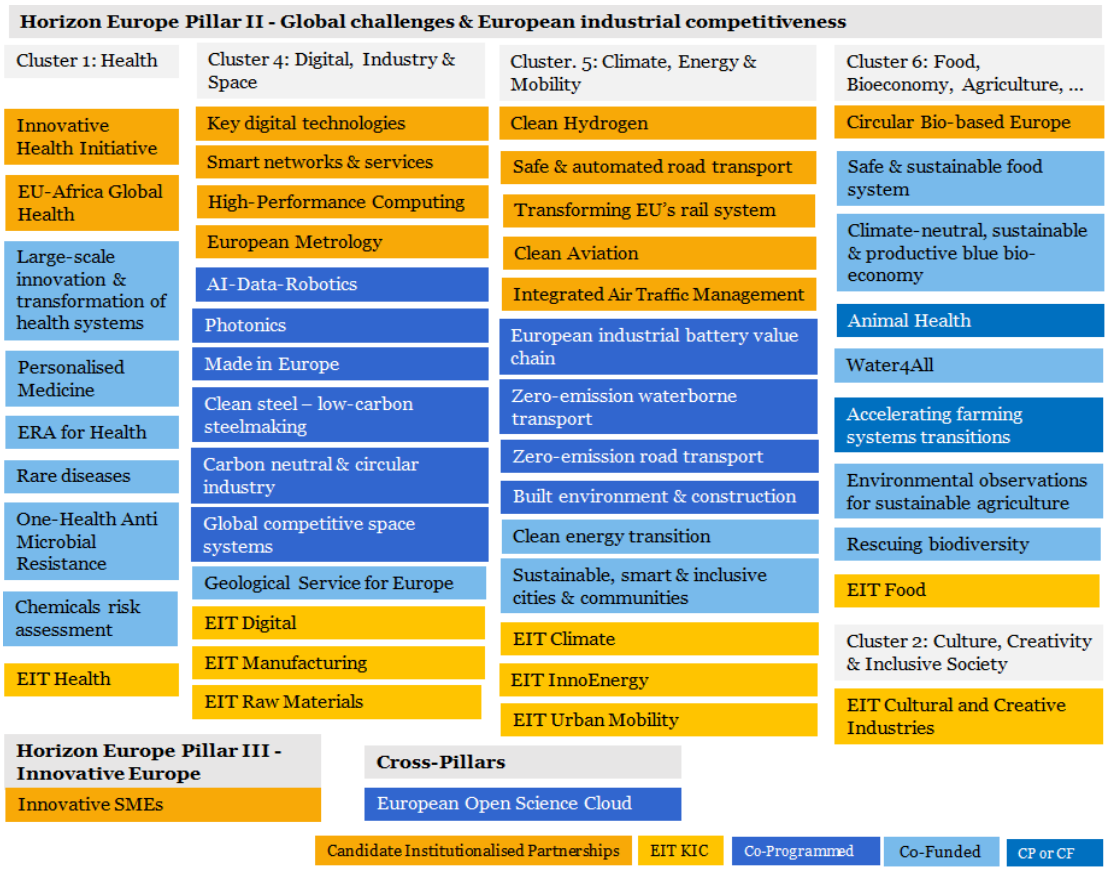
[22] Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.
[23] The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate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

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

2.1. Portfolio of candidates for Institutionalised European Partnerships

– The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation[24], a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of **49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships**[25]. Out of these, **13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope**[26]. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

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



- *Source: Technpolis group (2020)*

[24] Horizon Europe Regulation (common understanding), Annex Va.
[25] Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7
[26] Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

– There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into '*horizontal*' partnerships and '*vertical*' partnerships.
– The **'horizontal' partnerships** have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. '**Vertical' partnerships** are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

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

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

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

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

2.2.1. Option 0 - Baseline option – Traditional calls

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

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

2.2.2. European Partnerships

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

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

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

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

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

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

2.2.3. Option 1 - Co-programmed European Partnership

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

2.2.4. Option 2 – Co-funded European Partnership

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

2.2.5. Option 3 – Institutionalised European Partnership

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

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding,

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

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

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

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

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

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines[27] to evaluate and compare options with regards to their **efficiency, effectiveness and coherence**. This also integrates **key selection criteria for European Partnerships**.

Box 2 Summary of European Partnerships selection criteria[28]

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

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.[29] For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative

[27] European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)
[28] For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.
[29] Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

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

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

2.3.2. Method for identifying the preferred option

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

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "**key functionalities needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)[30].

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored

[30] 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.

compared to the baseline with a + and – system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options[31].

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[32] 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[33]. 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.[34] 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

[31] 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.

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

[33] 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.

[34] 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).

pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).

- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution[35] (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[36]. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution[37]. 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[38]. 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 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

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

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

[35] Minimum contributions from partners equal to the Union contribution
[36] Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.
[37] Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.
[38] Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

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**)[39]. In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

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

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the '**necessity test'**.[40] The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

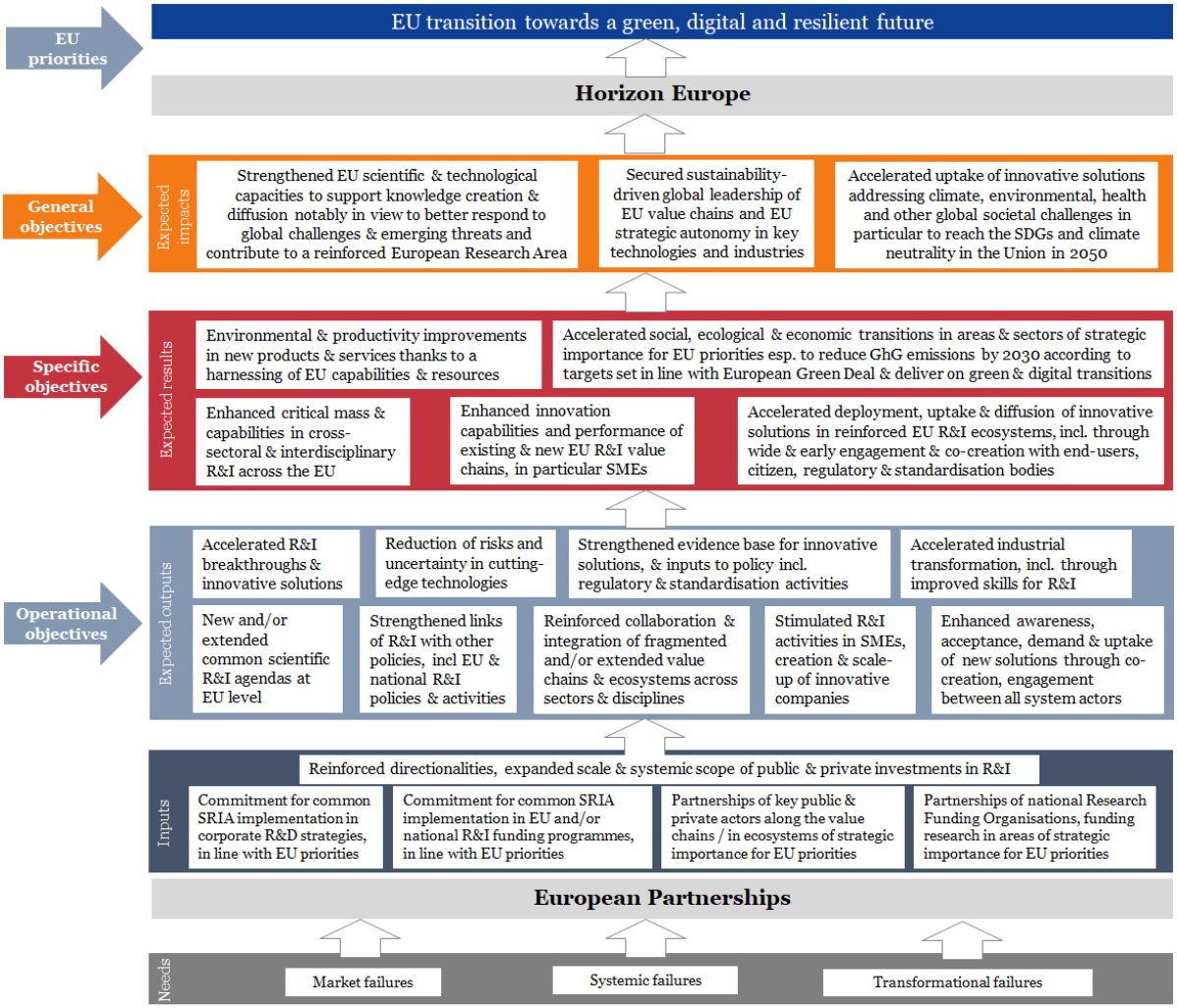
2.4.1. Overall impact orientation, coherence and efficiency needs

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

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

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

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



Source: European Commission, DG Research & Innovation, Unit A2 Programme Analysis and Regulatory Reform, adapted from Technopolis Group (2020)

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

a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;

c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

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

- **Coherence for impact:** The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- **Collaboration for impact:** Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives**,** Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- **Efficiency for impact:** Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office[41]**.** A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

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

Looking at the coherence of the set of initiatives at the thematic level, the "**digital centric**" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G

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

connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

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

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

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

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health**

address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

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

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON EU-AFRICA GLOBAL HEALTH

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

The death toll from infectious diseases is spread disproportionally around the world, with low- and middle- income countries being most affected, particularly sub-Saharan Africa.[42,43] **Infectious diseases**, such as lower respiratory infections, HIV/AIDS, diarrhoeal diseases, malaria and tuberculosis, remain the main cause of death, disability, and ill-health in sub-Saharan Africa.[44]

The current Sars-CoV-2, also called COVID-19, pandemic is a clear reminder, that due to increased global connectivity through world trade and tourism, infectious diseases spread rapidly around the globe causing huge human and also economic suffering in many countries, including Europe. Therefore research into health technologies to detect, treat and prevent infectious diseases will not only protect people's right to health worldwide, but might also contribute to halt the spread of emerging epidemics.

Medical and technological research and innovation are needed to accelerate the production of key interventions such as precise diagnostics tests, therapeutic treatments and preventive vaccines to alleviate the burden of infectious diseases and ensure a healthy and productive life, especially in the most vulnerable and affected region such as sub-Saharan Africa. The successful development and deployment of such interventions needs to take into account the environmental and social context, including the capacities of the health systems, of countries in which these diseases are prevalent. In addition, the development of health technologies, especially at the late stage of clinical development, is an expensive process with high costs and a long timeframe, hence it requires large scale and especially coordinated funding.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative under Horizon Europe, which would focus on joint research and innovation activities to accelerate the development of suitable, effective, safe, accessible and affordable health technologies to fight infectious diseases affecting sub-Saharan Africa. The assessment will help to decide on which of the following different policy options should be pursued in order to legally establish and financially support this partnership:

- Option 0: Traditional Framework Programme calls
- Option 1: Co-funded partnership, based on a grant agreement
- Option 2: Co-programmed partnership, based on a memorandum of understanding;
- Option 3a: Institutionalised partnership, based on a decision of European Parliament and Council under Article 185 TFEU;
- Option 3b: Institutionalised partnership, based on a Council regulation under Article 187 TFEU.

[42] Bhutta ZA, Sommerfeld J, Lassi ZS, Salam RA, Das JK (2014). Global burden, distribution, and interventions for infectious diseases of poverty. Infectious Diseases of Poverty 3(21)
[43] von Philipsborn P, Steinbeis F, Bender M, Regmi S, Tinnemann P (2015). Poverty-related and neglected diseases: An economic and epidemiological analysis of poverty relatedness and neglect in research and development. Global Health Action 8, 25818.
[44] https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html

1.1. Emerging challenges in the field

The World is undergoing rapid population growth with more than 9.7 billion people by 2050,[45] whereby Africa is accounting for more than half of the projected global population growth.[46] Climate and environmental changes such as hotter summers, warmer winters or increased annual rainfalls, potentially introduce diseases to new areas,[47] and increase the disease burden of many tropical and neglected diseases.[48]

Antimicrobials agents or antibiotics are crucial in the treatment of many infectious diseases, but the spread of drug-resistance, or **antimicrobial resistance** (AMR), could undermine the progress made to date. Although, due to lack of monitoring,[49] the precise levels of AMR in the African region are not recorded, available data suggest that the African region follows the global trend of rising AMR prevalence, with significant resistance, found for numerous treatments against tuberculosis, malaria, HIV/AIDS, cholera, and dysentery.[50] Apart from increasing the level of mortality and morbidity in the region, drug-resistance puts a financial burden on health systems as it increases the costs of treatment.

In addition to the burden posed by well-recognised diseases such as HIV, malaria and tuberculosis, as well as neglected tropical diseases, the world is seeing an increasing number of outbreaks of **emerging infectious diseases**, which may be further exacerbated by climate change.[51] Emerging infectious diseases can be caused by newly identified infectious pathogens which cause public health problems either locally or internationally[52] such as Ebola[53] or the new corona viruses. Pathogens may also re-emerge with new characteristics, such as multidrug-resistance, or in different places, to cause new epidemics.[54] Outbreaks of emerging infectious diseases have the potential to cause enormous social and economic damage globally and particularly in already heavily constrained health systems in Africa.[55,56,57] Outbreaks can also discourage use of healthcare, indirectly leading to greater morbidity, mortality and financial costs.[58]

Moreover, previously unknown or new strains of virus can emerge due to close contact with animals, spread by modern transportation[59] or crowded urban environments,[60] causing epidemics, such as the current COVID-19 pandemic.[61] This is a global health

[45] https://www.worldometers.info/world-population/, Accessed on 16 March 2020
[46] Data from https://www.un.org/en/sections/issues-depth/population/, Accessed 29 August 2019
[47] Data from https://ecdc.europa.eu/en/climate-change/climate-change-europe
[48] WHO (2003). A.J. McMichael, et al Climate change and human health - risks and responses.
[49] Antimicrobial resistance in the WHO African region: current status and roadmap for action https://academic.oup.com/jpubhealth/article/39/1/8/3065721
[50] WHO African Health Monitor (2013). J. B. Ndihokubwayo et al "Antimicrobial resistance in the African Region: Issues, challenges and actions proposed". https://www.afro.who.int/publications/antimicrobial-resistance-african-region-issues-challenges-and-actions-proposed
[51] Smith KF, Goldberg M, Rosenthal S, Carlson L, Chen J, Chen C, Ramachandran S. (2014) Global rise in human infectious disease outbreaks. J R Soc Interface. 1(101):20140950.
[52] World Health Day (1997). Emerging infectious diseases. Available at: https://www.who.int/docstore/world-health-day/en/documents1997/whd01.pdf
[53] The Ebola outbreak, 2013–2016: old lessons for new epidemics https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5394636/
[54] Van Doorn HR (2014). Emerging infectious diseases. Medicine (Abingdon). 42(1): 60–63.
[55] If COVID-19 is not beaten in Africa it will return to haunt us all. Only a global victory can end this pandemic, not a temporary rich countries' win. Financial Times 25 March 2020 https://www.ft.com/content/c12a09c8-6db6-11ea-89df-41bea055720b
[56] Looming threat of COVID-19 infection in Africa: act collectively, and fast https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30464-5/fulltext?dgcid=raven_jbs_etoc_email
[57] Smith, K. M., Machalaba, C. C., Seifman, R., Feferholtz, Y., & Karesh, W. B. (2019). Infectious disease and economics: The case for considering multi-sectoral impacts. One health (Amsterdam, Netherlands), 7, 100080. doi:10.1016/j.onehlt.2018.100080
[58] Wilhelm JA, Helleringer S. Utilization of non-Ebola health care services during Ebola outbreaks: a systematic review and meta-analysis. J Glob Health. 2019;9(1):010406. doi: 10.7189/jogh.09.010406.
[59] Zaheer Ahmad Nasir et al. Airborne biological hazards and urban transport infrastructure: current challenges and future directions (2016)
[60] Duane J. Gluber Dengue, Urbanization and Globalization: The Unholy Trinity of the 21st Century (2011)
[61] https://unsdg.un.org/sites/default/files/2020-03/SG-Report-Socio-Economic-Impact-of-Covid19.pdf

crisis unlike any in the last 75 years history, killing people, spreading human suffering, and upending people's lives.[62] Previously other recent known outbreaks have been: SARS in 2002–2003, H1N1 in 2009 or MERS in 2014,[63] Zika in 2016[64] and Ebola in 2014 and 2016.[65]

Preparedness and response research, that can provide an evidence base to increase individual and community resilience, facilitate operational readiness, improve decision-making during emergency response, and speed the recovery of public health and healthcare systems and communities, remain the preferred path to contain epidemics and pandemics, and early public health interventions are the second and essential line of attack.

A further important challenge is the **rise of chronic non-communicable diseases (NCDs)**, such as cardiovascular disease, diabetes and cancer also in Africa.[66] Along with the unresolved epidemic of infectious diseases, this presents Africa with an unwelcome double burden of disease. Diabetes patients are over three times more likely to become infected with tuberculosis,[67] while COVID-19 infection is more severe in patients with high blood pressure, heart disease, lung disease, cancer or diabetes.[68] The resulting increased levels of comorbidity are likely to create new challenges for the development and use of effective treatment strategies, in particular in sub-Saharan Africa, overstretching the already strained health systems.[69]

Encouragingly, over the past decade, there have been significant **scientific and technological advances** in the development of health technologies, such as those in the areas of DNA sequencing and genome editing that are opening up new avenues, to prevent, diagnose and treat infectious diseases.

In addition, since the Ebola crisis in West Africa, the **industry** seems to be gaining interest in global health projects targeting priority R&D gaps.[70] Some of them have created integrated global health R&D units. Moreover, large **philanthropic foundations** have found the challenges of global health as too big to tackle on their own, and therefore are more willing than before to join forces and collaborate with public organisations to fund research & innovation in the field of infectious diseases.[71]

Noteworthy is furthermore the **digitalisation of Africa** and the increasing use of mobile technologies.[72] Digital technology has the potential to accelerate and transform health research and product development, as well as the delivery of healthcare itself. For instance, it can be used to improve the collection, analysis and sharing of high-quality

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[62] https://www.nzma.org.nz/journal-articles/covid-19-another-infectious-disease-emerging-at-the-animal-human-interface
[63] http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic
[64] https://web.archive.org/web/20160804185858/http://www.who.int/mediacentre/news/statements/2016/emergency-committee-zika-microcephaly/en/
[65] https://www.who.int/csr/disease/ebola/en/
[66] World Health Organization (2016). Burden of non-communicable diseases on the rise.
[67] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6029598/
[68] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30116-8/fulltext
[69] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3600620/
[70] G-FINDER Report 2019 Neglected Diseases Research and Development: Uneven Progress
[71] https://www.gatesnotes.com/2020-Annual-Letter
[72] Biarritz Declaration for a G7 and Africa Partnership: Digital transformation in Africa (2019).

research data. It can also change the way services are delivered in hard-to-reach areas, for instance, using digital diagnostics or drones.[73,74]

1.2. EU relative positioning in the field

Europe has been traditionally strong in tropical diseases research[75] and during the last two decades the EU has provided support to research and innovation on infectious diseases through the different EU Framework Programmes FP6 (2002-2006), FP7 (2007-2013) and Horizon 2020 (2014-2020). This funding has covered all the phases of the research and innovation pathway from pre-clinical discovery to clinical trials for diagnostics, vaccines, therapeutics, as well as microbicides and vector control.[76,77,78]

The strength of European research has not been so much in the quantity of investment, but rather in the way funding is addressing the needs of the research community and the impacts on shaping the environment for research. There has been a strong focus on collaboration between researchers from different countries, sectors and disciplines. This has helped to build wide networks of scientists who can cover the entire innovation cycle, from basic research to implementation in order to support crucial discoveries, as well as drive economic growth and job creation.

In 2018, the EU was the third largest public funder of neglected infectious diseases with USD 113 million.[79] This funding also includes the EU funding to the European and Developing Countries Clinical Trials Partnership (EDCTP).

Table 1: Public R&D funders 2018 on poverty related & neglected infectious diseases

Country	US$ (millions)										2018 % of total
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	
United States of America	1,798	1,706	1,672	1,769	1,574	1,583	1,516	1,615	1,631	1,779	68
United Kingdom	131	144	116	81	111	116	95	105	197	230	8.8
EC	123	96	115	99	118	116	141	85	125	134	5.2
Germany	35	38	33	56	46	50	56	50	70	73	2.8
India	28	43	48	48	56	43	48	55	76	66	2.6
France	49	41	62	55	81	66	66	52	50	44	1.7
Australia	26	29	36	46	24	36	21	23	25	36	1.4
Japan	6.2	9.4	3.5	2.6	11	11	14	17	18	33	1.3
Netherlands	28	19	25	16	24	19	5.4	25	25	21	0.8
Switzerland	8.7	15	15	17	17	19	21	19	18	17	0.7
Canada	18	9.5	9.6	18	20	13	10	7.1	13	15	0.6
South Africa	7.3	7.8	7.1	5.7	13	4.4	6.9	12	15	13	0.5
Subtotal of top 12^	2,319	2,176	2,163	2,242	2,100	2,082	2,007	2,075	2,264	2,462	95
Total public funding	2,444	2,320	2,289	2,348	2,219	2,166	2,102	2,200	2,385	2,599	100

[73] Mumley J, Thakker AN (2018). Africa leading way in healthcare tech: the continent is ahead of the game in cutting-edge drone use. HealthManagement 18(3)..
[74] Marketwatch (2019). Ghana : Zipline Drone Makes Delivery of Sickle Cell Medication
[75] Watson M: African Highway: The Battle for Health in Central Africa London: John Murray; 1953.
[76] A. Holtel et all EU-funded malaria research under the 6 and 7 Framework Programmes for research and technological development
[77] Tuberculosis research in the European Union: Past achievements and future challenges. https://www.sciencedirect.com/science/article/pii/S1472979209000882
[78] Increasing European Support for Neglected Infectious Disease Research https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5294741/
[79] G-FINDER 2019 Neglected Disease Research and Development: Uneven Progress

The European and Developing Countries Clinical Trials Partnership, was launched in 2003 to accelerate the development of medical interventions to prevent, control and treat HIV/AIDS, malaria and tuberculosis contributing to reduce the economic burden caused by these diseases in sub-Saharan Africa.[80] Under the second EDCTP programme[81] this scope was extended in 2014 to include the neglected infectious diseases. Currently it is a partnership of 16 African[82] and 14 European[83] member countries, assembled around the EDCTP Association (established under Dutch law), and the European Union. The EU financial contribution to the second EDCTP programme (2014-2020), up to EUR 683 million, comes from the H2020 framework programme, based on the decision of the European Parliament and the Council under Article 185 of the Treaty.

The new partnership, the EU-Africa Global Health Partnership under Horizon Europe, builds on the first and second EDCTP programmes and aims to advance the clinical development of suitable, effective, safe, accessible and affordable health technologies (e.g. diagnostics, treatments and vaccines) to help reduce the burden of infectious diseases in sub-Saharan Africa and strengthen capacities to improve the R&I response to (re-)emerging infectious diseases.

EDCTP has delivered, since 2003, more than 800 scientific peer-reviewed publications, built ethical review panels, regulatory capacity and networks of scientists for exchange high-quality clinical research, generating data with a significant impact on global and national health policy and practice. Moreover, since 2014, EDCTP has integrated the global health Participating States Initiated Activities in the EDCTP work annual plans, providing alignment of the European countries research efforts in this area.

During 2014-2019, EDCTP2 has awarded EUR 605 million in grant funding, supporting 83 clinical trials and other clinical research activities conducted by European-Africa consortia, 130 fellowships in career development of researchers from sub-Saharan Africa, and 57 grants to strengthen the enabling environment for conducting clinical trials and clinical research in Africa. As result, nearly 7,500 people in Africa have participated in training and workshops on study protocol, specimen collection, research administration, good clinical practice and epidemics preparedness, etc. EDCTP-funded studies have made vital contributions to the development of HIV antiretroviral drug formulations tailored to children; EDCTP has also supported the evaluation of the Xpert MTB/RIF diagnostic technology for the detection of drug-resistant tuberculosis bacteria, now recommended by the WHO and implemented globally. EDCTP studies have generated key evidence on malaria treatments for pregnant women, who are particularly susceptible to malaria, among other examples.

Thus, EDCTP is already a well-branded global health initiative that has made vital contributions to the development of treatments against diseases like AIDS, tuberculosis, malaria and neglected infectious diseases. It has strengthened capacity in sub-Saharan Africa and fostered strong research collaboration between the EU and Africa.

[80] Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:169:0001:0005:EN:PDF

[81] Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014D0556

[82] Burkina Faso, Cameroon, Congo, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda and Zambia

[83] Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom

The global spreading of COVID-19, in a pandemic of unprecedented global scale, could not be avoided despite existing knowledge about other coronaviruses of earlier epidemics. This means that the GHP candidate becomes even more relevant to addressing explicitly the research preparedness and response in case of emerging epidemics and in its role of coordinating research and innovation support with other funders. Therefore, the proposed EU-Africa Global Health partnership will explicitly address strengthening capacities to improve the R&I response to (re-)emerging infectious diseases.

The scope of the new partnership should also be extended to better cover the threat of antimicrobial resistance (AMR) and emerging infectious diseases with the potential to cause pandemics. This widened scope would also be reflected in the goal of the GHP, also called EDCTP3. The name 'EU-Africa Global Health Partnership' was proposed to give an indication of ambition. However, dialogue with Member States and African countries revealed that they would in a first stage prefer to focus on sub-Saharan Africa, as that is where the main burden of infectious diseases lies.

In the **evaluation of all the EU partnerships of Horizon 2020 based on Article 185** carried out in 2017, the Commission has underscored that 'the topics addressed by […] EDCTP2 are to a large extent not tackled with other Horizon 2020 actions'.

Moreover, the thematic **EDCTP2 independent Interim Evaluation** panel highlighted the invaluable and unique contribution of the programme to sub-Saharan Africa and that that EDCTP had 'made important inroads in **strengthening cooperation** and partnership between European and sub-Saharan African countries and **developing clinical trial capacity and scientific career development in Africa'**. It also noted that, because of the long timescales associated with new healthcare product development and implementation, achieving EDCTP's ambitious goals will **require long-term commitment and investment**.

An impact assessment **study on the EU funding on poverty related and neglected infectious diseases**[84] concluded that to ensure that innovations can be adopted, more health systems and **implementation research** is needed; as well as to **include the low and middle income countries** at different stages of the health research and innovation pathway. Overall, there is a need for more 'pull' policy incentives to help bridge research and impacts, as well as to increase awareness of EU funding efforts for **better coordination** with other funders.

A **SWOT analysis** (strengths, weaknesses, opportunities, threats) of the first two EDCTP programmes carried out by EDCTP, drawing on the independent Evaluations and impact assessments, as well as the insights of Scientific Advisory Committee members and other key stakeholders, suggested that EDCTP has established itself as an important contributor to health research in sub-Saharan Africa, with a distinct niche in the funding landscape – particularly through its progressive commitment to **later-stage trials** and to **under-served groups** with unmet medical needs. The analysis further showed that the partnership's integration of capacity-building activities into EDCTP projects, as well as its dedicated capacity-building funding, through the regional networks and fellowship programme in sub-Saharan Africa, was a notable feature of the partnership's work (details in Annex 6).

1.3. EU policy context beyond 2021

The European Commission is committed to the United Nations 2030 Agenda for Sustainable Development, with a set of Sustainable Development Goals directly related to global health: (SDG3), calling to 'ensure healthy lives and promote well-being for all

[84] EDCTP-funded clinical studies for medical interventions 2003-2018 http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa_EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf

at all ages' and SDG1 'to end poverty in all its forms everywhere'. Supporting global health is also related to SDG 9 'Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation' and SDG17 'Strengthen the means of implementation and revitalize the global partnership for sustainable development".

The Commission reflection paper *Towards a Sustainable Europe by 2030,* adopted in January 2019, outlines three scenarios on how best to progress on the SDGs: 1) an overarching EU SDGs strategy to guide all actions by the EU and Member States; 2) continued mainstreaming of the SDGs in all relevant EU policies by the Commission, but not enforcing Member States' action; and 3) putting enhanced focus on external action while consolidating current sustainability ambition at EU level. It emphasizes the continuous need to face persisting or novel challenges in science, society and policy for achieving a sustainable Europe by 2030. In this context health research and related innovation actions play a significant role in improving productivity, health care systems and the functioning of its industries.[85]

The proposed initiative is fully in line with the recent Communication on the *Global EU response to COVID-19*[86] that asks for 'Stepping up the preparation with EU Member States and third countries of the Global Health Partnership' and the Commission's comprehensive Africa Strategy '*Towards a comprehensive Strategy with Africa*'[87] adopted in March 2020. It is also in line with the '*EU-Africa Alliance for Sustainable Investments and Jobs*'[88] of September 2018, where the EU is committed to increase access to quality education, skills, research, innovation, health and social rights, and to reinforce Africa as a partner in trade, in foreign investment and in development, and to tackle together the green and digital transformations, as well as promoting sustainable investments and jobs.

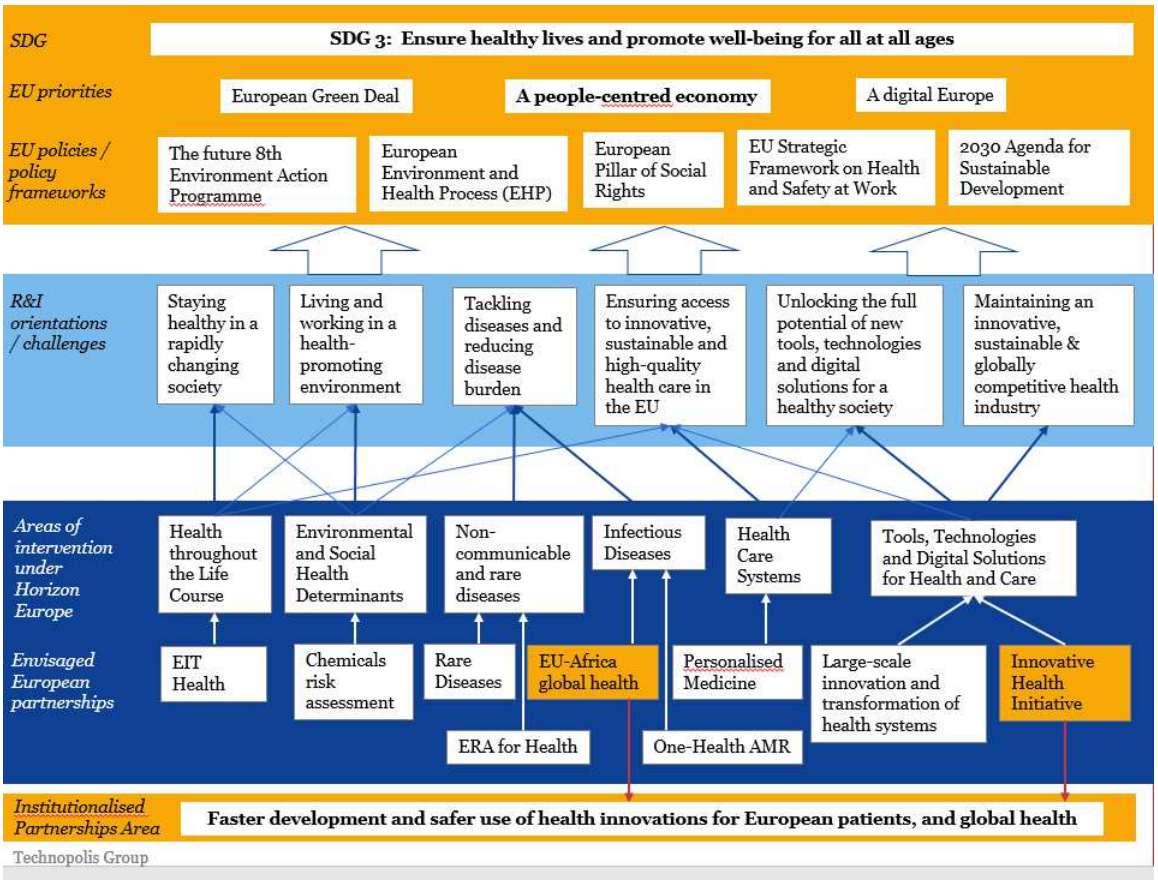
In December 2019, when the new Commission took office, it presented its new priorities for the upcoming years, including the '*A European Green Deal*', '*A people-centred economy*' and '*A Digital Europe*', which are particularly relevant for health research and innovation.[89] In her letter to the Commissioner for Innovation, Research, Culture, Education and Youth, Mariya Gabriel, the President of the European Commission, Ursula von der Leyen requests the maximisation 'of the potential of the EC exchange programmes to foster international cooperation in education, research and innovation'.[90] Moreover, to the Commissioner for International Partnerships, Jutta Urpilainen, she asks to 'make the most of the political, economic and investment opportunities that Africa offers, with its growing economies, populations and digital innovations, and to work on a new comprehensive strategy for Africa creating a partnership of equals and mutual interest'.[91]

Under Horizon Europe, the GHP/EDCTP3 would be part of R&I activities funded under Pillar II Cluster 1 Health, which is one of the six Horizon Europe clusters. Pillar II addresses global challenges and industrial competitiveness. Cluster Health is supporting

[85] Data from Sustainable Europe 2030. Available at: https://ec.europa.eu/commission/sites/beta-political/files/rp_sustainable_europe_30-01_en_web.pdf
[86] https://ec.europa.eu/international-partnerships/system/files/joint-comm-2020-eu-global-response_en.pdf
[87] https://eur-lex.europa.eu/legal-content/FR/TXT/?qid=1583753318333&uri=JOIN:2020:4:FIN
[88] Progress factsheet Africa-Europe Sustainable investments and Jobs Alliance (2018). Available at: https://ec.europa.eu/commission/africaeuropealliance_en
[89] https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf
[90] European Commission (2019). Mariya Gabriel: Commissioner-designate for Innovation and Youth. Mission letter: https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-mariya-gabriel-2019_en.pdf
[91] European Commission (2019). Jutta Urpilainen: Commissioner-designate for International Partnerships. Mission letter: https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-jutta-urpilainen_en.pdf

the Sustainable Development Goals, notably SDG 3 'Ensure healthy lives and promote well-being for all at all ages'. *The potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe and other EU policies and priorities are presented in Figure 6.*

Figure 6: Potential inter-connections between the Health cluster of Horizon Europe and EU policies and priorities.



2. PROBLEM DEFINITION

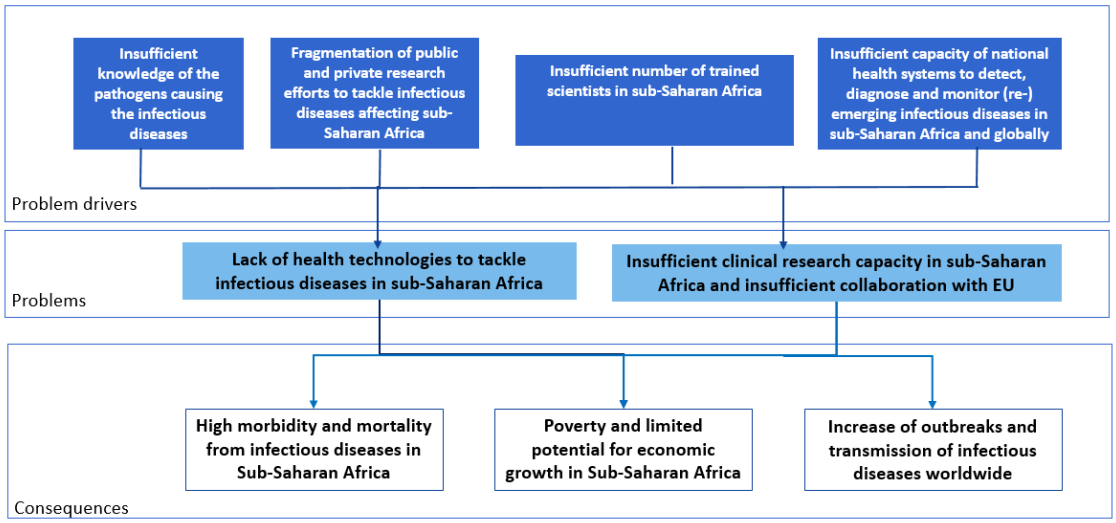
Taken into consideration the scale of the challenges ahead for addressing infectious diseases threats globally and the current scientific, technological and economic positioning of Europe, as well as the overarching EU policy context, a set of problems have been identified where EU research and innovation in the field of Global Health would have a specific role to play.

This has been summarised in a problem tree presented in Figure 7 portraying the identified problems, their drivers and potential consequences if the problems are not addressed. The lack of robust health technologies and the insufficient clinical research capacity for tackling infectious diseases in sub-Saharan Africa are due largely to a number of problem drivers: insufficient knowledge of the pathogens causing the diseases; fragmentation of public and private research efforts to tackle infectious diseases affecting sub-Saharan Africa, insufficient number of trained scientists in sub-Saharan Africa and the insufficient capacity of national health systems in sub-Saharan Africa to detect, diagnose and monitor (re) emerging infectious diseases

As well as impacts on population, these factors undermine economic development in the region and increase the risk of global dissemination of novel pathogens. In order to

address these problems and their drivers, it is important to establish a partnership structure that is most suitable for the needed actions. Let us first look at the problems and their drivers in more detail in order to understand what kind of partnership is needed.

Figure 7: Problem tree behind an initiative for European R&I on EU-Africa Global Health



2.1. What are the problems?

The main problem the partnership aims to address is the lack of suitable diagnostics, treatments and vaccines, the so-called health technologies, to address infectious diseases, such as HIV, malaria, tuberculosis but also leishmaniosis that are prevalent in Africa, especially in sub-Saharan Africa. One of the lessons learnt, also now with the COVID-19 pandemic, is that with the increased connectivity of different regions in the world, through world trade and tourism, infectious diseases in one part of the world do not stay there but can rapidly affect other regions. Therefore, developing these health technologies in sub-Saharan Africa is the starting point to contain infectious diseases in this region and protect the health of the citizens in the concerned countries and globally, including in Europe.

1. *Lack of health technologies or interventions for tackling infectious diseases in sub-Saharan Africa*

Although important strides have been made in combating infectious diseases, much still needs to be done at scientific level. For instance, although the development of antiretroviral therapy in the fight against HIV has been a major game changer,[92] there still is no effective vaccine to prevent HIV infection.[93] Likewise, whilst there are numerous treatments against tuberculosis, the increasing threat of (multi-)drug-resistant forms of the disease increase the urgency for the development of new vaccines with greater efficacy and broader application, as well as for continued development of new (combination) treatments.[94] For other diseases, such as Dengue – a mosquito-borne viral

[92] Broder S. (2010). The development of antiretroviral therapy and its impact on the HIV-1/AIDS pandemic. Antiviral research, 85(1), 1–18. doi:10.1016/j.antiviral.2009.10.002
[93] HIV vaccine: better to start together? Felber, Barbara K et al. The Lancet HIV, Volume 6, Issue 11, e724 - e725
[94] McShane, Helen. Insights and challenges in tuberculosis vaccine development The Lancet Respiratory Medicine, Volume 7, Issue 9, 810 - 819

infection affecting around 390 million people annually –, there is no effective treatment.[95]

Moreover, the progress made in combatting infectious diseases is being increasingly challenged by the rising levels of drug resistance or antimicrobial resistance. For instance, whilst chloroquine has long been used as a malaria treatment, there now is widespread resistance against it in most areas of the world.[96]

Intensified research efforts aiming at introduction of new modern health technologies in sub-Saharan Africa would have a major effect on the infectious disease burden in this region.

2. *Insufficient clinical research capacity for tackling infectious diseases in sub-Saharan Africa associated with insufficient knowledge exchange and research collaboration with EU*

Even where suitable health technologies are available, there often is a challenge in getting them to where they are most needed and ensuring that they are used to optimal effect. Most sub-Saharan African countries are faced with weak, under-resourced health systems. As a result, health technologies that have proven efficacious in trial environments may show reduced effectiveness in real-world settings, when they are not used correctly, or if they are used only intermittently as a result of insufficient availability.

While development aid and local capacity development activities have led to some progress in the delivery of existing health technologies such as diagnostics, vaccines and therapeutics to the region, much remains to be achieved to ensure that new health technologies are available and accessible to the people in need, calling also for implementation research. [97]

In many disease-endemic countries in Africa, there is insufficient capacity for conducting health research and clinical trials.[98] This concerns the equipment and tools needed to support trials (e.g. laboratory equipment, computers), as well as the human resources (e.g. health care workers, technicians, researchers) and the broader enabling research environment (e.g. ethical review boards,[99] and national medicines regulatory authorities). There is also an insufficient capacity to harness and package available local, regional and global evidence to inform health policies and practice.[100] In line with this challenge is the growing importance of implementation research to achieve the Sustainable Development Goals.[101]

As discussed, research and product development to combat infectious diseases require a multi-stakeholder approach and a common research agenda that brings together different forms of expertise. Crucially, this also demands strong involvement from funders and

[95] Data from https://www.who.int/en/news-room/fact-sheets/detail/dengue-and-severe-dengue, Accessed 1 Sept 2019.
[96] D'Alessandro U, Buttiëns H (2001). History and importance of antimalarial drug resistance. Trop Med Int Health 6(11):845-8
[97] WHO Regional Office for Africa (2018). The state of health in the WHO African Region: an analysis of the status of health, health services and health systems in the context of the Sustainable Development Goals.
[98] Whitworth JA, Kokwaro G, Kinyanjui S, et al. (2008). Strengthening capacity for health research in Africa. Lancet. 372(9649):1590–1593
[99] Ndebele P, Wassenaar D, Benatar S, Fleischer T, Kruger M, Adebamowo C, Kass N, Hyder AA, Meslin EM. (2014). Research ethics capacity building in Sub-Saharan Africa: a review of NIH Fogarty-funded programs 2000–2012, J Empir Res Hum Res Ethics. 9(2):24-40
[100] Edwards, A., Zweigenthal, V. & Olivier, J. Evidence map of knowledge translation strategies, outcomes, facilitators and barriers in African health systems. Health Res Policy Sys 17, 16 (2019). https://doi.org/10.1186/s12961-019-0419-0
[101] Alonge O, Rodriguez DC, Brandes N, et al. How is implementation research applied to advance health in low-income and middle-income countries? BMJ Glob Health 2019;4:e001257. doi:10.1136/ bmjgh-2018-001257

stakeholders, including researchers from disease-endemic countries,[102] as these are best placed to understand the specific needs of the populations and how research is expected to serve. This includes increasing attention for principles of fair research,[103] needed to ensure that African researchers can play a full and equitable role in research collaborations.

2.2. What are the key problem drivers?

The key causes of the problems from the R&I perspective, are the following:

1. *Insufficient knowledge of the pathogens causing infectious diseases that have high capacity to evade immune responses and develop resistance to treatment.*

The most prevalent pathogens that are predominantly affecting low- and middle-income countries, such as HIV, the causative agent of tuberculosis Mycobacterium tuberculosis and the malaria parasite Plasmodium, have shown tremendous resilience against control measures against them. One of the main reasons is the insufficient knowledge about host-pathogen interaction and about the mechanism on how they cause disease and escape human immune system.[104] This has made the search for new vaccines and treatment a slow process, emphasizing the need to conduct clinical trials in many different target populations and settings.[105]

Clinical trials are essential to know how pathogens react to medical interventions and to determining the efficacy and safety of such interventions. While valuable safety and efficacy data can be drawn from studies in high-income countries, often studies need to be conducted within sub-Saharan Africa itself. This may be because the infections are found only in this region, or particular strains of pathogen are found mainly in sub-Saharan Africa. In addition, responses to drugs or vaccines may be different in various populations, because of genetic differences or environmental factors. For example, particular genetic variations found in Africa affect responses to some antiretroviral drugs, while responses to rotavirus vaccine are generally lower in sub-Saharan Africa than in high-income countries.

Importantly, for later-stage and post registration trials and implementation studies, the nature of local health systems is a crucial factor, central to study design. Given their high degree of local relevance, these studies generally deliver the evidence most useful to national policymakers. A collaborative approach is required to develop and evaluate vaccines, drugs and other tools needed to control these diseases. Partnerships across a wide range of actors are needed to chaperone new interventions through complex evaluations in disease-endemic settings, regulatory pathways, and implementation into health systems. Collaboration between public and private funders, together with research institutes, product development partnerships and national health authorities, is therefore key to further progress.

[102] Lansang MA, Dennis R (2004) Building capacity in health research in developing World Bull World Health Organ 2004 82(10):764-70

[103] Musolino N, Lazdins J, Toohey J, IJsselmuiden C (2015). COHRED Fairness Index for international collaborative partnerships, The Lancet 385(9975):1293-1294

[104] DeRycker, M., Baragana, B., Duce, S.I. & Gilbert, I.H. (2018). Challenges and recent progress in drug discovery for tropical diseases. Nature 559: 498-506. https://doi.org/10.1038/s41586-018-0327-4

[105] Rappuoli, R. & Aderem, A. (2011) A 2020 vision for vaccines against HIV, tuberculosis and malaria. Nature 473: 463-469. Doi:10.1038/nature10124

2. *Fragmentation of public and private research efforts to tackle infectious diseases affecting sub-Saharan Africa.*

There are few economic incentives for companies to invest in interventions for diseases that predominantly affect low-resource settings. Development of vaccines and drugs is both costly and high risk, and the lack of financial resources in countries in sub-Saharan Africa inevitably makes them an unattractive market for commercial organisations. The low commercial potential for achieving enough return on investment has led the industry to show, until recently, limited interest to invest in R&I for infectious diseases, especially those that are prevalent in LMICs.

For devices such as diagnostics, a further challenge is the need for products that are affordable, reliable, easy to use, and robust enough for challenging environmental settings. This demanding set of criteria deters investment when the potential to achieve a reasonable return on investment is highly uncertain.

As a result, the product development pipeline for infectious diseases is poorly stocked, and the progress has been slow. For instance, in 2019, there were only 129 active clinical studies/trials on poverty related neglected diseases, compared to 3,499 oncology studies/trials.[106] The 2018 Access to Medicines Index showed that in the pipelines of the 20 largest pharmaceutical companies, out of 1,314 R&D projects, only 298 targeted priority gaps products[107] for infectious diseases.[108]

Most of the support to R&I in this area in sub-Saharan Africa has been provided through public sources. Europe has a long history of supporting medical research in sub-Saharan Africa, often being based on informal contacts between researchers and institutions, and bilateral arrangements that reflect long-standing geopolitical legacies. While excellent research has been carried out, clinical evaluation of medical interventions requires systematic investment in infrastructure, generally across several countries, which can be challenging to achieve through bilateral or project-based initiatives.

Tackling infectious diseases affecting sub-Saharan Africa with modern technology tools requires the involvement of a large set of actors. These range from academic researchers to international development agencies, philanthropies and pharmaceutical companies. As each of these actors have their own priorities and focus areas,[109] one of the main challenges is uniting such diverse actors around a common strategic agenda and roadmaps, in order to use resources effectively and efficiently.

Although Member States have shown willingness to align and coordinate their national programmes for R&D infectious diseases around a common strategic research agenda, these efforts are hindered by national political priorities for international cooperation and development, which often follow political international agreements with different criteria than the research and innovation agenda efforts.

Individual funders, both public and private, including industry, and scientists often address a scientific problem in infectious diseases with a single hypothesis or theory. In

[106] WHO Global Observatory on Health R&D, data from July 2019. Available at: https://www.who.int/research-observatory/monitoring/processes/health_products/en/

[107] Priority product gaps are indicated: Policy Cures Research G-FINDER neglected diseases, products and technologies (2017); Policy Cures G-FINDER reproductive health areas, products and technologies (2014); WHO R&D Blueprint (2017), WHO Initiative for Vaccine Research gaps (2017), WHO priority pathogens list for R&D of new antibiotics (2017)

[108] Access to Medicines Foundation. Access to Medicines Index 2018. Available at: https://accesstomedicinefoundation.org/media/uploads/downloads/5d25b3dd5f128_5cb9b00e8190a_Access-to-Medicine-Index-2018.pdf

[109] Sridhar D (2012) Who sets the global health research agenda? The challenge of multi-bi financing. PLoS Med. 9(9)

case of complex diseases and circumstances, it would be advantageous to combine the knowledge and hypothesis of several groups and get a comprehensive understanding of the disease process. Infectious diseases that represent the most sophisticated mechanisms of evasion and escape from our defences, require a collaborative approach to tackle them, and partnerships with a wide range of actors have the best chances of finding the vaccines and drugs against these diseases. Communication between public and private funders together with scientists and scientists is one of the keys of finding comprehensive solutions.

3. *Insufficient number of trained scientists on infectious diseases clinical research in sub-Saharan Africa (medical doctors, researchers)*

Sub-Saharan Africa is faced with a lack of adequate research infrastructure and established researchers capable of initiating and maintaining competitive research outputs. Despite the many gains over the last few years, sub-Saharan Africa is still faced with a dearth of recognised researchers capable of maintaining competitive research outputs. Many researchers are working in isolation and engaging in activities that may have short-term economic advantages but are often not relevant to clinical research. Partnership-centered networks are needed to train scientists and build clinical research capacity so that more African scientists become experts of clinical research.

Clinical studies are governed by stringent international regulations, covering areas such as the conduct of trials, ethical approvals and the quality of laboratory analyses. Studies therefore require sufficient infrastructure and an appropriately trained workforce in order to carry out studies generating data consistent with the standards imposed by national and international regulatory agencies.

Furthermore, as well as shortcomings in institutional and individual capacity, many countries also have limited capabilities to ensure effective oversight and governance of research. This includes the capacity to oversee ethical approvals and ensure compliance with national and international regulatory standards.

To conduct high-quality clinical trials and implementation research in sub-Saharan Africa, consistent with fundamental ethical principles and recognised international regulatory standards, good participatory practices as well as to perform research effectively, efficiently, and in a sustainable manner, complementary fellowship training programmes are also necessary.

Many resolutions of the World Health Assembly and the WHO Regional Committee for Africa have called upon African countries and their development partners to make the required investments in National Health Research Systems (NHRS) to generate knowledge and promote its use in dealing with priority public health challenges. Implementation of these resolutions is critical to achieving the Sustainable Development Goals.[110] Recent review of the NHRS in Africa has observed that despite an improvement in the average NHRS Barometers scores from 43% in 2014 to 61% in 2018, a number of challenges remain. These include lengthy ethical clearance processes; weak research coordination mechanisms, weak enforcement of research laws and regulation, inadequate infrastructure, limited resource mobilisation skills and donor dependence.[111] This underscores the need to continue to strengthen the NHRS in order to

[110] Kirigia, J.M., Ota, M.O., Motari, M. et al. National health research systems in the WHO African Region: current status and the way forward. Health Res Policy Sys 13, 61 (2015). https://doi.org/10.1186/s12961-015-0054-3

[111] Rusakaniko, S., Makanga, M., Ota, M.O. et al. Strengthening national health research systems in the WHO African Region – progress towards universal health coverage. Global Health 15, 50 (2019). https://doi.org/10.1186/s12992-019-0492-8

not only strengthen clinical research capacity but to also facilitate knowledge translation and implementation science in general. This strategy would help reduce the knowledge-practice gap that persists in many LMICs.

4. *Insufficient capacity of national health systems to detect, diagnose and monitor (re-) emerging infectious diseases in sub-Saharan Africa and globally.*

As mentioned before, due to increased globalisation and migration, with overpopulated urban environments, climate change and closer contact with wild animals in certain areas of the world, the potential for infectious diseases to rapidly spread around the world has increased.

Early detection and diagnosis are vital to responding and limiting the number of new infections in case of an outbreak. This can be particularly challenging in sub-Saharan Africa where systems for detection, diagnosis and monitoring are inadequate. In its first annual report, *A World at Risk*, published in September 2019,[112] the Global Preparedness Monitoring Board concluded that the world is poorly prepared to respond to new global threats. It suggested that global actions are still dominated by responses to outbreaks, with too little investment in preparedness. This is well illustrated by the current COVID-19 outbreak.[113]

Compared to many other countries, the health systems in sub-Saharan Africa show limited capacity for research and innovation. This low research capacity not only impedes the achievement of health SDGs, but causes a slow response to emerging infectious disease threats and insufficient preparedness to epidemics. This leads to less than optimal control of outbreaks, and the potential for further spread to populations at risk and international dissemination. Low level of domestic funding makes it further challenging for health systems to control infectious diseases.

It is critical that African countries are involved in rapid and responsive clinical research to develop diagnostics, treatment regimens, vaccines and other health solutions during a public health emergency. Rapid and responsive research during a public health emergency should also be extended to socio-behavioural research, medical anthropology research as well as applied and translational research. The Ebola and other outbreaks left a legacy that research should take a centre stage and become the norm in responding to a public health emergency, especially when the cause is unknown or novel.

The emergency epidemic infectious diseases such as COVID-19 makes it even more imperative to have both strong and resilient health systems and strong NHRS. The latter is critical to coordinate and facilitate rapid generation of evidence as well as facilitating utilization of that evidence. The COVID-19 pandemic has re-emphasized to the global community the importance of research and innovation and the need to invest more in Research and Development (R&D); as both finding a cure and a vaccine have remained elusive, while both the public health and economic impacts escalate. R&D cannot progress without a functioning NHRS just as Universal Health Coverage would remain a pipedream without strong and resilient National Health Systems. Lastly, this EU-Africa Global Health Partnership rightly places great emphasis on Global Health Security which would be impossible to achieve without strengthening R&D and the NHRS.

[112] Global Preparedness Monitoring Board. A World at Risk: Annual Report on global preparedness for health emergencies. 2019. Geneva: WHO. Available at https://apps.who.int/gpmb/annual_report.html

[113] https://www.ecdc.europa.eu/sites/default/files/documents/RRA-sixth-update-Outbreak-of-novel-coronavirus-disease-2019-COVID-19.pdf

African leadership is essential in examining how governments should engage to improve health systems, a critical step in improving population health. African governments should make an effort to assess the return of investment of different health sector interventions, and to improve data and understand the costs, effectiveness and long-term effects of the investment on both health and economic outcomes.

2.3. How will the problems evolve?

The nature of infectious disease threats is constantly changing, with varying consequences for morbidity and mortality, as well as for social and economic outcomes. However, the major infectious diseases, such as HIV/AIDS, tuberculosis and malaria, are likely to continue causing the greatest disease burden in sub-Saharan Africa also in the near future. Infectious diseases can be combatted with different responses, ranging from clean water provision to new biomedical countermeasures.[114] The rise of new antimicrobial resistance mechanisms is reducing the impact of previously effective treatments[112,113,114] and the climate crisis will only worsen the situation. [115,116]

Emerging and re-emerging infections present major challenges and represent a grave threat to global health security. As the current global health system is called into question by the current corona virus COVID-19 pandemic, and before by other outbreaks such as the Ebola outbreak, the need for diagnostics, vaccines and drugs for key infectious diseases, as well as novel approaches for rapid detection and effective response to infectious diseases outbreaks, including surveillance and control, remains as pressing as ever.

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

Technologies and tools for tackling infectious diseases remain insufficiently available, while there still is a significant disease burden. The EU's commitment to the Sustainable Development Agenda calls for a dedicated approach to support the achievement of SDG3, thus including support for the research and development of vaccines and medicines for infectious diseases that affect developing countries, as well as the European Member States. In the 2019 Eurostat report on the progress towards the SDGs in an EU context, it is noted that while the number of deaths due to HIV, malaria and tuberculosis decreased in the EU, deaths due to other infectious and parasitic diseases rose.[117] In light of the **EU's commitment to achieving SDG3**, an initiative to advance a collaborative effort for global health research is deemed necessary, and it should be based on legal structure that would be most effective in reaching its objectives.

[114] Bloom DE, Cadarette D (2019) Infectious Disease Threats in the Twenty-First Century: Strengthening the Global Response. Frontiers in Immunology, 10, 549.
[112] Tadesse, B. T., Ashley, E. A., Ongarello, S., Havumaki, J., Wijegoonewardena, M., González, I. J., & Dittrich, S. (2017). Antimicrobial resistance in Africa: a systematic review. BMC infectious diseases, 17(1), 616. doi:10.1186/s12879-017-2713-1
[113] WHO. Antimicrobial resistance. Available at: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[114] WHO African Health Monitor (2013). J. B. Ndihokubwayo et al "Antimicrobial resistance in the African Region: Issues, challenges and actions proposed".
[115] Data from https://ecdc.europa.eu/en/climate-change/climate-change-europe
[116] Wu X, Lu Y, Zhou S, Chen L, Xu B (2016) Impact of climate change on human infectious diseases: Empirical evidence and human adaptation. Environ Int, 86:14-23.
[117] Eurostat (2019). Sustainable development in the European Union Monitoring report on progress towards the SDGs in an EU context.

The development of health technologies, especially at the late stage of clinical development, is an expensive process with **high costs and a long timeframe,** which requires large scale funding. In addition, much of the research on infectious diseases, including clinical trials, needs to be conducted in the areas where a disease is most prevalent taking into account the environmental and social context, including the capacities of the **health systems**. An underdeveloped health infrastructure does not allow vulnerable populations to benefit from newly developed health technologies, especially if they are not adapted to local circumstances and need.

The **low commercial potential** of the research and development on infectious diseases affecting sub-Saharan has discouraged private **pharmaceutical companies** to invest in this area, as their investments are based on the purchasing power of potential clients or health systems. This means that most of the support, also to cover access and capabilities, needs to be provided through **public sources**, which are very scarce in the sub-Saharan region. Moreover, this lack of investment hinders the development of the scientific leadership of African researchers.

Funding from public sources or philanthropies acting separately is not always sufficient and more international development cooperation is needed. It is crucial to **pool enough funding** for the development of these technologies among public funders in different countries and private philanthropies. There is a strong need of economies of scale, better coordination of efforts, avoiding duplications and generating synergies between public and private funders. In addition, more coordination is needed between European governments. The EU has supported the first and second EDCTP programmes that have helped to conduct clinical trials and to develop research capacity in Africa. Most importantly, they have demonstrated that working in partnership delivers. The results have shown that European and African governments can join forces with the EU around common objectives, and create an enabling environment to obtain results that individual countries, or the EU framework programme alone, could not have achieved.

For instance, in the CHAPAS consortium, five research organisations from Zambia, United Kingdom, Ireland, Spain and India, worked on combination antiretroviral formulations for first-line treatment of HIV-infected children. The consortium provided important data on first-line treatment of HIV-infected children in Africa and data to support the current WHO guidelines for first-line paediatric antiretroviral therapy. The results led to licensed combinations for treatment of children. Other type of results are those stemming from the support and coordination actions funding the four Networks of Excellence that address disparities between countries in terms of clinical research capacity. The East Africa Consortium for Clinical Research (EACCR) includes 23 research organisations from Kenya, Sudan, Ethiopia, Tanzania and Uganda. This network has achieved success in terms of capacity building, staff training and research outputs, playing a pivotal role in supporting South-South cooperation in Africa (e.g. training 281 clinicians, 33 Master students, 5 PhD, 5 Post Docs, 8 training courses, and producing 15 scientific publications).

Recent EDCTP2 support to clinical development of tuberculosis vaccines gives another example. Three Phase II multi-site clinical trials were funded. This has helped to build capacity for late stage clinical development. The next step would be a Phase III trial, which costs more than EUR 100 million. This requires even more pooling of resources from several funders and capacity for multi-centre trials. In addition, many of the diseases that the new partnership would be addressing are not only affecting sub-Saharan Africa, but also other parts of the world. In Europe, the most important problem with

tuberculosis is the high rate of antimicrobial resistance, making the infection very difficult and expensive to cure. The clinical trials conducted in sub-Saharan Africa can provide new efficient drugs and vaccines for tuberculosis that can be globally used, also in Europe.

The EDCTP2 programme has also supported more than 50 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa, including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice, and supporting the establishment of functional regulatory systems and capacities for ethical review of clinical research. EDCTP is also a member of the African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. Moreover, EDCTP has established a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF).

It is important to continue public support to a stable, long-term cooperation that only an institutionalised partnership can offer, in order to address a market failure and the low commercial potential for the private sector to develop health technologies that are appropriate for use also in Africa. The **EU has an important role to play** in the funding and facilitating coordination of funders in this area. The strong and long-term support of the EU can provide a sustainable and well-defined funding stream, around a strategic research and innovation agenda, which would encourage Member States, sub-Saharan countries, pharmaceutical industry and other private funders to invest in this area. Therefore the intervention at EU level is necessary with an initiative that would encourage both public and private sector to invest in this area..

Around three quarters of respondents to the **structured consultation of Member States** agreed that a partnership would be more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, underlying the necessity for EU action.

Among respondents to the **open public consultation**, 34 out of 47 respondents indicated that a European partnership of this kind was fully needed to be more responsive towards societal needs and to make a significant contribution to achieving the SDGs.

Interviewees across all stakeholder groups expressed similar opinions on the importance of EU action. A number of **interviewees** furthermore expressly highlighted the EU's moral responsibility to support LMICs, sometimes referring to European values of solidarity. Some interviewees also stressed the need to support Africa as an emerging economy, and an economic partner to the EU. Furthermore, interviewees regularly indicated that EU action is necessary to ensure the continuity of EU investment efforts in R&I for infectious diseases.

3.2. Subsidiarity: Added value of EU action

Coordinated and coherent EU action would help overcome the current fragmentation of research and help to put together a critical mass of organisations and the investment required to address this important global health challenge. Coordinated action will increase the impact and cost-effectiveness of European activities and investments. Moreover, the high application rate to the EU Framework Programmes[118] shows the relevance and attractiveness of the EU support to R&I and the capacity of the EU to convene stakeholders, also in the area of infectious diseases.

[118] Interim Evaluation of Horizon 2020, Commission Staff Working Document, SWD (2017)221 and 222

The Interim Evaluation[119] of EDCTP2 indicated that EDCTP provides an important mechanism for joint discussions and planning, and identified that the co-leadership provided by European and African Participating States is critical to success.

The candidate initiative would facilitate collaboration and strategic response to existing and emerging infectious diseases by acting as a go-between and knowledge broker in a way that would be difficult to achieve for any national actor or initiative. Moreover, because of the strong role that EDCTP has already played in the global health research arena since its establishment in 2003,[120] the new initiative would have a competitive advantage by building upon the success of EDCTP.

During EDCTP2 several European Participating States have contributed to calls for proposals launched by EDCTP with EU funding, increasing the number of projects that could be financed and the chances to better tackle the challenges. However, pooling of funding across participating states has been one of the weaker areas until now. The new initiative will revise the mechanism to facilitate alignment of funding around a strategic research and innovation agenda.

The Interim Evaluation found uneven leadership and gaps in joint leadership among European Participating States, and has recommended that additional efforts need to be done. The Participating States Initiated Activities, initially intended to provide a mechanism for synergistic activities among European Participating States, however to be more effective, this mechanism should be revised.

Sub-Saharan African countries are strong stakeholders of EDCTP, and the new initiative would offer a good platform for better pooling of resources and deepened interaction between the European and African countries.

The **Interim Evaluation** identified efforts and successes to exploit synergies with other EU policy directions. However, the Panel advised that the EDCTP Strategic Research Agenda should include explicit strategic direction with respect to collaborative partnerships that would purposefully exploit synergies with other EU policies. To achieve value-add of EDCTP2 and to align efforts of EDCTP2 with other significant global funders and with politically driven goals and directions, the EDCTP2 Interim Evaluation Panel recommended that EDCTP should develop a strategic policy plan and catalyse the development and strengthening of national health research plans especially for African Participating States.

Interviewees almost unanimously stress the added value of EU investments because of the ability to support large-scale activities, going beyond the remits of national research funders. In addition, some interviewees note that having a dedicated initiative can incentivise additional funding for infectious disease research from national funders and other funding bodies (such as charitable foundations).

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

Based on the problems described in Section 2, the following general objectives have been identified for an initiative supporting an EU-Africa Global Health partnership:

[119] https://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf
[120] http://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf

- To reduce the socio-economic burden of infectious diseases in sub-Saharan Africa through the development and uptake of new or improved health technologies against infectious diseases;
- To increase health security in sub-Saharan Africa and globally by strengthening the R&I-based capacities for preparedness and response to control infectious diseases.

These general objectives are directly aligned with SDG3.3 'By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other infectious diseases' and SDG3.B 'Support the research and development of vaccines and medicines for the communicable […] diseases that primarily affect developing countries, […]'. Likewise, these objectives need to be interpreted in the context of resilience and health systems strengthening. Ultimately, they also support the general objectives of Horizon Europe, in particular that of tackling global challenges, including the SDGs.

An initiative in this area would mainly focus on conducting clinical trials in the field of infectious diseases and building clinical research capacity in sub-Saharan Africa.

Both in the structured open consultation of Member States and in the dedicated interviews performed for the study supporting this impact assessment,[121] some respondents have argued that whilst a focus on diseases affecting sub-Saharan Africa is appropriate, this should not exclude the possibility of supporting activities that are outside of the region when they are relevant to sub-Saharan Africa. This could include the ability to support large multi-centre clinical trials, with some of the trial sites located both in Africa and, for example, in Asia or Latin America. This concerns also the objective to contribute to the control of (re-)emerging infectious diseases, of relevance in sub-Saharan Africa, with global impacts.

The large majority of **interviewees**, regardless of the stakeholder group they represent, support the outlined general objectives for the candidate initiative. Interviewees also acknowledge the rise of non-communicable diseases in Africa and see many ways in which the candidate initiative could address them. However, they also state that maintaining the focus on infectious diseases is essential to ensure that research funding is adequate and can lead to substantial progress.

The **specific consultation of African countries** reflected that for the African countries the most important objectives of the current EDCTP2 were: 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. The study also reflected the importance of contributing to the regional and global health research agenda and informing about the most appropriate products and interventions for health security.

4.2. Specific objectives

In order to achieve the general objectives, four specific objectives, which respond to each of the problem drivers discussed in Section 2.2, have been identified together with indicative targets:[122]

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

[122] Indicative targets based on the experience of the EDCTP2 programmes and if the initiative could have a similar budget size as of the EDCTP2 programme.

1. Advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of clinical trials in sub-Saharan Africa.
    - Target: by the end of the initiative to have progressed to license at least two new or improved health technologies in the field of infectious diseases; to deliver evidence to be able to issue 30 guidelines for improved or extended use of existing health technologies; and to have progressed the clinical development of approximately 30 candidate health technologies.

2. Facilitate better alignment of R&I funders around a common strategic research and innovation agenda to increase the cost-effectiveness of European public investments.
    - Target: by the end of the initiative to have launched joint actions with other public and private funders, and increased the budget of the joint actions to at least EUR 500 million compared to EUR 300 million under EDCTP2.

3. Strengthen research and innovation capacity and the national health research systems[123] in sub-Saharan Africa for tackling infectious diseases.
    - Target: by the end of the initiative to have supported at least 50 coordination and support actions and at least 250 fellowships, reinforcing the environment for conducting clinical trials in sub-Saharan countries, and in compliance with fundamental ethical principles and relevant national, Union and international legislation.

4. Strengthen capacity in sub-Saharan Africa for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of (re-)emerging diseases of epidemic potential.
    - Target: by the end of the initiative to have strengthened the preparedness of 100 research institutes in at least 30 sub-Saharan countries for an effective and rapid research response to develop essential diagnostics, vaccines and therapeutics to tackle re-emerging epidemics in accordance to international health regulations.

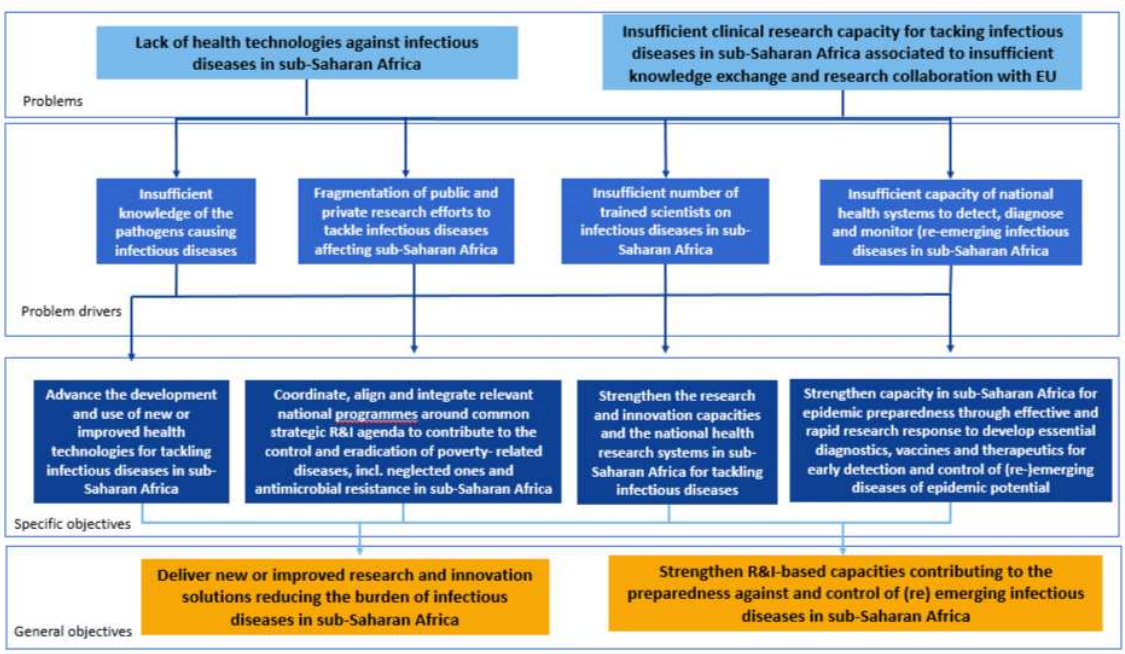
The research priorities should be established in an objective-orientated manner in order to accelerate results and contribute to the control and eradication of poverty- related diseases, including neglected ones, (re-)emerging epidemics, antimicrobial resistance and co-morbidities in sub-Saharan Africa.

4.3. Intervention logic of the initiative

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

Figure 8: Intervention logic for the initiative EU-Africa Global Health

[123] Following the WHO-AFRO Research for Health: a Strategy for the African Region, 2016-2025 https://www.afro.who.int/publications/research-health-strategy-african-region-2016-2025



The lack of health technologies, the fragmentation of the research efforts, the insufficient research capacity for tackling infectious diseases in sub-Saharan Africa, and the insufficient capacity of the sub-Saharan Africa national health systems to detect, diagnose, and monitor emerging infectious diseases, are to a large extent consequence of the insufficient knowledge of the pathogens causing the diseases, the fragmentation of the research funding efforts, the insufficient number of trained scientists in sub-Saharan Africa, and the insufficient R&I capacity of the national health systems in these countries.

The partnership will address the problem drivers by advancing the development of new or improved health technologies in sub-Saharan Africa, facilitating the alignment of the different R&I funders in the region, strengthening the R&I capacities of the national health research systems in sub-Saharan Africa and the preparedness capacity for a rapid R&I response to develop essential diagnostics, vaccines and therapeutics for early detection and control epidemics, which are the specific objectives of the initiative. To reach such ambitious objectives the partnership will need to involve as many partners as possible, from both, public and private sectors, and that all of the partners can commit for a long period of time.

How would success look like?

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

Scientific impacts

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

- Strengthened EU scientific excellence in clinical research for infectious diseases;
- Increased scientific leadership of sub-Saharan Africa in the infectious diseases field;
- Increased research response capacity to control of (re-)emerging epidemics in sub-Saharan Africa;

- Increased evidence base for national and international health policy-making (bridging the gap between science and policy for health).

Economic/technological impacts

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

- Increased research capacity of institutions in sub-Saharan Africa to design, conduct and manage infectious disease research projects;
- Higher capacity of the research institutions to attract funding;
- Increased industry participation in research projects in sub-Saharan Africa;
- Increased number of employed researchers in sub-Saharan Africa.

Societal impacts

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

- Higher retention of scientific talent in sub-Saharan Africa;
- Increased uptake of new or improved health technologies;
- Increased gender equality (Tropical diseases can disproportionally affect and disadvantage women),[124] increasing the protection of the fundamental rights.

The initiative can contribute to better living conditions in sub-Saharan Africa, particularly by increasing and building the capacity of the health research systems and addressing issues affecting vulnerable populations (e.g. women and children).

As the initiative is expected to contribute to reduce disease burden in sub-Saharan Africa and increase employment opportunities, these will also have an impact on poverty reduction and will have a direct effect on an individual's quality of life and social opportunities.

Because it is intended to accelerate the development and production of new health technologies, including pharmaceutical products, the initiative has the potential for negative environmental impacts resulting from pharmaceutical production. Pharmaceutical pollution forms a significant threat to population health and ecosystems globally.[125] On the other hand, this risk would be mitigated with the aim of the new initiative to use new appropriate technologies with a reduced risk to the environment.

Interviewees across different stakeholder groups expect that the Initiative will have the ability to create impact in the societal domains, particularly through improving access to medicines, reducing disease burden, and encouraging development of the African scientific leadership.

[124] Uniting to Combat Neglected Tropical Diseases (2016). Neglected tropical diseases: women and girls in focus. Summary report of meeting held on July 27-28, 2016 in London, UK. Available at: https://unitingtocombatntds.org/wp-content/uploads/2017/11/women_and_girls_in_focus_english.pdf

[125] Maghear A, Milkowska M (2018) The environmental impact of pharmaceutical manufacturing: how does industry address its own waste? Health Care Without Harm, Belgium. Available at: https://noharm-europe.org/sites/default/files/documents-files/5731/2018_PharmaceuticalIndustryReport_WEB.pdf

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

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

Type and composition of the actors to be involved

The partnership will harness the investments of the EU, the EU Member States and Associated States to the Framework Programme and African countries. In addition, for specific trials or diseases, philanthropies, industry and other third countries will join and contribute to the partnership.

The motivation for the **EU, European and African countries** comes mainly from the successes of 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. The governance of EDCTP2 is based on an EDCTP Association that provides meaningful participation and involvement of the sub-Saharan countries in the decision-making, essential for tackling the burden of diseases in sub-Saharan countries.

For example, EDCTP PREGACT studies have generated key evidence on malaria treatments for pregnant women who are particularly susceptible to malaria. These studies involved several countries in Africa: Burkina Faso, Ghana, Malawi and Zambia, (to be able to better study exposure) and several partners in Europe: Austria, Belgium, The Netherlands and United Kingdom, harnessing the necessary multidisciplinary teams to study such a complex disease as malaria and transfer knowledge to African scientists.

In addition, to further leverage larger and sustained funding and to play a stronger global health leadership than the current EDCTP2, the candidate partnership should be able to answer to the emerging infectious diseases threats, exacerbated by the COVID-19 pandemic, and to the ever increasing problem of antimicrobial resistance and co-morbidities with non-communicable diseases, requiring to coordinate with other funders[126] and to speed up research by harnessing different investments. Therefore, the initiative should include other international research funders, such as the philanthropies and pharma industry as contributors that will contribute to the partnership on *ad hoc basis*. Based on this ambition, the new global health partnership should evolve from EDCTP2 framework to be more inclusive and to have a broader base of funding from partners, which the EU funding can also match.

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

[126] As recommended by the Evaluation of the impact of the European Union's research funding for poverty-related and neglected diseases – Lessons from EU research funding (1998-2013) https://op.europa.eu/en/publication-detail/-/publication/1f324128-a4c1-11e7-837e-01aa75ed71a1/language-en

RTS,S malaria vaccine candidate) and they are therefore seeking partners to join forces with. These philanthropies have flexibility in their investments and can act speedily when new developments emerge or in the case of a public health emergency.

The Ebola epidemics in West Africa and the Democratic Republic of Congo have 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,[127] GSK[128]) 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. While industry has already taken part in some projects under EDCTP2, the limitations were that it was done on an ad hoc basis for a specific disease, and no forward looking dialogue to plan for potential further investments. 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. This is to be seen in contrast to the proposed Innovative Health Initiative partnership that focuses on research on 'integrated' product development that will help transform health systems in Europe, explicitly integrating the pharma, med tech and digital industries.

The current COVID-19 pandemic and the ongoing EU led Coronavirus Global Response pledge[129] illustrate the need for the public sector, philanthropies and the industry to join forces to combat infectious threats effectively. All these partners working around the same strategic research agenda are seeking partners for cooperation so that they jointly can support larger clinical trials as well as fund research capacity building more efficiently, therefore achieving greater the impact.

Other essential stakeholders such as researchers, scientific leaders and clinical product development experts, product development partnerships, that have often been crucial for ensuring the final development of products and their delivery of to the market,[130] and national and international institutions focused on infectious disease research (e.g. WHO-TDR, GHIT[131]), etc., will also participate but through calls for proposals, projects, consultative groups, etc.

The **Interim Evaluation of EDCTP2** recommended that, 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. Furthermore it recommended that EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships.

The EDCTP2 **Interim Evaluation Panel** recommended that in order to reach its full potential and ambitious goals, 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 Participating States and the EC. The Participating States should enhance the executive and political level of EDCTP General Assembly representatives and ensure that representatives are clear on their responsibility to report

[127] https://www.jnj.com/responsibility/
[128] https://www.gsk.com/en-gb/responsibility/
[129] https://global-response.europa.eu/index_en
[130] The Initiative on Public-Private Partnerships for Health, Global Forum for Health Research (2004). Combating Diseases Associated with Poverty - Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships. Available at: http://www.who.int/intellectualproperty/topics/ppp/en/CombatingDiseases-Abridged.pdf
[131] The Global Health Innovative Technology (GHIT) Fund focuses on investments in the discovery and development of medicines, diagnostics and vaccines (referred to as health technologies) for TB, malaria, NTDs and other diseases. The GHIT Fund supports partnerships and identifies global opportunities for collaboration with Japanese organizations involved in the R&D of global health technologies.

back to their respective government agencies that have the mandate to deliver on their governments' commitment to EDCTP.

In the **specific consultation of African countries**, 94 (81.7%) of the 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector including industry and foundations. However, the majority of the responders thought it was a highly risky venture. The main risks identified relate to conflicts of interest and loss of control.

Type and range of activities needed

The candidate initiative should first and foremost be an instrument for funding **collaborative research and innovation actions**, in particular, those focused on the clinical development of health technologies for prevention, diagnosis and treatment of infectious diseases affecting sub-Saharan Africa, as well as supporting the portfolio approach.

The candidate initiative should also play a significant role in the strengthening of research capacity in sub-Saharan Africa. For this, it needs to fund **coordination and support actions** that allow for, among other things, creation and strengthening of networks of excellence, supporting the **career development and scientific leadership** of African researchers, actions to support **knowledge dissemination**.

All stakeholders indicate that funding and implementation of research and innovation actions should be the primary focus of the initiative. Stakeholders view late-stage clinical trials as the primary area, where initiative can deliver direct impacts, while lower, in financial terms, share of the investment should be directed at capacity building activities.

The **EDCTP2 Interim Evaluation Panel** recommended adopting a portfolio approach in order to use its funding instruments (including competitive calls) more strategically, to enhance the value-add of EDCTP and maximize impact. The Panel viewed 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. To support the networks in achieving this next phase of their evolution, the level of funding for networks should increase.

The **EDCTP2 Interim Evaluation Panel** recommended to 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, and assess opportunities in this area to strategically align with other funders and programmes on career development.

The **specific consultation of African countries** revealed that clinical epidemiology activities should also be included in the follow up programme. This consultation also stressed the lessons learned from the COVID-19 pandemic with the critical role played by the regional entities, like Africa CDC and WHO-AFRO as well as the EDCTP Regional Networks of Excellence, for managing public health emergencies.

Directionality and additionality required

Directionality

One of the drivers for the current lack of health technologies for tackling infectious disease is the fragmentation of research and innovation efforts in this field. A jointly agreed **strategic research and innovation agenda** is therefore needed so that the shared vision aligns with the individual goals of the members of the partnership, and so that all actors have a clear understanding of how the various elements of the initiative will fit

together in a coherent manner, building commitment and trust and contributing to reaching the jointly agreed objective and thus impacts. The strategic vision should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

The candidate initiative thus has an important role to play in bringing together different actors and aligning their efforts around a common strategic vision and research agenda, reducing duplication of efforts. To be able to do so, there is the need to have a credible and strong position within the stakeholder landscape. EDCTP is already widely recognized as a key player, as confirmed by various stakeholders throughout the consultation and evident in the substantial research output to which it has contributed. Therefore, a new initiative, building on EDCTP2 would have real potential to further focus and strengthen the measures of various countries and organisations towards common global health goals.

Although EDCTP has positioned itself as a key research funder and contributor to the global health research agenda, it could better align its partners' national efforts. Most of the contributions by the Participating States have been delivered in-kind, through Participating States' Initiated Activities.[132] At present, these activities need to be in line with the overarching objectives of EDCTP, to be included in the EDCTP2 Annual Work Plans and, once they are executed, to be formally approved by the EC, before their value can be matched from the EU budget. As currently there is no compulsory requirement for the Participating States to align each other's activities, as a result there have been problems in terms of directionality and duplications of efforts from the national funding schemes. Therefore in the future partnership, the Participating States would need to demonstrate upfront the added value of being part of the initiative for their activities to be eligible for matching the EU funding.

The **EDCTP2 Interim Evaluation Panel** recommended that 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 Participating States.

Additionality

Being part of the partnership must be viewed as an added value by the countries. As even countries that are not part of the EDCTP Association have been able to participate in all EDCTP-supported activities, there has been limited incentive for formal commitment and alignment of national activities. Therefore, the establishment of an effective partnership arrangement among Participating States to incentivise participation needs to be further developed. Targeted or restricted calls for specific challenges should be further explored.

As a potential incentive, the **Interim Evaluation** suggested that EDCTP country membership should be a requirement for their legal entities applying to EDCTP calls.

The EU contribution is expected to mobilise an additional (at least 100%) funding from Member States and Associated States to the Framework programme, as well as third countries, private funders and industry contribution (in-kind or financial). This type of commitment to pool resources only happens beyond the scope of individual projects and requires long-term predictability and commitment to the jointly accepted strategic research agenda. Thanks to these additional resources, the initiative will ensure the

[132] EDCTP Annual Report 2019 http://www.edctp.org/publication/edctp-annual-report-2019/

necessary leverage to be able to successfully tackle its objectives and deliver on its impacts.

To be able to set up the partnership and reach the expected impact, it will be necessary to reach a level of financing similar to the one under the current EDCTP2.[133] The EU contribution should be at least EUR 700 million with contribution from the partners at least at the same level.

The future partnership with its proposed additional focus on (re) emerging infectious diseases is extremely relevant, also post COVID-19 pandemic, as epidemics are likely to occur more and more often.[134] There is of course a certain level of uncertainty around Member States and African countries, philanthropies and industry's capacity to commit sizeable amounts, seeing the economic impact of the COVID-19 pandemic. Should fewer resources become available, strategic prioritisation will need to be made on the thematic scope and coverage. This would happen at the level of the annual work programme to be co-developed with the stakeholders.

A number of **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.

Interviewees questioned what can be done to increase the incentives to participate and to increase the leveraging effect for the candidate partnership. Some have suggested that certain activities should be accessible only to active participants in the partnership. The Interim Evaluation Panel suggested that only legal entities in participating countries should be eligible for funding.

The **EDCTP2 Interim Evaluation** recommended that EDCTP will need to understand the goals and priorities of Participating States and work with them to align EDCTP strategy and programmes. EDCTP should thus actively support the Participating States in developing their own national research agendas.

The Interim Evaluation also found that 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 African Participating States to engage with less resourceful African nations in all EDCTP activities.

Moreover, EDCTP should initiate a process for in-depth analysis of the outcome of the activities initiated by the Participating States in order to identify synergies, gaps and overlaps. These activities should be prospectively and strategically integrated with EDCTP programmes and calls in order to minimize gaps. In addition, they should be strategically integrated among themselves to efficiently maximize their impact. EDCTP and the EC should jointly modify the entire process around the Participating States Initiated Activities (which are the countries' in-kind contributions to the partnership) to improve efficiency and to enhance impact. The aims of these activities must be articulated with consideration given to how they can be used to enhance strategic value-add of both EDCTP and the Participating States. 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.

[133] At present EDCTP2 has the EU contribution of €683M plus the same amount €683M from the Participating States.

[134] https://www.ncbi.nlm.nih.gov/pubmed/27318484 Nazir et al. Airborne biological hazards and urban transport infrastructure: current challenges and future directions (2016); Duane J. Gluber Dengue, Urbanization and Globalization: The Unholy Trinity of the 21st Century (2011)

Coherence needed with the internal and external environment

Due to its versatility and cross-sectoral integration, the candidate EU-Africa Global Health Partnership should be managed through close collaboration with other programmes and initiatives to create synergies and limit duplications. It is essential to design administrative mechanisms to appropriately address these synergies and complementarities.

The initiative, that promotes clinical research on infectious diseases in sub-Saharan Africa, would have some areas of common interest, with Horizon Europe work programmes and other EU initiatives or programmes with shared objectives to enable effective prevention, diagnosis and treatment of diseases and to facilitate the uptake of new interventions, in the field of infectious diseases.

In Horizon Europe, health is one of the six Horizon Europe clusters under the Pillar II addressing global challenges and industrial competitiveness through targeted funding of collaborative R&I projects. Cross-cluster research on antimicrobial resistance is expected with the future partnership on One Health Antimicrobial Resistance, focused on animal health and its interaction with human health.[135] Within Cluster Health, a very relevant candidate partnership is the One Health AMR, which aims at facilitating the fight against the rise of antimicrobial resistance by coordinating activities and facilitate national coherence between different services and ministries with responsibility for the various aspects of AMR (e.g. human and animal health, agriculture, environment, industry, finances, etc).

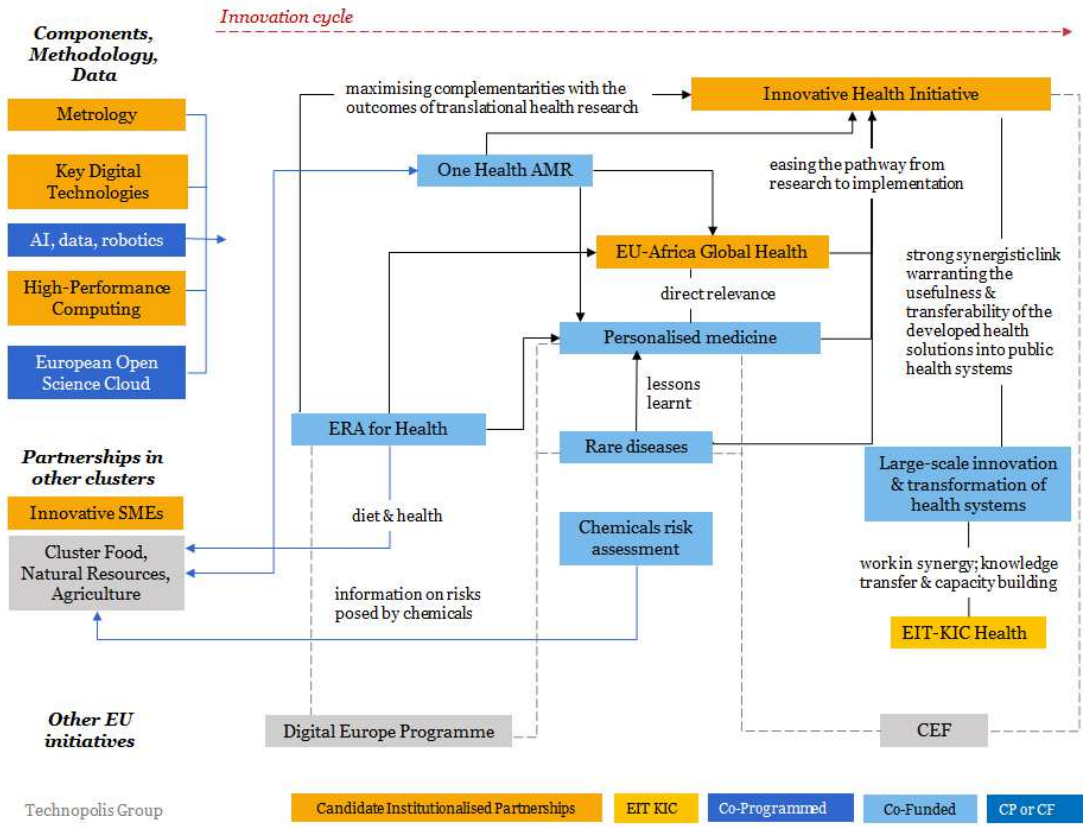
In addition, the Innovative Health Initiative,[136] is expected to contribute to advance the development and uptake of health care technologies and innovations to help transform health systems, mainly in Europe. Some solutions developed under IHI, for example those related to novel health technologies to address infectious diseases or new and validated methods for conducting clinical trials, could be relevant for the EU-Africa Global Health partnership. In addition, methods developed under the candidate public-public partnership on Health and Care Systems Transformation, aiming to facilitate the uptake of those solutions into health care systems[137] might be appropriate for sub-Saharan Africa.

Beyond Cluster Health, the proposed partnership on Key Digital Technologies (successor of ECSEL JU[138]), could provide access to the latest digital technologies and data-driven tools, applicable to several fields. Some of them could prove essential for IHI and GHP/EDCTP3 due to the key role of health data for innovative, integrated health technologies. Another instrument with shared interests in infectious diseases is the InnovFinID[139] and the future EuropeInvest of the European Investment Bank that foresee support through loans in the infectious diseases area.

[135] https://ec.europa.eu/health/amr/antimicrobial-resistance_en
[136] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11906-European-Partnership-for-innovative-health
[137] It is important to emphasise that solutions proposed by IHI would be concrete goods or services (e.g. medicines, diagnostics, medical devices incl. digital tools etc) rather than organisational solutions. Organisational processes will be in the remit of health care authorities/organisations to consider whether and how these could be deployed in the best way.
[138] https://www.ecsel.eu/
[139] https://www.eib.org/en/products/blending/innovfin/products/infectious-diseases.htm

Potential initiatives in the Health cluster, where complementarities and interconnections are expected, both in terms of research topics covered and stakeholders involved are shown in the Figure 9 below.

Figure 9: EU initiatives related to the SDG 3



The problems that the candidate initiative would address are highly complex and are set in the context of weak health systems and institutions for the delivery of health care. This was particularly evident in the devastating 2014–2016 Ebola Virus Epidemic in West Africa.[140]

The candidate partnership aims to support the research and the strengthening of the health research systems in sub-Saharan Africa, and will need to seek for synergies with the EU programmes and initiatives that aim to build resilient and responsive health systems and to implement the International Health Regulations in the region, so that health innovations can be accessible to the poorest populations. The development aid is to be provided through the EU instruments of the Development Cooperation and External Action, the future European Neighbourhood, Development and International Cooperation Instrument,[141] the Universal Health Coverage Partnership[142] and other initiatives in the region, including the support to global initiatives such as The Global Fund,[143] GAVI the Vaccine Alliance[144] and the Global Financing Facility.[145]

These instruments also support health systems in case of public health emergencies by fast-tracking approval and subsidizing their delivery in countries once a health

[140] WHO. 2020. Ebola virus disease. https://www.afro.who.int/health-topics/ebola-virus-disease
[141] https://ec.europa.eu/commission/publications/neighbourhood-and-world_en
[142] https://www.uhcpartnership.net/
[143] https://www.theglobalfund.org/en/
[144] https://www.gavi.org/
[145] https://www.globalfinancingfacility.org/

technology is available, strengthening regional health security organisations and supporting epidemiological surveillance. The EU Emergency Trust Funds,[146] provides emergency medical assistance and support in basic health services to irregular migration and displaced persons in Africa.

The support will be done in a coordinated fashion with the European Centre for Disease Prevention and Control (ECDC) and the African CDC (ACDC), both in human capital (doctors, nurses, community health workers, technicians etc.) and in infrastructures (hospitals, equipment, vehicles etc.), which are necessary. In case of outbreaks, the initiative will also contribute and take into account the recommendations of GloPID-R,[147] the unique international network of the major research funding organizations to facilitate a rapid and effective research response.

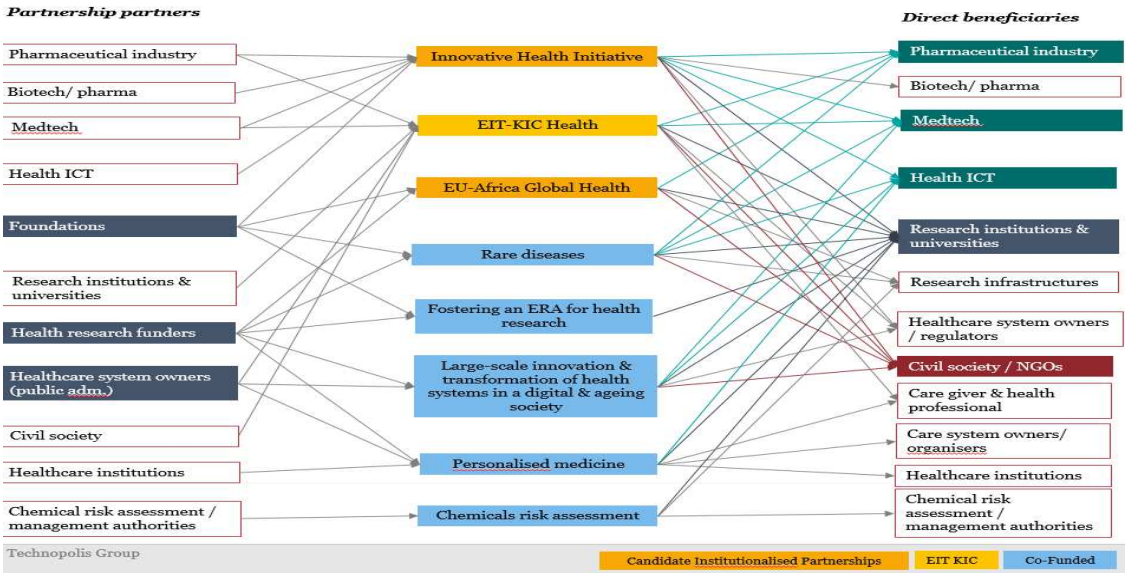
Whilst development of new health technologies is essential, they cannot be used unless they are authorized for use where they are needed. The regulatory capacity in Africa for assessment and approval of medicines, as well as for conducting post-authorisation pharmacovigilance is still weak. Here, the recently established African Medicines Agency (AMA) will have an important role to play and the initiative will contribute to it through the regulatory capacity building and through interactions with AMA and other agencies, such as the European Medicines Agency (EMA) and the US Food and Drug Administration (US FDA).

The candidate initiative will need to actively pursue synergies through consultative mechanisms or partnering on ad-hoc basis with other initiatives or programmes taken by other funders with shared objectives to enable effective prevention, diagnosis and treatment of diseases and to facilitate the uptake of new interventions (Figure 10). Therefore, it is important to position the candidate initiative clearly in the global health spectrum to avoid duplications. This initiative will be focused on clinical development and uptake of health technologies addressing infectious diseases affecting sub-Saharan Africa.

The **EDCTP2 Interim Evaluation Panel** recommended that 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 communication role within EDCTP will require considerable networking and coordination across Participating States to identify synergies and to achieve better alignment and coordination with their clinical research activities in sub-Saharan Africa.

[146] https://ec.europa.eu/trustfundforafrica/index_en
[147] https://www.glopid-r.org/

Figure 10: Potential synergies with the stakeholders of the EU-Africa Global Health Partnership candidate



As in the case of internal coherence, **interviewees widely agree** that the candidate partnership should coordinate its efforts with other key stakeholders in the field, often without being specific. Some have noted a proliferation of initiatives, some of which appear to share focal areas with the candidate partnership. In addition to EU programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and the Bill & Melinda Gates Foundation. These interviewees indicated that it will be important for the candidate partnership to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities.

The **EDCTP2 Interim Evaluation** recommended that EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged, and complementary programmes aligned for greater impact and reach. In addition, EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships and current communication strategy to become more focused on building relationships and dialogue with Participating States governments and European and International funders and stakeholders.

The **EDCTP2 Interim Evaluation** also recommended that the function of strategic communication and advocacy within EDCTP should be elevated to the highest level of leadership. Closer coordination and planning between the EC leadership and the EDCTP Secretariat and General Assembly will also help to achieve the level of communication and advocacy needed. These coordinated leadership roles will require a mind-set change across organizations and individual leaders.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

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

5.1. What is the baseline from which options are assessed?

Baseline: Traditional calls under the Framework Programme

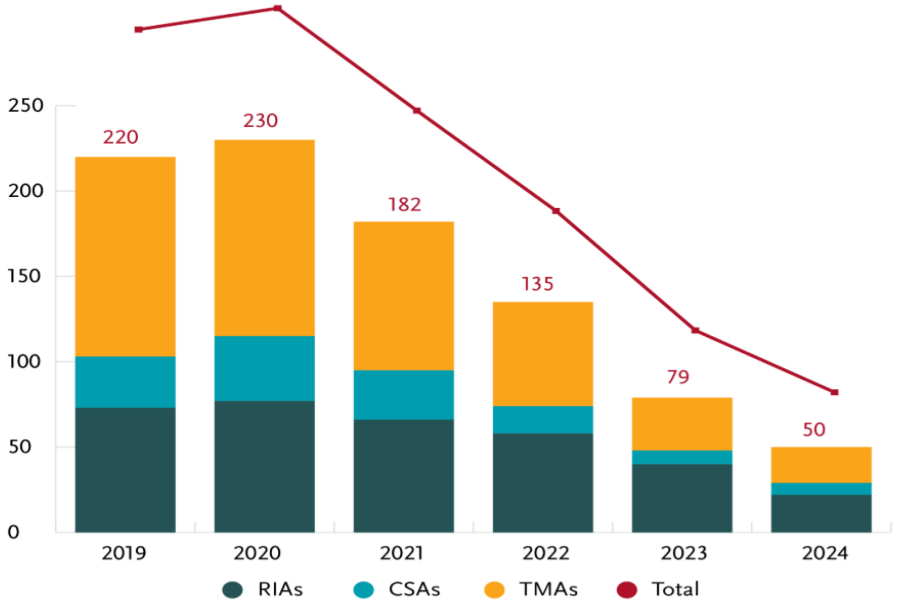
The baseline scenario used in this impact assessment is a situation without a Partnership, where traditional calls under the Framework Programme, Horizon Europe, are the means

to award grants. Given that there is a predecessor Partnership, the current EDCTP, as well as other funders in the area, most probably will continue collaborations, even if to a lesser extent, generating outputs and results of relevance even in the absence of a new Partnership. It is expected that these already existing initiatives will still have an impact on the burden of infectious diseases. This is taken into account in the effectiveness assessment of the baseline.

In parallel, the baseline option means that the current implementation structure of the Article 185 would be closed, which bears winding down and social discontinuation costs. Traditional calls would represent financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

The closing down of the current EDCTP2 programme is shown in Figure 11. The last EDCTP2 calls, launched during 2020, take into consideration the need to wind down, asking for a shorter duration of projects.

Figure 11: Predicted attrition of EDCTP2 projects (2019-2024)



Notes: RIA: Research and Innovation Actions; CSA: Coordination and Support Actions; TMA: Training and Mobility Actions.

It will be important to take into consideration in this projection another consequence of COVID-19 pandemic and its confinement measures: many of these projects will be obliged to extend their duration by half a year in order to be able to execute them as planned.

Table 2: Key characteristics of the baseline - Traditional calls

Functionalities of option	Key characteristics of Traditional calls
Enabling appropriate profile of participation	Partners: There are no partners, and no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning. Given the broad range of activities, the Commission would need to consult with a large group of stakeholders, both from Europe and Africa, to develop the Horizon Europe annual work programmes.

	Participation in R&I activities: fully open in line with standard Horizon Europe rules No common set of actors that engage in planning and implementation. Participation in traditional calls is open to any Horizon Europe eligible legal entity within a consortium. This includes research organisations in Africa, although these are not automatically eligible for funding.
Supporting implementation of R&I agenda	Activities: Horizon Europe standards that allow broad range of individual actions. Calls for proposals would be published in the work programmes of Horizon Europe. No additional activities and investments outside the funded projects. Implementation would rely on standard infrastructure underpinning the open calls procedure, drawing on resources of the Commission or relevant executive agency and Commission IT systems No systemic approach beyond individual actions. Transparency and open publication of results would ensure their availability to all interested parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Strategic programming and the research agenda would be defined by the European Commission via co-creation, with the support of an advisory group and the programme committee. Work programmes would need to reflect the requirement for R&I activity across the health technologies clinical development, with input from representatives of all relevant stakeholders. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap
Securing effective leveraging of resources	Internal coherence between different parts of the Annual Work programme can be ensured by the Commission. This option does not require upfront determination of a budgetary EU envelope. External coherence limited for other Union programmes, no synergies with national/regional programmes and activities.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme. With traditional calls under Horizon Europe, there is no common set of actors nor a long-term commitment as the maximum duration of a SRIA or roadmap would be 4 years. The baseline does not foresee a dedicated implementing structure to help leveraging resources.

5.2. Description of the European Partnership policy options

Option 1 – Co-programmed European Partnership

The co-programmed partnership is based on a Memorandum of Understanding of the partners (the EU, Member and Associated States, African countries and/or other Third countries), or another non-legally binding contractual agreement, around a common strategic research and innovation agenda. The contributions may be financial or in-kind, and any financial risks would be covered by the parties' own contributions to the partnership. The EU calls would be published through the Horizon Europe Work Programme. A co-programmed partnership does not require a separate legislative procedure, and the EU budget is managed by the EC or an EC executive agency.

Table 3: Key characteristics of Option 1 – Co-programmed

Functionalities	**Key characteristics of Option 1 – Co-programmed**

of option	
Enabling appropriate profile of participation	Partners: Suitable for all types: private and/or public partners, philanthropies. Based on a declaration of intentions, the co-programmed option enables participation from any kind of partner; EU Member States and Associated States to the Framework Programme, as well as African countries, charitable foundations and the pharmaceutical industry. The composition of partners can change over time, allowing for flexibility and adaptation to emerging needs and priorities in the global health arena 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; the relationships built under the current EDCTP can be maintained.
Supporting implementation of R&I agenda	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake. The co-programmed partnership allows the Commission to launch collaborative R&I actions, coordination and support actions, and training actions towards a common strategic agenda launched through the Horizon Europe annual work programme Additionality: Activities/investments of partners and national funding. Limitations: Limited systemic approach beyond individual actions. Other partners would have limited control over the precise definition of the EU calls, limiting the extent to which calls can be adapted to the specific needs of certain partners. This may hinder the possibility to issue *ad hoc* joint calls with other parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. Input to FP annual work programme drafted by partners, finalised by EC (comitology). Under the co-programmed option, a strategic roadmap is agreed between the EC and the partners involved. All partners can contribute to the development of the work programme, but not to the implementation of the calls and actions themselves. Objectives and commitments are set in the contractual arrangement or Memorandum of Understanding. The alignment with other initiatives and parties outside of the partnership would be the responsibility of the EC, or EC Agency, in charge of the programme implementation
Securing effective leveraging of resources	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM. This option allows an upfront EU budgetary envelope. Commitments by partners only represent political/best efforts, but these are usually honoured. External: Limited synergies with other Union programmes and industrial strategies as well as with national/ regional programmes and activities. This option allows for the creation of a dedicated small office to manage the coordination of the partners contributions and alignment with the R&I agenda. Under the Co-programmed option, both cash and in-kind contributions can be leveraged for increased impact.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme. With Co-Programmed option, there is a limited systemic approach beyond individual actions. Other partners would have limited control over the precise definition of the EU calls, limiting the extent to which calls can be adapted to the specific needs of certain partners.

Option 2 – Co-Funded European Partnership

A Co-Funded partnership is based on a Grant Agreement between the Commission and a consortium of public partners (particularly research funders), with a certain degree of flexibility for the involvement of philanthropies and international partners. Whilst public

sector partners can make contributions and formal commitments to the partnership, industry can only apply to calls for proposals. Partner contributions are often financial contributions used for calls for proposals but can also be in-kind.

Table 4: Key characteristics of Option 2 – Co-Funded European Partnership

Functionalities of option	Key characteristics of Option 2 – Co-Funded European Partnership
Enabling appropriate profile of participation	Partners: core of national funding bodies or governmental research organisations. A Co-Funded partnership would be mainly limited to public sector parties and possibly philanthropies. Industry parties would not be able to contribute to the partnership but could be involved in activities (projects). Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries. Under national rules, Member States could issue calls open only to legal entities from countries that are part of the partnership. This form of implementation requires partners (Member States, Associated States, but also charities, product development partnerships, international organisations, among others) to sign a Grant Agreement. Collaborations built under EDCTP, including those with African countries under the EDCTP Association, could be largely maintained, although the type of involvement of parties would be different than under EDCTP.
Supporting implementation of R&I agenda	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake. Based on a EU Horizon Europe Grant Agreement between the Commission and the consortium of participating partners, this option would allow for the support of a broad range of R&I activities, coordination and support actions and training of researchers and technical clinical support, around a strategic R&I agenda. Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale. Other partners would have limited control over the precise definition of the calls, limiting the extent to which calls can be adapted to the specific needs of certain partners. This may hinder the possibility to issue ad hoc joint calls with other parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC. A Co-Funded partnership will have a strategic R&I agenda/roadmap, to be agreed between partners and the EC, and the joint drafting of an annual work programme 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. A large number of parties (Member States, Associated States, Third countries, private funders, product development partnerships, etc.) would likely need to be included in the Grant Agreement.
Securing effective leveraging of resources	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. The Co-Funded partnership option allows for leveraging the commitments made by partners from the EU budget. This includes both financial and in-kind contributions. This form of partnership represents a high degree of political commitment from partners as the funding is committed upfront. This option allows for the creation of a dedicated 'programme office', within one of the beneficiary organisations, to manage the coordination of the partners contributions and alignment with the R&I agenda.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme.

	With Co-Funded option, there is the limitation in the participation to only public organisations and philanthropies. Member States could issue calls open only to legal entities from countries that are part of the partnership.

Option 3a and 3b - Institutionalised European Partnerships

The institutionalised European partnerships are subject to implementation under Article 185 or Article 187 of the Treaty on the Functioning of the European Union (TFEU). Both types of initiatives are governed through separately established entities, with partners tied through legally binding commitments. The flexibility of these partnerships is limited since the composition of partners cannot be changed easily, and the strategic priorities and goals are set in advance. The implementation of activities is set up through a specifically created entity (Dedicated Implementation Structures (DIS) or Joint Undertaking (JU) respectively) with a mandate to launch calls and distribute grants based on the annual work programmes, which are approved by the EC.

For both partnership types, contributions from partners can be in-kind and financial, while EU financial contributions are implemented through matching mechanisms and are distributed through the dedicated entity. In both cases, the financial risk at the project level would be covered by the Mutual Insurance Mechanism of Horizon Europe (the former Participant guarantee funds).

The below paragraphs outline the key differences between these two types of institutionalised partnership in relation to the candidate EU-Africa Global Health Partnership.

Option 3a – Institutionalised European Partnership under Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and Associated Countries, aimed at achieving the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of public research investments. Involvement is limited to Member States and Associated States. Non-associated countries can only participate if foreseen in the basic act, and their participation is subject to concluding individual international agreements. Under EDCTP2, African countries can take part indirectly in the partnership through their involvement in the EDCTP Association, a private association under Dutch law. Private sector actors or charitable foundations cannot formally join the partnership and, whilst they can be partners in specific activities, their contributions cannot be matched from the EU budget. This form of partnership requires participation of at least 40% of all EU Member States.

Table 5: Key characteristics of Option 3a – Institutionalised European Partnership – Article 185 TFEU

Functionalities of option	**Key characteristics of Option 3a – Article 185 TFEU**
Enabling appropriate profile of	Partners: National funding bodies or governmental research organisation. This form of partnership is open only to Member States and Associated States, represented by public sector organisations. Third countries, private sector organisations and charitable foundations can be involved indirectly, through the partnership's projects, and their

participation (*actors involved*)	contributions cannot be matched from the EU budget. 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. EU funding is open to legal entities in all Member States and Associated States, as well as third countries if eligible for funding under Horizon Europe.
Supporting implementation of R&I agenda (activities)	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach. Implementation of activities would be responsibility of the Dedicated Implementing Structure, the existing EDCTP Association, which will publish the calls for proposals. Additionality: EU plus national funding.
Ensuring alignment with R&I agenda (directionality)	Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. By participating in the development of a common strategic agenda, partners are encouraged to improve their alignment and transnational cooperation. Annual work programme drafted by partners, approved by EC Objectives and commitments are set in the legal base.
Securing leveraging effects (additionality)	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. National R&I activities can be integrated into the programme, and can then be matched from the EU budget to increase the synergies and promote transnational cooperation. Legally binding funding requirements would be clearly defined at the outset, with partners other than the EU expected to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments. This form of partnership comes with very high visibility and political commitment from partners with upfront commitments. A Dedicated Implementation Structure (DIS) would be responsible for implementing the programme and aligning partners around a shared strategic agenda jointly prepared with the EC. The DIS would also look for synergies between EU and national/regional programmes and activities, as well as with other EU and international programmes or initiatives.
Key differences compared to the current situation	Article 185 option is the current situation. No difference.

Option 3b – Institutionalised European Partnership – Article 187

Whilst the Institutionalised Partnership under Art. 187 shares many characteristics with that under Art. 185, a key difference lies in the possibility of involvement of partners beyond the Member States and Associated States. Under Art. 187 private sector actors and charitable foundations can be included in the partnership and their contributions can be matched from the EU budget. Similar to the Art. 185 option, participation of non-associated countries is possible if foreseen in the basic act. The implementation of the programme is usually managed by a Joint Undertaking, with the European Commission being fully involved in the governance. In comparison with Option 3a under Article 185, which is a Member State led programme where the Commission acts as an observer in the Board, in an Article 187, the Commission will have co-ownership of the programme and will be sitting in the Board, thus participating fully in the decision-making process.

Table 6: Key characteristics of Option 3b – Institutionalised European Partnership under Article 187 TFEU

Functionalities of option	**Key characteristics of Option 3b – Article 187**

Enabling appropriate profile of participation (*actors involved*)	Partners: Suitable for all types: private and/or public partners, philanthropies. This form of partnership would enable participation by the key global health stakeholders, contributing to the development and execution of the strategic R&I agenda. It is open to Member States and Associated States, represented by public sector organisations, as well as private sector organisations and charitable foundations. Third countries can participate if foreseen in the basic act. 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. EU funding would be open to legal entities in all Member States and Associated States, as well as third countries if eligible for funding under Horizon Europe. Funding is not limited to institutions from countries in the partnership.
Supporting implementation of R&I agenda (*activities)*	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. Implementation of activities would be the responsibility of a Joint Undertaking. This form of partnership allows for funding of R&I activities, as well as coordination and support actions and capacity building. This full mix of activities is foreseen as needed for the fulfilment of the candidate partnership's objectives. Additionality: Activities/investments of partners including national funding.
Ensuring alignment with R&I agenda (directionality)	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. By participation in the development of a strategic agenda, partners are encouraged to improve their alignment and transnational cooperation. Annual work programme drafted by partners, approved by EC (veto-right in governance). Objectives and commitments are set in the legal base.
Securing leveraging effects (additionality)	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC. External: Synergies with other Union programmes, industrial strategies, philanthropies and Member States with national/ regional programmes and activities. National R&I activities can be integrated into the programme, which can then be matched from the EU budget to increase the synergies and promote transnational cooperation. Legally binding funding requirements would be clearly defined at the outset, with partners other than the EU expected to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments. Each partner's contribution can be matched from the EU budget.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme. With an Article 187 option, in addition to Member States and Associated States, other key global players would be able to join the initiative, and also contribute to the partnership. These are philanthropies (BMGF, Wellcome Trust, etc.), industry (EFPIA, etc.) and other third countries (e.g. United Kingdom, Japan, etc.) and they can participate on ad-hoc basis. Moreover, all these partners contributions would be able to be matched by the EU contribution, increasing the leveraging effect and the coherence of the initiative.

5.3. Option discarded at an early stage

The Co-Funded partnership is unlikely to be feasible for the EU-Africa Global Health Partnership because this form of implementation only allows for public partners (mainly EU Member States and sub-Saharan countries) to participate in the partnership. Industry, which is a key player in the global health area, would not be able to contribute to the partnership, but could only be involved in specific activities (projects). In addition, only

legal entities from countries that are part of the partnership can apply to calls. This means that institutions from non-participating countries would not be able to receive funding. This could hinder access of certain sub-Saharan African countries that are unable to participate in the partnership. Moreover, it is also very unlikely that this form of partnership would be able to raise the amount of funding needed to have a significant impact. This option has thus hereafter been discarded from further assessment.

Although the option of Article 185 also has the disadvantage that key partners, such as industry, can only participate at project level, we have included the assessment of the Article 185 option, since it is the current set up of EDCTP2.

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

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

6.1. Effectiveness

To be in line with the Horizon Europe impact framework,[148] the achievement of the initiative's specific objectives is translated to 'expected impacts' – i.e. how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow in **delivering these expected impacts** – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system.

In line with the Better Regulation guidelines,[149] the baseline has a score of 0 and is used as a basis for comparison for the other options. The other options receive a score of 0 if they have the same potential as the baseline, a score of (+) if they have a *good* potential compared to the baseline and a score of (++) if they have a *high* potential compared to the baseline.

Scientific impacts

Baseline: Horizon Europe traditional calls

Under the baseline option, calls for proposals launched under the Horizon Europe Health Cluster could focus on: the development of new or improved health technologies to strengthen the EU's scientific excellence in clinical research on infectious diseases

[148] https://ec.europa.eu/info/publications/horizon-europe-impact-assessment-staff-working-document_en

[149] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

relevant to sub-Saharan Africa, increasing the scientific leadership of African researchers, increasing the capacity of the research response to effectively control (re) emerging epidemics in sub-Saharan Africa, and increasing evidence base for national and international health policy-making (bridging the gap between science and policy for health).

Horizon Europe calls are expected to lead to scientific discoveries that are of a precursory and exploratory nature and that lead to the elucidation of the underlying mechanisms of health and disease conditions. Therefore under this option there would be a potential to establish new scientific paradigms providing the foundation for innovative health technologies. However, by themselves, these calls would likely not be focused on long-term clinical development, nor would they deliver implementable solutions. For that to happen, a more strategic approach is needed, with a 'portfolio-level' thinking, directionality towards common objectives, alignment of individual projects and the joint participation of key partners.

Under this option, the initiative's objective of reducing the risk of spread of (re) emerging infectious diseases would be possible, by supporting networks to promote knowledge exchange between disease control institutions and countries, since these activities are typically less resource-intensive than large-scale clinical trials.

However, as this option does not allow for the pooling of additional resources from countries and for cooperation with additional stakeholders around a common strategic agenda, support long-term, multisite and international clinical trials would be difficult. Moreover, the baseline option does not have a dedicated implementing structure that can effectively coordinate the key partners around a common strategic agenda.

In addition, under the baseline option, neither the Commission nor the partners make an upfront budgetary commitment. This implies less political commitment and reduced visibility to the field compared to under a partnership approach. The existing collaboration built under the first and second EDCTP programmes, between the EU, European countries and African countries, would not be maintained at the level that it is currently. Additionally, the scientific leadership and ownership by sub-Saharan African countries would be reduced, as well as the potential to bridge the gap between science and policy for health or evidence base health policy-making.

Even under the current COVID-19 crisis, the baseline scenario is still a valid baseline for the different options. However, if due to the consequences of the pandemic there was a delay in the process for the adoption of the partnerships under Horizon Europe, or a reduced expected budget availability, this option might become the only option, at least for the starting year (2021).

All interviewed stakeholders, from all stakeholder groups, agree that the baseline option is undesirable and would result in a near-complete loss of the momentum that EDCTP has been able to generate. It is thus seen as a major step backwards.

Option 1: Co-Programmed European Partnership

Under a co-programmed option, compared to the baseline option, the partnership is more likely to support late-stage clinical trials, because of the ability of partners to actively align activities around a common research agenda. Therefore it has an increased chance

of contributing to successful product development, thus receiving a score of +, i.e. a *good* potential compared to the baseline.

Under this option, the initiative's objective of reducing the risk of spread of (re) emerging infectious diseases would also be possible, by supporting networks to promote knowledge exchange between disease control institutions and countries, since these activities are typically less resource-intensive than large-scale clinical trials.

However, in all other aspects, the co-programmed option has similar drawbacks as the baseline option. As in the baseline option, there will no dedicated implementing structure, which will reduce the capacity to effectively coordinate countries and other key partners around the common strategic agenda.

Option 3a: Institutionalised European Partnership under Article 185

This form of institutionalised partnership would bring together Member States and Associated States and their contributions would be matched from the EU budget. Other stakeholders could participate indirectly in the partnership. This is the current form of the EDCTP2 programme. This option would generate sufficient financial space to support mid- to late-stage clinical research, where the costs are highest. Additionally, the institutionalised partnership approach encourages partners to come together to commit budget to a common strategic research vision and to plan their activities accordingly.

Since it has the same legal basis as the current EDCPT2, under the Article 185 option, the candidate EU-Africa Global Health Partnership would be able to retain the current programme office, knowledge and know-how of sub-Saharan clinical trials management, and relations with key stakeholders in the region. However, under an Article 185, the EU would not be able to match the contributions from third countries nor from philanthropies or industry.

Compared to the baseline option, this option would have significantly better prospects to reach a high scientific impact. This option has therefore received a score of ++, i.e. a *high* potential compared to the baseline.

Option 3b: Institutionalised European Partnership under Article 187

This option would allow to bring together EU Member States and Associated States, as well as third countries, philanthropies, industry and international organisations around a strategic research and innovation agenda. It would also foresee a long-term budgetary commitment from all parties, which could be matched by the EU budget. A Joint Undertaking would implement the programme under full control of the Commission, which would have a seat in the governing board. The greater number of partners and the possibility for the EU budget to match third parties' contributions, in addition to the Member and Associated States' contributions, would represent greater budget commitments and a greater pooling of resources around a common objective.

In terms of scientific impact, an Article 187 institutionalised partnership appears to be the best option to mobilise the resources needed to support a sustained and coordinated response to infectious diseases in sub-Saharan Africa, as well as to have a significant impact by strengthening the knowledge of clinical research on infectious diseases relevant to sub-Saharan Africa, increasing the scientific leadership of African

researchers, the capacity to control (re) emerging epidemics in sub-Saharan Africa and to have evidence-based national and international health policy making. This option has therefore received a score of +++, i.e. a very high potential compared to the baseline.

Interviewees unanimously express a strong preference for an institutionalised partnership approach. Opinions are, however, divided on whether this should take the form of an Article 185 partnership or an Article 187 partnership. Many acknowledge 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 the EC would have over the partnership.

Numerous interviewees have expressed varying degrees of concern that countries that cannot substantially contribute to the partnership financially will be left out of the decision-making. Not all stakeholders fully understand the advantages and disadvantages of these two options and question why a change from one to the other would even be under consideration.

In the responses to the **open public consultation,** 26 out of 41 respondents indicated that an institutionalised partnership would be the preferred option, emphasising in particular the need for strong (financial and political) commitment and long-term stability. The consultation, however, did not allow respondents to distinguish between the two individual forms of institutionalised partnership. Among those who expressed a preference for a Co-Funded or Co-Programmed option, the reasons given related to a need for flexibility, inclusiveness of the partnership, and lower costs. Similar to the case among interviewees, however, the open comments provided in response to the consultation clearly show that many respondents struggle to fully understand the details of different forms of partnership.

While consulted non-government stakeholders indicated their preference for an institutional partnership, many of them could not position themselves in favour of Article 185 or Article 187, leaving it to the Commission and the Member States to decide which form of implementation was best suited. The governmental stakeholders consulted for the GHP/EDCTP3 have the experience with an Article 185 for EDCTP2 and an Article 187 for the Innovative Medicine Initiative (IMI), which is a public–private partnership with industry. Consulted governmental stakeholders indicated their preference for an Article 187, since it would allow philanthropies and the industry to join. They highlighted the importance of transparency on industry participation and its contribution, to safeguard public interests.

Summary

Table 7 lists the scores for each of the policy options as regards to the effectiveness criteria for scientific impacts, based on the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 7: Overview of the options' effectiveness compared to the baseline - Scientific impacts

Scientific Impacts	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Strengthened EU scientific excellence	0	+	++	+++

Scientific Impacts	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
in clinical research for infectious diseases				
Increased scientific leadership of sub-Saharan Africa in the infectious diseases field	0	0	++	+++
Increased research response capacity to control of (re-)emerging epidemics in sub-Saharan Africa	+	+	++	+++
Increased evidence base for national and international health policy-making (bridging the gap between science and policy for health)	0	0	++	+++

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

Economic/Technological impacts

Baseline: Horizon Europe traditional calls

The lack of commitment to a strategic research and innovation agenda would likely result in a much-reduced ability to support end-of-pipeline product development. This means a lower impact on the capacity of institutions in sub-Saharan to design, conduct and manage infectious diseases research projects, on the number of employed researchers in sub-Saharan Africa, and lower capacity to attract funding in the region. On the other hand, the lack of long-term commitment would discourage industry from participation in research projects in sub-Saharan Africa.

Option 1: Co-Programmed European Partnership

Economic impacts are tied to the increased ability to reduce health care related expenditure, increase the number of employed researchers, and strengthen the capacity in sub-Saharan Africa to manage research projects and attract funding, all resulting in a more attractive environment for industry to participate in research projects in the region. Economic impacts depend not only on the implementation of research results, but also on the level of funding and alignment. In a co-programme partnership, the engagement of all the actors around a strategic research agenda would provide a directionality for all the partners, thus having a higher impact than the baseline option. This option has received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 and Article 187

The economic and technological impacts are largely dependent on the attainment of scientific results and impacts. With its greater possibility to focus on clinical research and product development and the higher level of budgetary commitments, the institutionalised partnerships have a higher chance to develop technologies ready for their production, distribution and uptake.

The extent of the economic impact resulting from increases in the skills of researchers and research activity depend on the scale as well as on the focus of the initiative. Under an institutionalised partnership, irrespective of whether this takes the form of an Article

185 or an Article 187 partnership, there will be greater opportunities for capacity strengthening in the area of clinical research than under the baseline option. In light of the above, the two institutionalised options have been scored with ++ compared to the baseline.

Summary

Table 8 lists the scores assigned to each of the policy options as regards to the effectiveness criteria for economic / technological impacts, based on the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 8: Overview of the options' effectiveness compared to the baseline – Economic / technological impacts

Economic/Technological impacts	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Increased research capacity of institutions in sub-Saharan Africa to design, conduct and manage infectious disease research projects	0	+	++	++
Higher capacity of the research institutions to attract funding	0	+	++	++
Increased industry participation in research projects in sub-Saharan Africa	0	+	++	++
Increased number of employed researchers in sub-Saharan Africa	0	+	++	++

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

Societal impacts (including environmental, social and fundamental rights)

Baseline: Horizon Europe traditional calls

The achievement of societal impacts, in particular those impacts directly associated with the health status of people, depend on the increased availability and uptake of new or improved health technologies.

The baseline scenario is likely to have some societal and environmental impact stemming from the funded projects, increasing the higher retention of scientific talent in sub-Saharan Africa. However, it is likely to lack a comprehensive strategic approach. Research focusing on developing and improving health technologies may reduce morbidity and mortality due to infectious diseases in sub-Saharan Africa, as well reduce antimicrobial resistance and the risks of (re-)emerging infectious diseases. To some extent, coordination and support actions could help to communicate and disseminate research results and increase the uptake of the results in the region. Similarly, supporting the training of researchers in sub-Saharan Africa could offer increased chances for their career development and retention in the country, and increase the capacity of the research institutions to manage clinical research, leading to an increased focus on unmet medical needs.

On the other hand, the capacity of the research institutions to provide safe medical interventions would be reduced, as well as the uptake of the health technologies in the

region, leading to a smaller chance of alleviating the infectious diseases burden in sub-Saharan Africa.

Whilst strengthening of research capacity in sub-Saharan Africa through Horizon Europe calls would be possible, it is difficult to foresee to what extent this would be translated into an increase in long-term employment opportunities for researchers and higher retention of scientific talent in the region. Additionally, project funding alone cannot influence nor stimulate the much-needed involvement of other stakeholders.

In the absence of a partnership, the baseline option would struggle to integrate research and innovation efforts to tackle the infectious diseases burden in sub-Saharan Africa.

Option 1: Co-Programmed European Partnership

Whilst a co-programmed partnership does not require formal commitments, it can be expected to leverage sufficient resources to support the research and innovation activities of the candidate partnership. As it would have better strategic vision, it would have greater likelihood of achieving the societal impacts, than the baseline option. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 / Article 187

Under the institutionalised partnership option, there would be a more strategic approach and vison, as well as a better integration. Greater emphasis would be placed on supporting the kind of research that is required to produce and deliver health technologies. An institutionalised partnership also has a more strategic approach and stronger impact on the uptake of the new or improved health technologies. As consequence this type of partnerships have higher capacity to reduce morbidity and mortality associated with infectious diseases in sub-Saharan Africa, as well reducing antimicrobial resistance and the risks of (re) emerging infectious diseases.

However, as previously mentioned, in the Article 185 option the EU budget can only match Member and Associated States' contributions, reducing significantly the possibility of leveraging enough resources and therefore reducing the expected impacts. This option has therefore received a score of ++ compared to the baseline. On the other hand, the Art. 187 option would allow the EU budget to match, in addition to the partners under an Art. 185, the contributions from sub-Saharan Africa countries, as well as private charitable funders, industry and other third countries, leveraging substantial and sustainable funding and integrating them around a common agenda. An institutionalised partnership under Art. 187 has the strongest chance to deliver the highest societal impacts, compared to the baseline, the co-programmed and the Art. 185 options. In light of the above, the Art. 187 option has been scored +++ compared to the baseline.

Summary

Table 9, below, lists the scores assigned to each of the policy options as regards the effectiveness criteria for societal impact, based upon the assessments above, as well as taking into account the opinion of the different stakeholders.

Table 9: Overview of the options' effectiveness compared to the baseline – Societal impacts

Societal impacts	Option 0: Horizon Europe calls	Option 1: Co-programmed European Partnership	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187

Societal impacts	Option 0: Horizon Europe calls	Option 1: Co-programmed European Partnership	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Higher retention of scientific talent in sub-Saharan Africa	0	+	++	+++
Better uptake of new or improved health technologies	0	+	++	+++
Better (gender) equality	0	+	++	+++

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

6.2. Efficiency

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

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

For this specific initiative under the **baseline scenario** of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 185 initiative. There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. These can be estimated at EUR 1.5 million per year of operation. Overall, it is estimated that the overall longer term cost savings from using traditional calls, instead of an existing Article 185 initiative, would considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

The overall administrative, operational and coordination costs of Option 3a (**Article 185** Partnership) would be close to those of the existing initiative EDCTP2, e.g. the EDCTP Secretariat, which has implemented efficiently the EDCTP2, ensuring that programme's administrative costs do not exceed 6% of the European Union's financial contribution of EUR 683 million (i.e. EUR 41 million for the period 2014-2024). These costs can be estimated at EUR 4.1 million per year. In this option, the initiative would benefit from the experience of the existing organisation/structure already in place.

Finally, Option 3b (an **Article 187** Partnership) would imply a change of legal basis from the current situation. The change of legal basis would generate some limited additional

costs to set up the Joint Undertaking from the EDCTP Secretariat. These would include an indicative one-off administrative expenditure to set up the Joint Undertaking of a maximum EUR 0.3 million for the new structure and a recurring annual cost of a maximum EUR 5.5 million depending on the size of the partnership. Further details are provided in Annex 3. It is worth noting, however, that these limited additional costs would be compensated by the yearly recurring costs savings from the simplification of procedures, as the Commission will be part of the decision Board of the Joint Undertaking. This would simplify the adoption of the annual work programmes and provide the JU with the possibility to benefit from the common support office of Horizon Europe for proposal submission, evaluation and selection, and other common services. An important consideration in this respect is the necessity of a mechanism to keep the knowledge generated during the implementation of EDCTP1 and 2 of the current programme office staff. This would require devising a proper solution to preserve this experience in the new partnership, including the expertise in clinical research projects in sub-Saharan Africa and building up relationships with key stakeholders in the region.

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 options. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is two percentage points more efficient than the baseline; an Article 185 Institutionalised Partnership somewhat less cost-efficient than the baseline, and an Article 187 Partnership is two percentage points less cost-efficient than the baseline.

A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnerships policy option.[150] It is worth noting that the adjusted cost scoring for the Article 185 in the case of the EU-Africa Global Health Partnership departs from the common approach adopted to cost-efficiency.[151] Indeed, Option 3a is scored (-) instead of (0). This is to reflect the specificity of this Partnership, involving an important number of third countries, which makes the Article 185 coordination costs higher than in other cases and thus potentially closer to the costs of an Article 187. The scoring for all the other options is in line with the common approach.

Table 10: Matrix on 'overall costs' and 'adjusted cost scoring'

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

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

[151] Under the common approach to assess efficiency (see Annex 4, p. 51), Options 3a and 3b (Institutionalised Partnerships under Article 185 and 187 respectively) score overall (-)(-) for total administrative/operational/coordination costs. Once these scores are adjusted to better reflect the expected co-financing rates and the total budget available for each option (cost-efficiency), the adjusted score for the Article 185 Partnership becomes 0 (equal to the baseline), while the adjusted score for the Article 187 Partnership becomes (-).

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

The Interim Evaluation of the EDCTP2 programme of 2017 assessed how competently and economically the activities had been executed under an Article 185 in relation to the objectives and indicators during the first two years of the programme implementation, 2014-2016. This evaluation recommended that, in order to ensure more efficient progression, EDCTP should understand the goals and priorities of Participating States and work with them to align EDCTP strategy and programmes, and that EDCTP should thus actively support the Participating States in developing their own national research agendas. The EDCTP2 Interim Evaluation Panel recommended that in addition to the 6% eligible administrative costs, and to reach the ambitious objectives of the partnership, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions.

6.3. Coherence

Internal coherence

This section assesses the extent to which the policy options could ensure and maximise coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

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

Baseline: Horizon Europe traditional calls

Traditional Horizon Europe calls may create opportunities to exploit synergies within the Health cluster to deliver on health-related challenges for the EU, as well as with other clusters although Coordination and Support Actions could catalyse some opportunities to identify linkages, opportunities for coordination and communication, with other stakeholders. However, it would be challenging for individual Research and Innovation Actions to make steady progress on advancing the development of diagnostics, vaccines, treatments and enabling the environment for the uptake of health innovation in sub-Saharan Africa, from the actions' limited budget, and without a long-term commitment and a dedicated implementing structure.

Work programmes would need to reflect the requirement for R&I activity across the health technologies clinical development, with input from representatives of all relevant stakeholders.

In the absence of a dedicated implementing structure, traditional calls cannot ensure alignment with other key initiatives and organisations in the global health arena.

Option 1: Co-Programmed European Partnership

Through a co-programmed European partnership, the partners can aim to achieve a certain coherence with other partners and with the Annual Work Programme of Horizon Europe, and implementing Coordination and Support Actions to facilitate relationships with European and African governments, funders, industry, academics, policy-makers and regulators. However, its decentralised management structure is not likely to

effectively support the building of strong and sustained integrated relationships with other organisations or initiatives keeping coherent linkages with other initiatives within Horizon Europe, which would be needed for this initiative. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 / Article 187

A clear coherence is required between the different types of activities to attain the initiative's objectives. The institutionalised form of implementation would be better placed to deliver this than the baseline option because it can take a more dedicated approach in the criteria of the calls for proposals.

The Article 185 Institutionalised European Partnership supports the widest possible participation of governments, and has a dedicated implementing structure that can facilitate new and deepen existing relationships with policy-makers, academics, industry, regulators, etc. It is also likely to reach a higher level of alignment and coordination of national budgets. It can also provide support to finding synergies with other parts of the Horizon Europe Work Programmes and other Partnerships, as well as with national development agencies and other stakeholders. This option has therefore received a score of + + compared to the baseline.

An Article 187 Institutionalised European Partnership provides a Joint Undertaking with the capacity to be a single point of access to partners, not only EU Member States and States Associated to the Framework Programme and sub-Saharan countries but also other third countries, industry and private funders, policy makers, regulators, academia and other stakeholders, within the context of Horizon Europe. This can better ensure that synergies are maximised across the Horizon Europe Work Programmes and Horizon Europe Partnerships. This option has therefore received a score of +++ compared to the baseline.

Respondents to the **Open Public Consultation**, as well as a number of 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 Directorate-Generals within the EC. In particular, this relates to the role of DG DEVCO in health systems strengthening and to DG ECHO and DG SANTE in the field of epidemic preparedness.

External coherence

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

Baseline: Horizon Europe traditional calls

To have an impact it is necessary to strategically share areas of common interest with other initiatives, organisations and research funders. It is important to coordinate and, where necessary, align activities to optimize synergy and minimize duplication. This can be done, for instance, through joint funding calls or collaborative activities. Under

EDCTP, for instance, joint calls have been issued with organisations such as the Bill & Melinda Gates Foundation, WHO-TDR, the Special Programme for Research and Training in Tropical Diseases.

Under traditional calls, the options for structured engagement with actors such as public health, institutions and regulatory authorities, as well as with philanthropies are limited. The baseline option offers few opportunities for regular and continued coordination. Participation in traditional calls is open to any Horizon Europe eligible legal entity within a consortium. This includes research organisations in Africa, although these are not automatically eligible for funding.

Under the baseline option there are no explicit incentives for Member States to increase or maintain their investments in research and innovation to combat infectious diseases as there is no matching of national contributions from the EU budget.

With the discontinuation of the dedicated implementing structure, it will not be possible to effectively facilitate the alignment of national and other funders' programmes around a strategic agenda and the knowledge and know-how of the current EDCTP implementing structure would be lost.

In addition, the current decision-making capacity of sub-Saharan countries within the EDCTP Association will not exist, losing the countries' trust and their buy-in, necessary for the local uptake of the potential innovations resulting from the Horizon Europe projects.

Option 1: Co-Programmed European Partnership

The ability for a co-programmed partnership to interact with other programmes or initiatives is similar to the baseline option. A co-programmed partnership, through the Horizon Europe Work Programme, can provide some opportunities to engage with other initiatives, organisations and research funders through collaborative research projects and coordination and support actions. In addition, individual partners may at a national level have the ability to improve coherence between activities supported within the partnership and those outside of it. However, alignment with globally operating initiatives would be difficult in the absence of a dedicated implementing structure. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Art. 185 / Art. 187

The institutionalised partnerships have the capacity to include many types of partners in the partnership. Under an Article 185 the EU can contribute to Member States programmes. Moreover, the dedicated implementing structure would engage with other initiatives, organisations, research funders, national development agencies,[152] EU Delegations in sub-Saharan Africa, and would manage such relations. In addition, an institutionalised partnership would have the capacity to launch calls within its own Work Plan to further engage with additional collaborations and to coordinate them. Therefore, the institutionalised partnership option under Article 185 offers greater ability to engage with other relevant actors, including those outside of the partnership increasing the coherence of the EU investment. This option has therefore received a score of ++ compared to the baseline.

[152] Under the current EDCTP2 programme, several national development agencies, (e.g. SIDA from Sweden, DLR from Germany), are already involved in the partnership, contributing to the programme and participating in the decision-making as part of the EDCTP Association.

Furthermore, under Article 187 the EU could set up a joint undertaking (JU) or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes with additional partners that would be more integrated and with a programme office that would ensure external coherence. Therefore this option has received a score of +++ compared with the baseline option.

As in the case of internal coherence, **interviewees** widely agree that the candidate partnership should coordinate its efforts with other key stakeholders in the field, often without being specific. Some have noted a proliferation of initiatives, some of which appear to share focal areas with the candidate partnership. In addition to EU programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and funders such as the Bill & Melinda Gates Foundation.

These interviewees indicated that it will be important for the candidate partnership to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities.

Summary

Table 11, below, lists the scores we assigned to each of the policy options as regards the internal and external coherence criteria, based upon the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 11: Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3 a Art 185	Option 3b Art 187
Internal coherence	0	+	++	+++
External coherence	0	+	++	+++

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

6.4. Tabular comparison of options and identification of preferred option

The scorecard below provides an overview of the assessment made of each option under each of the criteria based on the performed analysis.

Table 12: Comparison - Ranking the policy options

	Criteria	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3a: Art. 185	Option 3b: Art. 187
Effectiveness	**Scientific impacts**	**0**	**+**	**++**	**+++**
	Economic/technological impacts	**0**	**+**	**++**	**+++**
	Societal impacts	**0**	**+**	**++**	**+++**
Efficiency	**Administrative, operational and coordination costs**	**0**	(0)	**(-)(-)**	**(-)(-)**

	Adjusted administrative, operational and coordination costs per expected co-funding (i.e. cost-efficiency)	**0**	(+)	**(-)**	**(-)**
Coherence	**Internal coherence**	**0**	**+**	**++**	**+++**
	External coherence	**0**	**+**	**++**	**+++**

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

Without long-term commitment, the traditional calls would not be able to attract funders and facilitate alignment between programmes of key initiatives and organisations active in the global health arena and they will not have a significant leveraging effect. As a consequence the traditional calls would have lower scientific, economic/technological and societal impacts.

A **co-programmed partnership** based on a **memorandum of understanding** between the Commission and the already established EDCTP Association would be **simple to establish,** however, it would have a **lower level of commitment and integration** than the current EDCTP2. In addition, the participation from the African countries in the decision-making would be reduced in comparison to EDCTP2. African countries could perceive this as **a step backwards**.

An **institutionalised partnership based on Article 185,** based on a decision of the European Parliament and the Council for an EU contribution to a Member States programme, would represent a continuity with the current EDCTP2. This form of partnership would allow the EDCTP Association to continue to function as it is, with a similar set of actors, roles and responsibilities. The EDCTP Association allows for participation of African countries in strategic discussions and decision-making. However, this option would be only possible if at least 40% of the Member States become members of the GHP/EDCTP3. In this option, only contributions from Member States and countries associated to Horizon Europe can be matched by the EU contribution. Other third parties, such as third countries, philanthropies or industry, could contribute at the level of call for proposals or in projects, but their contributions would not able to be considered for the matching of EU contribution. There is a certain level of uncertainty around Member States' capacity to commit sizeable amounts, seeing the economic impact of the COVID-19 pandemic. This could make an Article 185 partnership even less likely seeing the requirement to have budgetary commitments from 40% of the Member States. This would **reduce the size of the budget and therefore the level of ambition for and the potential impact of the partnership**.

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

- Provide greater effectiveness by maximising leverage effects, allowing for greater strategic alignment among partners, and supporting a broader range of activities in research and innovation.

- Improve coherence by enhancing collaboration and alignment with the other key stakeholders in the area of combatting infectious diseases and strengthening research capacity in sub-Saharan Africa.

The lower scores of the Art. 185 assessment option are based on the fact that the EU can only match the European countries contributions, and not the third countries, nor the private founders or industry, reducing largely the leverage effect of the partnership. The size of the initiative would be smaller than in an Art. 187, and thus the impact reduced.

The conclusion of the assessment is that the **Institutionalised European Partnership based on Article 187** TFEU is the preferred option, showing a better cost-effectiveness than the other options and in light of the need to strengthen the partnership through increased participation in comparison to the current EDCTP2.

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

7.1. The preferred option

Based on the comprehensive analysis of the available data, this study concludes that the preferred option for the candidate EU-Africa Global Health Partnership is that of an Institutionalised Partnership under Art. 187. This option would also allow the EU budget to match, the sub-Saharan Africa countries contributions as well as the private charitable funders, industry and other third countries contributions, leveraging substantial and sustainable funding around a common agenda. This type of institutionalised partnership is the most likely option to deliver the targeted impacts, and offers the greatest potential for alignment of partners around shared strategic objectives.

Table 13 shows the alignment of the preferred option with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation. Considering that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion at the time of writing, the criteria of additionality/directionality and long-term commitment are covered in terms of expectations rather than ex-ante demonstration.

The COVID-19 crisis does not fundamentally change the foreseen Partnership and confirms the relevance of the proposed initiative. An Article 187 Institutionalised Partnership scores significantly higher overall than the baseline option (traditional calls under Horizon Europe) and Option 1 (Co-Programmed Partnership) in terms of effectiveness. The preferred option remains the Article 187 with the highest capacity to coordinate and generate impact in research preparedness and response research, to provide an evidence base to increase individual and community resilience, facilitate operational readiness, and improve decision-making during emergency response.

Table 13: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	As an Institutionalised Partnership based on Art. 187, provides the closest integration of key stakeholder groups across the value chain to ensure that the initiative can respond to ambitious objectives corresponding to scientific, technological/economic and societal impacts. This mode of implementation will ensure a sufficient scale, commitment, leverage and long-term vision for the accelerated development and deployment of health innovations in sub-Saharan Africa. The EU-Africa Global

Criterion	Alignment of the preferred option
	Health Partnership is expected to generate highly competitive knowledge and scientific, economic/technological, and societal impacts in partnership with sub-Saharan Africa countries, as well as to contribute to the integration of research resources, secure sustainability, and strengthen the European Research and Innovation Area.
Coherence and synergies	The preferred option will be able to fulfil a unique position with the EU and global health research and innovation landscape to ensure coordination and complementarity with the EU programmes, as well as with national and international initiatives. Coherence and synergies will be achieved by maintaining a clear focus on infectious diseases affecting sub-Saharan Africa and contributing to the EU international commitments.
Transparency and openness	Under an Art. 187 the Partnership will work around common priorities under a strategic research and innovation agenda. Partners and stakeholders from across the whole clinical development process of health technologies, and from different sectors, backgrounds and disciplines, including international ones, will participate in the initiative. The Partnership will promote principles of research fairness and transparency as well as promote the dissemination and exploitation of results. It will be able as well to design exit-strategy and measures for phasing-out from the Programme.
Additionality and directionality	The financial or in-kind contributions from governments and private partners other than the EU will be between 50% and 75% of the aggregated Partnership budgetary commitments, working towards the common strategic vision and achieving the expected impacts. The partnership will also be able to set up the appropriate approaches to ensure flexibility of implementation of a strategic research and innovation agenda and to adjust to changing policy, societal, market needs and/or scientific advances, and to increase policy coherence between regional, national and EU level, resulting in better health for all (SDG3).
Long-term commitment	The Partnership under the Art. 187 option offers the possibility of a long-term commitment and would cover the whole duration of Horizon Europe.

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 and not only an observer, as is the case in the current partnership. In this partnership, based on the Article 185, the EU participates under the H2020 Framework Programme, in a programme jointly undertaken by several Member States (the EDCTP2 programme) and the legal base foresees the Commission's role as an observer.

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, with the Commission having a clear role in its governance that ensures that public interests are at the core of the partnership.

While consulted non-government stakeholders clearly indicated their preference for an institutional partnership, many of them could not position themselves in favour of Article 185

and Article 187, leaving it to the Commission and the Member States to decide which form of implementation was best suited.

Consulted governmental stakeholders, who have the experience with both an Article 185 (through EDCTP2) and an Article 187 (through IMI2) partnership, have indicated their preference for an Article 187, embracing the idea that it would allow also public funds to join forces with philanthropies and the industry. However, they highlighted the importance to safeguard transparency and public interests when considering industry participation.

A partnership under Article 187 would attract the widest range of actors, leveraging and pooling resources: the EU, Member States and countries associated to Horizon Europe, third countries,[153] philanthropies (e.g. Bill and Melinda Gates Foundation, the Wellcome Trust) and pharma industry. One example of this is, as mentioned above, the response to the COVID-19 pandemic, bringing public, industry/private sector and philanthropies together to address the problem.

An **institutionalised partnership based on Article 187** would require a Council regulation to set up a new structure or joint undertaking. While it would be **more demanding in the set-up,** it would however **offer a long-term perspective, a strong political commitment as well as leveraging and pooling resources** from the EU. The **EU would become a full partner** and the **EDCTP Association** would become its **counterpart**, representing its members (EU member states, countries associated to Horizon Europe, third countries from sub-Saharan Africa and any other third country). Any third party could participate as 'associated partners' on an *ad hoc* basis. This option would allow the EU to match contributions from the EDCTP Association and its members as well as from the other 'associated partners'. In turn, it would leverage budgetary commitments and coordination. It would also allow **maintaining inclusive governance with African countries**, as part of the EDCTP Association, which has proven to work. This option has a higher chance of obtaining **higher impact, greater visibility of EU investment and positions the partnership as a stronger global player**.

The **Interim Evaluation of EDCTP2** specified that to improve the efficiency and effectiveness of EDCTP, the partnership should be strengthening the links to policymakers in African Participating States. EDCTP needs to better understand the goals and priorities of Participating States and further work with them to align EDCTP strategy and programmes; EDCTP should thus actively support the Participating States in developing their own national research agendas. An additional emphasis should be on strategic alliances, and a strong focus on developing African scientific leadership. Opportunities to extend the range of partners were also noted, including organisations working in related areas such as antimicrobial resistance and global health security.

As indicated previously, **interviewees** strongly favour an institutionalised partnership approach to the Candidate Initiative, whereas among respondents to the **open public consultation** just over half (26 out of 41) view the institutionalised partnership approach as the best way to address the identified problems. Respondents to the **open public consultation** furthermore see the relevance of a specific dedicated structure to govern the initiative in many different aspects. In particular, they see such a structure as relevant or even very relevant to the Candidate Initiative's ability to implement activities more effectively (35 out of 45 respondents) and transparently (32 out of 45).

[153] African countries, United Kingdom, Japan, etc.

All **interviewees** agree 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 a General Assembly, voting rights and funding decisions have been widely discussed among interviewees but there appears to be no consensus on the best format of participation.

Interviewed representatives of national governments stress the importance of European and African country participation, and their ability to "steer the processes". All interviewees encourage third party participation, in the form of private entities, associated countries, and charitable foundations. In case of industry participation, many interviewees welcome their inclusion 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 partnership.

The need for ensuring involvement of a broad range of partners is confirmed also by respondents to the **open public consultation**: 17 out of 47 deemed it relevant, and 25 out of 47 very relevant. Parties that are considered relevant for pooling and leveraging resources include in particular Member States, Associated Countries and African countries. Most respondents also agree on the need to include industry, academia, philanthropies and NGOs in the partnership, although some respondents expressed some reluctance about doing so.

Interviewees widely agree that funding and implementation of research and innovation actions should be the primary focus of the Candidate Initiative. Interviewees with whom the optimal positioning for the Candidate Initiative was explored in more depth, mostly viewed late-stage clinical trials as the primary area where the Candidate Initiative could deliver direct impacts. Nonetheless, among all interviewees there was a large degree of consensus that investments in research and innovation actions should be done alongside investments in research capacity development activities.

Respondents to the **open public consultation** hold similar views on how best to allocate resources to different types of activities. A large majority are strongly supportive of investment in collaborative R&I projects (35 out of 45 respondents) and in co-creation of solutions with end-users (30 out of 45). These respondents were not explicitly asked to indicate their support for investment in research capacity development, nor did the question allow for open comments.

Among **interviewees**, some representatives of the EC as well as current members of the EDCTP Association agreed that EDCTP has played an important role in maintaining national commitments to combating infectious diseases but felt that this has not necessarily resulted in increased national investments.

Box 2 Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
• The current scientific scope covering HIV/AIDS, tuberculosis, malaria and neglected infectious diseases, but it will be enlarged. • Geographical focus in sub-Saharan Africa. EU Member States, Associated States to the Framework Programme and sub-Saharan States will part of the EDCTP3, through the EDCTP Association, under Dutch law, enabling all Participating States, also the sub-Saharan countries, to be part in the decision-making.	• The scientific scope will be enlarged to include (re-)emerging epidemics, antimicrobial resistance and co-morbidities of infectious diseases with non-communicable diseases, affecting sub-Saharan Africa. • Additional key global players such as philanthropies (BMGF, Wellcome Trust, etc.), industry (EFPIA, etc.) and other third countries (e.g. United Kingdom, Japan, etc.) would be able to join the initiative, and contribute to the partnership on ad-hoc basis, and their funds would be able to be matched by the EU contribution, increasing the leveraging effect and the coherence of the initiative.

One particular issue raised by **representatives of EDCTP Participating States** in regard to the current EDCTP2 programme, is that even legal entities whose countries are not part of the EDCTP Association, are able to participate in all EDCTP2-supported activities, meaning there has been limited incentive for formal commitment and alignment of activities. Under these conditions, some countries, in particular from the sub-Saharan region, would not see the benefit in committing to the partnership. They question what can be done to increase the leveraging effect for the Candidate Initiative. To encourage countries to participate in the initiative, it is proposed to consider the introduction of provisions that would limit eligibility for funding for certain activities.

7.2. Objectives and corresponding monitoring indicators

Operational objectives

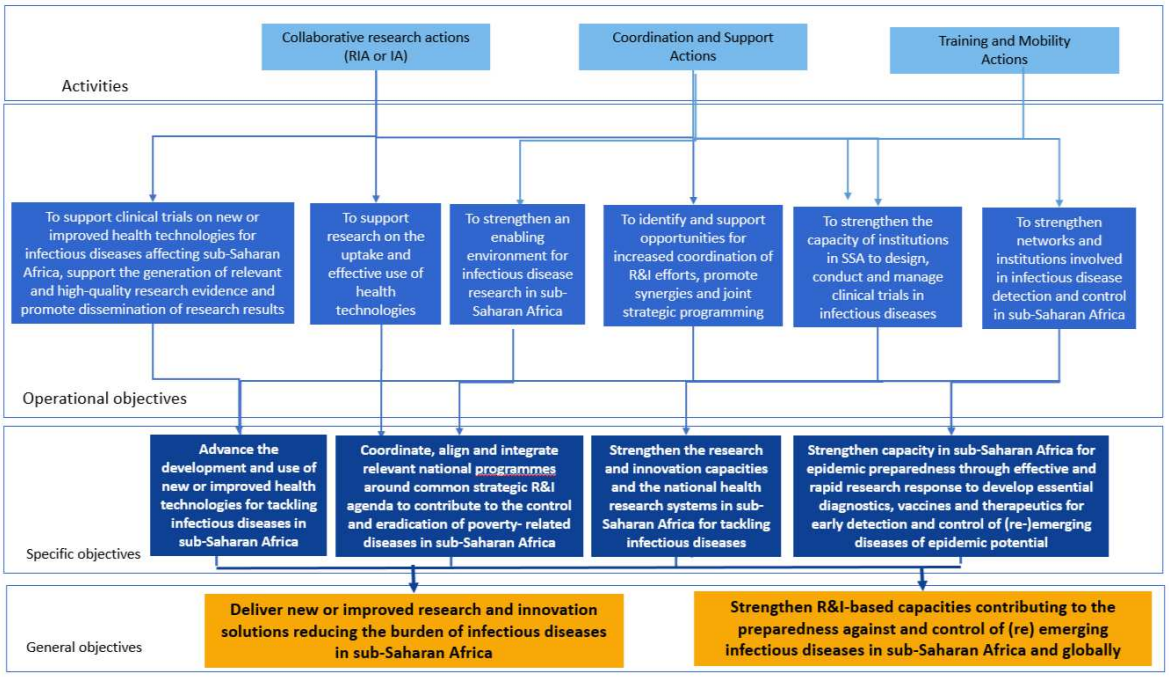
Figure 12 below lists a range of actions and activities to be carried out, which go also beyond the R&I activities that can be implemented under Horizon Europe. This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake." This figure also shows the links between the actions, operational objectives and the specific and general objectives of the initiative.

A set of six operational objectives have been developed for the initiative, which feed into the previously identified specific objectives, subsequently feeding into the general objectives. These operational objectives are:

- To support clinical trials on new or improved health technologies for infectious diseases affecting sub-Saharan Africa, generating relevant and high-quality research evidence and to promote dissemination of research results;
- To support research on the uptake and effective use of new or improved health technologies

- To identify and support opportunities for increased coordination of research and innovation efforts, promote synergies and joint strategic programming, and the dissemination of research results
- To strengthen the capacity of institutions in sub-Saharan Africa to design, conduct and manage clinical trials in infectious diseases
- To strengthen an enabling environment for infectious disease research in sub-Saharan Africa
- To strengthen networks and institutions involved in infectious disease detection and control in sub-Saharan Africa.

Figure 12: Operational objectives of the candidate in relation to the specific and general objectives



Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. Whenever possible these indicators will be reported in relation to the initial baseline at country level.

In the medical sector, the timelines for development are long, taking up to 12-15 years on average for the development of a new drug, and approximately 2-8 years for the development of a new medical device. The necessary regulatory acceptance/approval and implementation process can add an additional 5 years. Therefore, the attainment of some of the initiative's objectives would not be appreciated until long after the projects have finished.

Table 14: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impacts	**Launching calls to pursue EU-Africa**	**Generating high quality R&I scientific knowledge of relevance**	**Advancing development of diagnostic kits, candidate vaccines and treatment products**

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Global health partnership (# of calls launched and projects funded in each scheme (RIA, TMA, CSA), and € invested. **Engaging stakeholders to promote generation of high quality scientific knowledge of relevance to EU-Africa GH priorities** (Outcomes of stakeholders' consultative meetings (# of topics informing future calls for proposals)	**to EU-Africa GH priorities** (# of peer-reviewed international publications generated by the partnership projects). **Increased cooperation and additional joint actions with other public and private funders, including WHO initiatives and increased aligned strategy with key global players including development agencies** (# of new or strengthened international networks sharing good practice, extending capacity, and creating platforms for multicentre trials). **Building South-South and North-South networks to facilitate (rapid) decisions, actions and information exchange for making (urgently needed) clinical resources and products available** (# of countries and institutions participating in Regional Networks,# of countries and institutions participating in projects addressing epidemic preparedness (# of clinical resources and products on track to gather information for regulatory approval)	**for addressing infectious diseases related challenges of relevance to EU and Africa** (# of new or improved health technologies progressed to licence; # of new or improved health technologies (diagnostics, vaccines, drug candidates, etc.) having progressed through key milestones **Improving R&D preparedness for diseases that might lead to epidemics (surveillance, response and health capacity) and readiness to promptly conduct R&D during an emergency** (#of projects resulting in, e.g. guidance and good practices, response mechanisms and other tools facilitating a coordinated response in case of epidemics, # of projects with activities/ deliverables oriented towards "twinning" between stronger and weaker regions/sites # of robust early warning systems in place; effectiveness of investments in building preparedness capacity as judged by independent evaluations)
Economic/ Technological impacts	**Supporting studies into cost-effectiveness and economic benefits of products** (# of projects addressing improved efficiency of research resources) **Facilitating industry and private foundations participation in EU-Africa GHP to speed up R&I process** (# of projects with industry and/or private foundations participation)	**Leveraging investments in R&I and developing partnerships to support joint working and minimising duplication** (€ leveraged though partnerships with other public and private funders, # of public - private publications) **More closely aligned national research programmes and activities on poverty-related diseases, at scientific, management, and financial levels Improving coordination of national PSs investments** (Participating States' budget in centrally funded activities and in joint activities with other Participating States.)	**Driving forward advancements in GH R&I through innovative public-private collaborations** (# of new or improved health technologies (diagnostics, vaccines, drug candidates # of new or improved health technologies submitted to standardisation or regulatory approval, or in use in at least one country, etc.) having progressed through key milestones) **Increased number of co-funding programs and co-funded activities in Europe** (# of new co-funded health technologies activities between Participating States programmes)
Societal impacts Incl. Environmental / sustainability impact	**Supporting human capital in R&I through training and mobility schemes** (# of TMA calls launched, # of TMA projects supported by gender) **Supporting enabling environment for conducting clinical studies in sub-Saharan countries, compliance with fundamental ethical principles and relevant national, Union and international legislation** (# number of Coordination and Support Action projects	**Addressing through research specific needs of more vulnerable groups** (# of clinical studies targeting vulnerable populations: women, children, adolescents, etc.) **Building and sustaining engagement and co-ownership EU-Africa Global health partnership and increased cooperation and additional joint actions with development partners**(#of sub-Saharan Africa and European institutions and countries participating in partnership projects, # of sub-Saharan African and European countries participating in EDCTP both through ongoing activities,	**Pursing effective and sustainable investments into and retention of human capital in R&I** (number of trainees retained by gender, career advancement and professional recognition of researchers following funding **Increased clinical research capacity and scientific leadership, including advancement of women scientists.** #projects completed -- categorised by gender, country and regional representation. **Enhanced ethics and regulatory capacities and more closely aligned regulatory mechanisms across countries, with increased common regulatory reviews of new products** (# of projects completed and committees created and active two years after creation - categorised by country and regional

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	funded)	and through political and financial commitment as members of the Partnership or joint undertaking) **Encouraging uptake of new or improved health technologies** (# of calls and projects addressing uptake of research results into policy and practice)	representation) **Increased influence on national and international policy guidelines and improved policy research uptake** (# of policy changes to which EU-Africa research contributed to –e.g. citations in clinical reviews, clinical guidelines, systematic reviews or other policy documents issued by national, regional or international policy-making bodies) **Enhanced implementation of evidence-based interventions** (# of interventions whose implementation has been enhanced)

Evaluation framework

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