



# Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

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

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# Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

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## Introduction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

## **PART II. Horizontal studies**

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

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

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

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

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

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

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

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

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

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## **Introduction**

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

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

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

The report is structured around two main headings:

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

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

### *1.1 The political and legal context*

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

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

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

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

These principles underlying the MFF 2021-27 are translated in the intent for Horizon Europe "to play a vital role, in combination with other interventions, for creating new solutions and fostering innovation, both incremental and disruptive."<sup>2</sup> The new Framework Programme finds its rationale in the daunting challenges that Europe is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses."

In the Orientations towards the first Strategic Plan for Horizon Europe, the need strategically to prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, "Actions under Pillar II of Horizon Europe will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union."

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

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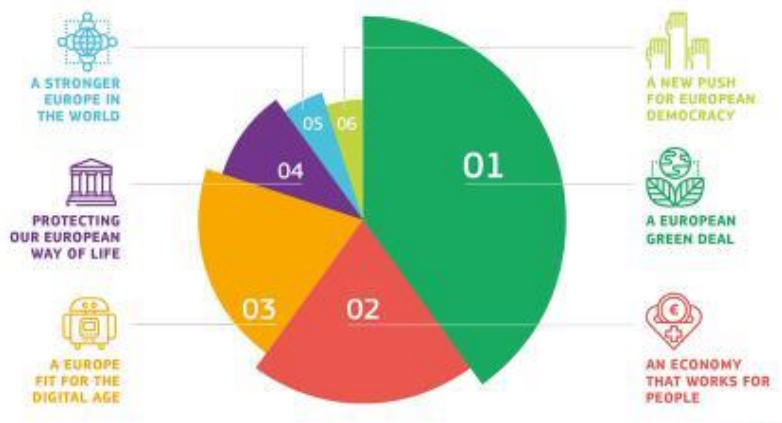
<sup>1</sup> EC (2018) *A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027*. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of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

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

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

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

Figure 1: Targeted impacts under Horizon Europe by priority



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

### 1.1.2 Renewed ambition for European Partnerships

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

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

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

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

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

### 1.1.3 Key evolutions as regards the partnership approach

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

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

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

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

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

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

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

#### 1.1.4 Overview of legal provisions

The Horizon Europe Regulation (common understanding) defines 'European Partnership' as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake." It stipulates that "parts of Horizon Europe may be implemented through European Partnerships".

The Horizon Europe Regulation (common understanding) also stipulates that the European Partnerships are expected to adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions." The provisions and criteria set out for the selection and implementation of the European Partnerships reflect these principles.

#### 1.1.5 Overview of the eight Partnership areas

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

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

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

- Adaptation to climate change including societal transformation



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

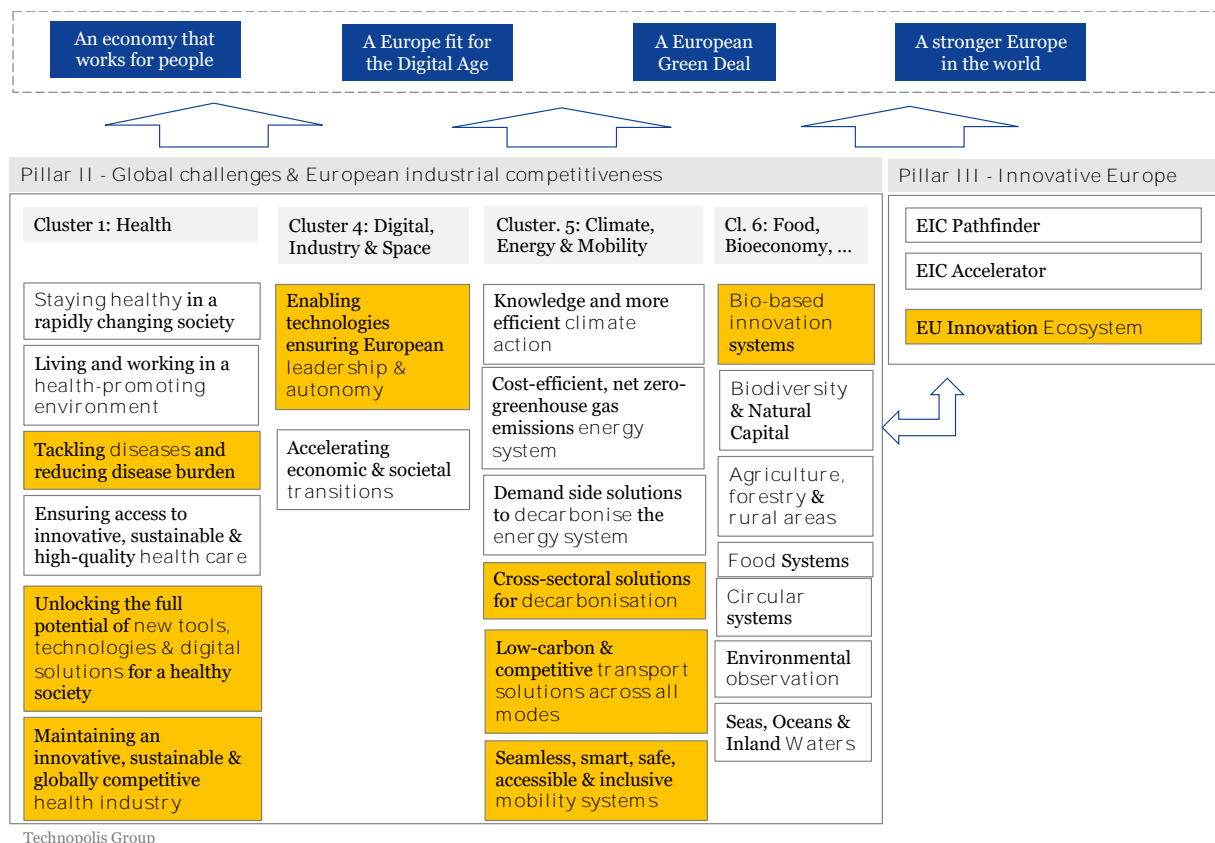
### 1.2 Typical problems and problem drivers

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

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

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

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



The European Partnerships under Horizon Europe most often find their rationale in addressing **systemic failures**. Their primary function is to create a platform for a strengthened collaboration and knowledge exchange between various actors in the European R&I system and an enhanced coordination of strategic research agenda and/or R&I funding programmes.

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

Especially in fast-growing technologies and sectors such as ICT, the envisaged European Partnerships also react on emerging opportunities and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.

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

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

### *1.3 Description of the options*

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

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

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

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

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

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

### 1.3.2 European Partnership

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

#### Option 1 - Co-programmed European Partnership

This form of European Partnership is based upon a *Memorandum of Understanding* or a *Contractual Arrangement* signed by the European Commission and the private and/or public partners. Private partners are typically represented by one or more industry association, which also functions as a back-office to the partnership. It allows for a *high flexibility* in the profile of organisation involved, objectives pursued, and/or activities implemented.

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

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

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

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

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

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

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

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

### Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement and will be based on a Council Regulation (Article 187) or a Decision by the European Parliament and Council (Art 185) and implemented by dedicated structures created for that purpose. The legal base for this type of partnership limits the flexibility for a change in core objectives, partners, and/or commitments as these would require amending legislation.

The basic rationale for this type of partnership is the need for a strong integration of R&I agenda's in the private and/or public sectors in Europe in order to address a strategic challenge or realise an opportunity. The focus is on major long-term strategic challenges and priorities beyond the framework of a single Framework Programme where collective action – by private and/or public sectors – is necessary to *achieve critical mass and address the full extent of the complexities* of the ecosystem concerned.

The long-term commitment expected from the European Union and its partners is therefore much larger than for any of the other options, given the considerably higher investment in the preparation and implementation of the Partnership. As a result, this type of partnership can be selected only if other parts of the Horizon Europe programme, including other forms of European Partnerships, would not achieve the objectives or would not generate the necessary expected impacts. The commitment for contributions by the partnership members is expected to be at least equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments.

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

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

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

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

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope of partners to Member States and Associated Third countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort.

It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a dedicated legal entity (Dedicated Implementation Structure) for the implementation. By default, membership of non-associated Third Countries is not foreseen. Such membership is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement. Eligibility for participation and funding follows by default the rules of the Framework programme, unless a derogation is introduced in the basic act.

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

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

It brings together a stable set of partners with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking) that carries full responsibility for the management of the partnership and implementation of the calls.

Different configurations are possible: partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners; partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries; or a combination of the two (the so-called tripartite model). By default, membership of non-associated Third Countries is not foreseen. Such membership is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement. Eligibility for participation and funding follows by default the rules of the Framework programme, unless a derogation is introduced in the basic act.

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

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

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

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

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

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

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

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

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

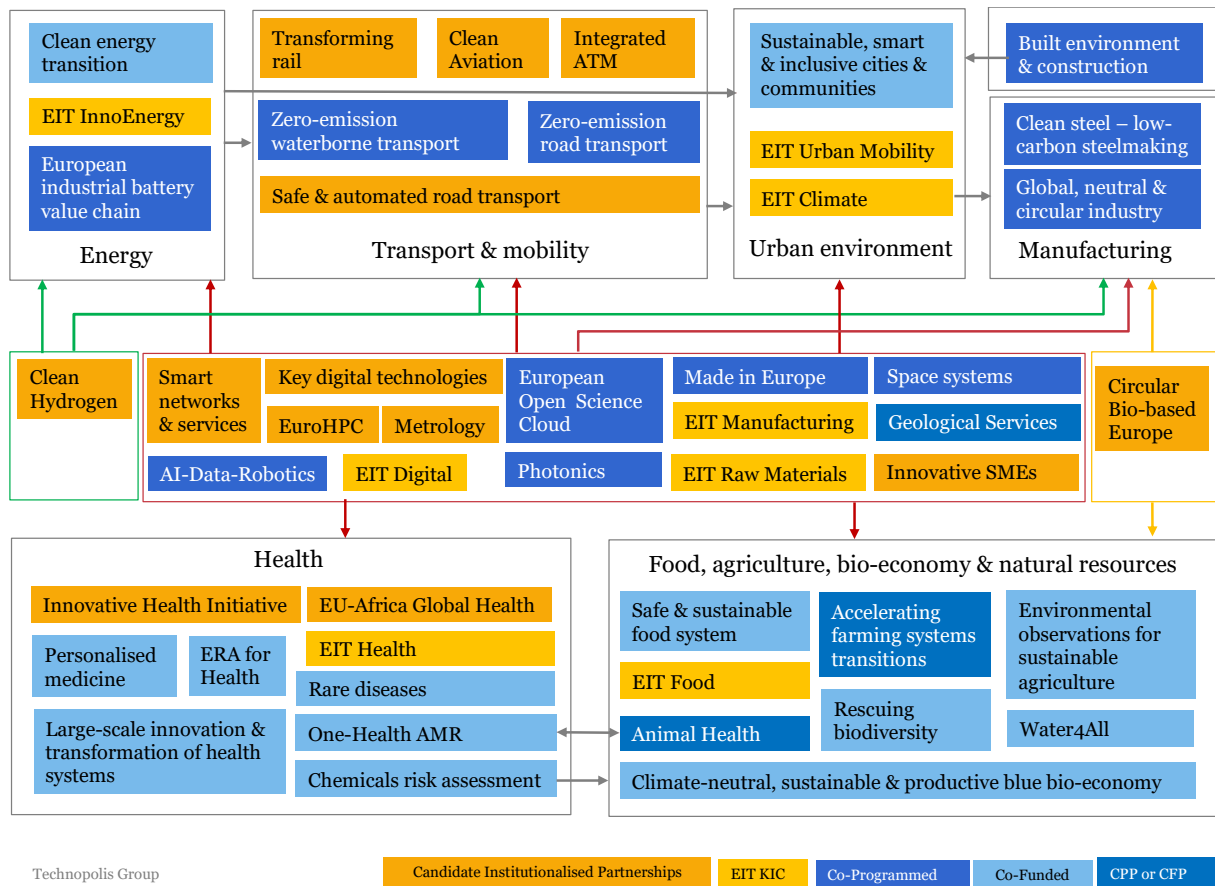
The diagram below shows the central position of the '**horizontal**' partnerships in the overall landscape, developing methodologies, technologies or data management infrastructures for application in the other priority areas. These 'horizontal' partnerships are predominantly proposed as Institutionalised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

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

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

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



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

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

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

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

#### 2.2.1 Assessment of the selection criteria

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



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

Table 1: Horizon Europe selection criteria for the European Partnerships

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

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

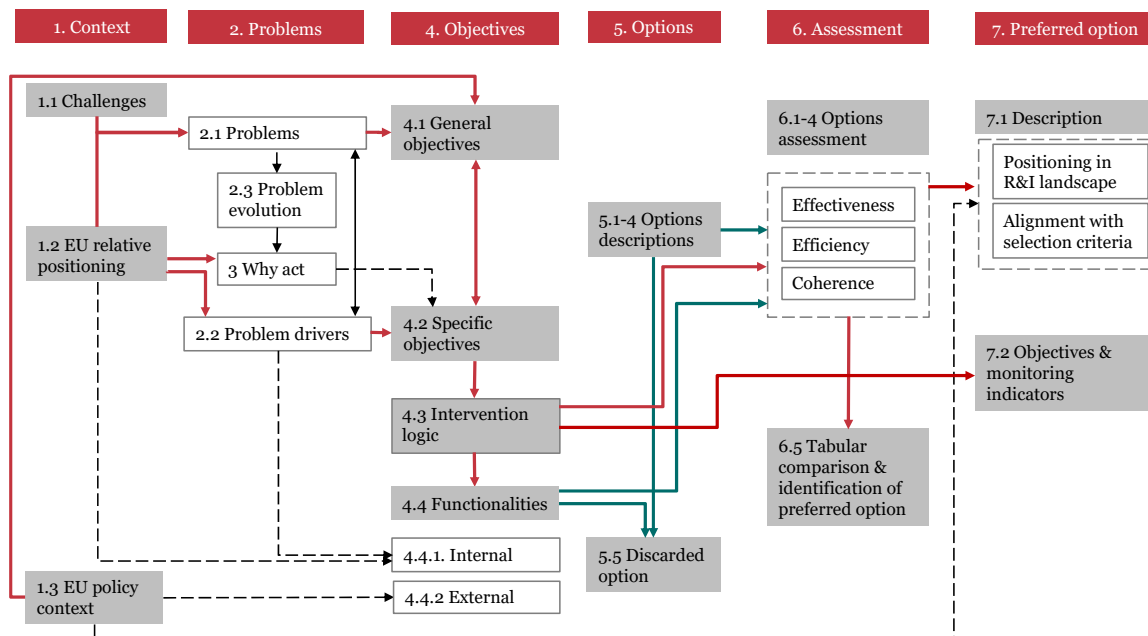


The **selection criteria** for the European Partnerships related to effectiveness and coherence fit reasonably well in the Better Regulation impact assessment structure. More problematic was the coverage of the other three criteria groupings, i.e. the criteria of Openness and Transparency, Additionality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

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

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

Figure 4: Flow of the analysis



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

## 2.2.2 Methodological approach

### Overview of the methodologies employed

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

from their predecessor partnerships (if any). This was complemented with a set of quantitative analyses of the Horizon 2020-funded partnerships, or in case these did not exist, the H2020-funded projects in the field. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options (see below).

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

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

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

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

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

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

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

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

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

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

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

## Options assessment related to efficiency

### **A standard cost model**

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

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

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

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

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

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

Cost items	Option 0	Option 1	Option 2	Option 3 -Art. 185	Option 3 -Art. 187
Ex-ante Impact Assessment for partnership	0	0	0	+++	+++
Preparation of EC proposal and negotiation	0	0	0	+++	+++
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0	+	0	+	+
Call and project implementation	0	0 In case of MS contributions: +	+	+	+
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				
Partners costs not covered by the above	0	+	0	+	+
Additional EC costs (e.g. supervision)	0	+	+	+	++
Winding down costs					
EC	0	0	0	0	+++
Partners	0	+	0	+	+

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

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

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

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

Table 3: Cost-efficiency matrix

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

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

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

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

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

In relation to **cost-efficiency**, we considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when we take into account financial leverage (co-financing rates) and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline and CPP policy options – and the least cost-efficient – the CFP and IP. We have therefore assigned a score of 3 to the baseline Option 0 and CPP options for cost-efficiency (no or minor additional costs, as compared with the baseline) and a score of 2 for the CFP and IP policy options (medium additional costs, as compared with the baseline).

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

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

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

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

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

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

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

#### 2.3.1 Cluster 1 – Health

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

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

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

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

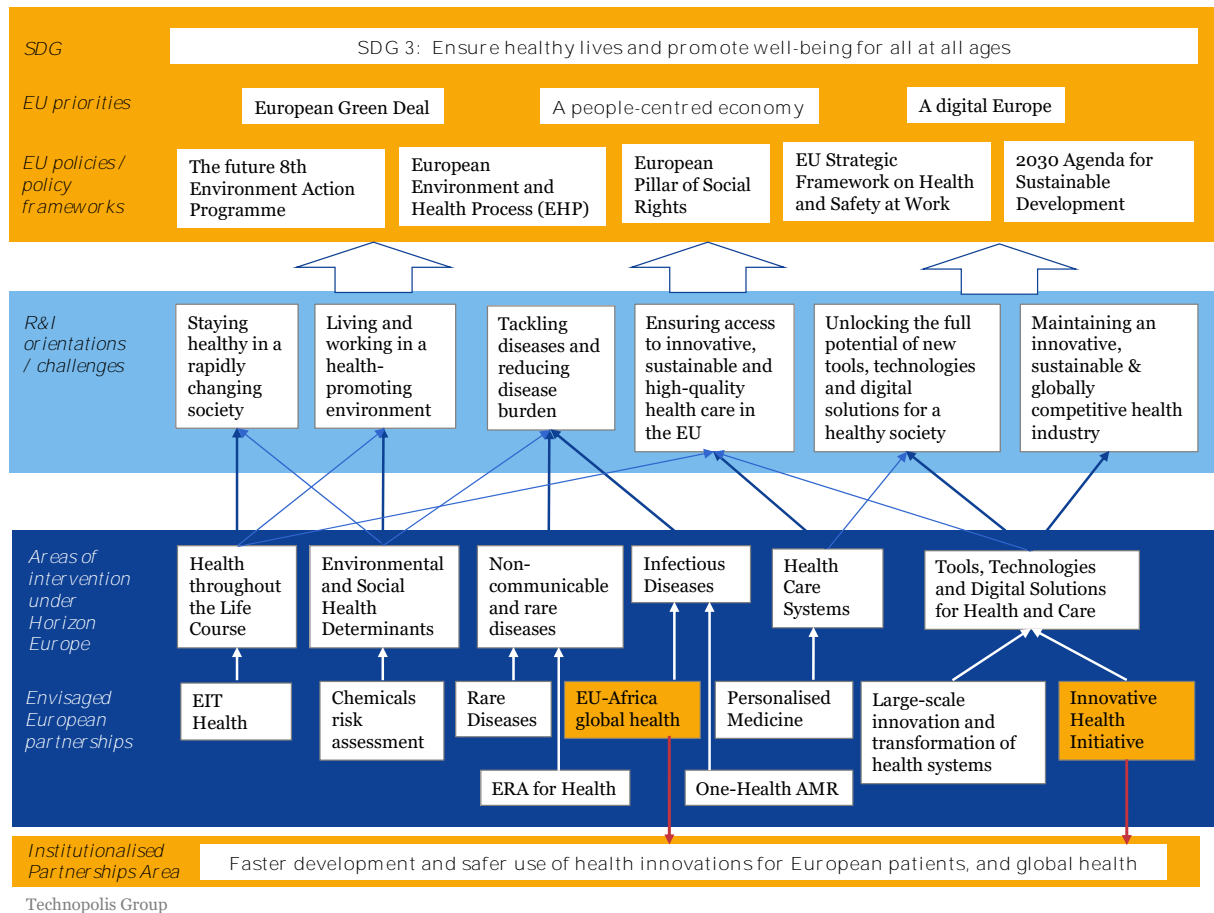
In this context, it should be noted that the portfolio of European Partnerships in this cluster predominantly encompasses Co-funded Partnerships, focused on joining the R&I programmes and investments at the national level. There is therefore overall a limited level of involvement of the private sector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

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

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

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



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

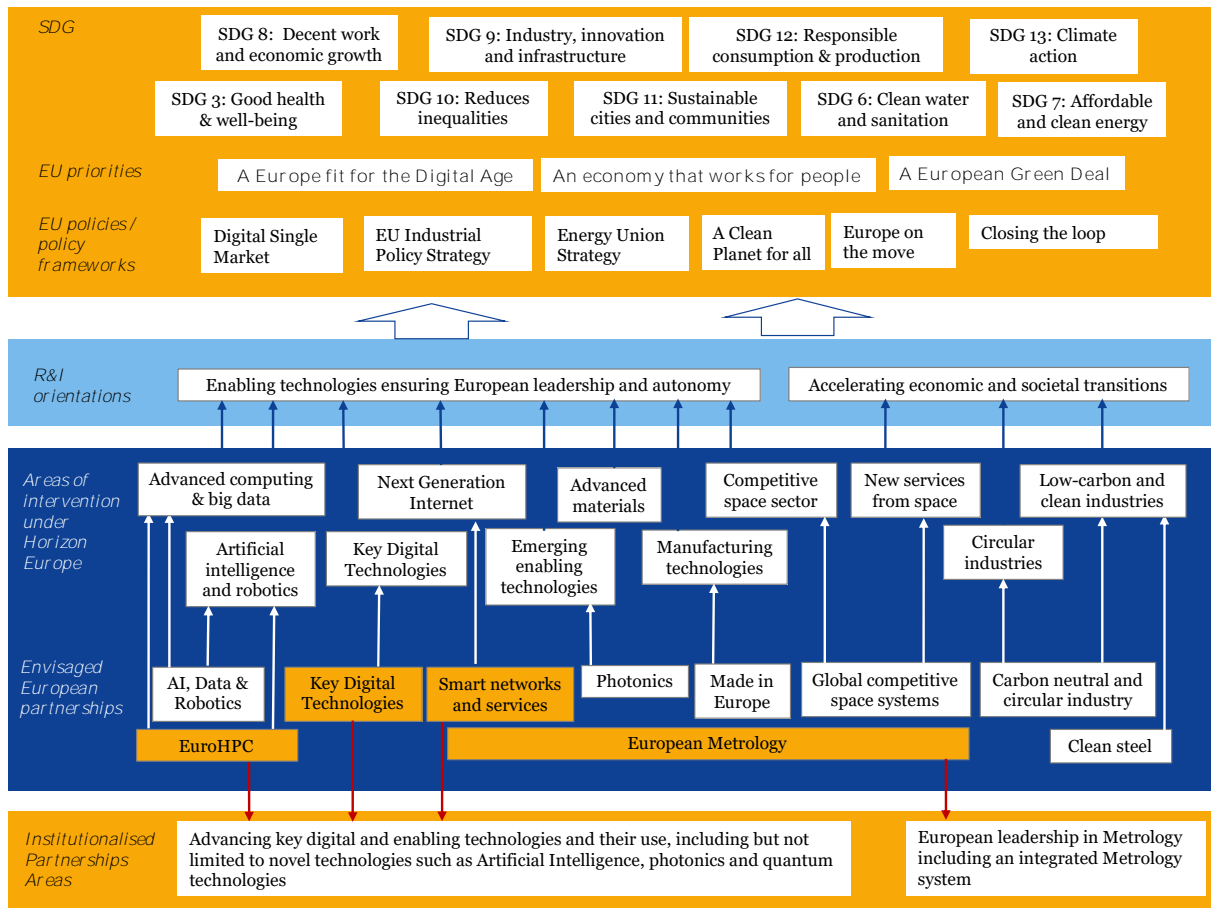
In this cluster the focus is on the digitisation of European industry and on advancing key enabling, digital and space technologies which will underpin the transformation of our economy and society at large. The overarching vision for R&I investments in this cluster is “a European industry with global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

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

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



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



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

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

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

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

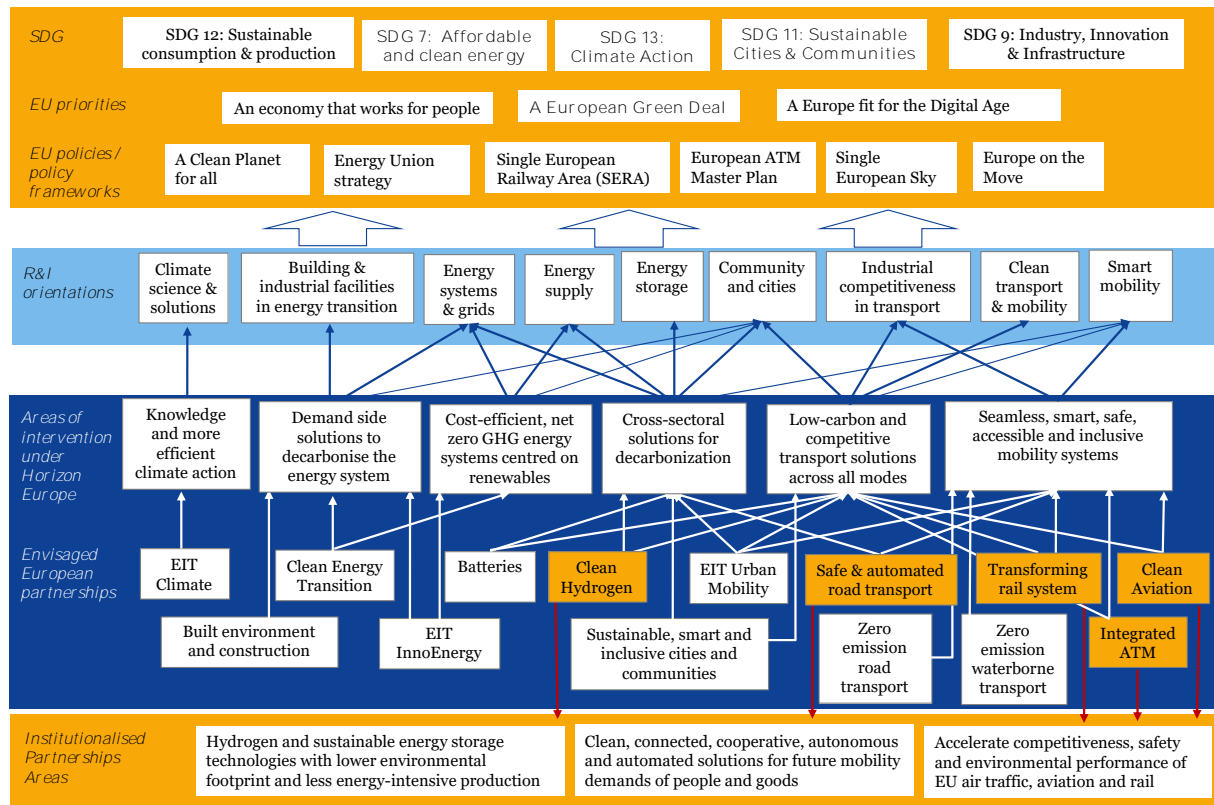
- Partnership Area 4: Accelerate competitiveness, safety and environmental performance of EU air traffic, aviation and rail



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

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

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



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

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

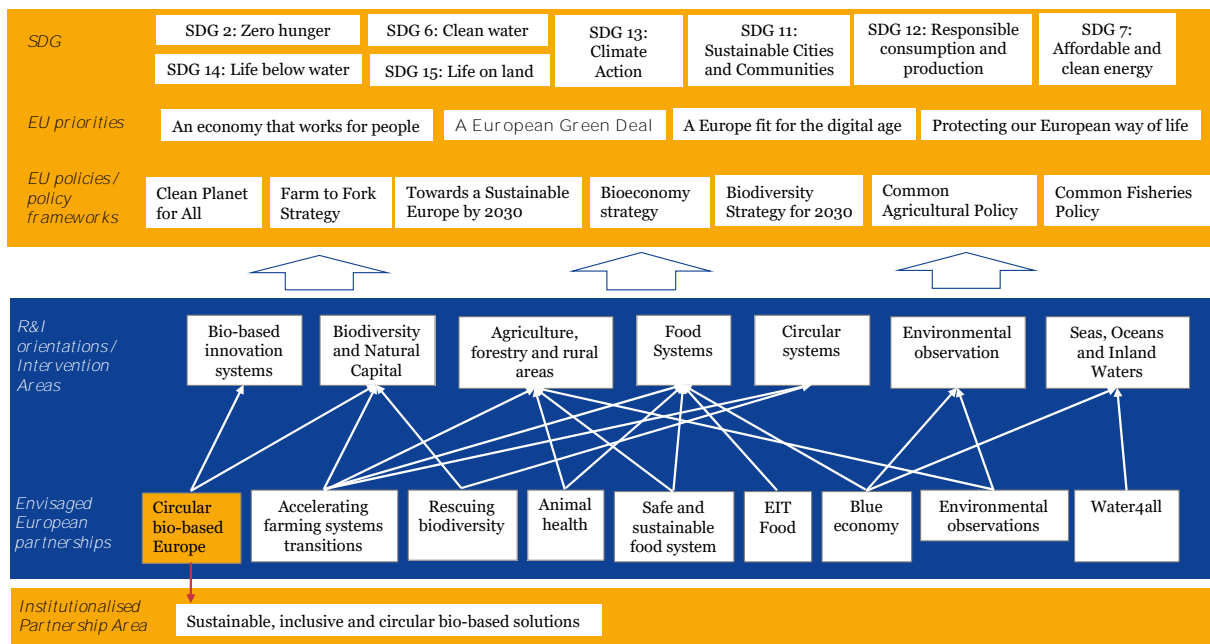
### 2.3.3 Cluster 6 – Food, Bioeconomy, Natural Resources, Agriculture and Environment

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

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

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

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



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

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

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

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

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



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

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

### **Authors**

Thyra de Jongh, Liana Petrosova, Anne-Laure Knellwolf, Janna van Belle



## **Abstract**

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

*This initiative focuses on research and innovation in the area of infectious diseases, with a particular focus on sub-Saharan Africa. It will address the challenges of a sustained high burden of infectious diseases in Africa, as well as the (re)emergence of infectious diseases worldwide. Its objectives will thus be to contribute to a reduction of the burden of infectious diseases in sub-Saharan Africa and to the control of (re)emerging infectious diseases globally. It will do so through investments in relevant research and innovation actions, as well as by supporting the further development of essential research capacity in Africa.*

*The study concluded that an Institutionalised Partnership under Art. 187 of the TFEU is the preferred option for the implementation of this initiative.*

## Executive Summary

This document is the final report of the Impact Assessment Study for the candidate EU-Africa Global Health Partnership under Horizon Europe. The study was conducted by Technopolis Group from July to December 2019. The methodological framework for this study, described in the report on the overarching context to the impact assessment studies, reflects the Better Regulation Guidelines and operationalises the selection criteria for European Partnerships set out in the Horizon Europe Regulation. This report contains the findings of this specific study.

The candidate EU-Africa Global Health Partnership is set to build upon and expand the activities performed within Horizon 2020, in particular, the European and Developing Countries Clinical Trials Partnership (EDCTP).

The impact assessment study has identified two main problems for the Candidate Initiative to address, namely the high burden of infectious diseases in sub-Saharan Africa and the (re)emergence of infectious diseases globally. These problems, although interlinked, present two distinct challenges in the field of global health and require multi-stakeholder collaboration and coordinated EU action to tackle.

The objectives of the candidate partnership are therefore two-fold: 1) to reduce the burden of infectious diseases in sub-Saharan Africa, and 2) to contribute to the control of (re-)emerging infectious diseases globally. The Candidate Initiative would require participation of different groups of stakeholders, including EU Member States and Associated States, African States, third countries, entities performing research and development, research funders, the pharmaceutical industry, charitable foundations, non-governmental organisations and international development and cooperation agencies. To realise its objectives, the Candidate Initiative should fund coordinated research and innovation actions in the field of infectious diseases and support partners in the coordination of their research efforts. In addition, the Candidate Initiative has an important role to play in growing and strengthening the research capacity of African countries.

The relevant policy options for this assessment were Horizon Europe calls (Option 0), Co-Programmed European Partnership (Option 1), Co-Funded European partnership (Option 2), and Institutionalised European Partnership (Option 3). Within Option 3, a further distinction is made between a partnership under Article 185 of the TFEU and one under Article 187. Our comparative assessment has taken into account domains of effectiveness (including the size of potential impacts for each option), internal and external coherence, and efficiency. Option 3 was found to be more cost-effective than the other options. Our conclusion is thus that Option 3 is the preferred option. Within this, the Art. 187 option is preferred due to the need for strong commitment of a broad range of partners and long-term sustainability.

## Résumé exécutif

Ce document est le rapport final de l'étude de support à l'analyse d'impact de la proposition d'un partenariat UE-Afrique pour la santé mondiale dans le cadre d'Horizon Europe. Cette étude a été menée par Technopolis Group entre juillet et décembre 2019. Le cadre méthodologique de cette étude, décrit dans le rapport sur le contexte général des études de support aux analyses d'impact, reflète les lignes directrices pour une meilleure réglementation et opérationnalise les critères de sélection des partenariats européens définis dans le règlement d'Horizon Europe. Le présent rapport contient les conclusions spécifiques à cette étude.

Le partenariat UE-Afrique pour la santé mondiale proposé vise à établir et étendre les activités menées au sein d'Horizon 2020, et en particulier le Partenariat Europe-Pays en développement pour les essais cliniques (EDCTP).

L'étude de support à l'analyse d'impact a identifié deux problématiques principales que l'initiative proposée doit pouvoir régler, à savoir le taux élevé de maladies infectieuses en Afrique subsaharienne et la (ré)émergence des maladies infectieuses dans le monde. Ces problématiques, bien qu'elles soient corrélées, présentent deux difficultés distinctes dans le domaine de la santé mondiale et nécessitent la collaboration de plusieurs intervenants et une action coordonnée de l'UE pour être surmontées.

L'objectif du partenariat proposé est donc double : 1) réduire le taux de maladies infectieuses en Afrique subsaharienne, et 2) contribuer au contrôle des maladies infectieuses (ré)émergentes dans le monde. Différents groupes d'intervenants participeront à l'initiative proposée, et notamment des États membres de l'UE et des pays associés, des États africains, des pays tiers, des organismes de recherche et développement, des bailleurs de fonds dans le domaine de la recherche, l'industrie pharmaceutique, des fonds de charité, des organisations non gouvernementales et des agences de développement et de coopération internationales. Pour atteindre ces objectifs, l'initiative proposée devra financer des actions coordonnées de recherche et d'innovation dans le domaine des maladies infectieuses et aider les partenaires à coordonner leurs efforts en matière de recherche. Par ailleurs, l'initiative proposée a un rôle important à jouer pour augmenter et renforcer la capacité de recherche des pays africains.

Les options stratégiques pertinentes pour cette analyse étaient les appels à projets d'Horizon Europe (option 0), les partenariats européens co-programmés (option 1), les partenariats européens cofinancés (option 2) et les partenariats européens institutionnalisés (option 3). Au sein de l'option 3, une distinction supplémentaire est faite entre un partenariat au titre soit de l'article 185 soit de l'article 187 du TFUE. Notre analyse comparative a tenu compte des aspects d'efficacité (et notamment de l'envergure des impacts potentiels de chaque option), de cohérence interne et externe et d'efficience. L'option 3 s'est avérée la plus rentable par rapport aux autres options. Nous avons donc conclu que l'option 3 était la meilleure option. L'option selon l'Art. 187 a été préférée, étant donné qu'un engagement ferme d'un large éventail de partenaires et une durabilité à long terme étaient nécessaires.



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## Glossary

AMR	Anti-Microbial Resistance
DIS	Dedicated Implementation Structure
EC	European Commission
EDCTP	European and Developing countries Clinical Trials Partnership
EU	European Union
FTE	Full-Time Equivalent
GA	General Assembly
ID	Infectious Disease
JU	Joint Undertaking
LMICs	Low- and Middle-Income Countries
MDGs	Millennium Development Goals
NCD	Non-Communicable Disease
OPC	Open Public Consultation
PRND	Poverty-Related and Neglected Disease
PS	Participating States
PSIAs	Participating States Initiated Activities
R&D	Research and Development
R&I	Research and Innovation
RIA	Research and Innovation Action
SDGs	Sustainable Development Goals
SSA	Sub-Saharan Africa
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization

## 1 Introduction: Political and legal context

This document presents the impact assessment of the candidate EU-Africa Global Health Partnership, which is one of the initiatives that will implement the Commission's vision for the period beyond 2020 under the Horizon Europe Pillar II/III, specifically the Cluster Health. It is one of the envisaged European Partnerships in the Partnership Area "Health".

### 1.1 Emerging challenges in the field

Despite significant progress against the Millennium Development Goal (MDG) 1 to 'eradicate extreme poverty and hunger' and a renewed commitment from the international community under Sustainable Development Goal 1 (SDG1) "to end poverty in all its forms everywhere", poverty remains a major problem in sub-Saharan Africa (SSA).<sup>1</sup> **Poverty** interacts with health in many ways, including by contributing to malnutrition and disability, limiting access to clean water and sanitation, and by reducing access to health services and technologies.<sup>2</sup> All these factors can increase a person's risk of contracting diseases, as well as prevent them from accessing necessary diagnostic services and treatments.

The slow progress against overcoming poverty in the SSA region contributes to the continued high prevalence of poverty-related and neglected diseases (PRNDs).<sup>3</sup> Meanwhile, the burden of PRNDs limits the economic growth potential of countries, by taking people out of the workforce and putting a financial burden on the health care and other sectors. There is therefore both a social and economic imperative to tackle PRNDs, with a view towards achieving large-scale growth and development of affected countries.<sup>4</sup> Beyond poverty, there are various further contributing factors driving the high burden of PRNDs in SSA.

First, Africa is undergoing rapid **population growth**, accounting for more than half of the projected global population growth between now and 2050.<sup>5</sup> As a result, Africa has become the 'youngest' continent with 60% of people below the age of 25. It now faces the challenge of successfully fostering these young people, after the HIV epidemic ravaged the continent and left many orphaned. From the perspective of research and innovation in Africa, this demographic shift presents both a challenge and an opportunity: on the one hand, there are currently few senior researchers, thereby limiting the capacity to train a new generation of scientists. At the same time, today's young people can be the future scientific leaders, provided that investments are made into their development.

Furthermore, as a result of **urbanisation**, population density in areas has significantly increased, raising the risk of outbreaks of infectious diseases that would previously be contained in smaller geographic areas.<sup>6</sup> The challenges posed by urbanisation are amplified by increasing **travel and migration**, within Africa but also into and within the EU region.

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<sup>1</sup> Data from <https://www.mdgmonitor.org/mdg-1-eradicate-poverty-hunger/> and <https://sustainabledevelopment.un.org/sdg>, Accessed 29 August 2019

<sup>2</sup> Murray S. (2006). Poverty and health. CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne, 174(7), 923. doi:10.1503/cmaj.060235

<sup>3</sup> Data from <https://www.worldbank.org/en/news/press-release/2018/09/19/decline-of-global-extreme-poverty-continues-but-has-slowed-world-bank> Accessed 28th August 2019

<sup>4</sup> European Commission (2017). RAND Europe and Technopolis Group "Evaluation of the impact of the European Union's Research Funding for Poverty-Related and Neglected Diseases". Available at: <https://publications.europa.eu/en/publication-detail/-/publication/1f324128-a4c1-11e7-837e-01aa75ed71a1/language-en>

<sup>5</sup> Data from <https://www.un.org/en/sections/issues-depth/population/>, Accessed 29 August 2019

<sup>6</sup> M. Awumbila (2017). Drivers of Migration and Urbanization in Africa: Key Trends and Issues: Background Paper prepared for UN Expert Group Meeting on Sustainable Cities, Human Mobility and International Migration. Available at: <https://www.un.org/en/development/desa/population/events/pdf/expert/27/papers/III/paper-Awunbila-final.pdf>

The 2014-2016 West Africa Ebola outbreak clearly highlighted this risk: after the first case was reported in Guinea, the disease quickly spread to neighbouring countries.<sup>7</sup> Through health care workers, the disease was then able to reach Spain, Italy and the UK. The rapid spread that occurred within West Africa was facilitated by poor detection systems, low preparedness against disease in the affected region, and a lack of proper infrastructures to diagnose and treat patients.<sup>8</sup> This underscores that disease preparedness is essential for tackling highly infectious diseases, necessitating effective disease surveillance and response systems and research to have performant systems.

**Climate change** will likely pose a further challenge to reducing the burden of infectious diseases, including that of (re)emerging infectious diseases.<sup>9</sup> Climatic changes, such as hotter and longer summers, warmer winters, and/or increased annual rainfalls are enabling disease vectors to shift their habitats, potentially introducing diseases to areas previously unfamiliar with them.<sup>10</sup> The disease burden of many tropical and neglected diseases could increase dramatically as global temperatures rise.<sup>11</sup> For example, in the case of malaria, an average global temperature increase of 2-3°C has been predicted to increase the number of people at risk of the disease by several hundred million. Further, the seasonal duration of malaria would increase in many currently already endemic areas. Beyond adding to the current disease burden, climate change may also accelerate the emergence of new diseases, including those with antimicrobial resistance.

A further important challenge facing Africa is the **rise of chronic non-communicable diseases**, like diabetes, cardiovascular disease and cancer.<sup>12</sup> Along with the unresolved epidemic of infectious diseases, this presents Africa with an unwelcome double burden of disease. The resulting increased levels of comorbidity are likely to create new challenges for the development and use of effective treatment strategies.

Encouragingly, over the past decade, there have been significant **scientific and technological advances** in the development of technologies to prevent, diagnose and treat PRNDs. Alongside the basic research that is typically done in research institutes, so-called Product Development Partnerships (PDPs) have often been crucial to ensuring the final development of products and their delivery of to the market.<sup>13</sup> The European and Developing countries Clinical Trials Partnership (EDCTP) has also successfully contributed to the development of medicines and diagnostic tools across the programme's target areas.<sup>14</sup> **Technological advances**, such as those in the areas of DNA sequencing and genome editing, are also opening up new avenues for the development of PRND treatments. Noteworthy is furthermore the **digitalisation of Africa** and the increasing

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<sup>7</sup> Data from <https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html>

<sup>8</sup> Peter Piot, Moses J Soka, Julia Spencer, Emergent threats: lessons learnt from Ebola, International Health, Volume 11, Issue 5, September 2019, Pages 334-337, <https://doi.org/10.1093/inthealth/ihz062>

<sup>9</sup> Flahault A, Ruiz de Casteneda R, Bolon I (2016). Climate change and infectious diseases. Public Health Reviews 37(21).

<sup>10</sup> Data from <https://ecdc.europa.eu/en/climate-change/climate-change-europe>

<sup>11</sup> WHO (2003). A.J. McMichael, et al Climate change and human health - risks and responses. Available at: <https://www.who.int/globalchange/publications/cchhbook/en/>

<sup>12</sup> World Health Organization (2016). Burden of non-communicable diseases on the rise. Available at: <https://www.afro.who.int/news/burden-non-communicable-diseases-rise>

<sup>13</sup> 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>

<sup>14</sup> EDCTP (2018). Tackling infectious disease in sub-Saharan Africa. Available at: <http://www.edctp.org/publication/tackling-infectious-disease-in-sub-saharan-africa-edctp-funded-clinical-studies-for-medical-interventions-2003-2018/>

use of mobile technologies.<sup>15</sup> 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 research data. It can also change the way services are delivered in hard to reach areas, for instance, using digital diagnostics or drones.<sup>16</sup>

The successful development of much-needed technologies alone, however, is not enough to ensure that patients receive **access** to them. This can be challenged by, for example, prohibitive costs or unsuitability to the environmental and social context of SSA. A key question for the global health research community is thus how to harness the power of new advanced technologies, whilst ensuring that the resulting products are affordable, available and suitable for populations most in need.

Whilst the development of new technologies remains essential to combat infectious diseases, there is also an important challenge in how to safeguard the effectiveness of those technologies that are already available. For example, antimicrobials agents are crucial in the treatment of many PRNDs, but the spread of **antimicrobial resistance** (AMR) could undermine the progress made to date. Although the precise levels of AMR in the African Region are not recorded<sup>17</sup> due to lack of monitoring, available data suggest that the African region follows the global trend of rising AMR prevalence, with significant resistance, found for numerous treatments against TB, malaria, HIV/AIDS, cholera, and dysentery.<sup>18</sup> Apart from affecting 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. It is therefore important to adopt a holistic approach to research and development of PRND-related technologies while investing in the capacity of African health systems to monitor and contain the spread of AMR.

R&D for health technologies (medicines, vaccines, and diagnostic tools) can be complex and expensive. As in many industries, private pharmaceutical companies base their R&D investments on the purchasing power of their clients or, in the case of healthcare, that of patients and health systems. Therefore, these companies may not see SSA as a region with sufficient potential of an adequate return on investment and may not be interested in funding research for diseases that are largely contained in that region. The **low commercial potential** of PRND-related clinical research means that most of its funding needs to be provided through public sources, which are scarce in SSA. International development cooperation is therefore crucial to **pooling enough funding** for the development of these technologies. Numerous actors, such as WHO's Special Programme for Research and Training in Tropical Diseases (TDR), the United Nations Development Programme (UNDP) and the World Bank, as well as individual countries and philanthropic organisations, have been involved in doing so. Efforts are also being made to boost the

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<sup>15</sup> Biarritz Declaration for a G7 and Africa Partnership: Digital transformation in Africa (2019). Available at: <https://www.consilium.europa.eu/media/40535/annex-2-digital-transformation-in-africa.pdf>

<sup>16</sup> 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). Accessible at <https://healthmanagement.org/c/hospital/issuearticle/africa-leading-way-in-healthcare-tech-the-continent-is-ahead-of-the-game-in-cutting-edge-drone-use>.

Marketwatch (2019). Ghana : Zipline Drone Makes Delivery of Sickle Cell Medication. Accessible at: <https://www.marketwatch.com/press-release/ghana-zipline-drone-makes-delivery-of-sickle-cell-medication-2019-06-23>

<sup>17</sup> 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

<sup>18</sup> WHO African Health Monitor (2013). J. B. Ndhokubwayo et al "Antimicrobial resistance in the African Region: Issues, challenges and actions proposed". Available at: <https://apps.who.int/medicinedocs/documents/s22169en/s22169en.pdf>



involvement of pharmaceutical companies.<sup>19</sup> In 2012, 13 of the world's largest pharmaceutical companies signed the London Declaration on Neglected Tropical Diseases,<sup>20</sup> representing a commitment to contribute over €700 million for R&D and large-scale drug donations for PRNDs.

The reliance on **public funding** and the commitment from **donors** is a major challenge for the field of PRND research and development, as it means that funding availability is closely tied to **policy priorities**. Over the past two decades, the world has expressed its commitment to combatting PRNDs which has been reflected in both the MDGs and the current Sustainable Development Goals (SDGs). In October 2019, the Global Fund announced that it had received pledges worth US\$14.02 billion from donors to help end the epidemics of AIDS, malaria and tuberculosis.<sup>21</sup> Nonetheless, a 2017 study evaluating the impact of the EU's research funding for PRNDs deemed it likely that continuously emerging policy priorities may call for increasing trade-offs in funding allocation in future.<sup>22</sup> Already some national governments have signalled **a shift in their policy priorities** for international cooperation and development.<sup>23</sup> However, clinical research can take many years and is highly costly. This, therefore, requires a strong and sustained commitment from funders.

A final challenge to note is that much of the research on PRNDs (including clinical trials) needs to be conducted in the areas where a disease is most prevalent, as this is where patients are. However, current **research capacity in LMICs** does not always allow the conduct of such trials, limited availability of trained personnel, inadequate laboratories and equipment, and lack of, among others, a physical and data infrastructure. Moreover, the lack of investment in clinical capacity building and research infrastructure hinders the development of the scientific leadership of African researchers.

Table 1: Overview of the challenges emerging

<b>Social</b>	<ul style="list-style-type: none"> <li>• Continued high rates of poverty contribute to PRNDs.</li> <li>• Africa is experiencing strong population growth and has an increasingly young population</li> <li>• Urbanisation, migration and globalisation increase the risks of disease outbreaks and enable faster transmission between localities</li> <li>• The increasing burden of non-communicable disease in SSA and co-morbidities with infectious diseases.</li> </ul>
<b>Technical and technological</b>	<ul style="list-style-type: none"> <li>• Technological advances could accelerate the development of health technologies for infectious diseases but lead to greater health inequality without safeguards for access.</li> </ul>

<sup>19</sup> [https://accesstomedicinefoundation.org/media/uploads/downloads/5cb9b00e8190a\\_Access-to-Medicine-Index-2018.pdf](https://accesstomedicinefoundation.org/media/uploads/downloads/5cb9b00e8190a_Access-to-Medicine-Index-2018.pdf)

<sup>20</sup> [https://www.who.int/neglected\\_diseases/London\\_Declaration\\_NTDs.pdf](https://www.who.int/neglected_diseases/London_Declaration_NTDs.pdf)

<sup>21</sup> The Global Fund (2019). Global Fund Donors Pledge US\$14 Billion in Fight to End Epidemics. Available at: <https://www.theglobalfund.org/en/news/2019-10-10-global-fund-donors-pledge-usd14-billion-in-fight-to-end-epidemics/>

<sup>22</sup> European Commission (2017). RAND Europe and Technopolis Group "Evaluation of the impact of the European Union's Research Funding for Poverty-Related and Neglected Diseases". Available at: <https://publications.europa.eu/en/publication-detail/-/publication/1f324128-a4c1-11e7-837e-01aa75ed71a1/language-en>

<sup>23</sup> The Netherlands, for instance, has chosen to focus its policy for international development cooperation on addressing issues around sexual and reproductive health and rights. Ministry of Foreign Affairs (2018). *Investeren in Perspectief (Beleidsnota 2018)*. Available at: <https://www.rijksoverheid.nl/onderwerpen/ontwikkelingssamenwerking/documenten/beleidsnota-s/2018/05/18/pdf-beleidsnota-investeren-in-perspectie>

	<ul style="list-style-type: none"> <li>• Loss of effectiveness of existing health technologies due, in part, to their inappropriate use (AMR)</li> <li>• Capacity for conducting clinical research in LMICs is limited</li> </ul>
<b>Economic</b>	<ul style="list-style-type: none"> <li>• Low return on investment</li> <li>• Low purchasing power in SSA to procure health technologies</li> <li>• Research and product development for PRNDs largely reliant on public sector and charitable funding</li> </ul>
<b>Environmental</b>	<ul style="list-style-type: none"> <li>• Climatic changes may cause major shifts in the burden of PRNDs and even lead to the emergence of new diseases</li> <li>• Weak systems for disease preparedness and outbreak management</li> </ul>
<b>Political, policy and regulatory framework</b>	<ul style="list-style-type: none"> <li>• Reliance on public funding makes R&amp;D for PRND highly dependent on, sometimes shifting, policy priorities, where sustained commitment is needed.</li> </ul>

## 1.2 EU relative positioning

### 1.2.1 Competitive positioning of Europe in the field

Over the past two decades, global concern about the disproportionate burden of PRNDs in low-income countries, especially in SSA, has led to a substantial influx of funding for research by many donor and research agencies.<sup>24</sup> In 2017, the global funding for PRND basic research and product development reached US\$3,566m.<sup>25</sup> Almost two-thirds (65%) came from the public sector. European public funders, both European governments and the EU are significant contributors to global PRND R&D efforts.

Although the United States remain the largest funder for R&D into product development for PRNDs (such as vaccines, drugs and diagnostics), the European Union and its member states also play a pivotal role.<sup>26</sup> Through its framework programmes of research and innovation and initiatives, such as EDCTP and the Innovative Medicines Initiative (IMI), the EU is an important contributor to PRND-related research. In the period 2007-2014, 28% of European public funding for PRND R&D was invested by the EU. The other 72% was invested by European governments. In Horizon 2020 the EU has increased its investment in product development, as reflected by the increased budgets for EDCTP2 and the significant new investment in Ebola early-stage research through IMI2.<sup>27</sup> The primary impact of EU-funded PRND R&D has been in knowledge generation for diagnosis, treatment and prevention, and research capacity strengthening in LMICs.<sup>26</sup>

Many European governments also engage in bilateral research support in the area of PRNDs: the UK, France, Germany, Austria and the Netherlands are among the top ten

<sup>24</sup> Collins, Francis & Beaudet, Alain & Draghia-Akli, Ruxandra & Gruss, Peter & Savill, John & Syrota, André & Dautry, Alice & Ulfendahl, Mats & Walport, Mark & Onken, James & Glass, Roger (2013). A database on global health research in Africa. *The lancet global health*. 1. e64-e65. 10.1016/S2214-109X(13)70012-3.

<sup>25</sup> G-Finder (2018). *Neglected Disease Research and Development: reaching new heights*. Available at: [https://www.policycuresresearch.org/wp-content/uploads/Y11\\_G-INDER\\_Full\\_report\\_Reaching\\_new\\_heights.pdf](https://www.policycuresresearch.org/wp-content/uploads/Y11_G-INDER_Full_report_Reaching_new_heights.pdf)

<sup>26</sup> European Commission (2017). *RAND Europe and Technopolis Group "Evaluation of the impact of the European Union's Research Funding for Poverty-Related and Neglected Diseases"*. Available at: <https://publications.europa.eu/en/publication-detail/-/publication/1f324128-a4c1-11e7-837e-01aa75ed71a1/language-en>

<sup>27</sup> DSW (2016). *Making the case for European investment in PRND R&D* Available at: <https://www.policycuresresearch.org/wp-content/uploads/2019/01/2016-Saving-Lives-Policy-Cures-Report-for-DSW.pdf>

funding countries.<sup>28</sup> Countries may do so by direct provision of national research grants or through research funding programmes entirely dedicated to supporting global health research.<sup>29</sup> European governments also support PDPs, which are public-private collaborations that are focused on the development of products to combat PRNDs, with public health rather than commercial gain as their primary objective. The governments of the United Kingdom, the Netherlands, Ireland, Germany, Denmark and France are particularly strong supporters of the PDP model.

Aside from being an important funder of PRND research, Europe also plays an important role in conducting such research. There are numerous European research institutes with a long tradition of high-quality research in the field. Several of these are linked in the European Global Health Research Institutes Network (EGHRIN).<sup>30</sup> In 2015, the staff of EDCTP, together with Thomson Reuters, published a study that measured the research output of European (and African) researchers on PRNDs, described collaboration patterns and assessed the citation impact.<sup>31</sup> They found that, in the period 2007 to 2011, European EDCTP member countries accounted for around one-third of the global research output in PRNDs. Over 90% of publications from EDCTP-funded research were published in high-impact journals and are highly cited (average citation impact 1.31). In Europe, particularly research institutions from the UK and France, and to a lesser extent the Netherlands, Belgium, Switzerland and Germany were found to be very active in this field. The bibliometric analysis for EDCTP, performed in a similar fashion across all Horizon Europe initiatives, identified a scientific output of 51 publications between 2016 and 2019. Numbers provided by EDCTP directly connected 775 publications to projects supported through EDCTP1, and 52 to projects under EDCTP2. These bibliometric analyses show that research institutions in Europe are at the forefront of research in this field.

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

As mentioned in the previous section, the EU has been an important funder of PRND research through its framework programmes for research and innovation. Most notably, in 2003, the EU together with 15 European countries set up the "European & Developing Countries Clinical Trials Partnership" (EDCTP).<sup>32</sup> EDCTP was the first initiative based on Article 185 of the Treaty on the Functioning of the EU (formerly Article 169), which allows the EU to participate in research programmes undertaken by the EU Member States. It was set up to accelerate the development of new clinical interventions to combat HIV/AIDS, malaria and tuberculosis in developing countries, particularly in SSA, and to improve the quality of research in relation to these diseases.

Its purpose was to boost the research capacity of SSA countries through a long-term partnership between Europe and African countries. It was furthermore designed to support high-quality collaborative research in an integrated approach, including clinical research, research capacity development and international networking. The first EDCTP programme

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<sup>28</sup> Investments by country (in million) from [https://www.who.int/research-observatory/monitoring/inputs/neglected\\_diseases\\_country/en/](https://www.who.int/research-observatory/monitoring/inputs/neglected_diseases_country/en/)

<sup>29</sup> Through science and technology agencies like UK-MRC, FR-INSERM or aid international development agencies like UK-DFID, SE-SIDA as reflected in the DSW 2016 report: Making the case for European investment in PRNDs R&D.

<sup>30</sup> <https://eghrin.eu/>

<sup>31</sup> Breugelmans JG, Makanga MM, Cardoso ALV, Mathewson SB, Sheridan-Jones BR, Gurney KA G, Mgone CS (2015). Bibliometric Assessment of European and Sub-Saharan African Research Output on Poverty-Related and Neglected Infectious Diseases from 2003 to 2011. PLOS Neglected Tropical Diseases, 11 August. Available at: <https://doi.org/10.1371/journal.pntd.0003997>.

<sup>32</sup> Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom (referred to as 'the participating Member States') and Norway.

(EDCTP1) (2003-2013) supported 102 clinical trials and clinical studies on the diagnosis, treatment and prevention of its three focus diseases.<sup>33</sup>

Despite the considerable achievements of EDCTP1, PRNDs still represented a major obstacle to the sustainable development of SSA. As there remained a need for effective, safe, suitable and affordable medical treatments tailored to the specific circumstances of developing countries for most of the poverty-related diseases, the scope of the second programme, EDCTP2 (2014-2024) was extended<sup>34</sup> to also cover neglected infectious diseases,<sup>35</sup> diarrhoeal diseases, lower respiratory tract infections, and (re-)emerging infections<sup>36</sup> affecting SSA (such as Ebola and yellow fever).<sup>37</sup> It was launched in 2014 by the EU and sixteen European Participating States.<sup>38</sup> The general objective of EDCTP2 is to contribute to the “reduction of the social and economic burden of poverty-related diseases in developing countries, and in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa.”.<sup>39</sup>

EDCTP2 is a public-public partnership between institutions mandated by national governments in Europe and SSA, supported by the EU. Under EDCTP2, African and European countries are members of the General Assembly of the EDCTP Association, settled under Dutch law, the implementing structure for the second EDCTP programme. The EU supports EDCTP2 with a financial contribution of up to €683 million from the Horizon 2020 programme’s societal challenge “Health, Demographic Change and Well-being” (“EDCTP2 Basic Act 2”) provided that the European Participating States contributions match this amount. This means that the partnership represents a total of €1.366 billion.

To support strategic activities with a high expected impact but requiring a critical scale of resources, the EDCTP implementing structure is partnering with third countries, or their scientific and technological organisations and agencies (e.g. DFID, SIDA), with international organisations (e.g. World Health Organization), private funders (e.g. Bill & Melinda Gates Foundation), or with other third parties, to jointly fund activities.

In the Evaluation of the Participation of the EU in research and development programmes undertaken by the several Member States based on Article 185 of the TFEU, the Commission has underscored that “the topics addressed by [...] EDCTP2 are to a large extent not tackled with other Horizon 2020 actions.”<sup>40</sup> Moreover, the independent Interim Evaluation of the EDCTP2 carried out in 2017 acknowledged the invaluable and unique

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<sup>33</sup> First EDCTP Programme Summary of Achievements. Available at: <http://www.edctp.org/web/app/uploads/2016/06/summary-of-achievement-digital.pdf>

<sup>34</sup> Decision n°556/2014/EU of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0556&from=EN>

<sup>35</sup> Based on the WHO list of neglected tropical diseases (excluding Chagas disease).

<sup>36</sup> Commission activities in the area of emerging and re-emerging infectious diseases, <https://ec.europa.eu/research/health/index.cfm?pg=area&areaname=emerging>

<sup>37</sup> EDCTP (2018). Strategic Business Plan 2014-2024, Available at: <http://www.edctp.org/web/app/uploads/2016/12/EDCTP-Strategic-Business-Plan-2014-2024.pdf>

<sup>38</sup> Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom

<sup>39</sup> Decision N0 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.

<sup>40</sup> European Commission (2017). Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU SWD(2017)340 Final.

contribution that the programme has made in sub-Saharan Africa in accordance with the objectives of EDCTP2.<sup>41</sup>

### 1.3 EU policy context beyond 2021

Of particular relevance to the candidate EU-Africa Global Health Partnership is the European Commission's commitment to the *UN's Sustainable Development Goals (SDGs)* calling to "ensure healthy lives and promote well-being for all at all ages" (SDG3) and, in particular, Goal 3.3b to "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries and provide access to affordable essential medicines and vaccines".<sup>42</sup> This initiative would also contribute to SDG 9 "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation" and SDG 17 "Strengthen the means of implementation and revitalize the global partnership for sustainable development Partnerships".

The Commission has pointed out (p.22-23) in the reflection paper *Towards a Sustainable Europe by 2030* that health research and related innovation actions have played a significant role in improving productivity and quality in health, health care systems and in the functioning of its relevant industries.<sup>43</sup> It has emphasized that there is a continuous need to face persisting or novel challenges in science, society and policy for achieving a sustainable Europe by 2030.

With the recently established *EU-Africa Alliance for Sustainable Investment and Jobs*,<sup>44</sup> the EU has also committed to reinforcing Africa as a partner in trade, in foreign investment and in development. Through its activities, the Alliance aims to contribute to the strengthening of the African business environment and investment climate, investing in people by investing in education and skills, and tapping the full potential of economic integration and trade. These actions are fully aligned with the *2030 Agenda for Sustainable Development*.

The Discussion Paper *H2020 Partnership Landscape and its relevance for Horizon Europe –Cluster 'Health'* (p.6), identifies eight major health challenges affecting European societies in the coming decades to be addressed within Horizon Europe.<sup>45</sup> Of these, the ones that are most pertinent to the candidate EU-Africa Global Health Partnership would be:

- the lack of effective health promotion and disease prevention
- the spread of antimicrobial drug resistance and the emergence of infectious epidemics
- the persistence of health inequalities among and within countries affecting disproportionately people that are disadvantaged or in vulnerable stages of life
- the detection, understanding, control, prevention and mitigation of health risks in a rapidly changing social, urban and natural environment

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<sup>41</sup> [http://ec.europa.eu/research/evaluations/pdf/edctp2\\_evaluation\\_experts\\_report\\_2017.pdf](http://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf)

<sup>42</sup> UN General Assembly (2015). Transforming our world: the 2030 Agenda for Sustainable Development, available at: <https://www.refworld.org/docid/57b6e3e44.html>

<sup>43</sup> Data from Sustainable Europe 2030. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/rp\\_sustainable\\_europe\\_30-01\\_en\\_web.pdf](https://ec.europa.eu/commission/sites/beta-political/files/rp_sustainable_europe_30-01_en_web.pdf)

<sup>44</sup> Progress factsheet Africa-Europe Sustainable investments and Jobs Alliance (2018). Available at: [https://ec.europa.eu/commission/africaeuropealliance\\_en](https://ec.europa.eu/commission/africaeuropealliance_en)

<sup>45</sup> H2020 Partnership Landscape and its relevance for Horizon Europe –Cluster 'Health': Discussion Paper (2019). Available at: [https://www.era-learn.eu/documents/thematic\\_analysis\\_health.pdf](https://www.era-learn.eu/documents/thematic_analysis_health.pdf) (last update 05/06/2019)

On 16 July 2019, the President-elect of the European Commission, Ursula von der Leyen, presented her political guidelines, “*A Union that strives for more. My agenda for Europe*”.<sup>46</sup> In this, six main ambitions for Europe have been articulated: (1) a European green deal; (2) a people-centred economy; (3) a digital Europe; (4) the protection of European values; (5) a stronger role for Europe on the international scene; and, (6) an enhanced European democracy. Whilst these ambitions do not bear an explicit focus on health in general, or on global health, health is mentioned in the context of improving the prospect of potential migration through development cooperation.

In her mission letter to the Commission-designate for Health, the President-elect has indicated a number of priority areas.<sup>47</sup> Combatting PRNDs is herein not explicitly mentioned. However, in her letter to the Commissioner-designate for Innovation and Youth, she requests the maximisation “of the potential of the EC exchange programmes to foster international cooperation in education, research and innovation”.<sup>48</sup> Moreover, to the Commissioner-designate for International Partnerships, 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”.<sup>49</sup>

The EU-Africa Global Health initiative is one of the two candidate partnerships in the *Pillar II Health Cluster*, which entails a relatively high number of envisaged European Partnerships (see The mapping shows that research-oriented envisaged partnerships can be expected to produce research results that will feed into the R&I activities of other initiatives. In the case of the One Health AMR, for example, the cross-cluster research on antimicrobial resistance can be expected to support the candidate EU-Africa Global Health Partnership in the efforts to accelerate the development and uptake of health care technologies and innovations in the field of infectious diseases.

Figure 1). Within the cluster, multiple complementarities and interconnections exist, both in terms of research topics covered and stakeholders involved in the funded R&I activities. In The mapping shows that research-oriented envisaged partnerships can be expected to produce research results that will feed into the R&I activities of other initiatives. In the case of the One Health AMR, for example, the cross-cluster research on antimicrobial resistance can be expected to support the candidate EU-Africa Global Health Partnership in the efforts to accelerate the development and uptake of health care technologies and innovations in the field of infectious diseases.

Figure 1, envisaged and candidate partnerships are presented along the innovation cycle: with more research-oriented initiatives to the left, and more innovation-related initiatives to the right.

The mapping shows that research-oriented envisaged partnerships can be expected to produce research results that will feed into the R&I activities of other initiatives. In the case of the One Health AMR, for example, the cross-cluster research on antimicrobial resistance can be expected to support the candidate EU-Africa Global Health Partnership

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<sup>46</sup> von der Leyen, U (2019). Political Guidelines for the next European Commission 2019-2024: A Union that strives for more. My agenda for Europe. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf)

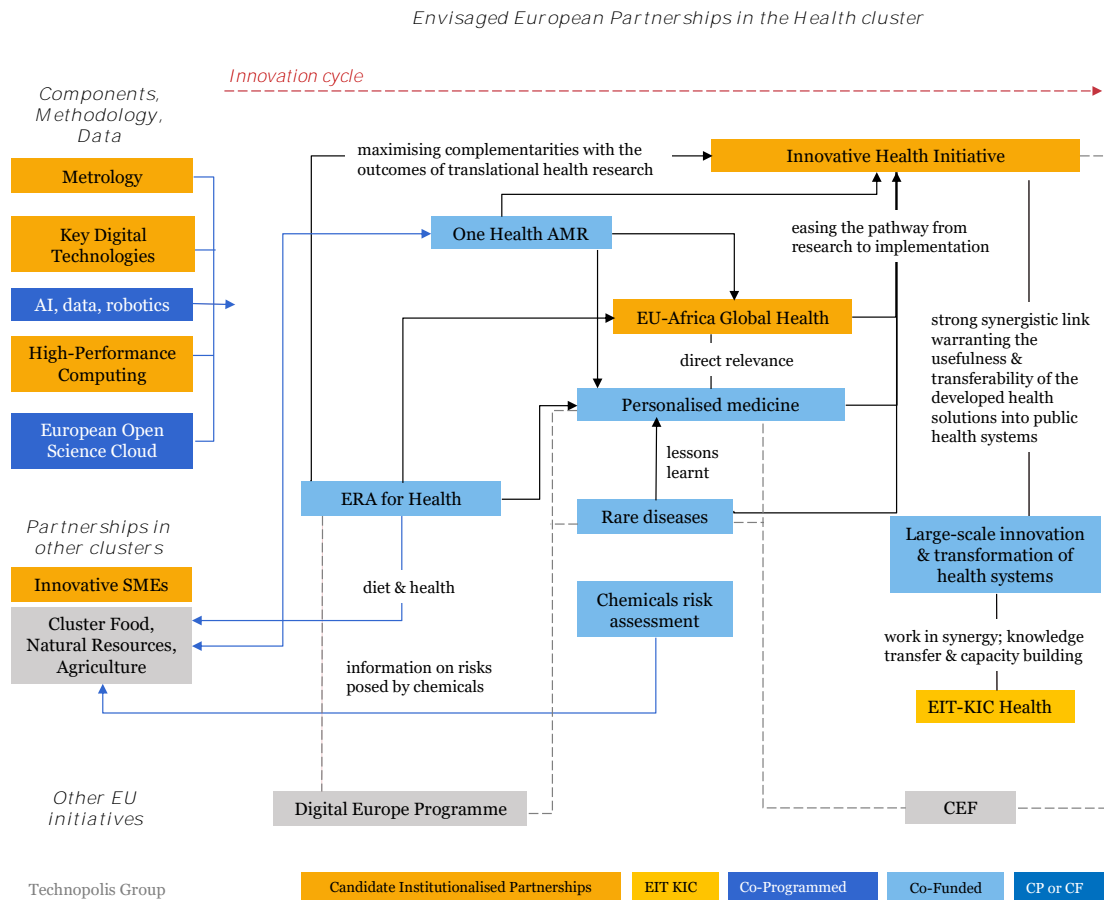
<sup>47</sup> European Commission (2019). Stella Kyriakides: Commissioner-designate for Health. Mission Letter: [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf)

<sup>48</sup> 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](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-mariya-gabriel-2019_en.pdf)

<sup>49</sup> 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](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-jutta-urpilainen_en.pdf)

in the efforts to accelerate the development and uptake of health care technologies and innovations in the field of infectious diseases.

Figure 1: Interconnections with and among the envisaged partnerships in the Health cluster



The figure above also illustrates the important contribution that can be expected from the technological partnerships in the digital sphere, including the contribution of the KDT candidate Institutionalised Partnership in the development of Smart Health and of the AI-data-robotics Co-Funded Partnership that is expected to deliver, e.g., new solutions from ageing – both to health and health care systems. Tapping on the developments in those key digital technology areas for the advancement and improvement of the European healthcare system reflects the EU priority of maximising the potential of the Digital Age.

The European Open Science Cloud partnership will also provide with an infrastructure for the storage, management, analysis and re-use of research data and facilitate research partnerships. Its operationalisation of the FAIR data principles will also help integration of digital technologies into health and health care innovations and contribute significantly to the development of personalised medicine.

The Innovative SMEs partnership will provide “horizontal” support to facilitate the cross-border deployment of innovative health solutions which discrepancies in the national regulatory and policy frameworks might otherwise hinder (especially in the health sector).



The majority of respondents (31 out of 39) to the open public consultation feel that it would be possible to rationalise and link the Initiative with other comparable and relevant initiatives under Horizon Europe. Some specify this by pointing out existing links between EDCTP2 and other (national/EU/international) initiatives, research programmes and research infrastructures. This includes, the WHO-TDR programme for research capacity development, ECRIN, and the One Health Initiative. Other comments more generally

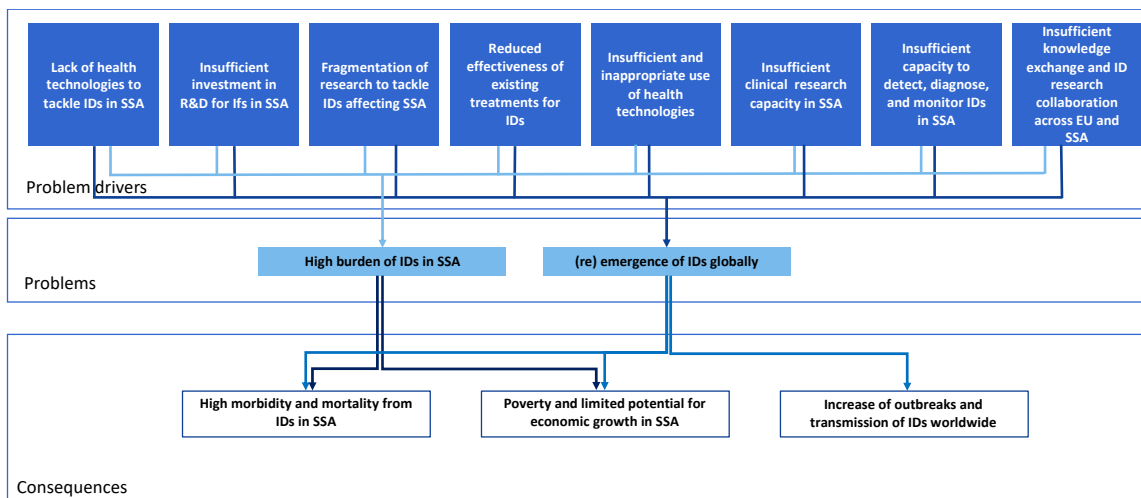
emphasise the importance of well aligned research agenda's. There are no clear differences of opinion across different types of respondents.

Some interviewees also saw possible links between the Candidate initiative and the Innovative Health Initiative and One Health AMR. However, these stakeholders stress that the Candidate initiative is positioned uniquely to address the needs of infectious diseases research in collaboration with Africa, a trait that is exclusive to this Initiative, and is therefore valuable in the context of Horizon Europe and beyond it.

## 2 Problem definition

This section presents the problem definition for the candidate EU-Africa Global Health Partnership. It does so by linking the identified problems (Section 2.1) to the underpinning problem drivers (Section 2.2) and the consequences of these problems. This has been summarized in Figure 2, below.

Figure 2: Problem tree for the candidate EU-Africa Global Health Partnership



### 2.1 What are the problems?

Two main problems have been identified: the high burden of infectious diseases in sub-Saharan Africa and the (re)emergence of infectious diseases globally. Whilst these two problems are clearly interlinked and share the same problem drivers, they have here been presented separately because they refer to a different scope. Whereas the former has been looked at principally from the point of view of sub-Saharan Africa, the latter requires a more global perspective.

#### 2.1.1 High burden of infectious diseases in sub-Saharan Africa

According to the WHO over 10 million people each year suffer the consequences of poverty-related and neglected diseases<sup>50</sup>, most of which are communicable or infectious diseases

<sup>50</sup> Poverty-related and neglected diseases include the three major ones HIV/AIDS, malaria and tuberculosis as well as neglected infectious diseases, which are caused by protozoal, bacterial, viral and helminth infections. The neglected infectious diseases may include, but will not be limited to, the 17 neglected tropical diseases (NTD) that are addressed by the WHO's department for NTD control.



(IDs).<sup>51</sup> HIV alone killed 770,000 people in 2018,<sup>52</sup> while TB and malaria have caused an estimated 1.5 million<sup>53</sup> and 405,000<sup>54</sup> deaths respectively in 2018. The burden of these diseases is spread disproportionately, with low- and middle- income countries (LMICs) being most affected.<sup>55,56</sup> This is due to, amongst others, weak health systems, poor quality of sanitation, low public awareness related to prevention of disease, and a lack of investment in and access to public health care.<sup>57,58</sup>

The burden of infectious diseases is particularly felt in sub-Saharan Africa, which is the only region in the world where infectious diseases affect more people than non-communicable diseases. This disease burden has and will continue to have major human and economic consequences. Although the African continent will carry, without a doubt, the largest share of these consequences, their effects are likely to be felt also in other parts of the world, including in the EU, which are not unaffected by infectious diseases.

Financial incentives for the delivery of health technologies to combat infectious diseases are limited as the purchasing power of the population in need of these technologies is typically low. Therefore, third parties, particularly from the pharmaceutical industry, are reluctant to invest. As a result, there remains a large unmet need for effective, affordable and safe treatments, vaccines and diagnostic tools to combat infectious diseases. While development aid and local capacity development activities have led to some progress in the delivery of needed health technologies to the region, much remains to be achieved.<sup>59</sup> This will only be possible with the large-scale and coordinated financial contributions from research and innovation funders, including the EU.

### 2.1.2 (Re-)emergence of infectious diseases globally

In addition to the burden posed by 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.<sup>60</sup> Furthermore, it is facing the re-emergence of diseases that had previously been largely eradicated, at

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<sup>51</sup> The World Health Organization defines infectious diseases as follows: "Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another. Zoonotic diseases are infectious diseases of animals that can cause disease when transmitted to humans.". Definition available at: [https://www.who.int/topics/infectious\\_diseases/en/](https://www.who.int/topics/infectious_diseases/en/). The terms 'communicable diseases' and 'infectious diseases' are often used interchangeably. For simplicity, as well as to underscore that the diseases of relevance to the initiative are not restricted to LMICs, we have hereafter used the term 'infectious diseases'.

<sup>52</sup> WHO, HIV/AIDS factsheet. Available at: <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>

<sup>53</sup> WHO, Global Tuberculosis Report (2019). [https://www.who.int/tb/publications/factsheet\\_global.pdf?ua=1](https://www.who.int/tb/publications/factsheet_global.pdf?ua=1)

<sup>54</sup> WHO, World malaria report 2019. <https://www.who.int/news-room/feature-stories/detail/world-malaria-report-2019>

<sup>55</sup> 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)

<sup>56</sup> 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.

<sup>57</sup> Federal Ministry of Education and Research: Poverty-related diseases. Available at: <https://www.bmbf.de/en/poverty-related-diseases-1430.html>

<sup>58</sup> Anna Palagyi, Ben J. Marais, Seye Abimbola, Stephanie M. Topp, Emma S. McBryde & Joel Negin (2019). Health system preparedness for emerging infectious diseases: A synthesis of the literature, *Global Public Health*, 14:12, 1847-1868, DOI: 10.1080/17441692.2019.1614645

<sup>59</sup> 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.

<sup>60</sup> 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.

least in parts of the world. Emerging infectious diseases are those due to newly identified and previously unknown infections which cause public health problems either locally or internationally.<sup>61</sup> Examples include Ebola, West Nile virus, and human Middle East respiratory syndrome coronavirus (MERS-CoV). Pathogens may also re-emerge with new characteristics, such as multidrug-resistance, or in different places, to cause new epidemics.<sup>62</sup> Outbreaks of emerging infectious diseases have the potential to cause enormous social and economic damage globally.<sup>63</sup>



Across all stakeholder groups, there is a large consensus on the need to address the problem of infectious disease burden in Africa. This consensus is apparent from the interviews, as well as from responses to the open public consultation and from feedback on the Inception Impact Assessment report.

Many stakeholders, across different stakeholder groups, agree that (re-)emergence of infectious diseases and the consequences of rapid disease spread may have serious implications for both Africa and the EU and need to be addressed.

Among respondents to the open public consultation, most felt that the scope and coverage proposed for the Candidate Initiative in the Inception Impact Assessment were right, in terms of research areas covered (29 out of 45), geographical coverage (26 out of 45) and sectoral coverage (26 out of 45). Those who disagree mostly view the scope and coverage in these areas as too narrow, rather than too broad. No statistical differences were found between the views of citizens and other respondents.

## 2.2 What are the problem drivers?

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

### 2.2.1 Lack of health technologies for tackling infectious diseases in SSA

Important strides have been made in combatting PRNDs. For instance, the development of antiretroviral therapy (ART) has been a major gamechanger in the fight against HIV.<sup>64</sup> Nonetheless, there still is no effective vaccine to prevent HIV infection.<sup>65</sup> Likewise, whilst there are numerous treatment regimens against tuberculosis, the increasing threat of (multi-)drug-resistant forms of the disease increases the urgency for the development of new vaccines with greater efficacy and broader application, as well as for continued development of new (combination) treatments.<sup>66</sup> For other diseases, such as Dengue – a mosquito-borne viral infection affecting around 390 million people annually –, there is no effective treatment.<sup>67</sup>

<sup>61</sup> World Health Day (1997). Emerging infectious diseases. Available at: <https://www.who.int/docstore/world-health-day/en/documents1997/whd01.pdf>

<sup>62</sup> Van Doorn HR (2014). Emerging infectious diseases. *Medicine (Abingdon)*. 42(1): 60–63.

<sup>63</sup> 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

<sup>64</sup> 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

<sup>65</sup> HIV vaccine: better to start together? Felber, Barbara K et al. *The Lancet HIV*, Volume 6, Issue 11, e724 - e725

<sup>66</sup> McShane, Helen. Insights and challenges in tuberculosis vaccine development *The Lancet Respiratory Medicine*, Volume 7, Issue 9, 810 - 819

<sup>67</sup> Data from <https://www.who.int/en/news-room/fact-sheets/detail/dengue-and-severe-dengue> Accessed 1 September 2019.

### 2.2.2 Insufficient investment in R&D for infectious diseases affecting SSA

This lack of vaccines and treatment options (as well as suitable diagnostics) is reflected in the level of R&D investment in this area worldwide. For instance, in 2019, there are only 129 active clinical studies/trials on PRNDs, compared to 3,499 oncology studies/trials.<sup>68</sup>

Despite the fact that a number of pharmaceutical companies have set up drug donation programmes for PRNDs (for instance, Merck & Co has been operating its Mectizan donation programme for more than 30 years, providing over 300 million treatments for river blindness),<sup>69</sup> or are engaged in PRND research through charitable foundations (e.g. GSK's Tres Cantos Open Lab Foundation),<sup>70</sup> the private for-profit sector has shown limited interest to invest in R&D for infectious diseases. Whilst there may be other factors fuelling this as well, a likely explanation resides in the low potential for achieving a commercially interesting return on investment. As a result, the product development pipeline for infectious diseases is poorly stocked and the progress is often slow. 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 target priority product gaps<sup>71</sup> for infectious diseases.<sup>72</sup>

### 2.2.3 Fragmentation of research to tackle infectious diseases affecting SSA

Addressing the complicated problems of tackling infectious diseases affecting SSA requires the involvement of a large set of actors. These span the range from academic researchers to international development agencies and pharmaceutical companies. Each of these actors can have their own priorities and focus areas.<sup>73</sup> One of the main challenges facing the field is therefore how to unite such diverse actors around common strategic agenda's and roadmaps to use resources effectively and efficiently.

### 2.2.4 Reduced effectiveness of existing treatments for infectious diseases

The progress made in combatting infectious diseases is increasingly being challenged by rising levels of drug resistance. For instance, whilst chloroquine has long been used as an effective and inexpensive malaria treatment, there now is widespread resistance against chloroquine in nearly all areas of the world.<sup>74</sup> Similar problems have arisen in the field of tuberculosis, where multi-drug resistant tuberculosis (MDR-TB) and even extremely drug-resistant tuberculosis (XDR-TB) are posing a growing threat to public health globally.<sup>75</sup> Whilst in sub-Saharan Africa the prevalence of MDR-TB in new cases remains low and is

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<sup>68</sup> WHO Global Observatory on Health R&D, data from July 2019. Available at: [https://www.who.int/research-observatory/monitoring/processes/health\\_products/en/](https://www.who.int/research-observatory/monitoring/processes/health_products/en/)

<sup>69</sup> <https://mectizan.org/#>, Accessed 1 September 2019.

<sup>70</sup> <https://www.openlabfoundation.org/>, Accessed 1 September 2019

<sup>71</sup> Here priority product gaps include: 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)

<sup>72</sup> Access to Medicines Foundation. Access to Medicines Index 2018. Available at: [https://accessmedicinefoundation.org/media/uploads/downloads/5d25b3dd5f128\\_5cb9b00e8190a\\_Access-to-Medicine-Index-2018.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5d25b3dd5f128_5cb9b00e8190a_Access-to-Medicine-Index-2018.pdf)

<sup>73</sup> Sridhar D (2012) Who sets the global health research agenda? The challenge of multi-bi financing. *PLoS Med.* 9(9)

<sup>74</sup> D'Alessandro U, Buttiens H (2001). History and importance of antimalarial drug resistance. *Trop Med Int Health* 6(11):845-8

<sup>75</sup> Lange C, Chesov D, Heyckendorf J, Leung CC, Udwadia Z, Dheda K (2018). Drug-resistant tuberculosis: An update on disease burden, diagnosis and treatment. *Respirology* 23(7):656-673

declining overall continued vigilance is needed as well as new effective treatment regimens.<sup>76</sup>

### 2.2.5 Insufficient and inappropriate use of health technologies

Even where suitable health technologies are available, there often is a challenge in getting treatments to where they are most needed and ensuring that they are used to optimal effect. Sub-Saharan African countries mostly are faced with weak, under-resourced health systems: there are shortages of skilled health care workers, health facilities are poorly equipped, diagnostic facilities are inadequate, and systems for procurement and supply chain management for health commodities are weak. 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. Such challenges call for the development of health technologies that are suitably adapted to the local conditions (e.g. using heat-stable formulations, easy to use point-of-care diagnostics).

Access to health technologies in SSA can also be hindered by other factors, in particular, the cost of treatments. For instance, whilst nearly all countries in SSA have adopted national policies to treat all persons living with HIV with ART, and many offer treatments free of any charge, over 10 million people remain untreated.<sup>77</sup> Although many of the factors limiting access are rooted in systemic and societal problems that cannot be easily addressed through research and innovation, affordability of treatments should be a prime ambition.

### 2.2.6 Insufficient clinical research capacity in SSA

As mentioned previously, the development of appropriate, safe and effective treatments for infectious diseases affecting SSA necessitates the conduct of clinical trials in African patients. However, in many disease-endemic countries in Africa, there is insufficient capacity for conducting health research and clinical trials.<sup>78</sup> This concerns the physical infrastructures 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,<sup>79</sup> national medicines regulatory authorities).

### 2.2.7 Insufficient capacity to detect, diagnose and monitor IDs in SSA

Because of globalisation and migration, the potential for infectious diseases to rapidly spread has increased tremendously, within Africa as well as between and within other parts of the world. Early detection is thus vital for being able to respond quickly and limiting the number of new infections. However, this can be particularly problematic when diseases have not previously been seen in a specific area, and when systems for early detection, diagnosis and information sharing are inadequate. The 2013-2016 Ebola outbreak in West Africa made painfully clear what can happen when the diagnosis is delayed, and information is not shared in a timely way.<sup>80</sup> In recognition of the need to strengthen Africa's capacity

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<sup>76</sup> Musa BM, Adamu AL, Galadanci NA, Zubayr B, Odoh CN, Aliyu MH (2017). Trends in prevalence of multi drug resistant tuberculosis in sub-Saharan Africa: A systematic review and meta-analysis.

<sup>77</sup> Nash D, Yotebieng M, Sohn AH (2018). Treating all people living with HIV in sub-Saharan Africa: a new era calling for new approaches. *J Virus Erad.* 4(Suppl 2):1-4.

<sup>78</sup> Whitworth JA, Kokwaro G, Kinyanjui S, et al. (2008). Strengthening capacity for health research in Africa. *Lancet.* 372(9649):1590-1593

<sup>79</sup> 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

<sup>80</sup> Malvy D, McElroy AK (2019). Ebola virus disease, *The Lancet* 393(10174), 936-948

to detect, diagnose and monitor diseases, including infectious diseases, in January 2017 the Africa Centres for Disease Control and Prevention (Africa CDC) were inaugurated.<sup>81</sup>

### 2.2.8 Insufficient knowledge exchange and research collaboration across EU and SSA

As underscored previously, 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, it also demands strong involvement from stakeholders, including researchers, from disease-endemic countries. These are best placed to understand the specific needs of the populations the research is expected to serve. The last decade or so has seen a strong recognition of the need to strengthen research networks in the SSA region as well as to strengthen the collaboration between research institutes in 'the global North', including the EU, and those in Africa. This includes increasing attention for principles of fair research,<sup>82</sup> needed to ensure that African researchers can play a full and equitable role in research collaborations.



The views of stakeholders are generally well aligned with the drivers presented here. Respondents to the open public consultation see the inability of health systems in Africa and in the EU to take up the research results of innovative health technologies (34 out of 47 respondents), insufficient research capacity to anticipate and react to infectious disease outbreaks (29 out of 47), and limited research capacity for clinical research in Africa (26 out of 47) as the most relevant problem drivers. There are no clear differences between different types of respondents.

Interviewees from different stakeholder groups have also widely confirmed each of these problem drivers. Many also stress that the nature of the problem is multi-faceted, with many drivers overlapping and building upon each other. The relative weight attributed to different drivers depends primarily on the individual areas of expertise of interviewees, with those working in academia and industry more commonly focussing on the lack of research capacity and the need for improved strategic alignment of research efforts and those in other stakeholder groups more often highlighting issues involving access to and uptake of health technologies.

### 2.3 How will the problems evolve?

The descriptions of the problems and problem drivers underpinning the candidate initiative offered in the preceding sections have been both backward and forward-looking, taking into account the current state of the field and trends therein. Those sections have outlined also how the problems may evolve, both for the better and for the worse.

Technological advances that lead to breakthrough medical interventions, such as highly effective vaccines, could, in the long run, negate the need for the candidate initiative by fulfilling its objectives. However, such significant breakthroughs are rare and, even when they occur, may take a great deal of support to be rolled out at a large scale. Moreover, the objectives of the candidate initiative are wide-ranging and breakthroughs in one area do not solve problems in others. It is therefore likely that the objectives of the candidate initiative will remain relevant and necessary in both the short-term and longer-term.

## 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

<sup>81</sup> <http://www.africacdc.org/>

<sup>82</sup> Musolino N, Lazdins J, Toohey J, IJsselmuiden C (2015). COHRED Fairness Index for international collaborative partnerships, *The Lancet* 385(9975):1293-1294

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 primarily affect developing countries. It is nonetheless worth bearing in mind that infectious diseases also affect 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.<sup>83</sup> Furthermore, the progress in the management of infectious disease in the EU remains unequal: for example, 237 new TB cases were reported in Finland in 2017 compared to 13,004 cases reported in Romania in the same year.<sup>84</sup> In light of the EU's commitment to achieving SDG3, an initiative to advance a collaborative effort for global health research should be deemed necessary.

Furthermore, as previously elaborated, the development of health technologies, especially at the late stage of clinical development, requires large-scale funding. This is often beyond the ability of individual Member States to provide. The EU thus has an important role to play in the funding of this type of research and development, providing a sustainable and well-defined funding stream.



The necessity for EU action is underscored by the responses to the structured consultation of Member States which took place during summer 2019. Around three quarters of respondents herein agreed that a partnership would be more effective in achieving the objectives and delivering clear impacts for the EU and its citizens.

Among respondents to the open public consultation, many indicated that a European partnership of this kind was fully needed to be more responsive towards societal needs (34 out of 47 respondents) and to make a significant contribution to achieving the SDGs (33 out of 47). The Candidate Initiative also received strong support in other dimensions of relevance. The only area where fewer than 30% of respondents expressed full agreement with the need for a partnership was in response toward priorities in national and/or regional R&I strategies. No statistically significant differences were found between the views of citizens and other respondents.

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 stress the need to support Africa as an emerging economy, and an economic partner to the EU. Furthermore, interviewees regularly indicated that 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

Apart from large-scale funding required to advance the development of health technologies for infectious diseases, the development process itself needs to be strategic and aligned across many actors. Here, the candidate initiative could 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. It can also allow the Member States align their research and innovation priorities in the area of global health with those of other global actors, thus delivering a more coordinated and targeted approach with less fragmentation and wastage. Moreover,

<sup>83</sup> Eurostat (2019). Sustainable development in the European Union Monitoring report on progress towards the SDGs in an EU context. Available at: <https://ec.europa.eu/eurostat/documents/3217494/9940483/KS-02-19-165-EN-N.pdf/1965d8f5-4532-49f9-98ca-5334b0652820>

<sup>84</sup> European Centre for Disease Control. Surveillance Atlas of Infectious Diseases. Available at: <https://atlas.ecdc.europa.eu/public/index.aspx>

because of the strong and well-recognised role that has been played by EDCTP in the global health research area since its establishment in 2003, the new initiative would have a competitive advantage by building upon the success of EDCTP.



Interviewees almost universally stress the added value of EU investments because of the ability to support large-scale activities, beyond the remits of national research funders. In addition, some 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).

Nonetheless, among stakeholders representing the EC and national representatives to the General Assembly of EDCTP, there is some discussion as to whether EDCTP has been sufficiently successful in incentivizing increased national funding. Some interviewees believe that, without the mechanism of matched funding, national investments in this type of research would have decreased. Others, however, state that reliance on in-kind contributions through national research programmes is disincentivizing financial contributions and therefore promotes “business-as-usual”. They argue that the ability for the initiative to deliver added value will, in part, depend on the extent to which it will be able to incentivize its participants to improve both the quantity and the quality of their contributions.

## 4 Objectives: What is to be achieved?

### 4.1 General objectives

To tackle the problems identified in Section 2, it is important to clarify the objectives of EU action in the field of research and innovation. We have identified two general objectives corresponding to the main problems discussed in Section 2.1. Based on an analysis of all available information, the following general objectives are proposed for the candidate EU-Africa Global Health Partnership:

- To reduce the burden of infectious diseases in sub-Saharan Africa
- To contribute to the control of (re)emerging infectious diseases globally

Both objectives can be seen as a logical extension of the EDCTP; the first in particular is a direct continuation of the general objective of EDCTP2. By taking a somewhat broader scope, both geographically and in terms of disease focus, the second objective may appear further removed. However, in essence, it is merely a more explicit articulation of what was already part of the objectives and activities under EDCTP. 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, [...]”). They thus also support the attainment of the general objectives of Horizon Europe, in particular, that of contributing to tackling global challenges, including the SDGs.

Both in the structured consultation of Member States and in interviews, some have argued that whilst a focus on diseases affecting sub-Saharan Africa is appropriate, this should not exclude the possibility of supporting the conduct of activities that are set outside of the region when such are relevant to SSA. 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 study concludes that this could be considered on a case-by-case basis, but that the primary focus should be on infectious diseases affecting SSA. This concerns also the objective to contribute to the control of (re)emerging infectious diseases globally. Here, the inclusion of the word ‘globally’ should not be taken to mean that the initiative should be deploying activities focused on addressing all (re)emerging infectious diseases. Rather, it refers to diseases of relevance to SSA but the impacts of which can be felt beyond the continent.



In the Inception Impact Assessment published by the European Commission, the general objectives specified were similar to those here but had been phrased as follows:

- To reduce the social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe
- To increase health security in sub-Saharan Africa, and by extension in Europe and worldwide, in particular in the context of environmental and climate change

The explicit reference to Europe within the first objective was intended to underscore that infectious diseases not only affect SSA and that this partnership is also in the direct interest of European Member States. Whilst among interviewed stakeholders there is support for this notion, there is also a feeling that willingness to join the initiative should not be based primarily in self-interest.

Regarding the second objective, representatives of DG RTD have indicated that their aim was to bring emerging infectious diseases and AMR in scope. The rationale for this was that these are issues that are seen as pressing on the health agenda of many EU Member States. Although the political value of this was widely recognized by interviewed stakeholders, it is clear that the term 'health security' itself should not be used in the articulation of the general objectives. It is insufficiently defined and could include too many issues beyond what the initiative should be focused on. There then is a risk of dilution of resources and duplication of activities with other initiatives active in this field, such as the Coalition for Epidemic Preparedness Innovations (CEPI), the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), and the candidate European Partnership on One Health AMR. For the initiative to be sufficiently effective, it is important to keep a relatively narrow and well-defined scope. In the description of the preferred option in section 7.2 recommendations are presented for the objectives and scope of the candidate partnership.



The large majority interviewees, regardless of the stakeholder group they represent, support the here 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 this problem. However, they also state that maintaining a focus on infectious diseases is essential to ensure research funding is concentrated and can lead to substantial progress and discovery. With only a few exceptions, interviewees therefore prefer to limit the inclusion of non-communicable disease to co-morbidities associated with infectious diseases. This sentiment is supported by the feedback on the Inception Impact Assessment Report.

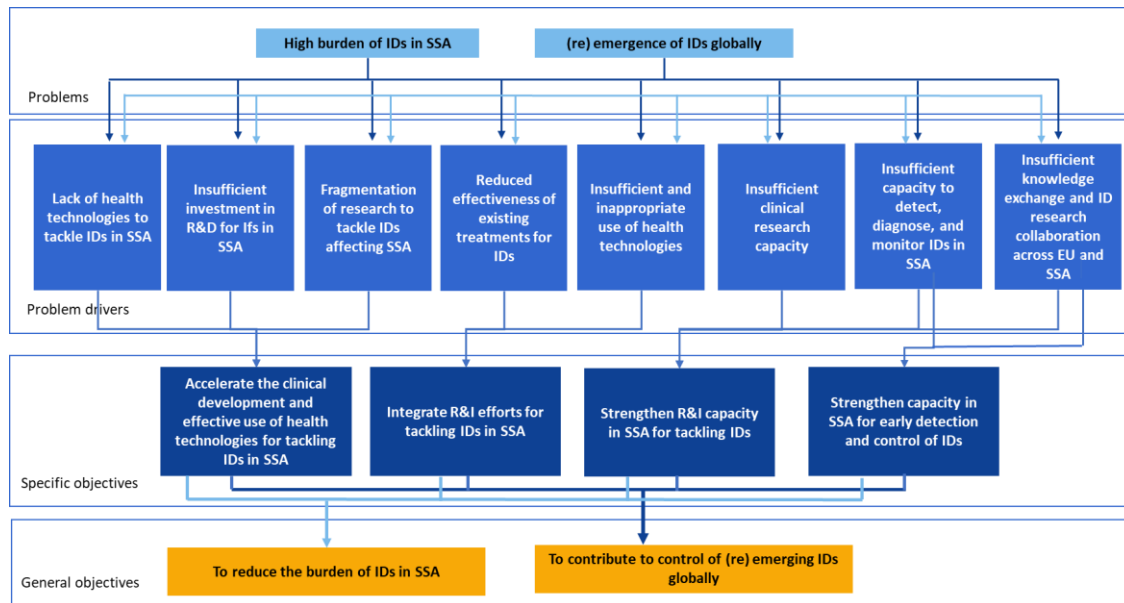
#### 4.2 Specific objectives

We have defined four specific objectives that would support the attainment of the general objectives. These specific objectives respond to each of the problem drivers discussed in Section 2.2. The relationship between the general and specific objectives is shown in Figure 3. The specific objectives are:

- Accelerate the clinical development and effective use of health technologies for tackling infectious diseases in sub-Saharan Africa
- Integrate research and innovation efforts for tackling infectious diseases in sub-Saharan Africa
- Strengthen research and innovation capacity in sub-Saharan Africa for tackling infectious diseases
- Strengthen capacity in sub-Saharan Africa for early detection and control of infectious diseases



Figure 3: Objectives tree for the candidate EU-Africa Global Health Partnership



The following paragraphs describe these specific objectives in more detail, placing them along the key impact pathways defined for Horizon Europe<sup>85</sup> and outlining how they connect to the targeted impacts for Horizon Europe in the cluster health.<sup>86</sup>

#### 4.2.1 Scientific objectives

The candidate initiative's main aim will be to support the generation of high-quality knowledge needed to accelerate the development or improvement of health technologies that can be used to prevent, diagnose and treat infectious diseases affecting SSA. It is expected to do so by taking a broad scientific view, covering multiple stages of clinical research, as well as implementation research. By emphasizing principles of research fairness and promoting sharing and dissemination of research, the initiative will deliver scientific impact. The initiative will thus support two of the key pathways for scientific impact defined for Horizon Europe, namely "creating high-quality new knowledge" and "fostering diffusion of knowledge and Open Science".

**Strengthening of the research and innovation capacity in SSA** includes strengthening of human capital and is expected to contribute to an improved needs-based approach. This means that the initiative will support the key pathway for the scientific impact of "strengthening human capital in R&I". It also aligns with two of the targeted health impacts of Horizon Europe, specifically:

- Health care systems benefit from strengthened research and innovation expertise, human capacities and know-how for combatting communicable and non-communicable diseases, including through international cooperation.
- The EU benefits from high visibility, leadership and standing in international fora on global health and global health security, especially in partnership with Africa.

This specific objective also aims at promoting networking and knowledge exchange between actors, both within SSA and between SSA and Europe, and between European countries to further contribute to a greater diffusion of knowledge and to delivery against

<sup>85</sup> European Commission DG Research and Innovation: Horizon Europe Key Impact Pathways

<sup>86</sup> Orientations towards the first Strategic Plan for Horizon Europe, revised following the co-design process. Version of 31 October 2019

SDG17 (“Strengthen the means of implementation and revitalize the global partnership for sustainable development”)<sup>87</sup>.

#### 4.2.2 Economic/technological objectives

The candidate EU-Africa Global Health Partnership can reasonably be expected to deliver positive economic impacts but, for the most part, these are not objectives in their own right. Nonetheless, two of the specific objectives envisaged for the candidate initiative support the key pathways for economic impact under Horizon Europe. Specifically, these are:

- Integrate research and innovation efforts for tackling infectious diseases in sub-Saharan Africa
- Strengthening research and innovation capacity in sub-Saharan Africa for tackling infectious diseases.

Integrating research and innovation efforts for tackling CDs is needed not only to promote alignment of research around a strategic research agenda but also to reduce ‘waste’ of financial resources for research resulting from duplicating activities or focusing resources on inappropriate priorities. This, in turn, may free up and attract new resources to be allocated to further areas of unmet need. This specific objective thus supports the key pathway for economic impact of “leveraging investments in R&I”.

Although the rationale for strengthening the research and innovation capacity is not foremost an economic one, it can be reasonably expected to contribute to more and better jobs in sub-Saharan Africa. This specific objective thus supports the key pathway for economic impact of “creating more and better jobs”.

Moreover, the initiative is expected to focus on addressing not only the social burden of infectious diseases but also the economic burden that those affected by these diseases experience. This economic burden is the result of the impact these diseases have on workforce participation and productivity on the one hand, and on health expenditure (both public and that of individuals) on the other. Catastrophic health expenditure is a key driver of poverty and socio-economic inequality. Addressing this economic burden, and thereby contributing to the attainment of SDG1 (No Poverty) and SDG10 (Reducing inequality), thus requires the candidate initiative to be focussed on supporting the development of effective and safe treatments (including prevention and diagnostics) whilst ensuring their affordability. This corresponds well with the targeted impact under Horizon Europe to support the development of technologies through which patients receive “effective, cost-efficient and affordable treatment”.

#### 4.2.3 Societal objectives (including environmental and social objectives)

Above all, the candidate EU-Africa Global Health Partnership serves a societal purpose, by reducing the burden of infectious diseases, both in SSA and globally. The specific objectives formulated for the initiative clearly reflect this, most notably through the following three objectives:

- Accelerating the clinical development and effective use of health technologies for tackling infectious diseases in sub-Saharan Africa

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<sup>87</sup> In particular SDG17.6 (“Enhance North-South, South-South and triangular regional and international cooperation on and access to science, technology and innovation and enhance knowledge sharing on mutually agreed terms, including through improved coordination among existing mechanisms [...]”), SDG17.7 (“Promote the development, transfer, dissemination and diffusion of environmentally sound technologies to developing countries on favourable terms [...]”) and SDG17.9 (“Enhance international support for implementing effective and targeted capacity-building in developing countries to support national plans to implement all the sustainable development goals, including through North-South, South-South and triangular cooperation”)

- Strengthening capacity in sub-Saharan Africa for early detection and control of infectious diseases
- Strengthening research and innovation capacity in sub-Saharan Africa for tackling infectious diseases

The specific objective to accelerate the development and effective use of health technologies for infectious diseases directly corresponds to the targeted impact of Horizon Europe for reducing the health burden of diseases in the EU and worldwide through effective disease management, “including through the development and integration of innovative diagnostic and therapeutic approaches [...]”. It also supports the targeted impact of reducing the “(cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide. In particular, the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other infectious diseases are being combated.” Furthermore, by inclusion of an emphasis on the effective use of health technologies, this specific objective feeds into the targeted impact of empowering patients and citizens to “make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies”.

This specific objective aligns well with two of the key pathways for societal impact defined under Horizon Europe. First, taking into consideration that the EU policy priorities include meeting the SDGs, the candidate initiative will support “addressing EU policy priorities through R&I” by contributing to the delivery of health technologies to combat infectious disease (SDG3.3 and 3.B). Second, through the inclusion of implementation research, it aims to “strengthen the uptake of innovation in society”.

The specific objective to strengthen the capacity in SSA for early detection and control of infectious diseases is, in essence, also a societal one as it is aimed at minimizing the risk of contracting disease. This objective is expected to support the attainment of the same set of targeted impacts described in the preceding section.

Last, as discussed in the previous section, the specific objective of strengthening research and innovation capacity in sub-Saharan Africa for tackling infectious diseases is expected to contribute to increased employment of researchers in SSA. The effects of this are not only economic but also societal, as increased employment will reduce poverty and, by extension, poverty-related illnesses.

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

The preceding sections considered what the general and specific objectives of the candidate EU-Africa Global Health Partnership should look like. In this next section, it is considered what the potential and likely impacts would be, taking into account both positive and negative potential impacts and, to the extent possible, estimating the magnitude and likelihood of these impacts. As with the specific objectives, the section is divided into scientific, economic/technological, and societal impacts.

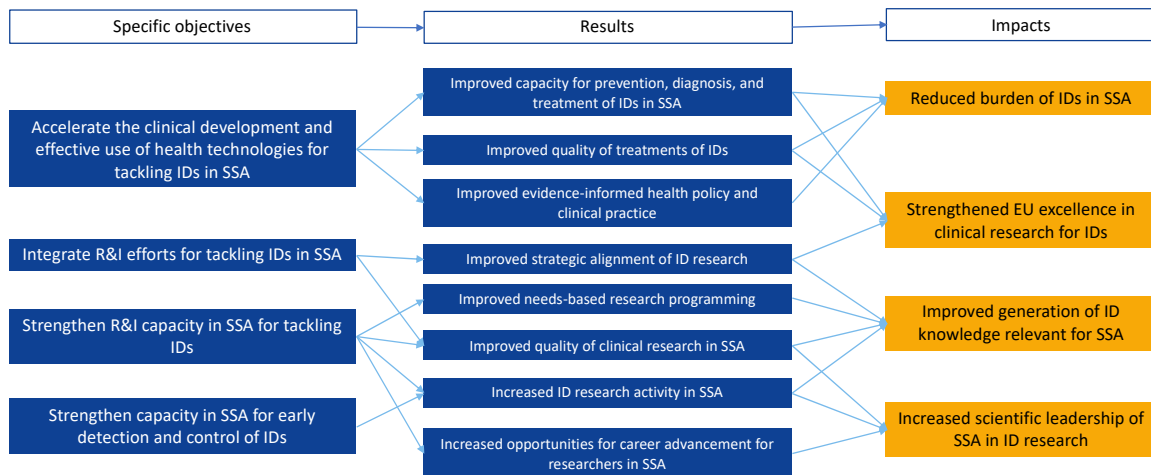
##### 4.3.1 Likely scientific impacts

Candidate initiative is expected to result in various types of scientific impacts, which are aligned with the priority areas for impact as identified by the Horizon Europe and Sustainable Development Agenda (see section 4.2 Specific objectives). These impacts, and the intermediate results, are summarized in Figure 4, below. Specifically, the expected impacts are:

- Reduced burden of infectious diseases in sub-Saharan Africa
- Strengthened EU excellence in clinical research for infectious diseases
- Improved generation of infectious disease knowledge relevant for sub-Saharan Africa

- Increased scientific leadership of sub-Saharan Africa in infectious disease

Figure 4: Impact pathway leading to scientific impacts



It should be born in mind that development of pharmaceutical products, and to a lesser degree diagnostic, is a very time-consuming and resources-intensive process with a high chance of failure. Therefore, it can take a long time for impact on the disease burden to become visible and its magnitude is hard to predict. Nonetheless, in the case of the candidate initiative, some measure of impact could be achieved already in the shorter term as the initiative should be able to build upon the work of EDCTP. Additionally, the candidate initiative will likely be supporting also relatively late-stage clinical development, where the risk of failure is much reduced, as well as implementation research that is aimed at improving the uptake and appropriate use of existing technologies.

The initiative is also expected to positively contribute to the development of both African and European scientific excellence. In this area, the short and mid-term impacts may include increased opportunities for the scientific development of African scientists and improved pathways for collaboration between European and African scientists leading to improved scientific leadership for both continents. In the mid to long term, the candidate initiative may improve scientific capacity and autonomy of Africa to conduct clinical research (including large-scale clinical trials) and strengthen EU research excellence.



The majority of all interviewees stress the potential of the initiative to deliver scientific impacts through collaborative research and knowledge sharing. They state that the development of new technologies and their uptake can lead to a large reduction of infectious disease burden in Africa. They also view increased capacity of Africa to conduct clinical trials, and overall better disease preparedness as critical impacts this initiative has the potential to deliver. These views are widely shared among all stakeholder types and opinion sources.

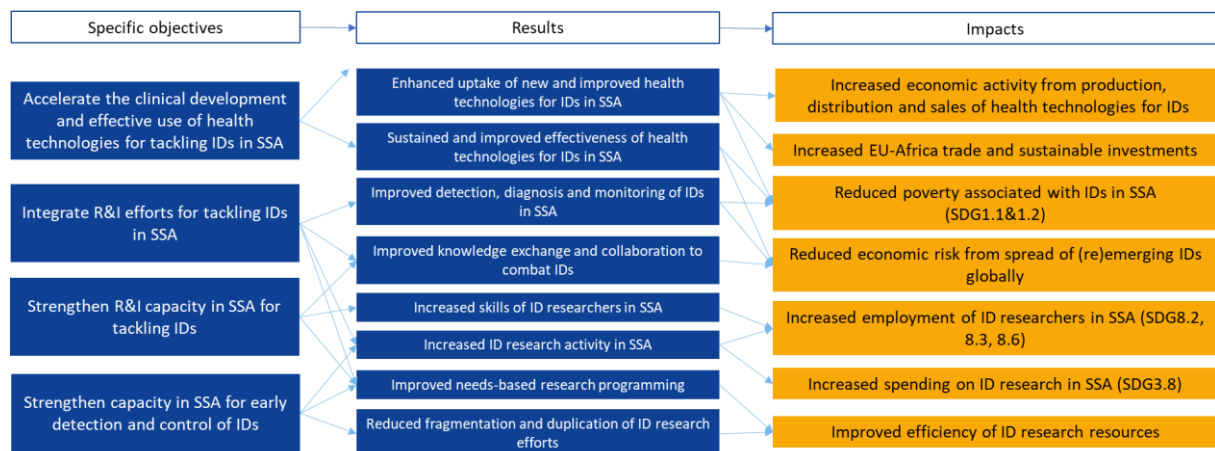
#### 4.3.2 Likely economic/technological impacts

The candidate initiative is expected to result in seven types of economic or technological impacts, corresponding to various of the impacts under Horizon Europe (see section 4.2 Specific objectives) and the SDGs. These impacts, and the intermediate results, have been summarized in Figure 5, below. Specifically, the expected impacts are:

- Increased economic activity from production, distribution and sales of health technologies for infectious diseases
- Increased EU-Africa trade and sustainable investments
- Reduced poverty associated with infectious diseases in SSA (SDG1.1 and 1.2)
- Reduced economic risk from spread of (re)emerging CDs globally

- Increased employment of infectious disease researchers in SSA (SDG8.2, 8.3 and 8.6)
- Increased spending on infectious disease research in SSA (SDG3.B)
- Improved efficiency of infectious disease research resources

Figure 5: Impact pathway leading to economic/technological impacts



Whereas the objectives of the candidate initiative are foremost societal in nature, rather than economic, their achievement depends on increased development of suitable health technologies, which should translate into increased economic activity resulting from the production, distribution and sales of these technologies. In this regard, it is important to note that this initiative is not aimed at profit maximization, as the lack of purchasing power of populations in need forms the very rationale for this initiative. Ideally, a substantial part of the increased economic activity takes place in sub-Saharan Africa itself, resulting in increased trade and sustainable investments in the region.

If successful, in the long-term the initiative can contribute to a reduction of the burden of infectious diseases in sub-Saharan Africa, which may facilitate improved economic outcomes of households and potentially reduce poverty through reduce healthcare-related expenditure, increase workforce participation and productivity, and increased opportunity to participate in education. It should be kept in mind, though, that the causes of poverty are complex and numerous. Combatting infectious diseases by itself is unlikely to be enough to substantially improve the economic outlook of sub-Saharan Africa at a macro-level but can reasonably be expected to have an impact at the level of individual households. An overall improvement of the economic indicators could also have a positive impact on EU-Africa trade and investment relations, but the size of that impact should not be overestimated.

Outbreaks of emerging infectious diseases have been known to have large scale economic impacts, not only in areas directly affected by the disease but also in other parts of the world by the need to impose restrictions on travel and exports. Studies have estimated the global economic burden of various outbreaks at tens of billions of dollars.<sup>88,89</sup> The potential economic impact of successful measures to limit (the effects of) large-scale outbreaks is thus very high but cannot be fully assessed as success implies there is no counterfactual scenario that would show the costs in the absence of the initiative. As highlighted

<sup>88</sup> Miles T (2018) Health News. West Africa's Ebola outbreak cost \$53 billion – study. Available at: <https://www.reuters.com/article/us-health-ebola-cost/west-africas-ebola-outbreak-cost-53-billion-study-idUSKCN1MY2F8>

<sup>89</sup> Huber C, Finelli L, Stevens W (2018). The Economic and Social Burden of the 2014 Ebola Outbreak in West Africa. *J Infect Dis.* 218(suppl\_5):S698-S704.

previously, it should be borne in mind that pharmaceutical product development has a high failure rate. Thus, while substantial economic impacts could be achieved in the case of successful product development, they cannot be guaranteed.

The most immediate economic effects are likely to be associated with the development and strengthening of research capacity in sub-Saharan Africa. Strengthened capacity is expected to attract more research to the region and provides improved employment opportunities for researchers. However, the candidate initiative is expected to spend a relatively small, though not insignificant, share of its resources on this type of activity. In the short-term, the magnitude of this impact will thus be contained to a limited number of research institutes across Africa and up to a few hundred individual researchers. However, if critical mass can be reached, the initiative could serve as a catalyst for further strengthening of the region, thus achieving an indirect impact well beyond that which can be directly attributed to the initiative itself.

Last, the initiative is expected to help reduce fragmentation of research and innovation efforts, including funding sources, by fostering greater strategic alignment. This should free up and attract new resources for other important areas of research and development relevant for sub-Saharan Africa.



Various interviewees underline that there is a degree of economic imperative to the initiative. However, they also stress that the primary focus of the initiative is to achieve scientific, technological, and societal impact. Economic gains – particularly those in Africa – are secondary, but nonetheless important impacts the initiative can contribute to.

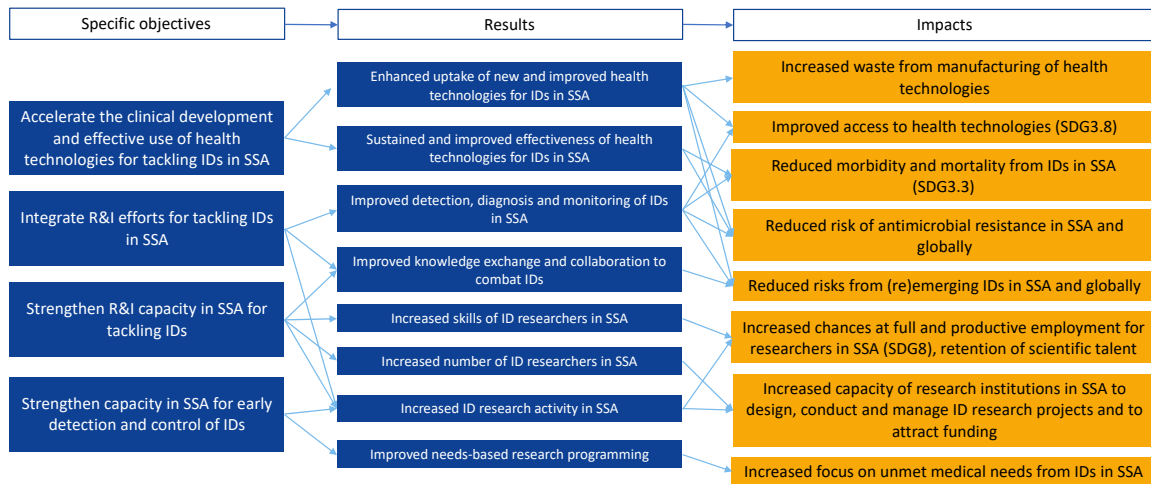
#### 4.3.3 Likely societal impacts

The candidate initiative is expected to result in eight types of societal impacts, aligned with the impacts under Horizon Europe (see section 4.2 Specific objectives) and the SDGs. These impacts, and the intermediate results, have been summarized in Figure 6, below. Specifically, the expected impacts are:

- Increased waste from manufacturing of health technologies
- Improved access to health technologies for infectious diseases in SSA (SDG3.8)
- Reduced morbidity and mortality from infectious diseases in SSA (SDG3.3)
- Reduced risk of antimicrobial resistance in SSA and globally
- Reduced risks from (re)emerging infectious diseases in SSA and globally
- Increased chances at full and productive employment (SDG8) for researchers in SSA and retention of scientific talent
- Increased capacity of research institutions in SSA to design, conduct and manage infectious disease research projects and to attract funding
- Increased focus on unmet medical needs from infectious diseases in SSA



Figure 6: Impact pathway leading to societal impacts



### Likely environmental impacts

The candidate initiative has no explicit environmental objectives. However, because it is intended to accelerate the development and production of new health technologies, including pharmaceutical products, it has the potential for negative environmental impacts resulting from pharmaceutical production. Pharmaceutical pollution forms a significant threat to population health and ecosystems globally.<sup>90</sup> On the other hand, whilst increased pharmaceutical production could result in more pharmaceutical waste, it is also possible that new technologies and production techniques replace existing ones with a higher ecological footprint (for instance, by using biodegradable components or improved wastewater management). The potential environmental impacts of the candidate initiative can thus not be predicted. Previous evaluations and impact assessments of EDCTP have not studied its environmental effects in any detail and thus offer no information upon which to base an estimate.

### Likely social impacts

The likely social impacts of the candidate initiative are strongly tied to the goal of reducing the burden of infectious diseases. The initiative would deliver social impacts through expanding the availability of and access to life-saving health technologies in sub-Saharan Africa (SDG3.8) and thereby reducing morbidity and mortality associated with infectious diseases (SDG3.3). As outlined previously, the timing and scale of these impacts are highly dependent on the number of new or improved health technologies the initiative is able to help bring to market. For instance, the development of a highly effective vaccine to prevent malaria infections could save millions of lives but success is far from guaranteed.

It is worth noting also that neglected tropical diseases can disproportionately impact and disadvantage women.<sup>91</sup> Thus, by focussing on such diseases the candidate initiative has the potential to contribute further to increased gender equality (SDG5), female empowerment and participation.

The initiative could also contribute to reducing the risks associated with AMR, on the one hand by supporting the development of new technologies to tackle drug-resistant infections, on the other by promoting appropriate use of existing health technologies. Africa

<sup>90</sup> 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](https://noharm-europe.org/sites/default/files/documents-files/5731/2018_PharmaceuticalIndustryReport_WEB.pdf)

<sup>91</sup> 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](https://unitingtocombatntds.org/wp-content/uploads/2017/11/women_and_girls_in_focus_english.pdf)

already faces substantial problems of drug resistance for a wide range of diseases, including malaria, tuberculosis, meningitis, and cholera.<sup>92</sup> If left unchecked, these problems are likely to increase further. Addressing the issues requires a substantial multisectoral response, however, that should include the implementation of appropriate policy interventions (for instance, limiting the use of antibiotics in animal farming, restrictions on sales of antibiotics). The type of actions the candidate initiative will support form only one aspect of that response. Therefore, whilst highly important, their potential can only be fully realized if other factors support this.

Emerging infectious diseases can have major social consequences: unfamiliarity with new pathogens means that not only the disease may go unrecognized initially, but that also no or few effective treatment options are available. Many of these diseases induce severe symptoms and can result in high rates of mortality. Ebola, for instance, has an average case fatality rate of around 50%,<sup>93</sup> with even higher fatality rates for certain strains. The consequences of outbreaks of such diseases can thus be disastrous. Prevention of new outbreaks, through vaccination, can save many thousands or even millions of lives. Also, disease outcomes can sometimes be improved if the disease is diagnosed and treated early. The impact of the candidate initiative in this area could be very significant, but – as with other impacts – depends both on the development of health technologies, with an uncertain chance of success, and on other factors outside of its scope.

In the assessment of likely economic impacts, it was already considered how the initiative could contribute to increased employment opportunities for researchers in SSA. Naturally, the impacts of this are not only economic but also social, as poverty reduction will have a direct impact on an individual's quality of life and their social opportunities.

Strengthening of the research capacity in sub-Saharan Africa is expected to result not only in an increased ability to participate in infectious disease research, but also to autonomously initiate and implement such research. This should lead to greater equity between African and European researchers and give African countries true ownership over their health research agendas. This, in turn, should enable an increased focus on the (research) needs of African countries, and a move away from donor-driven research.

#### 4.3.4 Likely impacts on simplification and/or administrative burden

The candidate initiative does not have any objectives aimed at simplification and/or reducing the administrative burden associated with research and innovation efforts. It is unclear if and how the candidate initiative would deliver impacts in these areas. Although the initiative is expected to contribute to integration of research efforts, this primarily concerns the focus of the research activities rather than a bundling of activities per se.

#### 4.3.5 Likely impacts on fundamental rights

The candidate initiative's focus on development of and improving access to health technologies means that it can be expected to positively contribute to the implementation of the Charter of Fundamental Rights of the European Union, particularly to "...have the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities." The right to health is also reinforced by the United Nation Human Rights

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<sup>92</sup> Ndiokubwayo JB, Yahaya AA, Desta AT, Ki-Zerbo G, Odei EA, Keita B, Pana AP, Nkhoma W. WHO, Regional Office for Africa (2013). Antimicrobial resistance in the African Region: issues, challenges and actions proposed. African Health Monitor. Available at: <https://apps.who.int/medicinedocs/documents/s22169en/s22169en.pdf>

<sup>93</sup> <https://www.afro.who.int/health-topics/ebola-virus-disease>



Council and WHO in the 1948 Universal Declaration of Human Rights and constitution of WHO of 1946.



Interviewees across different stakeholder groups expect that Candidate 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.

These opinions are shared by respondents to the online public consultation. The most relevant area of impact is deemed to be that of stimulation of the development of effective, affordable and appropriate health products for developing countries (37 out of 45 respondents indicate they consider this 'very relevant'). Also impact on the development of local capacity to support and conduct clinical trials is seen by many as very relevant (32 out of 45), as is the resulting increased ability of developing countries to participate in and conduct clinical research (30 out of 45). Least relevance is seen in contributing to more innovative, sustainable and globally competitive health industries (including SMEs).

#### 4.4 Functionalities of the initiative

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

##### 4.4.1 Internal factors

#### Type and composition of the actors involved

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

To understand the type and composition of the actors to be involved in the candidate initiative, it is necessary to briefly review the evolution that EDCTP has undergone to deliver similar objectives. Under the first programme, EDCTP1, the governance of the partnership initially consisted of a General Assembly made up by European Participating States.<sup>94</sup> In the transition to EDCTP2, the governance structure was changed to an association settled under Dutch law. Purpose of this change was to give African countries, as well as alliances of countries or institutions, when mandated by their national governments, the opportunity to become full members of the partnership. Under EDCTP2, membership of the Association has been open to:<sup>95</sup>

- Sovereign states from the European Union
- Other sovereign states associated to the EU's Framework Programme for research, technological development and demonstration activities (Horizon2020)

<sup>94</sup> Technopolis Group (2014). Assessment of the performance and impact of the first programme of the European & Developing Countries Clinical Trials Partnership (EDCTP). Available at [http://www.edctp.org/web/app/uploads/2015/03/Assessment-of-the-performance-and-impact-of-the-first-EDCTP-Programme\\_Technopolis-Group\\_18SEP2014.pdf](http://www.edctp.org/web/app/uploads/2015/03/Assessment-of-the-performance-and-impact-of-the-first-EDCTP-Programme_Technopolis-Group_18SEP2014.pdf)

<sup>95</sup> Data from <http://www.edctp.org/see-work/governance/membership-edctp-association/>

- Sovereign states from sub-Saharan Africa
- (Groups of) institutions specifically mandated for this purpose by the aforementioned states
- Alliances of sovereign states and/or mandated institutions from the EU, and
- Alliances of sovereign states and/or mandated institutions from sub-Saharan Africa

The EDCTP Association currently counts 30 countries as full members. These include 14 European<sup>96</sup> and 16 Sub-Saharan African<sup>97</sup> countries. In addition, there are two aspirant members.<sup>98</sup> The Candidate Initiative should draw upon a similar set of stakeholders and remain mindful of the lessons learned to date by maintaining the meaningful participation of sub-Saharan African partners. In addition to the national governments of the European Participating States and National governments of sub-Saharan African countries as members, other important stakeholders for the Candidate Initiative include:

- Other third countries (non sub-Saharan)
- International health organisations
- Scientific leaders and clinical product development experts
- National and international institutions focused on infectious disease research
- National and international research funders, including charitable foundations (including in sub-Saharan Africa)
- Pharmaceutical industry
- Product development partnerships (PDPs)
- International development and cooperation agencies

Third-party organisations, such as those from the pharmaceutical industry and charitable foundations, have been involved in EDCTP activities on an ad hoc basis. In its annual report for 2018, for instance, EDCTP2 reports having issued joint and coordinated calls with several private charities (e.g. Africa Research Excellence Fund, Fundación Mundo Sano, Bill & Melinda Gates Foundation) and international organisations (e.g. WHO-TDR, GHIT).<sup>99</sup>

For the candidate initiative, the need to raise significant amounts of sustained funding requires greater involvement of such third-party stakeholders. A key question for the candidate initiative will be how to engage with these actors in a way that safeguards the public health objectives of the initiative (by maintaining a focus on areas of research where there are limited commercial interest and substantial unmet need and emphasising the affordability of products).

### **Type and range of activities**

This functionality relates to the criterion "Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances". It

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<sup>96</sup> Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom

<sup>97</sup> Burkina Faso, Cameroon, Rep of Congo, Ethiopia, Gabon, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia

<sup>98</sup> Angola, Switzerland

<sup>99</sup> EDCTP (2019), Annual Progress Report 2018.

concerns the types of activity that the initiative is intended to encourage, such that it is able to respond effectively to the challenges and problems described in Section 2.

The Candidate Initiative should first and foremost be an instrument for funding collaborative research and innovation actions (RIAs), in particular, those focused on the clinical development of health technologies for prevention, diagnosis and treatment of infectious diseases affecting SSA. Its emphasis should be on supporting Phase II (efficacy) and III (therapeutic confirmatory) clinical trials, where few other funding opportunities exist. Funding for Phase IV (post-licensing) trials and implementation research should be possible, as this will further enhance the initiative's capacity for impact but will be a relatively minor component.

In the transition from EDCTP1 to EDCTP2, the disease scope of the partnership was extended<sup>100</sup> to also cover neglected tropical diseases,<sup>101</sup> diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections<sup>102</sup> affecting sub-Saharan Africa (such as Ebola and yellow fever). This scope remains appropriate also for the Candidate Initiative. Further expansion is not recommended within the limits of the expected budget, as this would result in dilution of resources whereas significant work remains to be done within the present scope. Although the scope of the initiative should thus be on infectious diseases affecting SSA, this can be interpreted to include also other diseases (co-morbidities) in so far as they interact with the causes or consequences of infectious diseases or affect the effectiveness of treatments for infectious disease.

In relation to the allocation of funding to research and innovation actions, lessons could be learned from the portfolio funding model commonly applied in the context of Product Development Partnerships. Here, funders opt to not support a single research project but rather a portfolio of activities. This allows the PDPs to more rapidly switch resources over to more promising parts of the portfolio, diversifying risk and decreasing the likelihood of failure.<sup>103,104</sup> Accommodating similar forms of portfolio funding in the candidate initiative would allow for more flexibility and adaptiveness to scientific developments than project grant funding only and would allow the initiative to work together more effectively with PDPs.

As mentioned, the candidate initiative is also envisaged to play a significant role in the strengthening of research capacity in SSA. For this, it needs to fund support actions that allow for, among other things, creation and strengthening of networks of excellence and actions to support knowledge dissemination. Under EDCTP, capacity strengthening has been linked, at least to a degree, to the support for research projects. Meanwhile, substantial capacity has already been developed in some parts of SSA, whereas in others there remains only very limited capacity. Focusing increasing attention on the latter areas

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<sup>100</sup> Decision n°556/2014/EU of the European Parliament and of the Council 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/PDF/?uri=CELEX:32014D0556&from=EN>

<sup>101</sup> Based on the WHO list of neglected tropical diseases (excluding Chagas disease).

<sup>102</sup> Commission activities in the area of emerging and re-emerging infectious diseases, <https://ec.europa.eu/research/health/index.cfm?pg=area&areaname=emerging>

<sup>103</sup> Mostert B, de Jongh T, Nooijen A, Ploeg M (2014) Review of the Product Development Partnerships Fund 2011-2014: final report to the Dutch Ministry of Foreign Affairs. Available at: [https://www.technopolis-group.com/wp-content/uploads/2014/11/141118\\_PDP\\_Review\\_Technopolis\\_Group4.pdf](https://www.technopolis-group.com/wp-content/uploads/2014/11/141118_PDP_Review_Technopolis_Group4.pdf)

<sup>104</sup> Boulton I, Meredith S, Mertenskoetter T, Glaue F (2014). Evaluation of the Product Development Partnerships (PDP) funding activities. Available at: [https://assets.publishing.service.gov.uk/media/57a0897140f0b649740000b0/Evaluation\\_of\\_the\\_Product\\_Development\\_Partnerships\\_funding\\_activities.pdf](https://assets.publishing.service.gov.uk/media/57a0897140f0b649740000b0/Evaluation_of_the_Product_Development_Partnerships_funding_activities.pdf)

could require a greater degree of ‘delinking’ of the support actions from the research and innovation actions.

### Directionality and additionality required

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

One of the drivers for the current lack of health technologies for tackling infectious disease is fragmentation of research and innovation efforts in this field. 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, it needs to have a credible and strong position within the stakeholder landscape. The groundwork for this has already been laid by EDCTP which is widely recognized as a key player, as confirmed by various stakeholders throughout this study and evident in the substantial research output to which it has contributed.

Notwithstanding the importance of EDCTP as a research funder and contributor to the global health research agenda, there are questions about the extent to which it has been able to align partners’ national efforts. The reason for this is that most of the contributions by the Participating States have been delivered in-kind, through Participating States’ Initiated Activities (PSIAs).<sup>105</sup> Although PSIAs need to be in line with the overarching objectives of EDCTP and need to be formally approved by the EC before their value can be matched from the EC budget, there is currently no requirement for the Participating States to align these activities with each other. Similar issues are likely to affect the candidate initiative if partners are not willing to convert a greater share of their contributions to cash rather than in-kind or agree to increased multilateral research collaboration.

#### 4.4.2 External factors

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

The problems that the candidate initiative will seek to address are highly complex and are set in the context of weak systems and institutions for the delivery of health care. Through the EC Directorate-General for International Cooperation and Development, the EU will need to continue to support the strengthening of health systems in sub-Saharan Africa, investing both in its human capital (doctors, nurses, community health workers, technicians etc) and in infrastructures (hospitals, equipment, vehicles etc).

Whilst development of new health technologies is essential, they cannot be used where they are needed unless they are authorized for use in those markets. The regulatory

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<sup>105</sup> Participating States’ Initiated Activities” (PSIAs) are nationally funded activities that are implemented by one or several Participating States, in line with common principles agreed between the EDCTP Association and the European Commission services. They represent in-kind contributions from the Member States and their value can be matched from the EU contribution.

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 will have an important role to play. To do so effectively, it is likely to need support from other agencies, such as the US Food and Drug Administration as well as the European Medicines Agency.

The candidate initiative will likely have some areas of common interest with other initiatives or programmes, such as the Coalition for Epidemic Preparedness Innovations, the Joint Programming Initiative on Antimicrobial Resistance, and the candidate European Partnership on One Health AMR. Here, it will be important to coordinate activities and to collaborate as and when appropriate to avoid unnecessary duplication or fragmentation of efforts.

## **5 What are the available policy options?**

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

To ensure a correct assessment of the different options and their effectiveness, it is crucial to take into consideration both the objectives and the functional requirements outlined in Section 4.4. The descriptions of the options in the sections below, therefore, focus on the implications of the options' characteristics related to these functionalities. They are based on the options' characteristics specifically related to the functionalities listed in Section 4.4. A full description of the options is provided in the report on the overarching context to the impact assessment studies.

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

Under the baseline option, no partnership structures are in place. Calls for respective research areas are implemented through traditional calls under the Framework Programme. In this scenario, the EC would publish calls for infectious disease-related research and development through the Horizon Europe calls without further involvement of partners. This option does not allow for the pooling of additional resources from countries and for cooperation between stakeholders around a common strategic agenda. Under the baseline option, neither the EC nor any partners make an upfront budgetary commitment. This implies less political commitment and reduced visibility to the field compared to under a partnership approach. In the absence of a dedicated partnership, there will no longer be an entity to continue the 'brand' of EDCTP, which has been build up over time and that is recognized and well-regarded by all stakeholders in the field.

The baseline option does not involve a dedicated implementing structure. Under EDCTP, a lot of content knowledge and expertise has been generated, including on how to manage research projects in Africa. Moreover, the EDCTP Secretariat has dedicated significant efforts into building up relationships with key stakeholders in the region. Under the baseline option, this know-how and network would almost certainly be lost as it cannot easily be replicated in-house by the EC Research Executive Agency that would be in charge of operations for Horizon Europe calls.

Table 2: Key characteristics of Option 0

	Implications of option
<b>Enabling appropriate profile of participation</b> <i>(actors involved)</i>	<ul style="list-style-type: none"> <li>Given the broad range of activities the initiative aims to support, the EC would need to consult with a very large group of stakeholders, both from Europe and Africa, to translate the strategic agenda into an annual work programme. However, under traditional calls the options for structured engagement with actors such as public health institutions and regulatory authorities, as well as with charitable foundations is limited.</li> <li>Participation in traditional calls is open to any legal entity within a consortium. This includes research organisations in Africa, although these are not automatically eligible for funding.</li> <li>No full involvement of African countries in decision taking. Loss of the brandina/label recognition and buy in by the African</li> </ul>
<b>Supporting implementation of R&amp;I agenda</b> <i>(activities)</i>	<ul style="list-style-type: none"> <li>Traditional calls do not allow for the development of a joint programme of R&amp;D activities between Member States and partners, whereas one of the specific objectives of the initiative should be to increase alignment between actors in research for infectious disease.</li> <li>Whilst the EU Framework Programme, through the Annual Work Programmes, can support also Coordination and Support actions and training actions, traditional calls are typically focused on supporting R&amp;I activities. Calls are not suited to supporting, for instance, the development and strengthening of the enabling environment for clinical research, such as systems for medical ethical review.</li> <li>EU FP Annual Work Programmes can support R&amp;I activities as well as Coordination and Support actions and Training actions</li> </ul>
<b>Ensuring alignment with R&amp;I agenda</b> <i>(directionality)</i>	<ul style="list-style-type: none"> <li>Traditional calls do not allow for the pooling of national resources needed to help support multisite, international trials that require (very) large investments.</li> <li>In the absence of a dedicated implementing structure, traditional calls cannot ensure alignment with other key initiatives and organisations in the global health arena. Such alignment is crucial given the often-large amounts of funding involved, and the substantial (political) interests.</li> <li>The baseline option does not promote a long-term vision for the R&amp;I agenda to combat infectious diseases, whereas health technology development is characterized by high risks and long development times calling for a sustained commitment.</li> </ul>
<b>Securing leveraging effects</b> <i>(additionality)</i>	<ul style="list-style-type: none"> <li>Under the baseline option, there are no explicit incentives for Member States to increase or even just maintain their investments in research and innovation to combat infectious disease as there is no matching of national contributions from the EU budget.</li> <li>This option does not require upfront determination of a budgetary EU envelope and does not call for financial commitments from partners. This thus implies less political commitment from all stakeholders involved and decreased visibility for this area of research.</li> </ul>

## 5.2 Option 1: Co-programmed European Partnership

Under a Co-programmed European Partnership, the initiative would consist of public and/or private partners acting through a Memorandum of Understanding or other contractual agreements. 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 not legally binding in co-programmed Partnerships and the contributions may be financial or in-kind. The calls would be published through the Horizon Europe Work Programme, and require relatively low effort in preparation, set-up and implementation from the EC.

For the EU-Africa Global Health Partnership, this type of agreement would mean that the relationships that were built under EDCTP, including those with African countries, could be largely maintained (or extended, depending on interest from partners). The partners would jointly provide input on the priority areas for the Horizon Europe calls, with efforts focused on aligning impact. Although there would not be a legally binding framework for collecting contributions and issuing calls, the EU budget envelope, could probably be set up front. Any financial risks would be covered by the parties own contributions to the partnership.

A co-programmed partnership is a relatively 'light' form of partnership that is easy to manage and that does not require a separate legislative procedure. However, as the EU calls would be managed by EC or an EC executive agency, there is reduced political commitment from partners. Also, similar to the discussion for the baseline option, in case of a co-programmed partnership there would be a loss of expertise and possible destabilisation of the relationships built under EDCTP.

Table 3: Key characteristics of Option 1

	Implications of option
<b>Enabling appropriate profile of participation (actors involved)</b>	<ul style="list-style-type: none"> <li>• The co-programmed option enables participation from any kind of partner, thus including African countries as well as industry and charitable foundations. The relationships built under the EDCTP Association could be maintained.</li> <li>• The composition of partners can change over time, allowing for flexibility and adaptiveness to emerging needs and priorities in the global health arena.</li> <li>• Under national rules, calls issued by Member States would usually be open only to legal entities from countries that are part of the consortia. This potentially limits the participation of in particular certain African countries that do not yet have the capacity to actively participate in consortia.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (activities)</b>	<ul style="list-style-type: none"> <li>• The co-programmed partnership would allow for the support of a broad range of R&amp;I activities, as well as other types of actions, such as coordination and support actions and technical support. These types of action, in particular those connected to capacity strengthening, should be a core component of the initiative.</li> <li>• Partners would have limited control over the precise definition of 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.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (directionality)</b>	<ul style="list-style-type: none"> <li>• Under the co-programmed option, a strategic roadmap is agreed between the EC and the partners involved. The ability to provide inputs into the work programme partners a measure of directional influence, but this is limited mainly to the upfront decision-making rather than over the implementation itself.</li> <li>• The alignment with other initiatives and parties outside of the partnership would be the responsibility of the EC agency in</li> </ul>



	Implications of option
	charge of the programme implementation. Opportunities for synergies with other programmes are limited.
<b>Securing leveraging effects (additionality)</b>	<ul style="list-style-type: none"> <li>• Commitments represent political/best efforts but are usually honoured. Under the co-programmed option, both cash and in-kind contributions can be leveraged for increased impact.</li> </ul>

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

A co-funded partnership would involve public partners (particularly research funders), with a certain degree of flexibility for the involvement of foundations and international partners. Whilst only public sector partners can make contributions and formal commitments to the partnership, industry can be addressed by the activities of the partnership. This partnership type allows partners and activities to evolve. For the candidate EU-Africa Global Health Partnership, this would mean that the relationships built through the EDCTP Association, including those with African countries, could be maintained whilst industry could be involved via specific activities. Under a co-funded partnership, usually only legal entities from countries that are part of the consortia can apply to calls. This could mean that, in particular, not all sub-Saharan African countries could participate if they are unable to commit to the partnership.

Compared to a Co-Programmed Partnership, a Co-Funded partnership requires a higher degree of oversight as the annual work plans of consortia need to be approved by the EC. Partner contributions can be either in-kind contributions or financial contributions (used for calls for proposals for third parties), and EC contributions are provided through reimbursement of incurred costs. A mutual insurance mechanism will cover beneficiaries' bankruptcies.

Legally, the commitments of the partners are ensured through Grant Agreements, which are the main instruments for co-funded actions. Under a co-funded partnership, the representatives of all partners making a contribution, so not only the Member States but also all organisations involved in implementing the activities of the partnership would need to be in a large Grant Agreement with the EC, who would reimburse the costs based on what is eligible. In the case of the candidate EU-Africa Global Health Partnership, this arrangement is unlikely to be manageable given the large number of organisations that have been involved in the implementation of EDCTP activities, both through the centrally funded calls and through the PSIA's. The extent to which this type of partnership would encourage additional investments from the Member States is unclear, as it requires less political commitment than was the case under EDCTP which itself already appears to have struggled with incentivising increased investment.

As with the previously discussed Option 0 and Option 1, a key concern affecting the desirability of the Co-Funded Partnership as a model for the EU-Africa Global Health Partnership is the likely disruption of operations established under EDCTP and the loss of expertise and relations resulting in case of the dissolution of the present EDCTP Secretariat. However, this option allows for the creation of a dedicated 'programme office' within one of the beneficiary organisations to manage the coordination of the partnership.

In the discussions with the Project Steering Group at the presentation of the Draft Final Report, and in the subsequent comments provided, the possibility of involvement of a co-fund was raised as a way to circumvent one of the problems affecting the Article 185 Institutionalised Partnership, namely the need to have 40% of Member States represented. These comments seemingly suggest the combination of an Institutionalised Partnership with a co-fund. This possibility was, however, not raised in previous discussions with the EC DG RTD, nor was it included in the consultation activities. As a result, no stakeholder



input was collected to support the assessment of this 'composite' option. The information provided by the EC during the final discussions on the specifics is as yet insufficient for the study team to independently assess the feasibility and desirability of this option.

Table 4: Key characteristics of Option 2

	Implications of option
<b>Enabling appropriate profile of participation</b> <i>(actors involved)</i>	<ul style="list-style-type: none"> <li>• A co-funded partnership itself would be limited to public sector parties and possibly foundations. Involvement of African countries is possible. Industry parties would not be in the partnership itself but could be involved in activities. Relationships built under EDCTP could be largely maintained, although the type of involvement of parties would be different than under an Institutionalised Partnership.</li> <li>• Activities funded via a co-funded partnership approach would typically be removed from the Horizon Europe work programme, thus requiring large scale commitment from Member States. Furthermore, only legal entities from countries that are part of the consortia can apply to calls. The option could thus incentivise participation (and reduce 'free riding'), as institutions from non-participating countries would no longer be able to receive funding for their activities in the core area of the partnership. This could, however, also hinder access for certain sub-Saharan African countries that are unable to participate in the partnership.</li> </ul>
<b>Supporting implementation of R&amp;I agenda</b> <i>(activities)</i>	<ul style="list-style-type: none"> <li>• Typically, the scale and scope of R&amp;I actions funded under a co-funded Partnership is smaller than that under traditional calls or those under an Institutionalised Partnership. It is therefore less well suited to the ambitious objectives of the candidate EU-Africa Global Health Partnership which involves substantial investment in large-scale multicentre clinical trials.</li> <li>• In principle, a co-funded partnership allows for funding of the type of capacity strengthening activities foreseen for the candidate partnership, but only to the extent that these are permitted according to national programmes and rules.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda</b> <i>(directionality)</i>	<ul style="list-style-type: none"> <li>• A co-funded partnership calls for the development of a strategic R&amp;I agenda/roadmap, to be agreed between partners and EC and the drafting of an annual work programme by the partners and approved by the EC, similar to how this would be done under an Article 185 Institutionalised Partnership like EDCTP. Technically, therefore, partners could maintain a similar role in the strategic decision-making to that which they held by membership of the EDCTP Association. However, their individual roles are likely to be diluted because of the increased number of partners.</li> <li>• The large number of parties that would likely need to be included in the Grant Agreement would be severely problematic for aligning activities around a common strategic agenda.</li> <li>• Thus far, Member States have shown limited willingness to improve coordination and alignment of their national efforts in the area of infectious disease research, which are influenced substantially by political priorities for international cooperation and development.</li> </ul>
<b>Securing leveraging effects</b> <i>(additionality)</i>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

### 5.4 Option 3: Institutionalised European Partnership

The institutionalised European partnerships are subject to implementation under Article 185 or Article 187 of the Treaty on the Functioning of the European Union. Both types of initiative 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 Undertakings (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 EC 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 only the key differences between these two types of institutionalised partnership in relation to the candidate EU-Africa Global Health Partnership.

#### 5.4.1 Institutionalised Partnerships under Art 185 TFEU

Under Art.185 involvement is limited to Member States and Associated Countries. Non-associated countries can only participate if foreseen in the basic act, and their participation is subject to concluding individual international agreements. In the EDCTP2, African countries are taking part indirectly in the current 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.

For the candidate EU-Africa Global Health Partnership, the Institutionalised Partnership approach under Art 185 would allow it to retain much of the independence that has been put in place via EDCTP. The DIS could largely be a continuation of the current EDCTP Secretariat.

Table 5: Key characteristics of Option 3: Institutionalised Partnership Art 185

	Implications of option
<b>Enabling appropriate profile of participation (actors involved)</b>	<ul style="list-style-type: none"> <li>This form of partnership is open only to Member States and Associated Countries, represented by public sector organisations. Non-associated countries, such as African countries, can participate if foreseen in the basic act. Private sector organisations and charitable foundations cannot be directly included in the partnership and their contributions cannot be matched from the EU budget.</li> <li>This form of partnership would effectively allow the EDCTP Association to continue to function as it is, with a similar set of actors, roles and responsibilities. It allows for meaningful participation of African countries in strategic discussions and decision-making.</li> <li>This form of partnership comes with high visibility and political commitment from partners.</li> </ul>
<b>Supporting implementation of</b>	<ul style="list-style-type: none"> <li>A Dedicated Implementation Structure would be responsible for aligning partners around a shared strategic agenda, with</li> </ul>

	Implications of option
<b>R&amp;I agenda (activities)</b>	<p>approval by the EC. This structure is in charge of overseeing the effective implementation of activities.</p> <ul style="list-style-type: none"> <li>This form of partnership allows for funding of R&amp;I activities, as well as coordination and support actions and technical support. This full mix of activities is foreseen as needed for the fulfilment of the candidate partnership's objectives.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (directionality)</b>	<ul style="list-style-type: none"> <li>By participation in the development of a strategic agenda, partners are encouraged to improve their alignment and transnational cooperation.</li> <li>Through the DIS, this form of partnership could improve synergies with national/regional programmes and activities, as well as with other EC and international programmes or initiatives. In the complex global health landscape, where there are numerous national, multinational and global initiatives, such synergies are extremely important not only to maximise effectiveness of efforts but also in light of possibly low absorptive capacity in certain beneficiary countries.</li> </ul>
<b>Securing leveraging effects (additionality)</b>	<ul style="list-style-type: none"> <li>National R&amp;I activities can be integrated into the programme, which can then be matched from the EU budget to increase scope and promote transnational cooperation.</li> </ul>

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

Whilst the Institutionalised Partnership under Art. 187 shares many characteristics with that under Art. 185, one key difference lies in the possibility of involvement of partners beyond the Member States and Associated Countries. Under Art. 187 private sector actors and charitable foundations can be included in the partnership and their contributions could 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. There is no requirement on the minimum number of partners involved.

Under Art. 187, the implementation of the programme is normally managed by a Joint Undertaking. Compared to the DIS of an Art. 185 institutionalised partnership, the Joint Undertaking is a more concentrated governance structure. The Joint Undertaking would not automatically be able to draw upon the know-how and network embodied by the current EDCTP Secretariat. Also, the roles and responsibilities of participants would be different than they are under EDCTP.

Table 6: Key characteristics of Option 3: Institutionalised Partnership Art 187

	Implications of option
<b>Enabling appropriate profile of participation (actors involved)</b>	<ul style="list-style-type: none"> <li>This form of partnership is open to Member States and Associated Countries, represented by public sector organisations, as well as to non-associated countries, private sector organisations and charitable foundations. Each of their contributions can be matched from the EU budget.</li> <li>Under an Art 187 partnership, Member States and African countries would have a relatively smaller role in oversight of implementation of activities than under Art 185.</li> <li>Participation in calls is normally not limited to institutions from countries that are included in the partnership. This is therefore a relatively open form of partnership.</li> </ul>

	Implications of option
	<ul style="list-style-type: none"> <li>• The Art 187 partnership has limited flexibility in its objectives, range of activities and partners as these need to be defined and negotiated upfront.</li> <li>• This form of partnership comes with high visibility and political commitment from partners.</li> </ul>
<b>Supporting implementation of R&amp;I agenda (activities)</b>	<ul style="list-style-type: none"> <li>• Implementation of activities would be the responsibility of a Joint Undertaking, an entity that would need to be newly created and which may not be able to draw upon existing know-how and relationships.</li> <li>• This form of partnership allows for funding of R&amp;I activities, as well as coordination and support actions and technical support. This full mix of activities is foreseen as needed for the fulfilment of the candidate partnership's objectives. However, the possible loss of expertise compared to an Art 185 partnership could be particularly problematic for effective coordination and implementation of such support activities, which depend highly on good relationships with institutions in Africa.</li> </ul>
<b>Ensuring alignment with R&amp;I agenda (directionality)</b>	<ul style="list-style-type: none"> <li>• By participation in the development of a strategic agenda, partners are encouraged to improve their alignment and transnational cooperation.</li> <li>• The Joint Undertaking allows for the development of synergies with other national and international initiatives and programmes in much the same way as the DIS for an Art 185 Institutional Partnership would. However, determining where areas of synergy are requires in-depth understanding of the landscape and good relationships with such initiatives.</li> </ul>
<b>Securing leveraging effects (additionality)</b>	<ul style="list-style-type: none"> <li>• National R&amp;I activities can be integrated into the programme, which can then be matched from the EU budget to increase scope and promote transnational cooperation.</li> <li>• This form of partnership potentially has the highest possibility for leveraging funding, as contributions from any type of actor can be matched.</li> </ul>

### 5.5 Options discarded at an early stage

The co-funded partnership (Option 2) is unlikely to be feasible for the EU-Africa Global Health Partnership as the Grant Agreement would need to include *all* consortium partners. This would have to include all the organisations whose activities need to be counted as in-kind contributions. The broad range of actors that would likely be involved in the partnership would mean that the Grant Agreement could have to include well over a hundred parties. This would require an enormous amount of administration and management. It is also very unlikely that this form of partnership would be able to raise the amount of funding needed for the ambitions of the candidate initiative. This option has thus hereafter been discarded from further assessment.

## 6 Comparative assessment of the policy options

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

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

The assessments in this section set the basis for the comprehensive *comparative* assessment of all retained options against all dimensions in Section 6.4.

Table 7, below, lists the likely impacts in the three impact areas.

Table 7: Likely impacts of the initiative

Impact area	Likely impacts
<b>Scientific impact</b>	Reduced burden of infectious diseases in sub-Saharan Africa
	Strengthened EU excellence in clinical research for infectious diseases
	Improved generation of infectious disease knowledge relevant for sub-Saharan Africa
	Increased scientific leadership of sub-Saharan Africa in infectious disease research
<b>Economic / technological impact</b>	Increased economic activity from production, distribution and sales of health technologies for infectious diseases
	Increased EU-Africa trade and sustainable investments
	Reduced poverty associated with infectious diseases in sub-Saharan Africa
	Reduced economic risk from spread of (re)emerging infectious diseases globally
	Increased employment of infectious disease researchers in sub-Saharan Africa
	Increased spending on infectious disease research in sub-Saharan Africa
	Improved efficiency of infectious disease research resources
<b>Societal impact</b>	Improved access to health technologies
	Reduced morbidity and mortality from infectious diseases in sub-Saharan Africa
	Reduced risk of antimicrobial resistance in sub-Saharan Africa and globally
	Reduced risks from (re)emerging infectious diseases in sub-Saharan Africa and globally
	Increased chances at full and productive employment for researchers in sub-Saharan Africa
	Increased capacity of research institutions in sub-Saharan Africa to design, conduct and manage infectious disease research projects and to attract funding
	Increased focus on unmet medical needs from infectious diseases in sub-Saharan Africa
	Increased waste from manufacturing of health technologies

## 6.1 Assessment of effectiveness

### 6.1.1 Scientific impacts

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

Under the baseline option, calls for proposals could be issued that are focused on generation of knowledge that can support the development of new or improved health technologies in the area of infectious diseases. The baseline option would thus be able to support the impact pathway for scientific impact in this area, as identified in section 4.3.1 (“improved generation of infectious disease knowledge relevant for SSA”). Whilst in principle there are no restrictions on the grant size possible under Horizon Europe calls, and the possibility for funding clinical research exists, traditionally the size of grants under such calls is smaller and the focus tends to be more on relatively upstream research (Phase I trials and pre-clinical research). This could mean that the pathway to impact in reducing the burden of infectious disease in SSA (see section 4.3.1) would become longer and have a reduced chance of success compared to an institutionalised partnership approach.

Strengthening of research capacity should be focused in particular also on the capacity to conduct clinical trials in Africa. Insufficient clinical trial capacity in disease endemic countries is a major obstacle to the development of health technologies that are suitably adapted to local contexts and needs. The baseline option is unlikely to be able to support strengthening of capacity to conduct clinical research to the extent needed if the focus of the research itself is primarily upstream. Impacts on the scientific leadership of SSA would therefore likely be much reduced under the baseline option.

All interviewed stakeholders, from all stakeholder groups included, 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**

Under a co-programmed partnership, scientific impacts are tied most closely to research and innovation support as it is less suited to coordination and support activities or technical support. The ability to leverage contributions means that this type of partnership could be used also to fund research activities requiring large scale investments. Compared to the baseline option, it is thus more likely to be able to support late-stage clinical trials, with an increased chance of contributing to successful product development.

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

Both forms of institutionalised partnership would bring together a set of partners that not only can pool resources, but their contributions will be matched from the EC budget. This is expected to 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 agree on a common strategic vision and to plan their activities accordingly. Compared to the baseline option, an institutionalised partnership will thus have significantly more ability to support research in the area of infectious diseases with high potential for scientific impact (see section 4.3.1).

Within EDCTP and at the level of the EC, discussions have been ongoing about setting up the EU-Africa Global Health Partnership as an Art.187 partnership, rather than as an Art.185 partnership as is the case for EDCTP. This discussion has been driven primarily by concerns about the financial sustainability of the partnership and the need to work more closely with third parties. A particular concern herein is the future role of the United Kingdom and its possible exit from the European Union (‘Brexit’). The UK has been the



largest contributor to EDCTP, funding by far the highest number of PSIA<sup>106</sup>. If the UK exits the Union without an agreement, under Art.185 their contributions could no longer be matched from the EC budget. Additionally, under Article 185, institutionalised partnerships are required to have a representation of a minimum of 40% of the EU Member States. At present, EDCTP2 counts 13 European Member States<sup>107</sup> as participants amounting to 46%. In case of a no-deal Brexit, and if there are no other changes to the membership for the candidate initiative, this percentage would drop further and come close to the point where sufficient participation is no longer reached, putting the future of the candidate initiative at risk. A greater number of partners, including third parties, would be beneficial for the candidate initiative as not only would it potentially increase funding commitments, but it also allows any financial risks to be spread over a greater number of actors. Several interviewed representatives of current and potential future partners have indicated that financial liability to partners is a significant concern, affecting their possible participation.

To expand the number of partners, it will be necessary to open up the partnership to non-state actors, such as those from international organisations, industry or charitable foundations. It is unlikely that a substantially greater number of European countries would join the candidate initiative than those that have joined EDCTP. The willingness of countries to participate appears to be linked closely to whether they have a tradition of conducting and supporting global health research. In the large majority of EU Member States that are not currently represented in EDCTP, such a tradition does not exist. A greater emphasis on the relevance of the candidate initiative for Europe may encourage some less obvious countries to consider joining, particularly if they face some of the same health challenges that are within the scope of the candidate initiative such as HIV and tuberculosis. However, the available information offers few indications of the extent to which this could be the case. Some early expressions of interest in joining the partnership, collected in the structured consultation of Member States, do not represent a firm commitment and should, therefore, be interpreted with a great deal of caution.

Whilst the potential for scientific impact is comparatively high under both forms of institutionalised partnership, the Art.187 institutionalised partnership appears most likely to mobilise the resources needed to support a sustained and coordinated response to the challenge of infectious diseases in sub-Saharan Africa. In the area of strengthening scientific leadership in SSA, though, it will be important for the partnership to meaningfully include and work together with African partners. This is possible under both forms of institutionalised partnership but requires careful consideration of how governance and advisory structures are set up.



Interviewees unanimously express a strong preference for an institutionalised partnership approach. Opinions are, however, somewhat divided on whether this should take the form of an Article 185 partnership or an Article 187 partnership. Many acknowledge, or even embrace, the advantages an Art.187 set-up would bring to the partnership, arguing that it allows for more meaningful inclusion of a greater range of stakeholders, creates more financial certainty, and would allow for a leaner and more efficient organisational structure. Others, however, have concerns about what this would mean for the relationships built with and between current EDCTP members and for the level of control that EC would have over the partnership, possibly at the expense of the representation of current members.

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. What is clear from the interviews is that not all stakeholders fully understand the

<sup>106</sup> Based on the assessment of EDCTP Workplans 2014-2019

<sup>107</sup> Norway is an Associated Country but not an EU Member State.

respective advantages and disadvantages of these two options and question why a change from one to the other would even be under consideration.

The preference for an institutionalised partnership approach was somewhat less evident in the responses to the open public consultation. Here, 26 out of 41 respondents indicated this as their 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 and their relation to the required functionalities of the Candidate Initiative. Therefore, their choices may not be adequately informed and these responses should be interpreted with due caution.

## Summary

Table 8, below, lists the scores we assigned for each of the policy options that was retained in the assessment, based upon the discussions above, as well as taking into account the support expressed by the different stakeholders.

Table 8: Overview of the options' potential for reaching the scientific impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 185	Option 3: Institutionalised Art 187
<b>Reduced burden of IDs in SSA</b>	+	++	+++	+++
<b>Strengthened EU excellence in clinical research for IDs</b>	++	++	+++	+++
<b>Improved generation of ID knowledge relevant for SSA</b>	++	++	+++	+++
<b>Increased scientific leadership of SSA in ID research</b>	+	++	+++	+++

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

### 6.1.2 Economic/technological impacts

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

The aforementioned shift to more upstream research that would likely result from the baseline option implies a much-reduced ability to support end-of-pipeline product development. The resulting decreased output of health technologies means less chance of impact from an increased economic activity from production, distribution and sales of health technologies for infectious diseases, and reduced impact on EU-Africa trade and sustainable investments (see section 4.3.2). Fewer products brought to market also means less likelihood of alleviating poverty associated with infectious diseases in SSA.

The economic impact associated with a reduced risk of spread of (re)emerging infectious diseases globally is linked not only to research and innovation activities but also to strengthen networks and promoting knowledge exchange between institutions and



countries. Under the baseline option, such activities could still be supported to an extent, as they are typically less resource-intensive than large-scale clinical trials.

As mentioned previously, the baseline option likely would entail a shift also in the type and scale of research capacity development that could take place. Whilst strengthening of research capacity for more fundamental research is certainly also needed in SSA, it is difficult to foresee to what extent this would be able to translate into increased employment opportunities for researchers in SSA.

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

As discussed in 4.3.2, economic impacts are tied both to increased ability to combat infectious diseases, by reducing health care related expenditure and increasing workforce participation, and to strengthening of research capacity in SSA and the resulting improved employment opportunities for researchers in the region. This means that economic impacts depend not only on the implementation and results of research activities, but also on the level of funding for coordination and support actions. The co-programmed option is expected to focus less heavily on these types of actions than an institutionalised partnership, but possibly more so than calls under the baseline option.

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

The considerations applied for the likely scientific impacts under an institutionalised partnership approach all apply equally for the possible attainment of economic/technological impacts, as these are closely intertwined: the economic impacts are largely dependent on the attainment of scientific results and impacts. With its greater possibility to focus on clinical research and product development, an institutionalised partnership has a higher chance to result in technologies ready for production, distribution and sales than the baseline option (see section 4.3.2). Their subsequent uptake and use are, in turn, what drives poverty reduction.

The link between research and innovation actions and support actions aimed at capacity strengthening means that the extent of economic impact resulting from increases in the skill level of researchers and increased research activity depends, in part, on the scale as well as the focus of the initiative. Under an institutionalised partnership, irrespective of whether this takes the form of an Art.185 or an Art.187 partnership, there will be greater opportunities for capacity strengthening in the area of clinical research than under the baseline option.

### **Summary**

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

Table 9: Overview of the options' potential for reaching the likely economic / technological impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 185	Option 3: Institutionalised Art 187
Increased economic activity from production, distribution and sales of health technologies for IDs	+	++	+++	+++
Increased EU-Africa trade and sustainable investments	+	++	++	++
Reduced poverty associated with IDs in SSA	+	++	++	++
Reduced economic risk from spread of (re)emerging IDs globally	+	++	+++	+++
Increased employment of ID researchers in SSA	+	++	+++	+++
Increased spending on ID research in SSA	++	++	+++	+++
Improved efficiency of ID research resources	+	++	+++	+++

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

### 6.1.3 Societal impacts

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

The achievement of societal impacts, in particular, those impacts directly associated with the health status of people, depends on the increased availability and uptake of new or improved health technologies (see section 4.3.3). As the preceding sections highlighted, the baseline option is not expected to be able to deliver on this to the extent the institutionalised partnership approach would. Bringing products to market requires sufficient clinical research to generate evidence that a product is safe and effective. The baseline option will not be able to support this often very costly form of research, which frequently also involves international multi-stakeholder collaboration.

As indicated in the previous discussion of economic impacts, it is difficult to predict to what extent the baseline option will be able to offer increased chances at employment for researchers and how this would compare to those offered by the institutionalised partnership approach. Given the assumption made throughout this options assessment that the baseline option would not be able to support large scale clinical research, it is unlikely that this option would be able to generate significant impacts on the capacity of research institutions to design, conduct and manage such research projects.

In the absence of a partnership, the baseline option would struggle to integrate research and innovation efforts for tackling infectious diseases around a common strategic research agenda. It thus has very little ability to contribute to country-led research programming and an increased focus on unmet medical needs in the region.

#### Option 1: Co-Programmed

As discussed in section 5.2, whilst a co-programmed partnership is relatively loose and does not require formal commitments, it can reasonably be expected to leverage sufficient

resources to support the research and innovation activities on which the candidate partnership should be focused. In this sense, it has a greater likelihood of achieving the scientific results that are needed to translate into the necessary health technologies to combat infectious diseases. It is less clear to what extent this form of partnership will be able to achieve the sort of societal impacts that are more closely associated with research capacity strengthening.

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

Under the institutionalised partnership option, greater emphasis will be possible on supporting the kind of research that is required to deliver health technologies to people in need thereof (see section 4.3.3). This, in turn, increases the likelihood of reducing morbidity and mortality associated with infectious diseases in SSA. Similar reasoning can be applied to other areas of societal impact. Nonetheless, it should be recognised that the achievement of societal impacts is heavily dependent on many contextual factors well outside the scope of the candidate partnership. Therefore, there should be somewhat modest expectations about the extent to which the initiative can impact on, for instance, overall disease burden and disease-associated mortality.

In respect of the two types of institutionalised partnership, the extent to which any societal impact can be expected appears to be linked more to the amount of resources that can be mobilized (which may be influenced by the type of institutionalised partnership) than to inherent differences between these two forms.

### Summary

Table 10, below, lists the scores we assigned for each of the policy options, based upon the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 10: Overview of the options' potential for reaching the likely societal impacts

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 185	Option 3: Institutionalised Art 187
<b>Increased waste from manufacturing of health technologies<sup>108</sup></b>	+++	++	+	+
<b>Improved access to health technologies</b>	+	++	+++	+++
<b>Reduced morbidity and mortality from IDs in SSA</b>	+	+	++	++
<b>Reduced risk of antimicrobial resistance in SSA and globally</b>	+	++	++	++
<b>Reduced risks from (re)emerging IDs in SSA and globally</b>	+	++	+++	+++

<sup>108</sup> For better comparison, here we have assigned a +++ score to the form of partnership with *least* expected impact on the production of pharmaceutical waste as this is an undesirable impact.

	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art 185	Option 3: Institutionalised Art 187
<b>Increased chances at full and productive employment for researchers in SSA, retention of scientific talent</b>	+	+	++	++
<b>Increased capacity of research institutions in SSA to design, conduct and manage ID research projects and to attract funding</b>	+	++	+++	+++
<b>Increased focus on unmet medical needs from IDs in SSA</b>	+	++	++	++

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

## 6.2 Assessment of coherence

### 6.2.1 Internal coherence

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

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

The formulation of the specific and operational objectives for the candidate initiative makes clear that the initiative will need to deploy two sets of separate, yet somewhat connected activities: those to support generation of relevant knowledge on infectious diseases and to accelerate product development on the one hand, and those to promote capacity strengthening and knowledge exchange. Whilst some of the latter will be stand-alone activities (e.g. career fellowship grants to researchers), others may take place in the context of implementing research activities. Traditional calls under Horizon Europe, the baseline option, will be aimed primarily at fostering and supporting research excellence and may thus not leave sufficient room for capacity strengthening activities within projects.

#### Option 1: Co-Programmed

Through a co-programmed partnership, the partners can aim to achieve a measure of coherence with other partnerships and with the Annual Work Programme of Horizon Europe. However, its decentralised management structure does not effectively support the building of strong and sustained relationships with other organisations or initiatives.

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

As highlighted in the preceding assessment of the baseline option, a measure of coherence is required between the different types of activities needed to attain the initiative's objectives. The institutionalised partnership option will be better placed to deliver this than the baseline option because it can take a somewhat more flexible approach to the criteria of the calls.



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. As mentioned previously, the same is seen among respondents to the open public consultation.

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

### 6.2.2 External coherence

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

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

The candidate initiative will share areas of common interest with other initiatives, organisations and research funders. It is strategically 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 funders such as the Bill & Melinda Gates Foundation or organisations such as WHO-TDR, the Special Programme for Research and Training in Tropical Diseases. The baseline option, however, offers few, if any, opportunities for such coordinated action.

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

The ability for a co-programmes partnership to manage relationships with other programmes or initiatives is largely similar, whether these relations are internal or external such as in the case of national research programmes. At a national level, individual partners may have the ability to improve coherence between activities supported within the partnership and those outside of it. However, alignment with globally operating initiatives would be difficult in the absence of a dedicated management structure.

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

The assessment of the baseline option also discussed in what areas external coherence is required. The institutionalised partnership option offers the greatest ability to engage with other relevant actors, including those outside of the partnership, as creating meaningful engagement may take a substantial investment of time and resources. The institutionalised partnership would have a dedicated structure to manage such relations.



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

## Summary

Table 11, below, lists the scores we assigned for each of the policy options, 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 2: Co-funded	Option 3: Institutionalised Art 185/187
<b>Internal coherence</b>	+	++	+++	+++
<b>External coherence</b>	+	++	+++	+++

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

### 6.3 Comparative assessment of efficiency

To compare the policy options under common standards, we developed a standard cost model for all 13 candidate Institutionalised Partnership studies. The model and the underlying assumptions and analyses are set out in the report on the overarching context to the impact assessment studies.

Table 12, below, shows the intensity of additional costs against specific cost items for the various options as compared to the baseline, i.e. Option 0 (Horizon Europe calls). In this table, we have taken into account that for Option 3 (Institutionalised Partnership) Art. 185 there would be a moderate additional cost for the set-up of a dedicated implementation structure seeing that such a structure already exists. In the case of an Institutionalised Partnership under Art. 187 these costs would be increased further, as this would require the creation of a new implementation structure (Joint Undertaking).

For Option 1 (Co-programmed), we considered an additional cost for the call and project implementation as ideally, MS would be providing contributions.

Table 12: Intensity of additional costs compared with HEU Calls (for Partners, stakeholders, public and EC)

Cost items	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 185	Option 3: Institutionalised Art. 187
<b>Preparation and set-up costs</b>				
<b>Preparation of a partnership proposal (partners and EC)</b>	0	++	++	++
<b>Set-up of a dedicated implementation structure</b>	0	0	+	+++
<b>Preparation of the SRIA / roadmap</b>	0	++		

Cost items	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Art. 185	Option 3: Institutionalised Art. 187
Ex-ante Impact Assessment for partnership	0	0	+++	+++
Preparation of EC proposal and negotiation	0	0	+++	+++
Running costs (Annual cycle of implementation)				
Annual Work Programme (AWP) preparation	0	+	+	+
Call and project implementation	0	+	+	+
Cost to applicants	0	0	0	0
Partners costs not covered by the above	0	+	+	+
Additional EC costs (e.g. supervision)	0	+	+	++
Winding down costs				
EC	0	0	0	+++
Partners	0	+	+	+

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

The scores related to the costs set out above will allow for a “value for money” analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4. For this purpose, in Table 13 where we provide the scores for the scorecard analysis, based on our insights and findings and based on the scores above, we assign a score 1 to the option with the highest costs and a score 3 to the lowest.

Table 13: Matrix on ‘overall costs’ and ‘cost-efficiency’

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

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

We considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when we take into account financial leverage (co-financing rates) and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline Option 0 and the Co-

Programmed (Option 1) policy options – and the least cost-efficient – the Institutionalised Partnership options. We have therefore assigned a score of 3 to the Option 0 and the Co-Programmed policy options for cost-efficiency and a score of 2 for the Institutionalised Partnership policy options.

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

One particular issue raised by representatives of participating states in regard to the financial management of EDCTP and its efficiency is the perceived ‘freeriding’ the partnership has allowed. It was pointed out that the current arrangement under EDCTP (as in all Horizon 2020 funding calls) allows institutions from non-Participating States to participate in all funding calls and activities in equal measure as institutions from the Participating States. This is seen as a disincentive for participation for some countries as they are able to benefit from the partnership without having to commit to it. To promote the willingness of countries to participate in the Partnership, it is thus proposed to limit access to certain activities or calls to partners only. This issue is specific to the partnership approach and does not apply in the case of the baseline option.

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

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

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

##### 6.4.1 Comparative assessment

#### **Effectiveness**

As explained in the preceding paragraphs of this section, for the candidate EU-Africa Global Health Partnership, the institutionalised partnership option is expected to outperform the baseline option on nearly all impact areas relating to effectiveness due to its increased ability to focus on clinical research that requires large-scale and sustained funding commitments, as well as its greater potential for aligning research and innovation efforts. The co-programmed option is likewise expected to exceed the baseline option in the ability to achieve impacts in nearly all areas but is expected to have more limited reach than any form of institutionalised partnership. These relative performances are reflected in the below presented scorecard.

Whereas there are important considerations in the choice between an Art. 185 or an Art. 187 institutionalised partnership, the inherent differences between the two forms are expected to have a comparatively smaller bearing on the partnership’s inherent ability to achieve impact than the choice for or against an institutionalised partnership. The question rather is one of stability and long-term sustainability of the partnership and the necessity to reach sufficient funding levels. As the consequences of the choice between these two forms of institutionalised partnership on the readiness of partners to commit, both financially and politically, are not yet known – and cannot easily be determined a priori – these two options have been scored similarly, even though in reality one may outperform the other.



## Coherence

The greatest level of coherence can be obtained when the partnership can be managed by a dedicated implementation structure. Both forms of institutionalised partnership offer this ability, but the Art. 185 form has the added advantage of being able to build upon the experience gained under EDCTP and the relations built with other important initiatives, at the EC level as well as internationally and with national-level stakeholders. This form would thus allow for least disruption of operations and maximum synergies.

By comparison, the co-programmed partnership has a much lesser ability to actively work together with other stakeholders on identifying common areas of interest and working to align activities, as and when appropriate. The baseline option scores lowest as, in the absence of any dedicated management structure, there are very few possibilities for aligning parties or engage in joint strategic programming.

These relative performances are reflected in the below presented scorecard.

Table 14: Scorecard of the policy options

	Criteria	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: IP Art. 185	Option 3: IP Art. 187
Effectiveness	<b>Scientific impacts</b> <ul style="list-style-type: none"> <li>Reduced burden of CDs in SSA</li> <li>Strengthened EU excellence in clinical research for CDs</li> <li>Improved generation of CD knowledge relevant for SSA</li> <li>Increased scientific leadership of SSA in CD research</li> </ul>	1	2	3	3
	<b>Economic/technological impacts</b> <ul style="list-style-type: none"> <li>Increased economic activity from production, distribution and sales of health technologies for CDs</li> <li>Increased EU-Africa trade and sustainable investments</li> <li>Reduced poverty associated with CDs in SSA</li> <li>Reduced economic risk from spread of (re)emerging CDs globally</li> <li>Increased employment of CD researchers in SSA</li> <li>Increased spending on CD research in SSA</li> <li>Improved efficiency of CD research resources</li> </ul>	1	2	3	3
	<b>Societal impacts</b> <ul style="list-style-type: none"> <li>Improved access to health technologies for CDs in SSA</li> <li>Reduced morbidity and mortality from CDs in SSA</li> <li>Reduced risk of antimicrobial resistance in SSA and globally</li> <li>Reduced risks from (re)emerging CDs in SSA and globally</li> <li>Increased chances at full and productive employment for researchers in SSA, retention of scientific talent</li> <li>Increased capacity of research institutions in SSA to design, conduct and manage CD research projects and to attract funding</li> <li>Increased focus on unmet medical needs from CDs in SSA</li> </ul>	1	1	2	2

	Criteria	Option 0: Horizon Europe calls	Option 1: Co-programmed	Option 3: IP Art. 185	Option 3: IP Art. 187
	<ul style="list-style-type: none"> <li>Increased waste from manufacturing of health technologies</li> </ul>				
Coherence	Internal coherence	1	2	3	3
	External coherence	1	2	3	3
Efficiency	Overall cost	3	2	1	1
	Cost-efficiency	3	3	2	2

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

#### 6.4.2 Identification of the preferred option

The scorecard in Table 14 shows that the baseline performs less well against all dimensions and criteria compared to Option 1 (Co-programmed) and Option 3 (Institutionalised Partnership). Even though it reached a higher score against the efficiency criteria, we considered that this does not weigh up against its lower performance against the dimensions of effectiveness and coherence.

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

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

The scorecard analysis, however, does not allow us to easily distinguish between the Art. 185 and Art. 187 options. Here, the assessment rests to a large extent on predictions about the ability and willingness of parties to commit themselves. Key considerations are the anticipated stability and financial sustainability of the partnership, which are not explicitly assessed in the scorecard other than in how these expectations translate into likely impacts. The determination of the 'preferred option' is thus made primarily on the basis of such expectations and stated preferences by stakeholders.

The conclusion of our assessment is that the Institutionalised Partnership is the preferred option, showing a higher level of cost-effectiveness than the other options and that within this option the Art. 187 should prevail in light of the need to strengthen the partnership through increased participation.

## 7 The preferred option – Description of the implementation and monitoring system

### 7.1 Description of the preferred option

Based on the comprehensive analysis of all 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. The institutionalised partnership option is most likely to be able to deliver on the targeted impacts and offers the greatest potential for alignment of partners around shared strategic objectives. The partnership will have a relatively unique position within the EU research and innovation landscape, as the only initiative to support large-scale clinical research.

The EU-Africa Global Health Partnership should maintain many of the elements that allowed EDCTP to be successful. First, it should keep a clearly defined focus on funding clinical research on infectious diseases affecting sub-Saharan Africa, supporting research capacity strengthening in the region, and supporting knowledge sharing needed for effective disease responses. Second, it should continue to work closely with a broad range of stakeholders, in particular with those from sub-Saharan Africa. Third, it should actively seek out and promote collaboration with other key actors in the field.

A key question looming over the preferred option is whether the institutionalised partnership should take the form of an Article 185 partnership or an Article 187 partnership. Each option has its benefits and risks. Based on the need for long-term financial sustainability and stability, we have determined Art.187 to be the preferred option. However, questions remain about the exact set-up of the partnership under this arrangement, in particular about how it will allow interested parties to contribute. Given the unique nature of this initiative in the landscape of European partnerships, due to its focus on Africa, special accommodations may be needed to ensure that African countries can continue to play an active and meaningful role in the partnership that is not contingent on their ability to financially contribute (for instance, by waiving membership fees).

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

Table 15: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
<b>Higher level of effectiveness</b>	As an Institutionalised Partnership, the EU-Africa Global Health Partnership is expected to be able to generate scientific, economic/technological, and societal impacts on a scale that is highly unlikely to be achieved through Traditional Calls under Horizon Europe. A partnership approach is needed to generate and pool the level of resources needed to support the kind of clinical research the partnership is focused on.
<b>Coherence and synergies</b>	The EU-Africa Global Health Partnership will fulfil a unique position with the EU research and innovation landscape. Coherence and synergies can be achieved by maintaining a clear focus on infectious diseases affecting sub-Saharan Africa.
<b>Transparency and openness</b>	The Partnership will promote principles of research fairness and transparency and will be open to participation to a wide range of stakeholders, including third parties. The partnership should be sufficiently open also to African countries with limited ability to contribute financially. It is as yet unclear how the design of the partnership will enable this.

Criterion	Alignment of the preferred option
<b>Additionality and directionality</b>	The matching of contributions of partners from the EC budget is hoped to leverage additional resources from national research funders, as well as third parties. The success of the partnership in terms of the additionality and directionality it can achieve will depend on the willingness of partners to either contribute financially rather than in-kind or to better align their in-kind contributions around a common strategic vision. It remains unclear what the willingness of potential partners is to do so.



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 legal 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).

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. Among interviewees, 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. Nearly all deem this relevant (17 out of 47) or even very relevant (25 out of 47). Parties that are considered to be relevant for pooling and leveraging resources include in particular Member States, Associated Countries and African countries (considered 'somewhat relevant' to 'very relevant' by all respondents). Most respondents also agree on the need to include industry, academia, foundations and NGOs in the partnership, although small numbers of respondents express 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. They also noticed that even countries that are not part of the EDCTP Association have been able to participate in all EDCTP-supported activities, meaning there has been limited incentive for formal commitment and alignment of activities. They question what can be done to increase the leveraging effect for the Candidate Initiative. Some have suggested that certain activities should be accessible to active participants in the partnership.

## 7.2 Objectives and corresponding monitoring indicators

### 7.2.1 Operational objectives

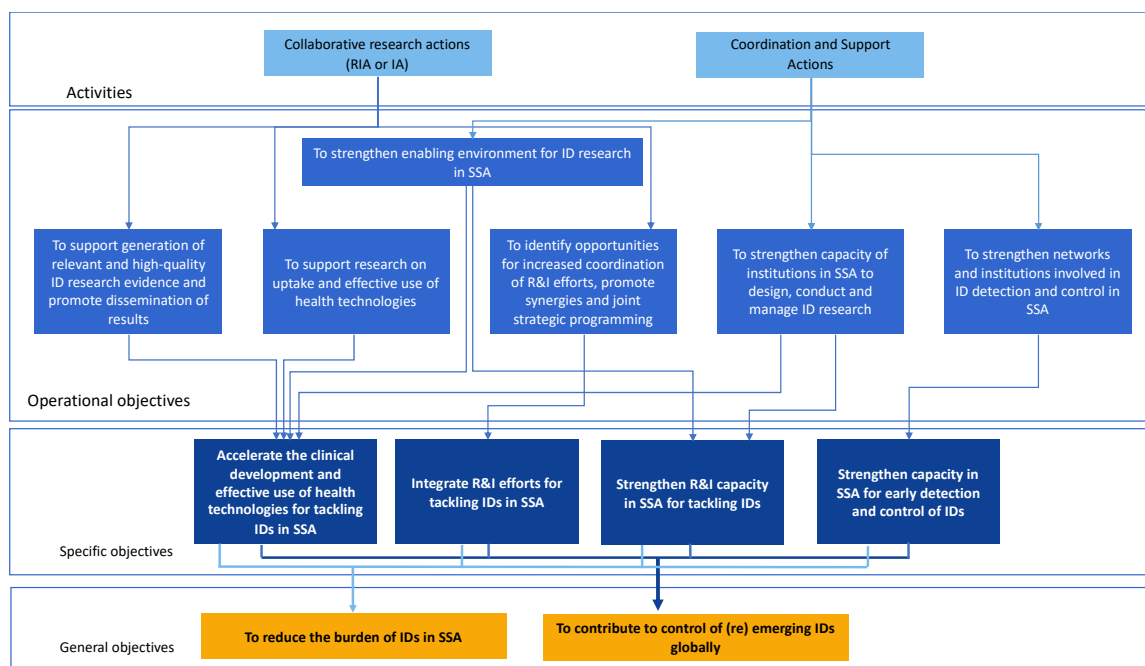
Figure 7, below, lists a range of actions and activities, going also beyond the R&I activities that can be implemented under Horizon Europe (highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners “commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake.”

Based on the identified general and specific objectives, a set of 6 operational objectives has been developed for the initiative that provide more concrete input for how the general objectives can be attained. Summarised in Figure 7, below, these are:

- To support the generation of relevant and high-quality infectious disease research evidence and promote dissemination of research results
- To support research on the uptake and effective use of health technologies
- To identify opportunities for increased coordination of research and innovation efforts, promote synergies and joint strategic programming
- To strengthen the capacity of institutions in SSA to design, conduct and manage infectious disease research
- To strengthen an enabling environment for infectious disease research in SSA
- To strengthen networks and institutions involved in infectious disease detection and control in SSA

To meet their operational objectives, European Partnerships can draw from a range of actions and activities, 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.” In the specific context of the EU-Africa Global Health Partnership, the main types of action foreseen are “Research and Innovation Actions” (RIAs) and “Coordination and Support Actions”. Alongside these actions, external action in the form of technical support to agencies and institutes involved in disease detection and control would be required.

Figure 7: Operational objectives of the initiative



### 7.2.2 Monitoring indicators

Key monitoring indicators have been identified that would enable tracking progress of the initiative towards its targeted impacts, in addition to the ones identified for the Horizon Europe key impact pathways (Table 16). Where applicable, the targeted impact indicators for Horizon Europe have been reformulated to be more partnership specific.

Table 16: 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+)
<b>Scientific impacts</b>			
Key Pathway 1. Creating high-quality new knowledge	Nr of peer-reviewed publications	Field-Weighted Citation Index of peer-reviewed publications	Number and share of peer-reviewed publications from projects that are core contribution to scientific fields
Key Pathway 2. Strengthening human capital in R&I	Number of researchers involved in upskilling (training, mentoring/coaching, mobility and access to R&I infrastructures) activities in projects	Number and share of upskilled FP researchers with increased individual impact in their R&I field	Number and share of upskilled researchers with improved working conditions, including researchers' salaries
Key Pathway 3. Fostering diffusion of knowledge and Open Science	Share of research outputs (open data/publication/ software etc) shared through open knowledge infrastructures	Share of open access research outputs actively used/cited	Share of beneficiaries having developed new transdisciplinary/ trans-sectoral collaborations with users of their open R&I outputs

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Share of research activities initiated that adhere to the principles of research fairness	Share of research outputs generated by activities that adhere to the principles of research fairness	Share of beneficiaries having developed new collaborations with others on the basis of the principles of research fairness
<b>Societal impact (environmental &amp; social)</b>			
Key Pathway 4. Addressing EU priorities & global challenges through R&I	Number and share of outputs aimed at addressing the SDGs	Number and share of innovations and scientific results addressing the SDGs	Aggregated estimated effects from the use of project results on tackling the SDGs
Key Pathway 6. Strengthening the uptake of innovation in society	Number of SSA countries in which health technologies developed through supported activities are authorised	Number of SSA countries in which health technologies developed through supported activities are being used	Number of SSA countries in which there is full access to, and uptake of health technologies developed through supported activities
<b>Economic / Technological impact</b>			
Key Pathway 7. Creating more & better jobs	Number of FTE research jobs created, and research jobs maintained in beneficiary entities for the supported project (by type of job)	Increase of FTE research jobs in beneficiary entities following supported project (by type of job)	Number of direct & indirect research jobs created or maintained in SSA (by type of job)
Key Pathway 9. Leveraging investment in R&I	Amount of public & private investment mobilised with the initial investment	Amount of public & private investment mobilised to exploit or scale-up project results	Global progress against international targets for official development assistance



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## **Appendix B Synopsis report on the stakeholder consultation – Focus on the candidate European Partnership for EU-AFRICA Global Health**

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

### **B.1 Introduction**

Following the European Commission's proposal for Horizon Europe in June 2018,<sup>109</sup> 12 candidates for institutionalised partnerships within 8 partnership areas have been proposed, based on the political agreement with the European Parliament and Council on Horizon Europe reached in April 2019.<sup>110</sup> Whether these proposed institutionalised partnerships will go ahead in this form under the next research and innovation programme is subject to an impact assessment.

In line with the Better Regulation Guidelines,<sup>111</sup> the stakeholders were widely consulted as part of the impact assessment process, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019,<sup>112</sup> gathering 350 replies for all 12 initiatives;
- A structured consultation of Member States performed by the EC services over 2019;
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A total of 608 Interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

This document is the synopsis report for the initiative "EU-Africa Global Health". It provides an overview of the responses to the different consultation activities. A full analysis of the results is provided in the study Data Report.

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<sup>109</sup> [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_18\\_4041](https://ec.europa.eu/commission/presscorner/detail/en/IP_18_4041)

<sup>110</sup> [https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT\\_19\\_2163](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_19_2163)

<sup>111</sup> [https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation\\_en](https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en)

<sup>112</sup> The full list of inception impact assessments is available here. They were open for public feedback until 27 August 2019.

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

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

For the initiative “EU-Africa Global Health” 34 individual feedback responses were collected, mainly from academic/research institutions, non-governmental organisations, EU and non-EU citizens, industry associations, and public authorities.<sup>113</sup> Among the elements mentioned were:

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

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<sup>113</sup> Feedback on inception impact assessment to be found on [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972489\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972489_en)

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

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

#### *B.3.1 Key messages overall for all candidate Institutionalised Partnerships*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

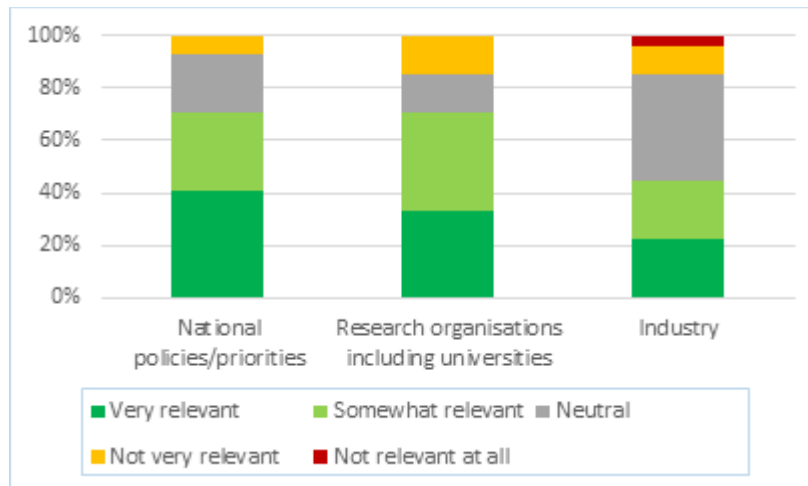
The feedback provided by 30 countries (all Member States, Iceland and Norway) has been analysed and summarised in a report, with critical issues being discussed at the Shadow Strategic Programme Committee meetings.

#### *B.3.2 Overall feedback for the initiative "EU-Africa Global Health"*

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

Overall the results of the Member State consultation confirm the relevance of the proposed EU-Africa partnership on health security to tackle infectious diseases, with 69% considering it relevant for national policies and priorities, and 70% for their research organisations, including universities. The proposed partnerships is considered less relevant for industry by most countries (46% relevant), see Figure 8.

Figure 8: Relevance of the EU-Africa partnership on health security to tackle infectious diseases in the national context



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

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

- The zoonotic origin of many tropical diseases should be strongly re-enforced and studies on vectors of tropical diseases included;
- Better definition of the role of AMR, also in relation to other partnerships candidates;
- Extension to investigating health behaviour. The fight against infectious diseases in Africa is more effective when it is approached systematically, not only from the clinical perspective;
- Increase the scope of infectious diseases covered, and geographical coverage (e.g. Latin America);
- Include major threats in terms of global burden such as diarrheal, respiratory diseases and meningitis as major causes of death for children under 5, or vector-borne diseases;
- Better alignment with policies in relation to sexual reproductive health and rights. Also, a clear gender analysis and approach;
- Increased efforts for engagement of more partners from the parts of Africa that have weak research culture (areas of greatest impact);
- Better involvement of countries that are not contributing with funding;

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

While most are undecided concerning their participation, many countries (74%) expressed interest in having access to results produced in the context of the partnership.



## Feedback on objectives and impacts

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

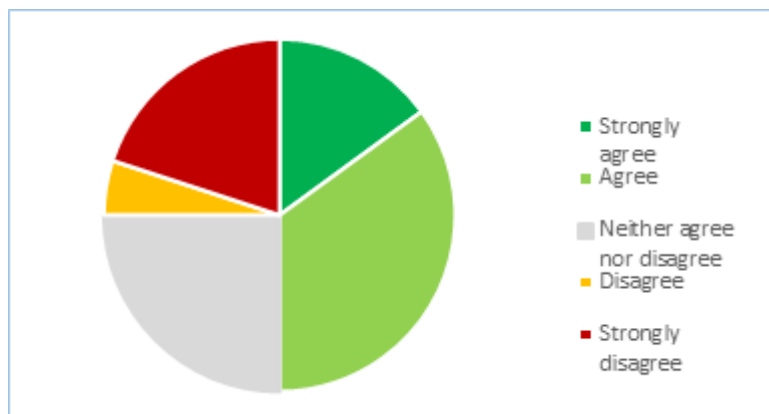
Countries indicate good agreement with the proposed objectives at short, medium and long term (84%) and the expected scientific, economic and societal impacts at European level (88%), with the remaining ones remaining neutral. Slightly less (72%) consider the impacts relevant in the national context.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

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

## Views on partners, contributions and implementation

There is no clear view between countries on the type and composition of partners (Figure 9), yet few comments (e.g. doubts on the inclusion of industry or foundations) are made that further elaborate their assessment.

Figure 9: Agreement on the types and composition of partners for the EU-Africa partnership on health security



At this stage most countries (68%) would need more information on contributions and level of commitments expected from partners, while 24% agree with the proposal.

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

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

#### ***B.4 Targeted consultation of stakeholders related to the initiative "EU-Africa Global Health"***

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

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

The objective of the interviews was to collect stakeholder insights on:

- The functionalities of the initiative required to attain the objectives
- The likely commitment of stakeholders along the value chain and Member States to the initiative
- The budgetary costs of the current partnership and the envisaged costs of the eventual future one
- The current leveraged R&D investment from the stakeholders
- The likely significant impacts and differentiators to take into account the options assessment

Potential interviewees were identified by the study team, who have expert knowledge of the global health area in EU and beyond. The study team prepared a core and secondary list of potential interviewees. The secondary list consisted of substitute names that could be contacted in case stakeholders from the core list were unavailable. The prevailing principle was to substitute stakeholders as much as possible with those from the same stakeholder category, or whom were reasonably deemed to represent similar perspectives.

Both the core and the secondary lists of stakeholders were reviewed by the members of our expert panel, as well as by the executive director of EDCTP. Their inputs were considered in the final selection, though the study team retained full independent control over the selection. The selection criteria were:

- Those involved directly in the functioning of EDCTP either through being a member of the Secretariat, Scientific Advisory Committee (SAC) or General Assembly (GA)
- Existing strategic partners of ECTP and potential partners of the candidate initiative
- Staff of various EC bodies directly involved in the functioning of EDCTP or in the global health R&I in the EU
- Experts in global health area, either involved or removed from EDCTP
- Academics and other researchers involved in EDCTP-funded research activities

The list of stakeholders was discussed with the members of the Project Steering Group on 13 September 2019. Based on their feedback, minor changes were made. Further suggestions were considered on an iterative basis, depending on the availability of identified core interviewees during the study period and on whether specific issues emerged that required further follow-up with interviewees not on the core list. Overall, the Project Steering Group (PSG) members approved of the list and gave their agreement to begin scheduling and conducting the interviews.

The core list of interviewees was first invited for interviews on 4th October, with reminders sent on 15th and 22nd October. The secondary interviewees were contacted on the 22nd October, with reminders sent on 30th October. Additionally, several interviewees were identified through snowballing technique and were contacted in the first half on November.

The interview master guide consisted of the questions presented in Table 17 below.

Table 17: Interview master guide

Domain	Question / issue	Interviewees
<b>A. Objectives</b>	<ul style="list-style-type: none"> <li>• What strategic and specific objectives would stakeholders expect to see for the partnership?</li> <li>• Should this include a broader focus on health security and, if so, why and how?</li> </ul>	All
<b>B. Scope</b>	<p>The scope of activities stakeholders would expect to see for the partnership. This includes:</p> <ul style="list-style-type: none"> <li>• Geographic scope of activities: should the partnership also support activities outside of Europe and sub-Saharan Africa?</li> <li>• Disease focus: should the partnership also support R&amp;D for non-communicable diseases or include a broader set of infectious diseases?</li> <li>• Scientific and technological focus: <ul style="list-style-type: none"> <li>▪ Should the partnership also support research and capacity development activities focused on health system strengthening?</li> <li>▪ Should it include support for non-medicinal treatments and interventions (e.g. vector control)?</li> <li>▪ What stages of (pre-)clinical development should the partnership support?</li> </ul> </li> <li>• Types of activities: how should the partnership balance different types of activities (e.g. supporting clinical trials, career development programmes, trial capacity development, new activities)?</li> </ul>	All
<b>C. Type of partnership / initiative</b>	<ul style="list-style-type: none"> <li>• Is there a need for a partnership approach to achieve the objectives of the candidate partnership?</li> <li>• What are the potential advantages and disadvantages of a partnership approach over other forms of intervention or EU funding instruments (considering all options)?</li> </ul>	All
<b>D. Partner engagement</b>	<ul style="list-style-type: none"> <li>• What are the expected consequences of different forms of partnership on the willingness of current Participating States to be involved?</li> <li>• What were the main reasons for former Participating States to leave the EDCTP partnership? Could and should these reasons be addressed by the candidate partnership and, if so, how?</li> <li>• What expectations do current and potential future partners hold in return for their potential participation in the candidate partnership?</li> <li>• How do current and potential future partners view the potential inclusion of partners from the private sector? What are the main benefits and risks? How could risks be mitigated?</li> </ul>	<p>Current EDCTP participating states and partners;</p> <p>Former EDCTP participating states;</p> <p>Potential future participants, including industry and foundations</p>
<b>E. Governance</b>	<ul style="list-style-type: none"> <li>• What are the main factors to consider in deciding on the governance structure and membership for the candidate partnership, in case of an institutionalised partnership?</li> <li>• What role should be given, if any, to private sector partners in the governance of the candidate partnership?</li> </ul>	<p>All, in particular:</p> <p>Current EDCTP participating states and partners;</p>

Domain	Question / issue	Interviewees
		Former EDCTP participating states; Potential future participants, including industry and foundations
<b>F. Coherence</b>	<ul style="list-style-type: none"> <li>• What are the main ongoing and potential future initiatives (including other European Partnerships in the health area, as well as with other international initiatives) with which the candidate partnership may share objectives?</li> <li>• How best can synergies be created and duplication be avoided with these initiatives?</li> </ul>	All, in particular representatives of the EU and of other EU and international initiatives
<b>G. Funding and sustainability</b>	<ul style="list-style-type: none"> <li>• What are the likely resources needed to achieve the objectives of the candidate partnership?</li> <li>• How can and should these resources be mobilised?</li> <li>• What will be the possible and likely consequences of a potential no-deal 'Brexit' for the candidate partnership and how could these be addressed best?</li> <li>• For how long would a partnership approach, if preferred, continue to be needed to achieve these objectives?</li> </ul>	EU; Current EDCTP participating states and partners; Former EDCTP participating states; Potential future participants
<b>H. Measuring impact</b>	<ul style="list-style-type: none"> <li>• What indicators could and should be used to measure the progress of the candidate partnership towards its objectives?</li> </ul>	EU; Current EDCTP participating states and partners; Former EDCTP participating states; Potential future participants

Whilst the majority of questions were applicable to all or most stakeholder groups, it was recognised that different types of stakeholders have different degrees of insight into each of the topics. Therefore, we developed four separate semi-structured interview guides for different groups of stakeholders, prioritising certain questions over others to make sure that each interview yielded as much usable information as possible.

All interview candidates were emailed individually with a request for an interview along with a briefing document containing background information, the questionnaire and a letter of support from the Commission. Interviews were arranged with those that responded. Where logical, joint interviews with representatives of same or related organisations were arranged instead of individual interviews. The majority of interviews were conducted by telephone or online conferencing. A small number of interviews was conducted face-to-face, with attendants of the meeting of the General Assembly of EDCTP.

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

The number of interviews with representatives in each stakeholder category, along with their percentage share is shown in Table 18. We note, however, that within the category “country representatives to the EDCTP GA”, a number of interviewed (European and African) representatives are affiliated with research institutions. Thus, the number of interviewed academics exceeds the number of interviews shown in the category ‘academia’. Furthermore, a number of interviews were performed as group interviews with two or more participants. In total, 44 individuals participated in the interviews.

Table 18: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
EDCTP Secretariat and SAC	7	18.9%
Country representatives to the EDCTP GA	9	24.3%
European Commission (EC) and related bodies	6	16.2%
Academia	3	8.1%
Product Development Partnerships (PDPs)	3	8.1%
Charitable foundations	2	5.4%
Industry	3	8.1%
International organisations	2	5.4%
Other	2	5.4%
<b>TOTAL</b>	<b>37</b>	<b>100%</b>

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

#### Political and legal context

Although no interview questions directly cover issues of political and legal context directly, interviewees were vocal in expressing their views on the subject.

Interviewees discussed areas where Africa has achieved substantial progress, such as scale up of e-health technologies, and overall digitalisation of the continent. These are discussed as potential enablers for more progress in the context of the Candidate Initiative and research and innovation efforts in general. However, respondents state that, although some progress has been achieved in the areas of tackling infectious diseases, much still needs to be done, particularly in development of new technologies and research capacity in Africa. Interviewees also stress that apart from the lack of technologies, sub-Saharan Africa is also lacking access to technologies that may have already been developed, therefore cost considerations are important.

Issues of emerging infectious diseases, climate change, and antimicrobial resistance were highlighted as external factors that may shape future policy priorities for global health.

Some interviewees suggest that the funding for poverty-related infectious diseases is decreasing in the EU, due to a shift in policy priorities and that pharmaceutical companies also continue to show low investment interest in this disease area.

## **Problem definition and drivers**

### **What are the problems?**

Interviewees across all categories agree that the burden of infectious disease is still high in Sub-Saharan Africa. A number of stakeholders (those of the EDCTP Secretariat, EC, PDPs, industry, and other) highlight that emerging diseases also constitute a problem that needs to be addressed by the initiative.

Lack of accessible and affordable technologies is discussed as a driver for this burden. Limited commercial interest in the area of infectious diseases is also highlighted by representatives of the EC and PDPs. Interviewees from all stakeholder categories stress that there remains a large unmet need for effective, affordable and safe treatments, vaccines and diagnostic tools to combat infectious diseases.

The large majority of stakeholders (across all categories) believe that limited capacity of African countries to conduct clinical research for disease affecting the continent is a major problem driver.

### **Why should EU act?**

Interviewees unanimously agree that there is a strong need for the EU to address the identified problems. Many stakeholders (across all stakeholder groups) believe that the Candidate Initiative is uniquely positioned to address the needs of infectious diseases research in collaboration with Africa and is therefore valuable in the context of Horizon Europe and beyond it.

Many stakeholders (from EDCTP, country representatives, PDPs, academia, international organisations) stress the added value the initiative brings to African countries in terms of strengthened research capacity and infrastructure. Moreover, interviewees (EDCTP Secretariat and SAC, academia, other) emphasise that the partnership format is effective in promoting long-term commitments from all partners, including African countries.

Since the costs of conducting late-stage clinical trials can be extremely high, many interviewees (EDCTP and SAC, country representatives, EC, academia, PDPs ) state that the Candidate Initiative would be essential to achieve a critical mass in terms of funding, as the expected costs are beyond the capacities of national funders..

Many interviewees (EDCTP and SAC, EC, academia,) also state that the Candidate Initiative could enhance coherence between national research programmes funded by EU Member States. Furthermore, some stakeholders (academia, other) believe that the large financial contributions made into EDCTP could be (partially) lost if no successor initiative is in place.

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

## **Objectives: What is to be achieved?**

### **General objectives**

Across all stakeholder groups, interviewees strongly favour a clear focus on diseases affecting sub-Saharan Africa, in particular on infectious diseases. It is viewed that there is still much to be done in this area and that it will be crucial to sustain and continue the

progress made to date. Several interviewees – including representatives of the EC, charitable foundations, and industry – have also highlighted the rise of non-communicable diseases in Africa with a limited number arguing in favour of inclusion of NCDs in the scope of the Candidate Initiative. However, numerous interviewees have indicated that a broadening of the scope of the Candidate Initiative, compared to that of EDCTP2, would necessitate a concomitant increase in funding. Also, industry has shown far greater commitment to development of health technologies for NCDs than for infectious diseases. They therefore indicate that the Candidate Initiative should include NCDs only in relation to tackling infectious diseases.

Interviewees widely agree that the primary focus of the Candidate Initiative should be on Sub-Saharan Africa. Nonetheless, some interviewees – in particular those working on emerging infectious diseases and diseases with a high prevalence in other parts of the world – have underscored that the problems the Candidate Initiative should be addressing are not exclusive to this region. These interviewees have thus suggested that the Candidate Initiative also allows for supporting some research and support activities in other regions and collaborates with other relevant initiatives.

### **Specific objectives**

All interviewees were familiar with the type of activities that were supported under EDCTP and have expressed that the Candidate Initiative should support a similarly wide range of activities. Both the research and innovation actions and the coordination and support actions are viewed as essential components, with the second type supporting the first. Across all stakeholder categories, interviewees indicate that support for the development of new or improved health technologies to tackle infectious diseases should be at the heart of the Candidate Initiative. Furthermore, several interviewees – including EDCTP staff, representatives of PDPs and academics – have expressed a desire for the Candidate Initiative to increase support for implementation research, aimed at improving uptake and effective use of existing health technologies. They point out that development of new health technologies is insufficient, if these are then not used properly.

A limited number of interviewees – in particular those working at a more overarching global health policy level – have underscored the need for the Candidate Initiative to promote and support integration of research efforts in the field of infectious diseases. A broader set of interviewees recognises the role that EDCTP has played in convening stakeholders across the world and express hope that the Candidate Initiative will fulfil a similar role.

Under EDCTP, numerous activities have been supported that were aimed at developing and strengthening the clinical research capacity in Sub-Saharan Africa. Interviewees are appreciative of this and indicate that sustained support for capacity strengthening would be needed under the Candidate Initiative. At the same time, several interviewees indicate that in various Sub-Saharan African countries already substantial capacity has been developed and that the Candidate Initiative should now focus attention on areas where this is most needed still, and on capitalising effectively on capacity already built through South-South networking and cooperation.

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

## Targeted impacts

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

Across stakeholder groups, interviewees anticipate that any new technologies developed could have important societal impacts, by reducing the burden of infectious diseases in the African region. This is universally viewed as the ultimate goal of the Candidate Initiative. At the same time, most interviewees have realistic expectations about the potential for the Candidate Initiative to deliver such societal impacts, recognising both the significant challenges associated with health technology development, and the broader socio-economic context of the African continent.

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

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

## Functionalities

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

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

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

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



## Comparative assessment of policy options and preferred option

### Effectiveness

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

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

### Coherence

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

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

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

### Efficiency

Few interviewees expressed any views on the comparative efficiency of the different policy options, as many lack the detailed understanding of the options to be able to comment on this meaningfully. Representatives of the EC, both in interviews and during meetings of the PSG, have expressed concerns that any change compared to the Art. 185 partnership that has been in place for EDCTP will result in loss of momentum and expertise. The main reason for this view is the fact that under any other arrangement, the current EDCTP Secretariat will effectively cease to exist. This is expected to result in important knowledge being lost, which cannot easily be found within the current EC services, and the breakdown of relationships that have been built with stakeholders and partners. Similar concerns have been voiced by members of the EDCTP Secretariat themselves.

## ***B.5 Open public consultation on the Candidate institutionalised European Partnerships***

### *B.5.1 Approach to the open public consultation*

The consultation was open to everyone via the EU Survey online system.<sup>114</sup> The survey contained two main parts and an introductory identification section. The two main parts collected responses on general issues related to European partnerships (in Part 1) and specific responses related to 1 or more of the 12 candidate initiatives (as selected by a participant).

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

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

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

The keyword graphs in the following sections have been built based on the relationships between words in the open responses of the survey participants. It features words that appear in the same answer either one after the other or with a maximum distance of two words between them. Each keyword is represented as a node and each co-occurrence of a pair of words is represented as a link. The size of the nodes and the thickness of the links vary according to the number of times that keywords are mentioned and their co-occurrence, respectively. In order to facilitate the visualisation of the network, the keyword graphs have been filtered to show the 50 most common co-occurrences. Although the keywords do not aim to substitute a qualitative analysis, they assist the identification of the most important topics covered in the answers and their most important connections with other topics, for later inspection in the set of raw qualitative answers.

### *B.5.2 Overview of respondents to the open public consultation*

#### **Profile of respondents**

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided

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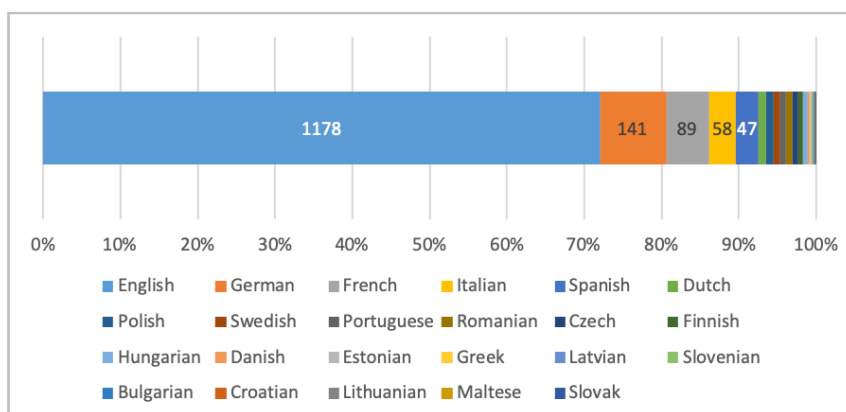
<sup>114</sup> <https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope>

coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not analysed separately from the general analysis.

Among the 1635 respondents, 1178 (72.05%) completed the online consultation in English, 141 (8.62%) in German, 89 (5.44%) in French, 58 (3.55%) in Italian and 47 (2.87%) in Spanish, see Figure 10. Respondents that belong to the 11 campaigns follow the same pattern of language distribution, with English being the dominant language of respondents in that group. Table 19 shows that over 50% of respondents come from 4 Western and Southern European countries – Germany, Italy, France and Spain. Overall, the number of respondents from Eastern and Northern Europe is lower, while among non-EU countries the greater number of respondents come from Switzerland, Norway and Turkey, which are countries associated to the Framework Programme. In the group of respondents labelled as campaigns, most respondents are from Germany (48 respondents or 17.65%), France (39 respondents or 14.34%), Italy (37 respondents or 13.6%), Belgium (23 respondents or 8.46%), the Netherlands (21 respondents or 7.72%) and Spain (17 respondents or 6.25%). Hence, a similar pattern of country of origin is observed in the entire sample of respondents and for the campaigns.

Across all respondents 40.80% indicated to answer to the open public consultation in a public way (non-anonymous) and 20.67% of all respondents indicated their Transparency Register number.

Figure 10: Language of the consultation (N=1635)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

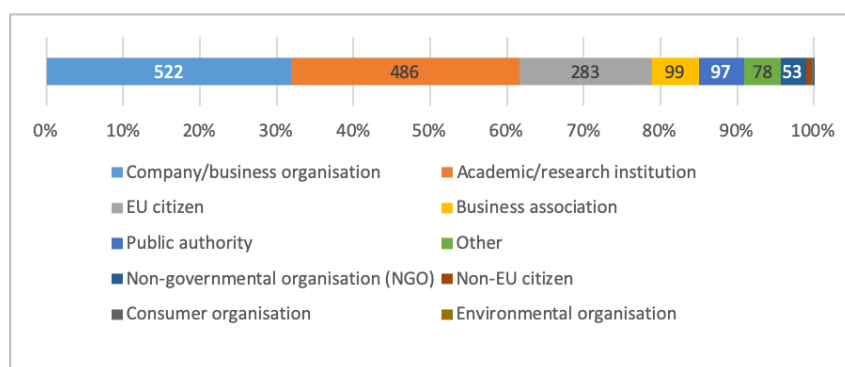
Table 19: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%

Country	Number of respondents	Percentage of respondents
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

According to Figure 11, the three biggest groups of respondents are companies and business organisations (522 respondents or 31.93%), academic and research institutions (486 respondents or 29.72%) and EU citizens (283 respondents or 17.31%). Business associations, representing multiple businesses, were the fourth largest responding group (99 respondents or 6.05%), no other types of associations were presented amongst the selectable options for respondents. Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely companies and business organisations (121 respondents or 44.49%), academic and research institutions (54 respondents or 19.85%) and EU citizens (42 respondents or 15.44%).

Figure 11: Type of respondents (N=1635)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

Respondents were asked to indicate the organisational size of the companies, organisations and institutions they work for. Based on Table 20, a greater number of respondents work in large companies and business organisations (295 respondents out of 522 or 56.51%) and large academic and research institutions (348 respondents out of 486 or 71.60%). A greater number of respondents that are employed by business associations and NGOs indicated an organisation size of 1 to 9 employees. Among the group of respondents that are marked as campaigns, a greater number of respondents work in large companies and business organisations (82 respondents out of 121 or 67.77%) and academic and research institutions (39 out of 54 respondents or 72.22%).

Table 20: Size of organisations that represent consultation respondents (N=1635)

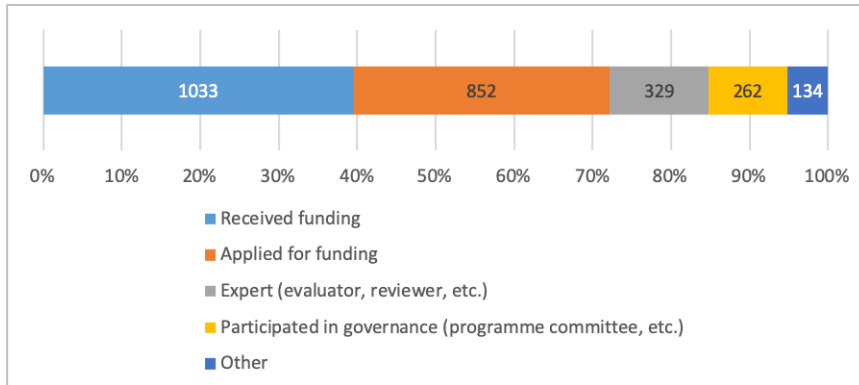
Type of respondents' organisations	Organisation size			
	Large (250 employees or more)	Medium (50 to 249 employees)	Small (10 to 49 employees)	Micro (1 to 9 employees)
Company/business organisation	295	66	90	71
Academic/research institution	348	95	31	12
Business association	15	6	34	44
Public authority	58	33	6	0
Non-governmental organisation (NGO)	7	9	11	26
Consumer organisation	1	0	2	1
Environmental organisation	0	0	1	0
Trade union	0	0	1	0
Other	24	16	19	19

Among all consultation respondents, 1303 (79.69%) have been involved in the on-going research and innovation framework programme Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon2020 or in the

preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated that they were a beneficiary (1033 respondents or 39.58%) or applicant (852 respondents or 32.64%).

The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents (see distribution in Figure 12). However, a few stakeholder categories have mainly been involved in the capacity of "Received funding" and/or "Applied for funding", this applies to business associations, NGOs and public authorities.

Figure 12: Capacity in which respondents were involved in Horizon 2020 or in the Framework Programme 7 (N=1303)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives

Among those who have been involved in the on-going research and innovation framework programme Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 21, the table also show the key stakeholder categories for each partnership.

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

Table 21: Partnerships in which consultation respondents participated (N=1035)

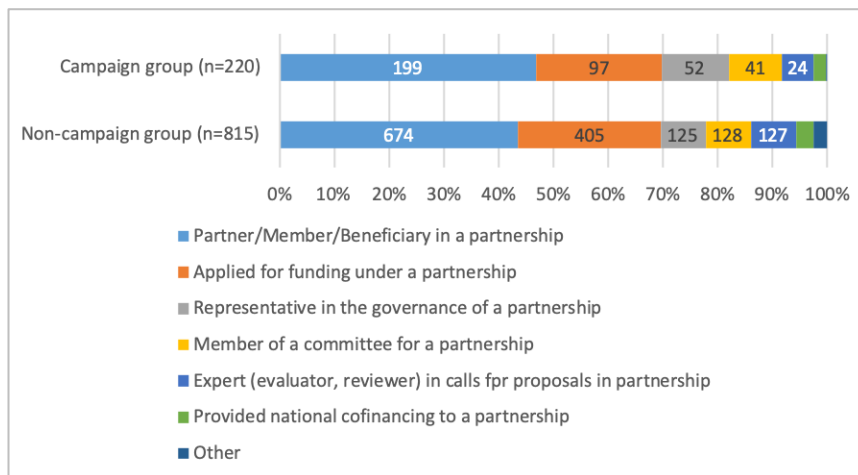
Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
Mediterranean Area (PRIMA)									
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High-Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

When respondents were asked in which role(s) they participate(d) in a partnership(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership (see, Figure 13). The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

The few respondents that selected “Other” as their role were provided with the opportunity to outline their role. A total of 25 people did provided description. The answers provided were very varied and could not be clustered in sub-groups, a few examples are: former communication and stakeholder relationship officer, chair of steering board, system engineer, grant manager, Joint Programming Initiative (JPI), or a role in advocacy of the partnership.

Figure 13: Role of respondents in a partnership (N=1035)



Notes: Non-campaign replies; Aggregation of responses of all candidate initiatives



In the open public consultation respondents could provide their views on each of the candidate Institutionalised European Partnerships, and each respondent could select multiple partnerships to provide their views on. The table below presents the number and percentage of respondents for each partnership. It is visible that the majority of respondents (31.37%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% of all respondents provided their views for the candidate partnerships European Metrology, Clean Aviation and Circular bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 22: Future partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
Clean Hydrogen	506 (31.37%)	382 (28.49%)	123	21		55	74	8	13
European Metrology	265 (16.43%)	225 (16.78%)	112	3	21	11	34	3	28
Clean Aviation	246 (15.25%)	191 (14.24%)	57	5	21	34	54	3	8
Circular bio-based Europe: sustainable Innovation for new local value from waste and biomass	242 (15%)	215 (16.03%)	63	19	36	35	31	7	13
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)	29	14	23	39	31	2	7
Key Digital Technologies	182 (11.28%)	162 (12.08%)	55	13	20	22	35	5	7
Innovative SMEs	111 (6.88%)	110 (8.20%)	19	12	39	4	14	4	10
Innovative Health Initiative	110 (6.82%)	108 (8.05%)	35	6	9	12	16	16	5
Smart Networks and Services	109 (6.76%)	107 (7.98%)	34	9	12	17	21	2	6
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)	25	12	11	19	10	3	9
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)	8	7	4	24	9	2	7

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)	15	2	4	3	12	6	4

### Campaigns per candidate Institutionalised European Partnership

As was mentioned above, 11 campaigns were identified, the largest of them includes 57 respondents. The table below presents the campaigns that replied for each candidate partnership. As presented, the candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few partnerships, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships, therefore, campaign #2 and #6 feature in several partnerships.

Table 23: Overview of campaigns across partnerships

Name of the candidate Institutionalised European partnership	Number of a campaign group (total number of respondents in a campaign)	Number of respondents that provided views about a partnership
Clean Hydrogen	Campaign #1 (57 respondents)	57 respondents
	Campaign #2 (41 respondents)	25 respondents
	Campaign #7 (18 respondents)	18 respondents
	Campaign #9 (14 respondents)	13 respondents
	Campaign #11 (10 respondents)	9 respondents
Clean Aviation	Campaign #2 (41 respondents)	17 respondents
	Campaign #6 (19 respondents)	19 respondents
	Campaign #8 (14 respondents)	13 respondents
Integrated Air Traffic Management	Campaign #2 (41 respondents)	10 respondents

Name of the candidate Institutionalised European partnership	Number of a campaign group (total number of respondents in a campaign)	Number of respondents that provided views about a partnership
	Campaign #6 (19 respondents)	12 respondents
European Metrology	Campaign #3 (36 respondents)	35 respondents
Circular bio-based Europe: sustainable Innovation for new local value from waste and biomass	Campaign #5 (20 respondents)	20 respondents
Transforming Europe's rail system	Campaign #4 (31 respondents)	29 respondents
Key Digital Technologies	Campaign #10 (12 respondents)	12 respondents
Innovative SMEs	-	-
Innovative Health Initiative	-	-
Smart Networks and Services	-	-
Safe and Automated Road Transport	-	-
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	-	-

### B.5.3 Responses to the open public consultation at programme level

The following section of the report presents the analysis of responses at programme level, meaning all respondents (excluding campaigns) were included, independent of which candidate European Partnerships respondents selected to provide their views upon. The results for responses as part of campaigns are presented separately.

#### Characteristics of future candidate European Partnerships

Respondents were asked to assess what areas, objectives, aspects need to be in the focus of the future European Partnerships under Horizon Europe and to what extent. According to Figure 14, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs (companies with less than 250 employees) value role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and

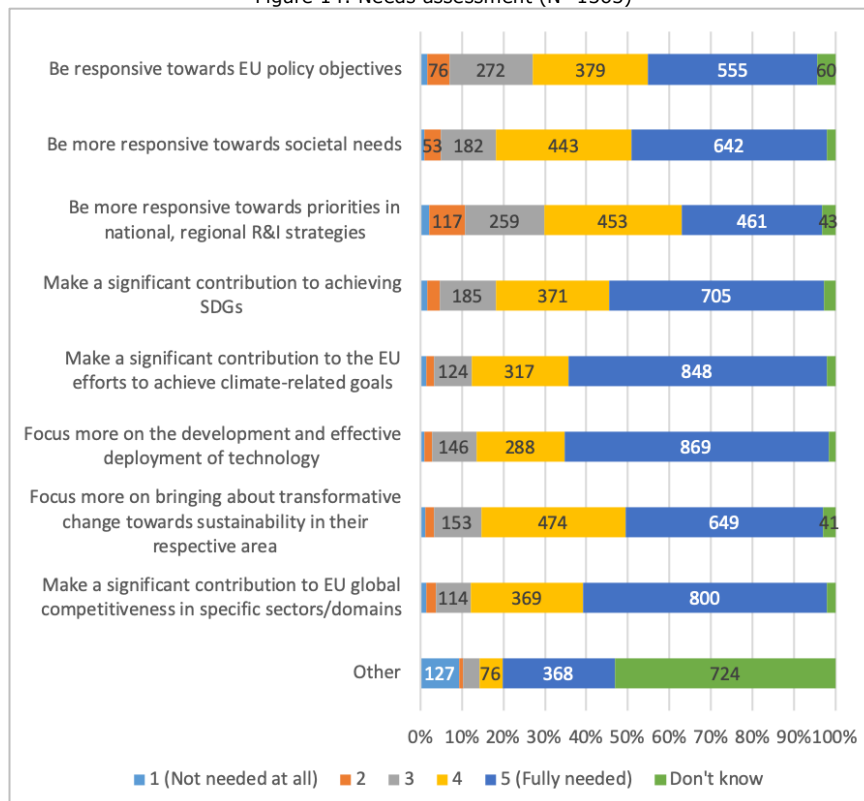
Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs.

The views of citizens (249, or 18.27%), both EU and non-EU citizens, that participated in the open public consultation do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

Among 272 respondents that are classified as **campaigns**, the majority (86.76%) indicated that the future European Partnerships should focus more on the development and effective deployment of technology. Other categories of presented needs that received a high score among many campaign respondents are the need to make a significant contribution to the EU efforts to achieve climate-related goals, Sustainable Development Goals and to EU global competitiveness in specific sectors/domains. The least number of campaign respondents valued the need to be more responsive towards priorities in national, regional R&I strategies (54 respondents gave a score "5 Fully needed", or 19.85%) and to be more responsive towards societal needs (71 respondents gave a score "5 Fully needed", or 26.10%).

Similarly as for non-campaign respondents, we find only minor differences between the main stakeholder categories amongst campaign respondents. Academic/research institutions indicated that the future European Partnerships need to focus a little less on development and effective deployment of technology than other respondents. On the contrary, large companies find the focus on the development and effective deployment of technology a little more needed than other respondents, as do public authorities. Furthermore, large companies feel responsiveness towards priorities in national, regional R&I strategies is a little less needed than other respondents. Public authorities, however, value the responsiveness towards societal needs and priorities in national, regional R&I strategies more than others.

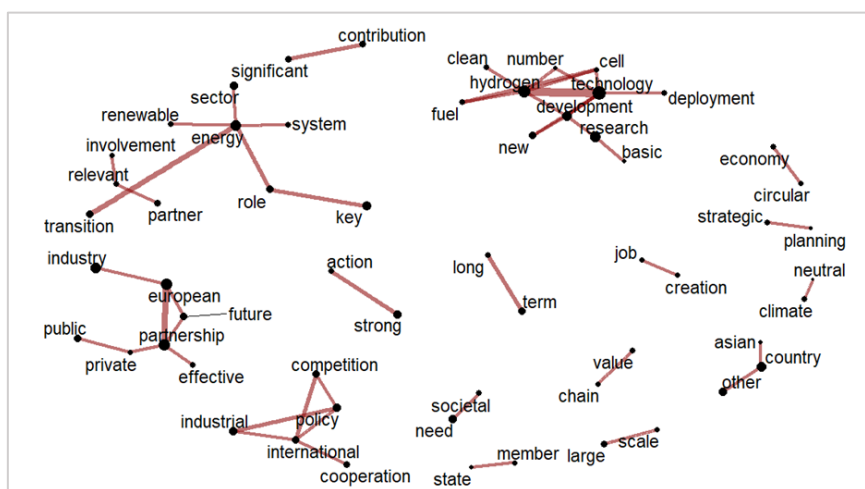
Figure 14: Needs assessment (N=1363)



Notes: Question: " To what extent do you think that the future European Partnerships under Horizon Europe need to ..."; Non-campaign replies; Aggregation of responses of all candidate initiatives

The analysis of the open answers provided to explain the “Other” field show that many respondents included the set-up of public-private European partnerships and the link between industrial policy and international competition and cooperation (see Figure 15). This is confirmed through qualitative analysis of answers, many of which mention the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals. Against this backdrop, fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are deemed as priorities. Next to that, many respondents provided answers related to the fields of hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate European Partnership specific questions related to these topics.

Figure 15: Needs assessment, open answers to “Other” field (N=734)



Notes: Question: “To what extent do you think that the future European Partnerships under Horizon Europe need to ...”; 50 most common co-occurring keywords; Non-campaign replies; Aggregation of responses of all candidate initiatives

Many of the respondents that are classified as campaigns took the opportunity of the “Other” field to underline their key messages. The main aspects mentioned were:

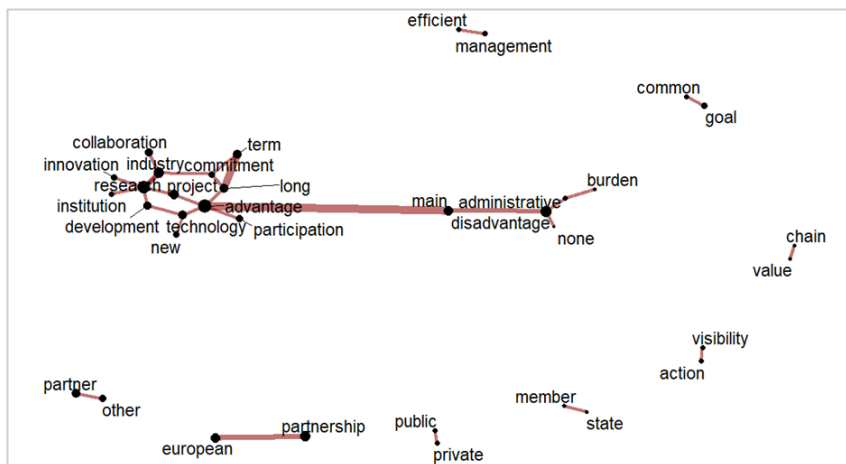
- The global positioning of Europe: outlining the role of global competition (including the role of technology), the importance of autonomy for Europe and the ability of Europe to act as a key player at the global level.
- The balance between policy objectives and private sector interests: Partnerships are regarded as an instrument to secure industry commitments due to the stability required for investments that serve policy goals.
- The importance of the transition between research and innovation (implementing research results in the market).
- The importance of multidisciplinary, and specifically cross-sectoral/cross-partnership collaboration.
- The importance of the long term commitment of a wide range of relevant stakeholders.

Next to that many respondents as part of campaigns stressed the importance of the energy transition, hydrogen and the environment, which corresponds to the high number of respondents that provided answers to the candidate European Partnership specific questions related to these topics.

## Main advantages and disadvantages of Institutionalised European Partnerships

In the next question, respondents were asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. This was an open question for which a keyword analysis was used (see the main results in Figure 16). As can be observed, the advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens.

Figure 16: Main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) (N=1551)



Notes: Question: "What would you see as main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe?"; 30 most common co-occurring keywords; Non-campaign replies; Aggregation of responses of all candidate initiatives

When asked about the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe, the following points were mentioned by respondents that are classified as campaigns:

### **Advantages:**

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

### **Disadvantages:**

- Slow processes
- System complexity

- Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation
- Lower funding percentage compared to regular Horizon Europe projects
- Cash contributions
- Administrative burdens
- Potential for IPR constraints

### Relevance of EU level efforts to address problems in selected areas of Partnerships

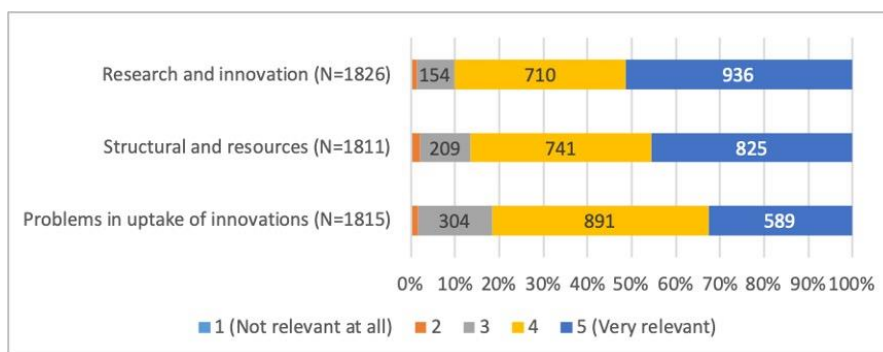
Per candidate European Partnership respondents were asked to rate the relevance of partnership specific problems in three main areas: Research and innovation problems, Structural and resource problems and Problems in the uptake of innovations. To aggregate results the average of the responses on partnership specific problems were calculated.

As presented in Figure 17, research and innovation related problems were rated as most relevant by the respondents across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant.

Only minor differences were found between the main stakeholder categories of respondents. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find it slightly more relevant to address problems in uptake of innovation than other respondents.

The views of citizens, both EU and non-EU citizens, are the same as other respondents (no significant differences). Respondents that are/were directly involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) find, however, the uptake of innovation problems slightly more relevant than other respondents.

Figure 17: Relevant problems to address



Notes: Question: "To what extent do you think it is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

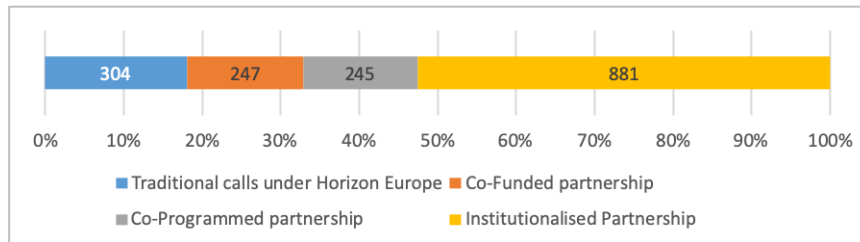
### Horizon Europe mode of intervention to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 18, just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, however, relatively strong differences



between stakeholder categories were found. The intervention of institutionalised partnerships was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens, compared to other respondents, indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, however, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 18: Options to address challenges



Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

When asked to reflect on their answers, respondents that pointed to the need for using the "institutionalised partnership" intervention mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Respondents that referred to possible approaches, sometimes gave examples of good experiences in with other interventions:

- Traditional calls because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy premier. This was mentioned by 94 participants, evenly distributed across companies (25 of them), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).

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

### Setting joint long-term agendas

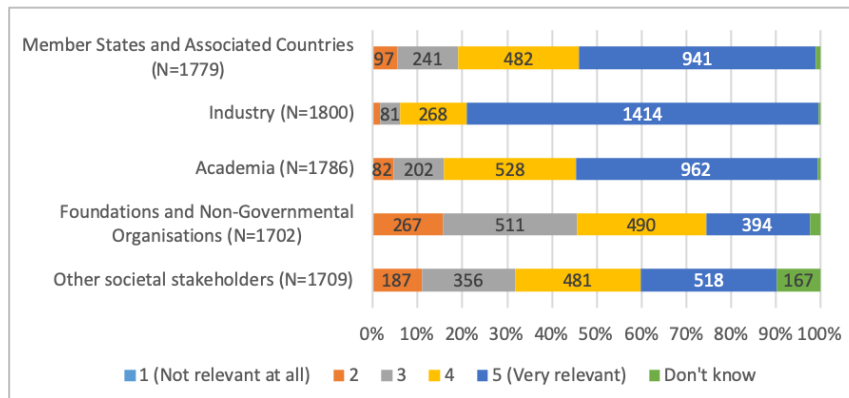
Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. As presented in Figure 19, collectively all respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents.

When looking at the differences between the answers of the main stakeholder categories only minor differences could be found. Overall, it could be observed that most respondents



indicated the stakeholder group they belong to themselves or that represent them as relevant to involve. Academic/research institutions find it more relevant to involve academia and less relevant to involve industry when compared to other respondents. The other way around large companies, SMEs and business associations find it more relevant to involve industry and less relevant to involve academia, Member States and Associated Countries and NGOs. The involvement of Member States and Associated Countries was found more relevant by academic/research institutions and public authorities. NGOs also values their own involvement and those of other societal stakeholders more than other respondents. The views of citizens also show a slightly higher relevance for foundations and NGOs. This is less so the case for respondents that are/were directly involved in a current/preceding partnership (most predominantly companies and academia).

Figure 19: Stakeholders to involve in setting joint long-term agenda's



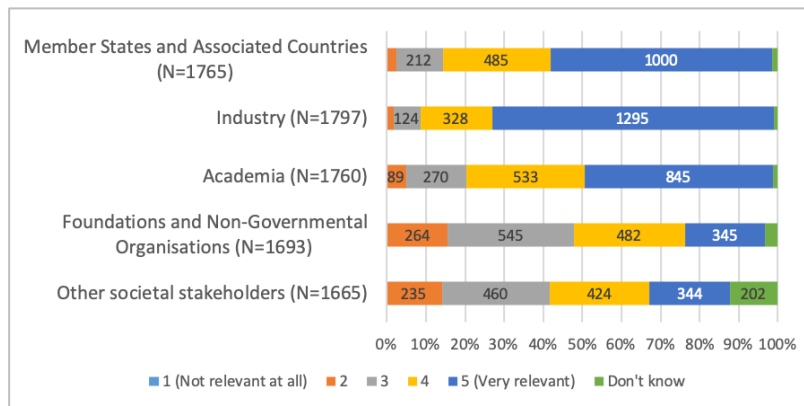
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of:"; Non-campaign replies; Aggregation of responses of all candidate initiatives

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

Respondents were also asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. As shown in Figure 20 - similarly as for the previous questions, respondents also see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents.

Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor. As such, academic/research institutions see the relevance of academia higher, while large companies, SMEs and business association indicated a lower relevance of academia than other respondents. Similarly, these private sector stakeholders valued the relevance of industry higher than others while valuing the relevance of NGOs and other societal stakeholders less. NGOs value themselves and other societal stakeholders however higher than other respondents, and also public authorities indicated a higher relevance for Member States and Associated Countries than other respondents. Citizens mainly put more emphasis on the role of NGOs and other societal stakeholders than other respondents.

Figure 20: Relevance of actors for pooling and leveraging resources



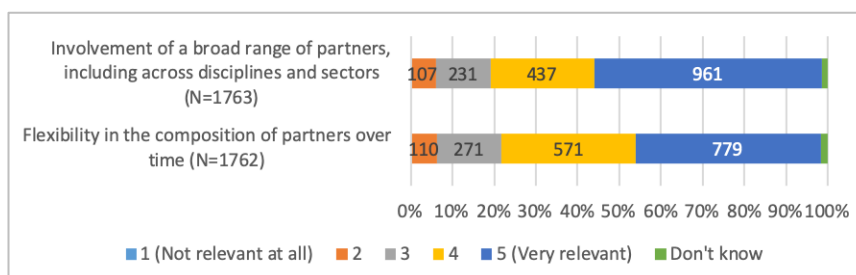
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with:"; Non-campaign replies; Aggregation of responses of all candidate initiatives

### Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 21).

When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

Figure 21: Assessment of the partnership composition



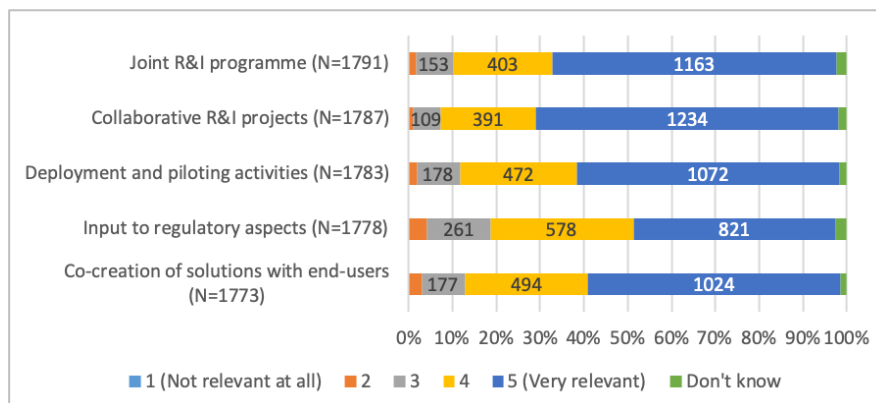
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition"; Non-campaign replies; Aggregation of responses of all candidate initiatives

## Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives (see Figure 22).

Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities shown in Figure 22.

Figure 22: Relevance of activities to implement



Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities"; Non-campaign replies; Aggregation of responses of all candidate initiatives

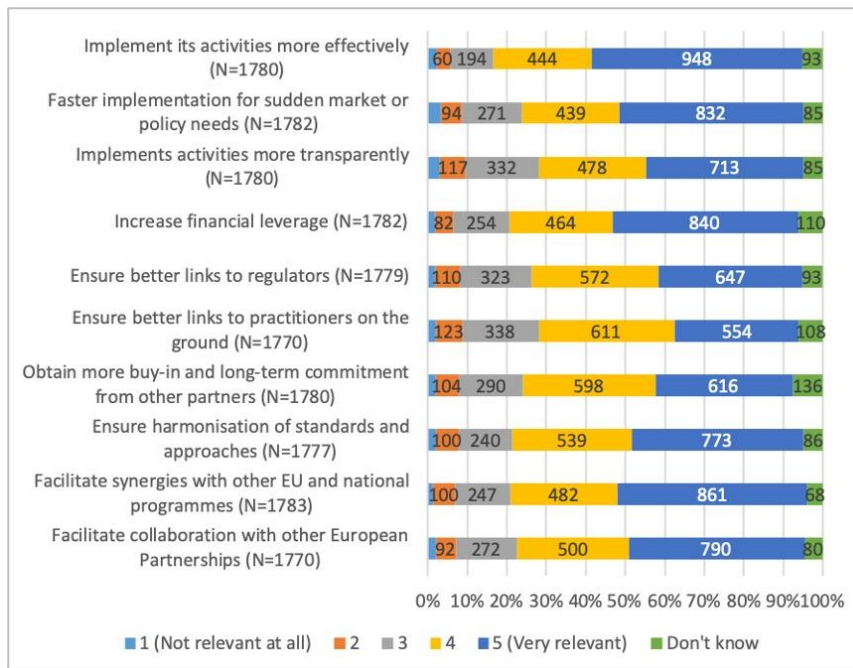
## Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were then asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as presented in Figure 23. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. The legal structure was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

When comparing the main stakeholder categories we found minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships than other open consultation respondents. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents.

The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Quite different results are shown for respondents that are/were directly involved in a current/preceding partnership when compared to respondents not involved in a current/preceding partnership, they indicated a higher relevance across all elements presented in Figure 23.

Figure 23: Relevance of setting up a legal structure (funding body)



Notes: Question: "In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

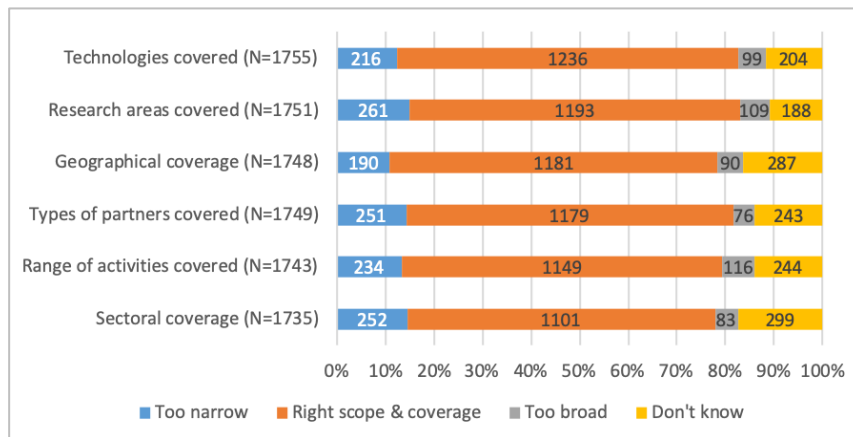
### Scope and coverage of the candidate European Partnerships based on their inception impact assessments

The response regarding the scope and coverage for the partnerships, based on inception impact assessments, shows that the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. Figure 24 shows the results. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". In the open answers respondents mostly reflected on specific aspects of the geographical and sectoral scope and coverage of the specific candidate European Partnerships, no overall lessons could be extracted.

Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" than other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow" when compared to other respondents. Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents.

The views of citizens are the same as for other respondents. Most notably, respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 24: Assessment of the proposed scope and coverage of the candidate European Partnerships



Notes: Question: "What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

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

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62.15%), while over one third answered "No" (609, or 37.85%). Nearly no differences were found between the main stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents.

The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

In the open responses respondents often referred to specific similar/comparable and complementary initiatives discussing the link with a specific candidate European Partnership, no overall lessons could be extracted, but more detailed results can be found in the partnership specific result sections.

### Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

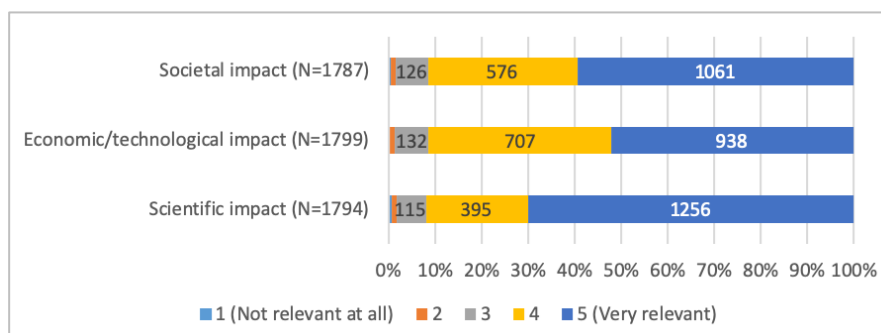
Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal impacts, Economic/technological impacts and Scientific impacts. To aggregate results the average of the responses on partnership specific impacts were calculated.

As presented in Figure 25, overall, all three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that these impacts were (very) relevant.

Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important.

Citizens, both EU and non-EU citizens, did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 25: Relevant impacts of future European Partnerships



Notes: Question: "In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts?"; Non-campaign replies; Aggregation of responses of all candidate initiatives

## **B.6 Responses to the open public consultation for the candidate partnership "EU-Africa Global Health"**

### **B.6.1 Introduction**

This section outlines the results of the Open Public Consultation for the candidate European Partnership on EU-Africa Global Health. The section outlines the following:

- Results on general questions, segregated for this candidate European Partnership:
- Views on the needs of the future European Partnerships under Horizon Europe
- Views on the advantages and disadvantages of participation in an Institutionalised European Partnership
- Results on specific questions for this candidate European Partnership:
  - Relevance of research and innovation efforts at the EU level to address problems
  - Views on Horizon Europe interventions to address these problems
  - Views on the relevance of elements and activities in:
    - setting a joint long-term agenda;
    - pooling and leveraging resources;
    - partnership composition;
    - implementation of activities.
  - Views on setting up a specific legal structure (funding body)
  - Views on the proposed scope and coverage of this candidate European Partnership
  - Views on the alignment of the European Partnership with other initiatives
  - Relevance of this candidate European Partnership to deliver impacts

### B.6.2 Characteristics of respondents

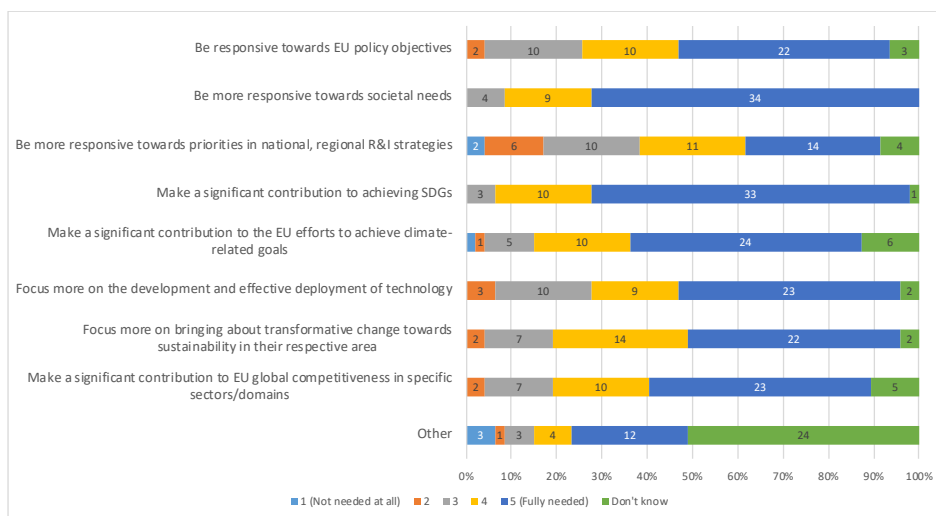
Only 47 respondents provided views on the EU-Africa Global Health partnership. Among them 13 respondents (27.66%) are citizens. The group is dominated by respondents from academic and research institutions (15 respondents or 31.91%), citizens and company/business organisations (7 respondents or 14.89%).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

### B.6.3 Characteristics of future candidate European Partnerships – as viewed by respondents to the EU-Africa Global Health initiative

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

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

Figure 26: Needs assessment (N=47)

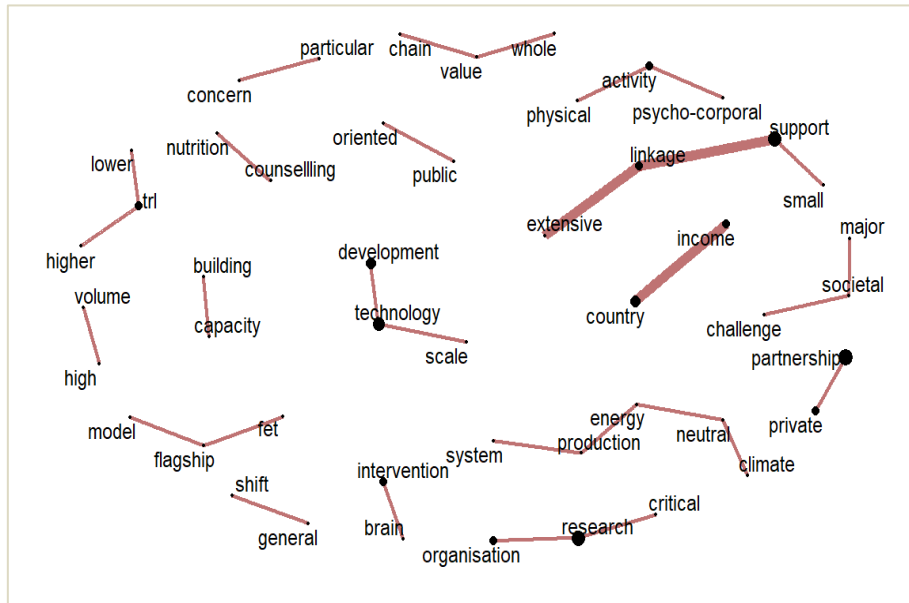


Notes: Question: " To what extent do you think that the future European Partnerships under Horizon Europe need to ..."

The respondents also had the option to indicate other needs. The results of the analysis resulted in the chart shown in Figure 27 showing the co-occurrences of keywords. The results show that respondents have indicated needs around extensive support linkage and the development and scaling of technology.



Figure 27: Needs assessment, open answers to "Other" field (N=18)

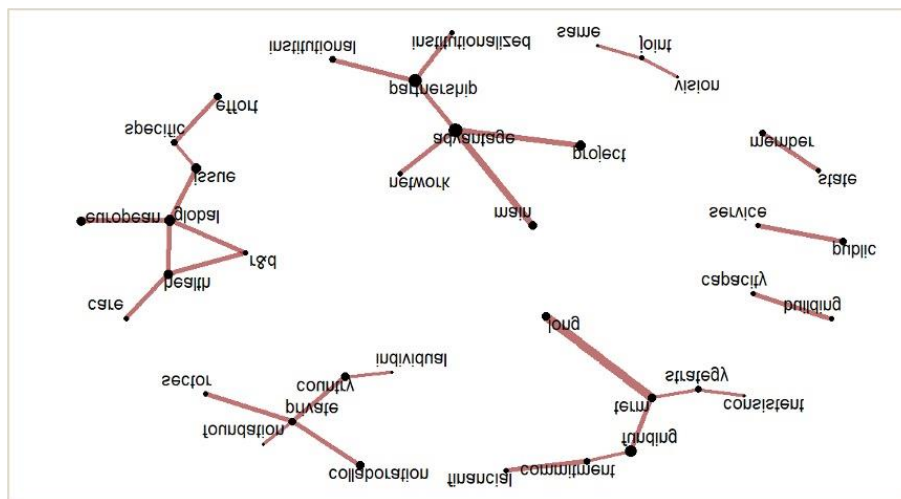


Notes: Question: " To what extent do you think that the future European Partnerships under Horizon Europe need to ..."; 50 most common co-occurring keywords

#### B.6.4 Main advantages and disadvantages of Institutionalised European Partnerships

The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. The keyword analysis used for open questions resulted in the graph shown in Figure 28. This analysis showed the respondents viewed a network as the main advantage of the institutionalized partnership, as well as long term funding.

Figure 28: Main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) (N=32)



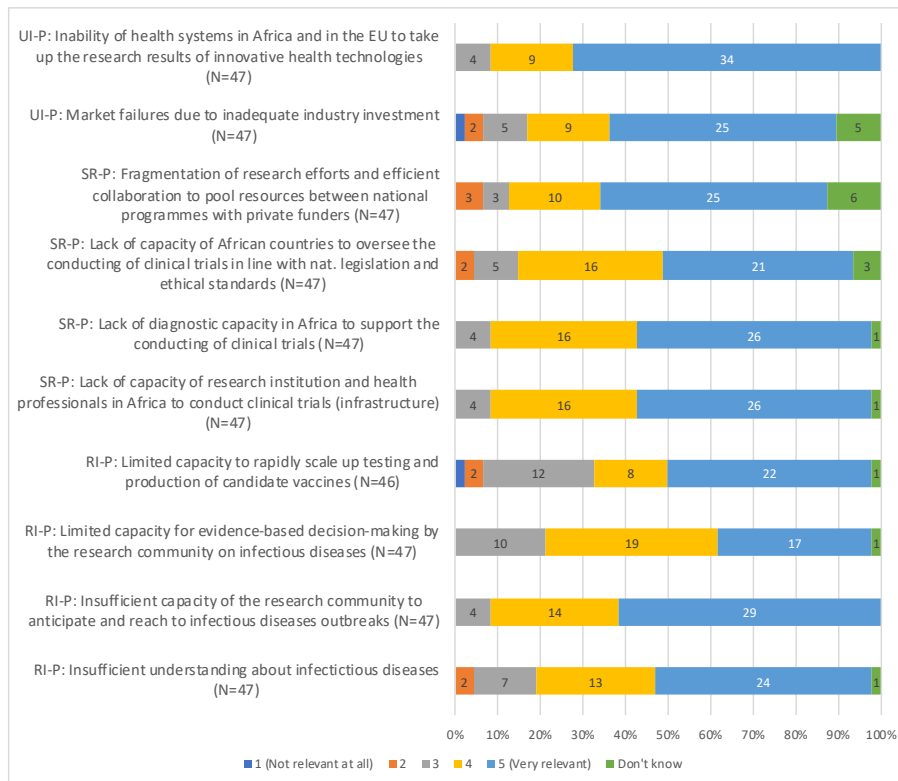
Notes: Question: " What would you see as main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe?"; 30 most common co-occurring keywords



### B.6.5 Relevance of EU level efforts to address problems in relation to the GLOBAL HEALTH

In the consultation, respondents were asked to provide their view on the relevancy of research and innovation efforts at EU level to address the following problems in relation to global, specifically on three types of problems: problems in uptake of health innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 29 the responses to these answers are presented.

Figure 29: Relevant problems to address in relation to global health



Notes: Question: "To what extent do you think it is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question?"

With regard to the uptake in innovation problems, the answer that received the most 5 (Very relevant) answers is the inability of health systems in Africa and in the EU to take up the research results of innovative health technologies (34, 72.34%). This option has received the most of these answers out of all the problems that were presented to the respondents.

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

Last, with regard to research and innovation problems, 29 respondents have indicated that they view insufficient capacity of the research community to anticipate and react to infectious diseases outbreaks as a very relevant problem (61.70%). Limited capacity for evidence-based decision-making by the research community on infectious diseases outbreaks has received the least amount of very relevant answers out of all the problems presented, as 17 respondents have indicated that it is relevant for research and innovation efforts at the EU level to address this issue (36.17%).

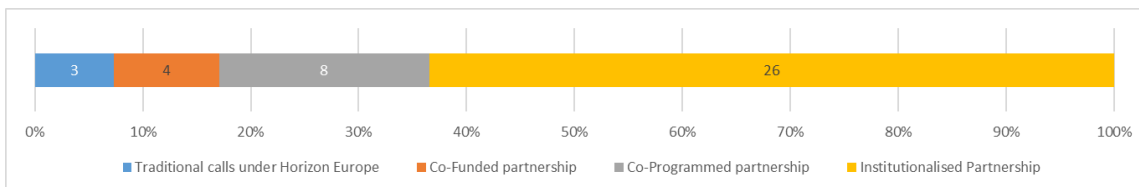
No statistical differences were found between the views of citizens and other respondents.

### B.6.6 Horizon Europe mode of intervention to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 30, just over 60% of respondents indicated that institutionalised partnerships were the best fitting intervention.

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

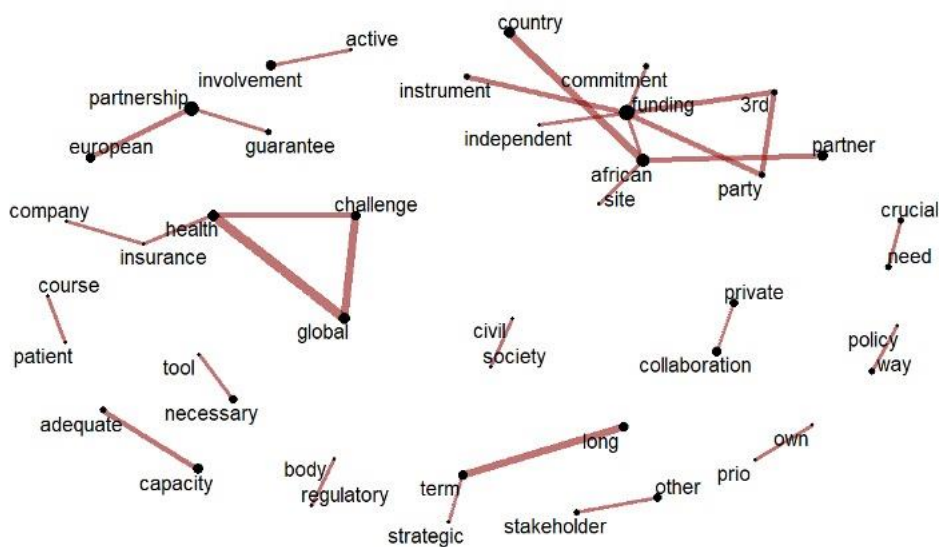
Figure 30: Options to address the challenges



Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"

The respondents were asked to briefly explain their answers to the question above. Figure 31 summarises the most common co-occurring key words used by respondents in their open comments to clarify their answers. A more in-depth analysis of the open responses shows that those in favour of an institutionalised partnership viewed this as offering the greatest stability, with long-term political and financial commitments. The view the institutionalised partnership as the best way to pool resources, foster collaboration between a wide range of partners and other stakeholders, with coordination and alignment of efforts. It was also noted that this partnership form best allows for a pipeline or portfolio management approach to selecting projects for funding. The small number of respondents in favour of a co-programmed partnership believe that this would allow for inclusion of a greater range of actors, including non-EU countries and SMEs, and comes with the lowest administrative cost. Flexibility and transparency are cited as reasons by respondents who opt for the co-funded partnership approach. There are no significant differences in preference or reasons stated between different groups of respondents.

Figure 31: Open answers to explain the choice institutionalised partnership in the assessment of the Horizon Europe intervention (N=18)



Notes: Question: "In your view, how should the specific challenges described above be addressed through Horizon Europe intervention?"

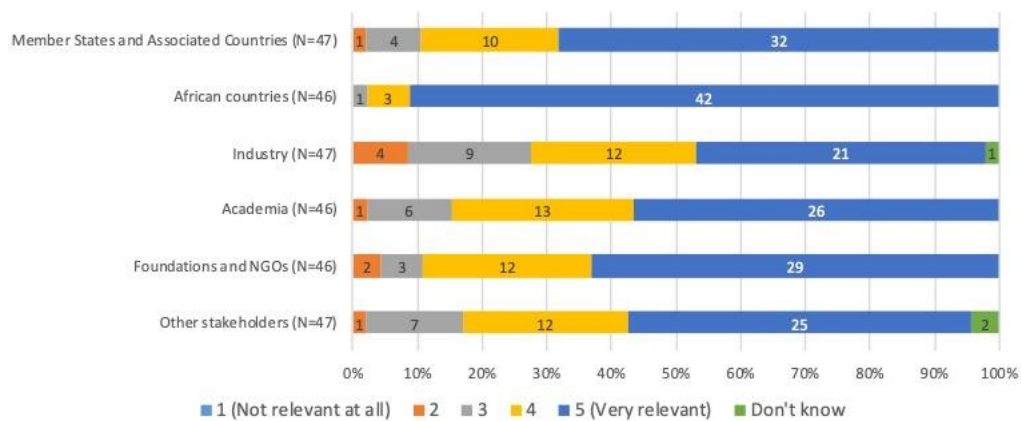
**B.6.7 Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives**

**Setting joint long-term agendas**

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives. According to over 90% of respondents, the involvement of African countries is very relevant (Figure 32). Over 60% of respondents suggest that the participation of Member States and Associated Countries, as well as, foundations and NGOs in the candidate Partnership is very relevant. The least number of respondents (21 respondents or 44.68%) suggested that industry should be involved in setting a joint long-term agenda .

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

Figure 32: Stakeholders to involve in setting joint long-term agenda's



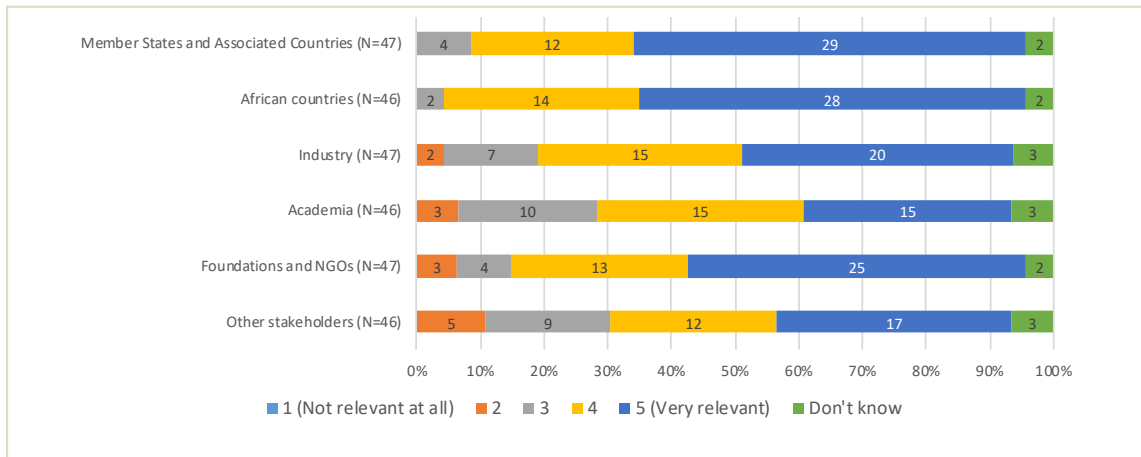
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of:"

**Relevance of elements and activities in pooling and leveraging resources**

With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise, to meet the candidate Partnership objectives, over 50% of respondents indicated Member States and Associated Countries, African countries, foundations and NGOs are most relevant. Based on opinions of respondents, the role of academia is considered smaller for pooling and leveraging resources, in contrast to setting long-term agenda, as only 15 respondents consider that their involvement is very relevant to pool and leverage resources.

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

Figure 33: Relevance of actors for pooling and leveraging resources



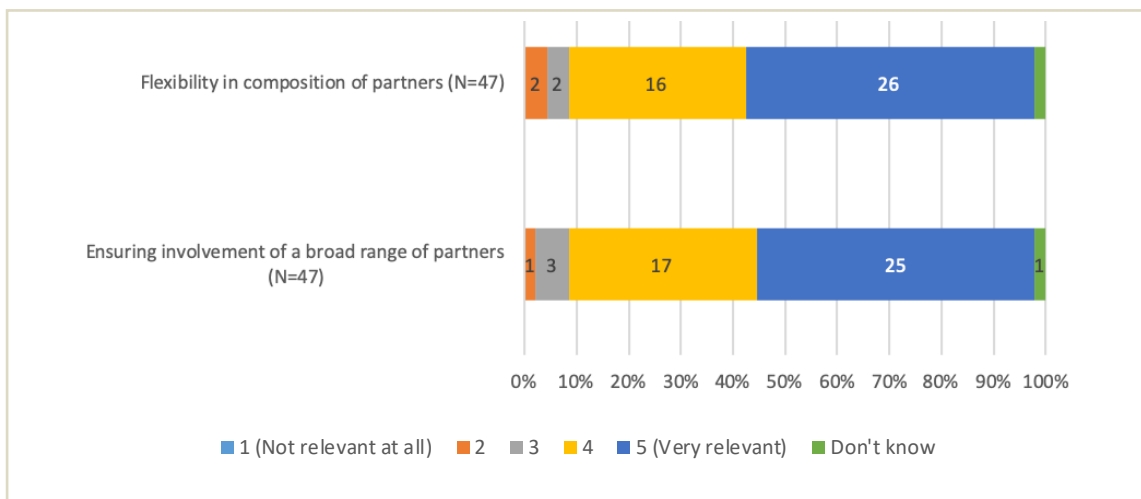
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with:"

### Relevance of elements and activities for the partnership composition

Respondents were asked about the relevance of Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. As it is visible in Figure 34, the pattern of responses is very similar for both composition elements – around 55% respondents consider that these elements are very relevant to reach Partnership objectives. Less than 10% of responders consider these elements not very relevant.

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

Figure 34: Relevant principles for the partnership composition



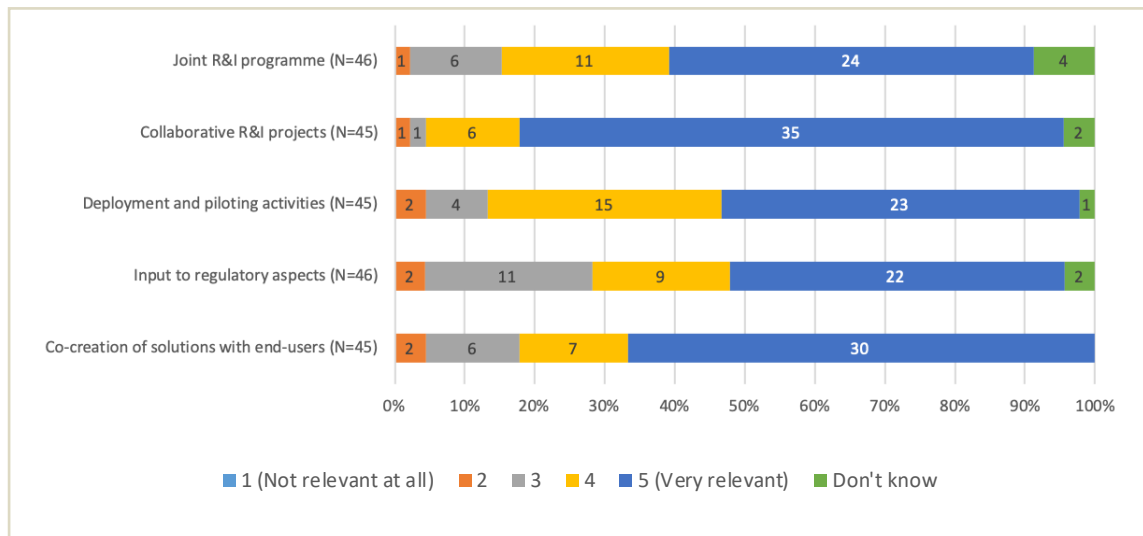
### Relevance of implementation of activities

Respondents were asked to provide opinions on relevance of implementation of several activities for meeting objectives of the Global Health Partnership. Among activities were listed – join R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects (i.e. to developers of medicines or health technologies on approvals and pre-qualifications) and co-creation of solutions with end-users (e.g. national health systems). Out of 45 respondents, 35 (77.77%) indicated that collaborative R&D projects are very relevant to ensure that the Global Health Partnership would meet its objectives. The co-creation of solutions with end-users has also been considered as very relevant by a large number of respondents (30 respondents or 66.6%).

In contrast, deployment and piloting activities, input to regulatory aspects is considered less relevant by respondents.

Overall, citizens provided similar views, but found Joint R&I programme more relevant.

Figure 35: Relevance of activities to implement



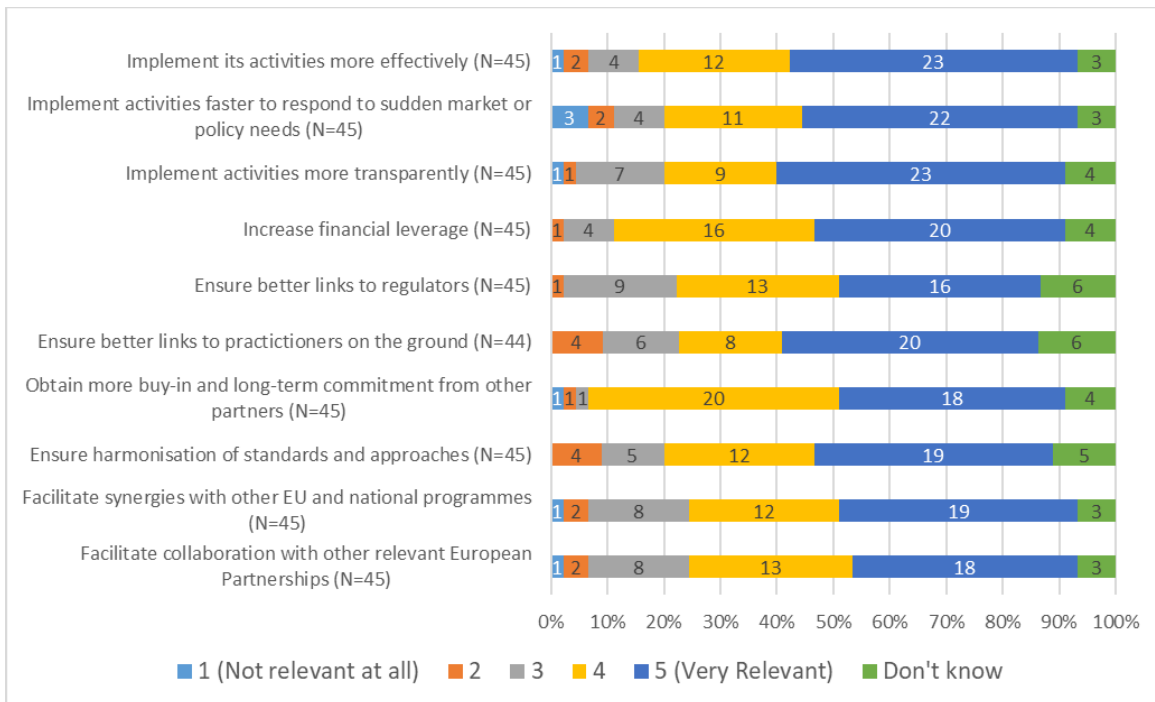
Notes: Question: "In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities"

**B.6.8 Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements**

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 36, a greater number of respondents indicated that the legal structure would be needed to obtain more buy-in and long-term commitment from other partners, to increase financial leverage and to implement activities more effectively. In contrast, the least number of respondents suggest that the legal structure would assist in ensuring better links to regulators, as only 16 respondents indicated that it would be very relevant for this purpose.

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

Figure 36: Relevance of setting up a legal structure (funding body)



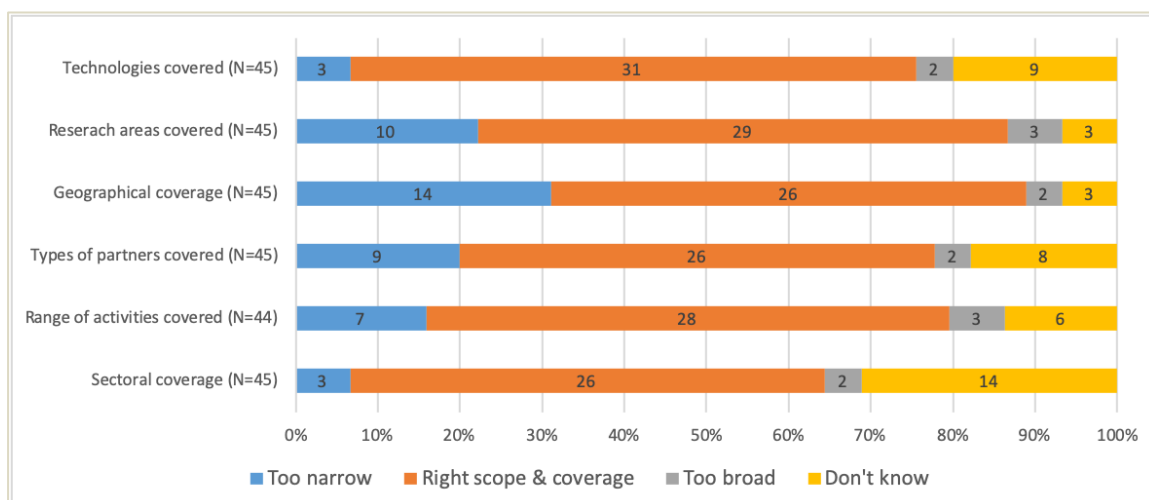
Notes: Question: "In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following?"

### B.6.9 Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Respondents were asked to assess the scope and coverage of the proposed Global Health Partnership, based on its inception impact assessment. According to respondents, the majority of them consider that the Partnership has a right scope and coverage in terms of technologies, research areas, geographical coverage, types of partners, range of activities and sectors. However, among listed areas, a higher share of respondents (14 respondents or 31.11%) indicated that the geographical coverage might be too narrow.

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

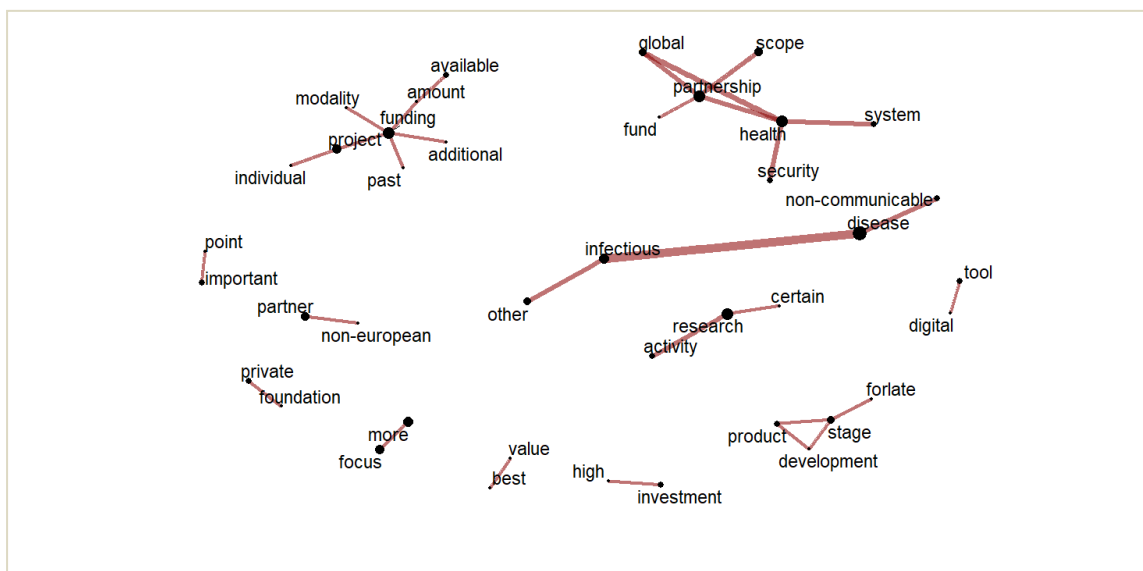
Figure 37: Scope and coverage proposed for the Global Health institutionalised Partnership



Notes: Question: "What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment?"

Respondents were also asked to comment on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword analysis used for open questions resulted in the graph shown in Figure 38. A more in-depth analysis of these responses shows that some suggested expanding the scope, compared to that proposed, to include also anti-microbial resistance and hospital-acquired infections, as well food-, water- and vector-borne diseases and zoonoses. This effectively calls for inclusion of a 'One Health' approach. Other research areas suggested for inclusion were non-communicable diseases, health systems research, and social and behavioural determinants of health. On the spectrum of research and development to be covered, comments were mixed. Whereas some suggested a full coverage from early stage research to bringing products to market, others advocated for keeping the focus on Phase I and II clinical trials. In terms of geographical scope, a small number of respondents suggested including areas other than sub-Saharan Africa, in particular the Middle East and South America. Other respondents, however, emphasised that sub-Saharan Africa continues to carry a disproportionate burden of poverty-related infectious diseases and thus argue that this focus remains appropriate. It is furthermore cautioned that expanding the scope of the partnership, both in terms of geography and disease areas covered, would dilute resources and focus, thereby jeopardising potential impact. In all cases, the number of clarifying comments was too small and answers were too heterogeneous to determine any significant differences between different groups of respondents.

Figure 38: Scope and coverage proposed for the Global Health institutionalised Partnership – open question (N=55)



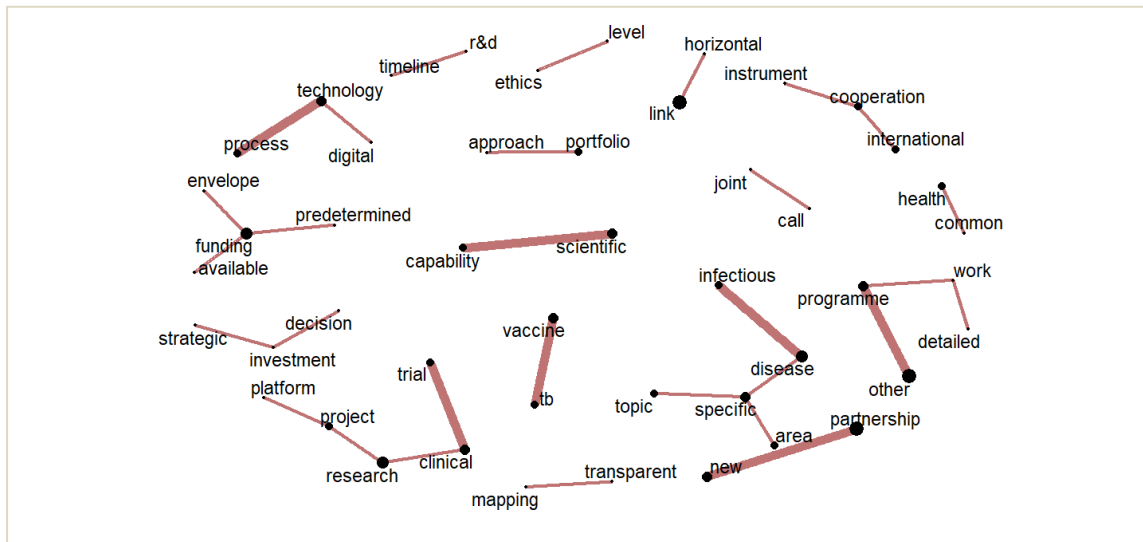
Notes: 30 most common co-occurring keywords

#### *B.6.10 Scope for rationalisation and alignment of candidate European Partnerships with other initiatives*

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

The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. The results of the analysis resulted in the chart shown in Figure 39 showing the co-occurrences of keywords. The results show that respondents mention scientific capability, infectious diseases, other programmes and new partnerships as well as clinical trials.

Figure 39: Comparable initiatives to link with the partnership on global health (N=23)

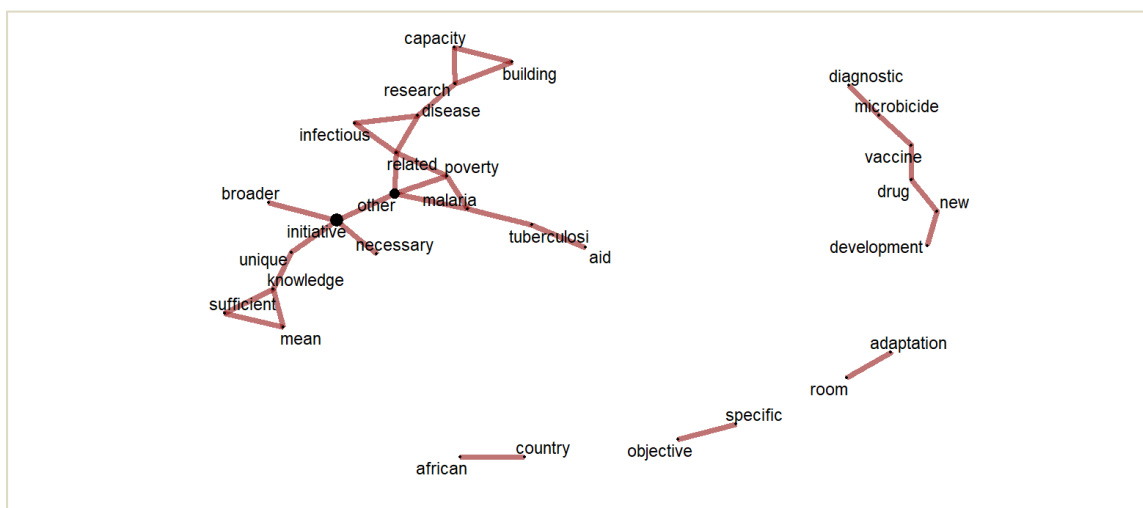


Notes: Open question: "Which other comparable initiatives could the partnership be linked with?"; 30 most common co-occurring keywords

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

For the respondents who answered negatively on the previous question, the results of the analysis resulted in the chart shown in Figure 40 showing the co-occurrences of keywords.

Figure 40: Other comparable initiatives – open question (N=4)



Notes: Open question: "why other comparable initiatives are not suitable to be linked"; 30 most common co-occurring keywords



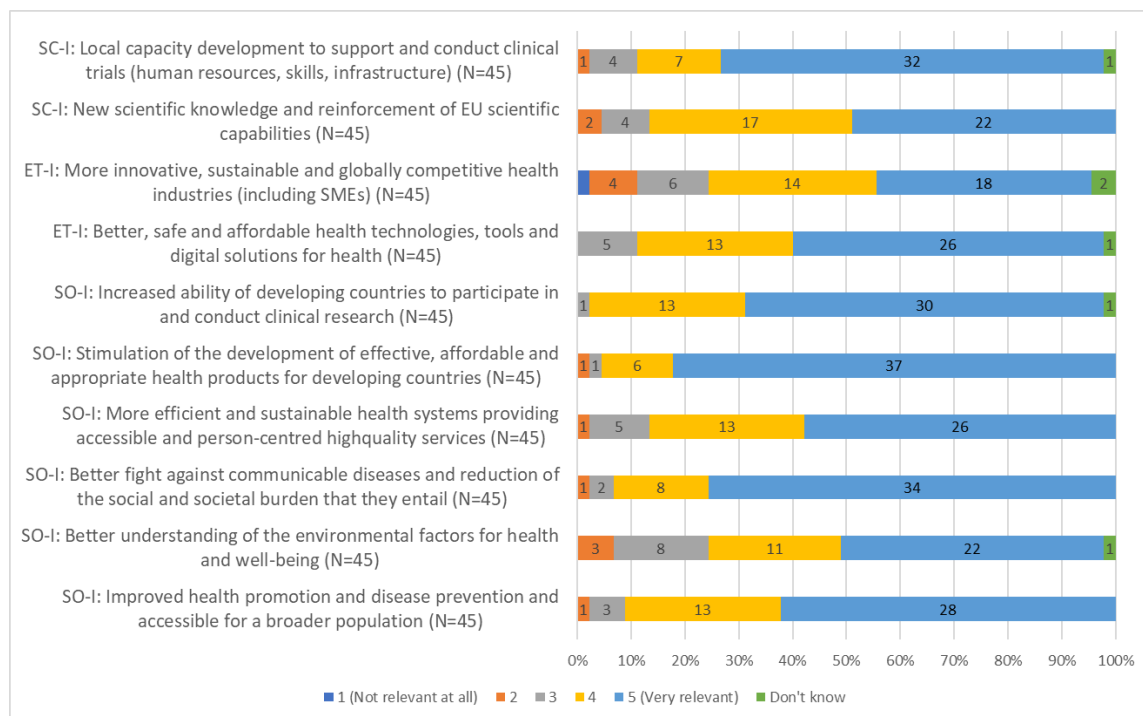
All respondents highlighted that the candidate partnerships have very specific objectives and that, like its predecessors, it is unique, so that there should not be any risk of duplication of research and innovation efforts. A representative from the industry sector, in the same line, stated that the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

*B.6.11 Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts*

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed impacts. Based on results, among societal impacts, the Partnership is expected to be 'very relevant' for stimulation of the development of effective, affordable and appropriate health products for developing countries and for fighting against communicable diseases and reduction of the societal and societal burden that they entail (Figure 41). Among presented economic impacts, a greater number of respondents, namely 26 out of 45 (57.78%), indicated that the candidate Partnership would be 'very relevant' for ensuring better, safe and affordable health technologies, tools and digital solutions for health. The majority of respondents (32 out of 45, or 71.11%) suggest that the candidate Partnership would have a significant effect on local capacity development to support and conduct clinical trials.

Overall, citizens provided similar views, but found the societal impact regarding More efficient and sustainable health systems more relevant.

Figure 41: Relevance of the candidate European Institutionalised Partnership to various impacts



Notes: Question: "In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts?"

*B.6.12 Summary of campaigns results for this specific initiative*

No campaigns were identified for this initiative.

## **Appendix C      Methodological Annex**

The Impact Assessment studies for all 13 candidate institutionalised European Partnerships mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. The Impact Assessment Study Teams went through grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for their candidate partnerships. The review of official documentations, especially from the European Commission, additionally helped understand the main EU policy proprieties that the initiatives under assessment could contribute to achieve.

Almost no candidate institutionalised European Partnership is intended to emerge ex nihilo. Partnerships already existed under Horizon 2020 and will precede those proposed by the European Commission. In the assessment of the problems to address, the Impact Assessment Study Teams therefore considered the achievements of these ongoing partnerships, their challenges and the lessons that should be drawn for the future ones. For that purpose, they reviewed carefully the documents in relation to the preceding partnerships, especially their (midterm) evaluations conducted. The bibliography in Appendix A gives a comprehensive overview of the documents and literature reviewed for the present impact assessment study.

Finally, the description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. The European Commission services and, where needed the ongoing Joint Undertakings or implementation bodies of the partnerships under Article 185 of the TFEU, provided data on the projects that they funded and their participants. These data served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to the countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and to the industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS. We used the NACE codification up to level 2. These data enabled identified the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that will need to be involved (further) in the future partnerships.

The horizontal teams also conducted a Social Network Analysis using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing European partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided by the European Commission finally served a bibliometric analysis aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

All together, these statistical analyses will complement the desk research for a comprehensive definition of the context in which the candidate institutionalised European Partnerships are intended to be implemented. The conclusions drawn on their basis will be confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European partnerships received in August 2019
- The open public consultation organised by the European Commission from September to November 2019
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020.

For instance, in all three exercises, the respondents were asked to reflect on the main challenges that the candidate institutionalised European Partnerships should address. In the open public consultations, they mainly reacted to proposals from the European Commission like when they were given to opportunity to give feedback to the inception impact assessment.

The views of stakeholders (and experts) were particularly important for determining the basic functionalities that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the Study Teams confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation. Appendix B includes also the main outcomes of these three stakeholder consultation exercises.

The comparison of different options for European partnerships additionally relied on a cost-effectiveness analysis. When it comes to research and innovation programmes, the identification of costs and benefits should primarily be aimed at identifying the “value for money” of devoting resources from the EU (and Member States) budget to specific initiatives. Based on desk research and consultation with the European Commission services, the horizontal study team produced financial estimates for different types of costs (preparation and setup costs, running costs and winding down costs) and per partnership option. The costs were common to all candidate European Partnerships. The results of the cost model were displayed in a table, where each cost was translated on a scale using “+” in order to ease the comparison between the partnership options.

A scorecard analysis, which allocated each option a score between 1 and 3 against selected variables, was used to highlight those options that stand out as not being dominated by any of the other options in the group: such options are then retained as the preferential ones in the remainder of our analysis. It also allowed for easy visualisation of the pros and cons of alternative options.

## **Appendix D Additional information on the policy context**

### ***D.1 Specific objectives and activities of EDCTP2***

To operationalize its general objective, EDCTP2 has set the following five specific objectives:<sup>115</sup>

- Increase the number of new or improved medical interventions for poverty-related diseases, including neglected ones
- Strengthen cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, EU and international legislation
- Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments
- Extend international cooperation with other public and private partners to ensure that the impact of all research is maximised and that synergies can be taken into consideration and to achieve leveraging of resources and investments
- Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance

To maximise impact, the EDCTP2 programme identifies strategically important areas of unmet medical need. Its annual work plans include calls for proposals reflecting specific current needs for each target disease area and research capacity development. The programme portfolio is monitored and evaluated by the EDCTP Secretariat, with the advice of the Scientific Advisory Committee. and regularly submitted for approval to the EDCTP General Assembly. EDCTP funds a higher number of phase II (efficacy) and IV (post-licensing) studies and fewer phase I (clinical pharmacology) and III (therapeutic confirmatory) studies. It also provides funding to support capacity development for the conduct of clinical trials and offers a programme of several types of fellowships in the context of clinical trials.

The activities of the EDCTP2 programme are included the EDCTP2 Annual Work Plans and are either implemented by the EDCTP Association (EU-funded actions, supported with the EU contribution to the EDCTP2 programme) or by the EDCTP2 Participating States (PS).

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<sup>115</sup> Decision N0 556/2014/EU and Strategic Business Plan 2014-2024, Available at: <http://www.edctp.org/web/app/uploads/2016/12/EDCTP-Strategic-Business-Plan-2014-2024.pdf>. In the EDCTP2 Decision they are presented in more detail.

## Appendix E Additional information related to the problem definition

### E.1 Taxonomy of failures requiring policy intervention

Market failures	
<b>Market power</b>	<p>Limited interest from private sector parties to invest in R&amp;D for the development of health technologies for PRNDs due to low potential for return on investment.</p> <p>Lack of universal health coverage means that individuals are often unable to cover the costs for treatments.</p>
<b>Externalities</b>	<p>There are weak and underfunded health systems in Africa.</p> <p>Capacity for conducting research in the region is similarly weak.</p>
<b>Information asymmetry</b>	<p>Pharmaceutical companies usually have a large extent of monopoly power, making it challenging for countries, in particular, LMICs, to negotiate affordable prices for health technologies.</p>
Systemic failures	
<b>Capability</b>	<p>Low capacity in Africa to conduct research and development locally</p>
<b>Network</b>	<p>Private sector parties have shown relatively limited interest in the development of suitable and affordable health technologies for PRNDs. Whereas public sector parties, including academic organisations, have shown greater interest in this, they usually lack the experience and resources to bring products through the clinical research and product development stages to bring a product to market. This calls for a partnership approach.</p> <p>Fragmentation in the research landscape should be reduced through stronger networking and a partnership approach.</p>
<b>Institutional</b>	<p>SSA countries require the development of a capacity to support the conduct of clinical trials in the region, including frameworks for regulatory oversight and medical ethics committees.</p>
<b>Infrastructural</b>	<p>Limited staff capacity for the conduct of clinical trials in the SSA region, as well as insufficient laboratory infrastructures (e.g. laboratory equipment, supply chain management systems, digital infrastructure to support data collection and analysis)</p>
Transformational failures	

<b>Directionality</b>	Need for a strong partnership to agree on shared objectives and development of global R&D roadmaps e.g. for TB vaccine development
<b>Demand articulation</b>	Equal voice and representation of SSA countries helps to ensure that supported activities are aligned with the local needs and demands for products of greatest relevance to the region
<b>Policy coordination</b>	There are many different stakeholders and initiatives in the global health field. A partnership approach allows ensuring proper coordination and alignment.
<b>Reflexivity</b>	EDCTP has developed a strong results-based management approach which supports is the ability to monitor its impacts and make necessary adjustments along the way. A strong partnership is able to more rapidly respond to emerging needs, as in the case of the 2014 West Africa Ebola outbreak.

Source: Weber and Rohracher (2012) adapted by Technopolis Group (2018)

## Appendix F Additional information related to the policy options descriptions

### F.1 Degree of coverage of the different functionalities by policy option

Table 24: Type and composition of actors (including openness and roles)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b> Any legal entity in a consortium can apply to Horizon Europe calls in ad hoc combinations Calls are open to participation from across Europe and the world (not all entities from third countries are eligible for funding)</p>	<p><b>What is possible?</b> Partners can include any national funding body or governmental research organisation, Possible to include also other type of actors, including foundations.</p>	<p><b>What is possible?</b> Partners can include MS and Associated Countries.</p>	<p><b>What is possible?</b> Suitable for all types of partners: private and/or public partners, including MS, regions, foundations. By default open to AC/ 3<sup>rd</sup> countries, but subject to policy considerations. Can cover a large and changing community. HE rules apply by default to calls included in the FP Work Programme, so any legal entity can apply to these.</p>	<p><b>What is possible?</b> Suitable for all types of partners: private and/or public partners, including MS, foundations. By default open to legal entities from AC/ 3<sup>rd</sup> countries, but subject to policy considerations. In case of countries participating non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements HE rules apply by default, so any legal entity can apply to partnership calls.</p>
<p><b>What is limited?</b> Systematic/ structured engagement with public authorities, MS, regulators, standard making bodies, foundations and NGOs.</p>	<p><b>What is limited?</b> Requires substantial national R&amp;I programmes (competitive or institutional) in the field. Usually only legal entities from countries that are part of the consortia can apply to calls launched by the</p>	<p><b>What is limited?</b> Non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements. Needs good geographical coverage – participation of at least 40% of Member States is required</p>	<p><b>What is limited?</b> If MS launch calls under their responsibility, usually only legal entities from countries that are part of the consortia can apply to these, under national rules</p>	<p><b>What is limited?</b> Requires a rather stable set of partners (e.g. if a sector has small number of key companies). Basic act can foresee exceptions for participation in calls / eligibility for funding.</p>

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
	<p>partnership, under national rules.</p>	<p>Requires substantial national R&amp;I programmes (competitive or institutional) in the field.</p> <p>While by default the FP rules apply for eligibility for funding/participation, in practice (subject to derogation) often only legal entities from countries that are Participating States can apply to calls launched by the partnership, under national rules.</p>		
<p><b>What is not possible?</b> To have a joint programme of R&amp;I activities between the EU and committed partners that is implemented based on a common vision.</p>	<p><b>What is not possible?</b> To have industry/ private sector as partners.</p>	<p><b>What is not possible?</b> To have industry/ private sector as partners.</p>		



Table 25: Type and range of activities (including flexibility and level of integration)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b></p> <p>Horizon Europe standard actions that allow <i>broad range of individual activities</i> from R&amp;I to TRL 7 or sometimes higher.</p> <p>Calls for proposals published in the Work Programmes of Horizon Europe (adopted via comitology).</p>	<p><b>What is possible?</b></p> <p>Activities may range from R&amp;I, pilot, deployment actions to training and mobility, dissemination and exploitation, but according to national programmes and rules.</p> <p>Decision and implementation by “beneficiaries” (partners in the co-fund grant agreement) e.g. through institutional funding programmes, or by “third parties” receiving financial support, following calls for proposals launched by the consortium.</p>	<p><b>What is possible?</b></p> <p>Horizon Europe standard actions that allow a broad range of coordinated activities from R&amp;I to uptake.</p> <p>In case of implementation based on national rules (subject to derogation)</p> <p>Activities according to national programmes and rules.</p> <p>Allows integrating national funding and Union funding into the joint funding of projects</p>	<p><b>What is possible?</b></p> <p><i>Horizon Europe standard actions</i> that allow a broad range of coordinated activities from R&amp;I to uptake.</p> <p>The association representing private partners allows to continuously build further on the results of previous projects, including activities related to regulations and standardisation and developing synergies with other funds</p> <p>Union contribution is implemented via calls for proposals published in the Work Programmes of Horizon Europe based on the input from partners (adopted via comitology).</p> <p>Open and flexible form that is simple and easy to manage.</p>	<p><b>What is possible?</b></p> <p><i>HE standard actions</i> that allow to build a portfolio with broad range of activities from research to market uptake.</p> <p>The back-office allows dedicated staff to implement integrated portfolio of projects, allowing to build a “system” (e.g. <i>hydrogen</i>) via pipeline of support to accelerate and scale up the take-up of results of the partnership, including those related to regulations and standardisation and developing synergies with other funds. E.g. setting up biorefinery plants and promoting their replication by additional investments from MS/ private sector.</p> <p>Procuring/purchasing jointly used equipment (e.g. HPC)</p> <p>Allows integrating national funding and Union funding into the joint funding of projects</p>
<p><b>What is limited?</b></p>	<p><b>What is limited?</b></p> <p>Scale and scope of the programme the resulting funded R&amp;I actions and depend on the participating programmes, typically</p>		<p><b>What is limited?</b></p> <p>Limited control over precise call definition, resulting projects and outcomes, as they are implemented by EC agencies.</p>	<p><b>What is limited?</b></p> <p>Limited flexibility because objectives, range of activities and partners are defined in the Regulation, and negotiated in the Council (EP).</p>

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
	smaller in scale than FP projects			
<p><b><i>What is not possible?</i></b></p> <p>To design and implement in a systemic approach a portfolio of actions.</p> <p>To leverage additional activities and investments beyond the direct scope of the funded actions</p>				

Table 26: Directionality

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b></p> <p>Strategic Plan (as implementing act), annual work programmes (via comitology). Possible also to base call topics on existing or to be developed SRIA/roadmap</p>	<p><b>What is possible?</b></p> <p>Strategic R&amp;I agenda/roadmap agreed between partners and EC</p> <p>Annual work programme drafted by partners, approved by EC</p> <p>Objectives and commitments are set in the Grant Agreement.</p>	<p><b>What is possible?</b></p> <p>Strategic R&amp;I agenda/roadmap agreed between partners and EC</p> <p>Objectives and commitments are set in the legal base.</p> <p>Annual work programme drafted by partners, approved by EC</p> <p>Commitments include obligation for financial contributions (e.g. to administrative costs, from national R&amp;I programmes).</p>	<p><b>What is possible?</b></p> <p>Strategic R&amp;I agenda/roadmap agreed between partners and EC</p> <p>Objectives and commitments are set in the contractual arrangement.</p> <p>Input to FP annual work programme drafted by partners, finalised by EC (comitology)</p> <p>Commitments are political/best effort, but usually fulfilled</p>	<p><b>What is possible?</b></p> <p>Strategic R&amp;I agenda/roadmap agreed between partners and EC</p> <p>Objectives and commitments are set in the legal base.</p> <p>Annual work programme drafted by partners, approved by EC (veto-right in governance)</p> <p>Commitments include obligation for financial contributions (e.g. to administrative costs, from national R&amp;I programmes).</p>
<p><b>What is limited?</b></p> <p>No continuity in support of priorities beyond the coverage of the strategic plan (4 years) and budget (2 years Annual work programme).</p>				
<p><b>What is not possible?</b></p> <p>Coordinated implementation and funding linked to the concrete objectives/ roadmap, since part of overall project portfolio managed by agency</p>				

Table 27: Coherence (internal and external)

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
<p><b>What is possible?</b> Coherence between different parts of the Annual Work programme of the FP ensured by EC</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities Synergies with other programmes</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC If MS participate: Synergies with national/regional programmes and activities Synergies with industrial strategies</p>	<p><b>What is possible?</b> Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with other programmes or industrial strategies If MS participate: Synergies with national/regional programmes and activities</p>
<p><b>What is limited?</b> Synergies with other programmes or industrial strategies</p>	<p><b>What is limited?</b> Synergies with other programmes or industrial strategies</p>	<p><b>What is limited?</b> Synergies with industrial strategies</p>	<p><b>What is limited?</b> Synergies with other programmes</p>	
<p><b>What is not possible?</b> Synergies with national/regional programmes and activities</p>				



