

## INCEPTION IMPACT ASSESSMENT

### Global Health Partnership

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

<b>TITLE OF THE INITIATIVE</b>	EU-Africa Global Health Partnership
<b>LEAD DG (RESPONSIBLE UNIT)</b>	DG Research and Innovation
<b>LIKELY TYPE OF INITIATIVE</b>	Proposal for a Council Regulation for a European Partnership EU-Africa on global health security to tackle infectious diseases under Horizon Europe
<b>INDICATIVE PLANNING</b>	Q1 2020
<b>ADDITIONAL INFORMATION</b>	–

**The Inception Impact Assessment is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.**

### A. Context, Problem definition and Subsidiarity Check

#### Context

The proposal for Horizon Europe, the future EU's future research and innovation (R&I) programme for 2021-2027, outlines the approach (Article 8) and criteria (Annex III) for R&I partnerships under the umbrella term 'European Partnerships'. According to the political agreement between the Council and European Parliament, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The overall financial framework for the upcoming partnerships still has to be agreed by the co-legislators. Different forms of partnerships can be implemented depending on needs and criteria. One such form is institutionalised partnerships set up under Article 185 or Article 187 of the Treaty on the Functioning of the European Union (TFEU). The draft legislation outlines possible areas in which institutionalised partnerships could be set up, including faster development and safer use of health innovations for European patients, and global health. In the course of the strategic planning, the Commission, in close cooperation with the Member States, has identified 'EU-Africa Global Health' as a candidate for such a partnership.

In the field of global health, the following Commission commitments provide the framework within which to develop an EU-African partnership on global health security to tackle infectious diseases:

- The [2030 Agenda for Sustainable Development](#) to combat poverty (SDG1) and reduce the social and economic burden caused by infectious diseases in sub-Saharan Africa, and by extension in Europe, thus contributing to better health for all (SDG3).
- [Towards a Sustainable Europe by 2030](#) with research and innovation as key enablers for the transition towards sustainability, improving European competitiveness and to further spur action by governments, institutions and citizens;
- The [Africa-Europe Alliance for Sustainable Investment and Jobs](#) to strengthen the EU's partnership with Africa by investing in people, education, science, technology and skills development, and unlocking the potential offered by research, technology and innovation.
- President Juncker's [2018 State of the Union Address](#) regarding an EU-Africa partnership of equals.

The Commission proposal for Horizon Europe, the EU's future research and innovation programme for 2021-2027, makes specific provisions for EU action on infectious diseases.

In order to more effectively tackle the burden posed by 'poverty related and neglected infectious diseases', hereafter referred to as 'infectious diseases', and the economic consequences they give rise to in sub-Saharan Africa and in Europe, the Commission is considering which form of European Partnership would be the most efficient way to combine action by the EU, Member States, associated countries, African states and other parties in this endeavour. The aim is to accelerate the development of health technologies (diagnostics, medical devices, medicines and vaccines) to combat infectious diseases, protect citizens from pandemics and increase global health security. A new partnership would build on the achievements of the current [European and Developing Countries Clinical Trials Partnership \(EDCTP\)](#) launched in 2003 and extended in 2014. The [EDCTP2 interim evaluation](#) positively assessed the EDCTP programme and acknowledged it as highly relevant as the challenges addressed by the EDCTP persist.

### Problem the initiative aims to tackle

Despite the work carried out by international funders over the last two decades to reduce the burden of infectious diseases, over 1 billion people, including 400 million children, still suffer from one or more of the three major poverty-related diseases (HIV/AIDS, malaria and tuberculosis), or from neglected infectious diseases, and mainly in sub-Saharan Africa. Malaria and tuberculosis alone kill an estimated 2.1 million people annually. As well as their impact on individuals, infectious diseases put a high socio-economic burden on sub-Saharan African countries and on Europe (e.g. in the EU/EEA, the incidence of [tuberculosis was 11.9 per 100 000 population](#) and [HIV 6.2 cases per 100 000](#)), curbing the country's development potential. Most of the countries affected still lack safe and effective medical intervention and new health technologies, validated through clinical trials, to tackle these diseases.

In addition, factors such as increased mobility, urbanisation, climate and environmental changes, have made outbreaks of infectious diseases (e.g. Ebola virus, Dengue fever, Lyme disease, Chikungunya, etc.) likely to happen more frequently and spread more widely, which represents a serious global security threat.

There are three main reasons why safe and effective health technologies to tackle these diseases are lacking:

- (i) [Fragmentation of research](#): EU Member States and other funders running uncoordinated research policies, programmes and projects compromise the critical mass and effectiveness of their action. The [human and financial resources required to perform clinical trials](#) are such that they cannot be provided either by individual national programmes or by global funders alone. The fragmentation of public research with a lack of a common vision causes duplicated efforts, resources wasted and uneven support for research in different regions. [The majority of research grants for infectious diseases are awarded in high-income countries](#), though the highest burden of these diseases is in low-income countries. Also, most health research funding in Africa is concentrated in East and South African countries, although West Africa has recently experienced several infectious disease outbreaks (such as Ebola, Dengue, and Lassa).
- (ii) [Inadequate capacity for clinical research in developing countries](#): Many sub-Saharan African countries still lack infrastructure and the know-how to conduct clinical trials that meet international standards of good clinical practice, and the human resources to run them.
- (iii) [Inadequate industry investment](#) due to market failure: The research required is risky (no guarantee of success) and expensive, especially late-stage clinical trials in humans. The financial commitment from industry represents only 9.7 % of total research spending in the field. Moreover, research costs cannot be fully recovered due to the lack of financial resources of the patients and the health systems of the countries most affected, which means a return on private investment is not guaranteed. For these reasons, pharmaceutical companies are reluctant to invest in infectious disease-related research without a guaranteed market to recover their costs.

Inadequate capacity for clinical research in disease-endemic countries is an issue to be tackled jointly by donors and the countries affected, following [common guiding principles](#). In addition, it is important for public funders to give incentives to the pharmaceutical industry to improve [access to medicines](#).

### Basis for EU intervention (legal basis and subsidiarity check)

The legal basis for EU intervention is the Horizon Europe programme (based on Article 182 TFEU). In implementing the programme, the EU may make provisions for participation in research and development undertaken by several Member States or in programmes run jointly by several Member States (in accordance with Article 185 TFEU), or may set up joint undertakings (in accordance with Article 187 TFEU). The nature and magnitude of the issues are such that action at EU level is needed, rather than the Member States acting alone.

To develop novel health technologies to better tackle the threat of infectious diseases, it is imperative to coordinate research at EU level, framed by a common research agenda and with funding strategies across national borders.

This will help overcome the fragmentation of research and achieve a critical mass of organisations and investment required to address this important global health challenge. It will increase the impact and cost-effectiveness of European action and investment in this field. It will also encourage the pharmaceutical industry to reinvest in this area and help improve access to medicines.

## B. Objectives and Mapping of Policy options

The proposed Global Health Partnership would aim to achieve the following research and innovation-related objectives:

- Reduced social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe, through the development and uptake of new or improved interventions against infectious diseases;
- Increased health security in sub-Saharan Africa, and by extension in Europe and worldwide, in particular in the context of environmental and climate change, by reducing the risk of outbreaks, pandemics or

antimicrobial resistance.

The relevance of the priority and continuation of support under the Framework programme, including the form of support, will be subject to evaluations and assessments in line with the criteria set out in the Regulation of Horizon Europe.

**There are different policy options for such a partnership:**

**Option 0: No partnership, calls for proposals under Horizon Europe work programmes.** The burden of infectious diseases in sub-Saharan Africa and beyond is addressed through project-based funding for collaborative research.

Compared with implementation through calls for proposals, partnerships (**options 1 and 2**) jointly address priorities together with Member States, the private sector, foundations and other stakeholders following a common strategy.

**Option 1: Co-programmed Partnership** — A memorandum of understanding between the European Commission and partner organisations allows partners, both public and private, to identify and agree on complementary research and innovation funding priorities with a relatively longer-term perspective. Each partner implements its own research programme.

**Option 2: Co-funded Partnership** — An EU grant for a research and innovation programme that has been jointly developed and to be jointly implemented by several organisations that have committed resources to a shared goal. It requires partner organisations, both public and private, to make a greater long-term commitment in terms of coordination and leverage of resources.

**Option 3: Institutionalised Partnership under Article 185 of the EU Treaty** — The EU would participate financially in a research and development programme undertaken by several Member States. This would require making a significant long-term political and financial commitment, and would provide high political and international visibility and high-level backing. It would facilitate coordination, alignment and, where possible, integration of the Member States' national programmes, and it would help leverage resources from other funders and from industry.

**Option 4: Institutionalised Partnership under Article 187 of the EU Treaty** — The EU would set up a joint undertaking or suitable structure to implement a jointly developed research programme. It would be open to any organisation, public or private, supporting R&I in the scope of the global health partnership to participate. It would facilitate coordination, alignment and, where possible, integration of national programmes and it would help leverage resources from other funders and industry. This type of partnership would entail full co-ownership by the EU and its partners, including African countries.

## C. Preliminary Assessment of Expected Impacts

The impact of the partnership will be fully assessed during the impact assessment. It will take into account its ability to help produce a scientific, technological and societal impact as outlined in Article 3 of the draft Horizon Europe programme, and to contribute to producing an impact for the EU's wider priorities and objectives.

### Likely scientific and economic impacts

The partnership is likely to significantly advance scientific knowledge, excellence and expertise in the fight against infectious diseases, thereby contributing to the reduction of the economic burden caused by these diseases. This will be achieved by:

- accelerating the development of effective, safe, accessible, suitable and affordable health technologies;
- improving health system interventions for infectious diseases;
- and taking into account co-morbidity and antimicrobial resistance related to these diseases.

Based on experience with EDCTP2, a partnership is likely to have a greater impact on the economy than the other options under consideration in the impact assessment. This is because a partnership is better suited to coordinate, align and, wherever possible, integrate national programmes. In addition, it would leverage resources from other funders and industry into research and innovation in this domain. The partnership would allow for support to be given to long-term and expensive clinical trials, to increase the number of new or improved health technologies and to build up African and European research capacity and expertise. A partnership would also increase European-African cooperation and cross-European collaborations, including with an extended group of countries on an ad-hoc basis (e.g. in action to combat tuberculosis). EDCTP-funded Networks of Excellence in four African regions have created platforms for high-quality clinical studies spanning multiple sites and have resulted in the sharing of research experience and expertise across 63 institutions in 21 African countries.

### Likely social impacts

The partnership is likely to contribute to society and to the public by providing innovative solutions for better health (e.g. prevention, treatment, etc.) thereby reducing the social burden of infectious diseases in sub-Saharan Africa

and in Europe. This partnership can make an important contribution to address the chronic shortage of health workers in developing countries by providing funding for capacity building, including support for African health researchers, and for strengthening national health research systems. European researchers would also be able to develop their skills by working within international consortia, giving them the opportunity to build international networks and expertise in managing global collaborative projects.

The EDCTP partnership has the potential to contribute to the Sustainable Development Goals (SDG 1, 3 and 9), and to international and EU policies in health research and cooperation through informed policy-making based on scientific results. EDCTP is [viewed as a major player and holds a unique place](#) in the global health landscape due to its focus on clinical trials, on developing scientists, and on fostering research networks.

#### **Likely environmental impacts**

Since the spread of many infectious diseases and of parasites and vectors is influenced by climate change, fighting vector-borne infectious diseases will help mitigate the effect of environmental and climate change on the population in Africa and in Europe.

#### **Likely impacts on fundamental rights**

The impact of infectious diseases is particularly strong on the most vulnerable populations, especially on women (usually the front-line informal caregivers) and children. People contracting diseases such as HIV, Tuberculosis, and Ebola can be stigmatised. Novel health technologies and health system interventions for infectious diseases will help improve the quality of life, dignity and reduce the stigma felt by these vulnerable populations by easing the burden.

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

A simpler, more strategic and coordinated approach to the setting-up and implementation of European Partnerships under Horizon Europe will significantly reduce the administrative burden for applicants and beneficiaries. Horizon Europe legal basis requires thorough assessment as to the necessity for establishing institutionalised partnerships, and whether other, more flexible partnership forms could achieve the identified objectives. In addition, it lays down requirements (e.g. related to central management of financial contributions, access to data, and links with the monitoring and evaluation framework of Horizon Europe etc.) that support further simplification, harmonisation and more effective implementation.

### **D. Evidence Base, Data collection and Better Regulation Instruments**

#### **Impact assessment**

An impact assessment is being prepared to inform the Commission's decision on whether to propose the establishment of an institutionalised European Partnership and to support the preparation of this initiative. If this decision is positive, the impact assessment is likely to be made available in the first quarter of 2020.

#### **Evidence base and data collection**

A full impact assessment is required for all partnerships, which might be institutionalised based on Articles 185 and 187 TFEU. In this context, an external study will provide coordinated input for the preparation of impact assessments, which could lead to and would accompany the proposals for institutionalised partnerships (based on Articles 185 and 187 TFEU). The study will be based on desk research, Commission and stakeholder consultation, quantitative and qualitative data collection and analysis and inputs from panels of experts. It will develop a single common methodology to ensure coordinated inputs to individual impact assessment studies of each envisaged partnership.

#### **Consultation of citizens and stakeholders**

In line with the Better Regulation guidelines, the Commission seeks to consult stakeholders as widely as possible. The consultation strategy aims to involve a broad range of stakeholders, including national authorities, the research community across the EU, industry, EU institutions and bodies, and others.

A structured consultation of Member States in the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May-June 2019 provided early input into the preparatory work.

A single open public consultation from mid-2019 (in English, French and German) will cover all 12 potential institutionalised partnerships based on Articles 185 and 187 TFEU. It will collect input from a broad range of stakeholders, on both the overall approach and the individual candidates for institutionalised partnerships based on Article 185 or Article 187 TFEU. It can be accessed via the Commission's Have Your Say web portal. As the results are expected to inform debate during the 'R&I days' (Brussels, 24-26 September), it might be necessary to shorten slightly the 12 week consultation period.

Once all consultation activities are closed, the Commission will publish a synopsis report (summarising the results) on the consultation page.